Comparative Effectiveness Review
Number 244

Safety of Vaccines Used for Routine Immunization in the United States: An Update

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None of the investigators have any affiliations or financial involvement that conflicts with the material presented in this report.

The information in this report is intended to help healthcare decision makers—patients and clinicians, health system leaders, and policymakers, among others—make well-informed decisions and thereby improve the quality of healthcare services. This report is not intended to be a substitute for the application of clinical judgment. Anyone who makes decisions concerning the provision of clinical care should consider this report in the same way as any medical reference and in conjunction with all other pertinent information, i.e., in the context of available resources and circumstances presented by individual patients.

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Preface

The Agency for Healthcare Research and Quality (AHRQ), through its Evidence-based Practice Centers (EPCs), sponsors the development of evidence reports and technology assessments to assist public- and private-sector organizations in their efforts to improve the quality of healthcare in the United States.

The reports and assessments provide organizations with comprehensive, evidence-based information on common medical conditions and new healthcare technologies and strategies. They also identify research gaps in the selected scientific area, identify methodological and scientific weaknesses, suggest research needs, and move the field forward through an unbiased, evidence-based assessment of the available literature. The EPCs systematically review the relevant scientific literature on topics assigned to them by AHRQ and conduct additional analyses when appropriate prior to developing their reports and assessments.

To bring the broadest range of experts into the development of evidence reports and health technology assessments, AHRQ encourages the EPCs to form partnerships and enter into collaborations with other medical and research organizations. The EPCs work with these partner organizations to ensure that the evidence reports and technology assessments they produce will become building blocks for healthcare quality improvement projects throughout the Nation. The reports undergo peer review and public comment prior to their release as a final report.

AHRQ expects that the EPC evidence reports and technology assessments, when appropriate, will inform individual health plans, providers, and purchasers as well as the healthcare system as a whole by providing important information to help improve healthcare quality.

If you have comments on this evidence report, they may be sent by mail to the Task Order Officer named below at: Agency for Healthcare Research and Quality, 5600 Fishers Lane, Rockville, MD 20857, or by email to epc@ahrq.hhs.gov.

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Technical Expert Panel

In designing the study questions and methodology at the outset of this report, the EPC consulted several technical and content experts. Broad expertise and perspectives were sought. Divergent and conflicted opinions are common and perceived as healthy scientific discourse that results in a thoughtful, relevant systematic review. Therefore, in the end, study questions, design, methodologic approaches, and/or conclusions do not necessarily represent the views of individual technical and content experts.

Technical Experts must disclose any financial conflicts of interest greater than $5,000 and any other relevant business or professional conflicts of interest. Because of their unique clinical or content expertise, individuals with potential conflicts may be retained. The Task Order Officer and the EPC work to balance, manage, or mitigate any potential conflicts of interest identified.

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Peer Reviewers

Prior to publication of the final evidence report, EPCs sought input from independent Peer Reviewers without financial conflicts of interest. However, the conclusions and synthesis of the scientific literature presented in this report do not necessarily represent the views of individual reviewers.

Peer Reviewers must disclose any financial conflicts of interest greater than $5,000 and any other relevant business or professional conflicts of interest. Because of their unique clinical or content expertise, individuals with potential nonfinancial conflicts may be retained. The TOO and the EPC work to balance, manage, or mitigate any potential nonfinancial conflicts of interest identified.

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Safety of Vaccines Used for Routine Immunization in the United States: An Update

Structured Abstract

Objective. To conduct a systematic review of the literature on the safety of vaccines recommended for routine immunization in the United States, updating the 2014 Agency for Healthcare Research and Quality (AHRQ) report on the topic.

Data sources. We searched MEDLINE®, Embase®, CINAHL®, Cochrane CENTRAL, Web of Science, and Scopus through November 9, 2020, building on the prior 2014 report; reviewed existing reviews, trial registries, and supplemental material submitted to AHRQ; and consulted with experts.

Review methods. This report addressed three Key Questions (KQs) on the safety of vaccines currently in use in the United States and included in the Centers for Disease Control and Prevention's (CDC) recommended immunization schedules for adults (KQ1), children and adolescents (KQ2), and pregnant women (KQ3). The systematic review was supported by a Technical Expert Panel that identified key adverse events of particular concern. Two reviewers independently screened publications; data were extracted by an experienced subject matter expert. Studies of vaccines that used a comparator and reported the presence or absence of adverse events were eligible. We documented observed rates and assessed the relative risks for key adverse events. We assessed the strength of evidence (SoE) across the existing findings from the prior 2014 report and the new evidence from this update. The systematic review is registered in PROSPERO (CRD42020180089).

Results. A large body of evidence is available to evaluate adverse events following vaccination. Of 56,608 reviewed citations, 189 studies met inclusion criteria for this update, adding to data in the prior 2014 report, for a total of 338 included studies reported in 518 publications.

Regarding vaccines recommended for adults (KQ1), we found either no new evidence of increased risk for key adverse events with varied SoE or insufficient evidence in this update, including for newer vaccines such as recombinant influenza vaccine, adjuvanted inactivated influenza vaccine, and recombinant adjuvanted zoster vaccine. The prior 2014 report noted a signal for anaphylaxis for hepatitis B vaccines in adults with yeast allergy and for tetanus, diphtheria, and acellular pertussis vaccines.

Regarding vaccines recommended for children and adolescents (KQ2), we found either no new evidence of increased risk for key adverse events with varied SoE or insufficient evidence, including for newer vaccines such as 9-valent human papillomavirus vaccine and meningococcal B vaccine. The prior 2014 report noted signals for rare adverse events—such as anaphylaxis, idiopathic thrombocytopenic purpura, and febrile seizures—with some childhood vaccines.

Regarding vaccines recommended for pregnant women (KQ3), we found no evidence of increased risk for key adverse events with varied SoE among either pregnant women or their

infants following administration of tetanus, diphtheria, and acellular pertussis vaccines during pregnancy.

Conclusion. Across this large body of research, we found no new evidence of increased risk since the prior 2014 report for key adverse events following administration of vaccines that are routinely recommended. Signals from the prior report remain unchanged for rare adverse events, which include anaphylaxis in adults and children, and febrile seizures and idiopathic thrombocytopenic purpura in children. There is no evidence of increased risk of adverse events for vaccines currently recommended in pregnant women. There remains insufficient evidence to draw conclusions about some rare potential adverse events.

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Evidence Summary

Main Points

- Since the prior 2014 Agency for Healthcare Research and Quality (AHRQ) report on vaccine safety, we found no new evidence of increased risk for key adverse events following administration of vaccines that are routinely recommended for adults, children, and pregnant women.
- Signals from the prior report remain unchanged for adverse events that include anaphylaxis in adults and children, and febrile seizures and idiopathic thrombocytopenic purpura in children. There continues to be no evidence of increased risk of adverse events for vaccines currently recommended in pregnant women.
- There remains insufficient evidence to draw conclusions about some rare potential adverse events.

Background and Purpose

Considered one of the greatest public health achievements, vaccines are effective in controlling the spread of and even eradicating a variety of infectious diseases. In 2014, AHRQ developed a report based on a systematic review of vaccine safety[1] building upon the 2011 Institute of Medicine (IOM) consensus report *Adverse Effects of Vaccines: Evidence and Causality*.[2] Since the 2014 AHRQ report,[1] the routine immunization schedule has continued to evolve, with the inclusion of newly approved vaccines and modified indications and schedules for several existing vaccines.

This update of the 2014 AHRQ report was commissioned by the Office of the Assistant Secretary for Health's Office of Infectious Disease and HIV/AIDS Policy (OASH/OIDP). The scope of this systematic review of the evidence was to assess the safety of vaccines in the immunization schedule recommended for children and adolescents (hereafter, we refer to children and adolescents simply as "children"), adults, and pregnant women. The list of vaccines is based on the Centers for Disease Control and Prevention's (CDC) recommended immunization schedules[3, 4] and includes only those currently licensed for use in the United States by the Food and Drug Administration (FDA).[5]

Methods

The methods for this report followed AHRQ's Methods Guide for Effectiveness and Comparative Effectiveness Reviews for the Evidence-based Practice Center Program.[6] The report addressed three Key Questions (KQs). Studies evaluating vaccines included in the CDC's routine immunization schedules recommended for adults (KQ1), children (KQ2), and pregnant women (KQ3) were eligible for inclusion if they compared the vaccine to either no vaccine or the prior standard of care. The evidence review team was supported by a Technical Expert Panel (TEP) that comprised a diverse set of relevant stakeholders, including vaccine experts with clinical expertise in key populations, vaccine safety methodologists, and consumers.

We searched MEDLINE® (including TOXLINE), Embase®, CINAHL®, Cochrane CENTRAL (including International Clinical Trials Registry Platform registry), Web of Science, and Scopus through November 9, 2020, building on the prior 2014 report. In addition, we reference-mined existing reviews; searched the trial registry Clinicaltrials.gov; reviewed supplemental material submitted to AHRQ following a Federal Register Notice posted regarding

the availability of a portal for submission of unpublished studies; and consulted with content experts.

With the assistance of the TEP, additional content expert input, and based on published literature, we determined a list of key adverse events *a priori* to allow synthesis across studies (Appendix A). Two reviewers independently screened citations; data were extracted by an experienced subject matter expert. We included experimental and observational studies with a comparator that reported the presence or absence of adverse events. We documented the observed rates of adverse events and assessed the relative risks between vaccinated and comparator groups. All studies that reported rates of adverse events that could be computed, whether from the prior 2014 report or the current search update, were combined in meta-analyses. When studies could not be combined statistically, we narratively synthesized the findings to inform the strength of evidence (SoE) assessment and to ensure that the available evidence was considered and integrated.

The SoE was assessed based on the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) approach and the AHRQ Methods Guide for Effectiveness and Comparative Effectiveness Reviews.[6] We used four criteria to grade the SoE (study limitations, consistency, precision, and reporting bias). We differentiated *high*, *moderate*, *low*, and *insufficient* evidence to communicate the confidence in the findings across studies, as follows.

- *High*: High confidence that the evidence reflects the true effect. Further research is very unlikely to change our confidence in the estimate of effect.
- *Moderate*: Moderate confidence that the evidence reflects the true effect. Further research may change our confidence in the estimate of effect and may change the estimate.
- *Low*: Low confidence that the evidence reflects the true effect. Further research is likely to change our confidence in the estimate of effect and is likely to change the estimate.
- *Insufficient* evidence: Evidence either is unavailable due to a lack of studies reporting on the outcomes, or the evidence does not permit a conclusion (e.g., due to conflicting results across studies or methodologic flaws).

The review protocol is posted on the Effective Health Care website at https://effectivehealthcare.ahrq.gov/products/safety-vaccines/protocol. The project was registered in PROSPERO (CRD42020180089).[7]

Results

We identified 189 studies in this update, adding to research studies reviewed in the original 2014 AHRQ report on the topic (which built on findings of a detailed IOM report on vaccine safety published in 2011).[1, 2] In total, 338 studies reported in 518 publications were reviewed across both reports.

Key Question 1: Safety of Vaccines in Adults

Table A synthesizes the findings across the prior 2014 report and the update for key adverse events following administration of vaccines routinely recommended for adults. Any findings originally from the prior report are noted as such, along with any changes to these findings. If no prior report findings are noted, this indicates that there were no findings for these key adverse events in the prior report. Additional key adverse events for which there was insufficient evidence (including for which there were no studies) can be found in the main report.

Table A. Strength of evidence for specific safety concerns in vaccines recommended for adults

Key:

Green box indicates no evidence of increased risk of specific adverse events

Red circle indicates evidence of risk of specific adverse events

White box indicates insufficient evidence to draw conclusions about the risk of specific adverse events

Vaccine (Abbreviation; Brand Name[s])	Strength of Evidence and Findings for Key Adverse Events
Hepatitis A (HepA; Havrix®, Vaqta®)	Insufficient evidence (no change from prior 2014 report; no new studies in update)
Hepatitis B (HepB; Engerix-B®, Recombivax HB®, HEPLISAV-B®)	Moderate: No evidence of increased risk of multiple sclerosis onset or exacerbation (no change from prior 2014 report; insufficient evidence in update) Moderate: No evidence of increased risk of diabetes (no change from prior 2014 report; update also identified no evidence of increased risk) Moderate: Anaphylaxis in patients allergic to yeast (causal relationship based on mechanistic evidence remains unchanged from prior 2014 report; no new studies in update) Low: No evidence of increased risk of asthma, autoimmune disease, cardiovascular events, death, herpes zoster, reproductive system events, stroke
Hepatitis A and hepatitis B (HepA-HepB; Twinrix®)	Insufficient evidence (no findings in prior 2014 report; insufficient evidence in update)
9-valent human papillomavirus (HPV9; Gardasil 9®)	Insufficient evidence (not in use at time of prior 2014 report; no new studies in update); see Table B for studies that combined children and adults
Influenza, inactivated (IIV; Afluria Quadrivalent®, Flucelvax Quadrivalent®, Fluarix Quadrivalent®, Flulaval Quadrivalent®, Fluzone High Dose Quadrivalent®, Fluzone Quadrivalent®)	Low: No evidence of increased risk of asthma, cardiovascular events, death, myocardial infarction, reproductive system events, seizures, stroke
Influenza, inactivated, adjuvanted (aIIV; Fluad®, Fluad Quadrivalent®)	Moderate: No evidence of increased risk of cardiovascular events, stroke Low: No evidence of increased risk of asthma, autoimmune disease, death, encephalitis/encephalopathy, Guillain-Barré syndrome, idiopathic thrombocytopenic purpura, myocardial infarction, seizures
Influenza, recombinant (RIV; Flublok Quadrivalent®)	Low: No evidence of increased risk of cardiovascular events, death, encephalitis/encephalopathy, myocardial infarction, reproductive system events, stroke
Influenza, live attenuated (LAIV; FluMist Quadrivalent®)	Insufficient evidence (no findings in prior 2014 report; insufficient evidence in update)
Measles, mumps, and rubella (MMR; M-M-R II®)	Moderate: No evidence of increased risk of type 1 diabetes mellitus (no change from prior 2014 report; no new studies in update)

Vaccine (Abbreviation; Brand Name[s])	Strength of Evidence and Findings for Key Adverse Events
Meningococcal A, C, W, and Y (MenACWY; MenACWY-D [Menactra®], MenACWY-CRM [Menveo®], MenACWY-TT [MenQuadfi®])	Moderate: No evidence of increased risk of death Low: No evidence of increased risk of cardiovascular events, myocardial infarction, stroke
Meningococcal B (MenB; MenB-4C [Bexsero®], MenB-FHbp [Trumenba®])	Insufficient evidence (not in use at time of prior 2014 report); see Table B for studies that combined children and adults
13-valent pneumococcal conjugate (PCV13; Prevnar 13®)	Moderate: No evidence of increased risk of cardiovascular events, herpes zoster, myocardial infarction, reproductive system events, stroke Low: No evidence of increased risk of acute disseminated encephalomyelitis, anaphylaxis or systemic allergic reaction, asthma, autoimmune disease, death, encephalitis/encephalopathy, herpes zoster, idiopathic thrombocytopenic purpura, meningitis, seizures
23-valent pneumococcal polysaccharide (PPSV23; Pneumovax®)	High: No evidence of increased risk of cardiovascular or cerebrovascular events in adults aged 65 years and older (no change from prior 2014 report; update also identified no evidence of increased risk or insufficient evidence) Moderate: No evidence of increased risk of death
Tetanus, diphtheria, and acellular pertussis (Tdap; Adacel®, Boostrix®) and tetanus and diphtheria (Td; TDVAX, Tenivac®)	High: Anaphylaxis to tetanus toxoid (causal relationship based on mechanistic evidence remains unchanged from prior 2014 report; no new studies in update)
Varicella (VAR; Varivax®)	Insufficient evidence (no findings in prior 2014 report; no new studies in update)
Zoster recombinant (RZV; Shingrix®)	High: No evidence of increased risk of herpes zoster Moderate: No evidence of increased risk of amyotrophic lateral sclerosis, anaphylaxis or systemic allergic reaction, asthma, cardiovascular events, death, diabetes, encephalitis/encephalopathy, Guillain-Barré syndrome, idiopathic thrombocytopenic purpura, meningitis, myocardial infarction, reproductive system events, seizures, stroke Low: No evidence of increased risk of acute disseminated encephalomyelitis, angioedema, ataxia, autoimmune disease, autoimmune thyroiditis (Hashimoto's disease)

Note: No evidence of increased risk indicates that the outcome was studied and that the findings of the studies did not constitute evidence of increased risk of the adverse event following administration of that vaccine (either because the risk was not statistically significantly increased or was reduced)

Key Question 2: Safety of Vaccines in Children

Table B synthesizes the findings across the prior 2014 report and the update for key adverse events following administration of vaccines routinely recommended for children. Any findings originally from the prior report are noted as such, along with any changes to these findings. If no prior report findings are noted, this indicates that there were no findings for these key adverse events in the prior report. Additional key adverse events for which there was insufficient

evidence (including for which there were no studies) and evidence for combination vaccines can be found in the main report.

Table B. Strength of evidence for specific safety concerns in vaccines recommended for children

Key:

Green box indicates no evidence of increased risk of specific adverse events

Red circle indicates evidence of risk of specific adverse events

White box indicates insufficient evidence to draw conclusions about the risk of specific adverse events

Vaccine (Abbreviation; Brand Name[s])	Strength of Evidence and Findings for Key Adverse Events
Diphtheria, tetanus, and acellular pertussis (DTaP; Daptacel®, Infanrix®)	Moderate: No evidence of increased risk of type 1 diabetes mellitus for vaccines containing diphtheria toxoid, tetanus toxoid, and acellular pertussis antigens (no change from prior 2014 report; no new studies in update) Low: No evidence of increased risk of asthma or death
Tetanus, diphtheria, and acellular pertussis (Tdap; Adacel, Boostrix)	Moderate: No evidence of increased risk of type 1 diabetes mellitus for vaccines containing diphtheria toxoid, tetanus toxoid, and acellular pertussis antigens (no change from prior 2014 report; no new studies in update) Low: No evidence of increased risk of cardiovascular events or death for Tdap
Haemophilus influenzae type b (Hib; PedvaxHIB®, ActHIB®, Hiberix®)	Insufficient evidence (no findings related to key adverse events in prior 2014 report; insufficient evidence in update)
Hepatitis A (HepA; Havrix, Vaqta)	Moderate: Idiopathic thrombocytopenic purpura in children aged 7 to 17 years (no change from prior 2014 report; no new studies in update)
Hepatitis B (HepB; Engerix-B, Recombivax HB)	Moderate: No evidence of increased risk of multiple sclerosis (no change from prior 2014 report; no new studies in update)
9-valent human papillomavirus (HPV9; Gardasil 9)	Low: No evidence of increased risk of autoimmune disease, birth defects, death, reproductive system events, seizures, spontaneous abortion
Inactivated poliovirus (IPV; IPOL®)	Insufficient evidence (no findings related to key adverse events in prior 2014 report; insufficient evidence in update)
Influenza, inactivated (IIV; Afluria Quadrivalent, Fluarix Quadrivalent, Flulaval Quadrivalent, Fluzone Quadrivalent, Flucelvax Quadrivalent)	Moderate: No evidence of increased risk of death Low: No evidence of increased risk of anaphylaxis or systemic allergic reaction, asthma, autoimmune disease, cardiovascular events, febrile seizures, seizures for quadrivalent IIV
Influenza, live attenuated (LAIV; FluMist Quadrivalent)	Low: No evidence of increased risk of death or seizures

Vaccine (Abbreviation; Brand Name[s])	Strength of Evidence and Findings for Key Adverse Events
Measles, mumps, and rubella (MMR; M-M-R II)	High: No evidence of increased risk of autism spectrum disorders (no change from prior 2014 report; update also identified no evidence of increased risk) High: Anaphylaxis in children with allergies (causal relationship based on mechanistic evidence remains unchanged from prior 2014 report; no new studies in update) High: Febrile seizures (no change from prior 2014 report; insufficient evidence in update) Moderate: Idiopathic thrombocytopenic purpura (no change from prior 2014 report; no new studies in update) Low: No evidence of increased risk for asthma
Meningococcal, A, C, W, and Y (MenACWY; MenACWY-D [Menactra], MenACWY-CRM [Menveo], MenACWY-TT [MenQuadfi])	Moderate: Anaphylaxis in children with allergies (causal relationship based on mechanistic evidence remains unchanged from prior 2014 report; update shows no evidence of increased risk among all children) Moderate: No evidence of increased risk of cardiovascular events, diabetes, febrile seizures, intussusception, idiopathic thrombocytopenic purpura, Kawasaki disease, seizures Low: No evidence of increased risk of acute disseminated encephalomyelitis, anaphylaxis or systemic allergic reaction (among all children), asthma, autoimmune disease, death, encephalitis/encephalopathy, meningitis, multiple sclerosis, reproductive system events, transverse myelitis
Meningococcal B (MenB; MenB-4C [Bexsero], MenB-FHbp [Trumenba])	Moderate: No evidence of increased risk of anaphylaxis or systemic allergic reaction, reproductive system events Low: No evidence of increased risk of asthma, death, seizures
13-valent pneumococcal conjugate (PCV13; Prevnar 13)	Moderate: No evidence of increased risk of death Low: No evidence of increased risk of asthma, cardiovascular events, intussusception, meningitis, reproductive system events, seizures Low: Febrile seizures (downgraded from moderate increased risk in prior 2014 report for inconsistency, as update identified some studies reporting no increased risk)
23-valent pneumococcal polysaccharide (PPSV23; Pneumovax)	Insufficient evidence (no findings in prior 2014 report; insufficient evidence in update)

Vaccine (Abbreviation; Brand Name[s])	Strength of Evidence and Findings for Key Adverse Events
Rotavirus (RV; Rotarix®, RotaTeq®)	High: No evidence of increased risk of diabetes Moderate: No evidence of increased risk of intussusception (downgraded from moderate increased risk in prior 2014 report, which was not confirmed when combining all available studies; some observational studies showed increased risk) Moderate: No evidence of increased risk of asthma, autoimmune disease, death, encephalitis/encephalopathy, febrile seizures, idiopathic thrombocytopenic purpura, seizures, stroke Low: No evidence of increased risk of anaphylaxis or systemic allergic reaction, autoimmune thyroiditis (Hashimoto's disease), Kawasaki disease, meningitis, reproductive system events
Varicella (VAR; Varivax)	High: Anaphylaxis (causal relationship based on mechanistic evidence remains unchanged from the prior 2014 report; no new studies in update) and herpes zoster, meningitis, or encephalitis as a result of vaccine strain viral reactivation (causal relationship based on mechanistic evidence remains unchanged from prior 2014 report; no new studies in update) Moderate: Idiopathic thrombocytopenic purpura in children aged 11 to 17 years (no change from prior 2014 report; no new studies in update)

Note: No evidence of increased risk indicates that the outcome was studied and that the findings of the studies did not constitute evidence of increased risk of the adverse event following administration of that vaccine (either because the risk was not statistically significantly increased or was reduced).

Key Question 3: Safety of Vaccines in Pregnant Women

Table C synthesizes the findings across the prior 2014 report and the update for key adverse events following administration of vaccines routinely recommended for pregnant women. Any findings originally from the prior report are noted as such, along with any changes to these findings. If no prior report findings are noted, this indicates that there were no findings for these key adverse events in the prior report. Additional key adverse events for which there was insufficient evidence (including for which there were no studies) can be found in the main report.

Table C. Strength of evidence for specific safety concerns in vaccines recommended for pregnant women

Key:

Green box indicates no evidence of increased risk of specific adverse events

Red circle indicates evidence of risk of specific adverse events

White box indicates insufficient evidence to draw conclusions about the risk of specific adverse events

Vaccine (Abbreviation; Brand Name[s])	Strength of Evidence and Findings for Key Adverse Events
Hepatitis B (HepB; Engerix-B, Recombivax HB)	Insufficient evidence (no findings in prior 2014 report; no new studies in update)

Vaccine (Abbreviation; Brand Name[s])	Strength of Evidence and Findings for Key Adverse Events
Influenza, inactivated (IIV; Afluria Quadrivalent, Flucelvax Quadrivalent, Fluarix Quadrivalent, Flulaval Quadrivalent, Fluzone Quadrivalent), Influenza, recombinant (RIV; Flublok Quadrivalent)	☐ Insufficient evidence (quadrivalent IIV and RIV not in use at time of prior 2014 report; no new studies in update)
Tetanus, diphtheria, and acellular pertussis (Tdap; Adacel, Boostrix)	■ Moderate: No evidence of increased risk of maternal cardiovascular events, maternal death, maternal diabetes, eclampsia/pre-eclampsia, preterm labor, maternal reproductive system events, stillbirth, cardiovascular events in infants, death in infants, encephalitis/encephalopathy in infants, seizures in infants ■ Low: No evidence of increased risk of maternal encephalitis/encephalopathy, autism in infants, birth defects in infants, febrile seizures in infants

Note: No evidence of increased risk indicates that the outcome was studied and that the findings of the studies did not constitute evidence of increased risk of the adverse event following administration of that vaccine (either because the risk was not statistically significantly increased or was significantly reduced).

Strengths and Limitations

Our review of the literature was extensive and designed to capture available evidence on the presence and absence of adverse events associated with vaccines currently in use in the United States for routine immunization. We used a broad search strategy and transparent protocol to minimize the risk of missing relevant studies. We reviewed the rates of key adverse events reported in vaccine studies that used a comparator, regardless of whether they could be definitively attributed to the intervention. Many new studies were randomized clinical trials or based on extensive administrative data sets.

While our literature search procedures were extensive, our report also had limitations. Many studies were not designed to assess safety of vaccines and reporting of adverse events varied. Identifying safety data is very challenging, since many publications focus on the clinical effectiveness of an intervention with either no, sparse, incomplete, or non-systematic assessment and/or reporting of safety aspects. Despite pooling data across studies, confidence intervals around risk estimates were often wide due to the rare nature of many of the events of interest. We considered all available data regardless of whether they could be combined statistically in the grading the SoE.

Discussion

This report evaluated adverse events in research studies of vaccines administered to adults, children, and pregnant women. The report reviews the evidence and provides the strength of evidence, communicating our confidence in the findings. The scope does not include the efficacy or effectiveness of vaccines, nor practice or policy recommendations regarding the administration of the vaccines. This report reviews currently recommended vaccines for routine use, and does not include new vaccines in development or under emergency use authorization, such as vaccines for the 2019 coronavirus disease (COVID-19) pandemic.

Regarding vaccines recommended for adults (KQ1), in this update we found either no new evidence of increased risk for key adverse events with varied SoE or insufficient evidence,

including for newer vaccines such as recombinant influenza vaccine, adjuvanted inactivated influenza vaccine, and recombinant adjuvanted zoster vaccine. The prior 2014 report noted a signal for anaphylaxis for hepatitis B vaccines in adults with yeast allergy and for tetanus, diphtheria, and acellular pertussis vaccines. Regarding vaccines recommended for children and adolescents (KQ2), we found either no new evidence of increased risk for key adverse events with varied SoE or insufficient evidence, including for newer vaccines such as 9-valent human papillomavirus vaccine and meningococcal B vaccine. The prior 2014 report noted signals for rare adverse events – such as anaphylaxis, idiopathic thrombocytopenic purpura, and febrile seizures – with some childhood vaccines. Regarding vaccines recommended for pregnant women (KQ3), we found no evidence of increased risk for key adverse events with varied SoE among either pregnant women or their infants following administration of tetanus, diphtheria, and acellular pertussis vaccine during pregnancy.

Despite the large literature, there remains insufficient evidence for rare potential adverse events for which very large samples would be needed to estimate the risk or to definitively exclude a risk of such adverse events. Careful consideration should be given to research gaps; however, important factors must be taken into account when determining whether studies are warranted, including the severity and frequency of the adverse event being studied and the challenges of conducting sufficiently powered studies when investigating rare events. Potential risks of rare adverse events should be weighed against the protective benefits that vaccines provide.

Conclusion

Across this large body of research, we found no new evidence of increased risk since the prior 2014 report for key adverse events following administration of vaccines that are routinely recommended. Signals from the prior report remain unchanged for rare adverse events that include anaphylaxis in adults and children, and febrile seizures and idiopathic thrombocytopenic purpura in children. There is no evidence of increased risk of adverse events for vaccines currently recommended in pregnant women. There remains insufficient evidence to draw conclusions about some rare potential adverse events.

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Introduction

Background

Vaccines are considered one of the greatest public health achievements, and the effectiveness of vaccines in controlling the spread of and even eradicating many infectious diseases is widely acknowledged.[1] It is estimated that vaccinations for children born between 1994 and 2013 alone will have prevented over 320 million illnesses and 730,000 deaths from vaccine-preventable diseases and will have saved over $1.3 trillion in societal costs over the children's lifetimes in the United States.[2] Vaccination of adults is cost-effective[3] and critical to mitigating the economic toll of influenza estimated to be approximately $87 billion per year,[4] and prevents other illnesses such as invasive pneumococcal disease, hepatitis A, hepatitis B, and herpes zoster.[5-7] As a result, vaccines have improved health outcomes and reduced mortality for adults, in addition to decreasing healthcare costs and preventing an untold amount of suffering.[4, 8-12] Influenza vaccine and tetanus, diphtheria, and acellular pertussis vaccine (Tdap) during pregnancy reduce the mother's risk for infection and can protect her infant with transplacental passive immunity against influenza, tetanus, diphtheria, and pertussis (whooping cough) in the critical first several months of life when the infant is too young to be vaccinated.[13-15]

Assessment of safety is an essential component of the process for developing and commercializing vaccines that provide these benefits. In the United States, the U.S. Food and Drug Administration (FDA) oversees regulatory review and approval of vaccines.[16] The clinical evaluation of a vaccine typically consists of three phases. Phase I studies are conducted among a small number of participants, generally approximately 20–80, to evaluate safety and tolerability and to generate preliminary immunogenicity data. Phase II studies evaluate the immunogenicity of the vaccine and provide initial estimates of the rates of common adverse events, typically enrolling several hundred participants. Phase III trials, which enroll thousands to tens of thousands of participants, provide individual- and population-based information on a vaccine's safety and efficacy to support licensure.

After a vaccine is licensed and recommended for use, multiple systems are in place to ensure ongoing assessments of safety through Phase IV studies.[17] These studies include safety surveillance conducted by manufacturers as post-marketing requirements (studies or clinical trials that sponsors are required to conduct under one or more statutes or regulations) or commitments (studies or clinical trials that a sponsor has agreed to conduct, but that are not required by a statute or regulation) to the FDA[18] and the FDA's Post-Licensure Rapid Immunization Monitoring (PRISM) system (the FDA's national system for monitoring medical products after they are licensed for use).[19-21] Multiple other Federal databases contribute to surveillance, such as the Vaccine Adverse Event Reporting System (VAERS) (co-managed by the FDA and the Centers for Disease Control and Prevention [CDC]),[22] as well as the Vaccine Safety Datalink[23, 24] and Clinical Immunization Safety Assessment project, which are both managed by the CDC.[25, 26] Using these vaccine safety monitoring systems, the FDA and CDC may change the terms of vaccine use based on available safety information.[27]

In 2014, the Office of the Assistant Secretary for Health's National Vaccine Program Office (which in 2019 became the Office of Infectious Disease and HIV/AIDS Policy [OASH/OIDP]) commissioned the Agency for Healthcare Research and Quality (AHRQ) to develop a report on vaccine safety entitled *Safety of Vaccines Used for Routine Immunization in the United States*.[28] The 2014 report was based on a systematic review and built upon the 2011 Institute of Medicine (IOM; now known as the National Academies of Sciences, Engineering, and Medicine)

consensus report *Adverse Effects of Vaccines: Evidence and Causality*.[29] Since the 2014 Agency for Healthcare Research and Quality (AHRQ) report,[28] the CDC's routine immunization schedules for children and adults have continued to evolve, with the inclusion of vaccines newly licensed by the FDA and modified indications and schedules for some existing vaccines (Table 1). These changes include the introduction of several new influenza vaccines; changes in recommended uses of influenza vaccines;[30] replacement of the 2- and 4-valent human papillomavirus (HPV) vaccines with the 9-valent HPV vaccine (HPV9), expanded indications for HPV9 to include men and women through 45 years of age;[31] and two new serogroup B meningococcal vaccines for use among adolescents and high-risk populations.[32] Vaccines with novel adjuvants, such as those for the new recombinant zoster vaccine, and the new 2-dose series hepatitis B vaccine with a novel immunostimulatory adjuvant were introduced in 2017.[33, 34]

In addition to an examination of the research published since the prior report, the current report includes the new vaccines, formulations, and schedules that have been approved since 2014 (Table 1). Note that the use of brand names in this report is for identification purposes only and does not indicate endorsement by AHRQ or OASH/OIDP.

Table 1. Vaccines, populations, and major changes since the 2014 AHRQ vaccine safety report[28]

Vaccine (Abbreviation; Brand Name[s])	Populations Recommended for Routine Use	New Formulation Since Prior Report	Change in Age Indication Since Prior Report	Change in Dosing Since Prior Report
Diphtheria, tetanus, and acellular pertussis (DTaP; Daptacel®, Infanrix®)	Children	None	None	None
Haemophilus influenzae type b (Hib; ActHIB®, Hiberix®, PedvaxHIB®)	Children	None	None	Hiberix approved in 2016 as a three-dose primary series at ages 2, 4, and 6 months (initially approved only as a booster dose for ages 15 months through 4 years).
Hepatitis A (HepA; (Havrix®, Vaqta®)	Adults, children	None	None	None
Hepatitis B (HepB; Engerix-B®, Recombivax HB®, HEPLISAV-B®)	Adults, children, pregnant women (except for HEPLISAV-B, which is not recommended for children and pregnant women)	HEPLISAV-B approved in 2017.	None	None
Hepatitis A and hepatitis B (HepA-HepB; Twinrix®)	Adults	None	None	None

Vaccine (Abbreviation; Brand Name[s])	Populations Recommended for Routine Use	New Formulation Since Prior Report	Change in Age Indication Since Prior Report	Change in Dosing Since Prior Report
9-valent human papillomavirus (HPV9; Gardasil 9®)	Adults, children	Gardasil 9 approved in 2014.	Gardasil 9 approval expanded to include use in women and men 27 through 45 years of age in 2018. Catch-up HPV9 vaccination recommended for all persons through age 26 years in 2019.	Gardasil 9 approved as a two-dose series if first dose initiated 9-14 years of age (otherwise three-dose series as before) in 2016.
Inactivated poliovirus (IPV; IPOL®)	Children	None	None	None
Influenza, inactivated (IIV; Afluria Quadrivalent®, Fluarix Quadrivalent®, Flucelvax Quadrivalent®, Flulaval Quadrivalent®, Fluzone High Dose Quadrivalent®, Fluzone Quadrivalent®)	Adults, children, pregnant women (except for Fluzone High Dose Quadrivalent, which is for adults aged 65 years and older)	Afluria Quadrivalent approved in 2016; Flucelvax Quadrivalent approved in 2016; Fluzone High Dose Quadrivalent approved in 2019. Changes to influenza strains for vaccine made annually.	Flulaval Quadrivalent expanded use to 6 months of age and older in 2016. Afluria Quadrivalent and Fluarix Quadrivalent expanded use to 6 months of age and older in 2018.	Fluzone Quadrivalent dose for children aged 6 through 35 months was updated to be either 0.25 mL or 0.5 mL in 2018.
Influenza, inactivated, adjuvanted (aIIV; Fluad®, Fluad Quadrivalent®)	Adults aged 65 years and older	Fluad approved in 2015; Fluad Quadrivalent approved in 2020. Changes to influenza strains for vaccine made annually.	N/A	N/A
Influenza, recombinant (RIV; Flublok Quadrivalent®)	Adults, pregnant women	Flublok Quadrivalent approved in 2017. Changes to influenza strains for vaccine made annually.	None	None
Influenza, live attenuated (LAIV; FluMist Quadrivalent®)	Adults (through 49 years of age), children	Changes to influenza strains for vaccine made annually.	None	None
Measles, mumps, rubella (MMR; M-M-R II®)	Adults, children	None	None	None
Serogroup A, C, W, and Y meningococcal (MenACWY-D, Menactra®; Men-ACWY-CRM, Menveo®; MenACWY-TT, MenQuadfi®)	Adults, children	MenQuadfi (MenACWY-TT) was approved in 2020.	None	None
Serogroup B meningococcal (MenB-FHbp, Trumenba®; MenB-4C, Bexsero®)	Adults, children	Trumenba was approved in 2014; Bexsero was approved in 2015.	N/A	N/A

Vaccine (Abbreviation; Brand Name[s])	Populations Recommended for Routine Use	New Formulation Since Prior Report	Change in Age Indication Since Prior Report	Change in Dosing Since Prior Report
13-valent pneumococcal conjugate (PCV13; Prevnar 13®)	Adults, children	None	Age indications were expanded from younger than 18 years and older than 50 years to include adults aged 18-49 years in 2016.	None
23-valent pneumococcal polysaccharide (PPSV23; Pneumovax®)	Adults, children	None	None	None
Rotavirus (RV; Rotarix®, RotaTeq®)	Children	None	None	None
Tetanus, diphtheria, and acellular pertussis (Tdap; Adacel®, Boostrix®)	Children, adults, pregnant women	None	Adacel approval expanded to include people 10 years of age in 2014 (previously approved for people 11-64 years of age).	Adacel approved for repeat dose in people 10 through 64 years of age in 2019. ACIP recommendation updated to allow for use of Tdap or Td as decennial booster, wound prophylaxis, and catch up vaccination in 2020.
Tetanus, diphtheria (Td; TDVAX®, Tenivac®)	Adults	None	None	None
Varicella (VAR; Varivax®)	Children, adults	None	None	None
Zoster recombinant (RZV; Shingrix®)	Adults	Shingrix was approved in 2017.	None	None
DTaP-IPV-Hib-HepB (Vaxelis®)	Children	Vaxelis was approved in 2018.	N/A	N/A
DTaP-HepB-IPV (Pediarix®)	Children	None	None	None
DTaP-IPV/Hib (Pentacel®)	Children	None	None	None
DTaP-IPV (Kinrix®, Quadracel®)	Children	Quadracel was approved in 2015	None	None
Measles, mumps, rubella, and varicella (MMR-V; ProQuad®)	Children	None	None	None

Abbreviations: ACIP—Advisory Committee on Immunization Practices; aIIV—Adjuvanted inactivated influenza vaccine; DTaP— Diphtheria and tetanus toxoids and acellular pertussis vaccine; HepA—Hepatitis A vaccine; HepB—Hepatitis B vaccine; HepA-HepB—Hepatitis A and Hepatitis B vaccines; Hib— *Haemophilus influenzae* type b vaccine; HPV9—9-valent human papillomavirus vaccine; IIV—Inactivated influenza vaccine; IPV—Inactivated poliovirus vaccine; LAIV—Live attenuated influenza vaccine; MenACWY—Serogroups A, C, W, and Y meningococcal vaccine; MenB—Serogroup B meningococcal vaccine; MMR—Measles, mumps, and rubella vaccine; MMR-V—Measles, mumps, rubella, and varicella vaccine; PCV13—13-valent pneumococcal conjugate vaccine; PPSV23—23-valent pneumococcal polysaccharide vaccine; RIV—Recombinant influenza vaccine; RV—Rotavirus vaccine; RZV—Recombinant zoster vaccine; Td—Tetanus and diphtheria toxoids; Tdap—Tetanus and diphtheria toxoids and acellular pertussis vaccine; VAR—Varicella vaccine

The concept of "safety" in medical literature is measured and described as the number, type, and severity of adverse events reported by study participants. For each population in this report—adults (including adults 65 years of age and older), children, and pregnant women—several important questions must be considered when evaluating adverse events associated with vaccines. First, what adverse events have been reported with vaccine use, and what is the certainty of the association? Clinicians, patients, and caregivers want information on the nature and the frequency of potential side effects to help them weigh the benefits of vaccines against potential risks. Another question for stakeholders is the severity of the adverse events, even when events are likely to be very rare. Finally, understanding the risk factors that may be associated with adverse events (e.g., age, sex, race/ethnicity, medical comorbidity, concomitant medications, adjuvants) is important for policymakers and clinicians to potentially modify vaccine recommendations as needed.

Purpose and Scope of the Systematic Review

This report assesses the evidence regarding the safety of vaccines routinely recommended for adults, children, and pregnant women in the United States by systematic review. The list of included vaccines in this report is based on the CDC's immunization schedules[35, 36] and comprises those currently licensed by the FDA.[37] See Appendix A for all vaccines that are within the scope of this report.

This report does not review the safety of FDA-licensed vaccines that were previously included in the immunization schedules but are no longer recommended or included in current immunization schedules or manufactured for use in the United States, such as the serogroups A, C, W, and Y meningococcal polysaccharide vaccine, 2-valent or 4-valent human papilloma vaccines, or most trivalent influenza vaccines. This report reviews currently recommended vaccines for routine use, and does not include new vaccines in development or under emergency use authorization, such as vaccines for the 2019 coronavirus disease (COVID-19) pandemic.

Finally, the scope of the report does not include the efficacy or effectiveness of vaccines, which must be considered alongside against any risks in decision making about vaccines.[38] The report does not provide guidance for patients or providers regarding the use of vaccines, nor does it make practice or policy recommendations on the use of vaccines.

Methods

This section briefly describes the methods used to conduct the evidence review. The methods are described in full in Appendix A.

Review Approach

The methods for the evidence review upon which this report is based follow the Methods Guide for Effectiveness and Comparative Effectiveness Reviews of the Evidence-based Practice Center (EPC) Program of the Agency for Healthcare Research and Quality (AHRQ), and reporting follows the Preferred Items for Reporting in Systematic Reviews and Meta-Analyses (PRISMA) guideline.[39, 40]

Throughout the project, the evidence review team was supported by a Technical Expert Panel (TEP), a diverse panel of relevant stakeholders that included vaccine experts with particular clinical expertise in key populations (children, adults, older adults, and pregnant women), vaccine safety methodologists, and consumers. The TEP members were not responsible for the content of the evidence report, but they provided the review team with important perspectives and advice on key components of the systematic review.

This update builds on the prior 2014 AHRQ report,[28] which itself built upon the 2011 Institute of Medicine (IOM) consensus report.[29] The IOM report assessed the causality between specified adverse events and vaccines, based on both epidemiologic evidence and mechanistic evidence (from animal and individual human case studies). The prior 2014 report did not search for or include studies on vaccines that were reviewed in the IOM report and published prior to 2011. Similarly, in this update only for vaccines for which there were new indications (or for new vaccines) did we perform targeted searches for research published prior to 2014.

We searched MEDLINE® (including TOXLINE), Embase®, CINAHL®, Cochrane CENTRAL (including International Clinical Trials Registry Platform registry), Web of Science, and Scopus, through November 9, 2020 for randomized controlled trials (RCTs), observational studies with a comparator, and studies that employed a self-controlled design. The searches built on the literature searches undertaken for the prior 2014 report. In addition, we reference-mined existing systematic reviews and Food and Drug Administration (FDA) reports; screened the trial registry, Clinicaltrials.gov; reviewed supplemental material submitted to AHRQ (following a Federal Register Notice posted regarding the availability of a portal for submission of unpublished studies); and consulted with content experts. The search strategy was not limited to specific adverse events and is documented in full in Appendix A.

The Key Questions were publicly posted on the AHRQ Effective Health Care website (https://effectivehealthcare.ahrq.gov/) to allow additional input. The final protocol was posted on the Effective Health Care website at https://effectivehealthcare.ahrq.gov/products/safety-vaccines/protocol and is registered with PROSPERO.[41] The draft report has been similarly posted for public comment on the Effective Health Care website.

Key Questions

The systematic review was guided by the following Key Questions and subquestions:

Key Question 1: What is the evidence that vaccines included in the immunization schedule recommended for adults in the United States (https://www.cdc.gov/vaccines/schedules/hcp/imz/adult.html) are safe in the short term (within 42 days following immunization) or long term (>42 days after immunization)?

a. What adverse events are collected in clinical studies (Phases I–IV) and in observational studies containing a control/comparison group?

b. What adverse events are reported in clinical studies (Phases I–IV) and in observational studies containing a control/comparison group?

c. What adverse events are associated with these vaccines?

1. For each adverse event associated with a particular vaccine, what is the average severity and frequency?
2. For adverse events without statistically significant associations with a particular vaccine, what is the range of possible effects?
3. For each adverse event associated with a particular vaccine, what are the risk factors for the adverse event (including age, sex, race/ethnicity, genotype, underlying medical condition, whether a vaccine is administered individually or in a combination vaccine product, schedule of vaccine administration, adjuvants, and medications administered concomitantly)?

Key Question 2: What is the evidence that vaccines included in the immunization schedules recommended for children and adolescents[a] in the United States (https://www.cdc.gov/vaccines/schedules/hcp/imz/child-adolescent.html) are safe in the short term (within 42 days following immunization) or long term (>42 days after immunization)?

a. What adverse events are collected in clinical studies (Phases I–IV) and in observational studies containing a control/comparison group?

b. What adverse events are reported in clinical studies (Phases I–IV) and in observational studies containing a control/comparison group?

c. What adverse events are associated with these vaccines?

1. For each adverse event associated with a particular vaccine, what is the average severity and frequency?
2. For adverse events without statistically significant associations with a particular vaccine, what is the range of possible effects?

[a] Throughout the remainder of the report, we use the term "children" to refer to both children and adolescents unless otherwise specified.

3. For each adverse event associated with a particular vaccine, what are the risk factors for the adverse event (including age, sex, race/ethnicity, genotype, underlying medical condition, whether a vaccine is administered individually or in a combination vaccine product, schedule of vaccine administration, adjuvants, and medications administered concomitantly)?

Key Question 3: What is the evidence that vaccines recommended for pregnant women, in the United States are safe in the short term (within 42 days following immunization) or long term (>42 days after immunization) for both the woman and her fetus/infant?

a. What adverse events are collected in clinical studies (Phases I–IV) and in observational studies containing a control/comparison group?

b. What adverse events are reported in clinical studies (Phases I–IV) and in observational studies containing a control/comparison group?

c. What adverse events are associated with these vaccines in pregnant women?

1. For each adverse event associated with a particular vaccine, what is the average severity and frequency?
2. For adverse events without statistically significant associations with a particular vaccine, what is the range of possible effects?
3. For each adverse event associated with a particular vaccine, what are the risk factors for the adverse event (including age, sex, genotype, underlying medical condition, whether the vaccine is administered individually or in a combination vaccine product, the schedule of vaccine administration, adjuvants, and medications administered concomitantly)?

d. What adverse events are associated with these vaccines in the fetus/infant?

1. For each adverse event associated with a particular vaccine, what is the average severity and frequency?
2. For adverse events without statistically significant associations with a particular vaccine, what is the range of possible effects?
3. For each adverse event associated with a particular vaccine, what are the risk factors for the adverse events (including age, gender, genotype, underlying medical condition, whether vaccine administered individually or in a combination vaccine product, vaccine schedule of administration, adjuvants, medications administered concomitantly)?

Of note, we use the term "pregnant women" throughout the report, mindful that some individuals who identify as male gender or have other gender identities can be pregnant. No studies of pregnant individuals that met inclusion criteria distinguished between gender and sex; all enrolled participants were identified as female.

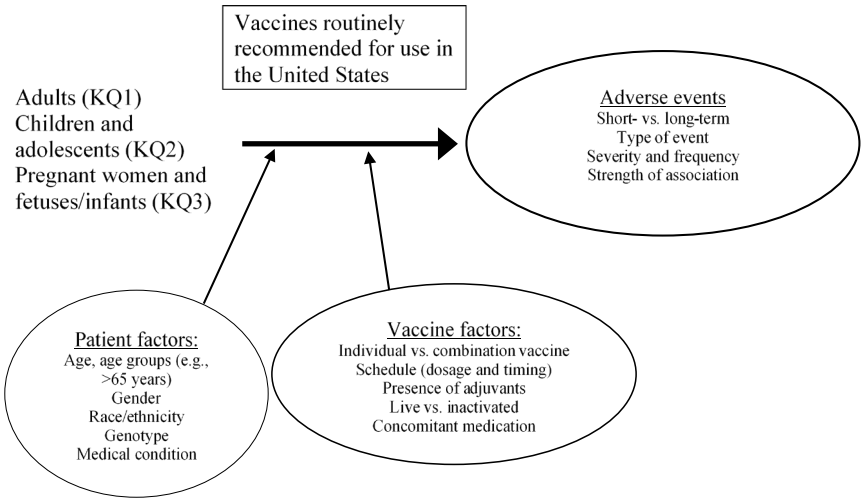
The Key Questions (KQs) mirror the KQs of the 2014 report. KQs 1a, 2a, and 3a examined which adverse events were collected, meaning that the authors stated that they planned to collect them or report them as having been collected. KQs 1b, 2b, and 3b look at the rates or risk estimates for adverse events as actually reported in the study. The synthesis is based on pre-specified outcomes selected with the help of the TEP.

The subquestions differentiate events for which a statistically significant effect indicating increased risk was found (KQ1c1, KQ2c1, KQ3c1, KQ3d1) and those for which there was not a statistically significant effect (KQ1c2, KQ2c2, KQ3c2, KQ3d2). The range of possible effects refers to the strength of association. We reviewed all instances in detail where there were more events in the vaccine group than in the comparison group as outlined further in the synthesis section.

Analytic Framework

This report was limited to a safety assessment and focuses on reported adverse events associated with vaccines; the effectiveness of vaccines is outside the scope of this report. The analytic framework (see Figure 1) outlines the populations and corresponding KQ, the interventions (vaccines routinely recommended for use in the United States), and the outcomes (key adverse events for the population and vaccines) that were addressed in the evidence synthesis. The analytic framework indicates patient and vaccine factors that could affect the type, severity, and frequency of adverse events associated with different vaccines in different populations. While we analyze the results of studies that report race or ethnicity as a risk factor for adverse events in this report, we recognize that race or ethnicity themselves are not risk factors because they are not biologically distinct entities. Rather, racism and social determinants of health equity are a risk factor that may manifest as differences in outcomes based on race or ethnicity.

Figure 1. Analytic framework for safety of vaccines used for routine immunization in the United States



Abbreviations: KQ—Key Question

Study Selection

Studies of vaccines included in the Centers for Disease and Prevention (CDC's) routine immunization schedules that reported presence or absence of adverse events in adults, children, and pregnant women were eligible for inclusion. To enable true assessments of risk, only studies with a comparator were included. We included comparisons to placebo, unvaccinated groups or time periods, or pre-vaccination status. We also included studies that compared new vaccines to the prior standard of care, meaning the previously available or closest vaccine formulation. Studies were excluded if they were non-English language or were published in abbreviated form (e.g., conference abstracts). No studies were excluded based on setting, timing of follow-up, or risk of bias. English language studies conducted outside of the United States were included if the vaccines studied were part of the current CDC immunization schedules and the formulations were approved for use in the United States. We included trial records from sources such as the Clinicaltrials.gov database, even in the absence of a corresponding publication, from which we extracted all serious adverse events and all adverse events graded as 3 or higher in severity according to Common Terminology Criteria for Adverse Events (CTCAE) criteria or described by study authors as severe, as well as deaths. Detailed inclusion and exclusion criteria are documented in Appendix A.

Titles and abstracts of studies identified by the searches described in Appendix A as well as those suggested by the TEP or public commenters were screened by two independent members of the research team using DistillerSR, an online data extraction program. Full-text versions were obtained for all studies identified for potential inclusion by either team member. Two reviewers independently screened full text publications; disagreements were resolved through discussion. Publications reporting on the same participants were consolidated into a single record for analysis. Excluded studies are listed in Appendix B.

Data Extraction and Risk of Bias Assessment

Study-level and outcome data were extracted for each study using a detailed data extraction form in online software for systematic reviews. Data were extracted by an experienced subject matter expert and were checked by methodologists and literature reviewers for accuracy and consistency across studies. Data extraction followed a specific algorithm detailed in Appendix A. We extracted some adverse events by outcome category (e.g., cardiovascular events). Because some patients may have experienced multiple events within an outcome category, if studies listed more than one relevant adverse event in a given outcome category then we selected the most commonly reported adverse event in the category. Given that some studies reported a large number of outcomes, for each Key Question and vaccine, we prioritized key adverse events to allow for synthesis across studies; these are included in summary of findings tables to assess the strength of the evidence. These key adverse events were identified *a priori* with the help of the TEP, with content expert input, and informed by published literature. The selection process and the included key adverse events are listed in Appendix A.

All included studies were assessed for sources of bias that could have influenced the reported results.[42] We used the McHarm scale, a tool for structured critical appraisal of adverse event data reported in research studies, for the assessment. Adverse event assessment and reporting are often lacking in rigor; thus, we applied critical appraisal criteria assessing two main domains:[42, 43] data collection of adverse events and reporting of adverse events.

Study details, findings of all included studies, the risk of bias domains, and the results of the risk of bias assessment are documented in Appendix C. All studies included in the prior 2014 report on which this report builds on are documented in detail in Appendix C in the 2014 report.[28]

The evidence tables (included in Appendix D) report all extracted outcomes in the individual studies, but the strength of evidence (SoE) assessment considered only key adverse events to evaluate the overall safety of the vaccines across studies. We reported on the longest follow-up available for each study to capture all relevant events.

Data Synthesis and Analysis

Data synthesis and analysis were conducted according to the AHRQ Methods Guide for Effectiveness and Comparative Effectiveness Reviews.[44] The synthesis is organized by KQ, then by type of vaccine, then by type of adverse event. Summary tables document evidence across studies. The synthesis documents the presence as well as the absence of adverse events. We report the relative frequency and severity of the adverse events and the SoE for the presence or absence of specific adverse events.

To answer KQ1a, KQ2a, and KQ3a, we documented the adverse events that have been assessed in the included studies.

To address KQ1b, KQ2b, and KQ3b, we documented the adverse events that were reported in the included studies.

To address KQ1c1, KQ2c1, and KQ3c1, where possible, we described the severity of the adverse events for which there was increased risk across included studies.[45] We extracted data using the CTCAE rating system, which includes 26 system categories and five severity grades ranging from 1 (mild) to 5 (death due to the event), as described in Appendix A.

To address KQ1c2, KQ2c2, and KQ3c2, we documented how many times the event occurred in a vaccinated group compared to a control group, and the range of possible effects based on the confidence interval surrounding the point estimate, where available, across studies. In addition, we characterized the severity and frequency of the events associated with the vaccines wherever the information was available.

To address KQ1c3, KQ2c3, and KQ3c3, we documented potential risk factors for adverse events reported in included studies; we had planned to explore subgroups and meta-regressions, but insufficient data were available.

We computed the effect size and 95 percent confidence interval (CI) for all individual studies and key adverse events. In a first step, we calculated the RR of an adverse event comparing a vaccinated group to a control group. Many adverse events of interest are not vaccine-specific, such as allergies and infections, and we first determined whether there are statistically more incidences of these events in the vaccinated group compared to a control group. Where studies did not report sufficient detail, we reported the metrics authors provided, which ranged from verbal statements of no difference, to p-values, to effect measures such as odds ratios.

For each key adverse event, we combined estimates across studies in random effects meta-analyses using Hartung-Knapp correction of standard errors where appropriate. For studies with zero events in one group, we added a constant to the empty cell to enable computation. We determined the most appropriate meta-analysis model as outlined in Appendix A, given that for many adverse events only a small number of studies was available, studies reported on rare events, and several studies reported zero events.[46-49]

For the synthesis of whether there is increased risk of adverse events, we reviewed the RR estimates across studies. In addition to the relative effect, we also documented the actual incidence rates, the sample sizes, and the resulting rates of adverse events in the vaccinated and the control groups for all individual studies. All findings of more adverse events in the vaccinated group were reviewed further and described in detail in the narrative synthesis. We also reviewed the risks reported in individual studies and highlighted all instances where individual studies had reported a statistically significant risk, both in the summary of findings tables as well as the narrative synthesis. Finally, since many estimates were very imprecise (given the small number of reported events and the small number of samples from which conclusions for the true risk could be estimated) the narrative synthesis also reported observed rates to transparently document the available evidence.

The results section describes in detail all new evidence identified since the 2014 report, followed by a synthesis across all available evidence.

Grading the Strength of the Body of Evidence

The strength of the body of evidence (SoE) was assessed based on the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) approach and the AHRQ Methods Guide for Effectiveness and Comparative Effectiveness Reviews.[50] For each KQ, we selected key adverse events that are documented in summary of findings tables to assess the SoE. The evidence tables in the appendix report all outcomes addressed in the individual studies, but the SoE assessment used the *a priori* determined list of adverse events to evaluate the overall safety of the vaccines across studies. We used four criteria to grade the SoE: study limitations, consistency, precision, and reporting bias. The outcomes and criteria for grading the SoE are described in detail in Appendix A. We differentiated *high*, *moderate*, *low*, and *insufficient* evidence to communicate the confidence in the summary estimates for the findings across studies. Briefly, *high* indicates high confidence that the evidence reflects the true effect, *moderate* indicates moderate confidence that the evidence reflects the true effect. *Low* indicates low confidence that the evidence reflects the true effect. *Insufficient* indicates that evidence either is unavailable due to a lack of studies reporting on the outcomes, or the evidence does not permit a conclusion (e.g., due to conflicting results across studies or methodologic flaws).

The summary of findings tables document the results across studies grouped by vaccines. For each key adverse event, we report the RR and CI, where available, of the adverse event among those who received the vaccine of interest compared to controls who did not receive the vaccine. The summary of findings tables include the relative effect across studies as well as the absolute rate of adverse events—number of events and assessed participants in the vaccine and control groups—reported in the individual studies. In addition, the summary of findings tables summarize any other studies that could contribute to the SoE but that could not be combined into the pooled risk estimates. We integrated data for vaccines still in use from studies identified in the 2014 report for which we could calculate the RR of an adverse event comparing a vaccinated group to a control group. In addition, we assessed all findings for which there was a graded SoE in the prior 2014 report and integrated any new evidence. The summary of findings tables document the reasons for downgrading the SoE where applicable; and the findings for the outcomes of interest together with a grading of the SoE. The summary of findings tables are followed by summary tables comparing the evidence identified in the 2014 report and the update, followed by a synthesis of SoE and findings.

Results

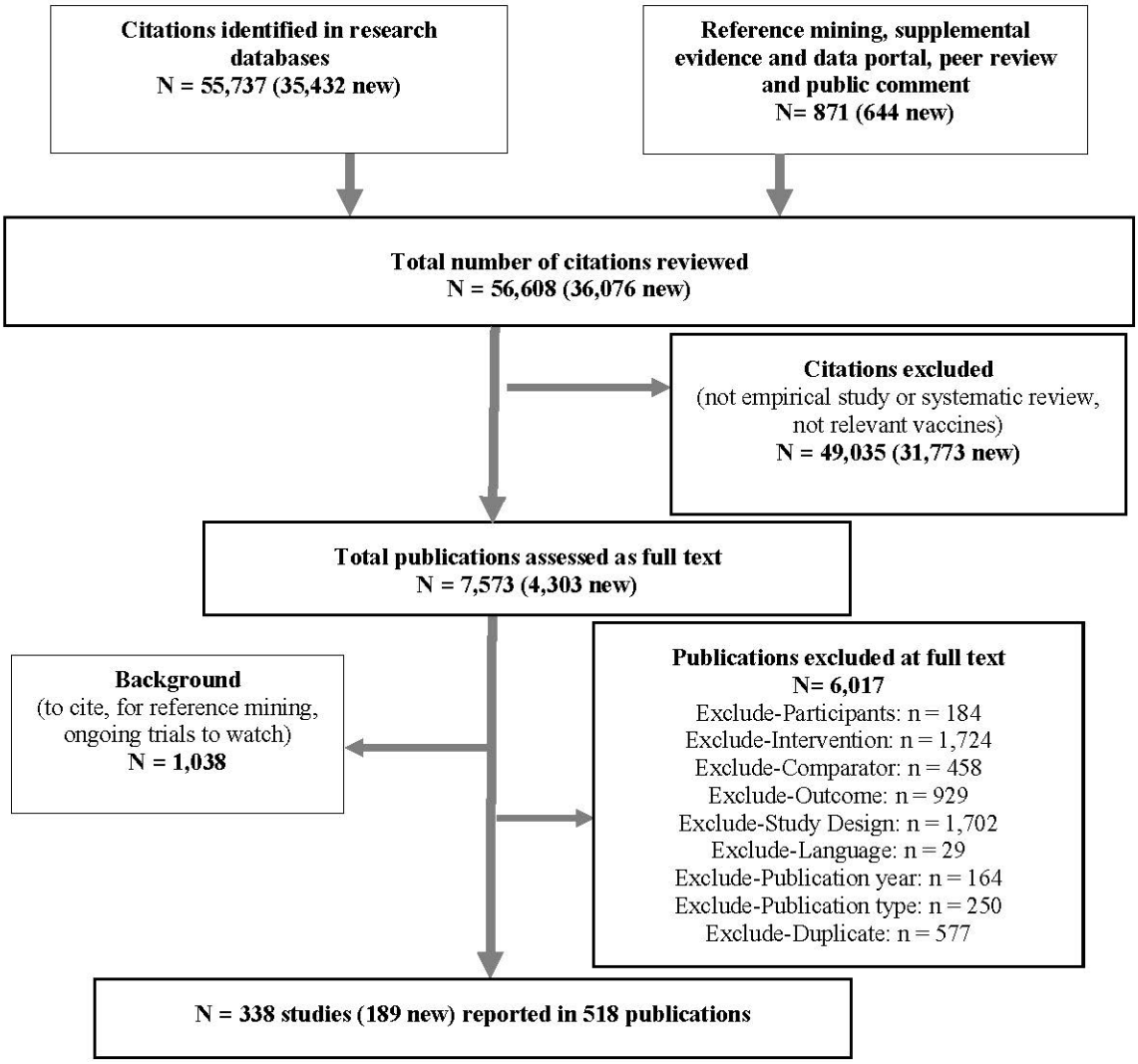
This chapter summarizes the results across studies included in the systematic review. For each Key Question (KQ), we list key points, summarize the update findings, and synthesize strength of evidence (SoE) across all available data.

Appendix B lists excluded studies and the reasons for exclusion. Appendix C details the literature search results and included studies. The evidence table of included studies is provided in Appendix D.

Description of Included Evidence

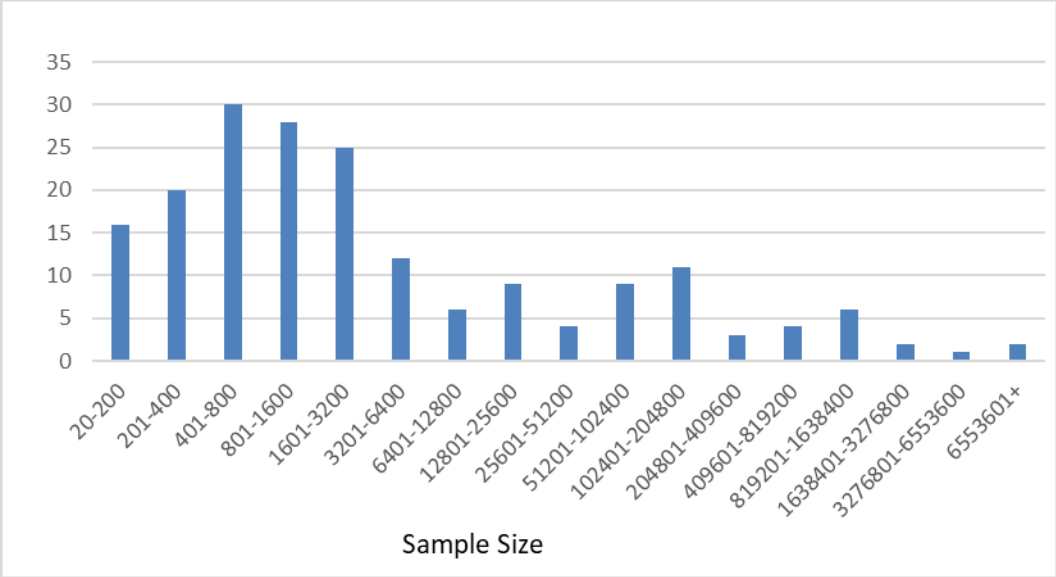
This update identified 189 studies reported in 338 publications.[51-388] Studies were identified through database and grey literature searches, public comments, and reference mining of relevant systematic reviews and package inserts. [2, 3, 5-7, 13-15, 18, 19, 21, 23, 25, 26, 28-30, 32-37, 389-906] As search filters for adverse events are often insufficient, we used a broad search strategy and screened 56,608 citations for this report. Of these, 7,573 publications were reviewed in detail as full text (Figure 2).

Figure 2. Literature flow diagram



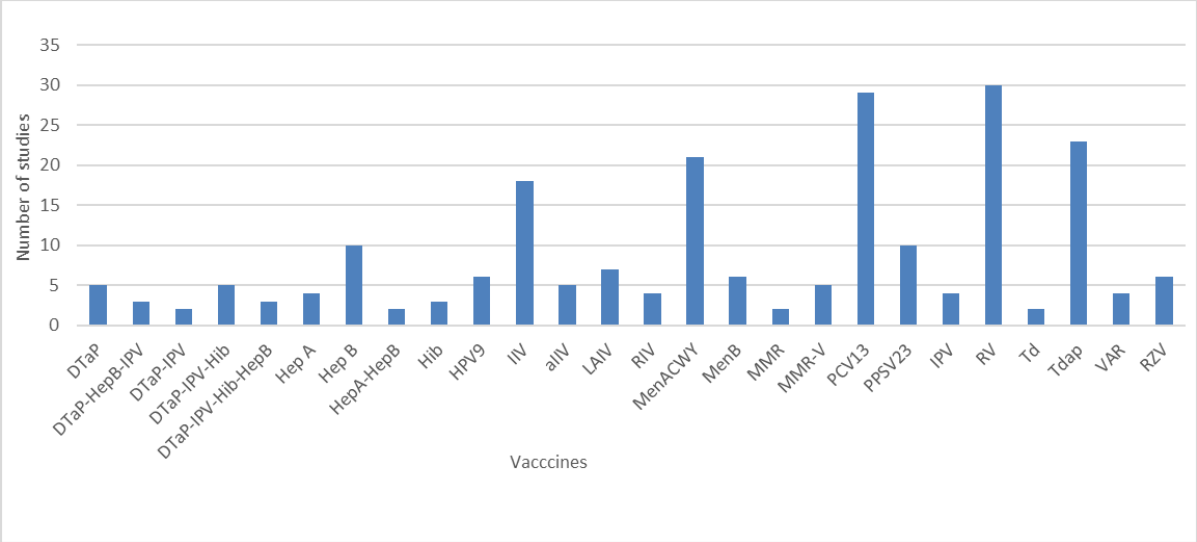
In total, 338 studies reported in 518 publications across both reports met inclusion criteria.[51-388, 907-1086] The most common reason for exclusion was the intervention type (n=1,724); some studies were excluded because they were included in the 2011 Institute of Medicine (IOM) report or were published prior to IOM report for vaccines included in that report (n=164). The most frequent study designs identified in the update were randomized controlled trials (RCTs) (n=104), followed by cohort studies (n=40), pre-post designs (n=15), case-control designs (n=12), and one non-randomized controlled clinical trial, along with 17 others that used self-controlled designs (either self-controlled risk interval or self-controlled case series analyses; two of these used self-controlled designs in conjunction with a cohort approach). Studies reported on a variety of datasets, ranging in size from fewer than 50 to millions of data points (Figure 3).

Figure 3. Range and frequency of sample sizes across studies



The number of studies for each vaccine is listed in Figure 4.

Figure 4. Number of studies evaluated for vaccines identified in this update

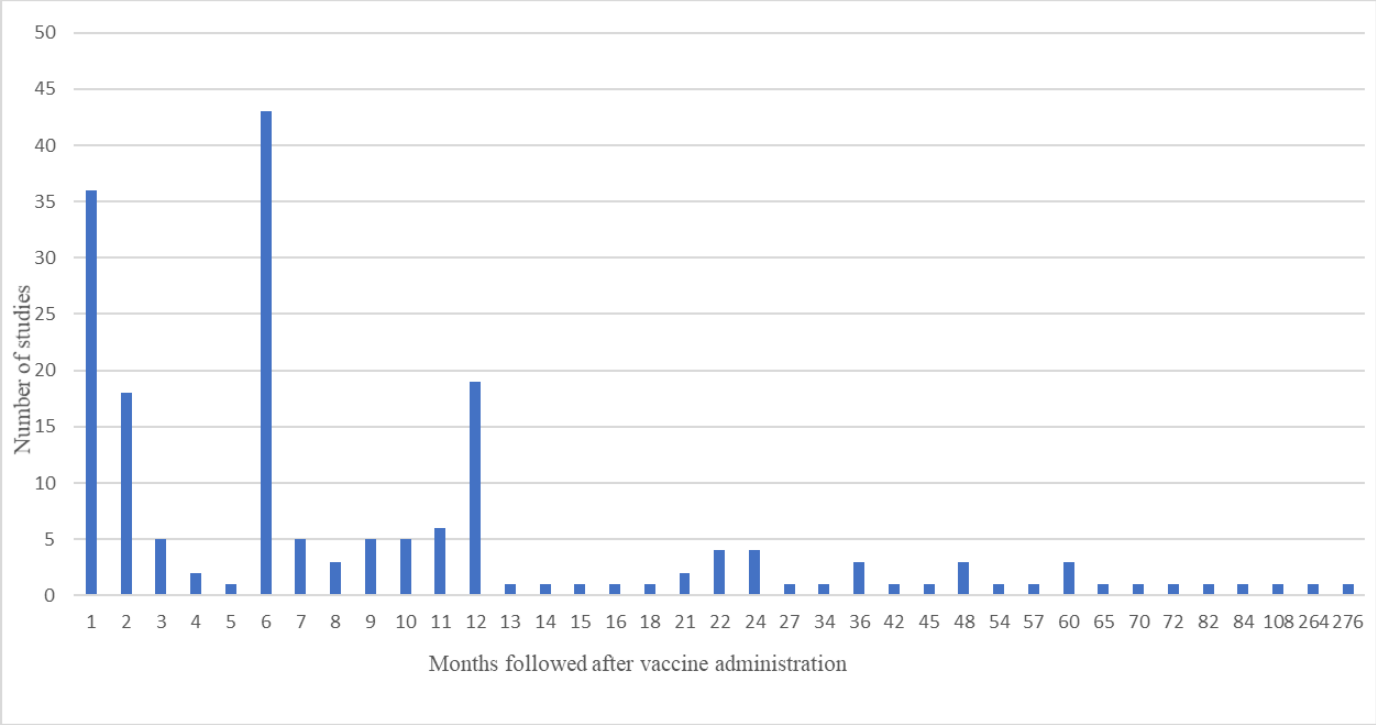


Notes: Data given for the report update at the time of the draft report. aIIV—Adjuvanted inactivated influenza vaccine; DTaP—Diphtheria, tetanus, and acellular pertussis vaccine; HepA—Hepatitis A vaccine; HepB—Hepatitis B vaccine; HepA-HepB—Hepatitis A and hepatitis B vaccine; Hib— *Haemophilus influenzae* type b vaccine; HPV9—9-valent human papillomavirus vaccine; IIV—Inactivated influenza vaccine; IPV—inactivated poliovirus vaccine; LAIV—Live attenuated influenza vaccine; MenACWY—Serogroups A, C, W, and Y meningococcal vaccine; MenB—Serogroup B meningococcal vaccine; MMR—Measles, mumps rubella vaccine; MMR-V—Measles, mumps, rubella, and varicella vaccine; PCV13—13-valent pneumococcal conjugate vaccine; PPSV23—23-valent pneumococcal polysaccharide vaccine; RIV—Recombinant influenza vaccine; RV—Rotavirus vaccine; Td—Tetanus, diphtheria vaccine; Tdap—Tetanus, diphtheria, and acellular pertussis vaccine; VAR—Varicella vaccine.

Studies most frequently evaluated influenza vaccines and rotavirus vaccines. Post-vaccination follow-up periods varied (Figure 5). A large number of studies followed patients for 6 months to record emerging adverse events, and some studies reported data of up to 15 years for

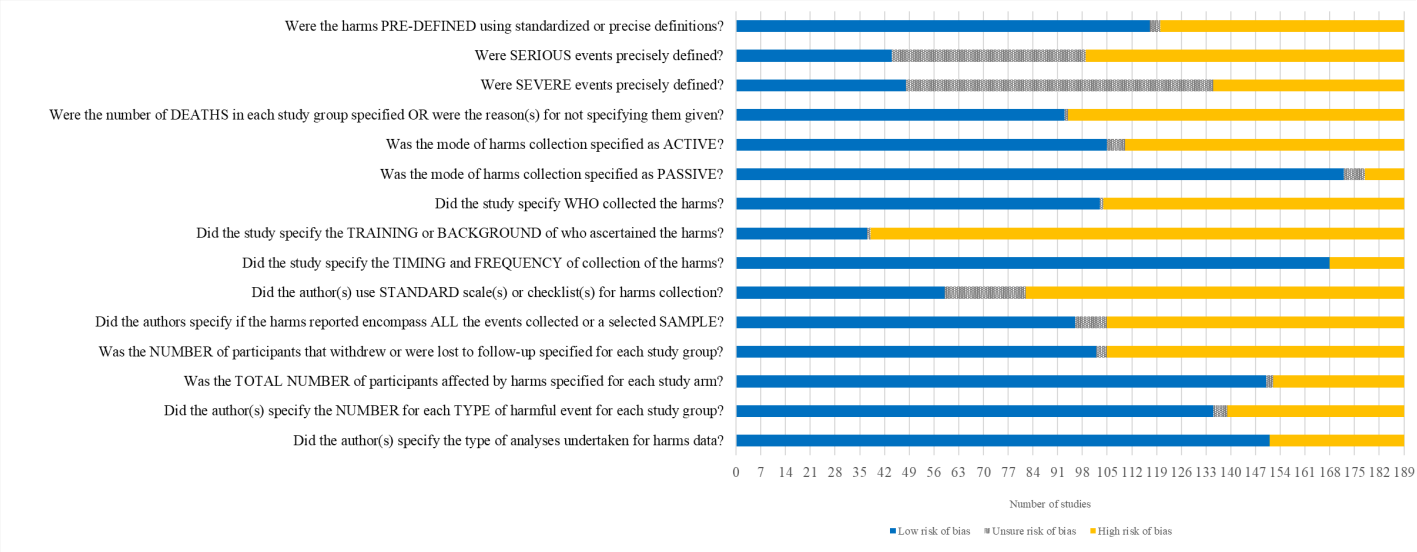
some of the included study participants. Of all studies that reported a follow-up period, 23 percent reported only on events occurring 42 days or less from vaccine administration.

Figure 5. Length of followup in included studies



The methodological quality and the reporting of the adverse events varied widely across studies over 15 assessed critical appraisal domains based on the McHarm tool (Figure 6). Details regarding these domains and their results are documented in more detail in Appendix C. Most studies reported the timing and frequency of the adverse events assessment, but only a few studies reported on the training and background of the outcome assessors.

Figure 6. Critical appraisal of included studies



In the remainder of this chapter, we describe the results stratified by population (KQ1 addresses adult populations; KQ2 addresses children as well as evidence from studies that included both children and adults; and KQ3 focuses on pregnant women and their offspring, specifically). Within populations, we stratify by vaccine.

We focus on the synthesis of findings across studies; more information on individual studies is reported in Appendix C. We summarize results for key adverse events selected with the help of content experts and other findings. Results for all other outcomes are shown in the evidence tables stratified by population in Appendix D. All included studies report on the presence or absence of at least one adverse event, but the number of adverse events varies across studies, and a small number of studies assess several hundred adverse events.

Many of the findings we describe are from RCTs, of which some were placebo-controlled (or in which both intervention and control groups received the same base treatment, such as other routine vaccines) while others used an active comparator. We note the comparator for each study directly in the results section, as well as in the evidence tables in Appendix D.

This chapter provides responses to each of the KQs. The responses are divided into subquestions that are parallel across each KQ, as follows.

KQ1a, 2a, and **3a** describe the spectrum of types of adverse events collected across all the included studies, and **KQ1b, 2b,** and **3b** identify the specific adverse events reported for each vaccine.

KQ1c, 2c, 3c, and 3d are further divided into three subquestions. In **KQ1c1, 2c1, 3c1,** and **3d1**, we examine the average severity and frequency of adverse events for which statistically significant associations were observed with a specific vaccine; KQ3c1 includes reports of associations that involve the pregnant woman, and KQ3d1 reports on associations that involve the fetus or infant. In **KQ1c2, 2c2, 3c2, and 3d2**, we assess the range of apparent associations between a vaccine and a specific type of event, including where the relative risk (RR) did not favor the intervention (meaning the RR was >1) but that did not reach statistical significance given that some of the adverse events are rare. In **KQ1c3, 2c3, 3c3, and 3d3** we describe the risk factors for adverse events. At the end of each Key Question section, the summary of findings is presented.

Key Question 1: What is the evidence that vaccines included in the immunization schedule recommended for adults are safe in the short term or long term?

This section describes the evidence for the safety of vaccines routinely recommended for use in adults.

Key Points

- Hepatitis B vaccines: No evidence of increased risk[b] of diabetes or multiple sclerosis onset or exacerbation (moderate SoE) both remain unchanged from prior report. Anaphylaxis in patients allergic to yeast (moderate SoE) also remains unchanged from prior report. No evidence of increased risk of asthma, autoimmune disease, cardiovascular events, death, diabetes, herpes zoster, reproductive system events, or stroke associated with the new hepatitis B vaccine with a novel immunostimulatory adjuvant (low SoE).
- Quadrivalent inactivated influenza vaccines: No evidence of increased risk of asthma, cardiovascular events, death, myocardial infarction, reproductive system events, seizures, or stroke (low SoE).
- Adjuvanted inactivated influenza vaccine (trivalent or quadrivalent): No evidence of increased risk of asthma, autoimmune disease, cardiovascular events, death, encephalitis/encephalopathy, Guillain-Barré syndrome, idiopathic thrombocytopenic purpura, myocardial infarction, seizures, or stroke (all low SoE except for cardiovascular events and stroke, which were moderate SoE).
- Quadrivalent recombinant influenza vaccine: No evidence of increased risk of cardiovascular events, death, encephalitis/encephalopathy, myocardial infarction, reproductive system events, or stroke (low SoE).
- Measles, mumps, rubella vaccine: No evidence of increased risk of type 1 diabetes mellitus (moderate SoE) remains unchanged from prior report.
- Serogroups A, C, W, and Y meningococcal vaccines: No evidence of increased risk of cardiovascular events, death, myocardial infarction, or stroke (low SoE except for death, which was moderate SoE).
- 13-valent pneumococcal conjugate vaccine: No evidence of increased risk of acute disseminated encephalomyelitis, anaphylaxis or systemic allergic reactions, asthma, autoimmune disease, cardiovascular events, death, encephalitis/encephalopathy, herpes zoster, idiopathic thrombocytopenic purpura, meningitis, myocardial infarction, reproductive system events, seizures, or stroke (low or moderate SoE).
- 23-valent pneumococcal polysaccharide vaccine: No evidence of increased risk of death (moderate SoE). No evidence of increased risk of cardiovascular or cerebrovascular events in adults (high SoE).
- Tetanus, diphtheria, and acellular pertussis and tetanus and diphtheria vaccines: Anaphylaxis to tetanus toxoid (high SoE) remains unchanged from prior report.

[b] "No evidence of increased risk" indicates that the outcome was studied and that the findings of the studies did not constitute evidence of increased risk of the adverse event following administration of that vaccine (because the risk either was not statistically significantly increased or was reduced).

- Recombinant zoster vaccine: No evidence of increased risk of amyotrophic lateral sclerosis, anaphylaxis or systemic allergic reaction, asthma, cardiovascular events, death, diabetes, encephalitis/encephalopathy, Guillain-Barré syndrome, herpes zoster, idiopathic thrombocytopenic purpura, meningitis, myocardial infarction, reproductive system events, seizures, or stroke (moderate or high SoE). No evidence of increased risk of acute disseminated encephalomyelitis, angioedema, ataxia, autoimmune disease, or autoimmune thyroiditis (Hashimoto's disease) (low SoE).
- Insufficient evidence to permit evidence statements for the following vaccines in adults: hepatitis A vaccine, combination hepatitis A and hepatitis B vaccine, 9-valent human papillomavirus vaccine, live attenuated influenza vaccine, serogroup B meningococcal vaccine, and varicella vaccine.

KQ1a. What adverse events are collected in clinical studies and in observational studies containing a control/comparison group?

The information on the data collection for vaccines in adults comes from trial records, published protocols, and all published papers available for an individual study. The information was collected from experimental and observational studies. The number and reporting detail of collected adverse events varied widely, and studies often assessed general, non-specific adverse events, such as hospitalizations, along with specific adverse events, such as Guillain-Barré syndrome. Some studies assessed dozens of adverse events, while others assessed several hundred. The table in Appendix C lists the adverse events collected in the included studies by vaccine to document the presence and the absence of adverse events. The table lists all assessed adverse events for a vaccine group (e.g., HepA) in alphabetical order.

The methods used to collect and assess adverse events are summarized for each study in the evidence tables in Appendix D. The risk of bias table in Appendix C documents the methods used to ascertain and report adverse events.

KQ1b. What adverse events are reported in clinical studies and in observational studies containing a control/comparison group?

The evidence tables in Appendix D contain all serious and severe adverse events reported in studies of adults.

KQ1c. What adverse events are associated with these vaccines?

This section further characterizes the risk of adverse events identified in studies of adults who received routinely recommended vaccines.

KQ1c1. For each adverse event associated with a particular vaccine, what is the average severity and frequency?

The prior 2014 report found several associations, which are detailed in that report and summarized at the end of this KQ section in tables that integrate the findings from both reports. Several of these associations were in trivalent inactivated influenza vaccine (IIV) or monovalent H1N1 influenza vaccine that are no longer in use because they have been replaced by quadrivalent influenza vaccines. For those vaccines that are still in use, the associations between adverse events and specific vaccines established in the prior 2014 report and/or Institute of Medicine (IOM) report remain unchanged because there were no new studies or the outcome was

not considered a key adverse event (in the case of transient arthralgia). These include anaphylaxis in patients allergic to yeast for hepatitis B vaccines (HepB; moderate SoE), transient arthralgia in women for measles, mumps, and rubella vaccine (MMR; moderate SoE), and anaphylaxis to tetanus toxoid for tetanus toxoid-containing vaccines (high SoE).

We did not find any new associations between any of the studied vaccines and the key adverse events, including for new vaccines not reviewed in the prior 2014 report. For all events, the severity for each event is documented in the evidence table in Appendix D.

KQ1c2. For adverse events without statistically significant associations with a particular vaccine, what is the range of possible effects?

We summarize the range of possible effects by vaccine below for all adverse events for which the primary relative risk estimate did not favor the intervention (i.e., RR>1), but the association was not statistically significant. We also note any instances where an individual study contributing to a pooled risk estimate indicated a statistically significant increased risk of an adverse event. Throughout this section, where possible, we describe caveats to contextualize the finding, such as noting the confidence interval (e.g., many confidence intervals were extremely wide because only a single event was reported in the study or several studies with rare events were combined for meta-analysis) or assessing whether study authors attributed the event to something other the vaccine (e.g., death due to a motor vehicle accident or drug overdose).

Hepatitis Vaccines

Hepatitis A Vaccine

We did not identify new studies reporting on hepatitis A vaccine (HepA) in this update.

Hepatitis B Vaccines

We identified five studies[99, 100, 132, 134, 151] evaluating HepB in this update. Three RCTs[99, 100, 132] compared HepB with a novel immunostimulatory adjuvant (HEPLISAV-B®) to the previously available HepB (Engerix-B®), one cohort study[134] compared HepB (Engerix-B or Recombivax HB®) to no vaccine, and one case-control epidemiological study[151] compared HepB (Engerix-B or Recombivax HB) to no vaccine.

Across the three RCTs[99, 100, 132] of HepB with novel adjuvant, we found no evidence of increased risk of herpes zoster (RR 1.95; confidence interval [CI] 0.45, 8.51), though one RCT[99] showed a significantly increased risk (RR 2.10; CI 1.02, 4.34; 38/5587 vs 9/2781). The relative risk of cardiovascular events across these same RCTs was 1.55 (CI 0.46, 5.18). Across two of the RCTs,[99, 132] we found no evidence of increased risk of myocardial infarction (RR 2.00; CI 0.00, 41600564). However, the effect estimate was imprecise and with substantial heterogeneity (I^2 64%), possibly due to a non-statistically significant imbalance of myocardial infarction (14/5887 [0.25%] vs 1/2781 [0.04%]) in one of the RCTs.[99] We found no evidence of increased risk of death (RR 0.97; 0.04, 23.18), although again one of the RCTs found a non-statistically significant imbalance in deaths (25/5587 [0.44%] vs 7/2781 [0.25%]). These events—and particularly an imbalance in the rate of death and myocardial infarction in one of the RCTs[99] though not the other two RCTs—were noted to be of concern to the Food and Drug Administration (FDA).[379] For myocardial infarction in particular, the rate remained similar even once cases were adjudicated by experts (0.25% vs 0.04%), and when looking more broadly at cardiac disorders (0.9% vs 0.5%), despite baseline risk factors for cardiovascular disease having

been balanced across the intervention and control groups. The manufacturer proposed two post-marketing observational surveillance studies of approximately 60,000 people—one assessing herpes zoster and other outcomes and the other acute myocardial infarction specifically—which started in August 2018.[1087] According to the manufacturer in a statement[1088] released in December 2019, interim results from the acute myocardial infarction study suggested no increased risk with the vaccine.

Across the three RCTs,[99, 100, 132] we found no evidence of increased risk of asthma (RR 0.83; CI 0.03, 22.31). We found no evidence of increased risk of autoimmune disease (RR 0.70; CI 0.15, 3.21) or reproductive system events (RR 0.21; CI 0.00, 13.46). Across two of these RCTs,[99, 100] we found no evidence of increased risk of stroke (RR 1.27; CI 0.00, 1430); the effect estimate was imprecise and based on two studies reporting 11/5587 cases in the vaccine group vs 4/2781 cases in the comparator group in one study and 1/1821 vs 0/607 cases in the other. One of these RCTs[99] found RR>1 for encephalitis/encephalopathy (RR 1.99; CI 0.09, 44.14), meningitis (RR 1.99; 0.09, 44.14), and seizures (RR 1.99; CI 0.22, 17.81). For encephalitis/encephalopathy and meningitis, the risk estimates were imprecise as there were only two cases each in the vaccinated group (2/5587 vs 0/2781). There were also few cases of seizures, resulting in a wide confidence interval (4/5587 vs 1/2781).

Another RCT[288] reported no significant difference in medically attended (meaning the subject sought medical attention for the adverse event) grade 3 or 4 adverse events (HEPLISAV-B 23.5%, Engerix-B 22.2%) in people aged 60 to 70 years with diabetes mellitus but the study reported not enough detail for further analyses. No serious adverse events related to vaccines were reported in either group. In one cohort study[134] comparing HepB (presumed to be Engerix-B or Recombivax HB as it took place prior to use of HEPLISAV-B) to no vaccine, there was no evidence of increased risk of diabetes (RR 0.61; CI 0.55, 0.67). When combined with an RCT[99] that compared HEPLISAV-B to a non-adjuvanted HepB, the risk estimate remained similar (RR 0.61; CI 0.33, 1.11). In the epidemiological study for HepB (Engerix-B or Recombivax HB),[151] vaccination was not associated with increased risk for central nervous system demyelinating syndromes (odds ratio [OR] 0.8; CI 0.4, 2.0), including acute disseminated encephalomyelitis (OR 1.5; CI 0.2, 12.1) and multiple sclerosis (OR 0.4; CI 0.1, 1.9) for up to three years post-vaccination.

Combined Hepatitis A-Hepatitis B Vaccine

This update identified two studies[62, 63] of HepA-HepB (Twinrix®), which included both children and adults; we presumed that only adults received HepA-HepB as the ages were not specified by vaccine. The case-centered analyses compared the vaccination status of each case to vaccination of all matched persons in the study population who received the same type of vaccine with respect to the exposure interval. One case-centered analysis[62] showed no evidence of increased risk of optic neuritis in the 2- to 42-day risk interval after HepA-HepB administration (adjusted OR was not estimable). Another case-centered analysis[63] detected no association between sudden sensorineural hearing loss and HepA-HepB within one week of vaccine administration (OR 2.39; CI 0.37, 9.14).

9-Valent Human Papillomavirus Vaccine

We did not identify studies assessing 9-valent human papillomavirus vaccine (HPV9) in adults in this update. More evidence on adverse events reported for HPV9 in studies of children and adults together is documented in KQ2.

Influenza Vaccines

We identified 17 studies assessing influenza vaccines currently in use (all quadrivalent, except for trivalent adjuvanted inactivated influenza vaccine [aIIV] as it is still in use) in this update. Thirteen studies (reported in 24 publications)[60, 66, 77, 103, 110, 118, 119, 145, 185, 204, 216, 218, 232, 259, 262, 264, 296, 329, 330, 360, 362, 368, 373, 374] assessed quadrivalent inactivated influenza vaccines (IIV) and four studies (reported in five publications)[84, 97, 98, 192, 378] assessed quadrivalent recombinant influenza vaccines (RIV). Studies of IIV included one study[60] of Flucelvax Quadrivalent®, two studies[66, 145] of Fluarix Quadrivalent®, two studies[118, 119] of Fluzone Quadrivalent®, one study[77] of Fluzone High Dose Quadrivalent® one study[216] of Flulval Quadrivalent®, and one study of Afluria Quadrivalent®.[218] We identified six studies[103, 110, 180, 185, 204, 232] of aIIV (four of Fluad® and two of Fluad Quadrivalent®). In addition, we identified one study[71] of quadrivalent live attenuated influenza vaccine (LAIV) in adults.

Quadrivalent Inactivated Influenza Vaccines (Non-Adjuvanted)

Across six studies[60, 66, 77, 118, 145, 218] that compared quadrivalent IIV to trivalent IIV, we found no evidence of increased risk of death (RR 1.03; CI 0.41, 2.59). Of the six studies, two studies reported no deaths in either group; two reported deaths that were explicitly not considered attributable to the vaccine by the study authors; one did not comment on whether deaths were related to the vaccine; and one found that one of the deaths was considered related to the intervention vaccine.

Across five studies[60, 77, 145, 216, 218] that compared quadrivalent IIV to trivalent IIV, we found no evidence of increased risk of cardiovascular events (RR 1.11; CI 0.34, 3.68) or of myocardial infarction specifically (RR 1.15; CI 0.27, 4.86). Although the RR was greater than 1, the estimate is not statistically significant. We also note that these studies compare quadrivalent to trivalent IIV; the prior report noted no increased risk of cardiovascular events (in adults aged 65 years and older; high SoE) when comparing trivalent IIV to a non-active comparator. Across four studies[77, 145, 216, 218] that compared quadrivalent IIV to trivalent IIV, we found no evidence of increased risk of stroke (RR 0.87; CI 0.13, 5.89). Across four studies,[60, 77, 145, 216] one that compared a quadrivalent cell-cultured IIV to trivalent IIV,[60] one[77] that compared quadrivalent IIV to two other trivalent IIVs, and two[145, 216] that compared quadrivalent IIV to one trivalent IIV, we found no evidence of increased risk of reproductive system events (RR 0.75; CI 0.06, 8.76). Across three studies,[145, 216, 218] each comparing quadrivalent IIV to trivalent IIV, we found no evidence of increased risk of asthma (RR 0.46; CI 0.01, 24.59). Across two studies,[60, 77] one that compared quadrivalent cell-cultured IIV to trivalent IIV[60] and one[77] that compared quadrivalent IIV to two other trivalent IIVs, we found no evidence of increased risk of seizure (RR 0.17; CI 0.00, 478774); the effect estimate was imprecise and based on with few events occurring across the two studies (0/1324 vs 2/673 and 0/1777 vs 1/893). Across another two studies,[66, 218] one[66] that compared quadrivalent IIV with trivalent IIV and one[218] that compared quadrivalent IIV with two trivalent IIVs containing alternate B strains, we found no evidence of increased risk of autoimmune disease (RR 1.49; CI 0.00, 24522910); the effect estimate was again imprecise due to only one event occurring across both studies (0/105 vs 0/105 and 1/1721 vs 0/1728). One study[60] found an RR greater than 1 when assessing amyotrophic lateral sclerosis (RR 2.02; CI 0.07, 60.19) and meningitis (RR 2.02; CI 0.07, 60.19); the risk estimates are imprecise as only one event each was reported in the vaccinated group (1/1324 vs 0/1338).

A sensitivity analysis of the new quadrivalent cell-based IIV (Flucelvax Quadrivalent, assessed in one study[60] in adults) compared to trivalent cell-based IIV showed no evidence of

increased risk of amyotrophic lateral sclerosis (RR 2.02; CI 0.07, 60.19; 1/1324 vs 0/1338), anaphylaxis or systemic allergic reaction (RR 0.51; CI 0.02, 15.05), cardiovascular outcomes (RR 2.53; CI 0.49, 13.00), meningitis (RR 2.02; CI 0.07, 60.19; 1/1324 vs 0/1338), myocardial infarction (RR 4.04; CI 0.45, 36.12), reproductive system events (RR 0.51; CI 0.02, 15.05), seizures (RR 0.13; CI 0.01, 2.81), or death (RR 0.72; CI 0.23, 2.27). A sensitivity analysis of the high-dose quadrivalent IIV for adults aged 65 years and older (Fluzone Quadrivalent High Dose, assessed in one study[77]) compared to high-dose trivalent IIV showed no evidence of increased risk of cardiovascular events (RR 0.34; CI 0.06, 2.00), myocardial infarction (RR 0.50; CI 0.07, 3.56), reproductive system events (RR 1.01; CI 0.09, 11.07), seizures (RR 0.25; CI 0.01, 7.48), stroke (RR 0.25; CI 0.01, 7.48), or death (RR 0.75; CI 0.13, 4.50).

Adjuvanted Inactivated Influenza Vaccines

For all outcomes except for seizures and death, the risk estimates were imprecise because a small number of events were being reported across only two studies (see rates of each event following the risk estimates).

Across three studies[103, 110, 232] (one[103] that compared quadrivalent aIIV to two strains of trivalent aIIV and two[110, 232] that compared trivalent aIIV to trivalent IIV), there was no evidence of increased risk of seizures (RR 0.93; CI 0.36, 2.38). Across two studies[103, 110] (one[103] that compared quadrivalent aIIV to two strains of trivalent aIIV, and one[110] that compared trivalent aIIV with trivalent IIV) there was no evidence of increased risk of death (RR 1.15; CI 0.09, 14.54). Although the RR was greater than 1, in neither study were any of the deaths attributed to vaccines.

Across the same two studies,[103, 110] there was no evidence of increased risk of cardiovascular events (RR 0.47; CI 0.00, 81.39; 1/888 vs 3/888 and 8/3545 vs 16/3537) or stroke (RR 1.18; CI 0.00, 33607; 0/888 vs 1/888 and 3/3545 vs 2/3537). A case-control study[185] of trivalent aIIV also showed no increased risk of acute coronary syndrome (adjusted odds ratio [aOR] 0.13; 0.03, 0.65) or stroke (aOR 0.07; CI 0.01, 0.48). There was also no evidence of increased risk of asthma (RR 0.76; CI 0.00, 836505; 0/888 vs 1/888 and 1/3545 vs 1/3537), myocardial infarction (RR 1.05; CI 0.00, 295; 0/888 vs 1/888 and 10/3545 vs 9/3537).

Across two studies,[103, 232] one[103] that compared quadrivalent aIIV to two strains of trivalent aIIV and one[232] that compared trivalent aIIV to trivalent IIV, there was no evidence of increased risk of autoimmune disease (RR 0.98; CI 0.00, 2288259; 1/888 vs 1/888, 0/88449 vs 0/82539) or encephalitis/encephalopathy (RR 0.48; CI 0.00, 2761252; 0/888 vs 1/888, 0/88449 vs 1/82539). Across another two studies[110, 232] that compared trivalent aIIV to trivalent IIV, there was no evidence of increased risk of Guillain-Barré syndrome (RR 0.29; CI 0.00, 44494; 0/3545 vs 1/3537, 1/88449 vs 4/82539). Across the same two studies,[110, 232] there was also no evidence of increased risk of idiopathic thrombocytopenic purpura (RR 2.52; CI 0.00, 505129; 1/3545 vs 0/3537, 3/88449 vs 1/82539). While both studies showed more events in the vaccinated group, in the first study[110] the investigators did not consider the event to be related to vaccine; the second study[232] did not comment on causality. In one active surveillance study[180] of Medicare beneficiaries following influenza vaccination that used a self-controlled risk interval analysis, there was an increased risk of Guillain-Barré syndrome following trivalent aIIV (OR 3.75; CI 1.01, 13.96) with an attributable risk of 2.5 episodes per million vaccinations. However, when adjusted for multiplicity the result was no longer robust (q=0.15). One RCT[232] found an RR greater than 1 for anaphylaxis (RR 1.87; CI 0.06, 55.63), but the risk estimate was imprecise due to one event occurring in the aIIV group (1/88449 vs 0/82539). When analyzed separately, trivalent aIIV and quadrivalent aIIV still showed no evidence of increased risk of any of the

above outcomes. One study[204] of trivalent aIIV plus PPSV23 versus PPSV23 alone reported no vaccine-related serious adverse events.

Quadrivalent Recombinant Influenza Vaccine

Across three studies[97, 98, 192] of quadrivalent RIV compared with quadrivalent IIV, we found no evidence of increased risk of cardiovascular events (RR 1.23; CI 0.34, 4.46). The RR was greater than 1, largely due to one study with four excess events (0/335 vs 0/508, 23/4328 vs 19/4344, 2/998 vs 0/332); no risk estimates from individual studies were statistically significant on their own. Across the same three studies, there was no evidence of increased risk of myocardial infarction specifically (RR 1.35; CI 0.08, 22.21); the risk estimate was imprecise due to few events occurring across three studies of varying sizes (0/335 vs 0/508; 4/4328 vs 3/4344; 2/998 vs 0/332). Across the same three studies, there was no evidence of increased risk of death (RR 0.66; CI 0.10, 4.26). Across two of the studies,[97, 98] we found no evidence of increased risk of encephalitis/encephalopathy (RR 0.58; CI 0.00, 3294190), or reproductive system events (RR 0.41; CI 0.00, 82495). The risk estimates for both outcomes were imprecise due to few events occurring across each of the two studies (0/4328 vs 1/4344 and 1/998 vs 0/332 for encephalitis/encephalopathy; 1/4328 vs 3/4344 and 1/998 vs 0/332 for reproductive system events).

Quadrivalent Live Attenuated Influenza Vaccine

No outcomes were assessed in more than one study of quadrivalent LAIV in adults. In one study[71] comparing quadrivalent LAIV to two different trivalent LAIV, we found no evidence of increased risk of anaphylaxis (RR 0.25; CI 0.01, 7.43), asthma (RR 0.25; CI 0.01, 7.43), cardiovascular events (RR 0.25; CI 0.01, 7.43), myocardial infarction (RR 0.25; CI 0.01, 7.43), reproductive system events (RR 0.12; CI 0.01, 2.76), or death (RR 0.50; 0.01, 25.13).

Measles, Mumps, and Rubella Vaccine

We did not identify studies assessing MMR in adults in this update. Results in children and mixed samples (adults and children) are documented in KQ2.

Meningococcal Vaccines

Meningococcal A, C, W, and Y Vaccines

We identified four studies[53, 54, 104, 147] assessing serogroups A, C, W, and Y meningococcal vaccine (MenACWY) in adults in this update. Studies compared MenACWY-TT versus meningococcal polysaccharide vaccine (MPSV),[104, 147] MenACWY-CRM plus typhoid and yellow fever vaccines versus typhoid and yellow fever vaccines alone,[53] and MenACWY-CRM plus HepA-HepB versus HepA-HepB alone.[54] No findings were reported for MenACWY in adults in the prior 2014 report.

Both studies[53, 54] of MenACWY-CRM were performed in adults aged 18-60 or 18-64 years of age; this vaccine is approved through 55 years of age, but the majority of adults in these studies fell within this range. Both studies[104, 147] of MenACWY-TT were performed in adults aged 56 years and older; this vaccine has no upper limit of age. Across the two studies[53, 54] that compared MenACWY-CRM to base treatment received by both the intervention and control groups, we found no evidence of increased risk of death (RR 0.99; CI 0.00, 60563320). The risk estimate was imprecise due to no events occurring in either study (0/99 vs 0/100 and 0/85 vs

0/84). Combining the four MenACWY studies also showed no evidence of increased risk of death (RR 0.53; CI 0.03, 10.33).

In a sensitivity analysis of the newer vaccine, MenACWY-TT, two studies[104, 147] that used an existing meningococcal polysaccharide vaccine as the comparator showed no evidence of increased risk of death (RR 0.33; CI 0.00, 2256832). In a study of MenACWY-TT compared to MenACWY-CRM,[104] there were no systematic difference in cardiovascular events (RR 0.25; CI 0.01, 5.59), myocardial infarction (RR 0.25; CI 0.01, 5.59), reproductive system events (RR 2.02; CI 0.07, 60.13), or stroke (RR 0.51; CI 0.02, 15.03). The RR was greater than 1 for reproductive events but was imprecise due to only one event occurring in the study (1/448 vs 0/453).

Meningococcal B Vaccines

We did not identify any evaluations of serogroup B meningococcal vaccine (MenB) in adults in this update or in the original 2014 report.

Pneumococcal Vaccines

We identified 31 studies[72, 80, 81, 101, 107, 109, 120, 137, 140, 142, 143, 159, 162, 171, 176, 184, 195, 197, 199-205, 210, 214, 222, 227, 231, 239] assessing pneumococcal vaccines (13-valent pneumococcal conjugate vaccine [PCV13] or 23-valent pneumococcal polysaccharide vaccine [PPSV23]). One study[935] of PPSV23 from the prior report that examined cardiovascular events and death could be pooled statistically with new studies from the update.

13-Valent Pneumococcal Vaccine

PCV13 was not assessed in the prior 2014 report for adults. In the current report, one study assessed PCV13 compared to placebo,[72] one assessed PCV13 plus trivalent aIIV versus trivalent aIIV alone,[202] three assessed PCV13 plus trivalent IIV (Fluzone® in one study, Fluarix® in two other studies) versus trivalent IIV plus placebo,[109, 195, 214] and one assessed PCV13 plus Td versus Td alone.[203] One large epidemiological study compared individuals vaccinated with PCV13 to individuals who were not vaccinated.[231] Twelve studies compared PCV13 to PPSV23.[101, 120, 140, 142, 143, 162, 184, 197, 200, 210, 222, 227]

Across four studies,[72, 109, 195, 214] we found no evidence of increased risk of cardiovascular events (RR 0.97; CI 0.58, 1.64) or myocardial infarction specifically (RR 1.76; CI 0.42, 7.39) and this finding remained consistent when we combined these studies with another two studies[120, 184] that used PPSV23 as an active comparator (RR 0.97 for cardiovascular events [CI 0.64, 146] and RR 1.51 for myocardial infarction [CI 0.52, 4.33]). Of the six studies[72, 109, 120, 184, 195, 214] that together found an RR greater than 1 for myocardial infarction, all but one of these studies had either no events or one events in the intervention and/or control group (1/576 vs 0/575, 0/551 vs 1/560, 12/42237 vs 6/42255, 1/478 vs 1/237, 0/439 vs 0/437, 1/417 vs 1/414).

Across four PCV13 studies,[72, 195, 214, 231] we found no evidence of increased risk of death (RR 1.85; CI 0.37, 9.31). We also found no increased risk of death when we combined these studies together with another four studies[120, 140, 200, 227] that used active pneumococcal vaccine comparators (RR 1.22; CI 0.40, 3.69), but there was substantial heterogeneity (I^2 99%). We note that one study[231] in particular had a significantly increased RR of 3.62 (CI 3.30, 3.96) based on unadjusted rates from the cohort (420/5010 vs 46845/2020720), which contributed to the pooled estimate. When the same study adjusted for age, sex, history of pneumococcal disease or pneumonia, and comorbidities, the risk estimate was lower and no longer significant (multivariate hazard ratio [mHR] 1.07 [0.97-1.18]). Of the eight studies[72, 120, 140, 195, 200, 214, 227, 231]

that examined the risk of death, four did not comment on whether the deaths could be attributed to the vaccine, one study noted that the one death was not attributable to the vaccine, and three studies reported no deaths. Although the relative risk is not statistically significant which precludes conclusions about the risk, increased mortality in conjunction with this vaccine would be surprising given that the PCV13 decreases pneumonia. It is also possible that the studies' time frames were too short to capture the decreased mortality over the longer term as a result of vaccination.

Across three studies,[72, 109, 214] we found no evidence of increased risk of reproductive system events (RR 0.59; CI 0.01, 42.46); this was consistent when we included two other studies[120, 184] that used PPSV23 as an active comparator (RR 0.71; CI 0.08, 6.42). Across two studies,[72, 195] we found no evidence of increased risk of herpes zoster (RR 1.49; CI 0.00, 24855526); the risk estimate was imprecise as it was based on two studies with only one event across the intervention and control groups (0/576 vs 0/575 and 1/42337 vs 0/42255). Across another two studies,[72, 109] we found no evidence of increased risk of stroke (RR 1.12; CI 0.00, 451); the risk estimate was imprecise given that the two studies were of different sizes and one study had no events (0/551 vs 0/560 and 9/42237 vs 8/42255). In one study,[72] we found no evidence of autoimmune disease (RR 1.00; CI 0.02, 50.42); of note this risk estimate was imprecise as it was based on one study with no events in either the intervention or control groups (0/42337 vs 0/42255). The finding remained similar when combined with another study[184] that used PPSV23 as an active comparator (RR 0.67; CI 0.00, 11165626).

One study[72] noted an RR greater than 1 for acute disseminated encephalomyelitis and meningitis following PCV13 (RR 2.00; CI 0.07, 59.64 for both outcomes, due to one event each in the intervention and control groups). Another study[109] noted an RR greater than 1 for encephalitis (RR 1.02; CI 0.02, 51.13) but neither group had any events of encephalitis. A cohort study[222] of over 545,000 people comparing PCV13 to PPSV23 found no evidence of increased risk of pre-specified adverse events with PCV13 compared to PPSV23. However, only anaphylaxis as an adverse event was verified by chart review; out of 9 anaphylaxis events (5 in the PCV13 group and 4 in the PPSV23 group), only one was verified as having occurred after vaccination, in a patient who received four other vaccines concomitantly. The study did not report sufficient detail for further analyses for other adverse events.

Regarding other outcomes that were not pre-specified key adverse events for the current report, a study[143] of PCV13 versus PPSV23 among individuals with Crohn's disease reported no serious adverse events in the PCV13 group compared to two serious adverse events in the PPSV23 group (infection with enterococcus faecalis and sinusitis). Adverse events were assessed as unrelated to vaccination. A study[162] of PCV13 compared to PPSV23 among individuals with HIV reported no serious adverse events in either group. A small RCT[210] of PCV13 versus PPSV23 in adults with leukemia reported no severe adverse events in either group. A small RCT[227] of PCV13 versus PPSV23 in hemodialysis patients reported no difference in the risk of developing pneumonia or undergoing a kidney transplant between the two groups. No specific adverse events data were reported. Finally, an RCT[101] of PCV13 versus PPSV23 in solid organ transplant recipients showed more serious adverse events following PCV13 within the first week following vaccination (7/66 among PCV13 recipients compared to 1/66 among PPSV23 recipients), but no events were considered related to vaccination and no vaccine-related allograft rejection was noted.

One study[203] reported that no serious adverse events occurred, while three others[142, 197, 202] reported that no vaccine-related serious adverse events occurred (though did not specify what other serious adverse events occurred).

23-Valent Pneumococcal Vaccine

Seven studies assessed PPSV23 versus placebo or no vaccine,[81, 159, 171, 176, 201, 239, 935] two[80, 137] assessed PPSV23 plus trivalent IIV (one used Vaxigrip®, a formulation of IIV not available in US and the other did not specify brand) versus trivalent IIV alone, and one each assessed PPSV23 plus trivalent IIV (a Japanese formulation not available in the US) versus trivalent IIV plus placebo,[199] PPSV23 plus quadrivalent IIV (Influsplit, a formulation of IIV not available in US) versus quadrivalent IIV alone,[273] and PPSV23 plus trivalent aIIV versus trivalent aIIV alone.[204, 205] A small cohort study[107] of individuals with a diagnosis of immune-mediated inflammatory disorder undergoing treatment with high-dose systemic corticosteroids and/or immunosuppressive drugs compared those vaccinated with PPSV23 with those not vaccinated against pnuemococcal disease.

Across four studies of PPSV23 (two cohort studies[239, 935] comparing to vaccinated to unvaccinated patients, one cohort study[80] comparing to trivalent IIV alone, and one RCT[199] comparing PPSV23 plus trivalent IIV to trivalent IIV plus placebo), we found no evidence of increased risk of cardiovascular events (RR 0.46; CI 0.27, 0.76). A cohort study[176] of people aged 60 years and older in Spain that compared PPSV23 to no vaccine reported no increased risk of no increased risk of myocardial infarction (mHR 0.95; CI 0.76, 1.18).

The same four studies[80, 199, 239, 935] found no evidence of increased risk of death (RR 0.62; CI 0.16, 2.44). A cohort study[137] comparing PPSV23 plus trivalent IIV to trivalent IIV alone reported that dual-vaccinees experienced fewer deaths (hazard ratio [HR] 0.65; CI 0.55, 0.77) and fewer cases of pneumonia (HR 0.57; CI 0.51, 0.64), ischemic stroke (HR 0.67; CI 0.54, 0.83), and acute myocardial infarction (HR 0.52; CI 0.38, 0.71). The study did not provide sufficient detail for further analyses. Another cohort study[159] specifically of patients with prostate cancer in Taiwan found that the seven-year overall survival rate was significantly higher in the PPSV23-vaccinated group than in the unvaccinated group (47.5% vs 42.3%, p=0.0003). Finally, a cohort study[176] of people aged 60 years and older in Spain that compared PPSV23 to no vaccine reported no increased risk of death (mHR 0.97; CI 0.89, 1.05). The same cohort study[176] found no increased risk of myocardial infarction (mHR 0.95; CI 0.76, 1.18) nor of stroke (mHR 1.04; CI 0.83,1.30).

One cohort study[81] found no increased risk of stroke (mHR 0.57; CI 0.31, 1.03 for the cohort study). A case-control study[201] also found no increased risk of stroke (aOR 0.94; CI 0.89 to 1.00) but found an increased risk of transient ischemic attacks (OR 1.16; 1.09, 1.23).

Regarding other outcomes, the cohort study[107] of PPSV23 in patients with immune-mediated inflammatory disorder found vaccinated and unvaccinated groups had a similar decrease in disease activity, and the study reported no adverse events. The RCT[171] of PPSV23 versus placebo reported an increased risk for extensive arm swelling among participants who received PPSV23 compared to saline (0.55% vs 0.00%, p<0.001). The remaining RCTs[177, 205] reported that no vaccine-related serious adverse events occurred, but did not provide more specific details about specific adverse events.

Tetanus, Diphtheria, and Acellular Pertussis Vaccines

We identified one study[124] that assessed Tdap in this update. This was an RCT of Tdap (Adacel®) compared to Td (Tenivac®) in adults who had received one dose of Tdap 8 to 12 years

earlier. There was no evidence of increased risk for autoimmune disease or spontaneous abortion in either group. There were no deaths in either group and no significant differences in serious adverse events overall.

Varicella Vaccine

We did not identify studies assessing varicella vaccines in studies in adults, in this update or the original report. Results from studies of children and adults together are documented in KQ2.

Zoster Vaccine

We identified six studies[82, 85, 150, 165, 194, 209] that assessed recombinant zoster vaccine (RZV) (which was not in use at the time of the prior report), all of which were RCTs comparing the vaccine to either placebo or a base treatment also received by the intervention group. One RCT[209] compared RZV plus Tdap to Tdap alone, but the control group later also received RZV; thus, we could only include events that occurred after the first visit, which did not include any key adverse events (not discussed further here).

Across five studies,[82, 85, 150, 165, 194] we found no evidence of increased risk for herpes zoster occurring as an adverse event after vaccination (RR 0.09; CI 0.02, 0.30), but there was heterogeneity across studies (I^2 58%). Across four studies[82, 85, 150, 194] we found no evidence of increased risk of death (RR 0.93; CI 0.78, 1.11). Across three studies,[82, 85, 150] we found no evidence of increased risk for cardiovascular events (RR 0.89; CI 0.66, 1.21) or myocardial infarction specifically (RR 0.89; CI 0.38, 2.05).

Many of the estimates across only two studies[85, 150] were imprecise given the low numbers of events across the intervention and control groups; we provide the rates as well for these estimates. We found no evidence of increased risk for anaphylaxis (RR 1.32; CI 0.00, 1463200; 1/6950 vs 1/6950 and 1/7695 vs 0/7710), asthma (RR 0.90; CI 0.00, 493; 2/6950 vs 4/6950 and 6/7695 vs 5/7710), autoimmune disease (RR 0.88; CI 0.23, 3.31), diabetes (RR 1.00; CI 0.00, 606; 5/6950 vs 6/6950 and 3/7695 vs 2/7710), encephalitis/encephalopathy (RR 0.50; CI 0.00, 2867570; 0/6950 vs 1/6950 and 0/7695 vs 1/7710), Guillain-Barré syndrome (RR 0.67; CI 0.00, 865; 1/6950 vs 2/6950 vs 1/7695 vs 1/7710), meningitis (RR 0.50; CI 0.00, 2867570; 0/6950 vs 1/6950 and 0/7695 vs 1/7710), reproductive system events (RR 1.04; CI 0.03, 37.17), or seizures (RR 1.34; CI 0.00, 13492; 2/6950 vs 0/6950 and 3/7695 vs 3/7710). For some of the key adverse events, there was a higher rate in the vaccine arm compared to the placebo arm in each of the two studies. For amyotrophic lateral sclerosis (RR 2.60; CI 0.00, 5715367; 2/6950 vs 0/6950 and 2/7695 vs 1/7710), none of the events were considered intervention-related by the investigators. For idiopathic thrombocytopenic purpura (RR 2.65; CI 0.00, 530690; 1/6950 vs 0/6950 and 3/7695 vs 1/7710), investigators blinded to the study arm thought that one case in the vaccine arm and one case in the placebo arm were intervention-related. For stroke (RR 1.44; CI 0.03, 71.52; 7/6950 vs 6/6950 and 19/7695 vs 12/7710), no events were considered intervention-related in the vaccine arm, and 1 was considered intervention-related in the placebo arm.

One RCT[85] identified an RR greater than 1 for angioedema (RR 2.00; CI 0.07, 59.61) based on one case among those vaccinated with RZV (1/6950 vs 0/6950), resulting in an imprecise risk estimate.

KQ1c3. For each adverse event associated with a particular vaccine, what are the risk factors for the adverse event?

No adverse events were significantly associated with a vaccine in our meta-analyses, but we discuss any risk factors that were examined for adverse events below.

In one RCT[85] of RZV conducted in multiple countries, the investigators performed adverse event analyses by race/ethnicity, gender, and age. Unsolicited adverse events were least commonly reported by people who are Black, most commonly reported by people who are Asian, more commonly reported by women than by men, and very slightly more commonly reported by people aged 50 to 69 years than by those aged 70 years and older.

Four studies identified risk factors for adverse events for PPSV23. An RCT[171] of PPSV23 versus placebo reported an increased risk for extensive arm swelling, which was significantly more likely in women (female 10/1138 vs male 3/1202, p=0.04). Another study[165] compared PPSV23 administered with RZV to PPSV23 alone. Solicited general adverse events were more frequently reported when the first dose of RZV and PPSV23 were co-administered than when PPSV23 was administered alone. A third study[176] that assessed myocardial infarction, stroke, deaths from myocardial infarction or stroke, and deaths from all causes found no increased risk of these outcomes when looking at those with and without history of prior coronary artery disease and those with and without a history of cerebrovascular disease. A fourth study[201] looked at risk of stroke following PPSV23, and found no difference in risk of stroke among those who were younger than 65 years compared to those who were 65 years and older. The same study looked at transient ischemic attacks and found an increased risk among those younger than 65 years (aOR 1.61; 1.40, 1.85) but not those 65 years and older (aOR 1.03; 0.96, 1.10).

Three studies[162, 222, 231] examined risk factors or sub-groups for adverse events associated with PCV13. One large cohort study[231] of over two million people found PCV13 to be significantly associated with increased risk of all-cause pneumonia among adults aged 65 years and older (mHR 1.76; CI 1.5, 2.04), immunocompromised persons (mHR 1.51; CI 1.24, 1.83), and immunocompetent persons (mHR 1.86; CI 1.55, 2.25) compared to no vaccination for pneumococcal disease but did not report sufficient detail for further analyses. Among people aged 50 to 64 years, there was no significant difference in all-cause pneumonia if vaccinated (mHR 1.21; CI 0.85, 1.72). Among all sub-groups, there was no significant association between vaccination and pneumococcal pneumonia or death. These findings are at odds with those from the large, high-quality study[72] of PCV13 in older adults, which evaluated 84,496 adults 65 years of age or older. This RCT found that PCV13 was not associated with increased risk, and in fact prevented, vaccine-type pneumococcal, bacteremic, and nonbacteremic community-acquired pneumonia and vaccine-type invasive pneumococcal disease, and found no increased risk of all-cause community-acquired pneumonia. Of note, some of the unvaccinated population in the cohort study was assumed to have potentially received PPSV23, which may have affected the relationship observed as older adults may have been more likely to have received PPSV23. In addition, the cohort study was an observational one that could have had some residual confounding by indication, despite multivariate analyses to adjust for this. Another cohort study[222] of over 545,000 people comparing PCV13 to PPSV23 found no evidence of increased risk of several pre-specified adverse events; however, anaphylaxis was the only adverse event verified by chart review, with only one event confirmed as having occurred after vaccination out of 9 events in total. Stratified analyses by age group (65–69 years, ≥70 years) were consistent with the findings from the main analysis. Finally, a study[162] of pneumococcal vaccine-naïve

adults with HIV found no serious adverse events associated with PCV13, though they were not compared to adults without HIV.

Three studies looked at risk factors for adverse events among recipients of different influenza vaccines. An RCT of quadrivalent IIV (Fluzone Quadrivalent, compared to its trivalent counterpart) found that solicited systemic reactions were reported more frequently by participants 18 to 60 years of age than by participants 61 years of age or over.[118] Another RCT of IIV (Flucelvax Quadrivalent, again compared to its trivalent counterpart) stratified risk of adverse events by age, sex, and race/ethnicity.[60] These subgroup analyses did not show any notable differences in terms of safety. Unsolicited adverse events and medically attended adverse events were reported by somewhat higher percentages in participants 65 years of age and older than in those 18 to 64 years of age, although rates of possibly vaccine-related adverse events were similar between the two subgroups. Another study was itself a subgroup analysis, examining the administration of PPSV23 with IIV compared to IIV alone.[177] There were no safety concerns, except that pain (Grade 3 and up, meaning more severe) occurred more often with co-administration of the vaccines compared to IIV alone (3.5% vs 0.0%).

For quadrivalent aIIV, one RCT[103] conducted in the United States found that rates of any solicited adverse events were higher in the 65 to 74 year age subgroup than in the 75 to 84 year age subgroup across both intervention and comparator arms of the study. No notable differences were observed in the subgroups by gender and race.

In an RCT[99] of HepB with novel adjuvant (HEPLISAV-B) compared to an existing HepB (Engerix-B), a subgroup analysis[288] of adults aged 60 to 70 years with diabetes mellitus found no increase in risk of adverse events when comparing the vaccines.

KQ1: Summary of Findings for Safety of Vaccines in Adults

The summary of findings tables document the results across studies grouped by vaccines. These tables show the number of RCTs, the number of other studies, the number of participants across pooled analyses, the studies contributing to the risk estimate, findings for the outcomes of interest, the criteria used to downgrade the SoE, and the SoE summary statement. The relative risk of an adverse event was derived by comparing the reported event rates in vaccinated participants compared to a control group across all studies that reported the data for that outcome. The absolute rates of adverse events (number of events, number of assessed participants) for the vaccine and the control group are also shown. In many instances, results were based on single occurrences of a specific adverse event. Where studies reported insufficient detail and did not contribute to the effect size estimates, the tables report the results as reported by the study authors.

Hepatitis Vaccines

Table 2 shows the evidence for key adverse events associated with HepA, HepB, and HepA-HepB vaccines.

Table 2. KQ1: Update summary of findings and SoE for safety of hepatitis vaccines in adults

Vaccine	Outcome	N RCTs, N Other; N Participants; IDs of Studies Contributing to RR	Risk Estimate: RR; CI (Event Rates in Individual Studies); Other Studies Contributing to SoE	Reasons for Downgrading	Update Evidence Statement and SoE
Hepatitis A (HepA; Havrix®, Vaqta®)	Acute disseminated encephalomyelitis, anaphylaxis or systemic allergic reaction, angioedema, cardiovascular events, death, diabetes, Guillain-Barré syndrome, seizures, stroke, transverse myelitis	0 RCTs, 0 Other; N 0; 0 studies	No studies	N/A	Insufficient evidence
Hepatitis B (HepB; Engerix-B, Recombivax HB, HEPLISAV-B)	Acute disseminated encephalomyelitis	0 RCTs, 0 Other; N 0; 0 studies	One study found no increased risk (OR 1.5; CI 0.2, 12.1)[151]	Study limitation,°° Precision,^^ Consistency↑	Insufficient evidence
	Asthma	3 RCTs, 0 Other; N 13245; Heyward, 2013,[132] Dynavax, 2015,[99] Dynavax, 2006[100]	RR 0.83; CI 0.03, 22.31 (2/1968 vs 1/481, 5/5587 vs 1/2781, 0/1821 vs 1/607)[#]	Study limitation,° Precision^	Low SoE for no evidence of increased risk
	Autoimmune disease	3 RCT, 0 Other; N 13245; Heyward, 2013,[132] Dynavax, 2015,[99] Dynavax, 2006[100]	RR 0.70; CI 0.15, 3.21 (3/1968 vs 0/481, 17/5587 vs 12/2781, 1/1821 vs 1/607)[#]	Study limitation,° Precision^	Low SoE for no evidence of increased risk
	Cardiovascular events	3 RCTs, 0 Other; N 13245; Heyward, 2013,[132] Dynavax, 2015,[99] Dynavax, 2006[100]	RR 1.55; CI 0.46, 5.18 (2/1968 vs 1/481, 51/5587 vs 15/2781, 1/1821 vs 0/607)[&,#]	Study limitation,° Precision^	Low SoE for no evidence of increased risk
	Death	3 RCTs, 0 Other; N 13245; Heyward, 2013,[132] Dynavax, 2015,[99] Dynavax, 2006,[100]	RR 0.97; CI 0.04, 23.18 (1/1968 vs 1/481, 25/5587 vs 7/2781, 0/1821 vs 0/607)[&,#]	Study limitation°, Precision^	Low SoE for no evidence of increased risk
	Diabetes	1 RCT, 1 Other; N 23684; Huang, 2015,[134]; Dynavax, 2015[99]	RR 0.61; CI 0.55, 0.67 (472/4063 vs 2154/11253) when compared to no vaccine;[#] combining with 1 other study with active comparator: RR 0.61; CI 0.33, 1.11	Study limitation,°	Moderate SoE for no evidence of increased risk

Vaccine	Outcome	N RCTs, N Other; N Participants; IDs of Studies Contributing to RR	Risk Estimate: RR; CI (Event Rates in Individual Studies); Other Studies Contributing to SoE	Reasons for Downgrading	Update Evidence Statement and SoE
Hepatitis B (HepB; Engerix-B, Recombivax HB, HEPLISAV-B) (continued)	Encephalitis/encephalopathy	1 RCT, 0 Other; N 8368; Dynavax, 2015[99]	RR 1.99; CI 0.09, 44.14 (2/5587 vs 0/2781)[&,#]	Study limitation,° Precision,^ Consistency↑	Insufficient evidence
	Guillain-Barré syndrome	1 RCTs, 0 Other; N 2428; Dynavax, 2006[100]	RR 0.67; CI 0.02, 19.85 (1/1821 vs 0/607)[#]	Study limitation,° Precision,^ Consistency↑	Insufficient evidence
	Herpes zoster	3 RCTs, 0 Other; N 13245; Heyward, 2013,[132] Dynavax, 2015,[99] Dynavax, 2006[100]	RR 1.95; CI 0.45, 8.51 (4/1968 vs 1/481, 38/5587 vs 9/2781, 3/1821 vs 0/607)[&,##]	Study limitation,° Precision^	Low SoE of no evidence of increased risk
	Meningitis	1 RCT, 0 Other; N 8368; Dynavax, 2015[99]	RR 1.99; CI 0.09, 44.14 (2/5587 vs 0/2781)[&,#]	Study limitation,° Precision,^ Consistency↑	Insufficient evidence
	Multiple sclerosis	0 RCTs, 0 Other; N 0; 0 studies	One study found no increased risk (OR 0.4; CI 0.1, 1.9)[151]	Study limitation,°° Precision,^^ Consistency↑	Insufficient evidence
	Myocardial infarction	2 RCTs, 0 Other; N 10817; Heyward, 2013,[132] Dynavax, 2015[99]	RR 2.00; CI 0.00, 41600564 (2/1968 vs 1/481, 14/5587 vs 1/2781)[&,#]	Study limitation,° Precision,^ Consistency↑	Insufficient evidence
	Reproductive system events	3 RCTs, 0 Other; N 13245; Heyward, 2013,[132] Dynavax, 2015,[99] Dynavax, 2006[100]	RR 0.21; CI 0.00, 13.46 (endometriosis, adenomyosis; 1/1968 vs 0/481, 0/5587 vs 2/2781, 0/1821 vs 1/607)[&,#]	Study limitation,° Precision^	Low SoE for no evidence of increased risk
	Seizure	1 RCT, 0 Other; N 8368; Dynavax, 2015[99]	RR 1.99; CI 0.22, 17.81 (4/5587 vs 1/2781)[&,#]	Study limitation,° Precision,^ Consistency↑	Insufficient evidence
	Spontaneous abortion	1 RCTs, 0 Other N 8368 Dynavax, 2015[99]	RR 0.75; CI 0.12, 4.47 (3/5587 vs 2/2781)[#]	Study limitation,° Precision,^ Consistency↑	Insufficient evidence
	Stroke	2 RCTs, 0 Other; N 10796; Dynavax, 2015,[99] Dynavax, 2006[100]	RR 1.27; CI 0.00, 1430 (11/5587 vs 4/2781, 1/1821 vs 0/607)[&,#]	Study limitation,° Precision^	Low SoE for no evidence of increased risk
	Anaphylaxis or systemic allergic reaction, angioedema, autoimmune thyroiditis (Hashimoto's disease), optic neuritis, transverse myelitis	0 RCTs, 0 Other; N 0; 0 studies	We did not identify studies reporting on these outcomes	N/A	Insufficient evidence

Vaccine	Outcome	N RCTs, N Other; N Participants; IDs of Studies Contributing to RR	Risk Estimate: RR; CI (Event Rates in Individual Studies); Other Studies Contributing to SoE	Reasons for Downgrading	Update Evidence Statement and SoE
Hepatitis A and hepatitis B (HepA-HepB; Twinrix)	Optic neuritis	0 RCTs, 0 Other; N 0; 0 studies	One study[62] of adults and children reported no increased risk	Study limitation,° Precision,^^ Consistency↑	Insufficient evidence
	Acute disseminated encephalomyelitis, anaphylaxis or systemic allergic reaction, angioedema, autoimmune disease, autoimmune thyroiditis (Hashimoto's disease), cardiovascular events, death, diabetes, encephalitis/encephalopathy, Guillain-Barré syndrome, multiple sclerosis, myocardial infarction, seizures, stroke, transverse myelitis	0 RCTs, 0 Other; N 0; 0 studies	We did not identify studies reporting on HepA	N/A	Insufficient evidence

Notes: CI —95% confidence interval; ID—study identifier; KQ—Key Question; N—number; N/A—not applicable; OR—odds ratio; RR—relative risk; RCT—randomized controlled trials; SoE—strength of evidence.[&]—potentially increased risk based on direction of effects across studies and investigated further but not statistically significant; [#]—none of the RR estimates in individual studies showed a statistically significantly increased risk; [##]—1 of the 3 studies reported an increased risk in the vaccine group (RR 2.10; CI 1.02, 4.34; events 38/5587 vs 9/2781); °—no unvaccinated control group; °°—effect based on observational evidence only; ^—imprecise estimate with wide CI; ^^—study provides insufficient detail for further analyses and independent estimate of effect size not possible; ↑—consistency could not be assessed as no other study reported on the outcome

HepA. The prior 2014 report had concluded that there was insufficient evidence to make evidence statements regarding an association between HepA and acute disseminated encephalomyelitis, transverse myelitis, multiple sclerosis, Guillain-Barré syndrome, chronic inflammatory demyelinating polyneuropathy, Bell's palsy, anaphylaxis, and autoimmune hepatitis across all identified studies (including samples in children) based on a review of the evidence by the IOM, and one additional post-licensure study with no association with adverse events. We identified no new studies evaluating key adverse events since the prior 2014 report. Thus, the evidence remains insufficient to draw conclusions about HepA.

HepB. The prior 2014 report found moderate SoE for no association with multiple sclerosis onset or exacerbation based on a 2002 IOM report[1089] on HepB and demyelinating disorders (HEPLISAV-B was not in use at that time). This finding remains unchanged for HepB (update identified no new studies except for HEPLISAV-B, for which the SoE was insufficient).

The prior 2014 report also found moderate SoE for no association of type 1 diabetes mellitus with HepB. Studies identified in the update found no evidence of increased risk of diabetes across all HepB (type of diabetes was not specified). Thus, across the prior 2014 report and this update, there was moderate SoE for no evidence of increased risk of diabetes (including type 1 diabetes mellitus).

The prior 2014 report found moderate SoE supporting a causal relationship between hepatitis B vaccine and anaphylaxis in patients allergic to yeast, which was based on mechanistic evidence from the IOM report; the estimate of the magnitude of increased risk was not determined. Of note, HEPLISAV-B was not in use at that time. This finding remains unchanged (update identified no new studies on anaphylaxis, including for HEPLISAV-B).

There was also low SoE for no evidence of increased risk for asthma, autoimmune disease, cardiovascular events, death, herpes zoster, reproductive system events, or stroke (all studies were of HEPLISAV-B).

The prior 2014 report found insufficient evidence for an association between the vaccine and optic neuritis, first demyelinating events in multiple sclerosis, Guillain-Barré syndrome, systemic lupus erythematosus, onset or exacerbation of vasculitis, polyarteritis nodosa, and onset or exacerbation of rheumatoid arthritis because there were no studies. The review of studies from the update found insufficient evidence for key adverse events either because the evidence was graded as insufficient or there were no studies.

HepA-HepB. In this update, we found no studies examining the key adverse events of interest for HepA-HepB, except for optic neuritis (which was judged as insufficient evidence). The prior 2014 report also did not identify any studies. Thus, there was insufficient evidence to draw conclusions about HepA-HepB.

Table 2a summarizes the findings across the prior 2014 report and the update.

Table 2a. KQ1: Safety of hepatitis vaccines in adults

Vaccine (Abbreviation; Brand Name[s])	2014 Report SoE and Findings	SoE and Findings in Update	Synthesis of SoE and Findings
Hepatitis A (HepA; Havrix, Vaqta)	Insufficient: Acute disseminated encephalomyelitis, transverse myelitis, multiple sclerosis, Guillain-Barré syndrome, chronic inflammatory demyelinating polyneuropathy, Bells' palsy, anaphylaxis, autoimmune hepatitis	No new evidence	☐ Insufficient evidence (no change from prior 2014 report; no new studies in update)

Vaccine (Abbreviation; Brand Name[s])	2014 Report SoE and Findings	SoE and Findings in Update	Synthesis of SoE and Findings
Hepatitis B (HepB; Engerix-B, Recombivax HB, HEPLISAV-B)	Moderate: No association with multiple sclerosis onset or exacerbation Moderate: No association with type 1 diabetes mellitus Moderate: Causal relationship between hepatitis B vaccine and anaphylaxis in patients allergic to yeast based on mechanistic evidence Insufficient, Optic neuritis, first demyelinating event, Guillain-Barré syndrome, systemic lupus erythematosus, onset or exacerbation of vasculitis, polyarteritis nodosa, onset or exacerbation of rheumatoid arthritis HEPLISAV-B not in use at time of prior report	Moderate: No evidence of increased risk of diabetes (across all hepatitis B vaccines) Low: No evidence of increased risk of asthma, autoimmune disease, cardiovascular events, death, herpes zoster, reproductive system events, stroke for HEPLISAV-B Insufficient: Acute disseminated encephalomyelitis, encephalitis/encephalopathy, Guillain-Barré syndrome, multiple sclerosis, myocardial infarction, seizure No studies: Anaphylaxis or systemic allergic reaction, angioedema, autoimmune thyroiditis (Hashimoto's disease), optic neuritis, transverse myelitis	Moderate: No evidence of increased risk of multiple sclerosis onset or exacerbation (no change from prior 2014 report for hepatitis B vaccines; insufficient evidence in update, including for HEPLISAV-B) Moderate: No evidence of increased risk of diabetes including type 1 diabetes mellitus (no change from prior 2014 report; update also identified no evidence of increased risk) Moderate: Anaphylaxis in patients allergic to yeast (no change from prior 2014 report for hepatitis B vaccines; no new studies in update, including for HEPLISAV-B) Low: No evidence of increased risk of asthma, autoimmune disease, cardiovascular events, death, herpes zoster, reproductive system events, stroke for HEPLISAV-B
Hepatitis A and hepatitis B (HepA-HepB; Twinrix)	No findings	Insufficient: Optic neuritis No studies: Acute disseminated encephalomyelitis, anaphylaxis or systemic allergic reaction, angioedema, autoimmune disease, autoimmune thyroiditis (Hashimoto's disease), cardiovascular events, death, diabetes, encephalitis/encephalopathy, Guillain-Barré syndrome, multiple sclerosis, myocardial infarction, seizures, stroke, transverse myelitis	Insufficient evidence to draw conclusions

Key: Green box indicates no evidence of increased risk of specific adverse events; Red circle indicates evidence of risk of specific adverse events; White box indicates insufficient evidence to draw conclusions about the risk of specific adverse events; Notes: KQ—Key Question; SoE—Strength of Evidence

9-Valent Human Papillomavirus Vaccine

The SoE for adverse events associated with HPV9 across all identified studies in adults is documented in Table 3.

Table 3. KQ1: Update summary of findings and SoE for safety of HPV9 in adults

Vaccine	Outcome	N RCTs, N Other; N Participants; IDs of Studies Contributing to RR	Risk Estimate: RR; CI (Event Rates in Individual Studies); Other Studies Contributing to SoE	Update Evidence Statement and SoE
9-valent human papillomavirus (HPV9; Gardasil 9®)	Acute disseminated encephalomyelitis, anaphylaxis or systemic allergic reaction, amyotrophic lateral sclerosis, angioedema, cardiovascular events, death, diabetes, Guillain-Barré syndrome, multiple sclerosis, reproductive system events, seizures, stroke, transverse myelitis	0 RCTs, 0 Other; N 0; 0 studies	We did not identify studies of HPV-9 in adults in this update	Insufficient evidence

Notes: CI —95% confidence interval; ID—study identifier; KQ—Key Question; N—number; RCT—randomized controlled trials; RR—relative risk, SoE—strength of evidence

There was insufficient evidence for all outcomes of interest for HPV9 because no study that evaluated the vaccine in adults only met inclusion criteria (Table 3a). Studies that combined children and adults are reported in KQ2. HPV9 was not available at the time of the prior 2014 report. Table 3a summarizes the findings across the prior 2014 report and the update.

Table 3a. KQ1: Safety of HPV9 in adults

Vaccine (Abbreviation; Brand Name[s])	2014 Report SoE and Findings	SoE and Findings in Update	Synthesis of SoE and Findings
9-valent human papillomavirus (HPV9; Gardasil 9)	HPV9 not in use at time of prior report	No new evidence	☐ Insufficient evidence to draw conclusions; see KQ2 for studies that combined children and adults

Key: ☐ White box indicates insufficient evidence to draw conclusions about the risk of specific adverse events; Notes: KQ—Key Question; SoE—Strength of Evidence

Influenza Vaccines

We identified a large number of studies evaluating influenza vaccines in adults. Table 4 documents results for the key adverse events.

Table 4. KQ1: Update summary of findings and SoE for safety of influenza vaccines in adults

Vaccine	Outcome	N RCTs, N Other; N Participants; IDs of Studies Contributing to RR	Risk Estimate: RR; CI (Event Rates in Individual studies); Other Studies Contributing to SoE	Reasons for Downgrading	Update Evidence Statement and SoE
Influenza, inactivated (IIV; Afluria Quadrivalent, Flucelvax Quadrivalent, Fluarix Quadrivalent, Flulaval Quadrivalent, Fluzone High Dose, Fluzone Quadrivalent)	Amyotrophic lateral sclerosis	1 RCT, 0 Other; N 2662; Bart, 2016[60]	RR 2.02; CI 0.07, 60.19 (1/1324 vs 0/1338)[&,#]	Study limitation,° Precision,^ Consistency↑	Insufficient evidence
	Anaphylaxis or systemic allergic reaction	1 RCT, 0 Other; N 2662; Bart, 2016[60]	RR 0.51; CI 0.02, 15.05 (0/1324 vs 1/1338)[#]	Study limitation,° Precision,^ Consistency↑	Insufficient evidence
	Asthma	3 RCTs, 0 Other; N 9198; Kieninger, 2013,[145] Tinoco, 2014,[216] Treanor, 2017[218]	RR 0.46; CI 0.01, 24.59 (1/3036 vs 1/1010, 0/1272 vs 1/431, 1/1721 vs 0/1728)[#]	Study limitation,° Precision	Low SoE for no evidence of increased risk
	Autoimmune disease	2 RCTs, 0 Other; N 3659; Beran, 2013,[66] Treanor, 2017[218]	RR 1.49; CI 0.00, 24522910 (0/105 vs 0/105, 1/1721 vs 0/1728)[&,#]	Study limitation,° Precision,^ Consistency↑	Insufficient evidence
	Cardiovascular events	5 RCTs, 0 Other; N 14530; Bart, 2016,[60] Chang, 2019,[77] Kieninger, 2013,[145] Tinoco, 2014,[216] Treanor, 2017[218]	RR 1.11; CI 0.34, 3.68 (5/1324 vs 2/1338, 2/1777 vs 3/893, 5/3036 vs 1/1010, 2/1272 vs 0/431, 3/1721 vs 3/1728)[&,#]	Study limitation,° Precision^	Low SoE for no evidence of increased risk
	Death	6 RCTs, 0 Other; N 13607; Beran, 2013,[66] Greenberg, 2013,[118] Bart, 2016,[60] Chang, 2019,[77] Kieninger, 2013,[145] Treanor, 2017[218]	RR 1.03; CI 0.41, 2.59 (0/105 vs 0/105, 0/190 vs 0/380, 5/1324 vs 7/1338, 3/1777 vs 2/893, 9/3036 vs 3/1010, 5/1721 vs 1/1728)[&,#]	Study limitation° Precision^	Low SoE for no evidence of increased risk

Vaccine	Outcome	N RCTs, N Other; N Participants; IDs of Studies Contributing to RR	Risk Estimate: RR; CI (Event Rates in Individual studies); Other Studies Contributing to SoE	Reasons for Downgrading	Update Evidence Statement and SoE
Influenza, inactivated (IIV; Afluria Quadrivalent, Flucelvax Quadrivalent, Fluarix Quadrivalent, Flulaval Quadrivalent, Fluzone High Dose, Fluzone Quadrivalent) (continued)	Encephalitis/encephalopathy	1 RCT, 0 Other; N 450; Greenberg, 2017[119]	RR 1.00; CI 0.02, 50.18 (0/225 vs 0/225)[#]	Study limitation,° Precision,^ Consistency↑	Insufficient evidence
	Guillain-Barré syndrome	1 RCTs, 0 Other; N 450; Greenberg, 2017[119]	RR 1.00; CI 0.02, 50.18 (0/225 vs 0/225)[#]	Study limitation,° Precision,^ Consistency↑	Insufficient evidence
	Meningitis	1 RCT, 0 Other; N 2662; Bart, 2016[60]	RR 2.02; CI 0.07, 60.19 (1/1324 vs 0/1338)[&,#]	Study limitation,° Precision,^ Consistency↑	Insufficient evidence
	Myocardial infarction	5 RCTs, 0 Other; N 14530; Bart, 2016,[60] Chang, 2019,[77] Kieninger, 2013,[145] Tinoco, 2014,[216] Treanor, 2017[218]	RR 1.15; CI 0.27, 4.86 (4/1324 vs 1/1338, 2/1777 vs 2/893, 5/3036 vs 1/1010, 2/1272 vs 0/431, 1/1721 vs 2/1728)[&,#]	Study limitation,° Precision^	Low SoE for no evidence of increased risk
	Optic neuritis	1 RCTs, 0 Other; N 450; Greenberg, 2017[119]	RR 1.00; CI 0.02, 50.18 (0/225 vs 0/225)[#]	Study limitation,° Precision,^ Consistency↑	Insufficient evidence
	Reproductive system events	4 RCTs, 0 Other; N 11081; Bart, 2016,[60] Chang, 2019,[77] Kieninger, 2013,[145] Tinoco, 2014[216]	RR 0.75; CI 0.06, 8.76 (e.g., endometriosis, prostate cancer, benign prostatic hyperplasia, cystocele; 0/1324 vs 1/1338, 2/1777 vs 1/893, 1/3036 vs 0/1010, 1/1272 vs 0/431)[#]	Study limitation°	Low SoE for no evidence of increased risk
	Seizure	2 RCTs, 0 Other; N 4667; Bart, 2016,[60] Chang, 2019[77]	RR 0.17; CI 0.00, 478774 (0/1324 vs 2/673, 0/1777 vs 1/893)[#]	Study limitation,° Precision^	Low SoE for no evidence of increased risk
	Spontaneous abortion	1 RCT, 0 Other; N 1703; Tinoco, 2014[216]	RR 0.68; CI 0.02, 20.16 (1/1272 vs 0/431)[#]	Study limitation,° Precision,^ Consistency↑	Insufficient evidence

Vaccine	Outcome	N RCTs, N Other; N Participants; IDs of Studies Contributing to RR	Risk Estimate: RR; CI (Event Rates in Individual studies); Other Studies Contributing to SoE	Reasons for Downgrading	Update Evidence Statement and SoE
Influenza, inactivated (IIV; Afluria Quadrivalent, Flucelvax Quadrivalent, Fluarix Quadrivalent, Flulaval Quadrivalent, Fluzone High Dose, Fluzone Quadrivalent) (continued)	Stroke	4 RCTs, 0 Other; N 11868; Chang, 2019,[77] Kieninger, 2013,[145] Tinoco, 2014,[216] Treanor, 2017[218]	RR 0.87; CI 0.13, 5.89 (0/1777 vs 1/893, 5/3036 vs 2/1010, 1/1272 vs 0/431, 2/1721 vs 1/1728)[#]	Study limitation,° Precision^	Low SoE for no evidence of increased risk
	Acute disseminated encephalomyelitis, angioedema, diabetes, transverse myelitis	0 RCTs, 0 Other; N 0; 0 studies	We did not identify studies reporting on these outcomes	N/A	Insufficient evidence
Influenza, inactivated, adjuvanted (Fluad, Fluad Quadrivalent)	Acute disseminated encephalomyelitis	0 RCTs, 1 Other N 170988 Villa, 2013[232]	RR 0.93; CI 0.02, 47.03 (0/88449 vs 0/82539)[#]	Study limitation,° Precision,^ Consistency↑	Insufficient evidence
	Amyotrophic lateral sclerosis	1 RCT, 0 Other; N 1776; Essink, 2020[103]	RR 0.50; CI 0.02, 14.88 (0/888 vs 1/888)[#]	Study limitation,° Precision,^ Consistency↑	Insufficient evidence
	Anaphylaxis	0 RCTs, 1 Other N 170988 Villa, 2013[232]	RR 1.87; CI 0.06, 55.63 (1/88449 vs 0/82539)[&,#]	Study limitation,° Precision,^ Consistency↑	Insufficient evidence
	Angioedema	1 RCT, 0 Other; N 7082; Frey, 2014[110]	RR 2.00; CI 0.07, 59.46 (1/3545 vs 0/3537)[&,#]	Study limitation,° Precision,^ Consistency↑	Insufficient evidence
	Asthma	2 RCTs, 0 Other; N 8858; Essink, 2020,[103] Frey, 2014[110]	RR 0.76; CI 0.00, 836505 (0/888 vs 1/888, 1/3545 vs 1/3537)[#]	Study limitation,° Precision^	Low SoE for no evidence of increased risk
	Autoimmune disease	1 RCT, 1 Other; N 172764; Essink, 2020,[103] Villa, 2013[232]	RR 0.98; CI 0.00, 2288259 (polymyalgia rheumatica, autoimmune hepatitis; 1/888 vs 1/888, 0/88449 vs 0/82539)[#]	Study limitation,° Precision^	Low SoE for no evidence of increased risk

Vaccine	Outcome	N RCTs, N Other; N Participants; IDs of Studies Contributing to RR	Risk Estimate: RR; CI (Event Rates in Individual studies); Other Studies Contributing to SoE	Reasons for Downgrading	Update Evidence Statement and SoE
Influenza, inactivated, adjuvanted (Fluad, Fluad Quadrivalent) (continued)	Cardiovascular events	2 RCTs, 0 Other; N 8858; Essink, 2020,[103] Frey, 2014[110]	RR 0.47; CI 0.00, 81.39 (1/888 vs 3/888, 8/3545 vs 16/3537);[#] 1 study[185] showed no increased risk of acute coronary syndrome (aOR 0.13; 0.03, 0.65)	Precision^	Moderate SoE for no evidence of increased risk
	Death	2 RCTs, 0 Other; N 8737; Essink, 2020,[103] Frey, 2014[110]	RR 1.15; CI 0.09, 14.54 (all instances were judged to be unrelated to the vaccine; 2/888 vs 0/888, 52/3479 vs 46/3482)[&,#]	Study limitation,° Precision^	Low SoE for no evidence of increased risk
	Diabetes	1 RCT, 0 Other; N 7082; Frey, 2014[110]	RR 2.49; CI 0.48, 12.85 (5/3545 vs 2/3537)[&,#]	Study limitation,° Precision,^ Consistency↑	Insufficient evidence
	Encephalitis/encephalopathy	1 RCT, 1 Other; N 172764; Essink, 2020,[103] Villa, 2013[232]	RR 0.48; CI 0.00, 2761252 (encephalopathy, encephalitis; 0/888 vs 1/888, 0/88449 vs 1/82539)[#]	Study limitation,° Precision^	Low SoE for no evidence of increased risk
	Guillain-Barré syndrome	1 RCT, 1 Other; N 178070; Frey, 2014,[110] Villa, 2013[232]	RR 0.29; CI 0.00, 44494 (0/3545 vs 1/3537, 1/88449 vs 4/82539);[#] 1 additional study[180] reported a potentially increased risk but the effect was not statistically significant	Study limitation,° Precision^	Low SoE for no evidence of increased risk
	Herpes zoster	1 RCTs, 0 Other; N 7082; Frey, 2014[110]	RR 0.50; CI 0.02, 14.87 (0/3545 vs 1/3537)[#]	Study limitation,° Precision,^ Consistency↑	Insufficient evidence
	Idiopathic thrombocytopenic purpura	1 RCT, 1 Other; N 178070; Frey, 2014,[110] Villa, 2013[232]	RR 2.52; CI 0.00, 505129 (event not considered vaccine related; 1/3545 vs 0/3537, 3/88449 vs 1/82539)[&,#]	Study limitation,° Precision^	Low SoE for no evidence of increased risk
	Meningitis	1 RCT, 0 Other; N 7082; Frey, 2014[110]	RR 0.50; CI 0.02, 14.87 (0/3545 vs 1/3537)[#]	Study limitation,° Precision,^ Consistency↑	Insufficient evidence
	Multiple sclerosis	0 RCTs, 1 Other N 170988 Villa, 2013[232]	RR 0.93; CI 0.02, 47.03 (0/88449 vs 0/82539)[#]	Study limitation,° Precision,^ Consistency↑	Insufficient evidence

Vaccine	Outcome	N RCTs, N Other; N Participants; IDs of Studies Contributing to RR	Risk Estimate: RR; CI (Event Rates in Individual studies); Other Studies Contributing to SoE	Reasons for Downgrading	Update Evidence Statement and SoE
Influenza, inactivated, adjuvanted (Fluad, Fluad Quadrivalent) (continued)	Myocardial infarction	2 RCTs, 0 Other; N 8858; Essink, 2020,[103] Frey, 2014[110]	RR 1.05; CI 0.00, 295 (0/888 vs 1/888, 10/3545 vs 9/3537)[&,#]	Study limitation,° Precision^	Low SoE for no evidence of increased risk
	Optic neuritis	0 RCTs, 1 Other N 170988 Villa, 2013[232]	RR 0.93; CI 0.02, 47.03 (0/88449 vs 0/82539)[#]	Study limitation,° Precision,^ Consistency↑	Insufficient evidence
	Reproductive system events	1 RCT, 0 Other; N 7082; Frey, 2014[110]	RR 2.00; CI 0.07, 59.46 (1/3545 vs 0/3537)[&,#]	Study limitation,° Precision,^ Consistency↑	Insufficient evidence
	Seizure	2 RCTs, 1 Other; N 179846; Essink, 2020,[103] Frey, 2014,[110] Villa, 2013[232]	RR 0.93; CI 0.36, 2.38 (1/888 vs 0/888, 2/3545 vs 0/3537, 39/88449 vs 41/82539)[#]	Study limitation, ° Precision^	Low SoE for no evidence of increased risk
	Stroke	2 RCTs, 0 Other; N 8858; Essink, 2020,[103] Frey, 2014[110]	RR 1.18; CI 0.00, 33607 (0/888 vs 1/888, 3/3545 vs 2/3537);[&,#] 1 additional study[185] reported no increased risk (aOR 0.07; CI 0.01, 0.48)	Precision^	Moderate SoE for no evidence of increased risk
	Transverse myelitis	0 RCTs, 1 Other N 170988 Villa, 2013[232]	RR 0.93; CI 0.02, 47.03 (0/88449 vs 0/82539)[#]	Study limitation,° Precision,^ Consistency↑	Insufficient evidence
Influenza, recombinant (RIV; Flublok Quadrivalent®)	Cardiovascular events	3 RCTs, 0 Other; N 10845; Cowling, 2019[84] Dunkle, 2017,[97] Dunkle, 2017[98]	RR 1.23; CI 0.34, 4.46 (0/335 vs 0/508, 23/4328 vs 19/4344, 2/998 vs 0/332)[&,#]	Study limitation,° Precision^	Low SoE for no evidence of increased risk

Vaccine	Outcome	N RCTs, N Other; N Participants; IDs of Studies Contributing to RR	Risk Estimate: RR; CI (Event Rates in Individual studies); Other Studies Contributing to SoE	Reasons for Downgrading	Update Evidence Statement and SoE
Influenza, recombinant (RIV; Flublok Quadrivalent®) (continued)	Death	3 RCTs, 0 Other; N 10122; Dunkle, 2017,[97] Dunkle, 2017,[98] Sanofi Pasteur, a Sanofi Company, 2019[192]	RR 0.66; CI 0.10, 4.26 (8/4328 vs 12/4344, 0/998 vs 0/332, 0/61 vs 0/59)[#]	Study limitation,° Precision^	Low SoE for no evidence of increased risk
	Encephalitis/encephalopathy	2 RCTs, 0 Other; N 10002; Dunkle, 2017,[97] Dunkle, 2017[98]	RR 0.58; CI 0.00, 3294190 (0/4328 vs 1/4344, 1/998 vs 0/332)[#]	Study limitation,° Precision^	Low SoE for no evidence of increased risk
	Myocardial infarction	3 RCTs, 0 Other; N 10845; Cowling, 2019[84] Dunkle, 2017,[97] Dunkle, 2017[98]	RR 1.35; CI 0.08, 22.21 (events not vaccine-related per the study authors; 0/335 vs 0/508, 4/4328 vs 3/4344, 2/998 vs 0/332)[&,#]	Study limitation,°°°° Precision^	Low SoE for no evidence of increased risk
	Reproductive system events	2 RCTs, 0 Other; N 10002; Dunkle, 2017,[97] Dunkle, 2017[98]	RR 0.41; CI 0.00, 82495 (e.g., ovarian cyst; 1/4328 vs 3/4344, 1/998 vs 0/332)[#]	Study limitation,° Precision^	Low SoE for no evidence of increased risk
	Spontaneous abortion	1 RCT, 0 Other; N 1330; Dunkle, 2017[98]	RR 0.67; CI 0.02, 19.79 (1/998 vs 0/332)[#]	Study limitation,° Precision,^ Consistency↑	Insufficient evidence
	Stillbirth	1 RCT, 0 Other; N 8672; Dunkle, 2017[97]	RR 1.00; CI 0.06, 16.04 (1/4328 vs 1/4344)[#]	Study limitation,° Precision,^ Consistency↑	Insufficient evidence
	Stroke	1 RCT, 0 Other; N 8672; Dunkle, 2017[97]	RR 0.84; CI 0.26, 2.74 (cerebrovascular accident ; 5/4328 vs 6/4344)[#]	Study limitation,° Consistency↑	Low SoE for no evidence of increased risk

Vaccine	Outcome	N RCTs, N Other; N Participants; IDs of Studies Contributing to RR	Risk Estimate: RR; CI (Event Rates in Individual studies); Other Studies Contributing to SoE	Reasons for Downgrading	Update Evidence Statement and SoE
	Acute disseminated encephalomyelitis, anaphylaxis or systemic allergic reaction, angioedema, asthma, diabetes, Guillain-Barré syndrome, seizures, transverse myelitis	0 RCTs, 0 Other; N 0; 0 studies	We did not identify studies reporting on these outcomes	N/A	Insufficient evidence
Influenza, live attenuated (LAIV; FluMist Quadrivalent®)	Anaphylaxis or systemic allergic reaction	1 RCTs, 0 Other N 1796 Block,2011[71]	RR 0.25; CI 0.01, 7.43 (0/1198 vs 1/598)#	Study limitation,° Precision,^ Consistency↑	Insufficient evidence
	Asthma	1 RCTs, 0 Other N 1796 Block,2011[71]	RR 0.25; CI 0.01, 7.43 (0/1198 vs 1/598)#	Study limitation,° Precision,^ Consistency↑	Insufficient evidence
	Cardiovascular events	1 RCTs, 0 Other N 1796 Block,2011[71]	RR 0.25; CI 0.01, 7.43; (cardiac failure, congestive; 0/1198 vs 1/598)#	Study limitation,° Precision,^ Consistency↑	Insufficient evidence
	Death	1 RCTs, 0 Other N 1796 Block,2011[71]	RR 0.50; CI 0.01, 25.13 (0/1198 vs 0/598)#	Study limitation,° Precision,^ Consistency↑	Insufficient evidence
	Myocardial infarction	1 RCTs, 0 Other N 1796 Block,2011[71]	RR 0.25; CI 0.01, 7.43; (0/1198 vs 1/598)#	Study limitation,° Precision,^ Consistency↑	Insufficient evidence
	Reproductive system events	1 RCTs, 0 Other N 1796 Block,2011[71]	RR 0.12; CI 0.01, 2.76; (uterine leiomyoma; 0/1198 vs 2/598)#	Study limitation,° Precision,^ Consistency↑	Insufficient evidence
	Acute disseminated encephalomyelitis, angioedema, diabetes, Guillain-Barré syndrome, seizures, stroke, transverse myelitis	0 RCTs, 0 Other; N 0; 0 studies	We did not identify studies reporting on these outcomes	N/A	Insufficient evidence

Notes: CI—95% confidence interval; ID—study identifier; KQ—Key Question; N—number; N/A—not applicable; RR—relative risk; RCT—randomized controlled trials; SoE—strength of evidence; &—potentially increased risk based on direction of effects across studies and investigated further but not statistically significant; #—none of the RR estimates in individual studies showed a statistically significantly increased risk; °—no unvaccinated control group; °°°°°—events have been investigated by authors and independently by the FDA and found to be unrelated; ^—imprecise estimate with wide CI, ↑—consistency could not be assessed as no other study reported on the outcome, ↑↑↑—conflicting results across studies

IIV (non-adjuvanted). Quadrivalent IIV was not reviewed in the prior 2014 report, only trivalent IIV and monovalent H1N1 influenza vaccine. The prior 2014 report found high SoE for anaphylaxis in allergic persons with prior influenza vaccines based on the IOM report for trivalent IIV only. The prior 2014 report also found high SoE for arthralgia, myalgia, malaise, fever, and pain at the injection site for trivalent IIV. There was also high SoE for no association with cardiovascular events in adults aged 65 years and older in the prior 2014 report for trivalent IIV (based on post-licensure studies). Finally, the prior 2014 report found high SoE that the monovalent H1N1 influenza vaccine was associated with increased risk of Guillain-Barré syndrome, but this was not examined in the update as the vaccine is no longer in use. There was insufficient evidence to conclude anything regarding influenza vaccines and multiple sclerosis onset and exacerbation in the prior 2014 report.

All evidence statements for quadrivalent IIV currently in use come only from the current report, which identified low SoE for no evidence of increased risk for asthma, cardiovascular events, death, myocardial infarction, reproductive system events, seizures, or stroke for quadrivalent IIV compared to existing vaccines. There was insufficient evidence or no studies for several other key adverse events.

aIIV. aIIV (Fluad and Fluad Quadrivalent) was not in use at time of prior 2014 report; all evidence statements are based on the current report. The current report found moderate SoE for no evidence of increased risk of cardiovascular events or stroke. The current report also found low SoE for no evidence of increased risk for asthma, autoimmune disease, death, encephalitis/encephalopathy, Guillain-Barré syndrome, idiopathic thrombocytopenic purpura, myocardial infarction, or seizures compared to existing influenza vaccines. There was insufficient evidence to judge the risk of other key adverse events.

RIV. Quadrivalent RIV was not in use at the time of prior 2014 report (and trivalent RIV results were combined with all IIV); all evidence statements are based on the current report. The current report found low SoE for no evidence of increased risk for cardiovascular events, death, encephalitis/encephalopathy, myocardial infarction, reproductive system events, or stroke for quadrivalent RIV compared to quadrivalent IIV. For some key adverse events, the evidence was judged to be insufficient or we did not find studies reporting on the outcome.

LAIV. We reviewed one study of quadrivalent LAIV in the current report, with insufficient evidence or no studies for key adverse events. Table 4a summarizes the findings across the prior 2014 report and the update.

Table 4a. KQ1: Safety of influenza vaccines in adults

Vaccine (Abbreviation; Brand Name[s])	2014 Report SoE and Findings	SoE and Findings in Update	Synthesis of SoE and Findings
Influenza, inactivated (IIV; Afluria Quadrivalent, Flucelvax Quadrivalent, Fluarix Quadrivalent, Flulaval Quadrivalent, Fluzone High Dose Quadrivalent, Fluzone Quadrivalent)	High: Arthralgia, myalgia, malaise, fever, and pain at injection site; anaphylaxis in allergic persons for trivalent IIV. High: Guillain-Barré syndrome with 2009 monovalent H1N1 influenza vaccine (vaccine no longer in use and not examined in this report) High: No association with cardiovascular events in adults aged 65 years and older for trivalent IIV. Insufficient: Multiple sclerosis onset and exacerbation Quadrivalent IIV not reviewed in prior report	Low: No evidence of increased risk of asthma, cardiovascular events, death, myocardial infarction, reproductive system events, seizures, stroke for quadrivalent IIV Insufficient: Anaphylaxis or systemic allergic reaction, autoimmune disease, Guillain-Barré syndrome No studies: Acute disseminated encephalomyelitis, angioedema, diabetes, transverse myelitis	Low: No evidence of increased risk of asthma, cardiovascular events; death, myocardial infarction, reproductive system events, seizures, stroke Trivalent IIV and monovalent H1N1 influenza vaccine no longer in use
Influenza, inactivated, adjuvanted (aIIV; Fluad, Fluad Quadrivalent)	aIIV not in use at time of prior report	Moderate: No evidence of increased risk of cardiovascular events, stroke Low: No evidence of increased risk of asthma, autoimmune disease, death, encephalitis/encephalopathy, Guillain-Barré syndrome, idiopathic thrombocytopenic purpura, myocardial infarction, seizures Insufficient: Acute disseminated encephalomyelitis, anaphylaxis or systemic allergic reaction, angioedema, diabetes, transverse myelitis	Moderate: No evidence of increased risk of cardiovascular events, stroke Low: No evidence of increased risk of asthma, autoimmune disease, death, encephalitis/encephalopathy, Guillain-Barré syndrome, idiopathic thrombocytopenic purpura, myocardial infarction, seizures
Influenza, recombinant (RIV; Flublok Quadrivalent)	Quadrivalent RIV not in use at time of prior report Trivalent RIV results were combined with all inactivated influenza vaccines in prior report	Low: No evidence of increased risk of cardiovascular events, death, encephalitis/encephalopathy, myocardial infarction, reproductive system events, stroke No studies: Acute disseminated encephalomyelitis, anaphylaxis or systemic allergic reaction, angioedema, asthma, diabetes, Guillain-Barré syndrome, seizures, transverse myelitis	Low: No evidence of increased risk of cardiovascular events, death, encephalitis/encephalopathy, myocardial infarction, reproductive system events, stroke

Vaccine (Abbreviation; Brand Name[s])	2014 Report SoE and Findings	SoE and Findings in Update	Synthesis of SoE and Findings
Influenza, live attenuated (LAIV; FluMist Quadrivalent)	No findings	Insufficient: Anaphylaxis or systemic allergic reaction, asthma, cardiovascular events, death No studies: Acute disseminated encephalomyelitis, angioedema, diabetes, Guillain-Barré syndrome, seizures, stroke, transverse myelitis	☐ Insufficient evidence to draw conclusions

Key: ■ Green box indicates no evidence of increased risk of specific adverse events; ☐ White box indicates insufficient evidence to draw conclusions about the risk of specific adverse events; Notes: KQ—Key Question; SoE—Strength of Evidence

Measles, Mumps, and Rubella Vaccine

Table 5 summarizes the SoE for studies of MMR in adults.

Table 5. KQ1: Update summary of findings and SoE for safety of MMR in adults

Vaccine	Outcome	N RCTs, N Other; N Participants; IDs of Studies Contributing to RR	Results	Update Evidence Statement and SoE
Measles, mumps, and rubella (MMR; M-M-R II®)	Acute disseminated encephalomyelitis, anaphylaxis or systemic allergic reaction, angioedema, autism, cardiovascular events, death, diabetes, encephalitis/encephalopathy, Guillain-Barré syndrome, idiopathic thrombocytopenic purpura, meningitis, multiple sclerosis, seizures, stroke, transverse myelitis	0 RCTs, 0 Other; N 0; 0 studies	We did not identify studies of measles, mumps, rubella vaccine in adults in this update; prior evidence is summarized in the text	Insufficient evidence

Notes: ID—study identifier; KQ—Key Question; N—number, RR—relative risk, RCT—randomized controlled trials; SoE—strength of evidence

There was insufficient evidence for all outcomes of interest for MMR in the update because no study that evaluated the vaccine in adults met inclusion criteria. The prior 2014 report found moderate strength evidence supporting a causal relationship between the rubella component of MMR and transient arthralgia in women from the IOM report, which was based on mechanistic evidence; the estimate of the magnitude of increased risk was not determined. This finding remains unchanged, as transient arthralgia was not examined as a key adverse event in the current report. The prior 2014 report found moderate strength evidence of no association of onset

of type 1 diabetes and insufficient evidence for Guillain-Barré Syndrome, onset of multiple sclerosis, chronic arthralgia in women, and chronic arthritis and arthropathy in men. These findings also remain unchanged given that there were no new studies in the update and/or these were not examined as key adverse events. Table 5a summarizes the findings across the prior 2014 report and the update.

Table 5a. KQ1: Safety of MMR in adults

Vaccine (Abbreviation; Brand Name[s])	2014 Report SoE and Findings	SoE and Findings in Update	Synthesis of SoE and Findings
Measles, mumps, and rubella (MMR; M-M-R II)	Moderate: No association with type 1 diabetes mellitus Moderate: Causal relationship between MMR and transient arthralgia in women based on mechanistic evidence (not examined as a key adverse event in current report) Insufficient: Multiple sclerosis, Guillain-Barré syndrome, and chronic arthralgia (in women); chronic arthritis and arthropathy (in men)	No new evidence	Moderate: No evidence of increased risk of type 1 diabetes mellitus (no change from prior 2014 report; no new studies in update)

Key: Green box indicates no evidence of increased risk of specific adverse events; Notes: KQ—Key Question; SoE—Strength of Evidence

Meningococcal Vaccines

Table 6 documents the findings for meningococcal vaccines in adults.

Table 6. KQ1: Update summary of findings and SoE for safety of meningococcal vaccines in adults

Intervention	Outcome	N RCTs, N Other; N Participants; IDs of Studies Contributing to RR	Risk Estimate: RR; CI (Event Rates in Individual Studies); Other Studies Contributing to SoE	Reasons for Downgrading	Update Evidence Statement and SoE
Meningococcal A, C, W and Y [MenACWY-D (Menactra®),	Cardiovascular events	1 RCT, 0 Other; N 901; Esteves-Jaramillo, 2020[104]	RR 0.25; CI 0.01, 5.59 (0/448 vs 2/453)[#]	Study limitation,° Consistency↑	Low SoE for no evidence of increased risk

Intervention	Outcome	N RCTs, N Other; N Participants; IDs of Studies Contributing to RR	Risk Estimate: RR; CI (Event Rates in Individual Studies); Other Studies Contributing to SoE	Reasons for Downgrading	Update Evidence Statement and SoE
MenACWY-CRM (Menveo®), MenACWY-TT (MenQuadfi®)]	Death	4 RCTs, 0 Other; N 1568; Alberer, 2015,[53] Alberer, 2015,[54] Esteves-Jaramillo, 2020,[104] Kirstein, 2020[147]	RR 0.99; CI 0.00, 60563320 (0/99 vs 0/100, 0/85 vs 0/84);[#] in 2 studies with unvaccinated control groups, combining these with 2 other studies with active comparators: RR 0.53; CI 0.03, 10.33; restricting to RCTs evaluating MenQuadfi also did not suggest an increased risk (RR 0.33; CI 0.00, 2256832)	Precision^	Moderate SoE for no evidence of increased risk
Meningococcal A, C, W and Y [MenACWY-D (Menactra®), MenACWY-CRM (Menveo®), MenACWY-TT (MenQuadfi®)] (continued)	Myocardial infarction	1 RCTs, 0 Other; N 901; Esteves-Jaramillo, 2020[104]	RR 0.25; CI 0.01, 5.59 (0/448 vs 2/453)[#]	Study limitation,° Consistency↑	Low SoE for no evidence of increased risk
	Reproductive system events	1 RCT, 0 Other; N 901; Esteves-Jaramillo, 2020[104]	RR 2.02; CI 0.07, 60.13 (benign prostatic hyperplasia; 1/448 vs 0/453)[&,#]	Study limitation,° Precision,^ Consistency↑	Insufficient evidence
	Stroke	1 RCT, 0 Other; N 901; Esteves-Jaramillo, 2020[104]	RR 0.51; CI 0.02, 15.03; (0/448 vs 1/453)[#]	Study limitation,° Precision^	Low SoE for no evidence of increased risk
	Acute disseminated encephalomyelitis, anaphylaxis or systemic allergic reaction, angioedema, diabetes, encephalitis/encephalopathy, Guillain-Barré syndrome, multiple sclerosis, seizures, transverse myelitis	0 RCTs, 0 Other; N 0; 0 studies	We did not identify studies reporting on the outcomes	N/A	Insufficient evidence

Intervention	Outcome	N RCTs, N Other; N Participants; IDs of Studies Contributing to RR	Risk Estimate: RR; CI (Event Rates in Individual Studies); Other Studies Contributing to SoE	Reasons for Downgrading	Update Evidence Statement and SoE
Meningococcal B [MenB; MenB-4C (Bexsero®),MenB-FHbp (Trumenba®)]	Acute disseminated encephalomyelitis, anaphylaxis or systemic allergic reaction, angioedema, cardiovascular events, death, diabetes, encephalitis/encephalopathy, Guillain-Barré syndrome, multiple sclerosis, seizures, stroke, transverse myelitis	0 RCTs, 0 Other; N 0; 0 studies	We did not identify studies reporting on Meningococcal B vaccines in adults	N/A	Insufficient evidence

Notes: CI—95% confidence interval; ID—study identifier; KQ—Key Question; N—number; N/A—not applicable; RR—relative risk; RCT—randomized controlled trials; SoE—strength of evidence; [&]—potentially increased risk based on direction of effects across studies and investigated further but not statistically significant; [#]—none of the RR estimates in individual studies showed a statistically significantly increased risk; °—no unvaccinated control group; ^—imprecise estimate with wide CI; ↑—consistency could not be assessed as no other study reported on the outcome

MenACWY. The prior 2014 report reported no findings on MenACWY in adults; all evidence statements are based on the current report. There was moderate SoE for no evidence of increased risk for death and low SoE for no evidence of increased risk for cardiovascular events, myocardial infarction, or stroke. The evidence was graded as insufficient or there were no studies for several other key adverse events.

MenB. There was insufficient evidence for evidence statements regarding MenB in adults as no studies of adults alone were identified in the update; studies of children and adults are under KQ2. MenB was not in use at time of prior 2014 report, so there is insufficient evidence to draw conclusions. Table 6a summarizes the findings across the prior 2014 report and the update.

Table 6a. KQ1: Safety of meningococcal vaccines in adults

Vaccine (Abbreviation; Brand Name[s])	2014 Report SoE and Findings	SoE and Findings in Update	Synthesis of SoE and Findings
Meningococcal A, C, W, and Y (MenACWY; MenACWY-D [Menactra], MenACWY-CRM [Menveo], MenACWY-TT [MenQuadfi])	No findings	Moderate: No evidence of increased risk of death Low: No evidence of increased risk of cardiovascular events, myocardial infarction, stroke No studies: Acute disseminated encephalomyelitis, anaphylaxis or systemic allergic reaction, angioedema, diabetes, encephalitis/encephalopathy, Guillain-Barré syndrome, multiple sclerosis, seizures, transverse myelitis	■ Moderate: No evidence of increased risk of death ■ Low: No evidence of increased risk of cardiovascular events, myocardial infarction, stroke
Meningococcal B (MenB; MenB-4C [Bexsero®],MenB-FHbp [Trumenba®])	MenB not in use at time of prior report	No new evidence	□ Insufficient evidence to draw conclusions; see KQ2 for studies that combined children and adults

Key: ■ Green box indicates no evidence of increased risk of specific adverse events; □ White box indicates insufficient evidence to draw conclusions about the risk of specific adverse events; Notes: KQ—Key Question; SoE—Strength of Evidence

Pneumococcal Vaccines

Table 7 documents results for pneumococcal vaccines in adults.

Table 7. KQ1: Update summary of findings and SoE for safety of pneumococcal vaccines in adults

Vaccine	Outcome	N RCTs, N Other; N Participants; IDs of Studies Contributing to RR	Risk Estimate: RR; CI (Event Rates in Individual Studies); Other Studies Contributing to SoE	Reasons for Downgrading	Update Evidence Statement and SoE
Pneumococcal conjugate vaccine (PCV13; Prevnar 13®) Pneumococcal conjugate vaccine (PCV13; Prevnar 13®) (continued)	Acute disseminated encephalomyelitis	1 RCT, 0 Other; N 84492; Bonten, 2015[72]	RR 2.00; CI 0.07, 59.64 (1/42237 vs 0/42255)[&,#]	Precision,^ Consistency↑	Low SoE for no evidence of increased risk
	Anaphylaxis or systemic allergic reaction	1 RCT, 0 Other; N 84492; Bonten, 2015[72]	RR 0.25; CI 0.01, 5.55 (0/42237 vs 2/42255);[#] 1 additional study found no increased risk (RR 1.32; CI 0.30, 5.79)[222]	Precision,^ Consistency↑	Low SoE for no evidence of increased risk
	Asthma	1 RCTs, 0 Other N 1151 Schwarz,2011[195]	RR 1.00; CI 0.02, 50.22 (0/576 vs 0/575)[#]	Precision,^ Consistency↑	Low SoE for no evidence of increased risk
	Autoimmune disease	2 RCTs, 0 Other; N 85323; Bonten, 2015,[72] Pfizer,2007[184]	RR 1.00; CI 0.02, 50.42 (polymyalgia rheumatica; 0/42237 vs 0/42255) when compared to placebo;[#] combining this with 1 other study with active comparator (reports on Crohn's disease): RR 0.67; CI 0.00, 11165626	Study limitation°°°° Precision,^	Low SoE for no evidence of increased risk

Vaccine	Outcome	N RCTs, N Other; N Participants; IDs of Studies Contributing to RR	Risk Estimate: RR; CI (Event Rates in Individual Studies); Other Studies Contributing to SoE	Reasons for Downgrading	Update Evidence Statement and SoE
Pneumococcal conjugate vaccine (PCV13; Prevnar 13®) (continued)	Cardiovascular events	6 RCTs, 0 Other; N 89176; Schwarz,2011,[195] Frenck,2012,[109] Bonten, 2015,[72] Greenberg,2014,[120] Thompson, 2019,[214] Pfizer, 2007[184]	RR 0.97; CI 0.58, 1.64 (1/576 vs 0/575, 0/551 vs 1/560, 72/42237 vs 74/42255, 0/439 vs 0/437) when compared to placebo or base treatment received by both the intervention and control groups;[#] combining this with 2 other studies with active comparators: RR 0.97; CI 0.64, 1.46	Study limitation°°°°	Moderate SoE for no evidence of increased risk
	Death	7 RCTs, 1 Other; N 2114602; Schwarz,2011,[195] Bonten, 2015,[72] Greenberg,2014,[120] Jackson, 2013,[140] Shiramoto, 2015,[200] Thompson, 2019,[214] Vandecasteele, 2018,[227] Vila-Corcoles, 2018[231]	RR 1.85; CI 0.37, 9.31 (0/576 vs 0/575, 3006/42237 vs 3005/42255, 1/421 vs 0/441, 420/5010 vs 46845/2020720) when compared to placebo or base treatment received by both the intervention and control groups;[&,##] combining these with 4 other studies with active comparators: RR 1.22; CI 0.40, 3.69[&]	Precision,^ Consistency↑↑	Low SoE for no evidence of increased risk
	Encephalitis/encephalopathy	1 RCTs, 0 Other N 1111 Frenck, 2012[109]	RR 1.02; CI 0.02, 51.13; (hepatic encephalopathy; 0/551 vs 0/560)[#]	Precision,^ Consistency↑	Low SoE for no evidence of increased risk
	Herpes zoster	2 RCTs, 0 Other N 85643 Schwarz, 2011,[195] Bonten, 2015[72]	RR 1.49; CI 0.00, 24855526; (0/576 vs 0/575, 1/42237 vs 0/42255)[#]	Precision,^	Moderate SoE for no evidence of increased risk
	Idiopathic thrombocytopenic purpura	1 RCT, 0 Other; N 84492; Bonten, 2015[72]	RR 0.50; CI 0.02, 14.91 (0/42237 vs 1/42255)[#]	Precision,^ Consistency↑	Low SoE for no evidence of increased risk
	Meningitis	1 RCT, 0 Other; N 84510; Bonten, 2015[72]	RR 2.00; CI 0.07, 59.64 (1/42237 vs 0/42255)[&,#]	Precision,^ Consistency↑	Low SoE for no evidence of increased risk
	Myocardial infarction	6 RCTs, 0 Other; N 89176; Schwarz, 2011,[195] Frenck, 2012,[109] Bonten, 2015,[72] Greenberg, 2014,[120] Thompson, 2019,[214] Pfizer,2007[184]	RR 1.76; CI 0.42, 7.39 (1/576 vs 0/575, 0/551 vs 1/560, 12/42237 vs 6/42255, 0/439 vs 0/437) when compared to placebo or base treatment received by both the intervention and control groups;[#] combining these with 2 other studies with active comparators: RR 1.51; CI 0.52, 4.33	Precision^	Moderate SoE for no evidence of increased risk

Vaccine	Outcome	N RCTs, N Other; N Participants; IDs of Studies Contributing to RR	Risk Estimate: RR; CI (Event Rates in Individual Studies); Other Studies Contributing to SoE	Reasons for Downgrading	Update Evidence Statement and SoE
	Reproductive system events	5 RCT, 0 Other; N 88025; Frenck, 2012,[109] Bonten, 2015,[72] Greenberg, 2014,[120] Thompson, 2019,[214] Pfizer, 2007,[184]	RR 0.59; CI 0.01, 42.46 (0/551 vs 0/560, 0/42237 vs 3/42255, 1/439 vs 0/437) when compared to placebo or base treatment received by both the intervention and control groups;[#] combining these with 2 other studies with active comparators: RR 0.71; CI 0.08, 6.42	Precision^	Moderate SoE for no evidence of increased risk
	Seizure	1 RCT, 0 Other; N 84492; Bonten, 2015[72]	RR 0.50; CI 0.05, 5.52 (1/42237 vs 2/42255)[#]	Precision^	Low SoE for no evidence of increased risk
	Stroke	2 RCT, 0 Other; N 85603; Frenck, 2012,[109] Bonten, 2015[72]	RR 1.12; CI 0.00, 451 (0/551 vs 0/560, 9/42237 vs 8/42255)[#]	Precision^	Moderate SoE for no evidence of increased risk
	Angioedema, diabetes, Guillain-Barré syndrome, transverse myelitis	0 RCTs, 0 Other; N 0; 0 studies	We did not identify studies reporting on these outcomes	N/A	Insufficient evidence
Pneumococcal polysaccharide vaccine (PPSV23; Pneumovax®)	Anaphylaxis or systemic allergic reaction	0 RCTs, 0 Other; N 0; 0 studies	One study found no increased risk	Study limitation,°° Precision,^ Consistency↑	Insufficient evidence
	Cardiovascular events	1 RCTs, 3 Other N 19129 Chang, 2012,[80] Eurich, 2012,[935] Shimada, 2020,[199] Zahid, 2012[239]	RR 0.46; CI 0.27, 0.76 (11/8142 vs 17/8142, 19/725 vs 52/724, 0/19 vs 0/21, 30/857 vs 37/499)[#] 1 other study[176] found no increased risk of myocardial infarction (mHR 0.95; CI 0.76, 1.18)	Study limitation°°	Moderate SoE for no evidence of increased risk

Vaccine	Outcome	N RCTs, N Other; N Participants; IDs of Studies Contributing to RR	Risk Estimate: RR; CI (Event Rates in Individual Studies); Other Studies Contributing to SoE	Reasons for Downgrading	Update Evidence Statement and SoE
	Death	1 RCTs, 3 Other N 19129 Chang, 2012,[80] Eurich, 2012,[935] Shimada, 2020,[199] Zahid, 2012[239]	RR 0.62; CI 0.16, 2.44 (13/8142 vs 17/8142, 6/725 vs 4/724, 0/19 vs 0/21, 71/857 vs 134/499);[#] 1 additional study[137] reported fewer deaths in patients vaccinated with PPSV23 (HR 0.65; CI 0.55, 0.77); 1 other study[159] reported increased 7-year survival for vaccinated participants (p<0.001); 1 other study[176] reported no increased risk (mHR 0.97; CI 0.89, 1.05)	Precision^	Moderate SoE for no evidence of increased risk
	Herpes zoster	0 RCTs, 1 Other; N 194; Fischer, 2015[107]	RR 0.82; CI 0.09, 7.73 (1/56 vs 3/138)[#]	Study limitation,° Precision,^ Consistency↑	Insufficient evidence
	Myocardial infarction	0 RCTs, 1 Other N 1356 Zahid, 2012[201]	RR 0.47; CI 0.3, 0.75; (30/857 vs 37/499); [#] 1 other study[176] reported no increased risk (mHR 0.95; CI 0.76, 1.18)	Study limitation,° Precision,^ Consistency↑	Insufficient evidence
	Stroke	0 RCTs, 0 Other; N 0; 0 studies	Three studies[81, 176, 201] reported no increased risk (mHR 0.57; CI 0.31, 1.03; aOR 0.94; CI 0.89 to 1.00; mHR CI 1.04; 0.83,1.30)	Study limitation,° Precision,^ Consistency↑	Insufficient evidence
	Acute disseminated encephalomyelitis, angioedema, diabetes, Guillain-Barré syndrome, seizures, transverse myelitis	0 RCTs, 0 Other; N 0; 0 studies	We did not identify studies reporting on these outcomes	N/A	Insufficient evidence

Notes: CI—95% confidence interval; ID—study identifier; KQ—Key Question; N—number; N/A—not applicable; RR—relative risk; RCT—randomized controlled trials; SoE—strength of evidence; &—potentially increased risk based on direction of effects across studies and investigated further but not statistically significant; #—none of the RR estimates in individual studies showed a statistically significantly increased risk; ##— 1 out of 8 studies reported an increased risk in the vaccine group (RR 3.62; CI 3.30, 3.96; events 420/5010 vs 46845/2020720; the authors also reported an adjusted mHR that was not statistically significant); °—no unvaccinated control group; °°—effect based on observational evidence only; °°°°—effect based on very different outcomes; ^—imprecise estimate with wide CI or CI could not be computed; ↑—consistency could not be assessed as no other study reported on the outcome

PCV13. There were no findings in the prior 2014 report for the safety of PCV13 in adults. Based on the current report, there was moderate SoE for no evidence of increased risk for cardiovascular events, herpes zoster, myocardial infarction, reproductive system events or stroke. Based on the current report, there was low SoE for no evidence of increased risk for acute disseminated encephalomyelitis, anaphylaxis or systemic allergic reaction, asthma, autoimmune

disease, death, encephalitis/encephalopathy, herpes zoster, idiopathic thrombocytopenic purpura, meningitis, or seizures. For several key adverse events, we found either evidence graded as insufficient or no studies reporting on these adverse events.

PPSV23. The prior 2014 report found high strength evidence for no association of PPSV23 with cardiovascular or cerebrovascular events in adults aged 65 years and older. This finding remains unchanged given that the update continues to find no evidence of increased risk of cardiovascular events (including myocardial infarction) or stroke across all studies that are now available. Based on the update, there was moderate SoE for no evidence of increased risk of death following PPSV23. Evidence was graded as insufficient or there were no studies for a number of other key adverse events.

Table 7a summarizes and synthesizes the findings across the prior 2014 report and the update.

Table 7a. KQ1: Safety of pneumococcal vaccines in adults

Vaccine (Abbreviation; Brand Name[s])	2014 Report SoE and Findings	SoE and Findings in Update	Synthesis of SoE and Findings
13-valent pneumococcal conjugate (PCV13; Prevnar 13)	No findings	Moderate: No evidence of increased risk of cardiovascular events, herpes zoster, myocardial infarction, reproductive system events, stroke Low: No evidence of increased risk of acute disseminated encephalomyelitis, anaphylaxis or systemic allergic reaction, asthma, autoimmune disease, death, encephalitis/encephalopathy, idiopathic thrombocytopenic purpura, meningitis, seizures No studies: Angioedema, diabetes, Guillain-Barré syndrome, transverse myelitis	Moderate: No evidence of increased risk of cardiovascular events, herpes zoster, myocardial infarction, reproductive system events, stroke Low: No evidence of increased risk of acute disseminated encephalomyelitis, anaphylaxis or systemic allergic reaction, asthma, autoimmune disease, death, encephalitis/encephalopathy, herpes zoster, idiopathic thrombocytopenic purpura, meningitis, seizures
23-valent pneumococcal polysaccharide (PPSV23; Pneumovax)	High: No association with cardiovascular or cerebrovascular events in adults aged 65 years and older	Moderate: No evidence of increased risk of cardiovascular events, death Insufficient: Anaphylaxis or systemic allergic reaction, stroke No studies: Acute disseminated encephalomyelitis, angioedema, diabetes, Guillain-Barré syndrome, seizures, transverse myelitis	High: No evidence of increased risk of cardiovascular or cerebrovascular events in adults aged 65 years and older (no change from prior 2014 report; update also identified no evidence of increased risk) Moderate: No evidence of increased risk of death

Key: Green box indicates no evidence of increased risk of specific adverse events; Notes: KQ—Key Question; SoE—Strength of Evidence

Tetanus, Diphtheria, and Acellular Pertussis Vaccines

Results regarding the safety of Tdap in adults are documented in Table 8.

Table 8. KQ1: Update summary of findings and SoE for safety of Tdap in adults

Vaccine	Outcome	N RCTs, N Other; N Participants; IDs of Studies Contributing to RR	Risk Estimate: RR; CI (Event Rates in Individual Studies); Other Studies Contributing to SoE	Reasons for Downgrading	Update Evidence Statement and SoE
Tetanus, diphtheria, and acellular pertussis (Tdap; Adacel, Boostrix®)	Autoimmune disease	1 RCT, 0 Other; N 1327; Halperin, 2019[124]	RR 0.66; CI 0.02, 19.53 (1/999 vs 0/328)#	Study limitation,° Precision,^ Consistency↑	Insufficient evidence)
	Death	1 RCT, 0 Other; N 1327; Halperin, 2019[124]	RR 0.33; CI 0.01, 16.51 (0/999 vs 0/328)#	Study limitation,° Precision,^ Consistency↑	Insufficient evidence
	Spontaneous abortion	1 RCT, 0 Other; N 1327; Halperin, 2019[124]	RR 0.66; CI 0.02, 19.53 (not considered vaccine-related; 1/999 vs 0/328)#	Study limitation,° Precision,^ Consistency↑	Insufficient evidence
	Acute disseminated encephalomyelitis, anaphylaxis or systemic allergic reaction, angioedema, brachial neuritis, cardiovascular events, diabetes, encephalitis/encephalopathy, Guillain-Barré syndrome, seizures, stroke, transverse myelitis	0 RCTs, 0 Other; N 0; 0 studies	We did not identify studies reporting on these outcomes	N/A	Insufficient evidence
Tetanus, diphtheria (Td; TDVAX®, Tenivac)	Acute disseminated encephalomyelitis, anaphylaxis or systemic allergic reaction, angioedema, brachial neuritis, cardiovascular events, death, diabetes, encephalitis/encephalopathy, Guillain-Barré syndrome, seizures, stroke, transverse myelitis	0 RCTs, 0 Other; N 0; 0 studies	We did not identify studies reporting on these outcomes for Td alone (used as comparator in studies for Tdap; see above)	N/A	Insufficient evidence

Notes: CI—95% confidence interval; KQ—Key Question; N—number, N/A—not applicable; RR—relative risk; RCT—randomized controlled trials; SoE—strength of evidence; #—none of the RR estimates in individual studies showed a statistically significantly increased risk; °—no unvaccinated control group; ^—imprecise estimate with wide CI; ↑—consistency could not be assessed as no other study reported on the outcome

The prior 2014 report described high strength of evidence supporting a causal relationship between tetanus toxoid vaccine and anaphylaxis from the IOM report, which was based on mechanistic evidence; the estimate of the magnitude of increased risk was not determined. This

finding remains unchanged as there were no studies examining anaphylaxis in the update. There were two additional RCTs in adults in the prior 2014 report, but they did not contribute to further evidence statements.

Although we identified one study evaluating Tdap in adults, we graded the evidence as insufficient or found no studies for a number of other key adverse events.

Table 8a summarizes the findings across the prior 2014 report and the update.

Table 8a. KQ1: Safety of Tdap in adults

Vaccine (Abbreviation; Brand Name[s])	2014 Report SoE and Findings	SoE and Findings in Update	Synthesis of SoE and Findings
Tetanus, diphtheria, and acellular pertussis (Tdap; Adacel, Boostrix) and tetanus and diphtheria (Td; TDVAX, Tenivac)	High: Causal relationship between anaphylaxis and tetanus toxoid based on mechanistic evidence	Insufficient: Death No studies: Acute disseminated encephalomyelitis, anaphylaxis or systemic allergic reaction, angioedema, brachial neuritis, cardiovascular events, diabetes, encephalitis/encephalopathy, Guillain-Barré syndrome, seizures, stroke, transverse myelitis	High: Anaphylaxis (no change from prior 2014 report; no new studies in update)

Key: Red circle indicates evidence of risk of specific adverse events; Notes: KQ—Key Question; SoE—Strength of Evidence

Varicella Vaccine

Evidence regarding the safety of varicella vaccines in adults is documented in Table 9.

Table 9. KQ1: Update summary of findings and SoE for safety of varicella vaccines in adults

Vaccine	Outcome	N RCTs, N Other; N Participants; IDs of Studies Contributing to RR	Results	Update Evidence Statement and SoE
Varicella (VAR; Varivax®)	Acute disseminated encephalomyelitis, anaphylaxis or systemic allergic reaction, angioedema, ataxia, cardiovascular events, death, diabetes, encephalitis/encephalopathy, Guillain-Barré syndrome, herpes zoster, meningitis, secondary transmission of live varicella virus, seizures, stroke, transverse myelitis	0 RCTs, 0 Other; N 0; 0 studies	We did not identify studies reporting on varicella vaccines in adults	Insufficient evidence

Notes: ID—study identifier; KQ—Key Question; RCT—randomized controlled trials; RR—relative risk; SoE—strength of evidence

The SoE was insufficient for evidence statements regarding varicella vaccines in adults as no study was identified that reported on the outcome in this update and the prior 2014 report. There were no studies of varicella vaccine in either report, and thus insufficient evidence to draw conclusions about risk. Table 9a summarizes the findings across the prior 2014 report and the update.

Table 9a. KQ1: Safety of varicella vaccine in adults

Vaccine (Abbreviation; Brand Name[s])	2014 Report SoE and Findings	SoE and Findings in Update	Synthesis of SoE and Findings
Varicella (VAR; Varivax)	No findings	No new evidence	☐ Insufficient evidence to draw conclusions

Key: ☐ White box indicates insufficient evidence to draw conclusions about the risk of specific adverse events; Notes: KQ—Key Question; SoE—Strength of Evidence

Zoster Vaccine

Evidence regarding the safety of zoster vaccine in adults is documented in Table 10.

Table 10. KQ1: Update summary of findings and SoE for safety of zoster vaccines in adults

Vaccine	Outcome	N RCTs, N Other; N Participants; IDs of Studies Contributing to RR	Risk Estimate: RR; CI (Event Rates in Individual Studies); Other Studies Contributing to SoE	Reasons for Downgrading	Update Evidence Statement and SoE
Zoster recombinant, RZV (Shingrix®) Zoster recombinant, RZV (Shingrix®) (continued)	Acute disseminated encephalomyelitis	1 RCT, 0 Other; N 15405; Lal, 2015[150]	RR 0.50; CI 0.02, 14.93 (0/7695 vs 1/7710)[#]	Precision,^ Consistency↑	Low SoE for no evidence of increased risk
	Amyotrophic lateral sclerosis	2 RCTs, 0 Other; N 29305; Cunningham, 2016,[85] Lal, 2015[150]	RR 2.60; CI 0.00, 571537 (no events were considered vaccine related; 2/6950 vs 0/6950, 2/7695 vs 1/7710)[&,#]	Precision^	Moderate SoE for no evidence of increased risk
	Anaphylaxis or systemic allergic reaction	2 RCTs, 0 Other; N 29305; Cunningham, 2016,[85] Lal, 2015[150]	RR 1.32; CI 0.00, 1463200 (1/6950 vs 1/6950, 1/7695 vs 0/7710)[&,#]	Precision^	Moderate SoE for no evidence of increased risk
	Angioedema	1 RCT, 0 Other; N 13900; Cunningham, 2016[85]	RR 2.00; CI 0.07, 59.61 (1/6950 vs 0/6950)[&,#]	Precision,^ Consistency↑	Low SoE for no evidence of increased risk
	Asthma	2 RCTs, 0 Other; N 29305; Cunningham, 2016,[85] Lal, 2015[150]	RR 0.90; CI 0.00, 493 (2/6950 vs 4/6950, 6/7695 vs 5/7710)[#]	Precision^	Moderate SoE for no evidence of increased risk
	Ataxia	1 RCT, 0 Other; N 13900; Cunningham, 2016[85]	RR 0.50; CI 0.02, 14.90 (0/6950 vs 1/6950)	Precision^	Low SoE for no evidence of increased risk
	Autoimmune disease	2 RCT, 0 Other; N 29308; Cunningham, 2016,[85] Lal, 2015[150]	RR 0.88; CI 0.23, 3.31 (92/6950 vs 97/6950, 78/7698 vs 97/7710)[#]	Precision,^ Consistency↑	Low SoE for no evidence of increased risk
	Autoimmune thyroiditis (Hashimoto's disease)	1 RCTs, 0 Other; N 13900; Cunningham, 2016[85]	RR 0.50; CI 0.02, 14.90 (0/6950 vs 1/6950)[#]	Precision,^ Consistency↑	Low SoE for no evidence of increased risk

Vaccine	Outcome	N RCTs, N Other; N Participants; IDs of Studies Contributing to RR	Risk Estimate: RR; CI (Event Rates in Individual Studies); Other Studies Contributing to SoE	Reasons for Downgrading	Update Evidence Statement and SoE
Zoster recombinant, RZV (Shingrix®) (continued)	Cardiovascular events	3 RCTs, 0 Other; N 29496; Chlibek, 2013,[82] Cunningham, 2016,[85] Lal, 2015[150]	RR 0.89; CI 0.66, 1.21; (1/150 vs 0/38, 268/6950 vs 315/6950, 145/7698 vs 147/7710)[#]	Precision^	Moderate SoE for no evidence of increased risk
	Death	4 RCTs, 0 Other; N 30327; Chlibek, 2013,[82] Cunningham, 2016,[85] Lal, 2015,[150] Schwarz, 2017[194]	RR 0.93; CI 0.78, 1.11 (no deaths were considered vaccine-related; 1/150 vs 0/38, 426/6950 vs 459/6950, 167/7698 vs 174/7713, 2/413 vs 5/415)[#]	Precision^^^	Moderate SoE for no evidence of increased risk
	Diabetes	2 RCTs, 0 Other; N 29305; Cunningham, 2016,[85] Lal, 2015[150]	RR 1.00; CI 0.00, 606 (5/6950 vs 6/6950, 3/7695 vs 2/7710)[#]	Precision^	Moderate SoE for no evidence of increased risk
	Encephalitis/encephalopathy	2 RCTs, 0 Other; N 29305; Cunningham, 2016,[85] Lal, 2015[150]	RR 0.50; CI 0.00, 2867570 (hypoxic-ischemic encephalopathy; 0/6950 vs 1/6950, 0/7695 vs 1/7710)[#]	Precision^	Moderate SoE for no evidence of increased risk
	Guillain-Barré syndrome	2 RCTs, 0 Other; N 29305; Cunningham, 2016,[85] Lal, 2015[150]	RR 0.67; CI 0.00, 86459 (1/6950 vs 2/6950, 1/7695 vs 1/7710)[#]	Precision^	Moderate SoE for no evidence of increased risk
	Herpes Zoster	5 RCTs, 0 Other; N 31177 Chlibek, 2013,[82] Cunningham, 2016,[85] Lal, 2015,[150] Schwarz, 2017,[194] Marechal, 2018[165]	RR 0.09; CI 0.02, 0.30 (local or disseminated zoster rash; 0/142 vs 0/38, 23/6950 vs 223/6950, 9/7695 vs 235/7713, 0/415 vs 2/413, 0/429 vs 0/432)[#]	N/A	High SoE for no evidence of increased risk
	Idiopathic thrombocytopenic purpura	2 RCTs, 0 Other; N 29305; Cunningham, 2016,[85] Lal, 2015[150]	RR 2.65; CI 0.00, 530690 (1/6950 vs 0/6950, 3/7695 vs 1/7710)[&,#]	Precision^	Moderate SoE for no evidence of increased risk
	Meningitis	2 RCTs, 0 Other; N 29305; Cunningham, 2016,[85] Lal, 2015[150]	RR 0.50; CI 0.00, 2867570 (0/6950 vs 1/6950, 0/7695 vs 1/7710)[#]	Precision^	Moderate SoE for no evidence of increased risk
	Myocardial infarction	3 RCTs, 0 Other; N 29493; Chlibek, 2013,[82] Cunningham, 2016,[85] Lal, 2015[150]	RR 0.89; CI 0.38, 2.05 (1/150 vs 0/38, 21/6950 vs 28/6950, 28/7695 vs 27/7710)[#]	Precision^^^	Moderate SoE for no evidence of increased risk
	Reproductive system events	2 RCTs, 0 Other; N 29308; Cunningham, 2016,[85] Lal, 2015[150]	RR 1.04; CI 0.03, 37.17 (16/6950 vs 18/6950, 10/7698 vs 7/7710)[&,#]	Study limitation°	Moderate SoE for no evidence of increased risk

Vaccine	Outcome	N RCTs, N Other; N Participants; IDs of Studies Contributing to RR	Risk Estimate: RR; CI (Event Rates in Individual Studies); Other Studies Contributing to SoE	Reasons for Downgrading	Update Evidence Statement and SoE
	Seizure	2 RCTs, 0 Other; N 29305; Cunningham, 2016,[85] Lal, 2015[150]	RR 1.34; CI 0.00, 13492 (2/6950 vs 0/6950, 3/7695 vs 3/7710)[&,#]	Precision^	Moderate SoE for no evidence of increased risk
	Stroke	2 RCTs, 0 Other; N 29305; Cunningham, 2016,[85] Lal, 2015[150]	RR 1.44; CI 0.03, 71.52 (7/6950 vs 6/6950, 19/7695 vs 12/7710)[&,#]	Precision^	Moderate SoE for no evidence of increased risk
	Secondary transmission of live varicella virus, transverse myelitis	0 RCTs, 0 Other; N 0; 0 studies	We did not identify studies reporting on these outcomes	N/A	Insufficient evidence

Notes: CI—95% confidence interval; ID—study identifier; KQ—Key Question; N—number; N/A—not applicable; RR—relative risk; RCT—randomized controlled trials; SoE—strength of evidence; &—potentially increased risk based on direction of effects across studies and investigated further but not statistically significant; #—none of the RR estimates in individual studies showed a statistically significantly increased risk; °—no unvaccinated control group; °°—effect based on observational evidence only; °°°°—possible causal mechanism not investigated; ^—imprecise estimate with wide CI; ^^—study provides insufficient detail for further analyses and independent estimate of effect size not possible; ^^^—the CI crosses the point of no difference and it was not possible to completely rule out the risk of adverse event; ↑—consistency could not be assessed as no other study reported on the outcome

RZV was approved after the publication of the prior 2014 report, so all evidence statements come from the current report. There was high SoE for no evidence of increased risk for herpes zoster. There was moderate SoE for no evidence of increased risk for amyotrophic lateral sclerosis, anaphylaxis or systemic allergic reaction, asthma, cardiovascular events, death, diabetes, encephalitis/encephalopathy, Guillain-Barré syndrome, idiopathic thrombocytopenic purpura, meningitis, myocardial infarction, reproductive system events, seizures, or stroke. There was low SoE for no evidence of increased risk for acute disseminated encephalomyelitis, angioedema, ataxia, autoimmune disease, or autoimmune thyroiditis (Hashimoto's disease). Table 10a summarizes the findings across the prior 2014 report and the update.

Table 10a. KQ1: Safety of zoster vaccines in adults

Vaccine (Abbreviation; Brand Name[s])	2014 Report SoE and Findings	SoE and Findings in Update	Synthesis of SoE and Findings
Zoster recombinant, (RZV; Shingrix)	RZV not in use at time of prior report	High: No evidence of increased risk of herpes zoster Moderate: No evidence of increased risk of amyotrophic lateral sclerosis, anaphylaxis or systemic allergic reaction, asthma, cardiovascular events, death, diabetes, encephalitis/encephalopathy, Guillain-Barré syndrome, idiopathic thrombocytopenic purpura, meningitis, myocardial infarction, reproductive system events, seizures, stroke Low: No evidence of increased risk of acute disseminated encephalomyelitis, angioedema, ataxia, autoimmune disease, autoimmune thyroiditis (Hashimoto's disease) No studies: Secondary transmission of live varicella virus, transverse myelitis	High: No evidence of increased risk of herpes zoster Moderate: No evidence of increased risk of amyotrophic lateral sclerosis, anaphylaxis or systemic allergic reaction, asthma, cardiovascular events, death, diabetes, encephalitis/encephalopathy, Guillain-Barré syndrome, idiopathic thrombocytopenic purpura, meningitis, myocardial infarction, reproductive system events, seizures, stroke Low: No evidence of increased risk of acute disseminated encephalomyelitis, angioedema, ataxia, autoimmune disease, autoimmune thyroiditis (Hashimoto's disease)

Key: Green box indicates no evidence of increased risk of specific adverse events; Notes: KQ—Key Question; SoE—Strength of Evidence

Key Question 2: What is the evidence that vaccines included in the immunization schedules recommended for children and adolescents are safe in the short term or long term?

This section describes the evidence for the safety of vaccines routinely recommended for use in children, including evidence from studies of children and adults together.

Key Points

- Diphtheria, tetanus, and pertussis vaccine: No evidence of increased risk[c] of asthma or death (low SoE). No evidence of increased risk of type 1 diabetes mellitus (moderate SoE) remains unchanged from prior report.
- Tetanus, diphtheria and acellular pertussis vaccine: No evidence of increased risk of cardiovascular events or death (low SoE).
- Hepatitis A vaccine: Increased risk of idiopathic thrombocytopenic purpura in children aged 7 to 17 years (moderate SoE) remains unchanged from prior report.

[c] "No evidence of increased risk" indicates that the outcome was studied and that the findings of the studies did not constitute evidence of increased risk of the adverse event following administration of that vaccine (because the risk either was not statistically significantly increased or was reduced).

- Hepatitis B vaccine: No evidence of increased risk of multiple sclerosis (moderate SoE) remains unchanged from prior report.
- 9-valent human papillomavirus vaccine: No evidence of increased risk of autoimmune disease, birth defects, death, reproductive system events, seizures, or spontaneous abortion (low SoE).
- Quadrivalent inactivated influenza vaccine: No evidence of increased risk of anaphylaxis or systemic allergic reaction, asthma, autoimmune disease, cardiovascular events, death, febrile seizures, or seizures (low SoE, except for death which was moderate SoE).
- Quadrivalent live attenuated influenza vaccine: No evidence of increased risk of death or seizures (low SoE).
- Measles, mumps, and rubella vaccine: No evidence of increased risk of autism (high SoE remains consistent from prior report). Increased risk of febrile seizures (high SoE) and idiopathic thrombocytopenia (moderate SoE) remains unchanged from prior report. Anaphylaxis (high SoE) remains unchanged from prior report. No evidence of increased risk of asthma (low SoE).
- Serogroup A, C, W, and Y meningococcal vaccines: No evidence of increased risk of acute disseminated encephalomyelitis, asthma, autoimmune disease, cardiovascular events, death, diabetes, encephalitis/encephalopathy, febrile seizures, intussusception, idiopathic thrombocytopenic purpura, Kawasaki disease, meningitis, multiple sclerosis, reproductive system events, seizures, or transverse myelitis (low or moderate SoE). Anaphylaxis in children with allergies remains moderate SoE, but there was no evidence of increased risk among all children (low SoE) based on the update.
- Serogroup B meningococcal vaccine: No evidence of increased risk of anaphylaxis or systemic allergic reaction, asthma, death, reproductive system events, or seizures (low or moderate SoE).
- 13-valent pneumococcal vaccine: No evidence of increased risk of asthma, cardiovascular events, death, intussusception, meningitis, reproductive system events, or seizures associated with pneumococcal conjugate vaccine (low SoE except for death, which was moderate SoE). Increased risk of febrile seizures (low SoE, which was downgraded from moderate from prior report).
- Rotavirus vaccine: No evidence of increased risk of intussusception across studies (moderate SoE, which was downgraded from moderate SoE for increased risk from prior report to moderate SoE for no increased risk when combining all available studies), though some observational studies indicated increased risk. No evidence of increased risk of anaphylaxis or systemic allergic reaction, asthma, autoimmune disease, autoimmune thyroiditis (Hashimoto's disease), death, diabetes, encephalitis/encephalopathy, febrile seizures, idiopathic thrombocytopenic purpura, Kawasaki disease, meningitis, reproductive system events, seizures, or stroke (varied SoE).
- Varicella vaccine: Anaphylaxis, disseminated varicella zoster virus, vaccine strain viral reactivation without other organ involvement, and vaccine strain viral reactivation with subsequent infection resulting in meningitis or encephalitis (high SoE) all remain unchanged from prior report, as does idiopathic thrombocytopenic purpura in children aged 11 to 17 years (moderate SoE).
- Combination vaccines: For DTaP-IPV-Hib-HepB: no evidence of increased risk of asthma, death, febrile seizures, or meningitis (low SoE). For DTaP-IPV/Hib: no evidence

of increased risk for anaphylaxis or systemic allergic reaction (low SoE). For DTaP-IPV: no evidence of increased risk for encephalitis/encephalopathy (low SoE).
- Insufficient evidence to permit evidence statements for the following vaccines in children: *Haemophilus influenzae* type b vaccine, inactivated poliovirus vaccine, 23-valent pneumococcal polysaccharide vaccine, and DTaP-HepB-IPV.

KQ2a. What adverse events are collected in clinical studies and in observational studies containing a control/comparison group?

Given the many types of events assessed across studies of vaccines in children, the complete list is shown in Appendix C. We differentiated adverse events collected in studies that included only children and those in studies that included both children and adults. The assessed adverse events include both prespecified and incidentally collected adverse events. The information comes from a variety of experimental and observational designs. Details of the studies, including the method used to assess adverse events, are documented in the evidence tables (Appendix D) and the risk of bias table (Appendix C).

Studies collected information about the presence and absence of a variety of different events encompassing the range of mild and transient events to serious adverse events with permanent consequences.

KQ2b. What adverse events are reported in clinical studies and in observational studies containing a control/comparison group?

The evidence tables in Appendix D contain all serious and severe adverse events reported in studies of children and studies of children and adults together.

KQ2c. What adverse events are associated with these vaccines?

This section further characterizes the risk of adverse events identified in studies of children who received routinely recommended vaccines.

KQ2c1. For each adverse event associated with a particular vaccine, what is the average severity and frequency?

The prior 2014 report found several associations, which are detailed in that report and summarized at the end of this Key Question section in tables that integrate the findings from both reports. Several of these associations were in vaccines that are no longer in use because they have been replaced by newer vaccines, including trivalent IIV and monovalent H1N1 influenza vaccine, and 2-valent and 4-valent human papillomavirus vaccines. For those vaccines that are still in use, the associations between adverse events and specific vaccines established in the prior 2014 report and/or IOM report remain largely unchanged because there were no new studies or the outcome was not considered a key adverse event. These include idiopathic thrombocytopenic purpura with HepA and MMR (moderate SoE); anaphylaxis in children with allergies with MMR, MenACWY, and varicella vaccine (moderate or high SoE); transient arthralgia with MMR (moderate SoE); and disseminated varicella zoster virus, vaccine strain viral reactivation without other organ involvement (i.e., herpes zoster), and vaccine strain viral reactivation with subsequent infection resulting in meningitis or encephalitis with varicella vaccine.

In the update, we found new studies of febrile seizures (or seizures that were presumed to be febrile seizures) that did not contradict the increased risk of febrile seizures with MMR found in

the prior 2014 report (high SoE) and we downgraded the SoE for febrile seizures with PCV13 (from moderate to low SoE); see KQ2c2 and summary of findings tables for more details.

We did not find any new statistically significant associations between any of the studied vaccines (including for new vaccines not reviewed in the prior 2014 report) and the key adverse events. Adverse events that are no longer considered to be associated with a particular vaccine are discussed in KQ2c2. For all events, the severity for each event is documented in the evidence table in Appendix D.

KQ2c2. For adverse events without statistically significant associations with a particular vaccine, what is the range of possible effects?

Although many studies contributed to the analyses, only a small number of studies reported sufficient detail about key adverse events to allow effect size estimates. Below we report all pooled risk estimates for adverse events that were reported on by more than one study. We note any instances where individual studies contributing to a pooled risk estimate were statistically significant on their own, indicating increased risk of an adverse event. We also report on studies with risk estimates that could not be computed and pooled statistically. Finally, as for KQ1, we summarize the range of possible effects by vaccine in brief below for all adverse events for which the primary relative risk estimate did not favor the intervention (i.e., RR>1), but the association was not statistically significant. Where appropriate, we contextualize the finding to understand the range of possible effects.

Diphtheria, Tetanus, and Acellular Pertussis Vaccines (DTaP, Tdap)

DTaP

We identified one RCT,[183] one pre-post analysis,[90] two self-controlled risk interval analyses,[96, 235] and two studies[62, 63] using case-centered methods assessing diphtheria, tetanus, and acellular pertussis vaccines (DTaP) in children in this update. One study[183] assessed the Infanrix® brand but the others did not specify the vaccine (vaccination status was determined using administrative data).

One study[183] of children that compared DTaP plus routine vaccines to vaccine routines alone reported one case of asthma in 145 intervention participants and none in the 146 control participants, which resulted in an imprecise risk estimate (RR 2.01; CI 0.07, 59.56). The same study also reported that no deaths occurred in the intervention or the control group, again with an imprecise risk estimate (RR 1.01; CI 0.02, 50.40). A pre-post study[90] reported an increased incidence of sepsis evaluation (adjusted rate ratio 3.2; CI 2.2, 4.5), respiratory support (adjusted rate ratio 1.9; CI 1.4, 2.6), and intubation (adjusted rate ratio 2.5; CI 1.3, 4.8) in extremely low birth weight infants after receipt of DTaP compared to the period before vaccination. One self-controlled risk interval analysis[235] using Vaccine Safety Datalink data from 1995 to 2015 identified a risk of seizures following DTaP among children aged 11 to 23 months, but subsequent analyses adjusting for age at vaccination and concomitant vaccines showed no evidence of increased risk (incidence risk ratio [IRR] 1.2; CI 0.9, 1.6). A related study using the same population for a subset of those same years (2004-2008) for children under 24 months of age showed no increased risk of seizures following DTaP for either children three months and younger (IRR 1.26; CI 0.65, 2.45) or 3-23 months (IRR 1.56; CI 0.19, 12.92). Another self-controlled risk interval analysis[96] looking at febrile seizures specifically found no increased risk during the first day following vaccination compared to a control period of 14 to 20 days (IRR

1.17; CI 0.52, 2.60). This same study found increased risk of febrile seizures when a DTaP-containing vaccine was given with trivalent IIV compared to trivalent IIV given on a separate day from DTaP-containing vaccines (ratio of IRRs 7.57; CI 2.40, 23.89), but the study only reported across all DTaP-containing vaccines (including combination vaccines such as Pediarix® and Pentacel®) for this analysis. One study[62] using case-centered methods reported no increased risk of acute disseminated encephalomyelitis in the 5- to 28-day risk interval following DTaP, compared to the remaining nine months after vaccination (aOR 0; CI 0.0, 270.4). Another case-centered analysis[63] detected no association between sudden sensorineural hearing loss and DTaP within one week of vaccination (OR 0; CI 0, 36.61).No other adverse events associated with DTaP were reported.

Tdap

We also identified four studies[62, 63, 173, 187] assessing Tdap and Td in samples containing children and adults. One was a study of Tdap plus MenACWY (Nimenrix®, which is a brand used in Europe) versus MenACWY alone;[187] the other three studies were case-centered analyses[62, 63, 173] that used a large dataset of participants who received Tdap or Td.

The study[187] of Tdap plus MenACWY versus MenACWY alone reported no elevated risk of cardiovascular events or death (RR 0.99; CI 0.02, 49.53 for both outcomes); the risk estimate was imprecise for both outcomes as no cases occurred among either intervention or control groups (0/231 vs 0/228).

One study[62] reported an increased risk of acute disseminated encephalomyelitis in the 5 to 28-day risk interval following Tdap, compared to the remaining nine months after vaccination (aOR 15.8; CI 1.2, 471.6). No other study investigated this outcome after Tdap, and the effect has not been replicated. The study reported insufficient detail to compute effect sizes, which would have allowed comparisons to other studies, so we could not pool results to better understand the frequency of this adverse event. In addition, severity was not reported, although in general acute disseminated encephalomyelitis—inflammation in the brain and spinal cord that damages myelin, which is the protective covering of nerve fibers—can have a variable course that can include severe illness. Overall, the number of cases (two) was very small. The investigators noted that one of the cases was a healthy adult who had been vaccinated 11 days prior to symptom onset, and the second case was a child who received both Tdap and meningococcal polysaccharide vaccine (which was not recommended for the child's age group at that time). One case would have been expected statistically, and thus it was the presence of a second case that made the result significant and as a result the confidence intervals were very wide (with the lower confidence interval being closer to 1). Finally, the study had a large number of statistical comparisons without adjusting for multiple testing, meaning that the result could also be due to chance alone. Assuming the result was real, the absolute estimated excess risk was extremely small at 0.385 (CI -.04, 1.16) cases per million doses. No risk factors were explored in this study given the small number of cases, but this could also be an area for future investigation.

The same study[62] found no increased risk of transverse myelitis during the immediate post vaccination period or optic neuritis in the 2- to 42-day risk interval after vaccination with Tdap or Td versus the remainder of the nine months after vaccination. Another case-centered analysis[63] detected no association between sudden sensorineural hearing loss and Tdap (OR 0.84; CI 0.39, 1.62) or Td (OR 0; CI 0.00, 2.67) within one week of vaccination. Finally, one study[173] reported no increased risk of primary ovarian failure after Tdap (aHR 0.88; CI 0.37, 2.10).

Haemophilus influenzae Type b Vaccines

We identified two self-controlled risk interval analyses,[96, 235] and one pre-post study[90] reporting on *Haemophilus influenzae* type b vaccine (Hib) in children in this update. The authors did not provide the specific brand names of Hib used. The pre-post study[90] found an increased incidence of sepsis evaluation (adjusted rate ratio 4.0; CI 3.3, 4.8), respiratory support (adjusted rate ratio 2.1; CI 1.8, 2.5), and intubations (adjusted rate ratio 1.6; CI 1.2, 2.7) in extremely low birth weight infants after vaccination with Hib compared to the period before vaccination; this was not replicated in other studies. One self-controlled risk interval analysis[235] using Vaccine Safety Datalink data from 1995 to 2015 identified no risk of seizures following Hib among children aged 11 to 23 months (IRR 1.0; CI 0.8, 1.2), nor did a related study using the same population for a subset of those same years (2004-2008) for children under 24 months of age. Another study[96] looking at febrile seizures specifically found no increased risk during the first day following vaccination compared to a control period of 14 to 20 days (IRR 1.53; CI 0.87, 2.72).

We identified one case-centered analysis[62] assessing Hib in a sample of children and adults. The study reported no increased risk of acute disseminated encephalomyelitis or transverse myelitis in the 5- to 28-day risk interval following vaccination with Hib (brand not specified) versus the remainder of the nine months after vaccination.

Hepatitis Vaccines

Hepatitis A Vaccine

We identified one case control study[158] and one self-controlled risk interval analysis[96] evaluating HepA (among other vaccines) in children in this update.[90] We also identified two case-centered analyses[62, 63] assessing HepA in mixed samples of children and adults.

The case-control study[158] assessed the relationship of HepA to adverse events in children with new neuropsychiatric disorders. The study reported a slight association between a broken bone (HR 1.08; CI 1.02, 1.13), obsessive compulsive disorder (HR 1.40; CI 1.07, 1.82), and attention deficit hyperactive disorder (HR 1.09; CI 1.02, 1.18) diagnosis but no association with open wound, anorexia, anxiety disorder, tic disorder, major depression, or bipolar disorder for HepA.[158] The self-controlled risk interval analysis[96] found no increased risk of febrile seizures during the first day following vaccination with HepA compared to a control period of 14 to 20 days (IRR 0.88; 0.56, 1.38).

Of studies that combined children and adults, one case-centered analysis[62] assessed HepA over a 10-month follow up. The authors reported no increased risk of acute disseminated encephalomyelitis, optic neuritis, or transverse myelitis in the short term interval following vaccines versus the remainder of the nine months after vaccination. Another case-centered analysis[63] detected no association between sudden sensorineural hearing loss and HepA (OR 0; CI 0.00, 3.42) within one week of vaccination.

Hepatitis B Vaccines

We identified one case-control study,[158] one self-controlled risk interval analysis,[96] and one pre-post study evaluating HepB (among other vaccines) in children in this update.[90] We also identified two case-centered analyses[62, 63] assessing HepB in mixed samples of children and adults.

The case-control study[158] assessed the relationship of HepB to adverse events in children with new neuropsychiatric disorders. There were no associations of adverse events with HepB.

The pre-post study[90] found an increased incidence of sepsis evaluation (adjusted rate ratio 3.1; CI 2.3, 4.1) and use of respiratory support (adjusted rate ratio 2.1; CI 1.6, 2.8), but not intubations (adjusted rate ratio 1.5; CI 0.9, 2.6) in extremely low birth weight infants after vaccination with HepB compared to the period before vaccination. The self-controlled risk interval analysis[96] found no increased risk of febrile seizures during the first day following vaccination with HepB compared to a control period of 14 to 20 days (IRR 1.17; CI 0.31, 4.40).

One case-centered analysis[62] combined children and adults and assessed HepB over a 10-month follow up. The authors reported no increased risk of acute disseminated encephalomyelitis, optic neuritis, or transverse myelitis in the short term interval following vaccines versus the remainder of the nine months after vaccination. Another case-centered analysis[63] detected no association between sudden sensorineural hearing loss and HepB (0.67; CI 0.03, 3.51) within one week of vaccination.

9-Valent Human Papillomavirus Vaccine

We identified two RCTs[114, 228] that assessed the risk for adverse events among children who received HPV9. HPV9 was not available at the time of the prior 2014 report.

Both RCTs[114, 228] assessing HPV9 in children compared the vaccine with HPV2 and HPV4 respectively. One outcome, death, was assessed in both studies (RR 0.58; CI 0.00, 362688); the risk estimate was imprecise as neither study reported any deaths (0/27 vs 0/93 and 0/299 vs 0/300). One study[228] reported one incidence of Henoch-Schönlein purpura and complex partial seizure each in the control group but not in the HPV9 group (RR 0.5; CI 0.02, 14.90 for both adverse events).

We identified four studies[95, 111, 136, 226] of HPV9 that included children as well as adults. Two studies were RCTs[136, 226] that compared HPV9 to HPV4, while another RCT[111] compared HPV9 to placebo. The fourth study[95] was a post-marketing real-time surveillance study.

In one study[111] that compared HPV9 to placebo, we found no evidence of increased risk of birth defects (RR 0.50; CI 0.01, 25.22). When combined with another study[136] that compared HPV9 to another HPV vaccine, there was still no evidence of increased risk (RR 0.33; CI 0.00, 2276574). In one study[111] that compared HPV9 to placebo, we found no evidence of increased risk of reproductive system events (RR 0.25; CI 0.01, 7.46). When combined with another study[136] that compared HPV9 to another HPV vaccine, there was still no evidence of increased risk (RR 1.01; CI 0.00, 383). Although the RR was greater than 1, this was due to one excess event in the intervention group in one[136] of the two studies (0/608 vs 1/305; 9/7071 vs 8/7078), resulting in extremely wide confidence intervals.

In one study[111] that compared HPV9 to placebo, we found no evidence of increased risk of death (RR 0.50; CI 0.01, 25.22). When combined with two other studies that compared HPV9 to another HPV vaccine, we still found no evidence of increased risk of death (RR 1.11; CI 0.10, 12.13) across the three studies.[111, 136, 226] Two of the RCTs[111, 226] had no deaths in either the intervention or control groups, and one RCT[136] had one excess death (6/7071 vs 5/7078; none were considered to be vaccine-related by the investigators).

One RCT[136] of HPV9 found an RR of 2.00 (CI 0.07, 59.66) for anaphylaxis or systemic allergic reaction, an RR of 2.00 (CI 0.07, 59.66) for asthma and an RR of 2.00 (CI 0.18, 22.07) for multiple sclerosis. All three of these estimates had extremely wide confidence intervals that suggest a wide range of either possible protective or higher risk. For anaphylaxis or allergic reaction and asthma, the RR estimate was due to one event each in the vaccine-treated group (out of 7071) and none among controls. For multiple sclerosis, there was only one excess event

among the vaccine-treated group (2/7071 vs 1/7078). The same RCT[136] identified an RR of 4.00 (CI 0.18, 88.77) for cardiovascular events (in this case, orthostatic tachycardia syndrome), which occurred in two patients in the intervention group (out of 7071) and none in the control group (out of 7078), resulting in the extremely wide confidence intervals.

A post-hoc analysis[1091] of spontaneous abortions following HPV9 did note an imbalance (28.4% [19/67] vs 12.7% [7/55]) when compared to HPV4 among women who became pregnant within 30 days of vaccination. No other meaningful differences in adverse events were reported in these studies.

One post-marketing real-time surveillance study[95] of HPV9 found no signals for any adverse events, including for pre-specified adverse events, including anaphylaxis, chronic inflammatory demyelinating polyneuropathy, Guillain-Barré syndrome, pancreatitis, seizure, stroke, or venous thromboembolism.

Inactivated Poliovirus Vaccine

We identified two self-controlled risk interval analyses,[96, 235] and one pre-post study[90] evaluating inactivated poliovirus vaccine (IPV) in children in this update. The authors did not provide the brand name of the IPV used. One self-controlled risk interval analysis[235] using Vaccine Safety Datalink data from 1995 to 2015 identified no risk of seizures following IPV among children aged 11 to 23 months (IRR 1.0; CI 0.7, 1.4), nor did a related study using the same population for a subset of those same years (2004-2008) for children under 24 months of age. Another study[96] found no increased risk of febrile seizures during the first day following vaccination compared to a control period of 14 to 20 days (IRR 1.41; 0.08, 24.53). A pre-post evaluation[90] reported an increased incidence of sepsis evaluation (adjusted rate ratio 3.0; CI 2.1, 4.2), use of respiratory support (adjusted rate ratio 2.1; CI 1.5, 2.9), and intubations (adjusted rate ratio 2.5; CI 1.3, 4.9) in extremely low birth weight infants before and after IPV. No other outcomes were assessed in studies in children.

We identified two case-centered analyses[62, 63] assessing IPV in a broader sample of children and adults. One of these studies[62] reported no increased risk of acute disseminated encephalomyelitis in the 5- to 28-day risk interval following administration of IPV compared with the remainder of the nine months after vaccination (aOR 0; CI 0.00, 270.1). The other case-centered analysis[63] detected no association between sudden sensorineural hearing loss and IPV within one week of vaccination (OR 0; CI 0, 92.95).

Influenza Vaccines

Quadrivalent Inactivated Influenza Vaccines

We identified eight RCTs[94, 117, 129, 152, 153, 188, 234] and one historically-controlled cohort design study combined with a self-controlled risk interval analysis[160] assessing quadrivalent IIV in children in this update. Studies assessed Fluzone Quadrivalent,[117, 233] Flucelvax Quadrivalent,[129] Fluarix Quadrivalent,[94, 152, 188] Flulaval Quadrivalent,[153, 234] and quadrivalent IIV not otherwise specified (study in the Vaccine Safety Datalink of available quadrivalent IIV in the United States).[160] Quadrivalent IIV was compared to trivalent IIV in all but one of the trials;[94, 117, 129, 152, 153, 188, 234] in that one trial, the control group received the same base treatment as the intervention group (PCV13 and DTaP).[233]

Across five studies,[94, 117, 129, 152, 234] there was no evidence of increased risk of seizures (RR 1.08; CI 0.11, 10.40). All five studies had one or no events occur—two studies[94, 152] had no events in either group, two studies[117, 129] had one event in the intervention group, and none in the

control group, and one study[234] had one event in the control group only. Across four studies,[94, 117, 152, 153] there was no evidence of increased risk of febrile seizures (RR 1.28; CI 0.17, 9.83). In the study[117] with the most events (8/2892 vs 2/734), none of the febrile seizures in the intervention group were attributed to the vaccine (one event was attributed to the control vaccine in the control group). Two studies[94, 152] had no febrile seizures in either group, and a fourth study[153] had one event in the intervention group (a simple partial febrile seizure 6 hours after vaccination that resolved without sequelae).

Across three studies,[94, 117, 152] there was no evidence of increased risk of cardiovascular events (RR 2.01; CI 0.03, 148). The relative risk estimate was imprecise as only one event (bradycardia not related to the vaccine in one study,[117] myocarditis not related to the vaccine in another study,[94] and hypertension in the third study[152]) occurred in the intervention group in each of the studies (1/915 vs 0/1823; 1/2892 vs 0/734; 1/932 vs 0/1861). Across another three studies,[117, 152, 153] we also found no evidence of increased risk of asthma (RR 1.77; CI 0.03, 117); the risk estimate was imprecise due to differing sizes of the intervention and control groups (8/2892 vs 0/734; 0/932 vs 0/1861; 0/299 vs 1/302). We detected no evidence of increased risk of autoimmune disease (RR 0.50; CI 0.00, 2849944) across two studies;[129, 153] the risk estimate was imprecise due to one event in each study (0/1149 vs 1/1149 and 0/299 vs 1/302). We found no evidence of increased risk of anaphylaxis or systemic allergic reaction (RR 1.41; CI 0.00, 8066971) across two studies;[129, 153] again the risk estimate was imprecise with only one case in each study (1/1149 vs 0/1149 and 0/932 vs 1/1861).

There was no evidence of increased risk of death in one RCT[233] when comparing to base treatment received by both intervention and control groups (RR 1.08; CI 0.02, 53.95), with no deaths occurring in either group in the study (0/99 vs 0/107). When combined with five RCTs[117, 129, 152, 188, 234] comparing to trivalent IIV, there was still no evidence of increased risk of death and the RR was no longer greater than 1 (RR 0.73; CI 0.10, 5.63).

In one study,[117] the RR for Kawasaki disease was greater than 1 but not statistically significant (RR 1.52; CI 0.08, 30.37) due to 3 events in the intervention group; none of these events were considered to be related to the vaccine by the study authors.

A self-controlled risk interval analysis[160] found no increased risk of febrile seizures following IIV4 when alone given without concomitant vaccines (OR 1.2; CI 0.12, 11.20) (the study also examined other outcomes using a larger cohort and found no increased risk, but risk estimates were not provided).

A sensitivity analysis of the new cell-based quadrivalent IIV (Flucelvax Quadrivalent) approved for children 4 years of age and older based on one study[129] that compared to trivalent cell-based IIV showed no evidence of increased risk of anaphylaxis or systemic allergic reaction (RR 2.00; CI 0.07, 59.56), autoimmune disease (RR 0.50; CI 0.02, 14.89), seizures (RR 2.00; CI 0.07, 59.56), or death (RR 1.00; CI 0.02, 50.35).

Quadrivalent Live Attenuated Influenza Vaccine

We identified three RCTs,[69, 163, 164] one pre-post study,[76] and one cohort study[207] assessing quadrivalent LAIV in this update. All studies were of FluMist Quadrivalent. Quadrivalent LAIV was compared to trivalent LAIV in two RCTs,[69, 163] placebo in one RCT,[164] IIV (trivalent or quadrivalent) in one cohort study,[207] and matched unvaccinated controls in one study.[76]

We found no evidence of increased risk of seizure across two studies[76, 164] that compared quadrivalent LAIV to placebo or no vaccine (RR 1.80; CI 0.06, 53.57); the risk estimate was imprecise as it was across only two studies, and the intervention and control groups differed in size (22/6745 vs 36/20163 and 1/868 vs 0/433). We also found no evidence of increased risk of

death across another two studies,[69, 163] both of which compared quadrivalent LAIV to trivalent LAIV (RR 0.82; CI 0.00, 50615229); the risk estimate was imprecise as no deaths occurred in either study (0/1382 vs 0/923 and 0/66 vs 0/67).

In one study[69] of quadrivalent LAIV, the RR for diabetes following vaccination was 1.34 (CI 0.04, 39.77), due to one event in the intervention group only which was not thought to be due to vaccination. In another study,[207] the RR of febrile seizures was 1.39 (CI 0.03, 69.76) but no events occurred in either the intervention or control groups (0/226 vs 0/314).

We identified one study[61] assessing quadrivalent LAIV that did not differentiate between children and adults. This study compared quadrivalent LAIV recipients to unvaccinated controls and controls who received IIV, and also performed a within-cohort analysis comparing risk interval and control windows. The study reported no cases of seizure or convulsions, Guillain-Barré syndrome, Bell's palsy, or encephalitis among vaccinated or unvaccinated participants. Significant findings included a lower risk of respiratory infection (adjusted HR 0.61; CI 0.50, 0.75), wheezing (adjusted HR 0.66; CI 0.52, 0.84) or any hospitalization (RR 0.35; CI 0.24, 0.50) compared to matched unvaccinated controls. There was a higher risk of wheezing (but not asthma specifically) among quadrivalent LAIV recipients two to four years of age than among unvaccinated controls (adjusted HR 1.50; CI 1.03, 2.20); none were hospitalized. There was no increased risk of wheezing among children with a history of wheezing or asthma.

Measles, Mumps, and Rubella Vaccine

We identified one case-control study,[224] three self-controlled risk interval analyses,[96, 167, 235] and four cohort studies[113, 138, 141, 215] evaluating MMR in children in this update. None of the studies specified the brand name of the specific vaccine used (all studies used administrative data to determine vaccination status and were presumed to use MMR-II based on the setting).

One self-controlled case series[235] of children who received MMR reported an increased risk of seizures following vaccination at 12 months (IRR 2.9; CI 2.1, 4.1), 15 months (IRR 4.3; CI 3.2, 5.9), and 18 months (IRR 6.4; CI 4.4, 9.3), but did not provide sufficient detail for further analyses. Of note, the majority of the seizure events were likely to be acute febrile seizures per the authors of a related study[282] considered to be a multiple publication (due to entirely overlapping population and time frame). A self-controlled risk interval analysis[167] comparing the risk of seizures during the seven to ten days following receipt of MMR to a control window of 15 to 42 days found significantly increased risk of seizures both in children who had been born full-term (IRR 2.7; CI 2.2, 3.2) and pre-term (IRR 3.2; CI 1.9, 5.3). Concomitant vaccines, including varicella, were not controlled for in this analysis. These authors also noted that the events represented primarily febrile seizures. However, this study is not included as independent evidence for the risk of seizures and febrile seizures due to the overlap entirely with the time frame and population in the prior study. A study[113] comparing a cohort of children who had received MMR to a cohort of those who had not found an increased risk of seizures (HR 5.94; 2.81, 12.58) and seizure disorders (HR 17.4; 2.23, 136) in adjusted analyses, and the finding was consistent in a self-controlled case series and additional sensitivity analyses. The authors did not distinguish between febrile and afebrile seizures. Another study[96] assessing febrile seizures specifically found no increased risk during the first day following vaccination compared to a control period of 14 to 20 days (IRR 0.78; 0.44,1.40). However, fever and febrile seizures tend to be seen later with vaccines such as MMR, hence the risk interval may have been too soon after vaccination to detect events.

Two cohort studies[138, 141] compared those who received MMR to those who had not and reported no evidence of increased risk of autism (RR 0.60; CI 0.09, 4.12). The studies did not report on other adverse events. A third study,[224] which used a case-control approach, also found no association between MMR and autism at any age, including up to 36 months of age (OR 1.04; CI 0.65, 1.68). A cohort study[215] examined the risk of asthma after MMR and found no evidence of increased risk (RR 0.37; CI 0.20, 0.67).

We identified two case-centered analyses[62, 63] assessing MMR in children and adults over a ten-month follow up period. One study[62] evaluated MMR (brand unspecified but presumed to be MMR-II) and reported adjusted risk ratios. The authors reported no increased risk of acute disseminated encephalomyelitis, optic neuritis, or transverse myelitis in the short term interval following vaccines versus the remainder of the nine months after vaccination. The other study[63] detected no association between sudden sensorineural hearing loss and MMR within one week of vaccination (OR 0; CI 0, 33.29).

Meningococcal Vaccines

Meningococcal A, C, W, and Y Vaccines

We identified eight RCTs[51, 57, 68, 79, 105, 112, 219, 978] across both reports and one self-controlled case series[127] assessing MenACWY in children in this update. Studies evaluated MenACWY-D (Menactra),[127] MenACWY-CRM (Menveo),[51, 68, 105, 112, 219, 978] and MenACWY-TT (MenQuadfi).[57, 79] Of studies that did not use a self-controlled design, four RCTs[51, 112, 219, 978] compared MenACWY-CRM to base treatment received by both the intervention and control groups and two RCTs[68, 105] compared MenACWY-CRM to meningococcal polysaccharide vaccine (MPSV; Menomune®, which is no longer in use). Of the two RCTs of MenACWY-TT, one RCT[57] compared to MPSV and one RCT[79] compared to MenACWY-CRM and to base treatment received by both the intervention and control groups. In terms of age groups studied, three studies[51, 219, 978] examined the use of MenACWY in young infants (55-89 days of age), four studies[57, 68, 105, 127] in children (2-9 or 2-10 years of age), and two studies[79, 112] in older children and adolescents (10-17 or 10-18 years of age.

One RCT[219] did not report on adverse events in a way that could be interpreted across intervention and comparator, except for severe local and systemic adverse events and is not discussed further here. One Phase II RCT[68] found no serious AEs comparing those vaccinated with MenACWY-CRM versus meningococcal polysaccharide vaccine.

Across four RCTs[51, 79, 112, 978] that compared MenACWY to a non-meningococcal vaccine comparator, there was no evidence of increased risk of death (RR 1.37; CI 0.11, 16.65). When including all RCTs even if the comparator was another meningococcal vaccine,[51, 57, 78, 79, 105, 112, 978] there was still no evidence of increased risk of death (RR 1.17; CI 0.24; 5.73). Of note, although the RR was greater than 1, only one[51] of the four studies had any deaths (7/5772 in vaccinated participants versus 1/1968 in the control group). The authors of this study examined the causes of these deaths and concluded that none were vaccine-related. When combined with another three RCTs[57, 78, 105] that compared to another meningococcal vaccine, the relative risk was similar (RR 1.17; CI 0.24, 5.73); there were no deaths in any of these three additional studies.

There was no evidence of increased risk of asthma in one RCT[79] (RR 1.51; CI 0.05, 44.86) when comparing MenACWY-TT plus routine vaccines to routine vaccines alone. The relative risk remained similar when combined with another group within the same RCT[105] that compared MenACWY-TT to MenACWY-CRM, and another two RCTs that compared MenACWY-CRM

to another meningococcal vaccine (one[105] to MPSV and the other[57] to MenACWY-CRM) (RR 1.14; CI 0.08, 16.49). The RR was greater than 1, but based on only two cases of asthma across the three studies (2343 vaccinated individuals in total). Given the prevalence of asthma among children, the observed incidence appears to be low and the severity of the events was not clear.

In one RCT[51] there was no evidence of increased risk of cardiovascular events (RR 0.34; CI 0.02, 5.46) or idiopathic thrombocytopenic purpura (RR 0.17; CI 0.01, 5.09). These results remained non-significant when combined with another RCT[57] that compared MenACWY-TT to MenACWY-CRM for cardiovascular events (RR 0.69; CI 0.00, 762141) and idiopathic thrombocytopenic purpura (RR 0.36; 0, 6069454). One RCT[51] with routine vaccines as a comparator reported no evidence of increased risk of febrile seizures (RR 0.51; CI 0.18, 1.44); the risk estimate did not change when combined with one RCT[105] with meningococcal polysaccharide vaccine as a comparator and another RCT[57] with MenACWY-CRM as a comparator (RR 0.57; CI 0.07, 4.65).

One RCT[79] that compared MenACWY plus routine vaccines to routine vaccines alone showed no evidence of increased risk of seizures (RR 1.51; CI 0.05, 44.86). When combined across another group from the same RCT[78] and two other RCTs[57, 105] where the comparators were other meningococcal vaccines, no evidence of increased risk was found (RR 0.97; CI 0.07, 12.98) and the RR no longer favored the control for seizures.

Across two RCTs,[79, 112] there was no evidence of increased risk of diabetes (RR 1.32; CI 0.00, 21861366); the risk estimate was imprecise because there was only one event across both studies (1/396 vs 0/397 and 0/392 vs 0/296). The relative risk of diabetes remained similar when including a second population from one of the RCTs where the comparison was another meningococcal vaccine (RR 1.53; CI 0.02, 137).

One RCT[51] examined the risk of Kawasaki disease among recipients of MenACWY, finding an RR of 1.37 (CI 0.15, 12.22). Of four cases observed in the vaccinated group, the authors believed that two could be related to vaccination, but there was also one case seen in the control group. Another RCT[57] that used an active comparator found no cases of Kawasaki disease; when combined the RR was 1.27 (CI 0.00, 306194). One RCT[79] found an RR of 1.51 for both asthma and seizures (CI 0.05, 44.86), due to one excess case in the intervention group (1/392 vs 0/296) resulting in extremely wide confidence intervals.

One study[127] of children through 10 years of age looked at the rates of outcomes per 1,000 person-months during a risk window compared to a control window and found no increased risk, including for asthma among children aged 2-10 years (RR 0.98; CI 0.03, 38.35), asthma among those aged 9-23 months (RR 1.48; 0.04, 57.69), convulsions among those aged 2-10 years (RR 0.00; 0.00, 18.68), and febrile seizures among those aged 9-23 months (RR not evaluable).

Looking specifically at the newest vaccine, MenACWY-TT (MenQuadfi), one RCT[79] had four groups constituting two comparisons: MenACWY-TT plus routine vaccines (Tdap and HPV4) versus routine vaccines alone, and MenACWY-TT versus MenACWY-CRM. Another RCT[57] compared MenACWY-TT to MenACWY-CRM. When comparing MenACWY-TT plus routine vaccines to routine vaccines alone, there were no deaths in either group (RR 0.76; CI 0.02, 37.94), nor when including the comparisons between MenACWY-TT and MenACWY-CRM (RR 0.91; CI 0.01, 130). There was no evidence of increased risk of asthma (RR 1.51; CI 0.05, 44.86), nor when including the two comparisons to MenACWY-CRM (RR 1.13; CI 0.02, 70.54). When compared to routine vaccines alone, there was no evidence of increased risk of diabetes (RR 0.76; CI 0.02, 37.94), nor was there evidence of increased risk when combined with a pair of groups from the same trial that compared MenACWY-TT to MenACWY-CRM (RR

1.31; CI 0.00, 21815040). When compared to routine vaccines alone, there was no evidence of increased risk of seizures (RR 1.51; CI 0.05, 44.86), nor was there evidence of increased risk when including the two comparisons of MenACWY-TT to MenACWY-CRM (RR 0.92; CI 0.02, 49.19). Only one RCT[57] comparing MenACWY-TT to MenACWY-CRM looked at cardiovascular events, and found no evidence of increased risk (RR 1.98; 0.07, 59.00). The same RCT looked at febrile seizures, Guillain-Barré syndrome, idiopathic thrombocytopenic purpura, and Kawasaki disease and found no evidence of increased risk (RR 0.99; CI 0.02, 49.89 for all).

We identified eight studies[56, 62, 63, 93, 128, 157, 173, 220] assessing meningococcal A, C, W and Y vaccines in samples of children and adults. Studies assessed MenACWY-D (Menactra), MenACWY-CRM (Menveo), and MenACWY-TT (MenQuadfi). One study[173] did not report the brand used, but took place in the United States. Of those studies that were not self-controlled, two[56, 93] compared MenACWY-TT to MenACWY-D, and one[157] compared MenACWY-CRM to placebo. In terms of age groups studied, three studies[93, 128, 157] examined children and adults 10 or 11 years of age through 55 years of age, one[220] examined children and adults 11 to 21 years of age, one examined children and adults 15 to 59 years of age,[56] one[173] examined female children and adults aged 11 through 34 years, and two[62, 63] did not specify the ages studied (used a large administrative database and presumably included all those individuals for whom the vaccine was indicated).

Three RCTs[56, 93, 157] reported on death as the outcome and found no evidence of increased risk (RR 0.50; CI 0.00, 71.42); the risk estimate was imprecise as deaths did not occur in any of the studies (0/297 vs 0/153; 0/2676 vs 0/635; 0/402 vs 0/407). An RCT[157] of MenACWY-CRM (Menveo) reported no serious adverse events in either the vaccine or placebo group.

Looking specifically at the newest vaccine, MenACWY-TT, (MenQuadfi), one RCT[93] that enrolled children and adults and compared MenACWY-TT to MenACWY-D reported no evidence of increased risk of anaphylaxis (RR 0.24; 0.00, 11.95); asthma, cardiovascular events (coronary artery disease), diabetes, multiple sclerosis, seizures (status epilepticus), or spontaneous abortion (RR 0.47; CI 0.02, 14.13 for all); or of autoimmune disease (Henoch-Schönlein purpura) (RR 0.12; CI 0.00, 3.53). In another RCT,[56] there was one case of pulmonary embolism in the MenACWY-TT group and no cases in the MenACWY-D group. Across the two RCTs[56, 93] of MenACWY-TT (both compared to MenACWY-D) there was no evidence of increased risk of death, with no deaths in either trial.

A self-controlled case series[220] of MenACWY-CRM (Menveo) in children and adults reported an increased risk for Bell's palsy in participants receiving concomitant vaccines (risk incidence [RI] 5.0; CI 1.4, 17.8) and no increased risk for those without concomitant vaccine (RI 1.1; CI 0.2, 5.5). The same study reported no elevated risk for other outcomes including anaphylaxis (confirmed by chart review), aseptic meningitis, asthma, autoimmune hemolytic anemia, Hashimoto's disease (confirmed by chart review), Henöch-Schonlein purpura, idiopathic thrombocytopenic purpura, juvenile diabetes, multiple sclerosis, rheumatoid arthritis, seizure (confirmed by chart review), or transverse myelitis. In a retrospective cohort study[128] of MenACWY-D (Menactra), the study investigator considered two serious adverse events possibly related to vaccination: new-onset diabetes mellitus in a participant with family history and new-onset juvenile rheumatoid arthritis in a patient with family history. After review of medical records, investigators concluded these conditions were not likely related to vaccination. This study also reported elevated short-term (0–30 days) risk (IRR 11.80; CI 2.04, 254.6) and long-term (6 months) risk (IRR 1.93; CI 1.18, 3.20) for febrile illness. Medical record review of

outcomes with significantly elevated IRRs did not suggest any relationship with MenACWY-D vaccine.

One study[62] of children and adults used a case-centered design to assess both MenACWY-D specifically as well as all MenACWY as a group over 10 months of follow up. For both vaccine types, the study reported no increased risk of acute disseminated encephalomyelitis or transverse myelitis, and for all MenACWY (Menactra alone not examined for this outcome) no increased risk of optic neuritis in the short term interval following vaccination versus the remainder of the nine months after vaccination. Another case-centered analysis[63] detected no association between sudden sensorineural hearing loss and MenACWY within one week of vaccination (OR 0; CI 0, 21.06). Finally, one study[173] reported no increased risk of primary ovarian failure after MenACWY (aHR 0.94; CI 0.27, 3.23).

Meningococcal B Vaccines

We identified five RCTs[156, 186, 193, 196, 230] assessing MenB in children (not in use at the time of the prior report). Studies assessed either Bexsero or Trumenba. Four studies[186, 193, 196, 230] compared to a non-active comparator (placebo or routine vaccines that the intervention group received); one study[156] of Bexsero compared the vaccine to placebo (for dose 1) and MenACWY-CRM (for dose 2). One study[193] reported that there were no vaccine-related serious adverse events.

The risk estimates were imprecise for all three outcomes reported across more than one study as there were only two or three studies and the events were infrequent (none or one per group); rates are reported after each risk estimate. Across two MenB studies[186, 196] in children, there was no evidence of increased risk of anaphylaxis or systemic allergic reaction (RR 0.56; CI 0.00, 34735108; 0/198 vs 0/121 and 0/992 vs 0/501) There was also no evidence of increased risk of death across another two studies[196, 230] (RR 1.12; CI 0.00, 18531125; 0/992 vs 0/501 and 1/374 vs 0/378); the one death that occurred in the vaccinated group was due to a motor vehicle accident. Across three studies,[156, 186, 230] there was no evidence of increased risk of reproductive system events (RR 0.89; CI 0.01, 65.20; 1/198 vs 0/121; 1/174 vs 0/99; 0/374 vs 1/378). One of the RCTs[230] also identified one case of idiopathic thrombocytopenic purpura among those vaccinated (N=374) compared to none in the control group (N=378), for an RR of 2.02 (CI 0.07, 60.07); the confidence intervals were extremely wide as a result.

We identified one RCT[178] in children and adults that compared MenB (Trumenba) to placebo. The study did not assess any key adverse events, but showed more reactogenicity events with the vaccine.

Pneumococcal Vaccines

13-Valent Pneumococcal Conjugate Vaccine

We identified five RCTs,[55, 86, 87, 146, 217] one cohort study,[206] two self-controlled risk interval analyses,[59, 96] one self-controlled case series analysis,[238] and two pre-post studies[58, 221] assessing PCV13 in children in this update. Of the studies that were not self-controlled, four RCTs[55, 87, 146, 217] compared PCV13 to PCV7 plus a base treatment received by both the intervention and control groups, and two studies (one RCT and one cohort study) compared PCV13 to a base treatment received by both groups (trivalent IIV in one study[206] and MenACWY-TT in the other[86]).

Across three RCTs,[87, 146, 217] there was no evidence of increased risk of asthma (RR 1.49; CI 0.15, 14.39), although all three identified studies reported more events in the PCV13 group

compared to PCV7 or routine vaccines received by all participants. The risk estimate across studies was greater than 1, but was imprecise due to few events occurring across three studies with variable sample sizes (1/84 vs 0/88; 7/882 vs 5/875; 1/183 vs 0/183). None of these events were attributed to PCV13 by the investigators. Across another three RCTs[55, 87, 146] there was no evidence of increased risk of cardiovascular events (RR 0.60; CI 0.01, 38.23) or seizures (RR 0.91; CI 0.05, 15.11).

For risk estimates across two studies, the risk estimate was imprecise due to the small number of studies and of events in each study. Across two RCTs,[55, 87] there was no evidence of increased risk of meningitis (RR 1.32; CI 0.00, 1451908; 1/354 vs 0/355 and 1/930 vs 1/931). Across two RCTs,[87, 146] there was no evidence of increased risk of intussusception (RR 1.33; CI 0.00, 1437199; 1/88 vs 0/89, 1/930 vs 1/933) or reproductive system events (RR 1.49; CI 0.00, 24350819; 0/88 vs 0/89, 1/882 vs 0/875).

Across two RCTs,[146, 217] there was no evidence of increased risk of Kawasaki disease (RR 1.33; CI 0.00, 1407345; 1/88 vs 0/89, 1/183 vs 1/183). In the study[146] with one excess case in the intervention group, the event was not attributed to PCV13. One self-controlled case series analysis[238] found no increased risk following any of three doses of PCV13, but did find an increased risk of complete Kawasaki disease specifically following the first dose of PCV13 (RI 2.59; CI 1.16, 5.81) based on seven patients who served as their own controls. One pre-post study[58] reported an age-adjusted risk estimate for Kawasaki disease of 1.07 (CI 0.70, 1.63) in a self-controlled case series and 0.97 (CI 0.79, 1.19) compared to an unvaccinated cohort. Another pre-post study[221] reported no evidence of increased risk of Kawasaki disease when comparing those who received PCV13 with those who received PCV7 (RR 1.94; 0.79, 4.86).

There was no evidence of increased risk of death in an RCT[86] that compared PCV13 to a base treatment received by both intervention and control groups (RR 2.02; CI 0.07, 59.88; 1/193 vs 0/195); the death that occurred was considered unrelated to the vaccine by study authors as the cause was asphyxiation 121 days post-vaccination. When combined with four other RCTs[55, 87, 146, 217] that compared PCV13 to PCV7, the risk estimate remained non-significant (RR 1.18; CI 0.12, 11.32). Across all five studies,[55, 86, 87, 146, 217] there were two deaths in the vaccinated group and one in the control group (0/84 vs 0/88; 0/354 vs 1/355; 1/193 vs 0/195; 1/884 vs 0/877; 0/183 vs 0/183). At least one of the two deaths in the vaccinated group was thought to be unrelated to the vaccine according to the study authors as above; the other was a sudden death of unknown cause.

One RCT[87] examined the risk of autoimmune disease (Henoch-Schönlein purpura) and identified one case in the vaccinated group and none in the control group (1/929 vs 0/931), resulting in an RR of 2.00 (CI 0.07, 59.07) with low precision given the rare events.

One study[59] found a significant association between PCV13 and febrile seizures. This effect held through both unadjusted and adjusted models, with an IRR adjusted for age, calendar time and concomitant IIV of 1.80 (CI 1.29, 2.52). This increased risk was not reported in five other studies. In a cohort study[206] comparing PCV13 plus IIV to IIV alone, there was no evidence of increased risk of febrile seizures (RR 0.98; CI 0.02, 49.22). When combined with the two RCTs[55, 217] that compared PCV13 to PCV7, the result remained non-significant (RR 1.24; CI 0.12, 12.81). A self-controlled risk interval analysis[96] reported no increased risk of febrile seizures during the first day following vaccination compared to a control period of 14 to 20 days (IRR 1.41; CI 0.08, 24.53). This same study found an increased risk of febrile seizures when a PCV vaccine was given with trivalent IIV compared to trivalent IIV given alone on a separate day from a PCV vaccine (ratio of IRRs IIV3 7.57; 1.91, 30.07, but the study mixed both PCV7

which is no longer in use and PCV13 in this analysis. A pre-post study[221] of PCV13 compared to PCV7 reported no increased risk of febrile seizures, but there was an overlap in population studied and time frame with the study[96] of febrile seizures detailed above.

One pre-post study[221] identified an increased risk for encephalopathy, but this was not confirmed following the medical record review. This same pre-post study[221] reported no increased risk of febrile seizures (as discussed above), urticaria or angioneurotic edema, asthma, thrombocytopenia, or anaphylaxis for PCV13 compared to PCV7.

There was one study of children and adults that used a case-centered design to assess PCV13 over ten months of follow up.[62] The study reported no increased risk of acute disseminated encephalomyelitis, or transverse myelitis in the short term interval following vaccination compared to the remainder of the nine months after vaccination.

23-Valent Pneumococcal Polysaccharide Vaccine

Among two studies that included children and adults in this update, one study[62] of children and adults used a case-centered design to assess PPSV23 over ten months of follow up. The study reported no increased risk of acute disseminated encephalomyelitis, optic neuritis, or transverse myelitis in the short term interval following vaccination compared to the remainder of the nine months after vaccination.

Another case-centered analysis[63] detected no association between sudden sensorineural hearing loss and PPSV23 within one week of vaccination (OR 0.81; CI 0.20, 2.26).

Rotavirus Vaccines

A large number of studies has addressed rotavirus vaccines. Across both reports, we identified 22 RCTs [92, 139, 161, 169, 229, 909, 924, 967, 969, 972, 973, 988, 1005, 1010, 1011, 1016, 1025, 1041, 1042, 1044, 1045, 1054] that assessed adverse events associated with the use of rotavirus vaccines in children. In this update we identified three case control studies,[75, 108, 175] nine pre-post studies,[73, 83, 106, 130, 131, 168, 190, 213, 223] and four cohort studies.[115, 155, 189, 225] We also identified eight self-controlled case series,[102, 122, 133, 135, 208, 212, 235, 237] and two self-controlled risk interval analyses.[96, 236] Studies assessed RotaTeq® or Rotarix® vaccines. In all studies that were not self-controlled, rotavirus vaccine was compared to either placebo or the same base treatment as was received by the intervention group (e.g., routine vaccines). One RCT[92] only reported on Grade 3 diarrhea and the overall rate of serious adverse events, and is not discussed further here.

Rotavirus vaccines and intussusception. Across all unique RCTs[139, 161, 169, 229, 909, 924, 967, 972, 973, 988, 1005, 1010, 1011, 1016, 1025, 1041, 1042, 1044, 1045] of rotavirus vaccine that examined intussusception as an outcome from both the prior report and the update, we found no evidence for increased risk of intussusception (RR 0.65; CI 0.41, 1.05) at the time of latest follow-up. Three additional studies[106, 131, 168] demonstrated no increase at the population level in intussusception rates before and after introduction of the rotavirus vaccine, and another two studies[122, 133] showed no significant difference in intussusception rates in a group of patients before and after receiving rotavirus vaccine. Another study[212] demonstrated no significant increase in intussusception risk following any dose of rotavirus vaccine. One study[108] showed no increased risk of intussusception with the first dose or any dose (though the vaccine coverage was low in the region, which may have precluded detecting an increased risk). A study[155] of infants who received rotavirus vaccine together with DTaP compared to infants who received DTaP alone found no increased risk of intussusception (nor of Kawasaki disease, febrile seizures, seizures, meningitis, or encephalitis). Finally, a study[74] of rotavirus vaccine found no increased risk of

intussusception, whether looking at children who were fully vaccinated (aHR 0.79; CI 0.57, 1.09) or partially vaccinated (aHR 0.89; CI 0.66, 1.19).

However, the authors of other studies identified in this update reported an increased risk of intussusception (primarily after the first dose). One study[75] showed an increase in the relative incidence of intussusception in infants seven days following the first dose of RotaTeq (RI 9.9; CI 3.7, 26.4) and Rotarix (RI 6.8; CI 2.4, 19.0). One study[102] reported an increased IRR in the days following the first RotaTeq vaccination (IRR 3.45; CI 1.85, 6.55). One study[175] showed a significantly increased adjusted odds of intussusception in individuals who received the first dose of rotavirus vaccine compared to those who did not (aOR 5.74; CI 1.51, 21.79). Another study[236] found an attributable risk of 1.5 excess cases intussusception per 100,000 recipients (CI 0.2, 3.2) in the 21 days following the first dose of RotaTeq but not following Rotarix (although the study was underpowered for Rotarix). A study[237] of infants in Singapore reporting an increased relative incidence of intussusception in the seven days following the first dose of Rotarix vaccination (RI 8.36; CI 2.42, 28.96). A self-controlled case series[135] in Taiwan showed an increase in intussusception risk in the first seven days (IRR 12.59; CI 8.07, 19.66) and eight to 21 days (IRR 1.78; CI 1.00-3.16) following the first dose of Rotarix, but not RotaTeq. Another self-controlled case series study[208] in England showed significantly increased relative incidence of intussusception in the 21 days after both the first (RI 4.53; CI 2.34, 8.58) and second (RI 2.60; CI 1.43, 4.81) doses of Rotarix, with the peak risk occurring one to seven days after the first dose (RI 13.81; CI 6.44, 28.32).

Several studies reported no significant increase in intussusception risk when looking at the second dose only,[75] and following the second or third doses.[102, 175, 236, 237] Finally, two studies[83, 213] showed an increase in the number of cases of intussusception at a population level following the introduction of rotavirus vaccine. A study[83] of infants reported an upward trend in yearly intussusception-related surgery during 2006 to 2010 (+2 excess cases per 100,000 births per year; p=0.023). Another study[213] of infants in the United States found significantly elevated rates of intussusception in 2007 (40.7 per 100 000 children <12 months of age; RR 1.13; CI 1.07, 1.20) and in 2010 (40.3 per 100 000 children <12 months of age; RR 1.12; CI 1.06, 1.20) but also reported that in other postvaccine introduction years, intussusception rates were not significantly different from baseline before rotavirus vaccine introduction.

Rotavirus vaccines and death. Across fourteen RCTs,[139, 161, 169, 909, 967, 969, 973, 1005, 1011, 1016, 1025, 1041, 1045, 1054] there was no evidence of increased risk of death (RR 1.05; CI 0.82, 1.35). All but six[139, 1011, 1016, 1025, 1045, 1054] of these RCTs had fewer deaths in the vaccinated group than in the unvaccinated groups (with roughly equal sample sizes in each), and none of the six studies had statistically significant risk estimates on their own. In one of these RCTs,[1016] there was an imbalance of deaths due to pneumonia that was further investigated and determined not to be of concern. In two RCTs,[1011, 1045]the causes of death were not specified but the study authors note that none were attributed to rotavirus vaccine. In another three RCTs,[139, 1025, 1054] no deaths in the vaccinated group were considered attributable to rotavirus vaccine (deaths were due to respiratory syncytial virus [RSV] bronchiolitis 36 days after dose 2, gastroenteritis of unknown etiology and bronchopneumonia 46 days after last dose, bronchopneumonia 124 days after last dose, and pneumonia 16 days after dose 1).

Rotavirus vaccines and cardiovascular events. Across seven studies,[73, 161, 169, 909, 969, 988, 1045] the relative risk of cardiovascular events was not significant (RR 1.79; CI 1.00, 3.20), but the lower CI was 1.00. We note that this relative risk reflected multiple types of events and was driven by one study[73] of rotavirus vaccine in premature infants who received RotaTeq and

experienced bradycardia (RR 1.87; CI 1.13, 3.10; 38/201 vs 20/198). In general, bradycardia events in premature infants are mild and in this study were considered clinically insignificant by the authors. There was no evidence of increased incidence of sepsis evaluation or elevation in respiratory support, which further suggests that these bradycardic events were mild. Most importantly, the study's results were inconsistent as this finding was apparent only when comparing vaccine recipients to historic controls. In conducting a pre-post analysis in the same study, there was no difference in the proportion of infants experiencing an increase in apnea and bradycardia events with and without stimulation in the week after rotavirus vaccination compared with the week prior. Moreover, in the same pre-post analysis, the total number of bradycardia (1,523 vs 1,236, p=0.003) and bradycardia with stimulation (882 vs 699, p=0.02) events was higher in the seven days before rotavirus vaccination than after vaccination (with none in the 1- and 3-day time periods). Finally, we note that many experts would consider the physiology of bradycardia in premature infants to be neurologic in nature rather than cardiovascular. Overall, this was a mild event that did not appear to be associated with more severe sequelae, and results within the same study using a different analytic approach varied. Adverse events in the other six studies occurred at a frequency of one or no excess events in each study, and included congestive heart failure, tachycardia, cardiomyopathy, myocarditis, neonatal hypertension.

Rotavirus vaccines and febrile seizures or seizures. Across seven RCTs,[161, 169, 967, 969, 988, 1010, 1045] there was no evidence of increased risk of febrile seizures (RR 0.82; CI 0.33, 2.05). Across five RCTs,[169, 909, 967, 988, 1045] we found no evidence of increased risk of seizures (RR 1.02; CI 0.25, 4.16). Although the RR was greater than 1, the event was rare and occurred more frequently in the vaccinated group in only two of the five studies (1/508 vs 2/257; 1/1647 vs 3/1641; 1/3744 vs 1/3745; 17/34904 vs 9/34862; 1/2015 vs 0/2019). An additional study that reported insufficient detail for our analyses evaluated seizures among infants in Spain before and after rotavirus vaccine introduction found decreasing risk of hospitalizations for seizures following the introduction of rotavirus vaccine.[190] A self-controlled case series also found no association between rotavirus vaccine and seizures.[235] Another study[96] found no increased risk of febrile seizures during the first days following vaccination with rotavirus vaccine (RotaTeq) compared to a control period of 14 to 20 days (IRR 1.18; 0.47, 2.99).

Other adverse events. Across five RCTs,[161, 169, 967, 988, 1045] there was no evidence of increased risk of asthma (RR 1.33; CI 0.65, 2.72). The RR was greater than 1, but no risk estimates were statistically significant on their own and no studies noted the severity of asthma or the nature of these events (5/508 vs 3/257; 3/1647 vs 2/1641; 10/34904 vs 11/34862; 3/1666 vs 1/1667; 17/2015 vs 9/2019). Across another five RCTs.[139, 161, 909, 988, 1045] there was no evidence of increased risk of meningitis (RR 1.18; CI 0.36, 3.89), nor any statistically significant increased risk when the studies were considered alone. Two of the studies[909, 1045] had fewer events in the vaccinated group (4/3744 vs 6/3745; 3/34904 vs 4/34862); two of the studies[139, 161] had one event in each of the vaccinated and control groups (1/380 vs 0/381, 1/1666 vs 0/1667; one event was specified to be due to coxsackie virus); and one study[988] had more cases in the vaccinated group with no further details provided (7/1647 vs 2/1641).

Across three studies,[115, 225, 1045] we found no evidence of increased risk of diabetes (RR 0.74; CI 0.45, 1.22). A cohort study of rotavirus vaccine and type 1 diabetes found a 33 percent reduction in the risk of type 1 diabetes among those who completed the rotavirus vaccine series compared to those not vaccinated.[189]

Across three RCTs,[967, 1010, 1045] we found no evidence of increased risk of Kawasaki disease (RR 2.08; CI 0.04, 123); the risk estimate was imprecise as the studies were of disparate sizes and with few events (1/508 vs 1/257; 5/34904 vs 0/34862; 1/4359 vs 0/4328). One self-controlled case series analysis[135] found no increased risk of Kawasaki disease in a primary analysis looking at 1-28 days post-rotavirus vaccine, but found an increased risk following the first dose of Rotarix at 22-28 days (IRR 1.98; CI 1.16, 3.40) and following the second dose of RotaTeq at 15–21 days (IRR 2.33; CI 1.35, 4.00). One pre-post study[223] that took place in Germany reported no increase in Kawasaki disease-related hospitalizations after introduction of rotavirus vaccine.

We found no evidence of increased risk of encephalitis/encephalopathy (RR 0.67; CI 0.00, 85995) across two RCTs,[988, 1045] of idiopathic thrombocytopenic purpura (RR 0.64; CI 0.00, 1778394) across two RCTs,[1010, 1045] or of stroke (RR 1.32; CI 0.00, 1459247) across two RCTs.[161, 1045] In all three cases, the risk estimates were imprecise as they were across only two studies and events were infrequent (encephalitis/encephalopathy 1/1647 vs 2/1641 and 1/34904 vs 1/34682; idiopathic thrombocytopenic purpura 1/34904 vs 0/34682 and 0/4359 vs 2/4328; stroke 1/34904 vs 0/34962 and 1/1666 vs 1/667). A small study in Aichi prefecture in Japan found no increased risk of encephalitis/encephalopathy or sudden death following rotavirus vaccine by self-report before and after rotavirus vaccine introduction.[130]

Across one RCT[1045] and one cohort study,[225] we found no evidence of increased risk of autoimmune disease (RR 0.65; CI 0.16, 2.67).

One RCT[1045] noted an RR greater than 1 (RR 2.00; CI 0.07, 59.94) for reproductive system issues based on one case of testicular torsion in the intervention group (1/34904 vs 0/34862), resulting in an imprecise risk estimate.

We identified one study[62] assessing rotavirus vaccine (RotaTeq) in children and adults in the Vaccine Safety Datalink population (presumably rotavirus vaccine was only administered to children, but the study did not specify). The study reported no increased risk of transverse myelitis (which was the only adverse event studied for rotavirus vaccine [RotaTeq]) in the 5- to 28-day risk interval following vaccination of versus the remainder of the nine months after vaccination.

Varicella Vaccine

We identified two self-controlled risk interval analyses,[96, 235] and one case control study[158] assessing varicella vaccine in children in this update. Studies assessed Varivax[158] and varicella vaccine with brand not otherwise specified[235] (study utilized administrative data to determine varicella vaccination status).

One self-controlled risk interval analysis[235] from the Vaccine Safety Datalink (1995-2015) found no increased risk of seizures following administration of varicella vaccine (IRR 0.8; CI 0.6, 1.0), controlling for concomitant vaccines. A related and overlapping case series of children also from the Vaccine Safety Datalink population (2004-2008) reported an increased risk of seizures following varicella vaccination at 12 to 15 months (IRR 2.75; CI 2.05, 3.70), as well as at 16 to 23 months (IRR 3.64; CI 1.86, 7.12). However, varicella vaccine was likely to have been given concurrently with MMR in this study, which was not controlled for (unlike the prior, larger study of the same population[235]). Another study[96] looking at febrile seizures specifically found no increased risk during the first day following vaccination compared to a control period of 14 to 20 days (IRR 0.80; 0.45, 1.42); however, the risk interval may have been too soon after vaccination to detect a risk.

One study[158] reported no association with a diagnosis of broken bone, open wound, obsessive-compulsive disorder, anorexia, tic disorder, attention deficit hyperactive disorder, major depression, or bipolar disorder.

We identified two studies[62, 63] of children and adults reporting on varicella vaccine (presumed to be Varivax as it took place in the United States). In one study,[62] the authors reported no increased risk of acute disseminated encephalomyelitis (aOR 4.3; CI 0.5, 25.4), optic neuritis (aOR 2.1; CI 0.1, 23.2), or transverse myelitis (aOR 0.0; CI 0 (0.0, 10.7) in the short term interval following vaccines versus the remainder of the nine months after vaccination. In a second study,[63] there was no association between sudden sensorineural hearing loss and varicella vaccine within one week of vaccination (OR 0; CI 0, 155.27).

Combination Vaccines

This section is subdivided according to the different combination vaccines.

DTaP-IPV-Hib-HepB

We identified three RCTs[70, 166, 211] assessing the new hexavalent combination vaccine DTaP-IPV-Hib-HepB. All three RCTs compared DTaP-IPV-Hib-HepB to the older combination vaccine DTaP-IPV/Hib plus HepB as well as other routine vaccines received by both intervention and control groups.

Across three studies,[70, 166, 211] there was no evidence of increased risk associated with DTaP-IPV-Hib-HepB, including for death (RR 0.90; CI 0.02, 45.23) and febrile seizures (RR 0.71 CI 0.03, 19.74). Across two studies,[70, 166] there was no evidence of increased risk of asthma (RR 0.68; CI 0.00, 222465); the risk estimate was imprecise due to studies of differing sizes, both with few events (1/2390 vs 0/397 and 2/983 vs 1/480). Across the same two studies, there was no evidence of increased risk of meningitis (RR 0.42; CI 0.00, 462552); again, the risk estimate was imprecise due to one or no cases in each study (1/2390 vs 0/397 and 1/980 vs 1/483).

One study[70] found a statistically insignificant reduction in the risk of diabetes, intussusception, and idiopathic thrombocytopenic purpura. A second study[166] reported a statistically insignificant reduction in the risk of Kawasaki disease.

DTaP-HepB-IPV

We identified one pre-post study[90] and one self-controlled risk interval analysis[96] that assessed DTaP-HepB-IPV in children in this update. In the pre-post study,[90] the authors reported that in a population of extremely low birth weight infants in the neonatal intensive care unit, the three-day period following DTaP-HepB-IPV vaccination was associated with an increase in incidence of sepsis evaluation (adjusted rate ratio 4.3; CI 3.6, 5.3), respiratory support (adjusted rate ratio 2.6; CI 2.1, 3.1), and intubation incidence (adjusted rate ratio 1.8; CI 1.3, 2.6) compared with the three day period prior to DTaP-HepB-IPV vaccination. The authors also noted that true bacteremia (sepsis) occurred rarely both before and after vaccination. A self-controlled risk interval analysis[96] looking at febrile seizures among children aged 6 to 23 months found no increased risk during the first day following vaccination compared to a control period of 14 to 20 days (IRR 1.64; 0.62, 4.35).

One case-centered analysis[62] in children and adults assessed DTaP-HepB-IPV. The study reported no increased risk of transverse myelitis in the 5- to 28-day risk interval following vaccination versus the remainder of the nine months after vaccination. None of the identified studies reported sufficient data to allow for further analyses such as an independent assessment of the relative risk.

DTaP-IPV/Hib

We identified one observational retrospective study,[126] one self-controlled risk interval analysis,[96] one cohort study,[174] and one pre-post study[90] assessing DTaP-IPV/Hib in children in this update. All studies except for one assessed Pentacel; the one study[90] did not identify the specific brand name of the DTaP-IPV/Hib vaccine used in the study (vaccination status was determined using administrative data). Three of the studies used a self-controlled design[90, 96, 126] and the fourth[174] compared DTaP-IPV/Hib to DTaP-containing vaccines in use prior to its introduction.

The observational retrospective cohort study[126] compared rates of outcomes during the post-vaccination risk interval with rates from a comparison interval for all non-elective hospitalizations, and all outcomes in the emergency department setting, and found no safety concerns. The study examined pre-specified outcomes in the outpatient setting, including Guillain-Barré syndrome, encephalopathy, encephalitis, meningitis, hypersensitivity reactions (urticaria, angioedema, or anaphylaxis), new-onset autoimmune disease (immune thrombocytopenic purpura [ITP], hemolytic anemia), type 1 diabetes, and Kawasaki disease, but as none of these outcomes had an elevated risk following vaccination they were not further assessed with any sort of comparator as part of the risk-interval analysis (and thus are not included in analyses for this report). One study[96] looking at febrile seizures specifically found no increased risk during the first day following vaccination compared to a control period of 14 to 20 days (IRR 0.72; 0.13, 3.85). The cohort study[174] reported that no cases of Guillain-Barré syndrome, anaphylaxis, or invasive Hib disease occurred among DTaP-IPV/Hib recipients during the study period, and the study reported no increased risk in serious allergic reaction (OR 1; CI 0.34, 2.99), encephalitis (OR 0.78; CI 0.23, 2.69), seizure (OR 0.91; CI 0.52, 1.57), or hospitalizations (OR 0.87; CI 0.73, 1.04) but the study reported events per dose rather than per participant, and the concurrent control group received DTaP as an individual injection.

The authors of the pre-post study[90] reported that in a population of extremely low birth weight infants in the neonatal intensive care unit, DTaP-IPV/Hib vaccination was associated with an increase in incidence of sepsis evaluation (adjusted rate ratio 4.0; CI 2.3, 6.9) and respiratory support (adjusted rate ratio 2.3; CI 1.3, 4.0); as noted previously, very few cases of true bacteremia (sepsis) occurred either pre or post vaccination.

One case-centered analysis[62] in children and adults also evaluated DTaP-IPV/Hib. The study reported no increased risk of acute disseminated encephalomyelitis in the 5- to 28-day risk interval interval following vaccination versus the remainder of the nine months after vaccination.

DTaP-IPV

We identified one pre-post study[88] assessing DTaP-IPV (Kinrix®) among children in this update (and none of Quadracel®). Among eight pre-specified events (meningitis/encephalitis/myelitis, seizures, stroke, Guillain-Barré syndrome, Stevens-Johnson syndrome, anaphylaxis, angioneurotic edema and other non-anaphylactic allergic reactions, and serious local reactions), there was no increased risk compared to historical incidence rates.

One case-centered analysis[62] in children and adults reported no increased risk of acute disseminated encephalomyelitis associated with DTaP-IPV (Kinrix) in the 5- to 28-day risk interval interval following vaccination versus the remainder of the nine months after vaccination.

MMR-V

We identified one RCT,[89] two self-controlled risk interval analyses,[96, 167] and two cohort studies[148, 149] assessing measles, mumps, rubella, and varicella vaccine (MMR-V) in children in this update. All studies assessed the ProQuad® vaccine.

An RCT[89] comparing MMR-V with a hexavalent vaccine to hexavalent vaccine alone identified two participants with febrile seizures in the intervention arm compared to none in the control arm. Both participants had concomitant infections and the difference was not statistically significant (RR 2.02; CI 0.09, 44.55). A cohort study[148] comparing children aged 12 to 23 months who received MMR-V to those who received MMR and varicella vaccine separately on the same day, reported an increased risk of febrile seizures (RR 1.98; CI 1.43, 2.73) during the seven to ten days following vaccination that was similar when looking only at chart-confirmed febrile seizures. The authors calculated that the excess risk for febrile seizures 7 to 10 days after MMR-V compared with separate MMR and varicella vaccination was 4.3 per 10,000 doses (CI 2.6, 5.6). Another study[96] looking at febrile seizures specifically found no increased risk during the first day following vaccination compared to a control period of 14 to 20 days (IRR 1.12; CI 0.49, 2.54). Of note, fever and the risk of febrile seizures tends to be later with vaccines such as MMR-V, so the risk interval was likely to have been too soon after vaccination to detect a risk. In addition, two of these studies overlapped in terms of the population studied (Vaccine Safety datalink) and time frame (2000-2008 for one study[148] and 2006-2011 for the other[96]).

For seizures, which were not differentiated from febrile seizures, a self-controlled risk interval analysis[167] comparing the risk during the seven to ten days following MMR-V vaccination to a control window of 15 to 42 days found significantly increased risk of seizures both in children who had been born full-term (IRR 5.7; CI 4.1, 7.8) and pre-term (IRR 7.9; CI 3.0, 20). Another cohort study[149] compared risk of seizures following MMR-V in a number of ways, including through unadjusted risk differences, case-centered analysis comparing MMR-V to itself, and a case-centered analysis comparing MMR-V to MMR and varicella vaccine separately. All analyses showed an increased risk of seizures, with an adjusted RR of 1.99 (CI 1.08, 3.52) reported by the authors among children, as well as risk of fever. The authors of both of the studies of MMR-V and seizures note that based on prior analyses, the majority of seizures were presumed to be febrile seizures. Again, both of these studies overlapped in terms of the population studied (Vaccine Safety datalink) and time frame (2000-2012 for one study[149] and 2003 to 2015 for the other[167]).

The same cohort study[149] also compared risk of acute demyelinating encephalomyelitis, anaphylaxis, arthritis/arthralgia, ataxia, idiopathic thrombocytopenia purpura, Kawasaki disease, meningitis/encephalitis. The risk of idiopathic thrombocytopenia purpura was elevated in the secondary analysis comparing MMR-V to itself (RR 11.28; CI 1.87, 68.2). Anaphylaxis risk was increased in the same secondary analysis based on two cases, but on chart review the two cases were confirmed not to be anaphylaxis.

Another study[62] that included both children and adults also reported no increased risk of acute disseminated encephalomyelitis associated with MMR-V (ProQuad) in the 5- to 28-day risk interval interval following vaccination versus the remainder of the nine months after vaccination.

KQ2c3. For each adverse event associated with a particular vaccine, what are the risk factors for the adverse event?

No adverse events were significantly associated with a vaccine in our meta-analyses, but we discuss any risk factors that were examined for adverse events below.

Rotavirus Vaccines

In one study[73] of rotavirus vaccine, the relative risk of cardiovascular events was largely driven by bradycardia events in a study of premature infants who received RotaTeq, an important subpopulation. Another study[139] noted that premature infants and term infants had a comparable incidence of adverse events following administration of rotavirus vaccines.

Some other rotavirus studies included subgroup analyses as well, with almost all looking at age as a risk factor or at results stratified by age group. In one study[83] that compared intussusception before and after rotavirus vaccine introduction, results were reported separately for three age groups. There was a 2-fold higher rate of intussusception among six to 14 week-olds in 2006 to 2010 compared with the 2000 to 2005 time period [IRR 1.90; CI 1.33, 2.74). A statistically significant difference between the last 2 periods was also detected for the 33 to 52 weeks of age subgroup; however, when the narrower 33 to 40 weeks age subgroup was considered, no difference was seen in the risk of intussusception among time periods. This is in keeping with other studies[75, 102, 135, 175, 208, 236, 237] that noted higher risk of intussusception after dose 1 (typically given to younger infants) compared to doses 2 and/or 3. In a study[213] of infants in the United States that found significantly elevated rates of intussusception in some years after rotavirus vaccine introduction, no consistent change in intussusception hospitalization rates was observed among all children under 12 months of age and among children 15 to 24 weeks and 25 to 34 weeks of age. The intussusception hospitalization rate for children aged 8 to 11 weeks was significantly elevated by 46 to 101 percent in all postvaccine years except 2011 and 2013 compared with the pre-vaccine baseline, further indicating that risk for intussusception after rotavirus vaccine may be age-related. However, a study[131] of the Canadian population that found no increase in incidence of intussusception following implementation of universal rotavirus (Rotarix) immunization programs also found no difference when limiting the age of intussusception incidence to infants two to eight months, and then further limiting it to infants two to six months and two to four months. A study in England[168] that examined admission rates for intussusception before and after introduction of rotavirus vaccine found no overall increase in hospital admission rate or disease severity, but found an increase in the admission rate in the 8–16 weeks age group (RR 1.46; CI 1.12, 1.91) that was compensated for by decreases in the 17 to 24 weeks (RR 0.77; CI 0.63, 0.94), 25 to 32 weeks (RR 0.71; CI 0.59, 0.86) and 41 to 52 weeks (RR 0.80; CI 0.66, 0.98) age groups. A case-control study[175] from Germany found that age at the start of rotavirus vaccine series did not modify the risk of intussusception.

In studies looking at the association of rotavirus vaccination and risk of type 1 diabetes, one study[189] found no statistically significant effect of year of birth and gender. A cohort study[115] that assessed the association between rotavirus vaccine and type 1 diabetes reported no increased risk among children partially exposed to rotavirus vaccine (aHR 1.03; CI 0.62, 1.72) or children fully exposed to all recommended doses of rotavirus vaccine (aHR 1.50; CI 0.81, 2.77) compared with children unexposed to rotavirus vaccination; there were also no differences by age and vaccine brand. A study[133] that found no risk of convulsions among children who received rotavirus vaccine (Rotarix) and IPV compared to those who received IPV alone showed no difference in the lack of risk when assessed by any dose, after the first dose, or after the second dose. Finally,

in a study[155] looking at a number of adverse events including otitis media, there was an association between otitis media and the second dose of rotavirus vaccine (HR 1.11; CI 1.08, 1.15), which was consistent across sex, region of the United States, and time period; this association was less pronounced with RotaTeq compared to Rotarix (HR 0.92; CI 0.89, 0.95).

Other Vaccines

A number of studies examined potential risk factors for adverse events associated with other vaccines.

One study[235] that assessed the risk of seizures with varicella vaccine given concomitantly with other vaccines, including MMR, found that the risk seven to ten days after vaccination increased with age, from an IRR of 2.75 (CI 2.05, 3.70) at age 12 to 15 months to 3.64 (CI 1.86, 7.12) when administered at 16 to 23 months of age. In the same study, both MMR (IRR 2.65; CI 1.99, 3.55 at 12-15 months vs IRR 6.35; CI 3.15, 13.53 at 16-23 months) and MMR-V (IRR 4.95; CI 3.68, 6.66 at 12-15 months vs IRR 9.80; CI 4.35, 22.06 at 16-23 months) were associated with increasing risk of seizures by age. A study[353] of measles-containing vaccines (including MMR-V) found lower increased risk of seizures when administered at 12-15 months of age compared to 16-23 months of age.

A study[167] examining the risk of seizures found no significant difference in the risk of seizures for children who had been born pre-term compared to full-term for MMR (IRR 1.2; CI 0.70, 2.0) or MMR-V (IRR 1.4; CI 0.51, 3.8).

Two studies examined risk factors for MMR and autism. A cohort study[138] in Denmark found no increased risk for autism, and this finding was consistently observed in subgroups of children defined according to sibling history of autism, autism risk factors based on a disease risk score, or receipt of other childhood vaccinations. Another study[141] found that receipt of the MMR was not associated with increased risk of autism spectrum disorder (ASD), regardless of whether older siblings had ASD. A case-control study[224] of MMR and autism found no increased risk of autism and no difference in the risk of autism following MMR at any age.

A study[174] of DTaP-IPV/Hib that found no increased risk of medically attended fever, seizure, meningitis/encephalitis/myelitis, non-anaphylactic serious allergic reaction, anaphylaxis, Guillain-Barré syndrome, or invasive Hib disease did identify an increased risk of medically attended fever among 1- to 2-year-olds who received DTaP-IPV/Hib vaccine versus historical comparators (RR 1.83; CI 1.34, 2.50) but not among infants under 1 year old (RR 0.83; CI 0.73, 0.94).

Five studies examined risk factors associated with PCV13 and adverse events. Two RCTs[55, 217] examined safety after both the infant and toddler doses, and found that PCV13 has an acceptable safety profile in both toddlers and infants, including one study[217] in which PCV13 was co-administered with DTaP. A pre-post study[221] of PCV13 compared to PCV7 that assessed pre-specified adverse events found no risk associated with PCV13, with no difference among age-stratified analyses. In a study[206] comparing fever in children who received PCV13 and trivalent IIV versus trivalent IIV alone, the finding that PCV13 and trivalent IIV were associated with higher rates of fever did not change when excluding children whose families reported antipyretic use on days 0 to 1 or when analyses were limited to first enrollments (children could enroll for more than one vaccination event; this analysis was restricted to their first enrollment in the study). Another study of PCV13[59] found higher risk of febrile seizures when administered with IIV (IRR 2.80; CI 1.63, 4.83) than when given alone (IRR 1.54; CI 1.04, 2.28). The study included a mix of trivalent and quadrivalent IIV.

Two studies assess risk factors for MenB and adverse events in children. One RCT[186] examined different doses of the vaccine, including the approved dose, and found all doses to be well tolerated. Another RCT[196] found that local reactions and systemic events did not increase with concomitant administration of other vaccines. A self-controlled cases series study[127] of MenACWY-D (Menactra) that assessed multiple outcomes stratified by age groups (2-10 years and 9-23 months). The only significantly elevated outcome was among 2–10-year-olds (two cases of cellulitis/abscess occurred during the risk interval versus none during comparison interval; after medical record review, the cases were considered unrelated to vaccination).

Four studies of influenza vaccines in children looked at risk factors for particular subgroups. A study[129] of quadrivalent IIV (Flucelvax Quadrivalent) stratified children into age groups of 4 to 5 years, 6 to 8 years, and 9 to 17 years, and found no major differences in non-serious and non-severe adverse events by age. A study[160] of all quadrivalent IIV (brand not specified) found an increased risk of febrile seizures when administering quadrivalent IIV with PCV 13 and other vaccines (RR 12.3; CI 2.50, 58.90), but not for quadrivalent IIV without PCV13 (RR 0.6; CI 0.07, 4.85) or quadrivalent IIV alone (RR 1.2; CI 0.12, 11.20). A study[76] of LAIV in children with asthma and high-risk conditions found no increased risk of hospitalization. A second study[207] of quadrivalent LAIV in children found no difference in fever when looking at those who received quadrivalent LAIV alone, when assessing only children aged 3 years and older, or when race/ethnicity or the presence of a high-risk medical condition were added to the model.

Among studies that included both adults and children, three reported sub-group analyses. In a study[61] of quadrivalent LAIV versus IIV, the authors analyzed risk for different age groups, separately as well as by history of wheezing. Compared to other age groups, children aged two to four years had significantly lower risk of wheezing (aHR 0.67; CI 0.48, 0.92), lower respiratory tract infection (aHR 0.69; CI 0.51, 0.93), and hospitalization (aHR 0.39; CI 0.18, 0.87) with LAIV than those who received IIV. This effect was not observed for the within-cohort analysis that looked at these outcomes pre- and post-vaccine, nor when comparing LAIV to no vaccine (both aHR <1). Children aged five to nine years who received LAIV had lower risk of lower respiratory tract infection (aHR 0.55; CI 0.39, 0.79) and hospitalization (aHR 0.12; CI 0.03, 0.54) than those who received IIV and lower risk of hospitalization (aHR 0.14; CI 0.03, 0.63) than those who received no vaccine. Adolescents aged 9 to 17 years had lower risk of wheezing (aHR 0.51; CI 0.27, 0.96) and lower respiratory tract infection (0.57; CI 0.35, 0.93) when comparing LAIV to IIV. Among adults aged 18 to 49 years, LAIV was associated with significant decrease in risk of hospitalization when compared to no vaccine (aHR 0.33; CI 0.13, 0.87) and compared to IIV (aHR 0.13; CI 0.06, 0.30), except for the within cohort analysis. Among children with a history of wheezing or asthma, LAIV was associated with significantly less wheezing than was IIV (aHR 0.25; CI 0.04, 0.96), but the result was not significant when LAIV was compared to no vaccine (aHR 0.45; CI 0.06, 2.12). When looking specifically at wheezing among children aged 2–4 years of age with a history of wheezing or asthma, there was no difference in effects associated with LAIV versus IIV. In this study, quadrivalent LAIV was not associated with any increased risk of the adverse events examined.

The recent studies of HPV9 resulted in a number of additional publications that pooled together multiple RCTs to assess safety by geographic region and gender. Two studies that were secondary analyses of one of the RCTs[136] looked specifically at participants in Asian countries[256] and in Latin American countries[354] and identified no new safety concerns.

In a study[220] of MenACWY-CRM (Menveo), the only significant finding was a reported association with Bell's palsy (relative incidence 2.9; CI 1.1, 7.5). Stratified analyses

demonstrated the increased risk only in participants receiving concomitant vaccines (RI 5.0; CI 1.4, 17.8), and no increased risk for those without concomitant vaccine (RI 1.1; CI 0.2, 5.5).

KQ2: Summary of Findings for Safety of Vaccines in Children

This section summarizes the findings across studies and safety of vaccines for children or children and adults for the pre-defined key adverse events. The section is stratified by vaccine type. The summary of findings tables document the results across studies grouped by vaccines. These tables show the number of RCTs, the number of other studies, the number of participants across pooled analyses, the studies contributing to the risk estimate, findings for the outcomes of interest, the criteria used to downgrade the SoE, and the SoE summary statement. The relative risk of an adverse event was derived by comparing the reported event rates in vaccinated participants compared to a control group across all studies that reported the data for that outcome. The absolute rates of adverse events (number of events, number of assessed participants) for the vaccine and the control group are also shown. In many instances, results were based on single occurrences of a specific adverse event. Where studies reported insufficient detail and did not contribute to the effect size estimates, the tables report the results as reported by the study authors.

Diphtheria, Tetanus, and Acellular Pertussis Vaccines

The summary of findings Table 11 documents the findings across studies of vaccines for diphtheria, tetanus, and pertussis (including DTaP and Tdap).

Table 11. KQ2: Update summary of findings and SoE for safety of diphtheria, tetanus, pertussis vaccines in children

Vaccine	Outcome	N RCTs, N Other; N Participants; IDs of Studies Contributing to RR	Risk Estimate: RR; CI (Event Rates in Individual Studies); Other Studies Contributing to SoE	Reasons for Downgrading	Update Evidence Statement and SoE
Diphtheria, tetanus, and acellular pertussis (DTaP; Daptacel®, Infanrix)	Acute disseminated encephalomyelitis	0 RCTs, 0 Other; N 0; 0 studies	One study[62] reported no increased risk (aOR 0; CI 0.00, 270)	Study limitation,°°° Precision,^^ Consistency↑	Insufficient evidence
	Asthma	1 RCT, 0 Other; N 291; Petrecz, 2016[183]	RR 2.01; CI 0.07, 59.56 (1/145 vs 0/146)[&,#]	Precision,^ Consistency↑	Low SoE for no evidence of increased risk
	Death	1 RCT, 0 Other; N 291; Petrecz, 2016[183]	RR 1.01; CI 0.02, 50.40 (0/145 vs 0/146)[&,#]	Precision,^ Consistency↑	Low SoE for no evidence of increased risk
	Febrile seizures	0 RCTs, 0 Other; N 0; 0 studies	One study[96] reported no increased risk in the 0-1 days following DTaP compared to a control period (IRR 1.17; CI 0.52, 2.60)	Study limitation,°° Precision,^^ Consistency↑	Insufficient evidence

Vaccine	Outcome	N RCTs, N Other; N Participants; IDs of Studies Contributing to RR	Risk Estimate: RR; CI (Event Rates in Individual Studies); Other Studies Contributing to SoE	Reasons for Downgrading	Update Evidence Statement and SoE
	Seizure	0 RCTs, 0 Other; N 0; 0 studies	One study[235] reported no increased risk in the period after DTaP compared to control periods after adjusting for age and concomitant vaccines	Study limitation,°° Precision,^^ Consistency↑	Insufficient evidence
	Anaphylaxis or systemic allergic reaction, angioedema, brachial neuritis, cardiovascular events, diabetes, encephalitis/encephalopathy, Guillain-Barré syndrome, idiopathic thrombocytopenic purpura, stroke, transverse myelitis	0 RCTs, 0 Other; N 0; 0 studies	We did not identify studies reporting on the outcomes	N/A	Insufficient evidence
Tetanus, diphtheria, and acellular pertussis (Tdap; Adacel, Boostrix)	Acute disseminated encephalomyelitis	0 RCTs, 0 Other; N 0; 0 studies	One study[62] reported an association of Tdap and acute disseminated encephalomyelitis (aOR 15.8 CI 1.2, 471.6)	Study limitation,°°° Precision,^^ Consistency↑	Insufficient evidence
	Cardiovascular events	1 RCT, 0 Other; N 469; Rivera, 2018[187]	RR 0.99; CI 0.02, 49.53 (0/231 vs 0/228) (study of children and adults)[&,#]	Precision,^ Consistency↑	Low SoE for no evidence of increased risk
	Death	1 RCT, 0 Other; N 469; Rivera, 2018[187]	RR 0.99; CI 0.02, 49.53 (0/231 vs 0/228) (study of children and adults)[#]	Precision,^ Consistency↑	Low SoE for no evidence of increased risk
	Optic neuritis	0 RCTs, 0 Other; N 0; 0 studies	One study[62] reported no statistically significant risk (aOR 2.7; CI 0.3, 15.6)	Study limitation,°°° Precision,^^ Consistency↑	Insufficient evidence
Tetanus, diphtheria, and acellular pertussis (Tdap; Adacel, Boostrix) (continued)	Reproductive system events	0 RCTs, 0 Other; N 0; 0 studies	One study[173] of adults and children reported no increased risk of primary ovarian failure (aHR 0.88; CI 0.37, 2.10)	Study limitation,°°° Precision,^^ Consistency↑	Insufficient evidence
	Transverse myelitis	0 RCTs, 0 Other; N 0; 0 studies	One study[62] reported no association (aOR 0.70; CI 0.00, 3.80)	Study limitation,°°° Precision,^^ Consistency↑	Insufficient evidence

Vaccine	Outcome	N RCTs, N Other; N Participants; IDs of Studies Contributing to RR	Risk Estimate: RR; CI (Event Rates in Individual Studies); Other Studies Contributing to SoE	Reasons for Downgrading	Update Evidence Statement and SoE
	Anaphylaxis or systemic allergic reaction, angioedema, brachial neuritis, diabetes, encephalitis/encephalopathy, Guillain-Barré, idiopathic thrombocytopenic purpura, seizures, stroke	0 RCTs, 0 Other; N 0; 0 studies	We did not identify studies reporting on the outcomes	N/A	Insufficient evidence

Notes: aOR—adjusted odds ratio; CI—95% confidence interval; ID—study identifier; KQ—Key Question; N—number; N/A—not applicable; RR—relative risk; RCT—randomized controlled trials; SoE—strength of evidence; &—potentially increased risk based on direction of effects across studies and investigated further but not statistically significant; #—none of the RR estimates in individual studies showed a statistically significantly increased risk; °—no unvaccinated control group; °°—effect based on observational evidence only; °°°—study in children and adults; ^—imprecise estimate with wide CI; ^^—study provides insufficient detail for further analyses and independent estimate of effect size not possible; ↑—consistency could not be assessed as no other study reported on the outcome

The 2014 AHRQ report concluded moderate SoE of no association of type 1 diabetes with DTaP/Tdap/Td (based on studies reviewed in the IOM report of vaccines containing diphtheria toxoid, tetanus toxoid, and acellular pertussis antigens either alone or in combination) and high SoE of no association with childhood leukemia with DTaP/Td (based on multiple large epidemiological studies). These findings remain unchanged with no new findings from this report (childhood leukemia was not examined as an outcome, and there were no studies on type 1 diabetes and DTaP or Tdap; Td no longer in use in children). The prior 2014 report found insufficient evidence for an association between acute disseminated encephalomyelitis, autism, cerebellar ataxia, idiopathic thrombocytopenic purpura, infantile spasms, multiple sclerosis relapse, seizures, serum sickness, sudden infant death syndrome, and transverse myelitis and DTaP/Tdap/Td based on the IOM report alone; these findings remain unchanged as the update either identified no new studies or the evidence continued to be insufficient.

For DTaP, the update found no evidence of increased risk of asthma or death (low SoE). The evidence was graded as insufficient or there were no new studies for several other key adverse events. For Tdap, the update found no evidence of increased risk of cardiovascular events or death (low SoE). There was either insufficient evidence or no new studies for several other key adverse events.

Table 11a summarizes the findings across the prior 2014 report and the update.

Table 11a. KQ2: Safety of DTaP and Tdap in children

Vaccine (Abbreviation; Brand Name[s])	2014 Report SoE and Findings	SoE and Findings in Update	Synthesis of SoE and Findings
Diphtheria, tetanus, and acellular pertussis (DTaP; Daptacel, Infanrix)	High: No association with childhood leukemia (not examined as a key adverse event in current report) Moderate: No association with type 1 diabetes mellitus for vaccines containing diphtheria toxoid, tetanus toxoid, and acellular pertussis antigens Insufficient: Infantile spasms, seizures, cerebellar ataxia, autism, acute disseminated encephalomyelitis, transverse myelitis, multiple sclerosis relapse, serum sickness, idiopathic thrombocytopenic purpura, sudden infant death syndrome (all diphtheria, tetanus, and acellular pertussis- containing vaccines were considered together)	Low: No evidence of increased risk of asthma or death Insufficient: Acute disseminated encephalomyelitis, febrile seizures, seizures No studies: Anaphylaxis or systemic allergic reaction, angioedema, brachial neuritis, cardiovascular events, diabetes, encephalitis/encephalopathy, Guillain-Barré syndrome, idiopathic thrombocytopenic purpura, stroke, transverse myelitis	Moderate: No evidence of increased risk of type 1 diabetes mellitus (no change from prior 2014 report; no new studies in update) Low: No evidence of increased risk of asthma or death
Tetanus, diphtheria, and acellular pertussis (Tdap; Adacel, Boostrix)	High: No association with childhood leukemia (for Td; not examined as a key adverse event in current report) Moderate: No association with type 1 diabetes mellitus for vaccines containing diphtheria toxoid, tetanus toxoid, and acellular pertussis antigens	Low: No evidence of increased risk of cardiovascular events, death Insufficient: Acute disseminated encephalomyelitis, transverse myelitis No studies: Anaphylaxis or systemic allergic reaction, angioedema, brachial neuritis, diabetes, encephalitis/encephalopathy, Guillain-Barré syndrome, idiopathic thrombocytopenic purpura, seizures, stroke	Moderate: No evidence of increased risk of type 1 diabetes mellitus (no change from prior 2014 report; no new studies in update) Low: No evidence of increased risk of cardiovascular events, death for Tdap Td no longer in use in children

Key: Green box indicates no evidence of increased risk of specific adverse events; Notes: KQ—Key Question; SoE—Strength of Evidence

Haemophilus influenzae Type b Vaccines

Table 12 documents the evidence for the identified studies of Hib.

Table 12. KQ2: Update summary of findings and SoE for safety of Hib in children

Vaccine	Outcome	N RCTs, N Other; N Participants; IDs of Studies Contributing to RR	Risk Estimate: RR; CI (Event Rates in Individual Studies); Other Studies Contributing to SoE	Reasons for Downgrading	Update Evidence Statement and SoE
Haemophilus influenzae type b (Hib; PedvaxHIB®, ActHIB®, Hiberix®)	Acute disseminated encephalomyelitis	0 RCTs, 0 Other; N 0; 0 studies	One study of children and adults[62] reported no association (aOR 0; CI 0.0, 25.3)	Study limitation,° Precision,^^ Consistency↑	Insufficient evidence
	Febrile seizures	0 RCTs, 0 Other; N 0; 0 studies	One study[96] reported no increased risk in the 0-1 days following Hib compared to a control period (IRR 1.53; CI 0.87, 2.72)	Study limitation,° Precision,^^ Consistency↑	Insufficient evidence
	Seizures	0 RCTs, 0 Other; N 0; 0 studies	One study[235] reported no association with postvaccination seizures (IRR 0.8l; CI 0.6, 1.0 for 11-23 months), including across multiple age groups	Study limitation,° Precision,^^ Consistency↑	Insufficient evidence
	Transverse myelitis	0 RCTs, 0 Other; N 0; 0 studies	One study[62] of children and adults reported no association (aOR 0; CI 0.0, 66.2)	Study limitation,° Precision,^^ Consistency↑	Insufficient evidence
Haemophilus influenzae type b (Hib; PedvaxHIB®, ActHIB®, Hiberix®) (continued)	Anaphylaxis or systemic allergic reaction, angioedema, cardiovascular events, death, diabetes, Guillain-Barré syndrome, idiopathic thrombocytopenic purpura, stroke	0 RCTs, 0 Other; N 0; 0 studies	We did not identify studies reporting on the outcomes	N/A	Insufficient evidence

Notes: aOR—adjusted odds ratio; CI—95% confidence interval; ID—study identifier; IRR—incidence risk ratio; KQ—Key Question; N—number; N/A—not applicable; RR—relative risk; RCT—randomized controlled trials; SoE—strength of evidence; °—no unvaccinated control group; ^^—study provides insufficient detail for further analyses and independent estimate of effect size not possible; ↑—consistency could not be assessed as no other study reported on the outcome

The prior 2014 report found high SoE for no association of Hib and childhood leukemia based on multiple large epidemiological studies; childhood leukemia was not examined as a key adverse event in the current report and the finding remains unchanged. The prior 2014 report also found moderate SoE for no association with short term serious adverse events following Hib across three high-quality RCTs; these vaccines had not been covered in the IOM report. This finding remains unchanged as there were either no studies in the update examining key adverse events or evidence was graded as insufficient due to study limitations.

Table 12a summarizes the findings across the prior 2014 report and the update.

Table 12a. KQ2: Safety of Hib in children

Vaccine (Abbreviation; Brand Name[s])	2014 Report Strength of Evidence and Findings	Strength of Evidence and Findings in Update	Synthesis of Strength of Evidence and Findings
Haemophilus influenzae type b (Hib; PedvaxHIB, ActHIB, Hiberix)	High: No association with childhood leukemia (not examined as a key adverse event in current report) Moderate: No association with serious adverse events in short term (not examined as a key adverse event in current report)	Insufficient: Acute disseminated encephalomyelitis, febrile seizures, seizures, transverse myelitis No studies: Anaphylaxis or systemic allergic reaction, angioedema, cardiovascular events, death, diabetes, Guillain-Barré syndrome, idiopathic thrombocytopenic purpura, stroke	☐ Insufficient evidence (no findings related to key adverse events in prior 2014 report; insufficient evidence in update)

Key: ☐ White box indicates insufficient evidence to draw conclusions about the risk of specific adverse events; Notes: KQ—Key Question; SoE—Strength of Evidence

Hepatitis Vaccines

Table 13 documents the evidence for the identified hepatitis vaccine studies.

Table 13. KQ2: Update summary of findings and SoE for safety of hepatitis vaccines in children

Vaccine	Outcome	N RCTs, N Other; N Participants; IDs of Studies Contributing to RR	Risk Estimate: RR; CI (Event Rates in Individual Studies); Other Studies Contributing to SoE	Reasons for Downgrading	Update Evidence Statement and SoE
Hepatitis A (HepA; Havrix, Vaqta)	Acute disseminated encephalomyelitis	0 RCTs, 0 Other; N 0; 0 studies	One study[62] reported no statistically significant increased risk (aOR 1.9 CI 0.1, 13.0)	Study limitation,° Precision,^^ Consistency↑	Insufficient evidence
	Febrile seizures	0 RCTs, 0 Other; N 0; 0 studies	One study[96] reported no increased risk in the 0-1 days following HepA compared to a control period (IRR 0.88; CI 0.56, 1.38)	Study limitation,° Precision,^^ Consistency↑	Insufficient evidence
	Optic neuritis	0 RCTs, 0 Other; N 0; 0 studies	One study[62] of children and adults reported no statistically significant increased risk (aOR 0 CI 0.0, 7.5)	Study limitation,° Precision,^^ Consistency↑	Insufficient evidence
	Transverse myelitis	0 RCTs, 0 Other; N 0; 0 studies	One study[62] reported no increased risk (aOR 0; CI 0.0, 12.6)	Study limitation,° Precision,^^ Consistency↑	Insufficient evidence

Vaccine	Outcome	N RCTs, N Other; N Participants; IDs of Studies Contributing to RR	Risk Estimate: RR; CI (Event Rates in Individual Studies); Other Studies Contributing to SoE	Reasons for Downgrading	Update Evidence Statement and SoE
Hepatitis A (HepA; Havrix, Vaqta) (continued)	Anaphylaxis or systemic allergic reaction, angioedema, cardiovascular events, death, diabetes, Guillain-Barré syndrome, idiopathic thrombocytopenic purpura, seizures, stroke	0 RCTs, 0 Other; N 0; 0 studies	We did not identify studies reporting on the outcomes	N/A	Insufficient
Hepatitis B (HepB; Engerix-B, Recombivax HB)	Acute disseminated encephalomyelitis	0 RCTs, 0 Other; N 0; 0 studies	One study[62] reported no association (aOR 0; CI 0.0, 128.7)	Study limitation,° Precision,^^ Consistency↑	Insufficient evidence
	Febrile seizures	0 RCTs, 0 Other; N 0; 0 studies	One study[96] reported no increased risk in the 0-1 days following HepB compared to a control period (IRR 1.17; CI 0.31, 4.40)	Study limitation,° Precision,^^ Consistency↑	Insufficient evidence
	Optic neuritis	0 RCTs, 0 Other; N 0; 0 studies	One study[62] of children and adults reported no association (aOR 0; CI 0.0, 6.5)	Study limitation,° Precision,^^ Consistency↑	Insufficient evidence
	Transverse myelitis	0 RCTs, 0 Other; N 0; 0 studies	One study[62] reported no association with transverse myelitis (aOR 0; CI 0.0, 30.0)	Study limitation,° Precision,^^ Consistency↑	Insufficient evidence
	Anaphylaxis or systemic allergic reaction, angioedema, autoimmune disease, autoimmune thyroiditis (Hashimoto's disease), cardiovascular events, death, diabetes, encephalitis/ encephalopathy, Guillain-Barré syndrome, idiopathic thrombocytopenic purpura, multiple sclerosis, myocardial infarction, seizures, stroke	0 RCTs, 0 Other; N 0; 0 studies	We did not identify studies reporting on the outcomes	N/A	Insufficient evidence

Notes: aOR—adjusted odds ratio; CI—95% confidence interval; ID—study identifier; IRR—incidence risk ratio; KQ—Key Question; N—number; N/A—not applicable; RR—relative risk; RCT—randomized controlled trials; SoE—strength of evidence;

°—no unvaccinated control group; ^^—study provides insufficient detail for further analyses and independent estimate of effect size not possible; ↑—consistency could not be assessed as no other study reported on the outcome

HepA. The prior 2014 report found moderate SoE for idiopathic thrombocytopenic purpura in association with HepA among children 7 to 17 years of age based on a large post-licensure study (cases were rare and the majority were mild; no summary risk estimate could be calculated). There were no studies of this outcome in the update, and the finding remains unchanged

The evidence was either graded as insufficient or there were no new studies for several other key adverse events.

HepB. The prior 2014 report found high SoE for no association of hepatitis B vaccine and childhood leukemia based on multiple large epidemiological studies; this outcome was not examined as a key adverse event in the current report and the finding remains unchanged. The prior 2014 report concluded insufficient SoE for statements regarding food allergy; this outcome was also not examined as a key adverse event in the current report. The prior 2014 report also concluded that there was moderate SoE for no association with multiple sclerosis; there were no studies examining this outcome in the current report, and the finding remains unchanged.

Evidence in the update for HepB was either graded as insufficient or there were no new studies.

Table 13a summarizes the findings across the prior 2014 report and the update.

Table 13a. KQ2: Safety of hepatitis vaccines in children

Vaccine (Abbreviation; Brand Name[s])	2014 Report SoE and Findings	SoE and Findings in Update	Synthesis of SoE and Findings
Hepatitis A (HepA; Havrix, Vaqta)	Moderate: Idiopathic thrombocytopenic purpura in children aged 7 to 17 years	Insufficient: Acute disseminated encephalomyelitis, febrile seizures, transverse myelitis No studies: Anaphylaxis or systemic allergic reaction, angioedema, cardiovascular events, death, diabetes, Guillain-Barré syndrome, idiopathic thrombocytopenic purpura, seizures, stroke	Moderate: Increased risk of idiopathic thrombocytopenic purpura in in children aged 7 to 17 years (no change from prior 2014 report; no new studies in update)

Vaccine (Abbreviation; Brand Name[s])	2014 Report SoE and Findings	SoE and Findings in Update	Synthesis of SoE and Findings
Hepatitis B (HepB; Engerix-B, Recombivax HB)	High: No association with childhood leukemia (not examined as a key adverse event in current report) Moderate: No association with multiple sclerosis Insufficient: Food allergy	Insufficient: Acute disseminated encephalomyelitis, febrile seizures, optic neuritis, transverse myelitis No studies: Anaphylaxis or systemic allergic reaction, angioedema, autoimmune disease, autoimmune thyroiditis (Hashimoto's disease), cardiovascular events, death, diabetes, encephalitis/encephalopathy, Guillain-Barré syndrome, idiopathic thrombocytopenic purpura, multiple sclerosis, myocardial infarction, optic neuritis, seizures, stroke	Moderate: No evidence of increased risk of multiple sclerosis (no change from prior 2014 report; no new studies in update)

Key: Green box indicates no evidence of increased risk of specific adverse events; Red circle indicates evidence of risk of specific adverse events; Notes: KQ—Key Question; SoE—Strength of Evidence

9-Valent Human Papillomavirus Vaccine

Table 14 documents the evidence for the identified studies of HPV9 in children.

Table 14. KQ2: Update summary of findings and SoE for safety of HPV9 in children

Vaccine	Outcome	N RCTs, N Other; N Participants; IDs of Studies Contributing to RR	Risk Estimate: RR; CI (Event Rates in Individual Studies); Other Studies Contributing to SoE	Reasons for Downgrading	Update Evidence Statement and SoE
9-valent human papillomavirus (HPV9; Gardasil 9) 9-valent human papillomavirus (HPV9; Gardasil 9) (continued)	Anaphylaxis or systemic allergic reaction	1 RCT, 0 Other; N 14149; Huh, 2017[136]	RR 2.00; CI 0.07, 59.66 (case was judged due to non-study medication; 1/7071 vs 0/7078) (study of children and adults);[&,#] a post-marketing surveillance study found no statistical signal for anaphylaxis[95]	Study limitation,°°° Precision,^ Consistency↑	Insufficient evidence
	Asthma	1 RCT, 0 Other; N 14149; Huh, 2017[136]	RR 2.00; CI 0.07, 59.66 (asthmatic crisis; 1/7071 vs 0/7078) (study of children and adults)[&,#]	Study limitation,°°° Precision,^ Consistency↑	Insufficient evidence
	Autoimmune disease	1 RCT, 0 Other; N 599; Vesikari, 2015[228]	RR 0.50; CI 0.02, 14.90 (Henoch-Schönlein purpura; 0/299 vs 1/300);[#] 1 RCT in children and adults reported no increased risk of Crohn's disease: RR 1.00; CI 0.06, 16.00[136]	Study limitation,° Precision^	Low SoE for no evidence of increased risk
	Birth defects	2 RCTs, 0 Other; N 15062; Garland, 2015[111], Huh, 2017[136]	RR 0.50; CI 0.01, 25.22 (0/608 vs 0/305) in 1 study of children and adults when compared to placebo;[#] combining with another RCT in children and adults that	Study limitation,°°° Precision,^ Consistency↑	Low SoE for no evidence of increased risk

Vaccine	Outcome	N RCTs, N Other; N Participants; IDs of Studies Contributing to RR	Risk Estimate: RR; CI (Event Rates in Individual Studies); Other Studies Contributing to SoE	Reasons for Downgrading	Update Evidence Statement and SoE
9-valent human papillomavirus (HPV9; Gardasil 9) (continued)			compared to another HPV vaccine, the risk remained non-significant: RR 0.33; CI 0.00, 2276574		
	Cardiovascular events	1 RCT, 0 Other; N 14149; Huh, 2017[136]	RR 4.00; CI 0.18, 88.77 (orthostatic tachycardia syndrome; 2/7071 vs 0/7078) (study of children and adults);[&,#] 1 post-marketing surveillance study found no statistical signal for venous thromboembolism[95]	Study limitation,°°° Precision,^ Consistency↑	Insufficient evidence
	Death	2 RCTs, 0 Other; N 966; Gilca, 2018,[114] Vesikari, 2015[228]	RR 0.58; CI 0.00, 362688 (0/274 vs 0/93, 0/299 vs 0/300);[&,#] 3 RCTs of children and adults also reported no increased risk: RR 1.11; CI 0.10, 12.13[111, 136, 226]	Study limitation,° Precision,^	Low SoE for no evidence of increased risk
	Diabetes	1 RCT, 0 Other; N 14149; Huh, 2017[136]	RR 0.50; CI 0.02, 14.92 (gestational diabetes; 0/7071 vs 1/7078) (study of children and adults)[#]	Study limitation,°°° Precision,^ Consistency↑	Insufficient evidence
	Guillain-Barré syndrome	0 RCTs, 0 Other; N 0; 0 studies	One post-marketing surveillance study[95] found no statistical signal	Study limitation,°° Precision,^^ Consistency↑	Insufficient evidence
	Multiple sclerosis	1 RCT, 0 Other; N 14149; Huh, 2017[136]	RR 2.00; CI 0.18, 22.07 (2/7071 vs 1/7078) (study of children and adults)[&,#]	Study limitation,°°° Precision,^ Consistency↑	Insufficient evidence
	Preterm labor	1 RCT, 0 Other; N 14149; Huh, 2017[136]	RR 1.00; CI 0.06, 16.00 (1/7071 vs 1/7078) (study of children and adults)[#]	Study limitation,°°° Precision,^ Consistency↑	Insufficient evidence
	Reproductive system events	2 RCTs, 0 Other; N 15062; Garland, 2015,[111] Huh, 2017[136]	RR 0.25; CI 0.01, 7.46 (induced abortion; 0/608 vs 1/305) in 1 study of children and adults when compared to placebo;[&,#] combining with another RCT in children and adults that compared to another HPV vaccine: RR 1.01; CI 0.00, 382.79	Study limitation,°°° Precision^	Low SoE for no evidence of increased risk
	Seizure	1 RCT, 0 Other; N 599; Vesikari, 2015[228]	RR 0.50; CI 0.02, 14.90 (0/299 vs 1/300);[#] 1 post-marketing surveillance study[95] found no statistical signal	Study limitation,° Precision^	Low SoE for no evidence of increased risk
	Spontaneous abortion	1 RCT, 0 Other; N 14149; Huh, 2017[136]	RR 1.00; CI 0.63, 1.59 (36/7071 vs 36/7078) (study of children and adults)[#]	Study limitation,°°° Precision,^ Consistency↑	Low SoE for no evidence of increased risk
	Stroke	1 RCTs, 0 Other; N 14149; Huh, 2017[136]	RR 0.50; CI 0.02, 14.92 (cerebral hemorrhage; 0/7071 vs 1/7078) (study of children and adults);[#] 1 post-	Study limitation,° Precision,^ Consistency↑	Insufficient evidence

Vaccine	Outcome	N RCTs, N Other; N Participants; IDs of Studies Contributing to RR	Risk Estimate: RR; CI (Event Rates in Individual Studies); Other Studies Contributing to SoE	Reasons for Downgrading	Update Evidence Statement and SoE
			marketing surveillance study[95] found no statistical signal		
	Acute disseminated encephalomyelitis, amyotrophic lateral sclerosis, angioedema, idiopathic thrombocytopenic purpura, transverse myelitis	0 RCTs, 0 Other; N 0; 0 studies	We did not identify studies reporting on the outcomes	N/A	Insufficient evidence

Notes: CI—95% confidence interval; ID—study identifier; KQ—Key Question; N—number; N/A—not applicable; RR—relative risk; RCT—randomized controlled trials; SoE—strength of evidence; &—potentially increased risk based on direction of effects across studies and investigated further but not statistically significant; #—none of the RR estimates in individual studies showed a statistically significantly increased risk; °—no unvaccinated control group; °°—effect based on observational evidence only; °°°—study includes children and adults; ^—imprecise estimate with wide CI; ^^—study provides insufficient detail for further analyses and independent estimate of effect size not possible; ↑—consistency could not be assessed as no other study reported on the outcome

The prior 2014 report found high SoE for increased risk of pain at injection site with HPV vaccines. The prior 2014 report also found moderate SoE for increased risk of anaphylaxis in persons with allergies, fever, headache, mild gastrointestinal adverse events, and skin infection with prior HPV vaccines. There was moderate SoE for no association with juvenile rheumatoid arthritis, type 1 diabetes, appendicitis, Guillain-Barré syndrome, seizures, stroke, syncope, or venous thromboembolism with prior HPV vaccines. The prior 2014 report indicated insufficient SoE for evidence statements regarding the presence or absence of acute disseminated encephalomyelitis, transverse myelitis, neuromyelitis optica, multiple sclerosis, onset of Hashimoto's disease, chronic inflammatory demyelinating polyneuropathy, brachial neuritis, amyotrophic lateral sclerosis, transient arthralgia, pancreatitis, thromboembolic events, spontaneous abortion, and hypercoagulable states. However, all of the evidence review was for HPV2 and HPV4, which are no longer in use.

The current report assessed only HPV9 and found low SoE for no evidence of increased risk for autoimmune disease, birth defects, death, reproductive system events, seizures, or spontaneous abortion, largely compared to prior vaccines (HPV2 or HPV4). The evidence was graded as insufficient or there were no studies for several other key adverse events. Table 14a summarizes the findings across the prior 2014 report and the update.

Table 14a. KQ2: Safety of HPV9 in children

Vaccine (Abbreviation; Brand Name[s])	2014 Report SoE and Findings	SoE and Findings in Update	Synthesis of SoE and Findings
9-valent human papillomavirus (HPV9; Gardasil 9)	High: Pain at injection site Moderate: No association with juvenile rheumatoid arthritis, type 1 diabetes mellitus, appendicitis, Guillain-Barré syndrome, seizures, stroke, syncope, venous thromboembolism Moderate: Anaphylaxis in persons with allergies, fever, headache, mild gastrointestinal adverse events, skin infection Insufficient: Acute disseminated encephalomyelitis, transverse myelitis, neuromyelitis optica, multiple sclerosis, onset of Hashimoto's disease, chronic inflammatory demyelinating polyneuropathy, brachial neuritis, amyotrophic lateral sclerosis, transient arthralgia, pancreatitis, thromboembolic events, spontaneous abortion, hypercoagulable states HPV9 not in use at time of prior report (findings above are for 2-valent [HPV2] or 4-valent [HPV4] human papillomavirus vaccines only)	Low: No evidence of increased risk of autoimmune disease, birth defects, death, reproductive system events, seizures, spontaneous abortion[a] Insufficient: Anaphylaxis or systemic allergic reaction, cardiovascular events, diabetes, Guillain-Barré syndrome, multiple sclerosis, stroke No studies: Acute disseminated encephalomyelitis, amyotrophic lateral sclerosis, angioedema, idiopathic thrombocytopenic purpura, transverse myelitis	Low: No evidence of increased risk of autoimmune disease, birth defects, death, reproductive system events, seizures, spontaneous abortion HPV2 and HPV4 no longer in use

Key: Green box indicates no evidence of increased risk of specific adverse events; Notes: aPregnancy-related outcomes, such as spontaneous abortion, are noted in their respective Key Questions (KQ1 for adults and KQ2 for children) when the study was not solely of pregnant women. This occurred when individuals became pregnant after receiving the vaccine; KQ—Key Question; SoE—Strength of Evidence

Inactivated Poliovirus Vaccine

Table 15 documents the evidence for the identified studies of IPV.

Table 15. KQ2: Update summary of findings and SoE for safety of IPV in children

Vaccine	Outcome	N RCTs, N Other; N Participants; IDs of Studies Contributing to RR	Risk Estimate: RR; CI (Event Rates in Individual Studies); Other Studies Contributing to SoE	Reasons for Downgrading	Update Evidence Statement and SoE
Inactivated polio vaccine (IPV; IPOL®)	Acute disseminated encephalomyelitis	0 RCTs, 0 Other; N 0; 0 studies	One study[62] of children and adults detected no increased risk (aOR 0; 0.0, 270.1)	Study limitation,°°° Precision,^^ Consistency↑	Insufficient evidence
	Febrile seizures	0 RCTs, 0 Other; N 0; 0 studies	One study[96] reported no increased risk in the 0-1 days following IPV compared to a control period (IRR 1.41; CI 0.08, 24.53)	Study limitation,° Precision,^^ Consistency↑	Insufficient evidence

Vaccine	Outcome	N RCTs, N Other; N Participants; IDs of Studies Contributing to RR	Risk Estimate: RR; CI (Event Rates in Individual Studies); Other Studies Contributing to SoE	Reasons for Downgrading	Update Evidence Statement and SoE
	Seizures	0 RCTs, 0 Other; N 0; 0 studies	One study[235] reported no association (IRR 1.0; CI 0.7, 1.4 for 11-23 months), including across multiple age groups	Study limitation,° Precision,^^ Consistency↑	Insufficient evidence
	Anaphylaxis or systemic allergic reaction, angioedema, cardiovascular events, death, diabetes, Guillain-Barré syndrome, idiopathic thrombocytopenic purpura, stroke, transverse myelitis	0 RCTs, 0 Other; N 0; 0 studies	We did not identify studies reporting on the outcomes	N/A	Insufficient evidence

Notes: aOR—adjusted odds ratio; CI 95% confidence interval; ID—study identifier; IRR—incidence risk ratio; KQ—Key Question; N—number; N/A—not applicable; RR—relative risk; RCT—randomized controlled trials; SoE—strength of evidence; °—no unvaccinated control group; °°°—study in children and adults; ^—imprecise estimate with wide CI; ^^—study provides insufficient detail for further analyses and independent estimate of effect size not possible; ↑—consistency could not be assessed as no other study reported on the outcome

The prior 2014 report concluded that there was insufficient evidence for food allergy related reactions based on one post-licensure study in newborns. This finding remains unchanged as the current report did not examine this outcome. The prior 2014 report found high SoE for no association with childhood leukemia based on multiple large epidemiological studies; childhood leukemia was not examined as a key adverse event in the current report and the finding remains unchanged.

The update either found insufficient evidence or no studies reporting on other key adverse events.

Table 15a summarizes the findings across the prior 2014 report and the update.

Table 15a. KQ2: Safety of IPV in children

Vaccine (Abbreviation; Brand Name[s])	2014 Report SoE and Findings	SoE and Findings in Update	Synthesis of SoE and Findings
Inactivated polio (IPV; IPOL)	High: No association with childhood leukemia (not examined as a key adverse event in current report) Insufficient: Food allergy	Insufficient: Acute disseminated encephalomyelitis, febrile seizures, seizures No studies: Anaphylaxis or systemic allergic reaction, angioedema, cardiovascular events, death, diabetes, Guillain-Barré syndrome, idiopathic thrombocytopenic purpura, stroke, transverse myelitis	☐ Insufficient evidence (no findings related to key adverse events in prior 2014 report; insufficient evidence in update)

Key: ☐ White box indicates insufficient evidence to draw conclusions about the risk of specific adverse events; Notes: KQ—Key Question; SoE—Strength of Evidence

Influenza Vaccines

Table 16 documents the evidence for the identified studies of influenza vaccine in children.

Table 16. KQ2: Update summary of findings and SoE for safety of influenza vaccines in children

Vaccine	Outcome	N RCTs, N Other; N Participants; IDs of Studies Contributing to RR	Risk Estimate: RR; CI (Event Rates in Individual Studies); Other Studies Contributing to SoE	Reasons for Downgrading	Update Evidence Statement and SoE
Influenza, Inactivated (IIV; Afluria Quadrivalent, Fluarix Quadrivalent, Flulaval Quadrivalent, Fluzone Quadrivalent, Flucelvax Quadrivalent)	Anaphylaxis or systemic allergic reaction	2 RCTs, 0 Other; N 5091; Hartvickson, 2015,[129] Langley, 2013[152]	RR 1.41; CI 0.00, 8066971 (1/1149 vs 0/1149, 0/932 vs 1/1861)[&,#]	Study limitation,° Precision^	Low SoE for no evidence of increased risk
	Angioedema	1 RCT, 0 Other; N 2793; Langley, 2013[152]	RR 0.50; CI 0.02, 11.06 (0/932 vs 2/1861)[#]	Study limitation,° Precision,^ Consistency↑	Insufficient SoE for no evidence of increased risk
	Asthma	3 RCTs, 0 Other; N 7020; Greenberg, 2014,[117] Langley, 2013,[152] Langley, 2015[153]	RR 1.77; CI 0.03, 117 (8/2892 vs 0/734, 0/932 vs 0/1861, 0/299 vs 1/302)[&,#]	Study limitation,° Precision^	Low SoE for no evidence of increased risk
	Autism	1 RCT, 0 Other; N 3626; Greenberg, 2014[117]	RR 0.51; CI 0.02, 15.12 (1/2892 vs 0/734)[#]	Study limitation,° Precision,^ Consistency↑	Insufficient evidence
	Autoimmune disease	2 RCTs, 0 Other; N 2899; Hartvickson, 2015,[129] Langley, 2015[153]	RR 0.50; CI 0.00, 2849944; (Henoch-Schönlein purpura and ulcerative colitis; 0/1149 vs 1/1149, 0/299 vs 1/302)[#]	Study limitation,° Precision^	Low SoE for no evidence of increased risk

Vaccine	Outcome	N RCTs, N Other; N Participants; IDs of Studies Contributing to RR	Risk Estimate: RR; CI (Event Rates in Individual Studies); Other Studies Contributing to SoE	Reasons for Downgrading	Update Evidence Statement and SoE
Influenza, Inactivated (IIV; Afluria Quadrivalent, Fluarix Quadrivalent, Flulaval Quadrivalent, Fluzone Quadrivalent, Flucelvax Quadrivalent) (continued)	Cardiovascular events	3 RCT, 0 Other; N 9157; Domachowske, 2013,[94] Greenberg, 2014,[117] Langley, 2013[152]	RR 2.01; CI 0.03, 148 (myocarditis and bradycardia not considered related to the vaccine, hypertension, 1/915 vs 0/1823, 1/2892 vs 0/734, 1/932 vs 0/1861)[&,#]	Study limitation,° Precision^	Low SoE for no evidence of increased risk
	Death	6 RCTs, 0 Other; N 9828; Greenberg, 2014,[117] Hartvickson, 2015,[129] Langley, 2013,[152] Rodriguez, 2014,[188] Wang, 2016,[234] Walter, 2020[233]	RR 1.08; CI 0.02, 53.95 (0/99 vs 0/107) when compared to base treatment received by both the intervention and control groups;[#] combining with 5 RCTs that compared to trivalent IIV: RR 0.73; CI 0.10, 5.63	Precision^	Moderate SoE for no evidence of increased risk
	Diabetes	1 RCTs, 0 Other N 2738 Domachowske,2013[94]	RR 1.00; CI 0.03, 29.67 (0/915 vs 1/1823)[#]	Study limitation,° Precision,^ Consistency↑	Insufficient evidence
	Febrile seizures	4 RCTs, 0 Other; N 9758; Domachowske, 2013,[94] Greenberg, 2014,[117] Langley, 2013,[152] Langley, 2015[153]	RR 1.28; CI 0.17, 9.83 (0/915 vs 0/1823, 8/2892 vs 2/734, 0/932 vs 0/1861, 1/299 vs 0/302)[&,#] 1 additional study[160] of children aged 6-23 months found no increased risk when IIV4 was given alone (RR 1.2; CI 0.12, 11.20) or without PCV13, but increased risk when given with PCV13 (RR 12.3; CI 2.50, 58.90)	Study limitation,° Precision^	Low SoE for no evidence of increased risk
	Kawasaki disease	1 RCT, 0 Other; N 3626; Greenberg, 2014[117]	RR 1.52; CI 0.08, 30.37 (not considered related to the vaccine; 3/2892 vs 0/734)[&,#]	Study limitation,° Precision,^ Consistency↑	Insufficient evidence
	Seizures	5 RCTs, 0 Other; N 11769; Domachowske, 2013,[94] Greenberg, 2014,[117] Hartvickson, 2015,[129] Langley, 2013,[152] Wang, 2016[234]	RR 1.08; CI 0.11, 10.40 (0/915 vs 0/1823, 1/2892 vs 0/734, 1/1149 vs 0/1149, 0/932 vs 0/1861, 0/158 vs 1/156)[#]	Study limitation,° Precision^	Low SoE for no evidence of increased risk

Vaccine	Outcome	N RCTs, N Other; N Participants; IDs of Studies Contributing to RR	Risk Estimate: RR; CI (Event Rates in Individual Studies); Other Studies Contributing to SoE	Reasons for Downgrading	Update Evidence Statement and SoE
Influenza, Inactivated (IIV; Afluria Quadrivalent, Fluarix Quadrivalent, Flulaval Quadrivalent, Fluzone Quadrivalent, Flucelvax Quadrivalent) (continued)	Acute disseminated encephalomyelitis, Guillain-Barré syndrome, idiopathic thrombocytopenic purpura, stroke, transverse myelitis	0 RCTs, 0 Other; N 0; 0 studies	We did not identify studies reporting on the outcomes	N/A	Insufficient evidence
Influenza, live attenuated (LAIV; FluMist Quadrivalent)	Death	2 RCTs, 0 Other N 2438 Block, 2012;[69] Mallory, 2020[163]	RR 0.82; CI 0.00, 50615228 (0/1382 vs 0/923, 0/66 vs 0/67)[#]	Study limitation,° Precision,^	Low SoE for no evidence of increased risk
	Diabetes	1 RCTs, 0 Other N 2305 Block, 2012[69]	RR 1.34; CI 0.04, 39.77 (type 1 diabetes, not thought to be related to vaccination; 1/1382 vs 0/923)[&,#]	Study limitation,° Precision,^ Consistency↑	Insufficient evidence
	Encephalitis/encephalopathy	0 RCTs, 1 Other; N 123843; Baxter, 2017[61]	RR 1.00; CI 0.02, 50.20 (0/62040 vs 0/61803) (study of children and adults)[#]	Study limitation,° Precision,^ Consistency↑	Insufficient evidence
	Febrile seizures	1 Cohort study; N 540; Stockwell, 2017[207]	RR 1.39; CI 0.03, 69.76 (0/226 vs 0/341)[&, #]	Study limitation,° Precision,^ Consistency↑	Insufficient evidence
	Guillain-Barré syndrome	0 RCTs, 1 Other; N 123843; Baxter, 2017[61]	RR 1.00; CI 0.02, 50.2 (0/62040 vs 0/61803) (study of children and adults)[#]	Study limitation,°,°°° Precision,^ Consistency↑	Insufficient evidence
	Seizures	1 RCT, 1 Other; N 28209; Caspard, 2018,[76] Mallory, 2018a[164]	RR 1.80; CI 0.06, 53.57 (22/6745 vs 36/20163, 1/868 vs 0/433)[&, #]	Study limitation,° Precision^	Low SoE for no evidence of increased risk
	Stroke	1 RCTs, 0 Other N 2305 Block, 2012[69]	RR 0.33; CI 0.01, 9.94 (0/1382 vs 1/923)[#]	Study limitation,° Precision,^ Consistency↑	Insufficient evidence

Vaccine	Outcome	N RCTs, N Other; N Participants; IDs of Studies Contributing to RR	Risk Estimate: RR; CI (Event Rates in Individual Studies); Other Studies Contributing to SoE	Reasons for Downgrading	Update Evidence Statement and SoE
Influenza, live attenuated (LAIV; FluMist Quadrivalent) (continued)	Acute disseminated encephalomyelitis, anaphylaxis or systemic allergic reaction, angioedema, asthma, cardiovascular events, idiopathic thrombocytopenic purpura, transverse myelitis	0 RCTs, 0 Other; N 0; 0 studies	We did not identify studies reporting on the outcomes	N/A	Insufficient evidence

Notes: CI—95% confidence interval; ID—study identifier; KQ—Key Question; N—number; N/A—not applicable; RR—relative risk; RCT—randomized controlled trials; SoE—strength of evidence; &—potentially increased risk based on direction of effects across studies and investigated further but not statistically significant; #—none of the RR estimates in individual studies showed a statistically significantly increased risk; °—no unvaccinated control group; °°°—study in children and adults; ^—imprecise estimate with wide CI; ↑—consistency could not be assessed as no other study reported on the outcome

IIV. The prior 2014 report only assessed trivalent IIV or monovalent H1N1 influenza vaccine. There was moderate strength evidence of an association of trivalent IIV with mild gastrointestinal events, which were not examined as a key adverse event in the current report. The prior report also found increased risk of febrile seizures with trivalent IIV (based on a self-controlled case series). The prior 2014 report found low SoE for no association between any serious adverse events in the short term with trivalent IIV in children who have received organ transplants and . The prior 2014 report also found low SoE for an association between influenza-type symptoms in children and influenza vaccines (which included both trivalent IIV and LAIV). There was insufficient evidence for acute disseminated encephalomyelitis and transverse myelitis based on the IOM report (trivalent IIV and LAIV assessed together). None of the influenza vaccines examined in the prior 2014 report are still in use.

The current report examines quadrivalent IIV only and found moderate SoE for no evidence of death. The current report also found low SoE for no evidence of increased risk for anaphylaxis or systemic allergic reaction, asthma, autoimmune disease, cardiovascular events, febrile seizures, or seizures. The evidence was graded as insufficient for several key adverse events, with no studies for others.

LAIV. The prior 2014 report combined findings across LAIV and IIV, and quadrivalent LAIV was not reviewed in the prior 2014 report (only trivalent LAIV). The prior 2014 report showed low SoE for increased risk of influenza-like symptoms with trivalent LAIV. There was also low SoE for no association with any serious adverse events in the short term in children with cancer (not examined as a key adverse event in current report). There was insufficient evidence for asthma exacerbation (LAIV specifically) and acute disseminated encephalomyelitis or transverse myelitis (all influenza vaccines assessed together). Trivalent LAIV, which was the subject of the prior 2014 report, is no longer in use.

The current report found low SoE for no evidence of increased risk for death and seizures with quadrivalent LAIV compared to IIV. Evidence was graded as insufficient for several key

adverse events; there were no studies for other key adverse events. Table 16a summarizes the findings across the prior 2014 report and the update.

Table 16a. KQ2: Safety of influenza vaccines in children

Vaccine (Abbreviation; Brand Name[s])	2014 Report SoE and Findings	SoE and Findings in Update	Synthesis of SoE and Findings
Influenza, inactivated (IIV; Afluria Quadrivalent, Fluarix Quadrivalent, Flulaval Quadrivalent, Fluzone Quadrivalent, Flucelvax Quadrivalent)	Moderate: Mild gastrointestinal disorders (trivalent IIV), febrile seizures (trivalent IIV) Low: Influenza-like symptoms (trivalent IIV and LAIV) Low: No association with any serious adverse events in the short term in children who have received organ transplants (trivalent IIV) Insufficient: Acute disseminated encephalomyelitis, transverse myelitis (trivalent IIV and LAIV) Quadrivalent IIV not reviewed in prior report, only trivalent IIV and monovalent H1N1 influenza vaccine	Moderate: No evidence of increased risk of death for quadrivalent IIV Low: No evidence of increased risk of anaphylaxis or systemic allergic reaction, asthma, autoimmune disease, cardiovascular events, febrile seizures, seizures for quadrivalent IIV Insufficient: Angioedema, diabetes No studies: Acute disseminated encephalomyelitis, Guillain-Barré syndrome, idiopathic thrombocytopenic purpura, stroke, transverse myelitis	Moderate: No evidence of increased risk of death Low: No evidence of increased risk of anaphylaxis or systemic allergic reaction, asthma, autoimmune disease, cardiovascular events, febrile seizures, seizures Trivalent IIV and monovalent H1N1 influenza vaccine no longer in use
Influenza, live attenuated (LAIV; FluMist Quadrivalent)	Low: Influenza-like symptoms (trivalent IIV and trivalent LAIV) Low: No association with any serious adverse events in the short term in children with cancer (trivalent LAIV) Insufficient: Asthma exacerbation (trivalent LAIV only), acute disseminated encephalomyelitis, transverse myelitis (trivalent IIV and trivalent LAIV) Quadrivalent LAIV not reviewed in prior report	Low: No evidence of increased risk of death or seizures for quadrivalent LAIV Insufficient: Diabetes, febrile seizures, Guillain-Barré syndrome, stroke No studies: Acute disseminated encephalomyelitis, anaphylaxis or systemic allergic reaction, angioedema, asthma, cardiovascular events, idiopathic thrombocytopenic purpura, transverse myelitis	Low: No evidence of increased risk of death or seizures Trivalent LAIV no longer in use

Key: Green box indicates no evidence of increased risk of specific adverse events; Notes: KQ—Key Question; SoE—Strength of Evidence

Measles, Mumps, and Rubella Vaccine

Table 17 documents the evidence for the identified studies of MMR in children.

Table 17. KQ2: Update summary of findings and SoE for safety of MMR in children

Vaccine	Outcome	N RCTs, N Other; N Participants; IDs of Studies Contributing to RR	Risk Estimate: RR; CI (Event Rates in Individual Studies); Other Studies Contributing to SoE	Reasons for Downgrading	Update Evidence Statement and SoE
Measles, mumps, and rubella (MMR; M-M-R II)	Acute disseminated encephalomyelitis	0 RCTs, 0 Other; N 0; 0 studies	One study[62] reported no increased risk (aOR 5; CI 0.6, 26.9)	Study limitation,°°° Precision,^^ Consistency↑	Insufficient evidence
	Asthma	0 RCTs, 1 Other N 546 Timmermann, 2015[215]	RR 0.37; CI 0.20, 0.67 (70/524 vs 8/22)[#]	Study limitation,°°° Consistency↑	Low SoE of no evidence of increased risk
	Autism	0 RCTs, 2 Other; N 255554; Hviid, 2019,[138] Jain, 2015[141]	RR 0.60; CI 0.09, 4.12 (289/150831 vs 32/9738, 60/79216 vs 19/15769);[#] 1 additional study[224] reported no evidence of increased risk but provided not enough detail for further analyses	Study limitation°° Precision^^	Low SoE of no evidence of increased risk
	Febrile seizures	0 RCTs, 0 Other; N 0; 0 studies	One study[96] reported no increased risk in the 0-1 days following MMR compared to a control period (IRR 0.78; CI 0.44, 1.40)	Study limitation,° Precision,^^ Consistency↑	Insufficient evidence
	Optic neuritis	0 RCTs, 0 Other; N 0; 0 studies	One study[62] reported no increased risk (aOR 0; CI 0.0, 136.1)	Study limitation,°°° Precision,^^ Consistency↑	Insufficient evidence
	Seizure	0 RCTs, 0 Other; N 0; 0 studies	Two studies[113, 235] reported significantly increased risk of seizures, but in one study they were presumed to be predominantly febrile seizures; studies provided insufficient detail for further analyses	Study limitation,°° Precision^^ Consistency↑	Insufficient evidence
	Transverse myelitis	0 RCTs, 0 Other; N 0; 0 studies	One study[62] of children and adults reported no increased risk (aOR 0; CI 0.00, 129.8)	Study limitation,°°° Precision,^^ Consistency↑	Insufficient evidence

Vaccine	Outcome	N RCTs, N Other; N Participants; IDs of Studies Contributing to RR	Risk Estimate: RR; CI (Event Rates in Individual Studies); Other Studies Contributing to SoE	Reasons for Downgrading	Update Evidence Statement and SoE
Measles, mumps, and rubella (MMR; M-M-R II) (continued)	Anaphylaxis or systemic allergic reaction, angioedema, cardiovascular events, diabetes, death, encephalitis/encephalopathy, Guillain-Barré syndrome, idiopathic thrombocytopenic purpura, meningitis, multiple sclerosis, stroke	0 RCTs, 0 Other; N 0; 0 studies	We did not identify studies reporting on the outcomes	N/A	Insufficient evidence

Notes: aOR—adjusted odds ratio; CI—95% confidence interval; ID—study identifier; IRR—incidence risk ratio; KQ—Key Question; N—number; N/A—not applicable; RR—relative risk; RCT—randomized controlled trials; SoE—strength of evidence; #—none of the RR estimates in individual studies showed a statistically significantly increased risk; °—no unvaccinated control group; °°—effect based on observational evidence only; °°°—study in children and adults; ^—imprecise estimate with wide CI; ^^—study provides insufficient detail for further analyses and independent estimate of effect size not possible; ↑—consistency could not be assessed as no other study reported on the outcome; ↑↑↑—conflicting results across studies

The prior 2014 report found high SoE for no association with autism spectrum disorders based on the IOM report and an additional case-control study; this finding remains unchanged as the update found no evidence of increased risk based on two studies.

The prior 2014 report also found high SoE supporting a causal relationship between MMR and anaphylaxis in children with allergies based on IOM report, which was based on mechanistic evidence; the estimate of the magnitude of increased risk was not determined. This finding remains unchanged as there were no studies in the update. The prior 2014 report found an increased risk of febrile seizures, which was based on epidemiologic evidence from the IOM report as well as additional evidence from the prior 2014 report; no summary risk estimate could be calculated. This finding remains unchanged as there was insufficient evidence in the update for febrile seizures.

The prior 2014 report found moderate SoE supporting a causal relationship between MMR and transient arthralgia, which was based on mechanistic evidence from the IOM report; the estimate of the magnitude of increased risk was not determined. This finding remains unchanged as it was not examined as a key adverse event in the current report. The prior 2014 report found moderate SoE for a rare association with idiopathic thrombocytopenic purpura among children based on post-marketing studies (no summary risk estimate could be calculated); this finding also remains unchanged as there were no studies of this outcome in the update.

The update found low SoE for no evidence of increased risk of asthma.

The prior 2014 report found insufficient evidence for evidence statements regarding encephalitis, afebrile seizures, meningitis, cerebellar ataxia, acute disseminated

encephalomyelitis, transverse myelitis, optic neuritis, neuromyelitis optica, multiple sclerosis onset, and chronic arthropathy. These findings remain unchanged as the update either did not find studies examining these outcomes, did not include these outcomes as key adverse events, or the new evidence was graded as insufficient (for acute disseminated encephalomyelitis, optic neuritis, and transverse myelitis). There were also several key adverse events for which there were no studies. Finally, the prior 2014 report noted that the IOM report found that evidence convincingly supported a causal relationship between MMR and measles inclusion body encephalitis in immunocompromised patients; the SoE for this finding was not graded and was not carried forward into this report as MMR would not be administered to immunocompromised patients.

Table 17a summarizes the findings across the prior 2014 report and the update.

Table 17a. KQ2: Safety of MMR in children

Vaccine (Abbreviation; Brand Name[s])	2014 Report SoE and Findings	SoE and Findings in Update	Synthesis of SoE and Findings
Measles, mumps, and rubella (MMR; M-M-R II)	High: No association with autism spectrum disorders, or with childhood leukemia (not examined as a key adverse event in current report) High: Causal relationship between MMR and anaphylaxis in children with allergies based on mechanistic evidence High: Febrile seizures Moderate: Causal relationship between MMR and transient arthralgia based on mechanistic evidence (not examined as a key adverse event in current report) Moderate: Idiopathic thrombocytopenic purpura Insufficient: Encephalitis, encephalopathy, afebrile seizures, meningitis, cerebellar ataxia, acute disseminated encephalomyelitis, transverse myelitis, optic neuritis, neuromyelitis optica, multiple sclerosis, and chronic arthropathy	Low: No evidence of increased risk for asthma, autism Insufficient: Acute disseminated encephalomyelitis, febrile seizures, seizures, transverse myelitis No studies: Anaphylaxis or systemic allergic reaction, angioedema, cardiovascular events, diabetes, death, encephalitis/encephalopathy, Guillain-Barré syndrome, idiopathic thrombocytopenic purpura, meningitis, multiple sclerosis, stroke	High: No evidence of increased risk of autism spectrum disorders (no change from prior 2014 report; update also identified no evidence of increased risk) High: Anaphylaxis in children with allergies (no change from prior 2014 report; no new studies in update) High: Increased risk of febrile seizures (no change from prior 2014 report; insufficient evidence in update) Moderate: Increased risk of idiopathic thrombocytopenic purpura (no change from prior 2014 report; no new studies in update) Low: No evidence of increased risk for asthma

Key: Green box indicates no evidence of increased risk of specific adverse events; Red circle indicates evidence of risk of specific adverse events; Notes: KQ—Key Question; SoE—Strength of Evidence

Meningococcal Vaccines

Table 18 documents the evidence for the identified studies of meningococcal vaccine in children.

Table 18. KQ2: Update summary of findings and SoE for safety of meningococcal vaccines in children

Vaccine	Outcome	N RCTs, N Other; N Participants; IDs of Studies Contributing to RR	Risk Estimate: RR; CI (Event Rates in Individual Studies); Other Studies Contributing to SoE	Reasons for Downgrading	Update Evidence Statement and SoE
Meningococcal, A, C, W, and Y [MenACWY-D (Menactra), MenACWY-CRM (Menveo), MenACWY-TT (MenQuadfi)]	Acute disseminated encephalomyelitis	1 RCT, 0 Other; N 7728; Abdelnour, 2014[51]	RR 0.68; CI 0.02, 20.36 (1 case potentially related to vaccine; 1/5760 vs 0/1968);# another study[62] of children and adults reported no increased risk (aOR 0; CI 0.0, 17.5)	Precision,^ Consistency↑	Low SoE for no evidence of increased risk
	Anaphylaxis or systemic allergic reaction	1 RCT, 0 Other N 3311 Dhingra, 2020[93]	RR 0.24; CI 0.00, 11.95 (0/2676 vs 0/635) (study of children and adults);# in addition, 1 study[220] of children and adults reported no elevated risk	Study limitation,°°° Precision,^^	Low SoE for no evidence of increased risk
	Asthma	4 RCTs, 0 Other N 4188; Chang, 2020a,[78] Novartis Vaccines and Diagnostics, 2014,[105] Chang, 2020b,[79] Baccarini, 2020[57]	RR 1.51; CI 0.05, 44.86 (1/392 vs 0/296) when compared to base treatment received by both the intervention and control groups;&,# combining with 3 RCTs that compared to meningococcal polysaccharide: RR 1.14; CI 0.08, 16.49;& 1 study[127] reviewed incidence rates per 1000 person-months and reported no increased risk among those aged 2-10 years (RR 0.98; CI 0.03, 38.35) or 9-23 months (RR 1.48; 0.04, 57.69); 1 RCT[93] of both children and adults reported no increased risk (RR 0.47; CI 0.02, 14.13); another study[220] of children and adults reported no effect (RI 1.1; CI 0.9, 1.3)	Precision,^ Consistency↑↑↑	Low SoE for no evidence of increased risk
	Autoimmune disease	1 RCT, 0 Other N 3311 Dhingra, 2020[93]	RR 0.12; CI 0.00, 3.53 (0/2676 vs 1/635) (study of children and adults);# 1 study[220] of children and adults reported no elevated risk for rheumatoid arthritis, Henoch-Schonlein purpura, or autoimmune hemolytic anemia	Study limitation,°°° Precision^	Low SoE for no evidence of increased risk
	Autoimmune thyroiditis	0 RCTs, 0 Other; N 0; 0 studies	One study[220] of children and adults reported no statistically significant effect (RI 5.1; CI 0.5, 55.0)	Study limitation,°°° Precision,^^ Consistency↑	Insufficient evidence

Vaccine	Outcome	N RCTs, N Other; N Participants; IDs of Studies Contributing to RR	Risk Estimate: RR; CI (Event Rates in Individual Studies); Other Studies Contributing to SoE	Reasons for Downgrading	Update Evidence Statement and SoE
Meningococcal, A, C, W, and Y [MenACWY-D (Menactra), MenACWY-CRM (Menveo), MenACWY-TT (MenQuadfi)] (continued)	Cardiovascular events	2 RCTs, 0 Other N 8720; Abdelnour, 2014[51] Baccarini, 2020[57]	RR 0.34; CI 0.02, 5.46 (tachycardia; 1/5760 vs 1/1968) when compared to base treatment received by both the intervention and control groups;# combining with another RCT that compared to another meningococcal vaccine: RR 0.69; CI 0.00, 762141; 1 RCT[93] of children and adults also found no increased risk of coronary artery disease (RR 0.47; CI 0.02, 14.13)	Precision^	Moderate SoE for no evidence of increased risk
	Death	7 RCTs, 0 Other; N 13657; Klein, 2012,[978] Abdelnour, 2014,[51] Chang, 2020a,[78] Novartis Vaccines and Diagnostics s.r.l, 2014,[105] Gasparini, 2014,[112] Chang, 2020b,[79] Baccarini, 2020[57]	RR 1.37; CI 0.11, 16.65 0/629 vs 0/311, 7/5772 vs 1/1968, 0/396 vs 0/397, 0/392 vs 0/296) in 4 studies when compared to placebo or base treatment;&,# combining with 3 RCTs that compared to another meningococcal vaccine: RR 1.17; CI 0.24, 5.73;& 3 studies[56, 93, 157] of children and adults reported no increased risk: RR 0.50; CI <0.00, 71.42	Precision,^ Consistency↑↑↑	Low SoE for no evidence of increased risk
	Diabetes	3 RCTs, 0 Other; N 2485; Chang, 2020a,[78] Gasparini, 2014,[112] Chang, 2020b[79]	RR 1.32; CI 0.00, 21861366 (1/396 vs 0/397, 0/392 vs 0/296) when compared to placebo or base treatment received by both the intervention and control groups;&,# combining with another RCT that compared to another meningococcal vaccine: RR 1.53; CI 0.02, 137;& 1 RCT[93] of both children and adults found no increased risk of diabetes: RR 0.47; CI 0.02, 14.13; 1 additional study[220] of children and adults reported no increased risk; a retrospective cohort study[128] considered 1 case of new-onset diabetes mellitus in a participant with family history possibly related;	Precision^	Moderate SoE for no evidence of increased risk

Vaccine	Outcome	N RCTs, N Other; N Participants; IDs of Studies Contributing to RR	Risk Estimate: RR; CI (Event Rates in Individual Studies); Other Studies Contributing to SoE	Reasons for Downgrading	Update Evidence Statement and SoE
Meningococcal, A, C, W, and Y [MenACWY-D (Menactra), MenACWY-CRM (Menveo), MenACWY-TT (MenQuadfi)] (continued)	Encephalitis/ encephalopathy	1 RCT, 0 Other; N 7728; Abdelnour, 2014[51]	RR 0.68; CI 0.02, 20.36 (encephalitis potentially related to the vaccine1/5760 vs 0/1968)#	Precision,^ Consistency↑	Low SoE for no evidence of increased risk
	Febrile seizures	3 RCTs, 0 Other; N 10220; Abdelnour, 2014[51] Novartis Vaccines and Diagnostics s.r.l, 2014,[105] Baccarini, 2020,[57]	RR 0.51; CI 0.18, 1.44 (9/5760 vs 6/1968) when compared to base treatment received by both the intervention and control groups;# combining with 2 RCTs that compared to another meningococcal vaccine: RR 0.57; CI 0.07, 4.65; 1 study[127] reviewed incidence rates per 1000 person-months and reported no increased risk among those aged 9-23 months (RR not evaluable)	Precision^^^	Moderate SoE for no evidence of increased risk
	Guillain-Barré syndrome	1 RCT, 0 Other N 992 Baccarini, 2020[57]	RR 0.99; CI 0.02, 49.89 (0/498 vs 0/494)#	Study limitation,° Precision,^^ Consistency↑	Insufficient evidence
	Intussusception	1 RCT, 0 Other; N 7728; Abdelnour, 2014[51]	RR 0.46; CI 0.10, 2.03 (4/5760 vs 3/1968)#	Consistency↑	Moderate SoE for no evidence of increased risk
	Idiopathic thrombocytopenic purpura	2 RCTs, 0 Other; N 8720; Abdelnour, 2014[51] Baccarini, 2020[57]	RR 0.17; CI 0.01, 5.09 (0/5760 vs 1/1968) when compared to base treatment received by both the intervention and control groups;# combining with another RCT that compared to another meningococcal vaccine: RR 0.36; CI 0.00, 6069454. 1 study[220] of children and adults reported no elevated risk (no risk estimate as one case in risk window and comparison) but did not report sufficient detail for further analyses	Precision^	Moderate SoE for no evidence of increased risk

Vaccine	Outcome	N RCTs, N Other; N Participants; IDs of Studies Contributing to RR	Risk Estimate: RR; CI (Event Rates in Individual Studies); Other Studies Contributing to SoE	Reasons for Downgrading	Update Evidence Statement and SoE
Meningococcal, A, C, W, and Y [MenACWY-D (Menactra), MenACWY-CRM (Menveo), MenACWY-TT (MenQuadfi)] (continued)	Kawasaki disease	2 RCTs, 0 Other; N 8720; Abdelnour, 2014[51] Baccarini, 2020[57]	RR 1.37; CI 0.15, 12.22 (2 of the 4 observed cases were possibly related to MenACWY-CRM; 4/5760 vs 1/1968) when compared to base treatment received by both the intervention and control groups;[&, #] combining with another RCT that compared to another meningococcal vaccine: RR 1.27; CI 0.00, 306194	Precision,^	Moderate SoE for no evidence of increased risk
	Meningitis	1 RCT, 0 Other; N 7728; Abdelnour, 2014[51]	RR 0.68; CI 0.02, 20.36 (1/5760 vs 0/1968)[#]	Precision,^ Consistency↑	Low SoE for no evidence of increased risk
	Multiple sclerosis	1 RCTs, 0 Other; N 3311; Sanofi Pasteur, 2017[93]	RR 0.47; CI 0.02, 14.13 (1/2676 vs 0/635) (study of adults and children);[#] 1 additional study[220] of children and adults reported no elevated risk	Study limitation,°°° Precision^	Low SoE for no evidence of increased risk
	Optic neuritis	0 RCTs, 0 Other; N 0; 0 studies	One study[62] reported no statistically significant effect (aOR 2.7; CI 0.3, 15.6)	Study limitation,°°° Precision,^^ Consistency↑	Insufficient evidence
	Reproductive system events	1 RCT, 0 Other; N 7728; Abdelnour, 2014[51]	RR 0.68; CI 0.02, 20.36 (1/5760 vs 0/1968);[#] 1 study[173] of adults and children reported no increased risk of primary ovarian failure (aHR 0.94; CI 0.27, 3.23)	Precision,^ Consistency↑	Low SoE for no evidence of increased risk

Vaccine	Outcome	N RCTs, N Other; N Participants; IDs of Studies Contributing to RR	Risk Estimate: RR; CI (Event Rates in Individual Studies); Other Studies Contributing to SoE	Reasons for Downgrading	Update Evidence Statement and SoE
Meningococcal, A, C, W, and Y [MenACWY-D (Menactra), MenACWY-CRM (Menveo), MenACWY-TT (MenQuadfi)] (continued)	Seizure	4 RCTs, 0 Other; N 4184; Chang, 2020a,[78] Novartis Vaccines and Diagnostics s.r.l, 2014,[105] Chang, 2020b,[79] Baccarini, 2020[57]	RR 1.51; CI 0.05, 44.86 (1/392 vs 0/296) when compared to base treatment received by both the intervention and control groups;[&,#] combining with 3 RCTs that compared to another meningococcal vaccine: RR 0.97; CI 0.07, 12.98); 1 study[127] of children looked at incidence rates per 1000 person-months and reported no increased risk among those aged 2-10 years (RR 0.00; 0.00, 18.68); 1 RCT[93] of both children and adults that compared MenACWY-TT to MenACWY-D found no increased risk of seizures: RR 0.47; CI 0.02, 14.13; 1 study[220] of children and adults reported no elevated risk for seizure confirmed by chart review (no risk estimate as no cases in the risk window) but did not report sufficient detail for further analyses	Precision^	Moderate SoE for no evidence of increased risk
	Spontaneous abortion	1 RCTs, 0 Other N 3311 Dhingra, 2020[93]	RR 0.47; CI 0.02, 14.13 (1/2676 vs 0/635) (study of adults and children)[#]	Study limitation,°°° Precision,^ Consistency↑	Insufficient evidence
	Transverse myelitis	0 RCTs, 0 Other; N 0; 0 studies	One study[220] of children and adults reported no elevated risk (no risk estimate as no cases in risk window); another study[62] of children and adults reported no statistically significant effect (aOR 5.2; CI 0.2, 70.9 for both)	Study limitation,°°° Precision^^	Low SoE for no evidence of increased risk
	Angioedema, stroke	0 RCTs, 0 Other; N 0; 0 studies	We did not identify studies reporting on the outcomes	N/A	Insufficient evidence
Meningococcal B [MenB; MenB-4C (Bexsero), MenB-FHbp (Trumenba)]	Anaphylaxis or systemic allergic reaction	2 RCTs, 0 Other; N 1812; Richmond, 2012,[186] Senders, 2016[196]	RR 0.56; CI 0.00, 34735108 (0/198 vs 0/121, 0/992 vs 0/501)[#]	Study limitation°	Moderate SoE for no evidence of increased risk
	Asthma	1 RCT, 0 Other; N 319; Richmond, 2012[186]	RR 0.61; CI 0.01, 30.6 (0/198 vs 0/121)[#]	Precision,^ Consistency↑	Low SoE for no evidence of increased risk

Vaccine	Outcome	N RCTs, N Other; N Participants; IDs of Studies Contributing to RR	Risk Estimate: RR; CI (Event Rates in Individual Studies); Other Studies Contributing to SoE	Reasons for Downgrading	Update Evidence Statement and SoE
Meningococcal B [MenB; MenB-4C (Bexsero), MenB-FHbp (Trumenba)] (continued)	Cardiovascular events	1 RCT, 0 Other; N 319; Richmond, 2012[186]	RR 0.61; CI 0.01, 30.6 (0/198 vs 0/121)[#]	Study limitation,° Precision,^ Consistency↑	Insufficient evidence
	Death	2 RCTs, 0 Other; N 2245; Senders, 2016,[196] Vesikari, 2016[230]	RR 1.12; CI 0.00, 18531125 (1 motor crash; 0/992 vs 0/501, 1/374 vs 0/378)[&, #]	Precision,^ Consistency↑	Low SoE for no evidence of increased risk
	Idiopathic thrombocytopenic purpura	1 RCT, 0 Other; N 752; Vesikari, 2016[230]	RR 2.02; CI 0.07, 60.07 (1/374 vs 0/378)[&, #]	Study limitation,° Precision,^ Consistency↑	Insufficient evidence
	Reproductive system events	3 RCTs, 0 Other; N 1344; Richmond, 2012,[186] Lee, 2016,[156] Vesikari, 2016[230]	RR 0.89; CI 0.01, 65.20 (e.g., ovarian cyst 1/198 vs 0/121, 1/174 vs 0/99, 0/374 vs 1/378)[#]	Precision,^	Moderate SoE for no evidence of increased risk
	Seizure	1 RCT, 0 Other; N 262; Lee, 2016[156]	RR 0.25; CI 0.01, 7.46 (0/174 vs 1/88)[#]	Precision,^ Consistency↑	Low SoE for no evidence of increased risk
	Acute disseminated encephalomyelitis, angioedema, diabetes, encephalitis/ encephalopathy, Guillain-Barré syndrome, multiple sclerosis, stroke, transverse myelitis	0 RCTs, 0 Other; N 0; 0 studies	We did not identify studies reporting on the outcomes	N/A	Insufficient evidence

Notes: aHR—adjusted hazard ratio; aOR—adjusted odds ratio; CI—95% confidence interval; ID—study identifier; KQ—Key Question; N—number; N/A—not applicable; RI—relative incidence; RR—relative risk; RCT—randomized controlled trials; SoE—strength of evidence; &—potentially increased risk based on direction of effects across studies and investigated further but not statistically significant; #—none of the RR estimates in individual studies showed a statistically significantly increased risk; °—no unvaccinated control group; °°—effect based on observational evidence only; °°°—study in children and adults; ^—imprecise estimate with wide CI; ^^—study provides insufficient detail for further analyses and independent estimate of effect size not possible; ^^^—the CI crosses the point of no difference and it was not possible to completely rule out the risk of adverse event; ↑—consistency could not be assessed as no other study reported on the outcome

MenACWY. The prior 2014 report found moderate SoE supporting a causal relationship between MenACWY and anaphylaxis in children with allergies, based on mechanistic evidence from the IOM report; the estimate of the magnitude of increased risk was not determined. In the update, there was low SoE for no evidence of increased risk of anaphylaxis or systemic allergic reaction among all children (not restricted to those with allergies to the vaccine) based on two studies.

The prior 2014 report found insufficient evidence for encephalitis, acute disseminated encephalomyelitis, transverse myelitis, multiple sclerosis, Guillain-Barré syndrome, chronic inflammatory demyelinating polyneuropathy, and chronic headache. The following outcomes were upgraded to low SoE for no evidence of increased risk based on new studies identified in the update: acute disseminated encephalomyelitis, encephalitis/encephalopathy, multiple sclerosis, and transverse myelitis. Evidence for Guillain-Barré syndrome, chronic inflammatory demyelinating polyneuropathy, and chronic headache remained insufficient, either because the evidence was graded as insufficient (as for Guillain-Barré syndrome) or because the outcomes were not included as key adverse events.

The update also found moderate SoE for no evidence of increased risk for cardiovascular events, diabetes, febrile seizures, intussusception, idiopathic thrombocytopenic purpura, Kawasaki disease, or seizures. The update found low SoE for no evidence of increased risk of asthma, autoimmune disease, death, meningitis, or reproductive system events. The evidence was graded as insufficient evidence or there were no studies for several other key adverse events.

MenB. MenB was not in use at the time of the prior 2014 report. The current report found moderate SoE for no evidence of increased risk for anaphylaxis or systemic allergic reaction or reproductive system events, and low SoE for no evidence of increased risk for asthma, death, or seizures. The evidence was graded as insufficient or there were no studies for several other key adverse events. Table 18a summarizes the findings across the prior 2014 report and the update.

Table 18a. KQ2: Safety of meningococcal vaccines in children

Vaccine (Abbreviation; Brand Name[s])	2014 Report SoE and Findings	SoE and Findings in Update	Synthesis of SoE and Findings
Meningococcal, A, C, W, and Y (MenACWY; MenACWY-D [Menactra], MenACWY-CRM [Menveo], MenACWY-TT [MenQuadfi])	Moderate: Causal relationship between meningococcal vaccines and anaphylaxis in children with allergies based on mechanistic evidence Insufficient: Encephalitis, encephalopathy, acute disseminated encephalomyelitis, transverse myelitis, multiple sclerosis, Guillain-Barré syndrome, chronic inflammatory demyelinating polyneuropathy, chronic headache Included MenACWY-D, MenACWY-CRM and meningococcal polysaccharide vaccine; did not include MenACWY-TT which was not in use	Moderate: No evidence of increased risk of cardiovascular events, diabetes, febrile seizures, intussusception, idiopathic thrombocytopenic purpura, Kawasaki disease, seizures Low: No evidence of increased risk of acute disseminated encephalomyelitis, anaphylaxis or systemic allergic reaction, asthma, autoimmune disease, death, encephalitis/encephalopathy, meningitis, multiple sclerosis, reproductive system events, transverse myelitis Insufficient: Guillain-Barré syndrome No studies: Angioedema, stroke	Moderate: Anaphylaxis in children with allergies (no change from prior 2014 report; update shows low SoE of no evidence of increased risk among all children) Moderate: No evidence of increased risk of cardiovascular events, diabetes, febrile seizures, intussusception, idiopathic thrombocytopenic purpura, Kawasaki disease, seizures Low: No evidence of increased risk of acute disseminated encephalomyelitis, anaphylaxis or systemic allergic reaction, asthma, autoimmune disease, death, encephalitis/encephalopathy, meningitis, multiple sclerosis, reproductive system events, transverse myelitis

Vaccine (Abbreviation; Brand Name[s])	2014 Report SoE and Findings	SoE and Findings in Update	Synthesis of SoE and Findings
Meningococcal B (MenB; MenB-4C [Bexsero], MenB-FHbp [Trumenba])	MenB not in use at time of prior report	Moderate: No evidence of increased risk of anaphylaxis or systemic allergic reaction, reproductive system events Low: No evidence of increased risk of asthma, death, seizures Insufficient: Cardiovascular events, idiopathic thrombocytopenic purpura No studies: Acute disseminated encephalomyelitis, angioedema, diabetes, encephalitis/encephalopathy, Guillain-Barré syndrome, multiple sclerosis, stroke, transverse myelitis	Moderate: No evidence of increased risk of anaphylaxis or systemic allergic reaction, reproductive system events Low: No evidence of increased risk of asthma, death, seizures

Key: Green box indicates no evidence of increased risk of specific adverse events; Red circle indicates evidence of risk of specific adverse events; Notes: KQ—Key Question; SoE—Strength of Evidence

Pneumococcal Vaccines

Table 19 documents the evidence for the identified studies of pneumococcal vaccines in children.

Table 19. KQ2: Update summary of findings and SoE for safety of pneumococcal vaccines in children

Vaccine	Outcome	N RCTs, N Other; N Participants; IDs of Studies Contributing to RR	Risk Estimate: RR; CI (Event Rates in Individual Studies); Other Studies Contributing to SoE	Reasons for Downgrading	Update Evidence Statement and SoE
13-valent pneumococcal conjugate vaccine (PCV13; Prevnar 13)	Acute disseminated encephalomyelitis	0 RCTs, 0 Other; N 0; 0 studies	One study[62] reported no statistically significant effect (aOR 3.6; CI 0.1, 95.4)	Study limitation,°°° Precision,^^ Consistency↑	Insufficient evidence
	Anaphylaxis or other systemic allergic reaction	0 RCTs, 0 Other; N 0; 0 studies	One study[221] reported no increased risk but provided insufficient detail for further analyses	Study limitation,°°° Precision,^^ Consistency↑	Insufficient evidence
	Angioedema	0 RCTs, 0 Other; N 0; 0 studies	One study[221] reported no increased risk but provided insufficient detail for further analyses	Study limitation,°°° Precision,^^ Consistency↑	Insufficient evidence
	Asthma	3 RCTs, 0 Other; N 2295; Kim, 2013,[146] Dagan, 2013,[87] Togashi, 2015[217]	RR 1.49; CI 0.15, 14.39 (not considered related to the vaccine; 1/84 vs 0/88, 7/882 vs 5/875, 1/183 vs 0/183);&,# 1 additional study[221] reported no increased risk	Study limitation,° Precision^	Low SoE for no evidence of increased risk

Vaccine	Outcome	N RCTs, N Other; N Participants; IDs of Studies Contributing to RR	Risk Estimate: RR; CI (Event Rates in Individual Studies); Other Studies Contributing to SoE	Reasons for Downgrading	Update Evidence Statement and SoE
13-valent pneumococcal conjugate vaccine (PCV13; Prevnar 13) (continued)	Autoimmune disease	1 RCT, 0 Other; N 1860; Dagan, 2013[87]	RR 2.00; CI 0.07, 59.67 (Henoch-Schönlein purpura; 1/929 vs 0/931)[&,#]	Study limitation,° Precision,^ Consistency↑	Insufficient evidence
	Cardiovascular events	3 RCTs, 0 Other; N 2749; Kim, 2013,[146] Amdekar, 2013,[55] Dagan, 2013[87]	RR 0.60; CI 0.01, 38.23 (0/88 vs 1/89, 0/354 vs 2/355, 1/930 vs 0/933)[#]	Study limitation,° Precision^	Low SoE for no evidence of increased risk
	Death	5 RCTs, 0 Other; N 3396; Kim, 2013,[146] Amdekar, 2013,[55] Cutland, 2018,[86] Dagan, 2013,[87] Togashi, 2015[217]	RR 2.02; CI 0.07, 59.88 (death considered unrelated to vaccine; 1/193 vs 0/195) when compared to base treatment received by both the intervention and control groups; [&,#] combining with 4 other RCTs that compared to PCV7: RR 1.18; CI 0.12, 11.32[&,#]	Precision^	Moderate SoE for no evidence of increased risk
	Encephalopathy/ encephalitis	0 RCTs, 0 Other; N 0; 0 studies	One study[221] reported no increased risk (confirmed by chart review)	Study limitation,°°° Precision,^^ Consistency↑	Insufficient evidence
	Febrile seizures	2 RCTs, 1 Other; N 1219; Amdekar, 2013,[55] Stockwell, 2014,[206] Togashi, 2015[217]	RR 0.98; CI 0.02, 49.22 (0/212 vs 0/208) when compared to base treatment received by both the intervention and control groups;[#] combining with 2 other RCTs that compared to PCV7: RR 1.24; CI 0.12, 12.81;[&,#] 1 additional study[221] that compared to PCV7 reported no increased risk; 1 other study[96] also reported no increased risk in the 0-1 days following PCV13 compared to a control period (IRR 1.41; CI 0.08, 24.53) but another study[59] did report an increased risk (IRR 1.80; CI 1.29, 2.5)	Precision,^ Consistency↑↑↑	Low SoE for no evidence of increased risk
	Idiopathic thrombocytopenic purpura	0 RCTs, 0 Other; N 0; 0 studies	One study[221] reported no increased risk of thrombocytopenia	Study limitation,°°° Precision,^^ Consistency↑	Insufficient evidence
13-valent pneumococcal	Intussusception	2 RCT, 0 Other; N 2040; Kim, 2013,[146] Dagan, 2013[87]	RR 1.33; CI 0.00, 1437199 (1/88 vs 0/89, 1/930 vs 1/933)[&,#]	Study limitation,° Precision^	Low SoE for no evidence of increased risk

Vaccine	Outcome	N RCTs, N Other; N Participants; IDs of Studies Contributing to RR	Risk Estimate: RR; CI (Event Rates in Individual Studies); Other Studies Contributing to SoE	Reasons for Downgrading	Update Evidence Statement and SoE
conjugate vaccine (PCV13; Prevnar 13) (continued)	Kawasaki disease	2 RCT, 0 Other; N 543; Kim, 2013,[146] Togashi, 2015[217]	RR 1.33; CI 0.00, 1407345 (1/88 vs 0/89, 1/183 vs 1/183);[&,#] 1 study[58] reported no association in a dataset of 6 million doses of PCV13 another study[221] that compared PCV13 to PCV7 reported no statistically significant effect (RR 1.94; CI 0.79, 4.86); 1 self-controlled case series analysis[238] reported increased risk only of complete Kawasaki disease (among 7 patients) following dose 1	Study limitation,° Precision,^ Consistency↑↑↑	Insufficient evidence
	Meningitis	2 RCTs, 0 Other; N 2570; Amdekar, 2013,[55] Dagan, 2013[87]	RR 1.32; CI 0.00, 1451908 (1/354 vs 0/355, 1/930 vs 1/931)[&,#]	Study limitation,° Precision^	Low SoE for no evidence of increased risk
	Reproductive system events	2 RCT, 0 Other; N 1934; Kim, 2013,[146] Dagan, 2013[87]	RR 1.49; CI 0.00, 24350819 (0/88 vs 0/89, 1/882 vs 0/875)[&,#]	Study limitation,° Precision^	Low SoE for no evidence of increased risk
	Seizure	3 RCTs, 0 Other; N 2749; Kim, 2013,[146] Amdekar, 2013,[55] Dagan, 2013[87]	RR 0.91; CI 0.05, 15.11 (0/88 vs 1/89, 2/354 vs 2/355, 2/930 vs 2/933)[#]	Study limitation,° Precision^	Low SoE for no evidence of increased risk
	Stroke	1 RCT, 0 Other; N 1863; Dagan, 2013[87]	RR 0.50; CI 0.02, 14.93 (0/930 vs 1/933)[#]	Precision,^ Consistency↑	Insufficient evidence
	Transverse myelitis	0 RCTs, 0 Other; N 0; 0 studies	One study[62] of children and adults reported no risk of optic neuritis (aOR 0; CI 0, 64.6) but the study reported insufficient detail for further analyses	Study limitation,°°° Precision,^ Consistency↑	Insufficient evidence
	Diabetes, Guillain-Barré syndrome	0 RCTs, 0 Other; N 0; 0 studies	We did not identify studies reporting on the outcomes	N/A	Insufficient evidence
23-valent pneumococcal polysaccharide vaccine (PPSV23; Pneumovax)	Acute disseminated encephalomyelitis	0 RCTs, 0 Other; N 0; 0 studies	One study[62] reported no statistically significant risk (aOR 0; CI 0.0, 14.5)	Study limitation,°°° Precision,^^ Consistency↑	Insufficient evidence
	Febrile seizures	0 RCTs, 0 Other; N 0; 0 studies	One study[96] reported no increased risk in the 0-1 days following PPSV23 compared to a control period	Study limitation,° Precision,^^ Consistency↑	Insufficient evidence
	Optic neuritis	0 RCTs, 0 Other; N 0; 0 studies	One study[62] reported no statistically significant risk (aOR 3.4; CI 0.4, 23.3)	Study limitation, °°° Precision,^^ Consistency↑	Insufficient evidence

Vaccine	Outcome	N RCTs, N Other; N Participants; IDs of Studies Contributing to RR	Risk Estimate: RR; CI (Event Rates in Individual Studies); Other Studies Contributing to SoE	Reasons for Downgrading	Update Evidence Statement and SoE
23-valent pneumococcal polysaccharide vaccine (PPSV23; Pneumovax) (continued)	Transverse myelitis	0 RCTs, 0 Other; N 0; 0 studies	One study[62] reported no increased risk (aOR 0; CI 0.0, 9.4)	Study limitation, °°° Precision,^^ Consistency↑	Insufficient evidence
	Anaphylaxis or systemic allergic reaction, angioedema, cardiovascular events, death, diabetes, Guillain-Barré syndrome, idiopathic thrombocytopenic purpura, seizure, stroke	0 RCTs, 0 Other; N 0; 0 studies	We did not identify studies reporting on the outcomes	N/A	Insufficient evidence

Notes: aOR-adjusted odds ratio; CI—95% confidence interval; ID—study identifier; IRR—incidence risk ratio; KQ—Key Question; N—number; N/A—not applicable; RR—relative risk; RCT—randomized controlled trials; SoE—strength of evidence; &—potentially increased risk based on direction of effects across studies and investigated further but not statistically significant; #—none of the RR estimates in individual studies showed a statistically significantly increased risk; °—no unvaccinated control group; °°°—study in children and adults; ^—imprecise estimate with wide CI; ^^—study provides insufficient detail for further analyses and independent estimate of effect size not possible; ↑—consistency could not be assessed as no other study reported on the outcome; ↑↑↑—conflicting results across studies

PCV13. The prior 2014 report found moderate strength evidence of an increased risk of febrile seizures with PCV13 among children based on one very large epidemiological study; no summary risk estimate could be calculated. The update identified six studies with conflicting evidence around the risk of febrile seizures (graded as low SoE for no evidence of increased risk). Thus, the original finding was downgraded from moderate to low SoE for an increased risk of febrile seizures.

The update found moderate SoE for no evidence of increased risk for death (most studies compared PCV13 to PCV7). The update also found low SoE for no evidence of increased risk for asthma, cardiovascular events, intussusception, meningitis, reproductive system events, or seizures (all compared PCV13 to PCV7). The update found insufficient evidence for several other key adverse events, and no studies for others.

PPSV23. There were no studies of PPSV23 in children in the prior 2014 report. In the update, the evidence was either graded as insufficient or there were no studies; thus, there was insufficient evidence to draw conclusions. Table 19a summarizes the findings across the prior 2014 report and the update.

Table 19a. KQ2: Safety of pneumococcal vaccines in children

Vaccine (Abbreviation; Brand Name[s])	2014 Report SoE and Findings	SoE and Findings in Update	Synthesis of SoE and Findings
13-valent pneumococcal conjugate (PCV13; Prevnar 13)	Moderate: Febrile seizures	Moderate: No evidence of increased risk of death Low: No evidence of increased risk of asthma, cardiovascular events, febrile seizures, intussusception, meningitis, reproductive system events, seizures Insufficient: Acute disseminated encephalomyelitis, anaphylaxis or systemic allergic reaction, angioedema, idiopathic thrombocytopenic purpura, stroke, transverse myelitis No studies: Diabetes, Guillain-Barré syndrome	Moderate: No evidence of increased risk of death Low: No evidence of increased risk of asthma, cardiovascular events, intussusception, meningitis, reproductive system events, seizures Low: Increased risk of febrile seizures (downgraded from prior 2014 report for inconsistency as update identified some studies reporting no increased risk)
23-valent pneumococcal polysaccharide (PPSV23; Pneumovax)	No findings	Insufficient: Acute disseminated encephalomyelitis, febrile seizures, transverse myelitis No studies: Anaphylaxis or systemic allergic reaction, angioedema, cardiovascular events, death, diabetes, Guillain-Barré syndrome, idiopathic thrombocytopenic purpura, seizures, stroke	Insufficient evidence to draw conclusions

Key: Green box indicates no evidence of increased risk of specific adverse events; Red circle indicates evidence of risk of specific adverse events; White box indicates insufficient evidence to draw conclusions about the risk of specific adverse events; Notes: KQ—Key Question; SoE—Strength of Evidence

Rotavirus Vaccines

The large number of identified studies evaluating rotavirus vaccines is documented in Table 20.

Table 20. KQ2: Update summary of findings and SoE for safety of rotavirus vaccines in children

Vaccine	Outcome	N RCTs, N Other; N Participants; IDs of Studies Contributing to RR	Risk Estimate: RR; CI (Event Rates in Individual Studies); Other Studies Contributing to SoE	Reasons for Downgrading	Update Evidence Statement and SoE
Rotavirus (RV; Rotarix, RotaTeq)	Anaphylaxis or systemic allergic reaction	1 RCTs, 0 Other; N 69766; Vesikari, 2006[1045]	RR 0.50; CI 0.02, 14.89 (0/34904 vs 1/34862)#	Precision,^ Consistency↑	Low SoE for no evidence of increased risk

Vaccine	Outcome	N RCTs, N Other; N Participants; IDs of Studies Contributing to RR	Risk Estimate: RR; CI (Event Rates in Individual Studies); Other Studies Contributing to SoE	Reasons for Downgrading	Update Evidence Statement and SoE
Rotavirus (RV; Rotarix, RotaTeq) (continued)	Asthma	5 RCTs, 0 Other; N 81186; Kawamura,2011,[967] Madhi,2010,[988] Vesikari, 2006,[1045] Li, 2014,[161] Mo, 2017[169]	RR 1.33; CI 0.65, 2.72 (5/508 vs 3/257, 3/1647 vs 2/1641, 10/34904 vs 11/34862, 3/1666 vs 1/1667, 17/2015 vs 9/2019)[&,#]	Precision^	Moderate SoE for no evidence of increased risk (Precision)
	Autoimmune disease	1 RCTs, 1 Other N 129994 Vesikari, 2006,[1045] Vaarala, 2017[225]	RR 0.65; CI 0.16, 2.67 (celiac disease; 48/5764 vs 29/2580, 201/94437 vs 92/27213)[#]	Precision^	Moderate SoE for no evidence of increased risk
	Autoimmune thyroiditis (Hashimoto's disease)	1 RCTs, 0 Other N 8344 Vesikari, 2006[1045]	RR 0.22; CI 0.02, 2.47; (1/5764 vs 2/2580)[#]	Precision,^ Consistency↑	Low SoE for no evidence of increased risk
	Cardiovascular events	6 RCTs, 1 Other; N 88509; Madhi, 2010,[988] Armah, 2010,[909] Vesikari, 2006,[1045] Kerdpanich,2010,[969] Briggs-Steinberg, 2019,[73] Li, 2014,[161] Mo, 2017[169]	RR 1.79; CI 1.00, 3.20 (1/1647 vs 0/1641, 1/3744 vs 0/3745, 2/34904 vs 1/34862, 1/174 vs 0/26, 38/201 vs 20/198, 1/1666 vs 0/1667, 1/2015 vs 1/2019),[##]	Study limitation,°°°° Precision,^ Consistency↑↑↑	Insufficient evidence
	Death	14 RCTs, 0 Other; N 153798; Kawamura, 2011,[967] Steele, 2010,[1025] Vesikari, 2006,[1041] Armah, 2010,[909] Vesikari, 2006,[1045] Ruiz-Palacios, 2006,[1016] Omenaca, 2012,[1005] Zaman, 2009,[1054] Kim,2012,[973] Kerdpanich, 2010,[969] Phua,2005,[1011] Iwata, 2013,[139] Li, 2014,[161] Mo, 2017[169]	RR 1.05; CI 0.82, 1.35 (0/508 vs 0/257, 2/190 vs 0/96, 0/328 vs 0/324, 79/3741 vs 86/3742, 24/34904 vs 20/34862, 56/31673 vs 43/31552, 0/670 vs 1/339, 1/196 vs 0/98, 0/508 vs 0/176, 0/174 vs 0/26, 2/653 vs 0/653, 1/380 vs 0/381, 6/1666 vs 7/1667, 0/2015 vs 0/2019)[&,#] 1 study[130] found a decrease in the absolute number of sudden deaths in the region after introduction of rotavirus vaccine	Study limitation°	Moderate SoE for no evidence of increased risk

Vaccine	Outcome	N RCTs, N Other; N Participants; IDs of Studies Contributing to RR	Risk Estimate: RR; CI (Event Rates in Individual Studies); Other Studies Contributing to SoE	Reasons for Downgrading	Update Evidence Statement and SoE
Rotavirus (RV; Rotarix, RotaTeq) (continued)	Diabetes	1 RCTs, 2 Other N 457138 Vesikari, 2006,[1045] Vaarala, 2017,[225] Glanz, 2020[115]	RR 0.74; CI 0.45, 1.22; (33/3184 vs 25/2580, 243/94437 vs 102/27213, 402/320881 vs 16/8843);# 1 additional study[189] found a 33% reduction in risk of type 1 diabetes compared to unvaccinated (IRR 0.59; CI 0.48, 0.73)	N/A	High SoE for no evidence of increased risk
	Encephalitis/encephalopathy	2 RCTs, 0 Other; N 73054; Madhi, 2010,[988] Vesikari, 2006[1045]	RR 0.67; CI 0.00, 85995; (1/1647 vs 2/1641, 1/34904 vs 1/34862);# 1 study[155] also found no increased risk in the 30 days following any dose of RV (mostly RV5); another study[130] found a decrease in the absolute number of encephalitis/encephalopathy in the region after introduction of rotavirus vaccine)	Precision^	Moderate SoE for no evidence of increased risk
	Febrile seizures	7 RCTs, 0 Other; N 90073; Kawamura, 2011,[967] Madhi, 2010,[988] Vesikari, 2006,[1045] Kerdpanich, 2010,[969] Li, 2014,[161] Mo, 2017,[169] Phua, 2012[1010]	RR 0.82; CI 0.33, 2.05 (4/508 vs 1/257, 4/1647 vs 6/1641, 6/34904 vs 4/34862, 0/174 vs 1/26, 0/1666 vs 2/1667, 0/2015 vs 3/2019, 1/4359 vs 0/4328);# 1 study[96] also reported no increased risk in the 0-1 days following RV5 compared to a control period (IRR 1.12; CI 0.49 to 2.54); 1 other study[155] also found no increased risk in the 30 days following any dose of RV (mostly RV5)	Precision^	Moderate SoE for no evidence of increased risk
	Idiopathic thrombocytopenic purpura	2 RCTs, 0 Other N 78453 Vesikari, 2006,[1045] Phua, 2012[1010]	RR 0.64; CI 0.00, 1778394 (1/34904 vs 0/34862, 0/4359 vs 2/4328)#	Precision^	Moderate SoE for no evidence of increased risk

Vaccine	Outcome	N RCTs, N Other; N Participants; IDs of Studies Contributing to RR	Risk Estimate: RR; CI (Event Rates in Individual Studies); Other Studies Contributing to SoE	Reasons for Downgrading	Update Evidence Statement and SoE
Rotavirus (RV; Rotarix, RotaTeq) (continued)	Intussusception	19 RCTs, 0 Other; N 170173; Kawamura, 2011[967], Vesikari, 2011,[1042] Steele, 2010,[1025] Madhi, 2010,[988] Vesikari, 2006,[1041] Armah, 2010,[909] Vesikari, 2004,[1044] Chang, 2009,[924] Kim, 2008,[972] Vesikari, 2006,[1045] Ruiz-Palacios, 2006,[1016] Omenaca, 2012,[1005] Kim, 2012,[973] Vesikari, 2007,[229] Phua, 2005,[1011] Iwata, 2013,[139] Li, 2014,[161] Mo, 2017,[169] Phua, 2012[1010]	RR 0.65; CI 0.41, 1.05 (0/508 vs 0/257, 0/86 vs 0/44, 0/190 vs 0/96, 0/1647 vs 0/1641, 0/328 vs 0/324, 0/3744 vs 1/3745, 0/265 vs 0/133, 0/95 vs 0/93, 0/115 vs 0/63, 13/34904 vs 22/34862, 9/31673 vs 16/31552, 0/670 vs 0/339, 0/508 vs 0/176, 2/2646 vs 1/1348, 0/653 vs 1/653, 0/380 vs 0/381, 1/1666 vs 1/1667, 2/2015 vs 0/2019, 2/4359 vs 1/4328);# 19 additional studies that did not provide sufficient detail for further analyses reported conflicting results.[74, 75, 83, 102, 106, 108, 122, 131, 133, 135, 155, 168, 175, 208, 212, 213, 223, 236, 237]	Consistency↑↑↑	Moderate SoE for no evidence of increased risk
	Kawasaki disease	3 RCTs, 0 Other N 79218 Kawamura, 2011,[967] Vesikari, 2006,[1045] Phua, 2012[1010]	RR 2.08; CI 0.04, 123 (1/508 vs 1/257, 5/34904 vs 0/34862, 1/4359 vs 0/4328);&,# 1 study[155] also found no increased risk in the 30 days following any dose of RV (mostly RV5); 1 study[135] found no increased risk in a primary analysis (1-28 days), but found an increased risk in a secondary analysis for some doses (RotaTeq, dose 2, at 15-21 days and Rotarix, dose 1 at 22-28 days); 1 study[223] reported no increase in Kawasaki disease-related hospitalizations after introduction of rotavirus vaccine	Precision,^ Consistency↑↑↑	Low SoE for no evidence of increased risk

Vaccine	Outcome	N RCTs, N Other; N Participants; IDs of Studies Contributing to RR	Risk Estimate: RR; CI (Event Rates in Individual Studies); Other Studies Contributing to SoE	Reasons for Downgrading	Update Evidence Statement and SoE
Rotavirus (RV; Rotarix, RotaTeq) (continued)	Meningitis	5 RCTs, 0 Other; N 84637; Madhi, 2010,[988] Armah, 2010,[909] Vesikari, 2006,[1045] Iwata, 2013,[139] Li, 2014[161]	RR 1.18; CI 0.36, 3.89 (7/1647 vs 2/1641, 4/3744 vs 6/3745, 3/34904 vs 4/34862, 1/380 vs 0/381, 1/1666 vs 0/1667);&,# 1 study[155] also found no increased risk in the 30 days following any dose of RV (mostly RV5)	Study limitation,° Precision^	Low SoE for no evidence of increased risk
	Reproduction system events	1 RCTs, 0 Other; N 69766; Vesikari, 2006[1045]	RR 2.00; CI 0.07, 59.54; (testicular torsion; 1/34904 vs 0/34862)&,#	Precision,^ Consistency↑	Low SoE for no evidence of increased risk
	Seizure	5 RCTs, 0 Other; N 85342; Kawamura, 2011,[967] Madhi, 2010,[988] Armah, 2010,[909] Vesikari, 2006,[1045] Mo, 2017[169]	RR 1.02; CI 0.25, 4.16 (1/508 vs 2/257, 1/1647 vs 3/1641, 1/3744 vs 1/3745, 17/34904 vs 9/34862, 1/2015 vs 0/2019);&,# 1 study[155] also found no increased risk in the 30 days following any dose of RV (mostly RV5); another study[235] found no increased risk of seizures in the 0-7 days following vaccination; another study[190] found that as rotavirus coverage increased, hospitalization for seizures decreased	Precision^	Moderate SoE for no evidence of increased risk
	Stroke	2 RCTs, 0 Other; N 73099; Vesikari, 2006,[1045] Li, 2014[161]	RR 1.32; CI 0.00, 1459247 (1/34904 vs 0/34862, 1/1666 vs 1/1667)&,#	Precision^	Moderate SoE for no evidence of increased risk
	Transverse myelitis	0 RCTs, 0 Other; N 0; 0 studies	One study[62] of children and adults reported no increased risk (aOR 0; CI 0.00, 73.5)	Study limitation,°°° Precision,^ Consistency↑	Insufficient evidence
	Acute disseminated encephalomyelitis, angioedema, Guillain-Barré syndrome	0 RCTs, 0 Other; N 0; 0 studies	We did not identify studies reporting on the outcomes	N/A	Insufficient evidence

Notes: aOR—adjusted odds ratio; CI—95% confidence interval; ID—study identifier; IRR—incidence risk ratio; KQ—Key Question; N—number; N/A—not applicable; RR—relative risk; RCT—randomized controlled trials; SoE—strength of evidence; &—potentially increased risk based on direction of effects across studies and investigated further but not statistically significant; #—none of the RR estimates in individual studies showed a statistically significantly increased risk; ##— 1 out of 7 studies reported an increased risk (RR 1.87; CI 1.13, 3.10; bradycardia events 38/201 vs 20/198 in premature infants [in whom the

physiology is more likely to be neurologic in nature than cardiac]; the effect was not shown in a second sample reported in the same study73); °—no unvaccinated control group; °°°—study in children and adults; °°°°—possible causal mechanism not investigated; ^—imprecise estimate with wide CI; ↑—consistency could not be assessed as no other study reported on the outcome; ↑↑↑—conflicting results across studies

The prior 2014 report found no other associations other than moderate SoE for increased risk of intussusception. The update found that the moderate SoE for risk from the last report was not confirmed when combining all studies that report sufficient detail at the latest time of follow-up. Some, but not all, observational studies showed increased risk of intussusception, particularly following the first dose of rotavirus vaccine. Taking all of the evidence together, the current report found moderate SoE for no risk of intussusception with rotavirus vaccine at the time of latest follow-up (SoE downgraded due to mixed results from observational studies that could not be combined).

The update found high SoE for no evidence of increased risk of diabetes, and moderate SoE for no evidence of increased risk for asthma, autoimmune disease, death, encephalitis/encephalopathy, febrile seizures, idiopathic thrombocytopenic purpura, seizures, or stroke. The update found low SoE for no evidence of increased risk of anaphylaxis or systemic allergic reaction, autoimmune thyroiditis (Hashimoto's disease), Kawasaki disease, meningitis, or reproductive system events. The current report found insufficient evidence or no studies for some key adverse events. Table 20a summarizes the findings across the prior 2014 report and the update.

Table 20a. KQ2: Safety of rotavirus vaccines in children

Vaccine (Abbreviation; Brand Name[s])	2014 Report SoE and Findings	SoE and Findings in Update	Synthesis of SoE and Findings
Rotavirus (RV; Rotarix, RotaTeq)	Moderate: Intussusception	High: No evidence of increased risk of diabetes Moderate: No evidence of increased risk of asthma, autoimmune disease, death, encephalitis/encephalopathy, febrile seizures, idiopathic thrombocytopenic purpura, intussusception, seizures, stroke Low: No evidence of increased risk of anaphylaxis or systemic allergic reaction, autoimmune thyroiditis (Hashimoto's disease), Kawasaki disease, meningitis, reproductive system events Insufficient: Cardiovascular events, transverse myelitis No studies: Acute disseminated encephalomyelitis, angioedema, Guillain-Barré syndrome	High: No evidence of increased risk of diabetes Moderate: No evidence of increased risk of intussusception (moderate SoE for increased risk from prior 2014 report was not confirmed when combining all available trials at the time of latest follow-up, though some observational studies showed increased risk). Moderate: No evidence of increased risk of asthma, autoimmune disease, death, encephalitis/encephalopathy, febrile seizures, idiopathic thrombocytopenic purpura, seizures, stroke Low: No evidence of increased risk of anaphylaxis or systemic allergic reaction, autoimmune thyroiditis (Hashimoto's disease), Kawasaki disease, meningitis, reproductive system events

Key: Green box indicates no evidence of increased risk of specific adverse events; Notes: KQ—Key Question; SoE—Strength of Evidence

Varicella Vaccine

Table 21 documents the evidence for the identified varicella studies.

Table 21. KQ2: Update summary of findings and SoE for safety of varicella vaccines in children

Vaccine	Outcome	N RCTs, N Other; N Participants; IDs of Studies Contributing to RR	Risk Estimate: RR; CI (Event Rates in Individual Studies); Other Studies Contributing to SoE	Reasons for Downgrading	Update Evidence Statement and SoE
Varicella (VAR; Varivax)	Acute disseminated encephalomyelitis	0 RCTs, 0 Other; N 0; 0 studies	One study[62] reported no systematic increased risk (aOR 4.3; CI 0.5, 25.4)	Study limitation, °°° Precision,^ Consistency↑	Insufficient evidence
	Febrile seizures	0 RCTs, 0 Other; N 0; 0 studies	One study[96] reported no increased risk in the 0-1 days following VAR compared to a control period (IRR 0.80; CI 0.45, 1.42)	Study limitation,° Precision,^ Consistency↑	Insufficient evidence

Vaccine	Outcome	N RCTs, N Other; N Participants; IDs of Studies Contributing to RR	Risk Estimate: RR; CI (Event Rates in Individual Studies); Other Studies Contributing to SoE	Reasons for Downgrading	Update Evidence Statement and SoE
Varicella (VAR; Varivax) (continued)	Optic neuritis	0 RCTs, 0 Other; N 0; 0 studies	One study[62] detected no systematic increased risk (aOR 2.1; CI 0.1, 23.2)	Study limitation, °°° Precision,^ Consistency↑	Insufficient evidence
	Seizure	0 RCTs, 0 Other; N 0; 0 studies	One study[235] reported no increased risk of seizures (a study that overlapped this study's time period entirely found an increased risk, but presumed to be due to MMR administered on the same day, which was not adjusted for)	Study limitation,° Precision,^ Consistency↑	Insufficient evidence
	Transverse myelitis	0 RCTs, 0 Other; N 0; 0 studies	One study[62] of children and adults reported no increased risk (aOR 0; CI 0.0, 10.7)	Study limitation,°°° Precision,^^ Consistency↑	Insufficient evidence
	Anaphylaxis or systemic allergic reaction, angioedema, ataxia, cardiovascular events, death, diabetes, encephalitis/encephalopathy, Guillain-Barré syndrome, herpes zoster, idiopathic thrombocytopenic purpura, meningitis, secondary transmission of live varicella virus, stroke	0 RCTs, 0 Other; N 0; 0 studies	We did not identify studies reporting on the outcomes	N/A	Insufficient evidence

Notes: aOR—adjusted odds ratio; CI—95% confidence interval; ID—study identifier; KQ—Key Question N—number; N/A—not applicable; RR—relative risk; RCT—randomized controlled trials; SoE—strength of evidence; °—no unvaccinated control group; °°°—study in children and adults; ^—imprecise estimate with wide CI; ^^—insufficient detail; ↑—consistency could not be assessed as no other study reported on the outcome; ↑↑↑—conflicting results across studies

The prior 2014 report found high SoE supporting a causal relationship between varicella vaccine and the following, based on mechanistic evidence from the IOM report: anaphylaxis; disseminated Oka varicella zoster virus without other organ involvement; disseminated Oka attenuated varicella zoster virus with subsequent infection resulting in pneumonia, meningitis, or hepatitis in individuals with demonstrated immunodeficiencies; vaccine strain viral reactivation without other organ involvement (herpes zoster); and vaccine strain viral reactivation with subsequent infection resulting in meningitis or encephalitis; estimates of the magnitude of increased risk was not determined. All of these findings remain unchanged, as there are no studies addressing these outcomes in the update.

The prior 2014 report also found moderate strength evidence of a rare association with thrombocytopenic purpura among children aged 11 to 17 years based on one large epidemiological study (no summary risk estimate could be calculated); this finding remains unchanged given that no new studies of this outcome were identified in this report.

At the time of the prior 2014 report, there was insufficient evidence regarding seizures, acute disseminated encephalomyelitis, transverse myelitis, Guillain-Barré syndrome, small fiber neuropathy, onset or exacerbation of arthropathy, and thrombocytopenia. SoE for these findings remains insufficient as new evidence was either graded as insufficient (for seizures, acute disseminated encephalomyelitis, and transverse myelitis), there were no studies, or the outcome was not included as a key adverse event. There was insufficient evidence or no studies for several other key adverse events.

Table 21a summarizes the findings across the prior 2014 report and the update.

Table 21a. KQ2: Safety of varicella vaccines in children

Vaccine (Abbreviation; Brand Name[s])	2014 Report SoE and Findings	SoE and Findings in Update	Synthesis of SoE and Findings
Varicella (VAR; Varivax)	High: Causal relationship between varicella vaccine and anaphylaxis; disseminated Oka strain of varicella zoster virus without other organ involvement (not examined as key adverse events in current report); disseminated Oka strain of varicella zoster virus with subsequent infection resulting in pneumonia, meningitis, or hepatitis in individuals with demonstrated immunodeficiencies (not examined as key adverse events in current report); vaccine strain viral reactivation without other organ involvement (herpes zoster); vaccine strain viral reactivation with subsequent infection resulting in meningitis or encephalitis, all based on mechanistic evidence Moderate: Idiopathic thrombocytopenic purpura among children aged 11 to 17 years Insufficient: Seizures, acute disseminated encephalomyelitis, transverse myelitis, Guillain-Barré syndrome, small fiber neuropathy, onset or exacerbation of arthropathy, thrombocytopenia	Insufficient: Acute disseminated encephalomyelitis, febrile seizures, seizures, transverse myelitis No studies: Anaphylaxis or systemic allergic reaction, angioedema, ataxia, cardiovascular events, death, diabetes, encephalitis/encephalopathy, Guillain-Barré syndrome, herpes zoster, idiopathic thrombocytopenic purpura, meningitis, secondary transmission of live varicella virus, stroke	High: Anaphylaxis; vaccine strain viral reactivation without other organ involvement (herpes zoster); and vaccine strain viral reactivation with subsequent infection resulting in meningitis or encephalitis (no change from prior 2014 report; no new studies in update) Moderate: Increased risk of idiopathic thrombocytopenic purpura among children aged 11 to 17 years (no change from prior 2014 report; no new studies in update)

Key: 🔴 Red circle indicates evidence of risk of specific adverse events; Notes: KQ—Key Question; SoE—Strength of Evidence

Combination Vaccines

Table 22 documents the evidence for the identified studies evaluating combination vaccines in children.

Table 22. KQ2: Update summary of findings and SoE for safety of combination vaccines in children

Vaccine	Outcome	N RCTs, N Other; N Participants; IDs of Studies Contributing to RR	Risk Estimate: RR; CI (Event Rates in Individual Studies); Other Studies Contributing to SoE	Reasons for Downgrading	Update Evidence Statement and SoE
DTaP-IPV-Hib-HepB (Vaxelis)	Asthma	2 RCTs, 0 Other; N 4250; Block, 2017,[70] Marshall, 2015[166]	RR 0.68; CI 0.00, 222465 (1/2390 vs 0/397, 2/983 vs 1/480)#	Study limitation,° Precision^	Low SoE for no evidence of increased risk
	Autoimmune disease	1 RCTs, 0 Other; N 2787; Block, 2017[70]	One RCT reported no increased risk of Crohn's disease: RR 0.33; CI 0.01, 9.89 (1/2390 vs 0/397)#	Study limitation,° Precision,^ Consistency↑	Insufficient evidence
	Death	3 RCTs, 0 Other; N 4550; Tapiero, 2013,[211] Block, 2017,[70] Marshall, 2015[166]	RR 0.90; CI 0.02, 45.23 (0/151 vs 0/149, 5/2390 vs 0/397, 1/980 vs 1/483)#	Study limitation,° Precision^	Low SoE for no evidence of increased risk
	Diabetes	1 RCT, 0 Other; N 2787; Block, 2017[70]	RR 0.33; CI 0.01, 9.89 (1/2390 vs 0/397)#	Study limitation,° Precision,^ Consistency↑	Insufficient evidence
	Febrile seizures	3 RCTs, 0 Other; N 4551; Tapiero, 2013,[211] Block, 2017,[70] Marshall, 2015[166]	RR 0.71; CI 0.03, 19.24 (0/151 vs 0/150, 4/2390 vs 0/397, 2/980 vs 2/483)#	Study limitation° Precision^	Low SoE for no evidence of increased risk
	Idiopathic thrombocytopenic purpura	1 RCT, 0 Other; N 2787; Block, 2017[70]	RR 0.33; CI 0.01, 9.89 (1/2390 vs 0/397)#	Study limitation,° Precision,^ Consistency↑	Insufficient evidence
	Intussusception	1 RCT, 0 Other; N 2787; Block, 2017[70]	RR 0.33; CI 0.01, 9.89 (1/2390 vs 0/397)#	Study limitation,° Precision,^ Consistency↑	Insufficient evidence

Vaccine	Outcome	N RCTs, N Other; N Participants; IDs of Studies Contributing to RR	Risk Estimate: RR; CI (Event Rates in Individual Studies); Other Studies Contributing to SoE	Reasons for Downgrading	Update Evidence Statement and SoE
DTaP-IPV-Hib-HepB (Vaxelis) (continued)	Kawasaki disease	1 RCT, 0 Other; N 1463; Marshall, 2015[166]	RR 0.25; CI 0.01, 7.33 (0/980 vs 1/483)#	Study limitation,° Precision,^ Consistency↑	Insufficient evidence
	Meningitis	2 RCTs, 0 Other; N 4250; Block, 2017,[70] Marshall, 2015[166]	RR 0.42; CI 0.00, 462552 (1/2390 vs 0/397, 1/980 vs 1/483)#	Study limitation,° Precision^	Low SoE for no evidence of increased risk
	Acute disseminated encephalomyelitis, anaphylaxis or systemic allergic reaction, angioedema, autoimmune thyroiditis (Hashimoto's disease), brachial neuritis, cardiovascular events, encephalitis/encephalopathy, Guillain-Barré syndrome, multiple sclerosis, myocardial infarction, optic neuritis, seizures, stroke, transverse myelitis	0 RCTs, 0 Other; N 0; 0 studies	We did not identify studies reporting on the outcomes	N/A	Insufficient evidence
DTaP-HepB-IPV (Pediarix)	Febrile seizures	0 RCTs, 0 Other; N 0; 0 studies	One study[96] reported no increased risk in the 0-1 days following DTaP-HepB-IPV compared to a control period (IRR 1.64; CI 0.62, 4.35)	Study limitation,°° Precision,^^ Consistency↑	Insufficient evidence
	Transverse myelitis	0 RCTs, 0 Other; N 0; 0 studies	One study[62] reported no increased risk of acute disseminated encephalomyelitis (aOR 0; CI 0.0, 10.7)	Study limitation,°°° Precision,^^ Consistency↑	Insufficient evidence
	Acute disseminated encephalomyelitis, anaphylaxis or systemic allergic reaction, angioedema, autoimmune disease, brachial neuritis, autoimmune thyroiditis (Hashimoto's disease), cardiovascular events, death, diabetes, encephalitis/encephalopathy, Guillain-Barré syndrome, idiopathic thrombocytopenic purpura, multiple sclerosis, myocardial infarction, optic neuritis, seizures, stroke	0 RCTs, 0 Other; N 0; 0 studies	We did not identify studies reporting on the outcomes	N/A	Insufficient evidence

Vaccine	Outcome	N RCTs, N Other; N Participants; IDs of Studies Contributing to RR	Risk Estimate: RR; CI (Event Rates in Individual Studies); Other Studies Contributing to SoE	Reasons for Downgrading	Update Evidence Statement and SoE
DTaP-IPV/Hib (Pentacel) DTaP-IPV/Hib (Pentacel) (continued)	Acute disseminated encephalomyelitis	0 RCTs, 0 Other; N 0; 0 studies	One study[62] of children and adults reported no increased risk (aOR 0; CI 0, 40.7)	Study limitation,°°° Precision,^^ Consistency↑	Insufficient evidence
	Anaphylaxis or systemic allergic reaction	0 RCTs, 0 Other; N 0; 0 studies	One study[174] reported no increase in serious allergic reaction (OR 1; CI 0.34, 2.99)	Study limitation,°° Precision,^^ Consistency↑	Low SoE for no evidence of increased risk
	Encephalitis/encephalopathy	0 RCTs, 0 Other; N 0; 0 studies	One study[174] reported no increase in encephalitis (OR 0.78; CI 0.23, 2.69)	Study limitation,°° Precision,^^ Consistency↑	Insufficient evidence
	Febrile seizures	0 RCTs, 0 Other; N 0; 0 studies	One study[96] reported no increased risk in the 0-1 days following DTaP-Hib-IPV compared to a control period (IRR 0.72; CI 0.13, 3.85)	Study limitation,°° Precision,^^ Consistency↑	Insufficient evidence
	Guillain-Barré syndrome	0 RCTs, 0 Other; N 0; 0 studies	One study[174] reported no cases of Guillain-Barré syndrome	Study limitation,°° Precision,^^ Consistency↑	Insufficient evidence
	Seizure	0 RCTs, 0 Other; N 0; 0 studies	One study[174] reported no increase in seizure (OR 0.91; CI 0.52, 1.57)	Study limitation,°° Precision,^^ Consistency↑	Insufficient evidence
	Angioedema, brachial neuritis, cardiovascular events, death, diabetes, idiopathic thrombocytopenic purpura, stroke, transverse myelitis	0 RCTs, 0 Other; N 0; 0 studies	We did not identify studies reporting on the outcomes	N/A	Insufficient evidence
DTaP-IPV (Kinrix, Quadracel)	Acute disseminated encephalomyelitis	0 RCTs, 0 Other; N 0; 0 studies	One study[62] of children and adults reported no increased risk (aOR 0; CI 0, 40.7)	Study limitation,°°° Precision,^^ Consistency↑	Insufficient evidence
	Anaphylaxis or systemic allergic reaction	0 RCTs, 0 Other; N 0; 0 studies	One study[88] reported no statistically significant risk	Study limitation,°° Precision,^^ Consistency↑	Insufficient evidence
	Angioedema	0 RCTs, 0 Other; N 0; 0 studies	One study[88] reported no statistically significant risk	Study limitation,°° Precision,^^ Consistency↑	Insufficient evidence

Vaccine	Outcome	N RCTs, N Other; N Participants; IDs of Studies Contributing to RR	Risk Estimate: RR; CI (Event Rates in Individual Studies); Other Studies Contributing to SoE	Reasons for Downgrading	Update Evidence Statement and SoE
DTaP-IPV (Kinrix, Quadracel) (continued)	Encephalitis	0 RCTs, 0 Other; N 0; 0 studies	One study[88] reported no increased risk of meningitis, encephalitis, or myelitis; a study[62] in children and adults reported no statistically significant effect (aOR 4.1; CI 0.1-44.0)	Study limitation,°° Precision^^	Low SoE for no evidence of increased risk
	Guillain-Barré syndrome	0 RCTs, 0 Other; N 0; 0 studies	One study[88] reported no statistically significant risk	Study limitation,°° Precision,^^ Consistency↑	Insufficient evidence
	Seizures	0 RCTs, 0 Other; N 0; 0 studies	One study[88] reported no statistically significant risk	Study limitation,°° Precision,^^ Consistency↑	Insufficient evidence
	Stroke	0 RCTs, 0 Other; N 0; 0 studies	One study[88] reported no statistically significant risk	Study limitation,°° Precision,^^ Consistency↑	Insufficient evidence
	Brachial neuritis, cardiovascular events, death, diabetes, idiopathic thrombocytopenic purpura, transverse myelitis	0 RCTs, 0 Other; N 0; 0 studies	We did not identify studies reporting on the outcomes	N/A	Insufficient evidence
MMR-V (ProQuad)	Acute disseminated encephalomyelitis	0 RCTs, 0 Other; N 0; 0 studies	Two cohort studies[62, 149] (1 in children and adults) reported no increased risk (no estimable risk for first study; aOR 0; CI 0.00, 292.0 in 2nd study)	Study limitation,°°° Precision^^	Low SoE for no evidence of increased risk
	Anaphylaxis or systemic allergic reaction	0 RCTs, 0 Other; N 0; 0 studies	One cohort study[149] reported an increased risk (RR 15.34; CI 2.16, 108.86) but on chart review both cases were noted not to be anaphylaxis	Study limitation,° Precision,^^ Consistency↑	Insufficient evidence
	Ataxia	0 RCTs, 0 Other; N 0; 0 studies	One cohort study[149] reported no increased risk	Study limitation,° Precision,^^ Consistency↑	Insufficient evidence
	Death	1 RCT, 0 Other; N 713; Deichmann, 2015[89]	RR 0.50; CI 0.01, 25.33; (0/474 vs 0/239)#	Precision,^ Consistency↑	Low SoE for no evidence of increased risk

Vaccine	Outcome	N RCTs, N Other; N Participants; IDs of Studies Contributing to RR	Risk Estimate: RR; CI (Event Rates in Individual Studies); Other Studies Contributing to SoE	Reasons for Downgrading	Update Evidence Statement and SoE
MMR-V (ProQuad) (continued)	Febrile seizures	1 RCT, 0 Other; N 713; Deichmann, 2015[89]	RR 2.02; CI 0.09, 44.55 (in participants with concomitant infections 2/474 vs 0/239);[&,#] 1 cohort study[148] reported an increased risk during the 7-10 days following MMR-V compared to MMR and varicella vaccines given separately (RR 1.98; CI 1.43, 2.73); 1 study[96] (partially overlapping with the above study, but using a different risk window) reported no increased risk of febrile seizures in the 0-1 days following MMR-V compared to a control period (IRR 1.12; CI 0.49, 2.54)	Study limitation,° Precision^ Consistency↑↑↑	Insufficient evidence
	Idiopathic thrombocytopenic purpura	0 RCTs, 0 Other; N 0; 0 studies	One cohort study[149] reported an increased risk for some some time intervals	Study limitation,° Precision,^^ Consistency↑	Insufficient evidence
	Kawasaki disease	0 RCTs, 0 Other; N 0; 0 studies	One cohort study[149] reported no increased risk	Study limitation,° Precision,^^ Consistency↑	Insufficient evidence
	Meningitis	0 RCTs, 0 Other; N 0; 0 studies	One cohort study[149] reported no increased risk of meningitis/encephalitis (combined outcome)	Study limitation,° Precision,^^ Consistency↑	Insufficient evidence
	Seizures	0 RCTs, 0 Other; N 0; 0 studies	Two studies[149, 167] reported an increased risk of seizures	Study limitation,°° Precision,^^ Consistency↑↑↑↑	Insufficient evidence

Vaccine	Outcome	N RCTs, N Other; N Participants; IDs of Studies Contributing to RR	Risk Estimate: RR; CI (Event Rates in Individual Studies); Other Studies Contributing to SoE	Reasons for Downgrading	Update Evidence Statement and SoE
MMR-V (ProQuad) (continued)	Angioedema, autism, cardiovascular events, diabetes, encephalitis/encephalopathy, Guillain-Barré syndrome, herpes zoster, multiple sclerosis, secondary transmission of live varicella virus, stroke, transverse myelitis	0 RCTs, 0 Other; N 0; 0 studies	We did not identify studies reporting on the outcomes	Study limitation,° Precision,^^ Consistency↑	Insufficient evidence

Notes: aOR—adjusted odds ratio; CI—95% confidence interval; ID—study identifier; IRR—incidence risk ratio; KQ—Key Question; N—number; N/A—not applicable; RR—relative risk, RCT—randomized controlled trials; SoE—strength of evidence; &—potentially increased risk based on direction of effects across studies and investigated further but not statistically significant; #—none of the RR estimates in individual studies showed a statistically significantly increased risk; °—no unvaccinated control group; °°—effect based on observational evidence only; °°°—study in children and adults; °°°°—possible causal mechanism not investigated; ^—imprecise estimate with wide CI; ^^—the study reported insufficient detail for an independent effect estimate; ↑—consistency could not be assessed as no other study reported on the outcome; ↑↑↑—conflicting results across studies; ↑↑↑↑—the two studies reported on in parts on the same dataset rather than independent data

DTaP-IPV-Hib-HepB. The current report examines DTaP-IPV-Hib-HepB, which was not in use at the time of the prior 2014 report. The current report found low SoE for no evidence of increased risk for asthma, death, febrile seizures, or meningitis, and evidence was graded insufficient for other outcomes. There were also no studies for several key adverse events.

DTaP-HepB-IPV. The prior 2014 report did not identify studies of DTaP-HepB-IPV and the update either found insufficient evidence or no new studies; thus, there was insufficient evidence to draw conclusions.

DTaP-IPV/Hib. The prior 2014 report found moderate strength evidence of an association of DTaP-IPV/Hib with febrile seizures based on one large, high quality post licensure study. This finding has been downgraded to insufficient taking into account both available studies (as there was a second study identified in this report with no evidence of increased risk). The update found low SoE for no evidence of increased risk for anaphylaxis or systemic allergic reaction.

DTaP-IPV. The prior 2014 report did not report findings related to DTaP-IPV. The update found low SoE for no evidence of increased risk for encephalitis/encephalopathy. Evidence was graded as insufficient or there were no studies for other key adverse events.

MMR-V. The prior 2014 report did not report findings related to MMR-V. The update found low SoE of no evidence of increased risk of encephalitis/encephalopathy and death. Evidence was graded as insufficient or there were no studies for other key adverse events.

Table 22a summarizes the findings across the prior 2014 report and the update.

Table 22a. KQ2: Safety of combination vaccines in children

Vaccine (Abbreviation; Brand Name[s])	2014 Report SoE and Findings	SoE and Findings in Update	Synthesis of SoE and Findings
DTaP-IPV-Hib-HepB (Vaxelis)	DTaP-IPV-Hib-HepB not in use at time of prior report	Low: No evidence of increased risk of asthma, death, febrile seizures, meningitis Insufficient: Autoimmune disease, diabetes, idiopathic thrombocytopenic purpura No studies: Acute disseminated encephalomyelitis, anaphylaxis or systemic allergic reaction, angioedema, autoimmune thyroiditis (Hashimoto's disease), brachial neuritis, cardiovascular events, encephalitis/encephalopathy, Guillain-Barré syndrome, multiple sclerosis, myocardial infarction, optic neuritis, seizures, stroke, transverse myelitis	■ Low: No evidence of increased risk of asthma; death; febrile seizures; meningitis
DTaP-HepB-IPV (Pediarix)	No findings	Insufficient: Febrile seizures, transverse myelitis No studies: Acute disseminated encephalomyelitis, anaphylaxis or systemic allergic reaction, angioedema, autoimmune disease, brachial neuritis, autoimmune thyroiditis (Hashimoto's disease), cardiovascular events, death, diabetes, encephalitis/encephalopathy, Guillain-Barré syndrome, idiopathic thrombocytopenic purpura, multiple sclerosis, myocardial infarction, optic neuritis, seizures, stroke	□ Insufficient evidence to draw conclusions
DTaP-IPV/Hib (Pentacel)	Moderate: Febrile seizures	Low: No evidence of increased risk of anaphylaxis or systemic allergic reaction Insufficient: Acute disseminated encephalomyelitis, encephalitis/encephalopathy, febrile seizures, Guillain-Barré syndrome, seizures No studies: Angioedema, brachial neuritis, cardiovascular events, death, diabetes, idiopathic thrombocytopenic purpura, stroke, transverse myelitis	■ Low: No evidence of increased risk of anaphylaxis or systemic allergic reaction □ Insufficient: Increased risk of febrile seizures (downgraded from prior 2014 report for inconsistency as update identified study reporting no increased risk)

Vaccine (Abbreviation; Brand Name[s])	2014 Report SoE and Findings	SoE and Findings in Update	Synthesis of SoE and Findings
DTaP-IPV (Kinrix, Quadracel)	No findings	Low: No evidence of increased risk encephalitis/encephalopathy Insufficient: Acute disseminated encephalomyelitis, anaphylaxis or systemic allergic reaction, angioedema, Guillain-Barré syndrome, seizures, stroke No studies: Brachial neuritis, cardiovascular events, death, diabetes, idiopathic thrombocytopenic purpura, transverse myelitis	Low: No evidence of increased risk of encephalitis/encephalopathy
Measles, mumps, rubella, and varicella (MMR-V; ProQuad)	No findings	Low: No evidence of increased risk of acute disseminated encephalomyelitis, death Insufficient: Anaphylaxis or systemic allergic reaction, ataxia, febrile seizures, idiopathic thrombocytopenic purpura, meningitis, seizures No studies: Angioedema, autism, cardiovascular events, diabetes, encephalitis/encephalopathy, Guillain-Barré syndrome, herpes zoster; multiple sclerosis, secondary transmission of live varicella virus, stroke, transverse myelitis	Low: No evidence of increased risk of acute disseminated encephalomyelitis, death

Key: Green box indicates no evidence of increased risk of specific adverse events; White box indicates insufficient evidence to draw conclusions about the risk of specific adverse events; Notes: KQ—Key Question; SoE—Strength of Evidence

Key Question 3: What is the evidence that vaccines recommended for pregnant women are safe in the short term or long term for both the woman and her fetus/infant?

This section describes the evidence for the safety of vaccines routinely recommended for use in pregnant women, both in the pregnant women and their fetuses/infants.

Key Points

- Insufficient evidence to permit evidence statements on hepatitis B vaccine, inactivated influenza vaccines, or recombinant influenza vaccine in pregnant women.
- Tetanus, diphtheria, and acellular pertussis vaccine: No evidence of increased risk[d] for maternal cardiovascular events, maternal death, maternal diabetes, eclampsia/pre-eclampsia, preterm labor, maternal reproductive system events, stillbirth, cardiovascular events in infants, death in infants, encephalitis/encephalopathy in infants, or seizures in

[d] "No evidence of increased risk" indicates that the outcome was studied and that the findings of the studies did not constitute evidence of increased risk of the adverse event following administration of that vaccine (because the risk either was not statistically significantly increased or was reduced).

infants (moderate SoE). No evidence of increased risk of maternal encephalitis/encephalopathy, autism in infants, birth defects in infants, or febrile seizures in infants (low SoE).

KQ3a. What adverse events are collected in clinical studies and in observational studies containing a control/comparison group?

Given the large number of adverse events that have been collected in the included studies, the table of collected adverse events is shown in Appendix C. The table lists both prespecified and incidentally collected, adverse events. The information comes from a variety of experimental and observational designs. Details of the studies, including the method used to assess adverse events, are documented in the evidence tables (Appendix D) and the risk of bias tables (Appendix C). Adverse events are shown in alphabetical order to facilitate the comparison across vaccines.

Studies collected adverse events for pregnant women and their infants/fetuses peri-and post-partum. The table lists the adverse events verbatim as reported in the original studies. As shown, the assessed adverse events varied greatly in detail as well as content. The collected data encompass the range of mild and transient events to serious adverse events with permanent consequences.

KQ3b. What adverse events are reported in clinical studies and in observational studies containing a control/comparison group?

The evidence tables in Appendix D contain all serious and severe adverse events reported in studies of pregnant women and their fetuses/infants.

KQ3c. What adverse events are associated with these vaccines in pregnant women?

This section further characterizes the risk of adverse events identified in studies of pregnant women who received routinely recommended vaccines.

KQ3c1. For each adverse event associated with a particular vaccine, what is the average severity and frequency?

No studies of key adverse events in pregnant women using HepB, quadrivalent IIV or quadrivalent RIV were found in this update. The prior 2014 report identified only evaluations of trivalent IIV and monovalent H1N1 influenza vaccine, which are no longer in use.

We did not detect any significant associations with adverse events following Tdap in pregnant women.

KQ3c2. For adverse events without statistically significant associations with a particular vaccine, what is the range of possible effects?

Below we report all pooled risk estimates for adverse events that were reported on by more than one study. We note any instances where individual studies contributing to a pooled risk estimate were statistically significant on their own, indicating increased risk of an adverse event. We also report on studies with risk estimates that could not be computed and pooled statistically. Finally, as for KQ1 and KQ2, we summarize the range of possible effects by vaccine in brief below for all adverse events for which the primary relative risk estimate did not favor the

intervention (i.e., RR>1), but the association was not statistically significant. Where appropriate, we contextualize the finding to understand the range of possible effects.

Hepatitis B Vaccines in Pregnant Women

We did not identify any studies that assessed adverse events associated with HepB, in pregnant women in this update or in our original report.

Influenza Vaccines in Pregnant Women

We did not identify any studies that assessed key adverse events associated with quadrivalent IIV or any studies of quadrivalent RIV in pregnant women in this update.

One study of active surveillance used automated text messaging to identify adverse events following Tdap or IIV (of which >95% were quadrivalent IIV) among pregnant women in Australia.[116] When comparing IIV plus Tdap to Tdap alone, there was no significant difference in women seeking medical advice via telephone for adverse events (RR 1.38; CI 0.60, 3.20) or being medically attended for adverse events (RR 1.79; CI 0.79, 4.04).

Tdap in Pregnant Women

We identified four RCTs[125, 172, 179, 181] and 13 cohort studies[52, 64, 65, 67, 91, 121, 123, 144, 154, 170, 182, 191, 198] that assessed adverse events in pregnant women and/or their offspring among women who received Tdap. RCTs assessed Adacel[125, 172, 179] or Boostrix;[181] in most cases, the vaccine(s) used for women followed in the cohort studies were not specified. Three of the RCTs[172, 179, 181] were placebo controlled, and one RCT[125] compared Tdap to Td. We did not separate out the one study that compared Tdap and Td in reporting results, as Tdap is sufficiently different from Td given the acellular pertussis component. The other studies used participants not vaccinated with Tdap as control groups. Two studies[52, 179] did not contribute to the meta-analyses as key adverse events were not reported; however, neither study found significant difference in maternal adverse events overall and one study[52] that also looked at infants found no difference in adverse events.

Across ten studies,[67, 121, 123, 125, 170, 172, 181, 182, 191, 198] we found no evidence of increased risk of preterm labor; women who received Tdap were at significantly lower risk for preterm labor (RR 0.62; CI 0.46, 0.82). However, the preterm labor analysis detected heterogeneity (I^2 85%). Across six studies,[121, 123, 125, 154, 181, 191] we found no evidence of increased risk of eclampsia/pre-eclampsia (RR 0.96; CI 0.92, 1.01); there was some evidence of publication bias (Egger p=0.063, Begg p=0.272). Across another six studies,[67, 170, 172, 181, 191, 198] there was no evidence of increased risk of stillbirth (RR 0.44; CI 0.11, 1.80). Across another six studies,[121, 125, 144, 172, 181, 191] there was no evidence of increased risk of cardiovascular disorders (RR 0.86; CI 0.41, 1.84); there was considerable heterogeneity (I^2 85%). Of note, one of the studies[121] reported an increased risk of cardiovascular events (gestational hypertension; RR 1.30; CI 1.15, 1.48; events 262/8178 vs 1484/60372); however, the authors noted that the adjusted hazard ratio (aHR) was no longer significant (aHR 1.02; CI 0.88, 1.19).

Across four studies,[121, 125, 181, 191] we found no evidence of increased risk for maternal deaths (RR 1.52; CI 0.07, 32.35). Although the RR was greater than 1, it is important to note that no deaths occurred in the intervention groups—one death occurred in a control group and the RR was inflated due to an imbalance in the sample sizes after adding a constant for computational purposes.

Across another four studies,[121, 144, 181, 191] we found no evidence of increased risk of diabetes (RR 0.98; CI 0.88, 1.10). Across three studies, [125, 181, 191] we found no evidence of increased risk

of reproductive system events (RR 0.52 CI 0.05, 5.91); we detected statistical heterogeneity (I^2 53%). Across two studies,[123, 198] we found no evidence of increased risk of spontaneous abortion (RR 0.66; CI 0.00, 1004); we detected statistical heterogeneity despite the small number of studies (I^2 81%). The risk estimate was imprecise as it was based on two studies of disparate size (4/138 vs 49/552 and 233/1252 vs 22931/130289).

Among other maternal outcomes, a cohort study reported that women who received Tdap had a decreased risk (adjusted) for caesarean delivery (aOR 0.78; CI 0.63, 0.98).[67] One cohort study[121] identified an increased risk of lactation disorders (aHR 1.63; CI 1.15, 2.33), but significantly decreased risk of antenatal bleeding (aHR 0.61; CI 0.49, 0.78) as well as pre-eclampsia with severe features and preterm labor/delivery (already captured in meta-analyses). In another cohort study,[154] there was increased risk of post-partum hemorrhage both among those with optimally timed Tdap (aHR 1.23; CI 1.18, 1.28) and early Tdap (aHR 1.34; CI 1.25, 1.44). However, in another study[181] which was an RCT, there was no increased risk of vaginal or intrauterine hemorrhage following Tdap (2.6%; CI 1.2, 5.0 vs 2.9%; CI 1.4, 5.3).

Among five cohort studies that assessed the risk for chorioamnionitis, two reported a slightly increased risk—one study[91] among 197,564 women (adjusted rate ratio 1.23; CI 1.17, 1.28) and one study[154] among 1,079,034 women (aHR 1.11; CI 1.07, 1.15) who received optimally timed Tdap. One study[121] of 68,550 women noted no difference in risk (aHR 1.10; CI 0.70, 1.75), as did a second study[170] that looked at 7,378 women who had received one dose of Tdap (6% vs 4%, p=0.31). Finally, one study[67] reported no difference in risk when evaluated in multiple ways among 1,759 women.

One study[125] assessed maternal autoimmune disease following Tdap and found a RR greater than 1 (RR 1.02; CI 0.06, 16.18) due to one event in each group of either Crohn's disease or ulcerative colitis. Another study[144] assessed maternal seizures, finding an RR of 2.07 (CI 0.12, 32.41) due to seizures occurring in one subject in each of the intervention and control groups.

One study[116] of active surveillance used automated text messaging to identify adverse events following Tdap or IIV (of which >95% were quadrivalent IIV) among pregnant women in Australia. When comparing Tdap plus IIV to IIV alone, there was no significant difference in women seeking medical advice via telephone for adverse events (RR 2.53; CI 0.89, 7.2) or being medically attended for adverse events (RR 1.82; CI 0.7, 4.51).

KQ3c3. For each adverse event associated with a particular vaccine, what are the risk factors for the adverse event?

As outlined, we did not find any adverse events associated with vaccines in pregnant women, but we discuss any risk factors that were examined for adverse events below.

Few studies addressed risk factors for adverse events, though three studies examined adverse events based on timing of Tdap. In one cohort study,[154] adverse events were stratified by timing of receipt of Tdap. Optimally timed vaccine was defined as 27 weeks onward, and early was defined as less than 27 weeks. Optimally timed Tdap was associated with significantly lower risk of preeclampsia/eclampsia (aHR 0.96: 0.94, 0.99), but early Tdap was not (aHR 1.05; CI 0.99, 1.12). Both optimally timed and early Tdap were associated with small increased relative risks of chorioamnionitis (aHR 1.11; CI 1.07, 1.15 for optimal and 1.19; CI 1.11, 1.28 for early) and postpartum hemorrhage (aHR 1.23; CI 1.18, 1.28 for optimal and 1.34; CI 1.25, 1.44 for early). However, these relative increases corresponded to low absolute risk increases. Early Tdap was associated with significantly increased risk of premature rupture of membranes (aHR 1.08; CI 1.02, 1.15), but optimally timed Tdap was not (aHR 1.03; CI 1.00, 1.06). However, it is possible

that the study failed to adjust for all residual confounding, and that receipt of the Tdap prior to the recommended timing might have been a proxy for atypical care or anticipated premature birth. In addition, there is no clear biologically plausible mechanism whereby greater time since having received Tdap is more highly associated with a mechanical rupture of membranes than more temporally associated Tdap administration. Two other studies of timing of Tdap administration raised no concerns for early administration of Tdap. In one cohort study,[144] the subset of women receiving Tdap at or after 20 weeks' gestation, as compared to their unvaccinated matches had no increased risk for incident gestational diabetes, thrombocytopenia, venous thromboembolism, or cardiac events (myocarditis, pericarditis, cardiomyopathy, or heart failure). In another study[123] comparing receipt of Tdap at 0 to 13 weeks' gestation with receipt at 27 to 36 weeks' gestation, earlier administration was not associated with increased risk of adverse events.

In a cohort study[65] of pregnant mothers in Australia who received Tdap compared to those who did, there was no increased risk of ADHD in their offspring compared to those who did not receive Tdap, including when looking by birth year and solely among nulliparous women.

KQ3d. What adverse events are associated with these vaccines in the fetus/infant?

KQ3d addresses the severity, range of possible effects, and risk factors for the adverse events in the fetus/infant of pregnant women.

KQ3d1. For each adverse event associated with a particular vaccine, what is the average severity and frequency?

We did not detect associations of *in utero* vaccine exposure with adverse events for the fetus or infant of vaccinated women. There were no studies in fetuses/infants of pregnant women using HepB, quadrivalent IIV or quadrivalent RIV. The prior 2014 report identified only evaluations of trivalent IIV and monovalent H1N1 influenza vaccine, which are no longer in use.

Among infants of women vaccinated for Tdap during pregnancy, we did not detect any statistically significant associations with adverse events.

KQ3d2. For adverse events without statistically significant associations with a particular vaccine, what is the range of possible effects?

Below we report all pooled risk estimates for adverse events that were reported on by more than one study. We note any instances where individual studies contributing to a pooled risk estimate were statistically significant on their own, indicating increased risk of an adverse event. We also report on studies with risk estimates that could not be computed and pooled statistically. Finally, as for KQ1 and KQ2, we summarize the range of possible effects by vaccine in brief below for all adverse events for which the relative risk estimate did not favor the intervention (i.e., RR>1), but the association was not statistically significant. Where appropriate, we contextualize the finding to understand the range of possible effects.

Hepatitis B Vaccines in the Fetus/Infant

We did not identify any studies that assessed adverse events associated with HepB, in the fetus/infant in this update or in our original report.

Influenza Vaccines in the Fetus/Infant

We did not identify any studies that assessed key adverse events associated with quadrivalent IIV or any studies of quadrivalent RIV in the fetus/infant in this update. The prior 2014 report identified only evaluations of trivalent IIV and monovalent H1N1 influenza vaccine, which are no longer in use.

Tdap in the Fetus/Infant

We identified four RCTs[125, 172, 179, 181] and 13 cohort studies[52, 64, 65, 67, 91, 121, 123, 144, 154, 170, 182, 191, 198] that assessed adverse events in pregnant women and/or their offspring among women who received Tdap. RCTs assessed Adacel[125, 172, 179] or Boostrix;[181] in most cases, the vaccine(s) used for women followed in the cohort studies were not specified. Three of the RCTs[172, 179, 181] were placebo controlled, and one RCT[125] compared Tdap to Td. As for outcomes in pregnant women, we did not separate out the one study that compared Tdap and Td, as Tdap is sufficiently different from Td given the acellular pertussis component. The other studies used participants not vaccinated with Tdap as control groups.

Fetal or infant outcomes of primary interest that were assessed in more than one study were birth defects, cardiovascular outcomes, death, encephalitis/encephalopathy, and seizures. We found no significant differences in fetal and infant adverse events across these studies.

Across eight studies,[67, 123, 125, 172, 181, 182, 191, 198] we found no evidence of increased risk of birth defects (RR 0.77; CI 0.43, 1.38), but we detected heterogeneity (I^2 81%) and some evidence of publication bias (Egger test p=0.007, Begg test p=0.399). Of note, one of the studies[182] reported an increased risk of birth defects (ankyloglossia [tongue tie]; RR 1.53; CI 1.33, 1.77; events 221/8299 vs 1063/61090); the next most common was congenital anomalies of the feet, which was less common in infants of mothers vaccinated with Tdap.

Across four studies,[154, 181, 182, 191] we found no evidence of increased risk of encephalitis/encephalopathy (RR 1.23; CI 0.60, 2.54). One of the studies[154] reported an increased risk of infant encephalopathy (RR 1.46; 1.23, 1.73; events 165/113094 vs 577/577000); however, this was based on crude rates, and in adjusted analyses there was no increased risk. Two[181, 191] of the remaining three studies showed either no cases of the adverse event (0/341 vs 0/346; 0/1199 vs 0/1259) and the remaining study[182] showed a lower rate of the adverse event in the intervention group (12/8299 [0.14%] vs 101/61090 [0.16%]).

Across three studies,[170, 181, 191] we found no evidence of increased risk of cardiovascular events in infants of vaccinated mothers (RR 0.77; CI 0.50, 1.20). Across another three studies,[181, 191, 198] we detected no evidence of increased risk of deaths in infants (RR 0.15; CI 0.00, 8.88). Across yet another set of three studies,[91, 154, 182] we found no evidence of increased risk of seizures in infants (RR 1.02; CI 0.76, 1.35). While the RR was technically greater than 1, the percentages in each group experiencing seizures were essentially the same (0.25% in both groups when combining across all three studies).

We found no evidence of increased risk of febrile seizures, intussusception, meningitis, or stroke based on single studies[125, 170, 172] reporting on the outcome. The study assessing meningitis was an RCT[125] with an RR of 1.03 (CI 0.07, 16.3). There was one case of infant meningitis in each of the two groups (N=134 versus N=138). No conclusions about the range of possible effects can be drawn based on the extremely wide confidence intervals.

Among other fetal or infant outcomes, one cohort study[64] of 81,993 infants in the United States found no difference in the risk of autism spectrum disorder between those exposed to Tdap *in utero* and those not exposed, with most who received a positive initial diagnosis

receiving a confirmatory diagnosis after the age of two. A cohort study[91] that followed 324,463 mother-infant pairs reported no difference in the risk for neonatal microcephaly between infants exposed to Tdap *in utero* and those not exposed.

One cohort study[170] found that infants exposed to Tdap *in utero* had a significantly higher gestational age at birth; a significantly decreased risk for preterm birth and small size for gestational age; and fewer days of hospitalization compared with those not exposed to Tdap. Likewise, another observational study[182] reported a decreased risk for preterm birth, low birth weight, small for gestational age, large for gestational age, respiratory distress syndrome, transient tachypnea of newborn, tachycardia or bradycardia, hemolytic diseases, other neonatal jaundice, anemia, syndrome of infant of mother with gestational diabetes, and hypoglycemia in infants born to mothers who received Tdap during pregnancy.

A cohort study[65] of pregnant mothers in Australia who received Tdap compared to those who did not showed no association between prenatal Tdap and ADHD in offspring (HR 1.00; CI 0.88, 1.14).

KQ3d3. For each adverse event associated with a particular vaccine, what are the risk factors for the adverse event?

As outlined, we did not find any association of adverse events with vaccines in fetuses/infants exposed *in utero*, but we discuss any risk factors that were examined for adverse events below.

Of the three studies[123, 144, 154] that compared early versus optimal timing of Tdap, none identified any increased risk of adverse events among infants of pregnant women by timing of vaccine.

One cohort study[170] examined adverse events among infants of women who received one dose of Tdap versus two or more (from prior pregnancies). No difference in postnatal outcomes was noted between women who were administered Tdap at least twice in the past 5 years and those who received only a single dose.

KQ3: Summary of Findings for Safety of Vaccines in Pregnant Women and Their Fetuses/Infants

Table 23 documents the evidence for all identified studies evaluating the effects of vaccines in pregnant women for the prespecified key adverse events. The summary of findings table documents the results across studies grouped by vaccines. The table shows the number of RCTs, the number of other studies, the number of participants across pooled analyses, the studies contributing to the risk estimate, findings for the outcomes of interest, the criteria used to downgrade the SoE, and the SoE summary statement. The relative risk of an adverse event was derived by comparing the reported event rates in vaccinated participants compared to a control group across all studies that reported the data for that outcome. The absolute rates of adverse events (number of events, number of assessed participants) for the vaccine and the control group are also shown. In many instances, results were based on single occurrences of a specific adverse event. Where studies reported insufficient detail and did not contribute to the effect size estimates, the table reports the results as reported by the study authors.

Table 23. KQ3: Update summary of findings and SoE for safety of vaccines in pregnant women and their fetuses/infants

Vaccine	Outcome	N RCTs, N Other; N Participants; IDs of Studies Contributing to RR	Risk Estimate: RR; CI (Event Rates in Individual Studies); Other Studies Contributing to SoE	Reasons for Downgrading	Update Evidence Statement and SoE
Hepatitis B (HepB; Engerix-B, Recombivax HB)	Autoimmune disease; birth defects; cardiovascular events; death; eclampsia/pre-eclampsia; encephalitis/encephalopathy; multiple sclerosis; optic neuritis; preterm labor; spontaneous abortion; stillbirth	0 RCTs, 0 Other; N 0; 0 studies	We did not identify studies evaluating HepB in pregnant women	N/A	Insufficient evidence
Influenza, inactivated (IIV; Afluria Quadrivalent, Flucelvax Quadrivalent, Fluarix Quadrivalent, Flulaval Quadrivalent, Fluzone Quadrivalent)	Asthma; birth defects; death; eclampsia/pre-eclampsia; preterm labor; spontaneous abortion; stillbirth	0 RCTs, 0 Other; N 0; 0 studies	We did not identify studies evaluating quadrivalent IIV in pregnant women reporting on these adverse events	N/A	Insufficient evidence
Influenza, recombinant (RIV; Flublok Quadrivalent)	Asthma; birth defects; death; eclampsia/pre-eclampsia; preterm labor; spontaneous abortion; stillbirth	0 RCTs, 0 Other; N 0; 0 studies	We did not identify studies evaluating quadrivalent RIV in pregnant women	N/A	Insufficient evidence
Tetanus, diphtheria, and acellular pertussis (Tdap; Adacel, Boostrix)	Maternal autoimmune disease	1 RCTs, 0 Other; N 273; Halperin, 2018[125]	RR 1.02; CI 0.06, 16.18 (1/135 vs 1/138)[&,#]	Study limitation,° Precision,^ Consistency↑	Insufficient evidence
	Maternal cardiovascular events	3 RCTs, 3 Other; N 235154; Griffin, 2018,[121] Halperin, 2018,[125] Kharbanda, 2016,[144] Munoz, 2014,[172] Perrett, 2019,[181] Sancovski, 2019[191]	RR 0.86; CI 0.41, 1.84 (gestational hypertension, congestive heart failure, cardiac events, moderate hypertension deep vein thrombosis; 262/8178 vs 1484/60372, 0/135 vs 1/138, 90/53885 vs 198/109253, 2/33 vs 0/15, 1/341 vs 0/346, 11/1199 vs 31/1259)[##]	Consistency↑↑	Moderate SoE for no evidence of increased risk

Vaccine	Outcome	N RCTs, N Other; N Participants; IDs of Studies Contributing to RR	Risk Estimate: RR; CI (Event Rates in Individual Studies); Other Studies Contributing to SoE	Reasons for Downgrading	Update Evidence Statement and SoE
Tetanus, diphtheria, and acellular pertussis (Tdap; Adacel, Boostrix) (continued)	Maternal death	2 RCTs, 2 Other; N 71968; Griffin, 2018,[121] Halperin, 2018,[125] Perrett, 2019,[181] Sancovski, 2019[191]	RR 1.52; CI 0.07, 32.25 (0/8178 vs 1/60372, 0/135 vs 0/138, 0/341 vs 0/346, 0/1199 vs 0/1259)[#]	Precision,^	Moderate SoE for no evidence of increased risk
	Maternal diabetes	1 RCT, 3 Other; N 234833; Griffin, 2018,[121] Kharbanda, 2016,[144] Perrett, 2019,[181] Sancovski, 2019[191]	RR 0.98; CI 0.88, 1.10 (gestational diabetes; 326/8178 vs 2426/60372, 1101/53885 vs 2263/109253, 0/341 vs 0/346, 10/1199 vs 22/1259)[#]	Study limitation°	Moderate SoE for no evidence of increased risk
	Eclampsia/pre-eclampsia	2 RCTs, 4 Other; N 1267812; Griffin, 2018,[121] Halperin, 2018,[125] Layton, 2017,[154] Perrett, 2019,[181] Sancovski, 2019,[191] Hall, 2020[123]	RR 0.96; CI 0.92, 1.01 (159/8178 vs 1278/60372, 1/135 vs 2/138, 6344/148795 vs 40930/930227, 1/341 vs 5/346, 12/1199 vs 30/1259, 548/10340 vs 5949/106482)[#]	Reporting bias$	Moderate SoE for no evidence of increased risk
	Maternal encephalitis/encephalopathy	0 RCTs, 1 Other; N 163138; Kharbanda, 2016[144]	RR 0.68; CI 0.18, 2.50 (meningoencephalitis; 3/53885 vs 9/109253)[#]	Study limitation,° Consistency↑	Low SoE for no evidence of increased risk
	Maternal Guillain-Barré syndrome	0 RCTs, 1 Other; N 163138; Kharbanda, 2016[144]	RR 0.34; CI 0.02, 6.75 (0/53885 vs 3/109253)[#]	Study limitation,° Precision,^ Consistency↑	Insufficient evidence
	Preterm labor	3 RCTs, 7 Other; N 267618; Berenson, 2016,[67] Griffin, 2018,[121] Halperin, 2018,[125] Morgan, 2015,[170] Munoz, 2014,[172] Perrett, 2019,[181] Sancovski, 2019,[191] Shakib, 2013,[198] Hall, 2020,[123] Petousis-Harris, 2019[182]	RR 0.62; CI 0.46, 0.82 (58/1109 vs 59/650, 10/8178 vs 292/60372, 2/135 vs 1/138, 526/7152 vs 35/226, 0/33 vs 1/15, 13/341 vs 11/346, 64/1199 vs 121/1259, 8/134 vs 38/505, 531/10463 vs 8160/105974, 398/8299 vs 3412/61090)[#]	Consistency↑↑	Moderate SoE for no evidence of increased risk
	Maternal reproductive system events	2 RCT, 1 Other; N 3423; Halperin, 2018,[125] Perrett, 2019,[181] Sancovski, 2019[191]	RR 0.52; CI 0.05, 5.91 (postpartum, vaginal or uterine hemorrhage; 1/135 vs 1/138, 9/346 vs 10/346, 4/1199 vs 19/1259)[#]	Precision^	Moderate SoE for no evidence of increased risk
	Maternal seizures	0 RCTs, 1 Other; N 163138; Kharbanda, 2016[144]	RR 2.03; CI 0.13, 32.41 (1/53885 vs 1/109253)[#]	Study limitation,° Precision,^ Consistency↑	Insufficient evidence
	Spontaneous abortion	0 RCTs, 2 Other; N 132231; Shakib, 2013,[198] Hall, 2020[123]	RR 0.66; CI 0.00, 1004 (4/138 vs 49/552, 233/1252 vs 22931/130289)[#]	Study limitation,° Precision^ Consistency↑↑	Insufficient evidence

Vaccine	Outcome	N RCTs, N Other; N Participants; IDs of Studies Contributing to RR	Risk Estimate: RR; CI (Event Rates in Individual Studies); Other Studies Contributing to SoE	Reasons for Downgrading	Update Evidence Statement and SoE
Tetanus, diphtheria, and acellular pertussis (Tdap; Adacel, Boostrix) (continued)	Stillbirth	2 RCTs, 4 Other; N 13020; Berenson, 2016,[67] Morgan, 2015,[170] Munoz, 2014,[172] Perrett, 2019,[181] Sancovski, 2019,[191] Shakib, 2013[198]	RR 0.44; CI 0.11, 1.80 (0/1109 vs 1/650, 25/7152 vs 1/226, 0/33 vs 0/15, 1/341 vs 1/346, 1/1199 vs 6/1259, 0/138 vs 5/552)[#]	Precision^^^	Moderate SoE for no evidence of increased risk
	Autism in infants	0 RCTs, 1 Other; N 81993; Becerra-Culqui, 2018[64]	RR 0.81; CI 0.73, 0.90 (569/39077 vs 772/42916)[#]	Study limitation,° Consistency↑	Low SoE for no evidence of increased risk
	Birth defects in infants	3 RCTs, 5 Other; N 179255; Berenson, 2016,[67] Halperin, 2018,[125] Munoz, 2014,[172] Perrett, 2019,[181] Sancovski, 2019,[191] Shakib, 2013,[198] Hall, 2020,[123] Petousis-Harris, 2019[182]	RR 0.77; CI 0.43, 1.38 (15/1109 vs 18/650, 0/134 vs 2/138, 0/33 vs 1/15, 24/341 vs 28/346, 5/1199 vs 22/1259, 5/134 vs 22/505, 33/970 vs 3091/103033, 221/8299 vs 1063/61090)[##]	Consistency,↑↑ Reporting bias$	Low SoE for no evidence of increased risk
	Cardiovascular events in infants	2 RCTs, 2 Other; N 70763; Munoz, 2014,[172] Perrett, 2020,[181] Shakib, 2013,[198] Petousis-Harris, 2019[182]	RR 0.77; CI 0.50, 1.20 (cardiomyopathy with biventricular hypertrophy, atrioventricular block, cardiovascular complex chronic conditions, tachycardia or bradycardia; 0/33 vs 1/15, 1/341 vs 1/346, 2/134 vs 14/505, 55/8299 vs 515/61090)[#]	Precision^^^	Moderate SoE for no evidence of increased risk
	Death in infants	1 RCT, 2 Other; N 10523; Morgan, 2015,[170] Perrett, 2019,[181] Sancovski, 2019[191]	RR 0.15; CI 0.00, 8.88 (2/7152 vs 0/226, 0/341 vs 0/346, 0/1199 vs 8/1259)[#]	Precision,^	Moderate SoE for no evidence of increased risk
	Encephalitis/encephalopathy in infants	1 RCT, 3 Other; N 762628; Layton, 2017,[154] Perrett, 2019,[181] Sancovski, 2019[191] Petousis-Harris, 2019,[182]	RR 1.23; CI 0.60, 2.54 (hypoxic-ischemic encephalopathy; 165/113094 vs 577/577000, 0/341 vs 0/346, 0/1199 vs 0/1259, 12/8299 vs 101/61090)[&,##]	Precision^	Moderate SoE for no evidence of increased risk
	Febrile seizures in infants	1 RCT, 0 Other; N 48; Munoz, 2014[172]	RR 0.91; CI 0.03, 25.64 (1/33 vs 0/15)[#]	Precision,^ Consistency↑	Low SoE for no evidence of increased risk
	Intussusception in infants	1 RCT, 0 Other; N 272; Halperin, 2018[125]	RR 0.51; CI 0.02, 15.22 (0/134 vs 1/138)[#]	Study limitation,° Precision,^ Consistency↑	Insufficient evidence
	Meningitis in infants	1 RCT, 0 Other; N 272; Halperin, 2018[125]	RR 1.03; CI 0.07, 16.30 (1/134 vs 1/138)[&,#]	Study limitation,° Precision,^ Consistency↑	Insufficient evidence

Vaccine	Outcome	N RCTs, N Other; N Participants; IDs of Studies Contributing to RR	Risk Estimate: RR; CI (Event Rates in Individual Studies); Other Studies Contributing to SoE	Reasons for Downgrading	Update Evidence Statement and SoE
Tetanus, diphtheria, and acellular pertussis (Tdap; Adacel, Boostrix) (continued)	Seizure in infants	0 RCTs, 3 Other; N 953852; DeSilva, 2017,[91] Layton, 2017,[154] Petousis-Harris, 2019[182]	RR 1.02; CI 0.76, 1.35 (68/45008 vs 261/152556, 336/112971 vs 1607/573928, 18/8299 vs 136/61090)[&,#]	Study limitation°°	Moderate SoE for no evidence of increased risk
	Stroke in infants	0 RCTs, 1 Other; N 7378; Morgan, 2015[170]	RR 0.06; CI 0.00, 1.88 (intraventricular hemorrhage 1/7152 vs 0/226)[#]	Study limitation,° Consistency↑	Insufficient evidence
	Brachial neuritis in mothers or infants	0 RCTs, 0 Other; N 0; 0 studies	We did not identify studies evaluating brachial neuritis in pregnant women	N/A	Insufficient evidence

Notes: CI—95% confidence interval; ID—study identifier; KQ—Key Question; N—number; N/A—not applicable; RR—relative risk; RCT—randomized controlled trials; SoE—strength of evidence; &—potentially increased risk based on direction of effects across studies and investigated further but not statistically significant; #—none of the RR estimates in individual studies showed a statistically significantly increased risk; ##— maternal cardiovascular events: 1 out of 6 studies reported an increased risk (RR 1.30; CI 1.15, 1.48 for gestational hypertension; events 262/8178 vs 1484/60372; the authors reported the adjusted HR was not significant aHR 1.02; CI 0.88, 1.19), birth defects: 1 out of 8 studies reported an increased risk (RR 1.53; CI 1.33, 1.77; events 221/8299 vs 1063/61090), encephalitis/encephalopathy in infants: 1 out of 4 studies reported an increased risk (RR 1.46; 1.23, 1.73; events 165/113094 vs 577/577000); °—no unvaccinated control group; °°—effect based on observational evidence only; ^—imprecise estimate with wide CI; ^^^—CI crosses 1; ↑—consistency could not be assessed as no other study reported on the outcome; ↑↑—heterogeneity detected; $ evidence of publication bias

Neither the prior 2014 report nor the update identified studies of HepB in pregnant women. The prior report found moderate SoE for no association of trivalent IIV and monovalent H1N1 influenza vaccine with serious adverse events in pregnant women. The update identified one study of quadrivalent IIV, but this study did not report on key adverse events. The update identified no studies of the quadrivalent RIV currently in use in pregnant women.

For Tdap, the update found no evidence of increased risk for maternal cardiovascular events, maternal death, maternal diabetes, eclampsia/pre-eclampsia, preterm labor, maternal reproductive system events, stillbirth, cardiovascular events in infants, death in infants, encephalitis/encephalopathy in infants, or seizures in infants (moderate SoE). The update found no evidence of increased risk of maternal encephalitis/encephalopathy, autism in infants, birth defects in infants, or febrile seizures in infants (low SoE). There was insufficient evidence due to the studies being graded as insufficient or no studies for some key adverse events.

Table 23a summarizes the findings across the prior 2014 report and the update.

Table 23a. KQ3: Safety of vaccines in pregnant women and their fetuses/infants

Vaccine (Abbreviation; Brand Name[s])	2014 Report SoE and Findings	SoE and Findings in Update	Synthesis of SoE and Findings
Hepatitis B (HepB; Engerix-B, Recombivax HB)	No findings	No new evidence	☐ Insufficient evidence to draw conclusions
Influenza, inactivated (IIV; Afluria Quadrivalent, Flucelvax Quadrivalent, Fluarix Quadrivalent, Flulaval Quadrivalent, Fluzone Quadrivalent)	Moderate: No association with serious adverse events with trivalent IIV or monovalent H1N1 influenza vaccine	No new evidence	☐ Insufficient evidence to draw conclusions Trivalent IIV and monovalent H1N1 influenza vaccine no longer in use
Influenza, recombinant (RIV; Flublok Quadrivalent)	Quadrivalent RIV not in use at time of prior report	No new evidence	☐ Insufficient evidence to draw conclusions
Tetanus, diphtheria, and acellular pertussis (Tdap; Adacel, Boostrix)	No findings	Moderate: No evidence of increased risk of maternal cardiovascular events, maternal death, maternal diabetes, eclampsia/pre-eclampsia, preterm labor, maternal reproductive system events, stillbirth, cardiovascular events in infants, death in infants, encephalitis/encephalopathy in infants, seizures in infants Low: No evidence of increased risk of maternal encephalitis/encephalopathy, autism in infants, birth defects in infants, febrile seizures in infants Insufficient evidence: Spontaneous abortion No studies: Brachial neuritis	■ Moderate: No evidence of increased risk of maternal cardiovascular events, maternal death, maternal diabetes, eclampsia/pre-eclampsia, preterm labor, maternal reproductive system events, stillbirth, cardiovascular events in infants, death in infants, encephalitis/encephalopathy in infants, seizures in infants ■ Low: No evidence of increased risk of maternal encephalitis/encephalopathy, autism in infants, birth defects in infants, febrile seizures in infants

Key: ■ Green box indicates no evidence of increased risk of specific adverse events; ☐ White box indicates insufficient evidence to draw conclusions about the risk of specific adverse events; Notes: KQ—Key Question; SoE—Strength of Evidence

Discussion

We assessed the evidence for the safety of vaccines used for routine immunization in the United States among children, adults of all ages, and pregnant women, according to the Centers for Disease Control and Prevention (CDC's) routine immunization schedules and based on vaccines currently licensed for use in the United States by the Food and Drug Administration (FDA). We conducted an extensive literature search and identified a substantial number of studies that compared the presence and absence of adverse events between vaccinated and comparator groups. Overall, our evidence review found vaccines to be safe across populations with serious adverse events being rare, consistent with other recent systematic reviews of vaccine safety.[535]

Findings in Relation to the Decisional Dilemma(s)

Vaccines for Adults

Since the prior 2014 report on vaccine safety, a number of new vaccines have become available for adults, including recombinant zoster vaccine (RZV), hepatitis B vaccine with a novel immunostimulatory adjuvant, and adjuvanted inactivated influenza vaccine (aIIV), of which many are indicated primarily or exclusively for older adults.

Zoster Vaccines

RZV has been of particular interest, given that it involves a novel adjuvant and is exclusively used in the older population. Of note, we found no evidence for increased risk of acute disseminated encephalomyelitis, amyotrophic lateral sclerosis, anaphylaxis or serious allergic reaction, angioedema, asthma, ataxia, autoimmune disease, autoimmune thyroiditis (Hashimoto's disease), cardiovascular events, death, diabetes, encephalitis/encephalopathy, Guillain-Barré syndrome, idiopathic thrombocytopenic purpura, meningitis, myocardial infarction, reproductive system events, seizures, or stroke for RZV (low or moderate strength of evidence [SoE]). We identified a reduced risk for herpes zoster (high SoE). This finding is presumably due to the vaccine itself reducing risk of zoster (as expected), but given concern for an association with herpes zoster for other vaccines containing novel adjuvants (e.g., HEPLISAV-B®; see below) the lack of increased risk is reassuring.

Hepatitis B Vaccines

The newest hepatitis B vaccine, which has a novel immunostimulatory adjuvant (cytidine-phosphate-guanosine oligodeoxynucleotide adjuvant), is another vaccine for adults approved since the last report. For outcomes for which there was sufficient evidence for this new vaccine, we found no evidence of increased risk for asthma, autoimmune disease, cardiovascular events, death, herpes zoster, reproductive system events, or stroke (low SoE). Of note, we identified a relative risk greater than one (but not statistically significant) for outcomes including cardiovascular events, herpes zoster, myocardial infarction, and stroke, although we combined three randomized controlled trials (RCTs), of which two included predominantly younger patients. These events—and particularly an imbalance in the rate of death and myocardial infarction in one of the RCTs[99] though not the other two RCTs—were noted to be of concern to the FDA.[379] The manufacturer is conducting two post-marketing observational surveillance studies, which are underway as of August 2018.[1087] One study is evaluating the occurrence of

herpes zoster, as well as new-onset immune-mediated diseases and anaphylaxis, and the other is examining acute myocardial infarction interim results[1088] announced by the manufacturer suggest no increased risk of acute myocardial infarction).

There is no evidence of increased risk of multiple sclerosis, as noted in the prior 2014 report which only evaluated the older hepatitis B vaccines (Recombivax HB® and Engerix-B®), which remains unchanged with moderate SoE. The current report also found no evidence of increased risk of diabetes across all hepatitis B vaccines (moderate SoE), based both on evidence both the prior report and the update.

Pneumococcal Vaccines

In the prior 2014 report, SoE was high that 23-valent pneumococcal polysaccharide vaccine (PPSV23) is not associated with risk for cardiovascular or cerebrovascular events in adults aged 65 years and older, and this SoE remains high in the current report based on the new evidence reviewed in the update. Across studies published since the 2014 report, there is insufficient evidence for most other outcomes associated with PPSV23, except for death for which there was no evidence of increased risk (moderate SoE). While these effects may be an indirect result of the effectiveness of the vaccine in preventing pneumococcal disease, the lack of harms is encouraging.

Overall, for 13-valent pneumococcal conjugate vaccine (PCV13), which was not examined in the prior 2014 report, there was moderate SoE for no increased risk of cardiovascular events, herpes zoster, myocardial infarction, reproductive system events, or stroke. There was low SoE for no increased risk of acute disseminated encephalomyelitis, anaphylaxis or systemic allergic reaction, asthma, autoimmune disease, death, encephalitis/encephalopathy, idiopathic thrombocytopenic purpura, meningitis, or seizures. In one large cohort study[231] of PCV13 compared to no PCV13, there was an increased risk of all-cause pneumonia among adults aged 65 years and older; no significant association was found between vaccination and death. Of note, this observational cohort study had some flaws, including that some of the unvaccinated population in the cohort study were assumed to have potentially received PPSV23 in the past. Importantly, a large RCT[72] of PCV13 in older adults, found no increase in all-cause community-acquired pneumonia.

Influenza Vaccines

The present report examined all currently available influenza vaccines, including the newer recombinant influenza vaccine (RIV) and aIIV. Since the prior 2014 report that included only trivalent inactivated influenza vaccine (IIV) and monovalent H1N1 influenza vaccine, almost all trivalent influenza vaccines except aIIV (available in trivalent and quadrivalent forms) have been replaced by quadrivalent influenza vaccines, which are the focus of the current report.

We note that in almost all studies examined in this report, quadrivalent influenza vaccines of any type were compared to the prior trivalent vaccines and adjuvanted influenza vaccines were compared either to a non-adjuvanted influenza vaccine (trivalent aIIV to non-adjuvanted IIV) or another adjuvanted influenza vaccine (quadrivalent aIIV to trivalent aIIV); this means that interpretation of findings is limited to these specific comparisons.

Looking at all of the non-adjuvanted quadrivalent IIV, we found no evidence for increased risk for a number of outcomes, including asthma, cardiovascular events, death, myocardial infarction, reproductive system events, seizures, or stroke (low SoE). There was insufficient

evidence for a number of outcomes, including Guillain-Barré syndrome, and comparisons tended to be to other influenza vaccines as opposed to no vaccine.

For the newer aIIV for older adults released since the prior 2014 report, we again identified no evidence of increased risk, including for asthma, autoimmune disease, death, encephalitis/encephalopathy, Guillain-Barré syndrome, idiopathic thrombocytopenic purpura , myocardial infarction, or seizures (low SoE). Most comparisons were made to other influenza vaccines. There was moderate SoE for no increased risk of cardiovascular events and stroke, which is important to note given that this vaccine is indicated in adults 65 years and older who may be at higher risk for these conditions.

For quadrivalent RIV, which is also newly approved for adults (including pregnant women, though we found no studies in this population), studies of non-pregnant adults showed no evidence of increased risk for adverse events such as cardiovascular events, death, encephalitis/encephalopathy, myocardial infarction, reproductive system events, or stroke (low SoE) compared to compared to other influenza vaccines (quadrivalent IIV).

Vaccines for Children

Among children, there continues to be a reasonably robust body of evidence related to vaccine safety.

Rotavirus Vaccines

The prior 2014 report identified moderate SoE for the association of rotavirus vaccine and risk for intussusception, based on one analysis from the United States' Post-Licensure Rapid Immunization Safety Monitoring (PRISM) program, although RCTs did not demonstrate an increased risk of intussusception following rotavirus vaccine. The package inserts for both rotavirus vaccines note intussusception as a risk, and it is also listed in the Vaccine Injury Table as a condition covered under the National Vaccine Injury Compensation Program if it occurs within 21 days of rotavirus vaccination.[1092] The update found no evidence of increased risk of intussusception following rotavirus vaccine at the latest time of follow-up across nineteen studies that could be pooled. This finding is consistent with a recent meta-analysis,[674] which examined the pooled estimated risks of intussusception within 31 days after each dose and one and two years after vaccination, and identified no association of risk of developing intussusception following receipt of the rotavirus vaccine. However, as in the prior 2014 report there were mixed findings across other studies, which included pre-post studies, cohort studies, and self-controlled case series. Seven studies[75, 102, 135, 175, 208, 236, 237] reported an increased risk of intussusception, with particular emphasis on the first dose of rotavirus vaccine: In addition, two population-level studies[83, 213] showed an increase in the number of intussusception cases following the introduction of rotavirus vaccine. In spite of these studies that showed positive associations, many other studies showed no association of rotavirus vaccine with an increase in the risk for intussusception. This included no difference before and after introduction of the rotavirus vaccine at a population level,[106, 131, 168] between patients who received rotavirus vaccine and patients who did not, [74, 108, 155, 212] and between patients before and after receiving rotavirus vaccine.[122, 133] While the trial-based data support a lack of association between rotavirus and intussusception at the time of latest follow-up, given these mixed findings from other study types regarding an association between rotavirus vaccine and intussusception, continued monitoring of rotavirus vaccine and risk for intussusception, particularly the risk following the first dose, may be helpful.

Measles, Mumps, and Rubella Vaccine

Both our own prior 2014 report and numerous other reviews conclude that measles, mumps, and rubella vaccine (MMR) is not associated with the onset of autism in children. Although the current report found insufficient evidence for most outcomes, two studies[138, 141] reported no association between administration of MMR and the risk for autism, including among children with siblings with autism. Based on both reports consistently showing lower risk of autism, taken together with the findings from the prior 2014 report, the SoE remains high for no evidence of increased risk of autism following MMR. The prior 2014 report found high SoE for increased risk of febrile seizures; this update identified evidence that did not change the prior evidence statement. In general, febrile seizures do not cause permanent harm and do not have any lasting effects.[1090] All other findings from the prior report remain unchanged as well, except that the update newly identifies no evidence of increased risk of asthma (low SoE).

Measles, Mumps, Rubella, and Varicella Vaccine

The prior 2014 report did not note adverse events associated with combined measles, mumps, rubella, and varicella vaccine (MMR-V). In the update, we reviewed one study[148] that showed an increased risk of febrile seizures in the seven to ten days following vaccination with MMR-V compared to MMR and varicella vaccines separately, which would result in approximately 4 excess cases per 10,000 children vaccinated. However, this result was not supported by the findings of an RCT[89] we reviewed or by those of another cohort study,[96] albeit with a risk window of interest likely too soon to detect the increased risk of febrile seizures. This resulted in the evidence for an association being judged as insufficient based on the studies reviewed as part of this update. Based on information in the package insert,[842] there was an increased rate of fever 5-12 days after vaccination with dose 1 in pre-licensure studies for those who received MMR-V compared to MMR and varicella vaccine separately. There was no increased risk of febrile seizures, but these studies were not designed nor statistically powered to detect such a difference. This finding led to a post-marketing study that found an increased risk of febrile seizures in the 5-12 days following dose 1 (relative risk 2.20; 95% confidence interval 1.04, 4.65), but not in the 0-30 days following dose 1 nor at any time following dose 2.

We note that even with this potentially increased risk with dose 1, febrile seizures are generally not harmful long-term and are already noted in the Warnings and Precautions section of the product labeling for the vaccine. In addition, the CDC recommends that providers who offer the combination MMR-V vaccine clearly communicate to parents and caregivers about the possibility of febrile seizures.

9-Valent Human Papillomavirus Vaccine

The prior 2014 report found moderate SoE that human papillomavirus (HPV) vaccines (either 2-valent or 4-valent, which were the available vaccines at that time) were not associated with increased risk for appendicitis, stroke, seizures, syncope, venous thromboembolism, onset of juvenile arthritis, or onset of Type 1 diabetes. One analysis of long-term follow-up data from Black adolescents and adults (aged 16–24 years) enrolled in two RCTs of 4-valent HPV vaccine (HPV4) showed a possible increased risk of miscarriage of pregnancies within 4 years of vaccination; however, this formulation of the vaccine is no longer in use, and it should be noted that HPV vaccines are contraindicated during pregnancy.

The current report reviewed studies of 9-valent HPV vaccine (HPV9) only, as this is the currently available vaccine, and raises no concerns around the safety of HPV9. We note that

most comparisons were made to prior 2-valent HPV vaccine (HPV2) and HPV4. Some post-marketing studies could not be analyzed as reported results did not differentiate between HPV9 and previous versions. We found no evidence of increased risk for autoimmune disease, birth defects, death, reproductive system events, seizures, or spontaneous abortion (for which participants were followed up to 6 years) (all low SoE). Of note, our report showed no evidence of increased risk across all available studies that examined spontaneous abortion at the time of latest follow-up. However, in a post-hoc analysis of data from one RCT[136] restricted to the subgroup of inadvertent pregnancies that occurred within 30 days of vaccination, there was a higher risk of spontaneous abortion with HPV9 (28.4%, 19/67) compared to HPV4 (12.7%, 7/55).[1091] Importantly, the higher rate of spontaneous abortion in the intervention group was found to be consistent with the background rate of the event.[1091]

Meningococcal Vaccines

Studies that assessed serogroup B meningococcal vaccine (MenB), which was newly approved since the prior 2014 report, found no evidence for increased risk of anaphylaxis or systemic allergic reaction, asthma, death, reproductive system events, or seizures (low or moderate SoE). Studies of existing serogroup A, C, W, and Y meningococcal vaccines (MenACWY-D and MenACWY-CRM) also found no evidence of increased risk, as did studies of the new vaccine MenACWY-TT, although there was insufficient evidence for some outcomes of interest.

Other Vaccines

The prior 2014 report noted an increased risk for febrile seizures associated with PCV13 (moderate SoE). However, based on some conflicting evidence from new studies included in the update, we have downgraded the SoE from moderate for an association between PCV13 and febrile seizures to low. Younger age was associated with increased risk for febrile seizures in some studies.

One pre-post study[90] of extremely low birth-weight infants comparing risk periods before and after different vaccines found an increased incidence of sepsis evaluation and need for respiratory support after DTaP, inactivated poliovirus vaccine (IPV), *Haemophilus* influenzae type B vaccine (Hib), hepatitis B vaccine (HepB), DTaP-IPV/Hib, and DTaP-HepB-IPV, and increased risk of intubation after DTaP, IPV, Hib, and DTaP-HepB-IPV. This special populations of extremely low-birth-weight infants may warrant further study.

Increased risk of encephalitis or encephalopathy is a concern following pertussis-containing vaccines, and is included as a covered condition in the Vaccine Injury Table.[1092] The update found no new studies addressing the possible association. The update identified one study[62] that reported an increased risk of acute disseminated encephalomyelitis in the 5 to 28-day risk interval following tetanus, diphtheria, and acellular pertussis vaccine (Tdap) compared to the following nine months, but this effect was not observed in the longer 2 to 42-day interval. The same study also showed no association with transverse myelitis. The excess risk for acute disseminated encephalomyelitis was calculated to be about 0.4 cases per one million doses of Tdap given (95% confidence interval -0.04, 1.16). However, the study authors noted that this finding is based on two exposed cases—one of which had also received a vaccine not recommended for his age group at that time. They also noted that because a large number of statistical comparisons were performed without adjusting for multiple testing, the result could be due to chance alone. Overall, acute disseminated encephalomyelitis appears to be rarely

associated with Tdap, if at all. Given that this finding was reported in only one study, we rated the evidence as insufficient, but note it as an area for possible future research.

Vaccines for Pregnant Women and Their Fetuses/Infants

This report also identified increasing evidence assessing the safety of vaccines among pregnant women. For this update, we identified no studies in pregnant women that assessed the effects of hepatitis B vaccines or RIV, which is an area that could be targeted for further research. We identified one study of quadrivalent IIV, but it did not assess any of the key adverse events pre-specified for this report, nor any other serious or severe adverse events. While we did not identify any studies of quadrivalent vaccines in pregnant women, our 2014 report uncovered no safety concerns related to trivalent IIV or monovalent H1N1 influenza vaccine, neither of which are currently in use. Although this report reviewed only vaccines in current use, we note that a recent case-control study[1093] of data collected over three influenza seasons (2012–13, 2013–14, 2014–15) found no increased risk of spontaneous abortions among pregnant women who received IIV (almost all trivalent vaccine).

We identified a number of new studies that examined the safety of Tdap for pregnant women and their newborn infants, including four RCTs and 12 cohort studies. This enabled us to make many new evidence statements, of which several had moderate SoE (maternal cardiovascular events, maternal death, maternal diabetes, eclampsia/pre-eclampsia, preterm labor, maternal reproductive system events, stillbirth, cardiovascular events in infants, death in infants, encephalitis/encephalopathy in infants, seizures in infants) and others had low SoE (maternal encephalitis/encephalopathy, autism in infants, birth defects in infants, febrile seizures in infants). We note that women who received Tdap had significantly lower risk of preterm labor (which included preterm delivery if preterm labor was not reported) than did comparison groups (moderate SoE). The mechanism for this protective effect is not clear, and our systematic review was not designed to assess the effectiveness of vaccines in reducing harms. Among five large cohort studies, two identified a slightly increased risk for chorioamnionitis,[91, 154] while others reported no difference in risk.[67, 121, 170] This potential slightly increased risk could be investigated further.

In terms of longer-term effects, we found a significantly decreased risk of autism (low SoE) among infants whose mothers received Tdap; this was based on one study,[67] and again the mechanism for this effect is not clear. Other studied outcomes for which no difference was found in infants exposed to Tdap *in utero* include neonatal microcephaly.

Strengths and Limitations

Strength of the Review

Our review of the literature was extensive and designed to maximally capture evidence on the presence or absence of adverse events associated with vaccines in studies with a comparator evaluating vaccines in human participants. To identify data, we relied not only on research databases, but also on publicly accessible grey literature. We searched Clinicaltrials.gov for information on unpublished trials with results posted in the trial record, as well as all Advisory Committee on Immunization Practices (ACIP) statements and vaccine package inserts. While we did not use FDA regulatory documents as a primary source, we drew upon such documents

whenever any signal was identified for potentially increased risk (e.g., HEPLISAV-B and myocardial infarction).

After searching the literature, we employed a transparent, established protocol to minimize the risk of missing relevant studies. The review team followed inclusive decision rules and ordered full text copies of any publications reporting on interventions or observational studies of the vaccines of interest—even if ostensibly reporting only on clinical effectiveness—in order to identify studies that reported on harms only in the full publication.

We reviewed adverse events reported in comparative vaccine studies regardless of whether or not they might be attributed definitively to the intervention. We systematically identified evidence of the absence of specific adverse events (i.e., events that were assessed in research studies but that did not occur if reported as such).

We allowed for complex comparisons where a vaccine was evaluated in the presence of a second vaccine (e.g., HPV9 and Tdap) and compared to the second vaccine alone (e.g., Tdap). For some vaccines, many of the studies included an active vaccine comparator to ensure that that the intervention is compared to the current standard of care. Thus, we also allowed for comparisons between a vaccine and the vaccine it was replacing (e.g., quadrivalent IIV and trivalent IIV) or to the newest similar vaccine (e.g., MenACWY-TT to MenACWY-CRM or MenACWY-D). A comparison between a vaccine and an active comparator may underestimate rate of adverse effects relative to a comparison between that same vaccine and placebo. Given this, we clearly note when an active vaccine comparator was used throughout the text of this report. To address the difference in studies, we report first the risk estimates for the vaccine of interest compared to either placebo or a base treatment that the intervention group also receives (e.g., routine vaccines), and then we report the risk estimate when combined with studies that included an active vaccine comparator. We also allowed for combining of studies where populations were different (e.g., one study of RZV given to healthy adults and another of RZV given to adults with stem cell transplants); including studies of non-healthy populations enabled us to assess the risk of adverse events in populations that might be at higher risk for such events. While our inclusive approach added to the complexity of the review, this approach has the benefit of capturing the fullest evidence base possible for the range of vaccines and potential harms.

Limitations of the Review

While our literature search procedures were extensive, some unpublished trial results may not have been identified. As noted above, we were able to mitigate this possibility by searching trial databases directly and reference mining relevant publications, including ACIP recommendations. We also may have missed studies due to the challenging nature of assessing harms as contrasted with assessing effectiveness, since many publications focus on the clinical effectiveness of an intervention with either no, sparse, incomplete, or non-systematic assessment and/or reporting of safety data. While search filters exist for effectiveness studies, filters to address harms are not as successful in identifying relevant studies. Thus, as noted above, we intentionally screened the full text of all vaccine intervention studies to minimize missing safety data. We also note that the current review builds on the prior 2014 report, which itself built upon the 2011 Institute of Medicine (IOM) report. The prior 2014 report did not search for or include studies on vaccines that were covered in the IOM report and published prior to 2011. In the current report, only for vaccines for which there were new indications or for new vaccines did we perform targeted searches for research published prior to 2014. Wherever possible, we used

data that could be combined in meta-analyses in this update from the prior report to estimate the relative risk based on all available research studies. In addition, we narratively synthesized research findings across both the prior 2014 report and the update to assess the SoE.

This report reviews currently recommended vaccines for routine use, and does not include new vaccines in development or under emergency use authorization, such as vaccines for the 2019 coronavirus disease (COVID-19) pandemic. We also excluded studies of vaccines not currently in use in the United States. For example, while HPV2 and HPV4 are no longer in use in the United States, studies of the safety of these vaccines (still in use in other countries) would likely inform discussions of the safety of HPV9. We acknowledge that studies of other widely used vaccines could be useful but were required to limit the scope to a focus on the United States. We also excluded non-English language studies. Although we were considering only vaccines approved for use in the United States, it is possible relevant epidemiological studies have been published in non-English journals.

While we did identify sub-group analyses within studies that met our inclusion criteria, there may be additional reports of studies that assessed specific risk factors but that would not have been included if there were no appropriate comparator (e.g., a study comparing HPV9 in men and women, where all participants receive the vaccine). Despite the large number of studies included, indirect analyses across studies to assess the effect of participant or administration variables were possible only for selected characteristics and selected outcomes. This was because studies varied widely in the strategy used to assess the safety of the vaccines and used different datasets (e.g., some used mining datasets that included data for many different vaccines). In addition, some studies reported adverse events of interest at a system or group level (e.g., rate of all cardiovascular events), but others did not. For studies that did not report system-level rates of system-level adverse events, we had to instead choose the most common adverse event within the relevant system (e.g., unstable angina) to use available data to the extent possible. This resulted in some estimates that are based on combined systems and event-level rates, but in cases where such analyses indicated more events in the vaccinated group, we also performed sensitivity analyses to assess the robustness of the findings and reviewed the nature of the events.

As was the case for the prior Agency for Healthcare Research and Quality 2014 report and the IOM report, the current report focused on the association of specific vaccines with particular adverse events. One of our inclusion criteria was that studies must include both an intervention vaccine and a comparator (either placebo, no vaccine, or the comparator vaccine closest to what the new vaccine is replacing). Because of this approach, drawing conclusions about the safety of the immunization schedule taken as a whole, multiple vaccines together, and/or certain adjuvants and preservatives is not generally possible from this report's findings.

A further limitation results from the fact that not all immunizations and thus adverse events may have been captured, particularly if they occurred outside of the medical home and/or if the state did not have a vaccine registry. Statewide registries for adults are much less common than they are for children. Adults are also more likely to get their vaccines at alternate locations such as their workplace or at pharmacies. Given the nature of the studies that were included, all of which had to have some comparator, loss of information from this limitation is less likely for this report.

Finally, we note that many of the harms we were assessing as our key adverse events (e.g., acute disseminated encephalomyelitis, Guillain-Barré syndrome, transverse myelitis, anaphylaxis) are quite rare and the number of studies that reported on the presence or absence of events for a vaccine was sometimes small. As a result, despite our extensive searches for data

that could be combined across studies, our confidence intervals are often wide, which make the risk estimates imprecise. Risk estimates had wide confidence intervals in individual studies given that often only one or two events occurred in the entire sample, but also in estimates combined across studies. Although statistical pooling is a data aggregation method, we used random effects meta-analyses, which do not average the results of the identified studies, but set out to estimate the true risk by treating the studies as samples from an underlying distribution. When only few studies are available, the effect estimates differ, and/or the event rate is rare, the confidence interval of the effect estimate will be very wide as the true effect is estimated from a very small sample of potential studies. With this review being no exception, rare events present considerable methodological challenges.[49] However, we investigated all instances of more observed events in the vaccinated group further regardless of the precision of the risk estimate and transparently present all rates. In addition, we considered all available data regardless of whether they could be combined in a pooled estimate, including post-marketing surveillance and other observational studies such as self-controlled case series and case-control studies, in the grading the SoE.

Strength of the Evidence Base

We identified a large number of studies reporting on the presence and absence of adverse events, and in particular a number of new studies on the use of Tdap in pregnant women. The studies reported on a group of patients vaccinated with the vaccine of interest and a control group, an important feature as many of the adverse events of interest are not unique to vaccines and we had to establish whether the event was more likely in the vaccine group. We included experimental and observational studies and many studies included in the current report are RCTs, which by design should minimize differences between intervention and control groups.

We extracted data both from published journal articles and clinical trial registries. The importance of trial registries has increased dramatically since reporting of results has become mandatory. Clinicaltrials.gov is set up to capture results that can be used in systematic reviews and meta-analyses, including data on severe adverse events, serious adverse events, and mortality. In general, the harms data in Clinicaltrials.gov have been found to be more complete than in the corresponding publications,[1094, 1095] although we note that the database tends to better capture the presence of adverse events than the absence of such events (that is, when no adverse event occurs in either the intervention or comparator group). As a result, our findings may well underestimate the safety of vaccines, as we did not count the absence of adverse events in the study record as evidence of absence of effects; we only considered studies that explicitly reported the presence or the absence of the adverse events of interest.

Other innovative methodologic approaches have also improved the analysis of adverse events, particularly for post-marketing studies. For example, in the United States, the CDC's Vaccine Safety Datalink uses data obtained through such systems at eight large healthcare organizations, enabling high-quality studies using methodologies such as self-controlled risk intervals analyses. Other nations with single payer healthcare can often leverage their extensive electronic registries, which allow for epidemiological studies of entire populations.

Limitations of the Evidence Base

An important limitation common to systematic reviews in general is the quality of the original studies included. We critically appraised included studies in detail. Studies that reported

timing and severity and defined adverse events using standard, precise definitions were rated higher than those that did not.

Limitations of studies vary according to their design. Controlled trials often have insufficient sample sizes to identify very rare adverse events as discussed above, and may not follow participants long enough to identify long-term sequelae. Even in studies with generous follow-up times, the timing of events is not always optimally reported. Except where explicitly noted in the text, controlled trials of vaccines tend to be conducted in healthy patients. Thus, persons who may be more susceptible to adverse events may be excluded from trials yet eligible to receive a vaccine after it is licensed.

Given the above limitations of controlled trials, comprehensive reviews of vaccine safety must include post-licensure studies, but these are not without their own limitations. People who avoid vaccinations whether deliberately or not, may differ from those who receive vaccinations in terms of race, sex, age, socioeconomic status, and preexisting medical conditions, and these differences may in turn be associated with health outcomes. Observational studies typically attempt to control for such potential confounders by using matched cohorts or multivariate regression analysis. However, some factors such as environmental exposures may be unmeasured or challenging to control for adequately. The self-controlled case series was developed specifically to assess the safety of vaccines; this method eliminates confounding by all time-independent variables by using cases as their own controls and predefined "time windows" before and/or after vaccination. While self-controlled case series control for patient characteristics that do not change over time (i.e., gender, race, ethnicity, genetics), they cannot capture factors that are time related. This is especially important when studying vaccinations of infants and toddlers. Another limitation of such studies is that the data provided typically do not allow for pooling across studies (e.g., combining a self-controlled case series study of rotavirus vaccine that provides adjusted relative risk with an RCT of rotavirus vaccine that provides counts of events).

Studies using passive surveillance such as the Vaccine Adverse Event Reporting System (VAERS) are crucial in identifying signals regarding adverse events post-licensure. By definition, they do not consider the rates of such events in non-vaccinated populations, and thus are not designed to assess a statistical association between a vaccine and an adverse event; thus, these studies were excluded from this project. VAERS data might contain important adverse event signals that are not identified in this report and that warrant future research.

Post-licensure epidemiological studies are conducted to investigate possible associations between vaccines and adverse events reported in passive surveillance or multiple case reports. Such studies often do not limit their investigation to a particular brand or formulation. It is difficult to assess the utility of studies that do not report specific details about vaccines, or lump vaccines against a specific disease together. For example, a study might investigate the effect of "seasonal influenza vaccines" in general, even when the vaccines used may be quite different (e.g., live attenuated influenza vaccine and IIV). We excluded such studies that reported on a category of mixed vaccine types, if there were distinct vaccines in use at the time of the study (e.g., "meningococcal vaccines" when both MenACWY and MenB were in use during the same period).

Applicability

Evidence related to vaccine safety was found for many key adverse events for most vaccines across all Key Questions (adults, children, and pregnant women and their infants). Generally,

results should be applicable to the populations receiving routine vaccines. However, we identified few sub-group analyses related to race and ethnicity differences; this may partially have been a function of excluding studies without a comparator, as noted above and/or what is published in the literature. Most studies included only healthy participants, although we did identify studies in vulnerable sub-populations (e.g., people with HIV infection, people with malignancies and stem cell transplants). While studies of pregnant women were still limited in number for HepB and influenza vaccines, there was robust new evidence to support an assessment of safety of Tdap.

Most vaccine interventions were tested either against placebo, against the closest comparator (e.g., MenACWY-TT versus MenACWY-CRM), or against the vaccine the newer formulation was replacing (e.g., HPV9 versus HPV4). In clinical practice, vaccines are often not given in isolation, particularly for children. A number of studies we identified were either clinical trials of a group of vaccines typically given together (e.g., MenACWY and Tdap and HPV9 versus Tdap and HPV9 alone; such studies would be included) or observational studies of children receiving routine vaccines, with a focus on one new vaccine (e.g., rotavirus and routine vaccines versus routine vaccines alone). While such studies better reflect the usual routine vaccination practices, they can be more challenging to analyze.

While some studies prespecified adverse events in response to the public's concern about vaccine safety, most did not explicitly state that this consideration was part of their selection process. Ensuring that studies are patient-centered and collect outcomes that consider concerns about vaccines would help to ensure that results are meaningful to patients. Studies such as those using the Vaccine Safety Datalink (VSD) and the Post-Licensure Rapid Immunization Safety Monitoring System (PRISM) typically analyzed data on prespecified outcomes that had been identified through other vaccine safety signal monitoring systems (e.g., VAERS).

Some published vaccine trials were not specific in reporting adverse events. Broad categories such as "injection-related adverse events," "systemic adverse events," "one or more adverse events," or "serious adverse events" were sometimes reported instead of specific harms, which tends to be less useful in support of public or other decision-making. In addition, many studies reported on a list of pre-defined adverse events but did not rate the severity or provide enough information to determine severity. Studies with entries in Clinicaltrials.gov tended to have much more complete results for serious adverse events reported on the site than in publications.

Timing was typically clearly specified for solicited local and systemic reactions (within 7–14 days), but the timing of serious adverse events was not always as granular. Publications most frequently discussed timing of deaths, but not that of other key adverse events.

Implications for Clinical Practice, Education, Research, or Health Policy

It is important to note that this report is not intended to provide direct guidance to healthcare providers, but rather to assess the current state of knowledge about vaccine safety and to identify research gaps for future exploration.

Overall, our report found vaccines to be safe across a spectrum of populations, which has important implications for decision-making at every level (patients, healthcare providers, policymakers). We did not identify any studies meeting our inclusion criteria that assessed HPV9 in adults over age 26. The prior 2014 report identified two RCTs of previous HPV vaccines in young adults, both in women and both reporting no serious adverse events. As HPV9 is now approved for adults up to age 45, epidemiological studies should track and report any adverse

events in adults over age 26 as a sub-group. Further study of the risk of spontaneous abortion among women who become pregnant shortly after vaccination may also be helpful.

We also did not identify studies assessing MMR in adults for this update. In the prior 2014 report, the SoE was insufficient to draw conclusions on risk for encephalitis, encephalopathy, afebrile seizures, meningitis, cerebellar ataxia, acute disseminated encephalomyelitis, transverse myelitis, optic neuritis, neuromyelitis optica, multiple sclerosis onset, and chronic arthropathy, due to the absence of evidence. The update identified one study on mixed samples (children and adults) that found no evidence of increased risk of transverse myelitis, acute disseminated encephalomyelitis, or optic neuritis. Epidemiological studies of adults should continue to assess and report on serious adverse events.

The potentially increased risk of herpes zoster and myocardial infarction following HEPLISAV-B noted as identified by the FDA warrants further research and ongoing post-marketing surveillance; studies are already underway to address these issues. Our study did not examine risk of local injection site reactions and symptoms such as pain following vaccination. However, for some vaccines such as RZV, the association with an increase in such reactions is well established, with grade 3 vaccine-related local and general adverse reactions within the seven days post-vaccination with RZV being more common than with placebo.[843] The increased rate of local reactions could potentially lead to increased rate of injury (e.g., from falls) due to functional limitations, which may warrant further research.

In terms of vaccines for children, our report shows that vaccines are generally very safe, continuing to show high SoE for no increased risk of autism following MMR across two studies and now moderate SoE for no increased risk of intussusception following rotavirus vaccine, although some studies still suggest increased risk particularly after the first dose. Some studies did find an increased risk of febrile seizures with MMR-V, and healthcare providers may wish to ensure that families are aware of this risk when balancing it against the benefit of giving one injection instead of two injections. Two studies that enrolled at-risk infants—one of DTaP in extremely low birth weight infants, and one of rotavirus vaccine in premature infants—reported an increased risk of certain adverse events such as evaluation for sepsis, need for respiratory support, and need for intubations after DTaP administration to extremely low birth weight infants, and bradycardia and apnea among premature infants receiving rotavirus vaccine. This population tends to be more medically fragile and may particularly benefit from vaccination, so potential risks of vaccination should be communicated to parents to inform decision making.

While studies of Tdap in pregnancy have greatly increased, we did not identify any studies that assessed adverse events associated with HepB or quadrivalent influenza vaccines in pregnant women or their infants in this update or in our original report. This is an important gap that warrants additional study, particularly given the need for clinicians to point pregnant women to evidence-based resources.[455] For Tdap, the possible slightly increased risk of chorioamnionitis among pregnant women in two of five studies could be investigated further, given potential implications for both pregnant women and their newborns.

Across all studies, severity of adverse events was often not well described or categorized, and better understanding of severity in addition to frequency will help inform future decisions about vaccines. In addition to the adverse events addressed in this report, future work may need to focus more strongly on perceived safety risks, in particular where they translate into vaccine hesitancy.

While some studies assessed the potential effects of factors such as age, concomitant vaccines, and sometimes co-existing morbidities on the risk for adverse events from vaccine

administration, subgroup analyses were frequently not reported by race/ethnicity among the studies that met inclusion criteria for this report. Differential analyses should identify risks specific to subgroups to ensure that vaccine safety is addressed through the lens of health equity. Ensuring that vaccine safety research includes important subgroup analyses where possible would help inform discussions of safety across all populations. For example, safety considerations may be unique for adults aged 65 years and older, in whom adverse events such as local reactions are more likely to affect the performance of activities of daily living.

Given the rare nature of some of the serious adverse events of interest, ongoing studies of large populations and post-marketing surveillance of vaccines after FDA licensure are needed. Currently, vaccines are closely monitored after licensure, using various surveillance systems such as the VAERS (co-managed by the FDA and the CDC),[500] PRISM (part of the Sentinel Initiative, which is FDA's national system for monitoring medical products after they are licensed for use),[22] and Vaccine Safety Datalink[23, 24] and Clinical Immunization Safety Assessment project (both managed by the CDC).[25, 26] Future vaccine research will also need to take into account the expanding landscape of new vaccines and vaccine technologies, in particular the new COVID-19 vaccines.[1096]

Conclusion

Across this large body of research, we found no new evidence of increased risk since the prior 2014 report for key adverse events following administration of vaccines that are routinely recommended for adults children, and pregnant women. Signals from the prior report remain unchanged for rare adverse events that include anaphylaxis in adults and children, and febrile seizures and idiopathic thrombocytopenic purpura in children. There was no evidence of increased risk of adverse events for vaccines currently recommended in pregnant women. Research gaps identified by this report included rare adverse events for which the evidence was insufficient to draw conclusions, as well as factors that may be associated with increased risk for adverse events. However, important considerations when deciding whether studies are warranted include the severity and frequency of the adverse event being studied and the challenges of investigating rare events. The scope of this report does not include the effectiveness of vaccines, nor does it make practice recommendations or policy regarding the administration of the vaccines. Potential risks for rare adverse events for some vaccines should be weighed against the protective benefits that those vaccines provide.

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Note: This list of references includes references from both the main report and the appendixes.

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401. Package insert - Twinrix.
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413. Package insert - Afluria QUADRIVALENT
414. Package insert - Flucelvax QUADRIVALENT
415. Package insert - Flulaval QUADRIVALENT
416. Package insert -Flumist QUADRIVALENT
417. Package insert - Fluarix QUADRIVALENT
418. Package insert - Fluzone QUADRIVALENT (including high dose and intradermal).
419. Package insert - Flublok QUADRIVALENT
420. Package insert - Proquad (includes fridge stable and frozen(s)).
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Abbreviations and Acronyms

ACIP	Advisory Committee on Immunization Practices
AE	Adverse event
AHRQ	Agency for Healthcare Research and Quality
ARR	Absolute risk reduction
aHR	Adjusted hazard ratio
aIIV	Adjuvanted influenza vaccine
aOR	Adjusted odds ratio
CDC	Centers for Disease Control and Prevention
CI	Confidence interval
CTCAE	Common Terminology Criteria for Adverse Events classification system
DTaP	Diphtheria, tetanus, and acellular pertussis vaccine
EPC	Evidence-based Practice Center
FDA	U.S. Food and Drug Administration
GRADE	Grading of Recommendations Assessment, Development and Evaluation
HepA	Hepatitis A vaccine
HepB	Hepatitis B vaccine
Hib	*Haemophilus influenzae* type b vaccine
HIV	Human immunodeficiency virus infection
HPV	Human papillomavirus
HPV9	Human papillomavirus, 9-valent vaccine
HR	Hazard ratio
IOM	Institute of Medicine
IIV	Inactivated influenza vaccine
IRR	Incidence rate ratio
IPV/IPOL	Inactivated polio vaccine
KQ	Key Question
LAIV	Live attenuated influenza vaccine
MenACWY	Meningococcal conjugate vaccine, serogroups A, C, W, Y vaccine
MenB	Meningococcal B vaccine
MMR	Measles, mumps, and rubella vaccine
MMR-V	Measles, mumps, rubella, and varicella vaccine
mHR	Multivariate hazard ratio
OASH/OIDP	The Office of the Assistant Secretary of Health's Office of Infectious Disease and HIV/AIDS Policy
OR	Odds ratio

PCV7	Pneumococcal conjugate, 7-valent vaccine
PCV13	Pneumococcal conjugate, 13-valent vaccine
PPSV23	Pneumococcal polysaccharide vaccine, 23-valent vaccine
PRISMA	Preferred Items for Reporting in Systematic Reviews and Meta-Analyses
RCT(s)	Randomized controlled trial(s)
RI	Risk incidence
RIV	Recombinant influenza vaccine
RR	Relative risk
RV	Rotavirus vaccine
RZV	Recombinant zoster vaccine
SARS-CoV-2	Severe acute respiratory syndrome coronavirus
SoE	Strength of evidence
SR(s)	Systematic review(s)
Td	Tetanus and diphtheria vaccine
Tdap	Tetanus, diphtheria, and acellular pertussis vaccine
TEP	Technical Expert Panel
TOO	Task Order Officer
TIV	Trivalent inactivated influenza vaccine
US	United States of America
VAERS	Vaccine Adverse Event Reporting System
VAR	Varicella vaccine
VZV	Varicella zoster virus

Appendix A. Methods

This appendix documents the report methods in detail. Note: The references in this appendix can be found in the list at the end of the main report.

Details of Study Selection

The evidence review built on the prior AHRQ 2014 report on vaccine safety,[28] which itself built on a prior Institute of Medicine (now National Academy of Medicine) 2011 report on vaccine safety.[29]

Sources

We searched the research databases MEDLINE (includes TOXLINE), Embase, CINAHL, Cochrane Central Register of Controlled Trials (CENTRAL, includes International Clinical Trials Registry Platform records), Web of Science, and Scopus to identify controlled studies evaluating vaccines. MEDLINE indexes a wide range of biomedical literature, TOXLINE indexes studies of adverse events associated with drugs and other chemicals, Embase emphasizes pharmacological and European journals, CINAHL includes nursing literature, the Web of Science and Scopus index many technology journals, and. Clinicaltrials.gov was searched for more information on published trials as well as results published in the trial record.

In addition, we reviewed Advisory Committee on Immunization Practices (ACIP) statements and the literature cited in the statements. We also reviewed vaccine package inserts to identify relevant safety information. We reference-mined published systematic reviews and FDA reports to ensure that all relevant studies were identified, i.e., rather than summarizing the reviews, we used them as sources to identify available research studies. Furthermore, the content experts on the TEP and experts serving as peer reviewers were asked to review the list of included studies to help ensure that all relevant studies were considered. Finally, a Supplemental Evidence And Data for Systematic review (SEADS) portal was provided and a Federal Register Notice was posted for this review to ensure that all relevant evidence was considered by allowing public comment and submission of information.

The search strategy for the databases is documented below. The search strategies were developed, executed, and documented by an experienced EPC librarian and peer-reviewed by an experienced methodologist. The literature search was updated while the draft report was under peer review to ensure that the evidence included in the final report is up to date.

Search Strategy

The literature search built on the prior AHRQ report on the topic.[29] For the prior AHRQ report, research databases and existing reviews were searched from inception through August 2013 for the vaccines not covered by the IOM report; for the vaccines covered by the IOM report, the searches dated from a year before that report (i.e., 2010) through August 2013. Zostavax® (live zoster vaccine) was originally included in the search and the report but was subsequently excluded because it became unavailable as of November 2020. For this update, we focused on literature published since the prior searches. However, the largest database, MEDLINE, was searched from inception of the database because of recent changes to the search interface. Search output was imported into the existing citation library from the prior 2014 report

and all duplicates were discarded where duplicates were detected. In cases where a vaccine was newly approved or had a new indication since the last report, we conducted new literature searches. In addition, we re-screened citations previously identified for the vaccine and applied the inclusion criteria for this update.

The employed search strategy focused on identifying empirical studies evaluating vaccines. The strategy was not limited to a set of known adverse events and instead aimed to identify evaluations of vaccines regardless of the included safety information. Publications and trial entries were obtained as full text and the full text was reviewed for data relevant to adverse events.

Databases

MEDLINE

OVID MEDLINE [includes TOXLINE]
Database: Ovid MEDLINE(R) and Epub Ahead of Print, In-Process & Other Non-Indexed Citations and Daily <1946 to December 15, 2020>
Date: 15 December 2020
Search terms:

1 (((diphtheria tetanus acellular pertussis or tetanus diphtheria acellular pertussis or tetanus toxoid or dt or td or tt or diphtheria tetanus or tetanus diphtheria or whooping cough or (tetanus and diphtheria)) and (vaccin* or immuniz* or immunis*)) or (dtap or tdap)).mp. or diphtheria-tetanus-acellular pertussis vaccines/ or diphtheria pertussis tetanus vaccine/ or tetanus toxoid/ or diphtheria-tetanus vaccine/ or ((diphtheria/ or Whooping Cough/ or tetanus/) and (vaccination/ or vaccines/)) or (adacel or boostrix or infanrix or daptacel or pediarix or kinrix or quadracel or vaxelis or pentacel or tdvax or tenivac).mp.

2 ((hepatitis a or HepA or hep a) and (vaccin* or immuniz* or immunis*)).mp. or hepatitis a vaccines/ or ((hepatitis a/ or hepatitis a virus, human/) and (vaccination/ or vaccines/)) or (havrix or vaqta or twinrix).mp.

3 ((hepatitis b or HepB or hep b) and (vaccin* or immuniz* or immunis*)).mp. or hepatitis b vaccines/ or ((hepatitis b virus/ or hepatitis b/) and (vaccination/ or vaccines/)) or (engerix-b or engerix b or recombivax hb or recombivax-hb or heplisav-b or heplisav b or twinrix or pediarix or vaxelis).mp.

4 ((haemophilus b or haemophilus type b or haemophilus influenzae type b or hib) and (vaccin* or immuniz* or immunis*)).mp. or (Haemophilus influenzae type b/ and (vaccination/ or vaccines/)) or haemophilus vaccines/ or haemophilus influenza type b polysaccharide vaccine-tetanus toxin conjugate.mp. or (pedvaxhib or acthib or hiberix or vaxelis).mp.

5 ((papillomaviridae or papillomavirus or hpv or hpv9) and (vaccin* or immuniz* or immunis*)).mp. or papillomavirus vaccines/ or ((papillomaviridae/ or papillomavirus infections/) and (vaccination/ or vaccines/)) or (Gardasil 9 or Gardasil-9).mp.

6 (polio* and (vaccine* or immuniz* or immunis*)).mp. or poliovirus vaccine, inactivated/ or (Poliomyelitis/ and (vaccination/ or vaccines/)) or (ipol or pentacel or kinrix or quadracel or vaxelis).mp.

7 ((influenza or flu or RIV or laiv or iiv or ipv) and (vaccin* or immuniz* or immunis*)).mp. or influenza vaccines/ or (influenza, human/ and (vaccination/ or vaccines/)) or (fluad or afluria or flucelvax or flulaval or flumist or fluarix or fluzone or flublok).mp.

8 ((measles or mumps or rubella or mmr) and (vaccin* or immuniz* or immunis*)).mp. or measles mumps rubella vaccine/ or measles vaccine/ or mumps vaccine/ or rubella vaccine/ or ((measles/ or mumps/ or rubella/) and (vaccination/ or vaccines/)) or (mmr 2 or mmr II or m-m-r II or mmr v or proquad).mp.
9 (mening* and (vaccin* or immuniz* or immunis*)).mp. or meningococcal vaccines/ or (exp meningitis/ and (vaccination/ or vaccines/)) or (menACWY-D or menACWY-CRM or MenACWY-TT or menB or menactra or MenQuadfi or menveo or bexsero or trumenba).mp.
10 ((pneumonia* or pneumococ*) and (vaccin* or immuniz* or immunis*)).mp. or pneumococcal vaccines/ or (pneumonia/ and (vaccination/ or vaccines/)) or (prevnar 13 or prevnar-13 or pneumovax or ppsv23 or pcv13).mp.
11 ((rotavirus or rv) and (vaccin* or immuniz* or immunis*)).mp. or (rotavirus/ and (vaccination/ or vaccines/)) or rotavirus vaccines/ or (rotarix or rotateq).mp.
12 ((chicken pox or chickenpox or varicella) and (vaccin* or immuniz* or immunis*)).mp. or exp chickenpox vaccine/ or (chickenpox/ and (vaccines/ or vaccination/)) or varivax.mp.
13 ((zoster or shingles or rzv or zvl) and (vaccin* or immuniz* or immunis*)).mp. or (exp herpes zoster/ and (vaccines/ or vaccination/)) or (shingrix or zostavax).mp.
14 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13
15 ("clinical trial" or "clinical trial, phase i" or "clinical trial, phase ii" or clinical trial, phase iii or
clinical trial, phase iv or controlled clinical trial or "multicenter study" or "randomized controlled trial").pt. or double-blind method/ or clinical trials as topic/ or clinical trials, phase i as topic/ or clinical trials, phase ii as topic/ or clinical trials, phase iii as topic/ or clinical trials, phase iv as topic/ or controlled clinical trials as topic/ or randomized controlled trials as topic/ or early termination of clinical trials as topic/ or multicenter studies as topic/ or ((randomi?ed adj7 trial*) or (controlled adj3 trial*) or (clinical adj2 trial*) or ((single or doubl* or tripl* or treb*) and (blind* or mask*))).ti,ab,kw. or ("4 arm" or "four arm").ti,ab,kw.
16 cohort studies/ or longitudinal studies/ or follow-up studies/ or prospective studies/ or retrospective studies/ or cohort.ti,ab. or longitudinal.ti,ab. or prospective.ti,ab. or retrospective.ti,ab. OR ("self controlled case series" or "self-controlled case series" OR "risk interval design" OR "control interval design" OR "self-controlled design" or "self controlled design")
17 15 or 16
18 14 and 17
19 limit 18 to yr="2013 -Current"
20 (study protocol or trial protocol or review protocol).ti.
21 19 not 20
22 exp animals/ not humans.sh.
23 21 not 22
24 review.pt.
25 23 not 24

Embase

Limits: 2013-current; Humans; Article or Article in Press; English
Date: 15 December 2020
Search terms

#1 ("diphtheria tetanus acellular pertussis" or "tetanus diphtheria acellular pertussis" or "tetanus toxoid" or dt or td or tt or "diphtheria tetanus" or "tetanus diphtheria" or "whooping cough" or (tetanus and diphtheria)) and ((vaccin* or immuniz* or immunis*)) or (dtap or tdap) OR 'diphtheria pertussis tetanus vaccine'/exp OR 'tetanus toxoid'/exp OR 'diphtheria tetanus vaccine'/exp OR (('diphtheria'/exp OR 'pertussis'/exp OR 'tetanus'/exp) AND ('vaccination'/exp OR 'vaccine'/exp)) or (adacel or boostrix or infanrix or daptacel or pediarix or kinrix or quadracel or vaxelis or pentacel or tdvax or tenivac)
#2 (("hepatitis a" or HepA or "hep a") and (vaccin* or immuniz* or immunis*)) or 'hepatitis A vaccine'/exp or (('hepatitis A'/exp or 'Human hepatitis A virus'/exp) and ('vaccination'/exp or 'vaccine'/exp)) or (havrix or vaqta or twinrix)
#3 ((hepatitis b or HepB or hep b) and (vaccin* or immuniz* or immunis*)) or 'hepatitis B vaccine'/exp or (('Hepatitis B virus'/exp or 'hepatitis B'/exp) and ('vaccination'/exp or 'vaccine'/exp)) or (engerix-b or engerix b or recombivax hb or recombivax-hb or heplisav-b or heplisav b or twinrix or pediarix or vaxelis)
#4 (("haemophilus b" or "haemophilus type b" or "haemophilus influenzae type b" or hib) and (vaccin* or immuniz* or immunis*)) or ('Haemophilus influenzae type b'/exp and ('vaccination'/exp or 'vaccine'/exp)) or 'Haemophilus vaccine'/exp or "haemophilus influenza type b polysaccharide vaccine-tetanus toxin conjugate" or pedvaxhib or acthib or hiberix or vaxelis
#5 ((papillomaviridae or papillomavirus or hpv or hpv9) and (vaccin* or immuniz* or immunis*)) or 'Wart virus vaccine'/exp or (('Papillomaviridae'/exp or 'papillomavirus infection'/exp) and ('vaccination'/exp or 'vaccine'/exp)) or ("Gardasil 9" or "Gardasil-9")
#6 (polio* and (vaccine* or immuniz* or immunis*)) or 'poliomyelitis vaccine'/exp or ('poliomyelitis'/exp and ('vaccination'/exp or 'vaccine'/exp)) or (ipol or pentacel or kinrix or quadracel or vaxelis)
#7 ((influenza or flu or RIV or laiv or iiv or ipv) and (vaccin* or immuniz* or immunis*)) or 'influenza vaccine'/exp or ('influenza'/exp and ('vaccination'/exp or 'vaccine'/exp)) or (fluad or afluria or flucelvax or flulaval or flumist or fluarix or fluzone or flublok)
#8 ((measles or mumps or rubella or mmr) and (vaccin* or immuniz* or immunis*)) or 'measles mumps rubella vaccine'/exp or 'measles vaccine'/exp or 'mumps vaccine'/exp or 'rubella vaccine'/exp or (('measles'/exp or 'mumps'/exp or 'rubella'/exp) and ('vaccination'/exp or 'vaccine'/exp)) or ("mmr 2" or "mmr II" or "m-m-r II" or "mmr v" or proquad)
#9 (mening* and (vaccin* or immuniz* or immunis*)) or 'Meningococcus vaccine'/exp or (meningitis/exp and ('vaccination'/exp or 'vaccine'/exp)) or (menACWY-D or menACWY-CRM or MenACWY-TT or menB or menactra or MenQuadfi or menveo or bexsero or trumenba)
#10 ((pneumonia* or pneumococ*) and (vaccin* or immuniz* or immunis*)) or 'Pneumococcus vaccine'/exp or ('pneumonia'/exp and ('vaccination'/exp or 'vaccine'/exp)) or ("prevnar 13" or prevnar-13 or pneumovax or ppsv23 or pcv13)
#11 ((rotavirus or rv) and (vaccin* or immuniz* or immunis*)) or ('rotavirus'/exp and ('vaccination'/exp or 'vaccine'/exp)) or 'rotavirus vaccine'/exp or (rotarix or rotateq)
#12 ((chicken pox or chickenpox or varicella) and (vaccin* or immuniz* or immunis*)) or 'chickenpox vaccine'/exp or ('chickenpox'/exp and ('vaccination'/exp or 'vaccine'/exp)) or varivax
#13 ((zoster or shingles or rzv or zvl) and (vaccin* or immuniz* or immunis*)) or ('herpes zoster'/exp and ('vaccination'/exp or 'vaccine'/exp)) or (shingrix or zostavax)
#14 (#1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9 OR #10 OR #11 OR #12 OR #13)

#15 (("clinical trial" or "multicenter study" or "randomized controlled trial") or 'clinical trial (topic)'/exp or 'phase 1 clinical trial (topic)'/exp or 'phase 2 clinical trial (topic)'/exp or 'double blind procedure'/exp or 'controlled clinical trial (topic)'/exp or 'phase 3 clinical trial (topic)'/exp or 'phase 4 clinical trial (topic)'/exp or 'randomized controlled trial (topic)'/exp or 'multicenter study (topic)'/exp or ((randomi?ed NEAR/7 trial*) or (controlled NEAR/3 trial*) or (clinical NEAR/2 trial*) or ((single or doubl* or tripl* or treb*) and (blind* or mask*))) or ("4 arm" or "four arm"))
#16 'cohort analysis'/exp or 'longitudinal study'/exp or 'follow up'/exp or 'prospective study'/exp or 'retrospective study'/exp or cohort:ti,ab or longitudinal:ti,ab or prospective:ti,ab or retrospective:ti,ab or ('self controlled case series' or 'self-controlled case series' or 'risk interval design' or 'control interval design' or 'self-controlled design' or 'self controlled design')
#17 (#15 OR #16)
#18 (#14 AND #17)
#19 (#14 AND #17 AND [English]/lim)
#20 #19 AND ('article'/it or 'article in press'/it)
#21 'study protocol':ti OR 'trial protocol':ti OR 'review protocol':ti
#22 (#20 NOT #21) AND [humans]/lim AND [embase]/lim AND [2013-2020]/py
Results: 11,719 – internal duplicates = 11626

CINAHL

CINAHL (phrase searching)
English Language, Journals, Dissertations; Exclude MEDLINE
Limit: January 2013-present
Date: 9 November 2020
1 (("diphtheria tetanus acellular pertussis" or "tetanus diphtheria acellular pertussis" or "tetanus toxoid" or dt or td or tt or "diphtheria tetanus" or "tetanus diphtheria" or "whooping cough" or (tetanus and diphtheria)) and (vaccin* or immuniz* or immunis*)) or (dtap or tdap) or (MH "Diphtheria-Tetanus-acellular Pertussis Vaccines") or (MH "diphtheria-pertussis-tetanus vaccine") or (MH "tetanus toxoid") or (MH "diphtheria-tetanus vaccine") or (((MH diphtheria) or (MH "Whooping Cough") or (MH tetanus)) and (MH vaccines)) or (adacel or boostrix or infanrix or daptacel or pediarix or kinrix or quadracel or vaxelis or pentacel or tdvax or tenivac)
2 (("hepatitis a" or HepA or "hep a") and (vaccin* or immuniz* or immunis*)) or (MH "hepatitis a vaccines") or ((MH("hepatitis a") and (MH vaccines)) or (havrix or vaqta or twinrix)
3 (("hepatitis b" or HepB or "hep b") and (vaccin* or immuniz* or immunis*)) or (MH "hepatitis b vaccines") or ((MH("hepatitis b") and (MH vaccines)) or (engerix-b or "engerix b" or "recombivax hb" or "recombivax-hb" or "heplisav-b" or "heplisav b" or twinrix or pediarix or vaxelis)
4 (("haemophilus b" or "haemophilus type b" or "haemophilus influenzae type b" or hib) and (vaccin* or immuniz* or immunis*)) or ((MH "Haemophilus influenzae") and (MH vaccines)) or (MH "HIB vaccine") or "haemophilus influenza type b polysaccharide vaccine-tetanus toxin conjugate" or (pedvaxhib or acthib or hiberix or vaxelis)
5 ((papillomaviridae or papillomavirus or hpv or hpv9) and (vaccin* or immuniz* or immunis*)) or (MH "papillomavirus vaccine") or (((MH papillomaviruses) or (MH "papillomavirus infections")) and (MH vaccines)) or ("Gardasil 9" or "Gardasil-9")
6 (polio* and (vaccine* or immuniz* or immunis*)) or (MH "poliovirus vaccine, inactivated") or ((MH Poliomyelitis) and (MH vaccines)) or (ipol or pentacel or kinrix or quadracel or vaxelis)

7 ((influenza or flu or RIV or laiv or iiv or ipv) and (vaccin* or immuniz* or immunis*)) or (MH "influenza vaccine") or ((MH "influenza, human") and (MH vaccines)) or (fluad or afluria or flucelvax or flulaval or flumist or fluarix or fluzone or flublok)
8 ((measles or mumps or rubella or mmr) and (vaccin* or immuniz* or immunis*)) or (MH "measles mumps rubella vaccine") or (MH "measles vaccine") or (MH "mumps vaccine") or (MH "rubella vaccine") or (((MH measles) or (MH mumps) or (MH rubella)) and (MH vaccines)) or ("mmr 2" or "mmr II" or "m-m-r II" or "mmr v" or proquad)
9 (mening* and (vaccin* or immuniz* or immunis*)) or (MH "meningococcal vaccines") or ((MH meningitis) and (MH vaccines)) or (menACWY-D or menACWY-CRM or MenACWY-TT or menB or menactra or MenQuadfi or menveo or bexsero or trumenba)
10 ((pneumonia* or pneumococ*) and (vaccin* or immuniz* or immunis*)) or (MH "pneumococcal vaccine") or ((MH pneumonia)and (MH vaccines)) or ("prevnar 13" or "prevnar-13" or pneumovax or ppsv23 or pcv13)
11 ((rotavirus or rv) and (vaccin* or immuniz* or immunis*)) or ((MH rotavirus) and (MH vaccines)) or (MH "rotavirus vaccines") or (rotarix or rotateq)
12 ((chicken pox or chickenpox or varicella) and (vaccin* or immuniz* or immunis*)) or (MH "chickenpox vaccine+") or ((MH chickenpox) and (MH vaccines)) or varivax
13 ((zoster or shingles or rzv or zvl) and (vaccin* or immuniz* or immunis*)) or ((MH "herpes zoster+") and (MH vaccines)) or (shingrix or zostavax)
14 S1 or S2 or S3 or S4 or S5 or S6 or S7 or S8 or S9 or S10 or S11 or S12 or S13
15 (PT "randomized controlled trial") OR (PT "clinical trial") or (MH "double-blind studies") or (MH "Clinical Trials+") or (MH "multicenter studies") or (randomi?ed N7 trial*) or (controlled N3 trial*) or (clinical N2 trial*) or ((single or doubl* or tripl* or treb*) and (blind* or mask*)) or ("4 arm" or "four arm") OR (MH "prospective studies") or (MH "retrospective panel studies") or (TI cohort) OR (AB cohort) or (TI longitudinal) OR (AB longitudinal) or (TI prospective) OR (AB prospective) or (TI retrospective) OR (AB retrospective)
16 S14 AND S15
17 (TI ("study protocol" or "trial protocol" or "review protocol")) OR ((MH mammals+) NOT (MH human)) OR (PT review)
18 S16 not S17
Results: 976, removed internal duplicates = 947

Web of Science

Limits: 2013-current; Humans; Article; English; Journals
Date: 5 November 2020
Search terms:
#1 TS= ("diphtheria tetanus acellular pertussis" or "tetanus diphtheria acellular pertussis" or "tetanus toxoid" or dt or td or tt or "diphtheria tetanus" or "tetanus diphtheria" or "whooping cough") or (TS=(tetanus and diphtheria) AND TS=(vaccin* or immuniz* or immunis*)) or TS=(dtap or tdap) or TS=(adacel or boostrix or infanrix or daptacel or pediarix or kinrix or quadracel or vaxelis or pentacel or tdvax or tenivac)
#2 (TS=("hepatitis a" or HepA or "hep a") AND TS=(vaccin* or immuniz* or immunis*)) or TS=(havrix or vaqta or twinrix)
#3 (TS=("hepatitis b" or HepB or "hep b") AND TS=(vaccin* or immuniz* or immunis*)) or TS=(engerix-b or "engerix b" or "recombivax hb" or recombivax-hb or heplisav-b or "heplisav b" or twinrix or pediarix or vaxelis)

#4 (TS=("haemophilus b" or "haemophilus type b" or "haemophilus influenzae type b" or hib) AND TS=(vaccin* or immuniz* or immunis*)) or TS=("haemophilus influenza type b polysaccharide vaccine-tetanus toxin conjugate" or pedvaxhib or acthib or hiberix or vaxelis)
#5 (TS=(papillomaviridae or papillomavirus or hpv or hpv9) AND TS=(vaccin* or immuniz* or immunis*)) or TS=("Gardasil 9" or "Gardasil-9")
#6 (TS=(polio*) AND TS=(vaccine* or immuniz* or immunis*)) or TS=(ipol or pentacel or kinrix or quadracel or vaxelis)
#7 (TS=(influenza or flu or RIV or laiv or iiv or ipv) AND TS=(vaccin* or immuniz* or immunis*)) or TS=(fluad or afluria or flucelvax or flulaval or flumist or fluarix or fluzone or flublok)
#8 (TS=(measles or mumps or rubella or mmr) AND TS=(vaccin* or immuniz* or immunis*)) or TS=("mmr 2" or "mmr II" or "m-m-r II" or "mmr v" or proquad)
#9 (TS=(mening*) AND TS=(vaccin* or immuniz* or immunis*)) or TS=(menACWY-D or menACWY-CRM or MenACWY-TT or menB or menactra or MenQuadfi or menveo or bexsero or trumenba)
#10 (TS=(pneumonia* or pneumococ*) AND TS=(vaccin* or immuniz* or immunis*)) or TS=("prevnar 13" or prevnar-13 or pneumovax or ppsv23 or pcv13)
#11 (TS=(rotavirus or rv) AND TS=(vaccin* or immuniz* or immunis*)) or TS=(rotarix or rotateq)
#12 (TS=("chicken pox" or chickenpox or varicella) AND TS=(vaccin* or immuniz* or immunis*)) or TS=(varivax)
#13 (TS=(zoster or shingles or rzv or zvl) AND TS=(vaccin* or immuniz* or immunis*)) or TS=(shingrix or zostavax)
#14 (#1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9 OR #10 OR #11 OR #12 OR #13)
#15 (TS=("clinical trial" or "multicenter study" or "randomized controlled trial") or TS=(randomi?ed NEAR/7 trial*) or TS=(controlled NEAR/3 trial*) or TS=(clinical NEAR/2 trial*) or (TS=(single or doubl* or tripl* or treb*) AND TS=(blind* or mask*))) or TS=("4 arm" or "four arm")
#16 TS=(cohort OR longitudinal OR prospective OR retrospective)
#17 (#15 OR #16)
#18 (#14 AND #17)
#19 TI=("study protocol" OR "trial protocol" OR "review protocol")
#20 #18 NOT #19
#21 TI=(review OR "meta analysis")
#22 (#20 NOT #21)
#23 TS=("transit time" OR "targeted therapy" OR "TT-173" OR "TT genotype" OR "serum TT" OR "total testosterone" OR "thrombin time" OR "thiazide type" OR "traditional teaching" OR "therapeutic touch" OR "tissue therapy" OR "treponema denticola" OR "typically developing" OR "thyroid dysfunction" OR "temporal difference" OR "GD-LVAD-DT" OR "decision tree" OR "double transgenic" OR "dystonic tremor" OR "deceleration time")
#24 #22 NOT #23
EXCLUDE : WoS Categories: Veterinary Sciences; Agricultural Dairy Animal Science; Zoology
Results: 12,452

Scopus

Limits: 2013-current; Humans; Article; English; Journals
Date: 4 November 2020
#1 TITLE-ABS ("diphtheria tetanus acellular pertussis" or "tetanus diphtheria acellular pertussis" or "tetanus toxoid" or dt or td or tt or "diphtheria tetanus" or "tetanus diphtheria" or "whooping cough" or ((tetanus and diphtheria) and (vaccin* or immuniz* or immunis*)) or (dtap or tdap) or (adacel or boostrix or infanrix or daptacel or pediarix or kinrix or quadracel or vaxelis or pentacel or tdvax or tenivac))
#2 TITLE-ABS ((("hepatitis a" or HepA or "hep a") and (vaccin* or immuniz* or immunis*)) or (havrix or vaqta or twinrix))
#3 TITLE-ABS ((("hepatitis b" or HepB or "hep b") and (vaccin* or immuniz* or immunis*)) or (engerix-b or "engerix b" or "recombivax hb" or recombivax-hb or heplisav-b or "heplisav b" or twinrix or pediarix or vaxelis))
#4 TITLE-ABS ((("haemophilus b" or "haemophilus type b" or "haemophilus influenzae type b" or hib) and (vaccin* or immuniz* or immunis*)) or "haemophilus influenza type b polysaccharide vaccine-tetanus toxin conjugate" or pedvaxhib or acthib or hiberix or vaxelis)
#5 TITLE-ABS (((papillomaviridae or papillomavirus or hpv or hpv9) and (vaccin* or immuniz* or immunis*)) or ("Gardasil 9" or "Gardasil-9"))
#6 TITLE-ABS ((polio* and (vaccine* or immuniz* or immunis*)) or (ipol or pentacel or kinrix or quadracel or vaxelis))
#7 TITLE-ABS (((influenza or flu or RIV or laiv or iiv or ipv) and (vaccin* or immuniz* or immunis*)) or (fluad or afluria or flucelvax or flulaval or flumist or fluarix or fluzone or flublok))
#8 TITLE-ABS (((measles or mumps or rubella or mmr) and (vaccin* or immuniz* or immunis*)) or ("mmr 2" or "mmr II" or "m-m-r II" or "mmr v" or proquad))
#9 TITLE-ABS ((mening* and (vaccin* or immuniz* or immunis*)) or (menACWY-D or menACWY-CRM or MenACWY-TT or menB or menactra or MenQuadfi or menveo or bexsero or trumenba))
#10 TITLE-ABS (((pneumonia* or pneumococ*) and (vaccin* or immuniz* or immunis*)) or ("prevnar 13" or prevnar-13 or pneumovax or ppsv23 or pcv13))
#11 TITLE-ABS (((rotavirus or rv) and (vaccin* or immuniz* or immunis*)) or (rotarix or rotateq))
#12 TITLE-ABS ((("chicken pox" or chickenpox or varicella) and (vaccin* or immuniz* or immunis*)) or varivax)
#13 TITLE-ABS (((zoster or shingles or rzv or zvl) and (vaccin* or immuniz* or immunis*)) or (shingrix or zostavax))
#14 (#1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9 OR #10 OR #11 OR #12 OR #13)
#15 TITLE-ABS-KEY-AUTH ("clinical trial" OR "multicenter study" OR "randomized controlled trial") OR (randomi?ed W/7 trial*) OR (controlled W/3 trial*) OR (clinical W/2 trial*) OR TITLE-ABS-KEY-AUTH ((single OR doubl* OR tripl* OR treb*) AND (blind* OR mask*)) or TITLE-ABS-KEY-AUTH("4 arm" or "four arm")
#16 TITLE-ABS (cohort OR longitudinal OR prospective OR retrospective)
#17 (#15 OR #16)
#18 (#14 AND #17)
#19 TITLE ("study protocol" OR "trial protocol" OR "review protocol")

#20 #18 AND NOT #19
#21 TITLE (review) OR KEY ("systematic review") OR KEY ("meta analysis")
#22 (#20 AND NOT #21)
EXCLUDE KeyWords: "Nonhuman" OR "Animals" OR "Animal"
((((TITLE-ABS ("diphtheria tetanus acellular pertussis" OR "tetanus diphtheria acellular pertussis" OR "tetanus toxoid" OR dt OR td OR tt OR "diphtheria tetanus" OR "tetanus diphtheria" OR "whooping cough" OR ((tetanus AND diphtheria) AND (vaccin* OR immuniz* OR immunis*)) OR (dtap OR tdap) OR (adacel OR boostrix OR infanrix OR daptacel OR pediarix OR kinrix OR quadracel OR vaxelis OR pentacel OR tdvax OR tenivac))) OR (TITLE-ABS ((("hepatitis a" OR hepa OR "hep a") AND (vaccin* OR immuniz* OR immunis*)) OR (havrix OR vaqta OR twinrix))) OR (TITLE-ABS ((("hepatitis b" OR hepb OR "hep b") AND (vaccin* OR immuniz* OR immunis*)) OR (engerix-b OR "engerix b" OR "recombivax hb" OR recombivax-hb OR heplisav-b OR "heplisav b" OR twinrix OR pediarix OR vaxelis))) OR (TITLE-ABS ((("haemophilus b" OR "haemophilus type b" OR "haemophilus influenzae type b" OR hib) AND (vaccin* OR immuniz* OR immunis*)) OR "haemophilus influenza type b polysaccharide vaccine-tetanus toxin conjugate" OR pedvaxhib OR acthib OR hiberix OR vaxelis)) OR (TITLE-ABS (((papillomaviridae OR papillomavirus OR hpv OR hpv9) AND (vaccin* OR immuniz* OR immunis*)) OR ("Gardasil 9" OR "Gardasil-9"))) OR (TITLE-ABS ((polio* AND (vaccine* OR immuniz* OR immunis*)) OR (ipol OR pentacel OR kinrix OR quadracel OR vaxelis))) OR (TITLE-ABS (((influenza OR flu OR riv OR laiv OR iiv OR ipv) AND (vaccin* OR immuniz* OR immunis*)) OR (fluad OR afluria OR flucelvax OR flulaval OR flumist OR fluarix OR fluzone OR flublok))) OR (TITLE-ABS (((measles OR mumps OR rubella OR mmr) AND (vaccin* OR immuniz* OR immunis*)) OR ("mmr 2" OR "mmr II" OR "m-m-r II" OR "mmr v" OR proquad))) OR (TITLE-ABS ((mening* AND (vaccin* OR immuniz* OR immunis*)) OR (menacwy-d OR menacwy-crm OR MenACWY-TT OR menb OR menactra OR MenQuadfi OR menveo OR bexsero OR trumenba))) OR (TITLE-ABS (((pneumonia* OR pneumococ*) AND (vaccin* OR immuniz* OR immunis*)) OR ("prevnar 13" OR prevnar-13 OR pneumovax OR ppsv23 OR pcv13))) OR (TITLE-ABS (((rotavirus OR rv) AND (vaccin* OR immuniz* OR immunis*)) OR (rotarix OR rotateq))) OR (TITLE-ABS ((("chicken pox" OR chickenpox OR varicella) AND (vaccin* OR immuniz* OR immunis*)) OR varivax)) OR (TITLE-ABS (((zoster OR shingles OR rzv OR zvl) AND (vaccin* OR immuniz* OR immunis*)) OR (shingrix OR zostavax)))) AND ((TITLE-ABS-KEY-AUTH (("clinical trial" OR "multicenter study" OR "randomized controlled trial") OR (randomi?ed W/7 trial*) OR (controlled W/3 trial*) OR (clinical W/2 trial*))) OR (TITLE-ABS-KEY-AUTH ((single OR doubl* OR tripl* OR treb*) AND (blind* OR mask*))) OR (TITLE-ABS-KEY-AUTH (("4 arm" OR "four arm"))) OR (TITLE-ABS (cohort OR longitudinal OR prospective OR retrospective)))) AND NOT (TITLE ("study protocol" OR "trial protocol" OR "review protocol"))) AND NOT (TITLE (review) OR KEY ("systematic review") OR KEY ("meta analysis")) AND (LIMIT-TO (PUBYEAR , 2021) OR (PUBYEAR , 2020) OR LIMIT-TO (PUBYEAR , 2019) OR LIMIT-TO (PUBYEAR , 2018) OR LIMIT-TO (PUBYEAR , 2017) OR LIMIT-TO (PUBYEAR , 2016) OR LIMIT-TO (PUBYEAR , 2015) OR LIMIT-TO (PUBYEAR , 2014) OR LIMIT-TO (PUBYEAR , 2013)) AND (LIMIT-TO (DOCTYPE , "ar")) AND (LIMIT-TO (LANGUAGE , "English")) AND (

LIMIT-TO (SRCTYPE , "j")) AND (EXCLUDE (EXACTKEYWORD , "Nonhuman") OR EXCLUDE (EXACTKEYWORD , "Animals") OR EXCLUDE (EXACTKEYWORD , "Animal"))
Results: 12567 – duplicates against EMBASE = 6750

Grey Literature

CENTRAL [includes International Clinical Trials Registry Platform]

Publication Year from 2013 to 2020, in Trials
Date: 5 November 2020
Search terms:
1 (("diphtheria tetanus acellular pertussis" or "tetanus diphtheria acellular pertussis" or "tetanus toxoid" or dt or td or tt or "diphtheria tetanus" or "tetanus diphtheria" or "whooping cough" or (tetanus and diphtheria)) AND (vaccin* or immuniz* or immunis*)) or (dtap or tdap) or [mh "diphtheria-tetanus-acellular pertussis vaccines"] OR [mh "diphtheria tetanus acellular pertussis vaccines"] or [mh "diphtheria pertussis tetanus vaccine"] or [mh "tetanus toxoid"] or [mh "diphtheria-tetanus vaccine"] or (([mh diphtheria] or [mh "Whooping Cough"] or [mh tetanus]) and ([mh vaccination] OR [mh vaccines])) or (adacel or boostrix or infanrix or daptacel or pediarix or kinrix or quadracel or vaxelis or pentacel or tdvax or tenivac)
2 (("hepatitis a" or HepA or "hep a") and (vaccin* or immuniz* or immunis*)) or [mh "hepatitis a vaccines"] or (([mh "hepatitis a"] or [mh "hepatitis a virus, human"]) and ([mh vaccination] or [mh vaccines])) or (havrix or vaqta or twinrix)
3 (("hepatitis b" or HepB or "hep b") and (vaccin* or immuniz* or immunis*)) or [mh "hepatitis b vaccines"] or (([mh "hepatitis b virus"] or [mh "hepatitis b"]) and ([mh vaccination] or [mh vaccines])) or (engerix-b or "engerix b" or "recombivax hb" or "recombivax-hb" or "heplisav-b" or "heplisav b" or twinrix or pediarix or vaxelis)
4 (("haemophilus b" or "haemophilus type b" or "haemophilus influenzae type b" or hib) and (vaccin* or immuniz* or immunis*)) or ([mh "Haemophilus influenzae type b"] and ([mh vaccination] or [mh vaccines])) or [mh "haemophilus vaccines"] or [mh "haemophilus influenza type b polysaccharide vaccine-tetanus toxin conjugate"] or (pedvaxhib or acthib or hiberix or vaxelis)
5 ((papillomaviridae or papillomavirus or hpv or hpv9) and (vaccin* or immuniz* or immunis*)) or [mh "papillomavirus vaccines"] or (([mh papillomaviridae] or [mh "papillomavirus infections"]) and ([mh vaccination] or [mh vaccines])) or ("Gardasil 9" or Gardasil-9)
6 (polio* and (vaccine* or immuniz* or immunis*)) or [mh "poliovirus vaccine, inactivated"] or ([mh Poliomyelitis] and ([mh vaccination] or [mh vaccines])) or (ipol or pentacel or kinrix or quadracel or vaxelis)
7 ((influenza or flu or RIV or laiv or iiv or ipv) and (vaccin* or immuniz* or immunis*)) or [mh "influenza vaccines"] or ([mh "influenza, human"] and ([mh vaccination] or [mh vaccines])) or (fluad or afluria or flucelvax or flulaval or flumist or fluarix or fluzone or flublok)
8 ((measles or mumps or rubella or mmr) and (vaccin* or immuniz* or immunis*)) or [mh "measles mumps rubella vaccine"] or [mh "measles vaccine"] or [mh "mumps vaccine"] or [mh "rubella vaccine"] or (([mh measles] or [mh mumps] or [mh rubella]) and ([mh vaccination] or [mh vaccines])) or ("mmr 2" or "mmr II" or "m-m-r II" or "mmr v" or proquad)

9 (mening* and (vaccin* or immuniz* or immunis*)) or [mh "meningococcal vaccines"] or ([mh meningitis] and ([mh vaccination] or [mh vaccines])) or (menACWY-D or menACWY-CRM or MenACWY-TT or menB or menactra or MenQuadfi or menveo or bexsero or trumenba)
10 ((pneumonia* or pneumococ*) and (vaccin* or immuniz* or immunis*)) or [mh "pneumococcal vaccines"] or ([mh pneumonia] and ([mh vaccination] or [mh vaccines])) or ("prevnar 13" or "prevnar-13" or pneumovax or ppsv23 or pcv13)
11 ((rotavirus or rv) and (vaccin* or immuniz* or immunis*)) or ([mh rotavirus] and ([mh vaccination] or [mh vaccines])) or [mh "rotavirus vaccines"] or (rotarix or rotateq)
12 (("chicken pox" or chickenpox or varicella) and (vaccin* or immuniz* or immunis*)) or [mh "chickenpox vaccine"] or ([mh chickenpox] and ([mh vaccination] or [mh vaccines])) or varivax
13 ((zoster or shingles or rzv or zvl) and (vaccin* or immuniz* or immunis*)) or ([mh "herpes zoster"] and ([mh vaccination] or [mh vaccines])) or (shingrix or zostavax)
14 #1 or #2 or #3 or #4 or #5 or #6 or #7 or #8 or #9 or #10 or #11 or #12 or #13
15 ("study protocol" or "trial protocol" or "review protocol"):ti
16 #14 not 15
17 [mh animals] NOT [mh humans]
18 #16 not #17
19 #18 with Publication Year from 2013 to 2020, in Trials
Results: 6527 – internal duplicates/protocols/CT.gov records = 4787 (including ICTRP:762)
Results: 4787- duplicates with WoS = 3090(761 WHO trials)

ClinicalTrials.gov

Completed, Suspended, Terminated, Unknown status Studies | Start date on OR after 01/01/2013 | Primary completion on OR after 01/01/2013 | First posted on OR after 01/01/2013 | Results first posted on OR after 01/01/2013 | Last update posted on OR after 01/01/2013
("diphtheria tetanus acellular pertussis" OR "tetanus diphtheria acellular pertussis" OR "tetanus toxoid" OR dt OR td OR tt OR "diphtheria tetanus" OR "tetanus diphtheria" OR "whooping cough") AND (vaccin* OR immuniz* OR immunis*) OR ((tetanus and diphtheria) AND (vaccin* OR immuniz* OR immunis*))
OR (dtap OR tdap) OR (adacel OR boostrix OR infanrix OR daptacel OR pediarix OR kinrix OR quadracel OR vaxelis OR pentacle OR tdvax OR tenivac)
Results: 36
OR
(("hepatitis a" OR HepA OR "hep a") AND (vaccin* OR immuniz* OR immunis*)) OR (havrix OR vaqta OR twinrix)
Results: 206 -duplicates= 199
OR
(("hepatitis b" OR HepB OR "hep b") AND (vaccin* OR immuniz* OR immunis*)) OR (engerix-b OR "engerix b" OR "recombivax hb" OR recombivax-hb OR heplisav-b OR "heplisav b" OR twinrix OR pediarix OR vaxelis)
Results: 17-duplicates =3
OR
(("haemophilus b" OR "haemophilus type b" OR "haemophilus influenzae type b" OR hib) AND (vaccin* OR immuniz* OR immunis*)) OR ("haemophilus influenza type b polysaccharide

vaccine-tetanus toxin conjugate" OR pedvaxhib OR acthib OR hiberix) OR (vaxelis)
Results: 7 – duplicates = 2
OR
((papillomaviridae OR papillomavirus OR hpv OR hpv9) AND (vaccin* OR immuniz* OR immunis*)) OR ("Gardasil 9" OR "Gardasil-9")
Results: 2
OR ((polio*) AND (vaccine* OR immuniz* OR immunis*)) OR (ipol OR pentacel OR kinrix OR quadracel OR vaxelis)
Results: 7 – duplicates = 3
OR
((influenza OR flu OR RIV OR laiv OR iiv OR ipv) AND (vaccin* OR immuniz* OR immunis*)) OR (fluad OR afluria OR flucelvax OR flulaval OR flumist OR fluarix OR fluvirin OR agriflu OR fluzone OR flublok)
Results: 205 - duplicates =191
OR
((measles OR mumps OR rubella OR mmr) AND (vaccin* OR immuniz* OR immunis*)) OR ("mmr 2" OR "mmr II" OR "m-m-r II" OR "mmr v" OR proquad)
Results 6 -duplicates = 3
OR
((mening*) AND (vaccin* OR immuniz* OR immunis*)) OR (menACWY-D OR menACWY-CRM OR menB OR menactra OR menveo OR bexsero OR trumenba)
Results 33 – duplicates = 27
OR
((pneumonia* OR pneumococ*) AND (vaccin* OR immuniz* OR immunis*)) OR ("prevnar 13" OR prevnar-13 OR pneumovax OR ppsv23 OR pcv13)
Results 48 – duplicates= 26
OR
((rotavirus OR rv) AND (vaccin* OR immuniz* OR immunis*)) OR (rotarix OR rotateq)
Results 12 – duplicates=6
OR
(("chicken pox" OR chickenpox OR varicella) AND (vaccin* OR immuniz* OR immunis*)) OR (varivax)
Results 9 – duplicates = 5
OR
((zoster OR shingles OR rzv OR zvl) AND TS=(vaccin* OR immuniz* OR immunis*)) OR (shingrix OR zostavax)
Results 22 – duplicates = 11
TOTAL: 514

ACIP Recommendations

Search strategy: all recommendations for all of the vaccines of interest
For two vaccines, guidance was published in addition to the recommendation (HPV and Polio) which was also retrieved

Package inserts
https://www.fda.gov/vaccines-blood-biologics/vaccines/vaccines-licensed-use-united-states
Search strategy: all inserts for vaccines of interest

Additional Input
We solicitated public comments for the project in two ways. The AHRQ EPC Program placed a notice in the Federal Register that described the project and requested public comment. In addition, we established a Supplemental Evidence and Data (SEADS) portal.

Screening Procedure

The citations were screened by two independent literature reviewers using a structured form in an online program designed for systematic reviews (DistillerSR). Citations deemed relevant by at least one reviewer were obtained as full text articles. Full text articles and grey literature material were screened by two independent reviewers against the explicit eligibility criteria. Any discrepancies in inclusion decisions were then discussed among the full review team. For studies that were excluded, reasons for exclusion were documented (see Appendix B for the list of excluded studies with reasons for exclusion).

Inclusion and Exclusion Criteria

The eligibility criteria are described in a PICOTSSO (population, intervention, comparator, outcomes, timing, setting, study design, and other limiters) framework in Table A.1.

Table A.1. Eligibility criteria

Domain	Inclusion	Exclusion
Population	• Human participants of all ages for whom the vaccines are recommended in the United States	• Studies in animals or mechanistic/in vitro studies • Studies exclusively in populations for whom the vaccine is not approved or is contraindicated (see Tables A.3-5)

Domain	Inclusion	Exclusion
Interventions	**All KQs** • Individual vaccines included in the CDC's routine immunization schedules recommended for adults, children and adolescents, and pregnant women, as well as combination vaccines in use in the United States (see Tables A.3- A.5) **Vaccines for adults (KQ1)** • Hepatitis A (HepA; Havrix®, Vaqta®); hepatitis B (HepB; Engerix-B®, Recombivax HB®, HEPLISAV-B®); human papillomavirus (HPV, HPV9; Gardasil 9®); influenza, inactivated (IIV; Afluria Quadrivalent®, Fluarix Quadrivalent®, Flucelvax Quadrivalent®, Flulaval Quadrivalent®, Fluzone High Dose®, Fluzone Quadrivalent®, Fluad®, Fluad Quadrivalent®); influenza, live attenuated (LAIV; FluMist Quadrivalent®); influenza, recombinant (RIV; Flublok Quadrivalent®); measles, mumps, rubella (MMR; M-M-R II®); meningococcal A, C, W, and Y (Menactra® [MenACWY-D], Menveo® [MenACWY-CRM], MenQuadfi® [MenACWY-TT]); meningococcal B (MenB; Bexsero® [MenB-4C], Trumenba® [MenB-FHbp]); pneumococcal conjugate vaccine (PCV13; Prevnar 13®); pneumococcal polysaccharide vaccine (PPSV23; Pneumovax®); tetanus, diphtheria, and acellular pertussis (Tdap; Adacel®, Boostrix®); tetanus, diphtheria (Td; TDVAX®, Tenivac®); varicella (VAR; Varivax®); zoster (recombinant, RZV, Shingrix®); HepA-Hep B (Twinrix®) **Vaccines for Children and Adolescents (KQ 2)** • Vaccines for children and adolescents will include diphtheria, tetanus, and acellular pertussis (DTaP; Daptacel, Infanrix®); hepatitis A (HepA; Havrix, Vaqta); hepatitis B (HepB; Engerix-B, Recombivax HB); Haemophilus influenzae type b (Hib; PedvaxHIB®, ActHIB®, Hiberix®); human papillomavirus (HPV, HPV9; Gardasil 9); inactivated polio vaccine (IPV; IPOL®); influenza, inactivated (IIV; Afluria Quadrivalent, Fluarix Quadrivalent, Flulaval Quadrivalent, Fluzone Quadrivalent, Flucelvax Quadrivalent); influenza, live attenuated (LAIV; FluMist Quadrivalent); measles, mumps, rubella (MMR; M-M-R II); meningococcal A, C, W, and Y (MenACWY-D, Men-ACWY-CRM; Menactra [MenACWY-D] , Menveo [MenACWY-CRM], MenQuadfi [MenACWY-TT; approved for 2 years and older]); meningococcal B (MenB; Bexsero [MenB-4C], Trumenba [MenB-FHbp]); pneumococcal conjugate vaccine (PCV13; Prevnar 13); pneumococcal polysaccharide vaccine (PPSV23; Pneumovax); rotavirus (RV; Rotarix®, RotaTeq®); tetanus, diphtheria, and acellular pertussis (Tdap; Adacel, Boostrix); varicella (VAR; Varivax); DTaP-HepB-IPV (Pediarix®); DTaP-IPV/Hib (Pentacel®); DTaP-IPV (Kinrix®, Quadracel®); MMR-V (ProQuad®); DTaP-IPV-Hib-HepB (Vaxelis®) **Vaccines for Pregnant Women (KQ3)** • Hepatitis B (HepB; Engerix-B, Recombivax HB); influenza, inactivated (IIV; Afluria Quadrivalent, Flucelvax Quadrivalent, Fluarix Quadrivalent, Flulaval Quadrivalent, Fluzone Quadrivalent); influenza, recombinant (RIV; Flublok Quadrivalent); tetanus, diphtheria, and acellular pertussis (Tdap; Adacel, Boostrix)	• Studies of vaccines not on the United States recommended schedules, including brands/formulations not available in the United States, or no longer used

Domain	Inclusion	Exclusion
Comparators	• Active comparators (e.g., other vaccines or other vaccination schedules) and inactive comparators (e.g., no vaccine) • Unvaccinated participants, everyone getting 1 vaccine but one group getting 2 [A+B vs A is an eligible design when B is the test vaccine]). • Concurrent (e.g., RCT) and historic control (e.g., pre-post study).	• Studies without intervention comparator
Outcomes	• Adverse events identified in participants, and, in the case of pregnant women, in their fetuses/infants (including the presence and the absence of harms, toxicities, transient side effects, and unintended adverse health effects)	• Studies reporting only on effectiveness outcomes
Timing	• Short term (within 42 days following immunization) as well as long term (>42 days after immunization) effects	• No exclusions apply
Setting(s)	• No restrictions with regard to settings	• No exclusions apply
Study design	• Controlled studies (randomized and non-randomized controlled clinical trials, cohort studies comparing two or more cohorts (observational, not under the control of the investigator), case-control studies, self-controlled case series)	• Studies without comparator (e.g., case studies*) • Studies need to have an unvaccinated group or a group that did not get the vaccine that is being evaluated. Historic comparators from the same institution are ok (e.g., comparing to last year's cohort) but studies comparing to external data (e.g., national surveys) are excluded.
Other limiters	• English language scientific journal publications and trial records with published results	• Studies published in abbreviated form only (e.g., letters, conference abstracts) • Studies reported only in non-English publications

*Case studies were outside the scope of the report because they do not include unvaccinated individuals for comparison.

To maximize the applicability of the report to the population of the United States, only studies that employed human participants and vaccines included in the CDC's routine immunization schedules recommended for adults, children and adolescents, and pregnant women, as well as combination vaccines in use in the United States were included. For the same reason, only English-language reports were included; however, we included English language studies conducted outside of the United States if the vaccines studied were included in the CDC immunization schedules and the formulations were approved for use in the United States. We accepted studies where a small proportion of participants (up to 20%) was included for whom the vaccine was not approved but we excluded studies exclusively in populations for whom the vaccine was not approved or was contraindicated, and we excluded studies that included participants for whom the vaccine was not approved or contraindicated and the proportion of these patients could not be determined.

To enable true assessments of risk, only studies with valid control groups were included. We accepted control groups receiving placebo; unvaccinated control groups; self-controlled studies where two risk intervals were compared (e.g., weeks immediately following the vaccine

administration and periods before or sufficiently distant from the vaccine administration); and studies where the intervention and the control group both received multiple vaccines but only the intervention group received a specific vaccine of interest ("add-on trial" design). For this update we also included control groups receiving the previously available vaccine (prior standard of care) and control groups receiving acceptable active comparators (e.g., combination vaccines that were compared to the individual vaccines). The definition of acceptable comparator depended on the particular vaccines. For HEPLISAV-B, the comparator could be an existing Hepatitis B vaccine. For HPV9, comparators could include HPV2 or HPV4. For quadrivalent IIV, the comparator could be trivalent influenza vaccines of the same type. For quadrivalent aIIV or RIV, the comparator could be IIV. For MenACWY-TT the comparator could be MenACWY-CRM or MenACWY-D. For PCV13, the comparator could be PCV7 or PPSV23 (for adults). For RZV, the comparator could be ZVL (though none of the included studies used this particular comparator). For Tdap the comparator could be Td. For combination vaccines, the comparator could be the individual vaccines given together at the same time. We accepted observational studies where not all relevant factors were under the control of the investigator, but we excluded studies where control groups were systematically different from the intervention groups in aspects other than the vaccine administration.

No studies were excluded based on setting, timing of follow up, or risk of bias. To ensure sufficient information was included to assess studies in detail, only studies published in full in a journal manuscript or in trial records were included.

Vaccines recommended for adults in the United States are described below in Table A.2.

Table A.2. Recommended vaccines for adults in the United States, 2020

Vaccine (Abbreviation; Brand Name[s])	Recommendation
Hepatitis A (HepA; Havrix, Vaqta)	12 months and older
Hepatitis B (HepB; Engerix-B, Recombivax HB, HEPLISAV-B)	All ages (Engerix-B, Recombivax-B) 18 years and older (HEPLISAV-B)
Hepatitis A-Hepatitis B (HepA-HepB; Twinrix)	18 years and older
9-valent human papillomavirus (HPV9; Gardasil 9)	9 through 45 years; routine through 26 years
Influenza, inactivated (IIV; Afluria Quadrivalent, Fluarix Quadrivalent, Flucelvax Quadrivalent, Flulaval Quadrivalent, Fluzone High Dose Quadrivalent, Fluzone Quadrivalent)	6 months and older (Afluria Quadrivalent, Fluarix Quadrivalent, Flulaval Quadrivalent, Fluzone Quadrivalent) 4 years and older (Flucelvax Quadrivalent) 65 years and older (Fluzone High Dose Quadrivalent)
Influenza, inactivated, adjuvanted (aIIV; Fluad, Fluad Quadrivalent)	65 years and older
Influenza, recombinant (RIV; Flublok Quadrivalent)	18 years and older
Influenza, live attenuated (LAIV; FluMist Quadrivalent)	2 through 49 years
Measles, mumps, and rubella (MMR; M-M-R-II)	12 months and older; routine if no evidence of immunity
Serogroups A, C, W, and Y meningococcal (MenACWY-D, Menactra; Men-ACWY-CRM, Menveo; MenACWY-TT, MenQuadfi)	9 months through 55 years (MenACWY-D); if at risk 2 months through 55 years (MenACWY-CRM); if at risk 2 months and older (MenACWY-TT); if at risk
Serogroup B meningococcal (MenB-FHbp, Trumenba; MenB-4C, Bexsero)	10 through 25 years; shared decision-making, unless in a high-risk group in which case routine
13-valent pneumococcal conjugate vaccine (PCV13; Prevnar 13)	65 years and older; shared decision-making (approved for 6 weeks and older)
23-valent pneumococcal polysaccharide vaccine (PPSV23; Pneumovax)	65 years and older; routine (approved for 2 years and older)

Vaccine (Abbreviation; Brand Name[s])	Recommendation
Tetanus, diphtheria, and acellular pertussis (Tdap; Adacel, Boostrix)	10 through 64 years (Adacel) 10 years and older (Boostrix)
Tetanus, diphtheria (Td; TDVAX, Tenivac)	7 years and older; Tdap or Td
Varicella (VAR; Varivax)	12 months and older; routine if no evidence of immunity
Zoster recombinant (RZV; Shingrix)	50 years and older; routine

Note: The table is based on the following sources:

- https://www.cdc.gov/vaccines/schedules/hcp/imz/child-adolescent.html
- https://www.cdc.gov/vaccines/schedules/hcp/imz/adult.html
- https://www.fda.gov/vaccines-blood-biologics/vaccines/vaccines-licensed-use-united-states

The age-range reflects the FDA-approved indications and the current CDC guidance.

Vaccines recommended for children in the United States are described below in Table A.3.

Table A.3. Recommended vaccines for children in the United States, 2020

Vaccine (Abbreviation; Brand Name[s])	Recommendation
Diphtheria, tetanus, and acellular pertussis (DTaP; Daptacel, Infanrix)	6 weeks through 6 years
Haemophilus influenzae type b (Hib; PedvaxHIB, ActHIB, Hiberix)	2 months through 5 years (PedvaxHIB, ActHIB) 6 weeks through 4 years (Hiberix)
Hepatitis A (HepA; Havrix, Vaqta)	12 months and older
Hepatitis B (HepB; Engerix-B, Recombivax HB)	All ages
9-valent human papillomavirus (HPV9; Gardasil 9)	9 through 26 years
Inactivated polio vaccine (IPV; IPOL)	6 weeks and older
Influenza, inactivated (IIV; Afluria Quadrivalent, Fluarix Quadrivalent, Flulaval Quadrivalent, Fluzone Quadrivalent, Flucelvax Quadrivalent	6 months and older (Afluria Quadrivalent, Fluarix Quadrivalent, Flulaval Quadrivalent, Fluzone Quadrivalent) 4 years and older (Flucelvax Quadrivalent)
Influenza, live attenuated (LAIV; FluMist Quadrivalent)	2 through 49 years; IIV or LAIV
Measles, mumps, and rubella (MMR; M-M-R II)	12 months and older for routine vaccination
Serogroups A, C, W, and Y meningococcal (MenACWY-D, Menactra; Men-ACWY-CRM, Menveo; MenACWY-TT, MenQuadfi)	9 months through 55 years (Menactra) 2 months through 55 years (Menveo) 2 years and older (MenQuadfi)*
Serogroup B meningococcal (MenB-FHbp, Trumenba; MenB-4C, Bexsero)	10 through 25 years; shared clinical decision making, unless in a high-risk group in which case routine
13-valent pneumococcal conjugate vaccine (PCV13; Prevnar 13)	6 weeks and older
23-valent pneumococcal polysaccharide vaccine (PPSV23; Pneumovax)	2 years and older; high-risk groups
Rotavirus (RV; Rotarix, RotaTeq)	6 through 24 weeks (Rotarix) 6 through 32 weeks (RotaTeq)
Tetanus, diphtheria, and acellular pertussis (Tdap; Adacel, Boostrix)	10 through 64 years (Adacel); routine (11 years per CDC for routine and as young as 7 years for catch-up 10 years and older (Boostrix); routine (11 years per CDC for routine and as young as 7 years for catch-up)
Varicella (VAR; Varivax)	12 months and older;
DTaP-IPV-Hib-HepB (Vaxelis*)	6 weeks through 4 years
DTaP-IPV/Hib (Pentacel)	6 weeks through 4 years
DTaP-IPV (Kinrix, Quadracel)	4 years through 6 years

Vaccine (Abbreviation; Brand Name[s])	Recommendation
Measles, mumps, rubella, and varicella (MMR-V; ProQuad)	12 months through 12 years

Note: The table is based on the following sources:

- https://www.cdc.gov/vaccines/schedules/hcp/imz/child-adolescent.html
- https://www.fda.gov/vaccines-blood-biologics/vaccines/vaccines-licensed-use-united-states

The age-range reflects the FDA-approved indications and the current CDC guidance.
* Noted on FDA website but not CDC website as combination vaccine currently in use.

Vaccines recommended for pregnant women in the United States are described below in Table A.4.

Table A.4. Recommended Immunizations for pregnant women in the United States, 2020

Vaccine (Abbreviation; Brand Name[s])	Recommendation
Hepatitis B (HepB; Engerix-B, Recombivax HB)	Recommended in some circumstances*
Influenza, inactivated (IIV; Afluria Quadrivalent, Flucelvax Quadrivalent, Fluarix Quadrivalent, Flulaval Quadrivalent, Fluzone Quadrivalent)	Recommended (any influenza vaccine that is IIV or RIV)
Influenza, recombinant (RIV; Flublok Quadrivalent)	Recommended (any influenza vaccine that is IIV or RIV)
Tetanus, diphtheria, and acellular pertussis (Tdap; Adacel, Boostrix)	Recommended

Note: * Hepatitis B vaccines are included in this report because they were included in the prior report. The table includes only those vaccines recommended per CDC and not those that may be used if otherwise indicated (or for which there is a recommendation to base decisions on risk versus benefit). The table is based on the following sources:

- https://www.cdc.gov/vaccines/pregnancy/hcp-toolkit/guidelines.html
- https://www.fda.gov/vaccines-blood-biologics/vaccines/vaccines-licensed-use-united-states

Data Extraction

Data identified in this update were extracted by an experienced subject matter expert in the online data extraction program for systematic reviews, DistillerSR. The extraction forms for study-level data were designed to include detailed instructions, definitions, and descriptions of categories to guide reviewers and to avoid ambiguities. These forms were repeatedly tested and refined to minimize ambiguity and to increase reliability. The data extraction was monitored frequently, questions were discussed among the review team, and additional guidance was added to the online forms as needed. Data from studies already included in the 2014 report were included in the same software.

The data extraction process was designed to capture all information published about the study, including the trial record, study protocol, interim analyses, main analysis, or subgroup analyses. Multiple publications reporting on the same participant groups were counted as single studies and entered the review analysis only one time for each relevant outcome. Throughout the data extraction process, data from publications reporting on the same participant group were consolidated.

The data extraction included study-level variables displayed in the evidence tables (Appendix D) and results variables used in the review analysis and critical appraisal of the study. These variables consisted of the following:

- Study ID

    - Author and publication year of the main publication, country, PubMed entry link, trial registration number, additional publications reporting on the study, type of publication (journal manuscript, trial record), study design (parallel RCT, cluster RCT, clinical trial, cohort study, case-control study), number of participants (study size indication), power calculation for non-inferiority analysis, funding type (industry-funded, industry-funded but unrestricted grant, unclear, non-industry funding)
- Participant characteristics
    - Key Question category (children, adults, pregnant women), age (mean, standard deviation [SD]), gender (percent female), race/ethnicity, genotype information, underlying medical conditions, inclusion criteria, proportion of participants given the vaccine who were outside of recommended age range
- Intervention arms
    - Vaccine type, dose and schedule, formulation, individual or combination vaccine, mode of administration; adjuvants, co-interventions (e.g., medications [including other vaccines] administered concomitantly)
- Control and comparator arms
    - Type, description
- Outcomes
    - Method of collection and type of safety information collected
- Results
    - Results for key adverse events: type of outcome, severity, and adverse event rates in intervention and control arms, other results, risk factor analyses

The included studies varied widely in the number and type of adverse events reported. In particular trial registries now allow authors to add all available data independent of journal manuscript restrictions, and some studies reported hundreds of different adverse event categories.

To ensure consistency across studies and a systematic approach to using the available data, our data extraction followed a specified algorithm. We extracted adverse events by outcome category (e.g., seizures). Where data on relevant summary categories (e.g., cardiovascular events) were presented together with a denominator, we extracted these to capture the maximum number of relevant data. Where studies listed more than one type of relevant adverse event and it was not clear whether some patients had experienced multiple events (e.g., chest pain and myocardial infarction), we selected the most frequent event. If events were equally frequent, the most severe adverse event in the category was selected (e.g., infertility for reproductive issues). Our unit of analysis was the number of participants with an event, rather than the number of events, as patients can experience multiple events, but the denominator for the vaccinated and the unvaccinated group is the number of participants. Furthermore, given the very large number of adverse event categories, except for the key adverse events selected in conjunction with the TEP for which all events were extracted, only serious and severe adverse events or those highlighted by the authors were extracted. We used the author's definition of serious and severe and considered adverse events to have been highlighted by the study authors if they were mentioned in the study's abstract. Hence, we would extract fever classified as "severe" but not mild fever.

To allow the reader to understand the type and severity of the events, we implemented a transparent and comprehensive categorization system, based on the Common Terminology

Criteria for Adverse Events (CTCAE) classification system,[45] to structure the safety assessment. The current CTCAE system (version 5) differentiates 837 adverse events within 26 adverse event categories. The system categories are described in Table A.5.

Table A.5. System category

System Organ Class	Numeric Code
Blood and lymphatic system disorders	1
Cardiac disorders	2
Congenital, familial and genetic disorders	3
Ear and labyrinth disorders	4
Endocrine disorders	5
Eye disorders	6
Gastrointestinal disorders	7
General disorders and administration site conditions	8
Hepatobiliary disorders	9
Immune system disorders	10
Infections and infestations	11
Injury, poisoning and procedural complications	12
Investigations	13
Metabolism and nutrition disorders	14
Musculoskeletal and connective tissue disorders	15
Neoplasms benign, malignant and unspecified (incl. cysts and polyps)	16
Nervous system disorders	17
Pregnancy, puerperium and perinatal disorders	18
Psychiatric disorders	19
Renal and urinary disorders	20
Reproductive system and breast disorders	21
Respiratory, thoracic and mediastinal disorders	22
Skin and subcutaneous tissue disorders	23
Social circumstances	24
Surgical and medical procedures	25
Vascular disorders	26

Each specific adverse event was graded for severity on a five-point scale. Grade 1 characterizes mild events or asymptomatic or mild symptoms, or clinical or diagnostic observations that do not require intervention. Grade 2 is a moderate event where minimal local or noninvasive intervention is indicated, and/or activities of daily living are limited. Grade 3 is a severe event that is medically significant but not immediately life-threatening, includes hospitalization or prolongation of hospitalization, or is disabling, limiting self-care activities of daily living. Grade 4 events are life-threatening consequences that require urgent intervention. Grade 5 describes death related to the adverse event. Rather than relying on the author's interpretation of outcomes, we applied the categorization and CTCAE system consistently to all included studies and rated the adverse event severity accordingly.

We applied the system to all assessed adverse events, thereby systematically identifying evidence of the presence as well as the absence of specific adverse events. Events that were assessed in research studies but that were reported not to have occurred were also extracted and entered in the analyses. Data were extracted for both the intervention and control groups. Study results were then converted to rates and proportions to facilitate comparisons among studies.

Risk of Bias Assessment of Individual Studies

All included studies were assessed for key sources of bias that could have influenced the reported results. The assessments were undertaken by one reviewer; a second reviewer checked

the assessment for accuracy and consistency across studies. We used the McHarm scale, a tool for structured critical appraisal of adverse event data reported in research studies, for the assessment. Adverse event assessment and reporting are often lacking in rigor; thus, we applied critical appraisal criteria assessing two main domains:[42, 43]

- Data collection of adverse events
- Reporting of adverse events

The appraisal of the data collection method evaluated the rigor of the adverse event assessment (e.g., use of a scale or checklist) and whether adverse event data were collected actively (e.g., all participants were asked about the occurrence of specific harms) or passively (e.g., participants might have reported events at their discretion, but without structured assessment or specific prompts).

The reporting appraisal assessed whether adverse events, including serious adverse events, were defined by the study authors. In addition, we reviewed whether the authors specified the number of participants affected by each type of adverse event (the number of adverse events per group is a problematic measure because some patients experience multiple events).

Data Synthesis and Analysis

The results are documented in a structured synthesis, supported by tables and figures, in the main report. The synthesis is organized by Key Question, then by type of vaccine, then by type of event. Summary tables synthesize evidence across studies. The included studies are broadly characterized based on study characteristics, participant details, intervention categories, identified comparator, and outcome categories employed in the published studies in Appendix C. Study details and results of all included studies for vaccines of interest are documented in evidence tables in Appendix D to provide a concise overview.

In the results section and in the summary tables, we report the relative frequency and severity of the adverse events and the SoE for the presence or absence of specific adverse events. To answer Key Question 1a, Key Question 2a, and Key Question 3a, the synthesis reports how many studies have assessed an adverse event. To address Key Question 1b, Key Question 2b, and Key Question 3b, i.e., to determine whether a specific adverse event is associated with a vaccine, we document how many times the event occurred in the study samples. The report included only studies that reported on a control group or comparator not exposed to the vaccine (or time prior to when an individual was exposed to a vaccine, in the case of self-controlled case series), on a different vaccine schedule, or exposed to a different formulation. Rates of adverse events in the intervention group were compared to those in an appropriate control group that ideally differed only in the exposure to the vaccine. We calculated the relative risk and the 95 percent confidence interval for the adverse events for all studies by comparing the intervention and control group rates. We also included observational and surveillance studies that analyzed medical records, health insurance claims, or government registries.

We combined study results for the studies included in this update in meta-analyses where studies reported sufficient detail and provided information of the rate in the vaccinated as well as a control or comparator group. We used random effects meta-analytic models with a modified Hartung-Knapp corrections using the metafor package in R, estimated with the restricted maximum likelihood estimator.[47, 48-50] As relative risks cannot be computed when cells are zero (e.g., one or both arms across studies had zero events), we added a constant of 0.5 to the empty cells as per Cochrane Handbook.[46] Random effects models are used in statistical models to estimate effects when we believe that we are combining effects from heterogenous

populations.[1097] Random effects analyses assume that there is a super-population of participants, which comprises a number of subpopulations.[1098] Each study takes a sample from a subpopulation of participants. The results of the subpopulation analyses cannot be combined without taking into account the random effects. The weight of a study in the meta-analysis is a function of the size of the study, and the magnitude of the effect in that study, relative to the other studies. Failing to take account of random effects can lead to dramatically inflated type I error rates. A random effects meta-analysis attempts to determine the average relative risk.[1099]

We investigated the performance of the various approaches to the calculation of the standard errors using a brief Monte-Carlo simulation investigation.[1100] In particular when a low number of studies is meta-analyzed, the Hartung-Knapp correction to the standard error (which uses the t, rather than the z distribution) is recommended to obtain appropriate standard errors (and hence confidence intervals and p-values). However, when the heterogeneity of trial effects is below the expected value, this correction can lead to much smaller standard errors, which can inflate the type I error rate. A recent suggestion, implemented in the metafor package in R, is to use an adjusted Hartung-Knapp procedure. When heterogeneity of effect sizes is equal to or greater than the expected value, the Hartung-Knapp correction is applied. When heterogeneity is lower than expected, the correction is not applied. To determine the most appropriate method for the standard error calculation we carried out Monte Carlo simulations and we identified the adjusted Hartung-Knapp approach as the most appropriate method as it gave the lowest type I error rate when population effects were both heterogenous and homogenous (when population effects were homogenous, the uncorrected standard error was equally appropriate when population effects were homogenous, and the Hartung-Knapp correction was equally appropriate when population effects were heterogenous).We also considered Bayesian analysis using the Stan package in R with a non-informative prior but encountered many convergence problems. In addition, when models satisfactorily converged, the substantive results did not change.

For all meta-analyses, we report the point estimates, the 95 percent confidence intervals, and the statistical significance of the summary estimates. To facilitate the interpretation of the results, we reported the absolute rate of adverse events (number of events for the vaccinated group, number of participants in the vaccinated group, number of events for each control group, number of participants in each control group) as well as the relative risk. The review of adverse events followed a cautious approach. We first computed relative risks to find signals for potential adverse events. In a second step, we reviewed all findings in detail that reported more adverse events in the vaccine group across studies.

Studies in adults (18 years and up) were described in KQ1, studies in children up or including 18 years of age were classified as KQ2 (meaning that if a study included both children and adults, the study was included under KQ2). As described above, in addition to documenting the types of adverse events, we characterized the severity and frequency of the events associated with the vaccines. To address sub-questions KQ1c1, KQ2c1, and KQ3c1 (the average severity and frequency of each adverse event associated with a particular vaccine), we used the CTCAE rating system to document the average severity of the specific adverse events reported in existing studies. To address KQ1c2, KQ2c2, and KQ3c2 (the range of possible effects for adverse events without statistically significant associations with a particular vaccine), we documented the range of possible effects based on the confidence interval surrounding the point estimate across studies.

To address KQ1c3, KQ2c3, and KQ3c3 (the risk factors for each adverse event associated with a particular vaccine), we explored potential risk factors for adverse events in meta-regressions and subgroups. These analyses explored whether patient or vaccine characteristics

are systematically associated with observed adverse events. In addition to the key subgroups of adults, children and adolescents, and pregnant women, an additional pre-specified subgroup comprised adults over the age of 65 years (KQ1c1). Furthermore, we differentiated live-attenuated and inactive vaccines where possible. For meta-regressions, we added patient variables (age, gender, race/ethnicity, genotype, or underlying medical conditions) and intervention variables (individual vs combination vaccines, schedule of administration, adjuvants, and medication administered concomitantly) of interest to the meta-analysis model.

For this update we had access to all new studies published in the last seven years as well as evidence included in the 2014 AHRQ report on the topic (we did not re-review prior excluded studies unless there was a new vaccine or new indication for a vaccine, for which we conducted targeted searches as needed). However, many evidence statements supported by statistical effect estimates in this update are based on evidence identified in the update. The prior 2014 report built on research undertaken by an IOM committee and the 2014 report reviewed if any new research confirmed or challenged conclusions or provided new insights. The IOM report was to some extent based on mechanistic evidence outlining possible biological associations between adverse events and a potential mechanism of action associated with the vaccine formulation. In addition, it integrated expert opinion about plausible mechanisms, in particular in the absence of research evidence in human participants comparing vaccinated and unvaccinated participants rather than focusing on empirical risk estimates for adverse events.

We qualitatively combined the findings from the 2014 report and new research identified in the update search for all included vaccines, populations, and key outcomes. We reviewed all instances where the SoE in the 2014 report and this update found differences and we integrated the SoE across the prior 2014 report and the update. All studies that reported rates of adverse events that could be computed, whether from the prior 2014 report or the update, were combined in meta-analyses. When studies could not be combined statistically, we narratively synthesized the findings to inform the SoE assessment and ensure that all available evidence was considered and integrated.

However, for many outcomes of interest, prior studies either did not provide data or reported data not in sufficient detail in order to allow analyses (e.g., reporting counts for the vaccinated and unvaccinated groups together with the number of participants). In other cases, the SoE was not based on research studies in human participants but rather mechanistic evidence and expert opinion. And some vaccines have changed over time - for example, the majority of influenza vaccines included in the prior report are not in use anymore. Where the update identified no studies, we provided information on research included in the prior report. All prior SoE findings were summarized narratively within each Key Question section.

Grading the Strength of the Body of Evidence

For each Key Question, we selected key adverse events that are documented in summary of findings tables to assess the strength of the evidence. The evidence tables report all outcomes addressed in the individual studies, but the SoE assessment used *a priori* defined outcomes to evaluate the overall safety of the vaccines across studies. These key adverse events were identified with the help of the TEP and content expert input that we engaged during the report update, and informed by published literature:

- Key adverse events for KQ 1 (adults): Acute disseminated encephalomyelitis, anaphylaxis or systemic allergic reaction, angioedema, death, diabetes, Guillain-Barré syndrome (Miller Fisher syndrome), cardiovascular events (prioritizing myocardial

infarction, cardiac disorders, major vascular event, angina and, if not available, then adverse events related to the cardiac or vascular systems), seizures, stroke, transverse myelitis
- Key adverse events for KQ 2 (children and adolescents): Acute disseminated encephalomyelitis, anaphylaxis or systemic allergic reaction, angioedema, cardiovascular events (as defined above), death, diabetes, Guillain-Barré syndrome (including Miller Fisher syndrome), idiopathic thrombocytopenic purpura, seizures, stroke, transverse myelitis
- Key adverse events for KQ 3 (pregnant women): Birth defects, death, eclampsia/pre-eclampsia, preterm labor (including preterm delivery if preterm labor was not reported), spontaneous abortion, stillbirth

In addition, for specific vaccines, additional key adverse events were determined:
- For DTaP, Tdap, and Td, these include encephalitis/encephalopathy (meaning encephalitis and/or encephalopathy) and brachial neuritis.
- For Hepatitis B vaccines, we assessed autoimmune disease, autoimmune thyroiditis (Hashimoto's disease), encephalitis/encephalopathy, multiple sclerosis, myocardial infarction, and optic neuritis.
- For HPV vaccines, we addressed amyotrophic lateral sclerosis, multiple sclerosis, and reproductive issues (prioritizing adverse events that would impede reproduction and, if not available, then adverse events related to reproductive organs).
- For all influenza vaccines, asthma was assessed.
- For meningococcal vaccines, we assessed encephalitis/encephalopathy and multiple sclerosis. For MMR, we documented autism, encephalitis/encephalopathy, idiopathic thrombocytopenic purpura, meningitis, and multiple sclerosis.
- For rotavirus vaccines, we specifically addressed febrile seizures, intussusception, and Kawasaki disease.
- For varicella and zoster vaccines, we assessed ataxia, encephalitis/encephalopathy, herpes zoster due to vaccine administration, meningitis, and secondary transmission of live varicella virus.

If we identified data for any key adverse event—even if not specific to the population/vaccine—we reported those findings in the evidence tables and summary of findings tables for that vaccine. The summary of findings tables document the results across studies for key adverse events as well as the quality of the evidence and our confidence in the effect estimates. The summary is organized by Key Question, vaccine, and outcome. The SoE assessment uses the AHRQ EPC program' SoE assessment categories, taking the following domains into account:
- Study limitations
- Consistency
- Precision
- Reporting bias
- Directness

Each domain encompasses a number of different reasons for downgrading the SoE. The summary of findings tables uses the connotation system that are presented here in detail. Each summary of findings table note section list all reasons for downgrading relevant to the findings in the individual table.

Study limitations (e.g., risk of bias in included studies) addressed the study design, sample composition, sample size, comparator, and rigor of reporting or identification of adverse events. We downgraded findings without concurrent control group, i.e., that were exclusively based on a comparator rather than a control group (comparing the adverse events of a new vaccine to that of an older vaccine that was previously in use) or that used pre-intervention data as comparator, or that compared control and text periods rather than unvaccinated and vaccinated groups (°). We downgraded findings that were exclusively based on observational data (°°). We also downgraded studies contributing to KQ2 (safety of vaccines in children) that combined children and adults (°°°). Furthermore, we downgraded studies reporting adverse events that ruled out that the event could be related to the vaccine (e.g., a death due to a car crash not associated with the study intervention) and studies that did not attempt to ascertain whether the adverse event could have been caused by the vaccine (°°°°). We would have also downgraded studies not reporting at least one event in the vaccine and the control group as the study sample was considered too small to detect events but this case did only occur in cases where the evidence had been already downgraded for other domains.

The domain *consistency* differentiated consistent and inconsistent findings across studies. We assigned "unknown" in the case of a result that was based on a single study whose findings or analysis had not been replicated yet and downgraded the evidence (↑). We reviewed how consistently studies reported the presence or the absence of specific effects for adverse events. We estimated the statistical heterogeneity in meta-analyses and reviewed the consistency of the direction of effects for other results. We downgraded for evidence of heterogeneity across studies ($I^2 > 70\%$, ↑↑) and for conflicting results regarding the risk of adverse events across studies (↑↑↑).

Precision was scored as either precise or imprecise, where precise indicated that the result reflects a clinically unambiguous conclusion. Precision was operationalized as the confidence interval surrounding the point estimate. We considered the statistical significance as well as the direction of effects given that rare events are difficult to detect. We used a threshold of a relative risk of >1 to determine the null effect where 1 indicates an equal risk of an adverse event in the vaccinated and the unvaccinated group and results above 1 indicate more events in the vaccinated group. We downgraded for wide confidence intervals; for example, where the confidence intervals indicated that the risk of an event may be a third of that of a control group or three times as high in the vaccine group compared to a control group (^). We downgraded studies that reported insufficient detail and that did not allow us to independently calculate the relative risk from the reported rates, i.e., where we had to rely on the authors' reporting of effects (^^). In order to receive a rating of high SoE for no evidence of increased risk, the confidence interval could not cross the threshold of 1 (which indicates that some values were consistent with an interpretation of an increased risk in the vaccine group, ^^^).

The domain *reporting bias* differentiated between suspected bias (e.g., there is indication of publication bias, selective outcome reporting, or selective reporting of the analysis) and undetected bias (no bias indicated). We did not expect substantial reporting bias, given that the decision to publish will have likely been driven by the effectiveness outcomes and not necessarily the outcomes of interest for this report (i.e., adverse events), but we did assess publication bias using standard tools (i.e., Begg and Egger tests) for the key adverse events. We downgraded for evidence of reporting bias where Begg's rank test, Egger's regression test, or both tests indicated evidence of reporting bias ($p<0.1$, $).

Directness differentiates between direct, i.e. head-to-head, comparisons (e.g., comparing a vaccinated and an unvaccinated group within a study) and indirect evidence derived from comparisons across studies (e.g., meta-regressions to assess the effect of combination versus individual vaccines). Given the small number of studies for each adverse event and the numerous differences between studies, we were unable to interpret the indirect analyses with confidence (we did not identify statistically significant moderators) and this criterion was not applied.

The SoE domains are compatible with the GRADE group's criteria to downgrade the quality of evidence. Each evidence statement was assessed with these criteria to determine the overall SoE. The SoE assessment differentiated the following levels:

- *High*: High confidence that the evidence reflects the true effect. Further research is very unlikely to change our confidence in the estimate of effect.
- *Moderate*: Moderate confidence that the evidence reflects the true effect. Further research may change our confidence in the estimate of effect and may change the estimate.
- *Low*: Low confidence that the evidence reflects the true effect. Further research is likely to change our confidence in the estimate of effect and is likely to change the estimate.
- *Insufficient* evidence: Evidence either is unavailable or does not permit a conclusion.

The categories communicate the confidence in the summary estimates for the findings across studies. In cases where the SoE was at the level of insufficient evidence, only one reason per domain was reported. The evidence statements were drafted by one literature reviewer and discussed among the team to ensure quality control and consistency of interpretation.

Assessing Applicability

Applicability refers to the extent to which the effects observed in published studies are likely to reflect the expected results when the intervention (i.e., vaccination) is applied to the population of interest under "real-world" conditions.

Relatively few clinical trials are designed with applicability in mind;[1101] furthermore, they sometimes report only a few of the factors needed to fully assess applicability. Thus, we are including observational studies that contain an unvaccinated control/comparison group such as population surveillance, self-controlled case series, retrospective and prospective cohorts, and analyses of administrative databases. Defining the populations, interventions, timing, and outcomes (as described in the Key Questions and analytic framework) inevitably considers factors that may affect the applicability of studies. Reviewers extracted this information and considered it in summarizing the applicability and limitations of the evidence. Evidence tables clearly distinguished studies designed to assess effectiveness from those designed specifically to assess safety. To make applicability information useful, the report addressed how specific aspects of study design affected the final population and how greatly (and in which direction) that final population might differ from more representative populations in practice.

Throughout, we also document the likelihood of association of reported adverse events with the vaccine, based on mechanism and biological plausibility, to provide the reader with additional contextual information.

Peer Review and Public Commentary

Experts (vaccine experts with clinical expertise in key populations, vaccine safety methodologists, and consumers) representing stakeholder and user communities were invited to provide external peer review of this report; AHRQ and an associate editor also provided comments. The draft report was posted on the AHRQ website for 4 weeks to elicit public comment. We addressed all reviewer comments, revising the text as appropriate. A disposition of comments table of public comments will be posted on the EHC website 3 months after the Agency posts the final report.

Appendix B. List of Excluded Studies

Note: after each reference is the aspect of the eligibility criteria the study failed to meet for inclusion.

1. Polio vaccine and congenital defects. British Medical Journal. 1967 Feb 25;1(5538):510. PMID: 6017538. *Study design*

2. Pneumococcal polysaccharide vaccine. Recommendation of the Immunization Practices Advisory Committee. Annals of Internal Medicine. 1982 Feb;96(2):203-5. PMID: 6277218. *Study design*

3. Pneumococcal vaccine. Health and Public Policy Committee, American College of Physicians. Annals of Internal Medicine. 1986 Jan;104(1):118-20. PMID: 3940479. *Study design*

4. Immunization during pregnancy. ACOG technical bulletin number 160--October 1991. International Journal of Gynaecology & Obstetrics. 1993 Jan;40(1):69-79. PMID: 8094357. *Study design*

5. Facts about pertussis and DTP vaccine. EPI Newsletter. 1994 Jun;16(3):5. PMID: 12345538. *Study design*

6. Erratum: Safety and efficacy of high-dose rhesus-human reassortant rotavirus vaccines - Report of the National Multicenter Trial (Pediatrics (1996) 97 (7-13)). Pediatrics. 1996 1996;98(1):A38. PMID: 1996204872. *Study design*

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1198. Ctri. Clinical trial on Rotavirus vaccine to check consistency of different lots of vaccines manufactured and to check vaccine interference with other childhood vaccines given under universal immunization program in India. http://www.who.int/trialsearch/Trial2.aspx?TrialID=CTRI/2015/07/006034. 2015. PMID: CN-01830599. *Intervention*

1199. Ctri. Clinical study to compare the immune response and safety of Chicken Pox vaccine manufactured by Cadila Healthcare Ltd. with another Chicken Pox vaccine marketed in India in children 1-12 years of age. http://www.who.int/trialsearch/Trial2.aspx?TrialID=CTRI/2015/07/006059. 2015. PMID: CN-01830586. *Intervention*

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http://www.who.int/trialsearch/Trial2.aspx?TrialID=CTRI/2015/11/006354. 2015. PMID: CN-01840902. *Outcome*

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http://www.who.int/trialsearch/Trial2.aspx?TrialID=CTRI/2015/12/006456. 2015. PMID: CN-01807965. *Intervention*

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http://www.who.int/trialsearch/Trial2.aspx?TrialID=CTRI/2016/06/007042. 2016. PMID: CN-01818356. *Intervention*

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1211. Ctri. clinical study of Meninigococcal vaccine for comparison of immunogenecity and safety with Menomune vaccine.
http://www.who.int/trialsearch/Trial2.aspx?TrialID=CTRI/2016/11/007477. 2016. PMID: CN-01852556. *Intervention*

1212. Ctri. Comparative evaluation of immunogenicity of various schedules and delivery options to provide fractional Dose Inactivated Poliovirus Vaccine in routine immunization. http://www.who.int/trialsearch/Trial2.aspx?TrialID=CTRI/2017/02/007793. 2017. PMID: CN-01818897. *Intervention*

1213. Ctri. Clinical study to compare the immune response and safety of vaccine for prevention of Measles and Rubella diseases (MR vaccine) manufactured by Cadila Healthcare Ltd. with MR vaccine manufactured by Serum Institute of India Ltd. in children 9-12 months of age. http://www.who.int/trialsearch/Trial2.aspx?TrialID=CTRI/2017/05/008701. 2017. PMID: CN-01884318. *Intervention*

1214. Ctri. A study to find out the effectiveness of measles, mumps, rubella(mmr) vaccine in the treatment of common warts and to compare its efficacy with formic acid treatment of common warts. http://www.who.int/trialsearch/Trial2.aspx?TrialID=CTRI/2017/07/009041. 2017. PMID: CN-01888935. *Intervention*

1215. Ctri. Clinical study to evaluate the immune response and safety of four valent flu vaccine manufactured by Cadila Healthcare Ltd. in healthy children aged 6 months to 17 years. http://www.who.int/trialsearch/Trial2.aspx?TrialID=CTRI/2017/08/009204. 2017. PMID: CN-01891876. *Intervention*

1216. Ctri. A study to determine the optimum timing of Hepatitis B vaccination during treatment of Acute Lymphoblastic leukemia(a type of blood cancer). http://www.who.int/trialsearch/Trial2.aspx?TrialID=CTRI/2017/08/009402. 2017. PMID: CN-01891644. *Outcome*

1217. Ctri. A clinical trial to describe the safety and immunogenicity of 13 valent pneumococcal conjugate vaccine formulated in multidose vials when given with routine pediatric vaccines in healthy infants in India. Title intended for the lay public in easily understood language. http://www.who.int/trialsearch/Trial2.aspx?TrialID=CTRI/2017/08/009492. 2017. PMID: CN-01891614. *Intervention*

1218. Ctri. Comparison of immunogenicity, safety and tolerability of Single Dose of Hepatitis A (Live) Vaccine obtained by Freeze-dried process from Sinopharm against BiovacTM-A (Freeze-dried Live Attenuated Vaccine from Wockhardt)in Healthy Indian Children. http://www.who.int/trialsearch/Trial2.aspx?TrialID=CTRI/2017/09/009760. 2017. PMID: CN-01892697. *Intervention*

1219. Ctri. Beneficial non-specific effects of BCG-Green signal and zero dose polio on neonatal survival in babies less than 2000 gram. http://www.who.int/trialsearch/Trial2.aspx?TrialID=CTRI/2018/08/015424. 2018. PMID: CN-01907868. *Intervention*

1220. Ctri. A study to compare SB12 (proposed eculizumab biosimilar) with Soliris® in patients with the disease Paroxysmal Nocturnal Haemoglobinuria. http://www.who.int/trialsearch/Trial2.aspx?TrialID=CTRI/2019/05/019148. 2019. PMID: CN-01969220. *Intervention*

1221. Ctri. A clinical study to assess the safety,tolerability & over all immune response of BEs Pneumococcal conjugate vaccine when administered in a three dose schedule. http://www.who.int/trialsearch/Trial2.aspx?TrialID=CTRI/2020/02/023129. 2020. PMID: CN-02166885. *Intervention*

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1621. EU/EEA EO. An Immunogenicity and Safety Study of GARDASIL™ in Chinese Female Subjects Aged 9 to 45 Years and Male Subjects Aged 9 to 15 Years. http://www.who.int/trialsearch/Trial2.aspx?TrialID=EUCTR2014-004581-16-Outside-EU/EEA. 2015. PMID: CN-01862280. *Intervention*

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1626. EU/EEA EO. Immunogenicity and safety of GlaxoSmithKline Biologicals' Havrix administered on a 0, 6-month schedule concomitantly with Merck and Company, Inc. M-M-R II and Merck and Company, Inc. VARIVAX to healthy children 15 months of age. http://www.who.int/trialsearch/Trial2.aspx?TrialID=EUCTR2015-001509-15-Outside-EU/EEA. 2015. PMID: CN-01851599. *Comparator*

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1629. EU/EEA EO. Study to evaluate the immunogenicity, safety, and reactogenicity of TWINRIX ADULT containing 720 ELISA units of hepatitis A antigen and 20 µg of hepatitis B surface antigen, administered following a two-dose (0, 6 months) schedule in healthy children between the ages of 1 and 11 years. http://www.who.int/trialsearch/Trial2.aspx?TrialID=EUCTR2015-001516-35-Outside-EU/EEA. 2015. PMID: CN-01860119. *Comparator*

1630. EU/EEA EO. Immunogenicity and safety study of GlaxoSmithKline Biologicals' Havrix administered on a 0, 6-month schedule concomitantly with GlaxoSmithKline Biologicals' Infanrix and Aventis Pasteur's Ac-tHIB in healthy children 15 months of age. http://www.who.int/trialsearch/Trial2.aspx?TrialID=EUCTR2015-001530-25-Outside-EU/EEA. 2015. PMID: CN-01807540. *Comparator*

1631. EU/EEA EO. Study to compare the immunogenicity of GlaxoSmithKline Biologicals' thiomersal-free 2-dose Engerix™-B and 3-dose preservative-free Engerix™-B vaccines administered according to a 0, 6 month and 0, 1, 6 month schedule, respectively, and to evaluate safety and reactogenicity of each vaccine in healthy adolescent volunteers (11 to 15 years). http://www.who.int/trialsearch/Trial2.aspx?TrialID=EUCTR2015-001531-20-Outside-EU/EEA. 2015. PMID: CN-01870881. *Intervention*

1632. EU/EEA EO. Study to evaluate the immunogenicity, reactogenicity and safety of two doses of GlaxoSmithKline (GSK) Biologicals' oral live attenuated human rotavirus (HRV) liquid vaccine, when given to healthy infants, in Philippines. http://www.who.int/trialsearch/Trial2.aspx?TrialID=EUCTR2015-001544-11-Outside-EU/EEA. 2015. PMID: CN-01872781. *Participants*

1633. EU/EEA EO. Study to evaluate the safety of Rotarix™ in Chinese children. http://www.who.int/trialsearch/Trial2.aspx?TrialID=EUCTR2015-001547-37-Outside-EU/EEA. 2015. PMID: CN-01841652. *Participants*

1634. EU/EEA EO. A phase II study to assess the safety and immunogenicity of GlaxoSmithKline Biologicals' rotavirus vaccine, RIX4414 when administered to HIV infected infants in South Africa. http://www.who.int/trialsearch/Trial2.aspx?TrialID=EUCTR2015-001484-39-Outside-EU/EEA. 2015. PMID: CN-01855362. *Intervention*

1635. EU/EEA EO. Immunogenicity and safety study of Infanrix hexa in healthy infants born to mothers vaccinated with Boostrix™ during pregnancy or immediately post-delivery. http://www.who.int/trialsearch/Trial2.aspx?TrialID=EUCTR2014-001117-41-Outside-EU/EEA. 2016. PMID: CN-01879672. *Intervention*

1636. EU/EEA EO. Immunogenicity and safety of the diphtheria, tetanus, pertussis and inactivated poliovirus (DPT-IPV) vaccine Squarekids™ co-administered with GSK Biologicals' human rotavirus (HRV) vaccine Rotarix™ (444563) in healthy infants. http://www.who.int/trialsearch/Trial2.aspx?TrialID=EUCTR2014-005282-78-Outside-EU/EEA. 2016. PMID: CN-01859228. *Participants*

1637. EU/EEA EO. Immunogenicity and safety study of GlaxoSmithKline (GSK) Biologicals' Boostrix™ vaccine and the Chinese DT vaccine, when administered as booster vaccination in healthy children aged 6-8 years. http://www.who.int/trialsearch/Trial2.aspx?TrialID=EUCTR2016-000644-34-Outside-EU/EEA. 2016. PMID: CN-01878659. *Intervention*

1638. EU/EEA EO. Immunogenicity and reactogenicity of a booster dose of GlaxoSmithKline Biologicals' GSK2036874A vaccine in healthy toddlers. http://www.who.int/trialsearch/Trial2.aspx?TrialID=EUCTR2016-000645-31-Outside-EU/EEA. 2016. PMID: CN-01881245. *Intervention*

1639. EU/EEA EO. This study will evaluate the immunogenicity, reactogenicity and safety of the routine infant vaccines Pediarix, Hiberix and Prevenar 13 when co-administered with GlaxoSmithKline (GSK) Biologicals' liquid human rotavirus vaccine (HRV) as compared to GSK's licensed lyophilized vaccine. http://www.who.int/trialsearch/Trial2.aspx?TrialID=EUCTR2016-003210-27-Outside-EU/EEA. 2017. PMID: CN-01893303. *Intervention*

1640. EU/EEA EO. Safety and Immunogenicity of Novartis Meningococcal Group B Vaccine When Administered Concomitantly With Novartis MenACWY Conjugate Vaccine to Healthy Infants. http://www.who.int/trialsearch/Trial2.aspx?TrialID=EUCTR2016-005117-44-Outside-EU/EEA. 2017. PMID: CN-01875841. *Participants*

1641. Euctr BE. Immunogenicity and Lot-to-Lot Consistency Study of a Quadrivalent Influenza Vaccine in Adult and Elderly Subjects. http://www.who.int/trialsearch/Trial2.aspx?TrialID=EUCTR2014-000785-21-BE. 2014. PMID: CN-01858964. *Comparator*

1642. Euctr BE. A vaccine study in healthy adults to evaluate the safety and immune response of a licensed oral polio vaccine containing 3 polio vaccine strains. http://www.who.int/trialsearch/Trial2.aspx?TrialID=EUCTR2015-003324-32-BE. 2015. PMID: CN-01879744. *Comparator*

1643. Euctr BE. A vaccine study in healthy adults to evaluate the safety and immune response of a licensed oral polio vaccine containing the polio vaccine 2 strain. http://www.who.int/trialsearch/Trial2.aspx?TrialID=EUCTR2015-003325-33-BE. 2015. PMID: CN-01858456. *Intervention*

1644. Euctr BE. A study to evaluate the reactogenicity, safety and immunogenicity of GlaxoSmithKline (GSK) Biologicals' investigational supra-seasonal universal influenza vaccines - inactivated (SUIVs) (GSK3816302A) in healthy adults aged 18 to 39 years. http://www.who.int/trialsearch/Trial2.aspx?TrialID=EUCTR2017-001584-20-BE. 2017. PMID: CN-01884767. *Intervention*

1645. Euctr BE. A Double-blind Randomized Controlled Trial to Assess the Lot-to-lot Consistency of Sci-B-Vac™ in Adults. http://www.who.int/trialsearch/Trial2.aspx?TrialID=EUCTR2017-001820-22-BE. 2018. PMID: CN-01910029. *Comparator*

1646. Euctr BE. Safety and Immunogenicity of V114 in Recipients of Allo-HSCT. http://www.who.int/trialsearch/Trial2.aspx?TrialID=EUCTR2018-000066-11-BE. 2018. PMID: CN-01906746. *Intervention*

1647. Euctr BE. A phase 2 vaccine study in healthy adults to evaluate the safety and immunogenicity of two oral polio type 2 vaccine candidates. http://www.who.int/trialsearch/Trial2.aspx?TrialID=EUCTR2018-001684-22-BE. 2018. PMID: CN-01906884. *Participants*

1648. Euctr CZ. Immunogenicity and Safety of Meningococcal MenABCWY Vaccine, and of rMenB+OMV NZ and MenACWY Administered Concomitantly in the Same Arm or in 2 Different Arms, or Alone. http://www.who.int/trialsearch/Trial2.aspx?TrialID=EUCTR2017-005128-12-CZ. 2018. PMID: CN-01905435. *Intervention*

1649. Euctr DE. Antibody persistence for GlaxoSmithKline (GSK) Biologicals' HPV-16/18 L1 VLP AS04 vaccine (GSK-580299) administered in healthy adults and adolescents, 6.5 years after first vaccination in the primary study. http://www.who.int/trialsearch/Trial2.aspx?TrialID=EUCTR2014-000060-17-DE. 2014. PMID: CN-01820270. *Participants*

1650. Euctr DE. Safety and immunogenicity study of GSK Biologicals' Quadrivalent Influenza Vaccine (GSK2321138A) manufactured with a new process in adults and children. http://www.who.int/trialsearch/Trial2.aspx?TrialID=EUCTR2014-000955-10-DE. 2014. PMID: CN-01797196. *Comparator*

1651. Euctr DE. A blinded study to compare the safety and immune response in children and adolescents aged 3-17 years between Abbott's Candidate Quadrivalant Influenza and Trivalent Influenza Vaccine. http://www.who.int/trialsearch/Trial2.aspx?TrialID=EUCTR2015-005482-23-DE. 2016. PMID: CN-01842151. *Intervention*

1652. Euctr DE. Evaluation of immunogenicity and safety of two formulations of human rotavirus (HRV) vaccine, in healthy infants starting at age 6-12 weeks. http://www.who.int/trialsearch/Trial2.aspx?TrialID=EUCTR2016-000598-19-DE. 2016. PMID: CN-01832734. *Intervention*

1653. Euctr DE. A Clinical Study to Assess the Safety and Immunogenicity of the Tetanus, Diphtheria and Pertussis Vaccine SIIPL Tdap in Comparison with Boostrix® in Healthy Adults, Adolescents and Children. http://www.who.int/trialsearch/Trial2.aspx?TrialID=EUCTR2019-002706-46-DE. 2019. PMID: CN-02169317. *Intervention*

1654. Euctr DK. Safety and efficay of 3 new low dose polio vaccines with adjuvant compared to a full dose polio vaccine without adjuvant. http://www.who.int/trialsearch/Trial2.aspx?TrialID=EUCTR2014-000052-29-DK. 2014. PMID: CN-01847542. *Intervention*

1655. Euctr EE. Clinical Study in Elderly to Evaluate the Safety, Immunogenicity and Efficacy of Investigational Flu Vaccine Compared to an Approved non-Flu Vaccine. http://www.who.int/trialsearch/Trial2.aspx?TrialID=EUCTR2015-000728-27-EE. 2015. PMID: CN-01808513. *Comparator*

1656. Euctr ES. Evaluation of immunogenicity and safety of a booster dose of Infanrix hexa? in healthy infants born to mothers vaccinated with Boostrix? during pregnancy or immediately post-delivery. http://www.who.int/trialsearch/Trial2.aspx?TrialID=EUCTR2014-001120-30-ES. 2016. PMID: CN-01818149. *Participants*

1657. Euctr ES. Study to assess the immunogenicity and safety of GSK's investigational vaccine (GSK3277511A) when given to healthy smokers and ex-smokers after Shingrix vaccination. http://www.who.int/trialsearch/Trial2.aspx?TrialID=EUCTR2018-002977-24-ES. 2019. PMID: CN-02068172. *Intervention*

1658. Euctr ES. Clinical trial in children from 12 to 35 months of the flu vaccine to estimate efficacy against influenza and other respiratory infections. http://www.who.int/trialsearch/Trial2.aspx?TrialID=EUCTR2019-001186-33-ES. 2019. PMID: CN-02068634. *Intervention*

1659. Euctr FI. Safety and Immunogenicity of Repeated Exposure to an Adjuvanted Quadrivalent Subunit Influenze Virus Vaccine Compared to Non-Adjuvanted Comparator Influenza Vaccine in Children Vaccinated in Trial V118_05. http://www.who.int/trialsearch/Trial2.aspx?TrialID=EUCTR2014-002599-95-FI. 2014. PMID: CN-01864823. *Participants*

1660. Euctr FI. A Phase II Study of the Immunogenicity and Safety of an Investigational Quadrivalent Meningococcal Conjugate Vaccines in Healthy Toddlers. http://www.who.int/trialsearch/Trial2.aspx?TrialID=EUCTR2014-004367-20-FI. 2014. PMID: CN-01838326. *Comparator*

1661. Euctr FI. A study to find out if a vaccine designed to protect against a disease (group B meningococcal meningitis) is safe and protects children aged from 24 months to less than 10 years. http://www.who.int/trialsearch/Trial2.aspx?TrialID=EUCTR2014-000933-21-FI. 2015. PMID: CN-01808436. *Participants*

1662. Euctr FI. Cross-vaccination study of GSK Biologicals' Herpes Zoster subunit (HZ/su) vaccine (GSK 1437173A) in subjects who previously received placebo in ZOSTER-006 (NCT01165177) and ZOSTER-022 (NCT01165229) studies. http://www.who.int/trialsearch/Trial2.aspx?TrialID=EUCTR2015-000965-30-FI. 2015. PMID: CN-01871402. *Comparator*

1663. Euctr FI. Clinical Study to Evaluate Safety and Immunogenicity of Investigational Flu Vaccine Compared to Approved Flu Vaccine (Fluzone) in Children. http://www.who.int/trialsearch/Trial2.aspx?TrialID=EUCTR2015-002973-39-FI. 2015. PMID: CN-01878806. *Intervention*

1664. Euctr FI. Immunogenicity and Safety of an Investigational Quadrivalent Meningococcal Conjugate Vaccine in Toddlers 12 to 23 Months of Age. http://www.who.int/trialsearch/Trial2.aspx?TrialID=EUCTR2016-000749-30-FI. 2016. PMID: CN-01814025. *Intervention*

1665. Euctr FI. Immunogenicity and Safety of Quadrivalent Influenza Vaccine (VaxigripTetra™) in Pregnant Women. http://www.who.int/trialsearch/Trial2.aspx?TrialID=EUCTR2016-004763-40-FI. 2017. PMID: CN-01866411. *Intervention*

1666. Euctr FI. Study to Evaluate the Effectiveness of a High-Dose Quadrivalent Influenza Vaccine (QIV-HD) Compared to a Standard-Dose Quadrivalent Influenza Vaccine (QIV-SD) in Adults 65 Years of Age and Older. http://www.who.int/trialsearch/Trial2.aspx?TrialID=EUCTR2019-001401-25-FI. 2019. PMID: CN-02068656. *Comparator*

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Background

1. SAS/STAT software, Version 9.3 of the SAS System for [Unix]. Copyright © 2011 SAS Institute Inc. SAS and all other SAS Institute Inc. product or service names are registered trademarks or trademarks of SAS Institute Inc., Cary, NC, USA. . *Background*

2. 130 STUDIES LINKING VACCINES TO NEUROLOGICAL AND AUTOIMMUNE ISSUES COMMON TO AUTISM. https://go.thetruthaboutvaccines.com/wp-content/uploads/130-STUDIES-LINKING-VACCINES-TO-NEUROLOGICAL-AND-AUTOIMMUNE-ISSUES-COMMON-TO-AUTISM.pdf. *Background*

3. Package Insert - Adacel. *Background*

4. Package insert - Boostrix. *Background*

5. Package insert - Infanrix. *Background*

6. Package insert - Daptacel. *Background*
7. Package insert - Pediarix. *Background*
8. Package insert - Kinrix. *Background*
9. Package insert - Quadracel. *Background*
10. Package insert - Vaxelis. *Background*
11. Package insert - Pentacel. *Background*
12. Package insert - Tdvax. *Background*
13. Package insert - Tenivac. *Background*
14. Package insert - Twinrix. *Background*
15. Package insert - Vaqta. *Background*
16. Package insert - Havrix. *Background*
17. Package insert - Energix-B. *Background*
18. Package insert - Recombivax-HB. *Background*
19. Package insert - Heplisav-B. *Background*
20. Package insert - Pedvaxhib. *Background*
21. Package insert - Acthib. *Background*
22. Package insert - Hiberix. *Background*
23. Package insert - Gardasil-9. *Background*
24. Package insert - IPOL. *Background*
25. Package insert - Fluad and Fluad QUADRIVALENT *Background*
26. Package insert - Afluria QUADRIVALENT *Background*
27. Package insert - Flucelvax QUADRIVALENT *Background*
28. Package insert - Flulaval QUADRIVALENT *Background*
29. Package insert -Flumist QUADRIVALENT *Background*
30. Package insert - Fluarix QUADRIVALENT *Background*
31. Package insert - Fluzone QUADRIVALENT (including high dose and intradermal). *Background*
32. Package insert - Flublok QUADRIVALENT *Background*
33. Package insert - Proquad (includes fridge stable and frozen(s)). *Background*
34. Package insert - Prevnar-13. *Background*
35. Package insert - Menacetra. *Background*
36. Package insert - MenQuadFi. *Background*
37. Package insert - Menveo. *Background*

38. Package insert - Bexsero. *Background*

39. Package insert - Trumenba. *Background*

40. Package insert - Rotarix. *Background*

41. Package insert - Rotateq. *Background*

42. Package insert - Varivax. *Background*

43. Package insert - Shingrix. *Background*

44. Package insert - Zostavax. *Background*

45. Package insert - Pneumovax 23. *Background*

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Appendix C. Results

This appendix provides more detail on the included studies. Note: The references in this appendix can be found in the list at the end of the main report

Results of Literature Searches

The literature searches and public posting identified a large number of relevant material.

Literature Searches

This update identified 36,076 citations. Of these, 4,303 were obtained as full text. In total, 189 studies reported in 338 publications were identified in this update.

SEADs Input

We solicited public comments for the project in two ways. The AHRQ EPC Program placed an advertisement in the FedEteral Register that described the project and requested public comment. In addition, we established a Supplemental Evidence and Data (SEADS) portal. Multiple submissions from single individuals or groups were counted as one submission. Content of submissions was assessed as pro-vaccine, neutral, or vaccine-hesitant.

A total of 67 submissions—from 14 organizations or individuals—were received through the EPC. These consisted of 11 vaccine-hesitant groups (accounting for 63 of 67 of the submissions) and three submissions that were vaccine neutral.

A total of 61 submissions were received through the SEADS portal, representing18 organizations or individuals. These consisted of 15 vaccine-hesitant submitters and three neutral.

Description of Included Studies

This update documents studies published since the last AHRQ report on the topic[28] and summarizes results from the prior report where appropriate. All included studies used participant samples where all or at least more than 50 percent were receiving recommended vaccines; none of the studies were exclusively in participants where the vaccine was counter-indicated for the participant group. We only included currently available vaccines recommended in the United States and excluded other vaccines. As described throughout, the included studies used a range of study designs and methods to collect safety data. The adverse events assessed for the individual vaccines are shown in the next table.

Table C.1. Assessed adverse events in vaccine studies in adults

Vaccine	Assessed Adverse Events			
Influenza RIV	Abdominal hernia repair Abdominal pain Abdominal wall neoplasm Abortion spontaneous Abscess intestinal Acute myocardial infarction Acute respiratory failure	Cough Craniocerebral injury Crying Cyclic vomiting syndrome Cystocele Death Decreased appetite Dehydration Device related infection Diabetes mellitus inadequate control Diabetic ketoacidosis	Injection site pain Injection site swelling International normalised ratio increased Intervertebral disc compression Intervertebral disc degeneration Intervertebral disc protrusion Intestinal obstruction	Pneumonia Pneumonia bacterial Procedural pain Productive cough Prostate cancer Pulmonary embolism Pyelonephritis Pyrexia Rash Renal cancer

Vaccine	Assessed Adverse Events			
Influenza RIV (continued)	Alcohol detoxification Anaemia Angina pectoris Angina unstable Anxiety Aortic aneurysm Aortic aneurysm rupture Aortic dissection Appendicitis Arm amputation Arrhythmia Arteriosclerosis Arthralgia Arthritis Aspiration Asthenia Atrial fibrillation Atrial flutter Back pain B-cell lymphoma Benign prostatic hyperplasia Bladder cancer Bladder neoplasm Bladder outlet obstruction Breast cancer Bronchitis Calculus ureteric Cardiac arrest Cardiac disorders Cardiac failure Cardiac failure congestive Cardiac tamponade Cardiogenic shock Cardio-respiratory arrest Cardiovascular disorder Cellulitis Cerebral haemorrhage Cerebrovascular accident Cervical vertebral fracture Chest pain Cholecystitis Cholelithiasis Chronic obstructive pulmonary disease Circulatory collapse Colitis ischaemic Colorectal cancer	Diverticulitis Diverticulum Diverticulum intestinal haemorrhagic Drug detoxification Drug withdrawal syndrome Dysphagia Embolic stroke Encephalopathy Endocarditis staphylococcal Epistaxis Erysipelas Eye abscess Failure to thrive Fatigue Food poisoning Gangrene Gastric bypass Gastric ulcer Gastroenteritis viral Gastrointestinal haemorrhage Gout Haematocrit decreased Haemorrhage Haemorrhagic stroke Haemorrhoids Head injury Headache Hepatic cancer Hepatic cirrhosis Hepatic haemorrhage Hepatitis alcoholic Hepatobiliary disorders Hernia obstructive Hernia repair Hiatus hernia Hip arthroplasty Hip fracture Hyperglycaemia Hyperhidrosis Hypertensive crisis Hypoglycaemia Hyponatraemia Hypotension Ileus Influenza Influenza like illness Inguinal hernia Inguinal hernia repair Injection site erythema	Intestinal perforation Intestinal resection Invasive ductal breast carcinoma Irritability Ischaemic cardiomyopathy Joint surgery Knee arthroplasty Lactic acidosis Lacunar infarction Leukocytosis Loss of consciousness Lower limb fracture Lumbar radiculopathy Lumbar spinal stenosis Lung Infection Malaise Menorrhagia Metabolic encephalopathy Metastases to liver Microcytic anaemia Mortality Muscular weakness Musculoskeletal pain Myalgia Myelomalacia Myocardial infarction Nasophayngitis Neck pain Neoplasms benign, malignant and unspecified (incl cysts and polyps) Nervous system disorders Non-cardiac chest pain Obesity Oedema peripheral Oesophageal carcinoma Oropharyngeal pain Osteoarthritis Osteomyelitis Osteomyelitis acute Osteomyelitis chronic Otitis media Ovarian cyst Overdose Pain Pain in extremity Pancreatic carcinoma metastatic Pancreatitis Peripheral arterial occlusive disease Periumbilical abcess Pleural effusion	Renal failure acute Renal necrosis Respiratory failure Rhabdomyolysis Rhabdomyoma Road traffic accident Rotator cuff repair Rotator cuff syndrome Salmonellosis Sick sinus syndrome Sinus headache Sinusitis Small intestinal obstruction Somnolence Spinal column stenosis Spinal compression fracture Squamous cell carcinoma of lung Stab wound Subarachnoid haemorrhage Suicidal ideation Supraventricular tachycardia Syncope Tendon rupture Tenosynovitis stenosans Testis cancer Thalamic infarction Thrombocytosis Thrombosis Thyroid cancer Thyroid neoplasm Tibia fracture Toxicity to various agents Transient ischaemic attack Transitional cell carcinoma Troponin increased Upper gastrointestinal haemorrhage Upper limb fracture Upper respiratory tract infection Urinary retention Urinary tract infection Urinary tract infection fungal

Vaccine	Assessed Adverse Events			
Influenza RIV (continued)	Colorectal cancer recurrent Convulsion Coronary artery disease Coronary artery insufficiency Coronary artery stenosis Coronary artery thrombosis			Urosepsis Uterine disorder Vertigo Viral upper respiratory tract infection Volvulus Vomiting Wound complication
Hepatitis B (HepB; Engerix-B, Recombivax HB, HELISAV-B)	Abdominal hernia Abdominal pain Abortion spontaneous Abscess limb Abscess neck Accident Accidental overdose Acquired central nervous system demyelinating syndromes (CNS ADS) Acute coronary syndrome Acute disseminated encephalomyelitis (ADEM) Acute myocardial infarction Acute prerenal failure Acute respiratory distress syndrome Acute respiratory failure Acute sinusitis Adenocarcinoma of colon Adenomyosis Alcohol poisoning Anaemia Anaemia vitamin b12 deficiency Angina pectoris Angina unstable Ankle fracture Aortic aneurysm Aortic stenosis Appendicitis Appendicitis perforated Appendix disorder Arterial injury Arthralgia Arthritis bacterial Asthma	Death Deep vein thrombosis Dehydration Delayed recovery from anaesthesia Delirium Depression Depression suicidal Device failure Device related infection Diabetes mellitus inadequate control Diabetic foot Diabetic foot infection Diabetic ketoacidosis Diaphragmatic paralysis Diaphragmatic rupture Diarrhoea Diverticular perforation Diverticulitis Diverticulum intestinal haemorrhagic Dizziness Drug withdrawal syndrome Ductal adenocarcinoma of pancreas Duodenal ulcer haemorrhage Dysfunctional uterine bleeding Dyslipidaemia Dyspnoea Ebstein's anomaly Electrophoresis protein abnormal Embolic stroke Endocrine disorders Endometrial cancer Endometriosis Erosive oesophagitis Erysipelas Facial bones fracture Fall Fatigue Femoral neck fracture Femur fracture Fever Fibula fracture	Ileus Ileus paralytic Impaired gastric emptying Inappropriate antidiuretic hormone secretion Infections and infestations Infectious colitis Inflammatory carcinoma of the breast Influenza Inguinal hernia Injection site pain Intentional overdose International normalised ratio increased Intervertebral disc degeneration Intervertebral disc protrusion Intestinal obstruction Intraductal papillary mucinous neoplasm Intraductal proliferative breast lesion Invasive ductal breast carcinoma Investigations Ischaemic hepatitis Ischaemic stroke Jaw fracture Joint injury Laceration Lacunar infarction Large intestine perforation Latent tuberculosis Leukocytosis Lobar pneumonia Localised infection Loose body in joint Lower gastrointestinal haemorrhage Lower limb fracture Lumbar radiculopathy Lumbar spinal stenosis	Pneumonia Pneumonia aspiration Pneumonia escherichia Pneumonia staphylococcal Pneumothorax Post procedural haematoma Post procedural infection Postmenopausal haemorrhage Postoperative fever Postoperative ileus Postoperative wound infection Prerenal failure Procedural intestinal perforation Procedural pain Prostate cancer Prostate cancer stage ii Prostatitis Psychiatric disorders Pulmonary embolism Pulmonary oedema Pulseless electrical activity Pyelonephritis Pyelonephritis acute Radial nerve palsy Rectal adenocarcinoma Rectal haemorrhage Rectal prolapse Redness Renal failure Renal failure acute Renal failure chronic Respiratory arrest

Vaccine	Assessed Adverse Events			
Hepatitis B (HepB; Engerix-B, Recombivax HB, HELISAV-B) (continued)	Atrial fibrillation Atrial flutter Atrial septal defect Back pain Bacteraemia Barrett's oesophagus Benign intracranial hypertension Bile duct stone Bipolar disorder Bladder disorder Bradycardia Brain neoplasm Brain neoplasm benign Breast cancer Bronchial hyperreactivity Bronchitis Bursitis Calculus ureteric Cardiac arrest Cardiac failure Cardiac failure acute Cardiac failure congestive Cardiac ventricular thrombosis Cardiogenic shock Cardiomyopathy Cardio-respiratory arrest Carotid artery stenosis Carotid sinus syndrome Cauda equina syndrome Cavernous sinus thrombosis Cellulitis Cellulitis of male external genital organ Cellulitis orbital Cerebrovascular accident Cervical myelopathy Cervical vertebral fracture Cervix carcinoma Chest pain Cholangiocarcinoma Cholecystitis Cholecystitis acute	Flank pain Foetal growth restriction Foetal heart rate abnormal Foot fracture Forearm fracture Gastric haemorrhage Gastric ulcer Gastric ulcer haemorrhage Gastritis Gastritis alcoholic Gastritis alcoholic haemorrhagic Gastritis haemorrhagic Gastroenteritis Gastroenteritis salmonella Gastroenteritis viral Gastrointestinal anastomotic leak Gastrointestinal haemorrhage Gastrooesophageal reflux disease Gestational diabetes Groin abscess Gun shot wound Haematemesis Haemorrhagic ovarian cyst Haemorrhagic stroke Haemothorax Hand fracture Head injury Headache Hepatic cirrhosis Hepatic encephalopathy Hepatitis c Hiccups Hidradenitis Hip fracture Hodgkin's disease Humerus fracture Hyperglycaemia Hypersensitivity Hypertension Hypertensive crisis Hypertensive heart disease Hypoaesthesia Hypoglycaemia Hypokalaemia Hyponatraemia Hypotension Hypothyroidism Hypoxia Hypoxic-ischaemic encephalopathy	Lumbar vertebral fracture Lung adenocarcinoma Lung cancer metastatic Lung infiltration Major depression Malaise Malignant melanoma Meningitis Meniscus injury Menstruation irregular Mental status changes Metabolism and nutrition disorders Metastatic renal cell carcinoma Microcytic anaemia Migraine Multiple sclerosis (MS) Muscle strain Muscular weakness Musculoskeletal chest pain Musculoskeletal pain Myalgia Mycobacterium avium complex infection Myocardial infarction Myocardial ischaemia Myositis Nasal polyps Nasopharyngitis Neck pain Nephrolithiasis Nervous system disorders Neuropathy peripheral Non-cardiac chest pain Non-small cell lung cancer metastatic Oesophageal adenocarcinoma Oesophageal spasm Oesophagitis Oligohydramnios Osteoarthritis Osteomyelitis Otitis media bacterial Ovarian cancer stage iii Ovarian germ cell teratoma Overdose Pain in extremity Pancreatic carcinoma Pancreatic carcinoma metastatic Pancreatitis Pancreatitis acute Papillary thyroid cancer Patella fracture	Respiratory failure Rhabdomyolysis Rib fracture Rotator cuff syndrome Scapula fracture Schizoaffective disorder Schizophrenia Sepsis Seroma Sickle cell anaemia with crisis Sinusitis Small cell lung cancer metastatic Small intestinal obstruction Social circumstances Spinal column stenosis Spinal fracture Spinal osteoarthritis Splenic abscess Spondylitic myelopathy Spondylolisthesis Squamous cell carcinoma of the cervix Squamous cell carcinoma of the oral cavity Stab wound Staphylococcal abscess Staphylococcal infection Staphylococcal osteomyelitis Subarachnoid haemorrhage Substance-induced psychotic disorder Suicidal ideation Suicide attempt Supraventricular tachycardia Swelling Syncope Thalamic infarction Thermal burn Thrombophlebitis superficial Thrombotic stroke Thyroid mass Tibia fracture Tibia fracture

Vaccine	Assessed Adverse Events		
Hepatitis B (HepB; Engerix-B, Recombivax HB, HELISAV-B) (continued)	Cholecystitis chronic Cholecystitis infective Cholelithiasis Chronic obstructive pulmonary disease Clear cell renal cell carcinoma Clinically isolated syndrome (CIS) Clostridium difficile colitis Colitis Colitis ulcerative Colon adenoma Colon cancer stage iv Complex partial seizures Concussion Confusional state Constipation Contusion Convulsion Coronary artery disease Coronary artery occlusion Coronary artery stenosis Costochondritis Cough Craniocerebral injury Cyclic vomiting syndrome Cystocele	Pelvic neoplasm Periorbital cellulitis Peripheral nerve injury Peripheral vascular disorder Perirectal abscess Pituitary-dependent cushing's syndrome Placenta praevia Plasma cell myeloma Pleural effusion Pleuritic pain	Toxicity to various agents Transient global amnesia Transient ischaemic attack Traumatic haemothorax Tubulointerstitial nephritis Type 2 diabetes mellitus Upper gastrointestinal haemorrhage Upper respiratory tract infection Urinary retention Urinary retention postoperative Urinary tract infection Urinary tract infection enterococcal Urosepsis Uterine leiomyoma Vaginal haemorrhage Varices oesophageal Vascular disorders Ventricular fibrillation Ventricular tachycardia Vertebral foraminal stenosis Vertigo Vertigo positional Victim of homicide Viral sepsis Vitiligo Water intoxication Wound infection Wound infection staphylococcal Wrist fracture
Hepatitis A and B (Twinrix)	N/A		
Haemophilus influenzae type b (Hib; PedvaxHIB, ActHIB, Hiberix)	N/A		

Vaccine	Assessed Adverse Events			
Human papillomavirus (HPV9; Gardasil 9)	N/A			
Inactivated influenza (IIV; Afluria Quadrivalent, Flucelvax Quadrivalent, Fluarix Quadrivalent, Fluzone Quadrivalent, Fluad)	Abdominal hernia Abdominal pain Abdominal pain upper Abdominal wall hematoma Abortion spontaneous Abscess intestinal Abscess limb Accelerated hypertension Acute abdomen Acute coronary syndrome Acute kidney injury Acute leukaemia Acute myeloid leukaemia Acute myeloid leukemia and worsening of diabetes Acute Myocardial Infarction Acute myocardial rejection Acute respiratory failure Adenocarcinoma Adenocarcinoma of colon Alcoholism Ammonia increased Amyotrophic lateral sclerosis Anaemia Anaemia postoperative Anaesthetic Complication Anaphylactic reaction Anemia Aneurysm ruptured Angina pectoris Angina unstable Angioedema Animal bite Ankle Fracture Aortic aneurysm Aortic dissection Aortic Stenosis Appendicitis Appetite lost	Costochondritis Cough Craniocerebral injury Crying abnormal Cystitis Cystocele Death Decreased appetite Deep Vein Thrombosis Dehydration Dementia alzheimer's type Dementia with lewy bodies Depressed level of consciousness Depression Device related infection Diabetes Mellitus Diabetes mellitus inadequate control Diabetic foot Diabetic ketoacidosis Diarrhea (prespecified) Diplopia Disseminated intravascular coagulation Diverticular perforation Diverticulitis Diverticulum Diverticulum intestinal Diverticulum Intestinal Haemorrhagic Dizziness Dressler's syndrome Drowsiness Drug hypersensitivity Duodenal ulcer perforation Dyspepsia Dysphagia Dyspnea Ecchymosis Electrolyte imbalance Embolic stroke encephalitis/myelitis (prespecified) Encephalopathy Endocarditis Endometrial adenocarcinoma Endometrial cancer Endometriosis Enteritis Erosive oesophagitis Erysipelas	Intestinal infarction Intestinal obstruction Intestinal perforation Intracranial aneurysm Invasive Ductal Breast Carcinoma Investigati Investigatio Investigations Iron deficiency anaemia Irritability Irritable bowel syndrome Ischaemic Cerebral Infarction Ischemic stroke Jaundice Jaw fracture Joint dislocation Joint pain Joint pain at other location than injection site Joint swelling Laceration Large intestinal obstruction Large intestine perforation Laryngitis Leptospirosis Leukocytosis Ligament rupture Lobar pneumonia Loss of appetite (prespecified) Loss of consciousness Lower gastrointestinal haemorrhage Lower limb fracture Lower respiratory tract infection Lumbar Spinal Stenosis Lumbar vertebral fracture Lung adenocarcinoma Lung cancer metastatic Lung carcinoma cell type unspecified stage IV Lung neoplasm malignant Lung squamous cell carcinoma stage unspecified Malaise	Radiculopathy Radius fracture Rash Rectal cancer Rectal haemorrhage Redness (prespecified) Renal and urinary disorders Renal cell carcinoma Renal Failure Renal Failure acute Renal failure chronic Renal impairment Renal mass Respiratory arrest Respiratory Failure Respiratory syncytial virus infection Respiratory Tract Infection Retina detachment Retinal neovascularisation Rhabdomyolysis Rhinorrhoea Rib Fracture Road Traffic Accident Rotator cuff syndrome Ruptured cerebral aneurysm Sarcoma Scapula fracture Seizure Sepsis Septic Shock Seroma Severe pain Shivering (prespecified) Sick sinus syndrome Sideroblastic anaemia Sinus Bradycardia Sinus node dysfunction Sinus Tachycardia Sinusitis Skin abrasion

Vaccine	Assessed Adverse Events			
Inactivated influenza (IIV; Afluria Quadrivalent, Flucelvax Quadrivalent, Fluarix Quadrivalent, Fluzone Quadrivalent, Fluad) (continued)	Arrhythmia Arteriosclerosis Arteriosclerosis coronary artery Arthalgia (prespecified) Arthralgia (prespecified) Arthritis Arthritis bacterial Arthritis infective Arthropathy Ascites Asthenia Asthma Asthmatic crisis Atelectasis Atrial Fibrillation Atrial tachycardia Atrioventricular Block Complete Atrioventricular block second degree Atypical pneumonia Azotemia Back injury Back Pain Bacteraemia Basal cell carcinoma B-cell lymphoma Bell's palsy (prespecified) Benign prostatic hyperplasia Bile duct stone Bipolar disorder Bladder adenocarcinoma stage unspecified Bladder Cancer Bladder transitional cell carcinoma Blindness unilateral Bone Contusion Bradycardia Brain herniation Brain Neoplasm Brain neoplasm malignant Breast Cancer Breast cancer stage II Bronchiolitis Bronchitis Bronchospasm	Erythema (prespecified) Escherichia sepsis Esophageal injury Eye disor Facial bones fracture Facial Paralysis Fall Fatigue (prespecified) Femoral hernia,obstructive Femoral neck fracture Femur Fracture Fever (prespecified) Foot fracture Forearm Fracture Fracture displacement Gait disturbance Gastric adenoma Gastric cancer Gastric ulcer Gastric ulcer haemorrhage Gastric ulcer perforation Gastritis Gastroenteritis Gastroenteritis viral Gastrointestinal adverse event(s) (prespecified) Gastrointestinal disorder Gastrointestinal Haemorrhage Gastrointestinal intolerance Gastrointestinal mucosal disorder Gastrointestinal perforation Gastrointestinal stromal tumor Gastrointestinal symptoms Gastrointestinal Ulcer Haemorrhage Gastrooesophageal reflux disease Generalised tonic-clonic seizure Gouty arthritis Granulomatosis with polyangiitis Groin abscess Groin Pain Guillain-barre syndrome Guillain-Barre syndrome (prespecified) Haematochezia Haemorrhage Haemorrhage intracranial Haemorrhagic Anaemia Head injury	Malaise (prespecified) Malaise (prespecified) Malignant Melanoma Malnutrition Meningioma Meningitis aseptic Meningitis viral Mental Status Changes Metabolic encephalopathy Metastases to lung Metastatic neoplasm Mitral valve incompetence Mortality Multi-organ failure Multiple injuries Muscle aches Muscle haemorrhage Muscular weakness Musculoskeletal chest pain Myalgia (prespecified) Myocardial infarction Myocardial Ischemia Nasopharyngitis Nausea (prespecified) Neoplasm Malignant Nephrolithiasis Nephropathy Nerve injury Nervous system disorder Nodal arrythmia Nodal rhythm Non-cardiac chest pain Non-small cell lung cancer Obstructive uropathy Oesophageal carcinoma Oesophagitis optic neuritis (prespecified) Oropharyngeal pain Osteoarthritis Osteomyelitis Ovarian adenoma Ovarian cancer Ovarian cancer stage IV Overdose Oxygen saturation decreased Pain (prespecified) Pain in extremity Pancreatic Carcinoma Pancreatic mass Pancreatic neoplasm Pancreatitis	Skin cancer Skin Ulcer Sleep apnoea syndrome Small cell lung cancer stage unspecified Small Fibre Neuropathy Small intestinal obstruction Spasmodic dysphonia Spinal column stenosis Spinal Compression Fracture Spinal cord injury Spinal Osteoarthritis Spondylolisthesis Squamous cell carcinoma Squamous cell carcinoma of the cervix Stab wound Staphylococcal Infection Stevens-Johnson syndrome (prespecified) Strangulated hernia Streptococcal Infection Streptococcal sepsis Stress Cardiomyopathy Stroke in evolution Subarachnoid hemorrhage Subdural haematoma Subjective fever Sudden Death Swelling (prespecified) Syncope Tenderness (prespecified) Tendon Rupture Tetanus Thalamic infarction Thoracic vertebral fracture Thrombocytopenia Thrombosis

Vaccine	Assessed Adverse Events			
Inactivated influenza (IIV; Afluria Quadrivalent, Flucelvax Quadrivalent, Fluarix Quadrivalent, Fluzone Quadrivalent, Fluad) (continued)	Bundle branch block left Calculus bladder Calculus ureteric Cardiac arrest Cardiac disorder Cardiac failure Cardiac failure acute Cardiac failure congestive Cardiogenic shock Cardiopulmonary failure Cardio-respiratory arrest Carotid artery disease Carotid Artery Occlusion Carotid Artery Stenosis Cellulitis Cellulitis staphylococcal Central nervous system infection Cerebellar infraction Cerebral haemorrhage Cerebral infraction Cerebral ischaemia Cerebrospinal Fluid Leakage Cerebrovascular Accident Cerebrovascular disorder Cervical myelopathy Cervical spinal stenosis Cervicobrachial syndrome Cervix carcinoma Chest discomfort Chest pain Chills (prespecified) Cholangiocarcinoma Cholangitis Cholangitis acute Cholecystitis Cholecystitis Acute Cholecystitis chronic Cholelithiasis	Headache (prespecified) Headcahe Hemiplegia Hemorrhage intracranial Hepatic cirrhosis Hepatic failure Hepatic neoplasm malignant Hepatobiliary disor Hernia obstructive Herpes zoster Hiatus hernia Hip fracture Histiocytosis haematophagic Hospitalization Humerus Fracture Hydrocele Hydronephrosis Hyperglycaemia Hypertension Hypertensive crisis Hypertensive heart disease Hypertrophic cardiomyopathy Hypoaesthesia Hypocalcaemia Hypoglycaemia Hypokalaemia Hypomagnesaemia Hyponatraemia Hypotension Hypovolaemia Hypoxia Idiopathic Thrombocytopenic coagulation Ileus Ileus paralytic Immune system disor Implantable defibrillator insertion Incision site infection Incisional Hernia Induration Infected skin ulcer Infections and infestat Infectious peritonitis Influenza Influenza symptoms Inguinal Hernia Inguinal hernia, obstructive Injection Site Erythema (prespecified) Injection site induration Injection Site Pain (prespecified)	Pancreatitis acute Parainfluenzae Viral Laryngotracheobronchitis Parathyroid tumor benign Patella fracture Pelvic fracture Pelvic inflammatory disease Peptic ulcer Peptic ulcer perforation Pericarditis Peripheral artery aneurysm Peripheral Vascular Disorder Perirenal haematoma Peritonsillar abscess Pituitary tumour benign Pleural effusion Pleurisy Pneumonia Pneumonia aspiration Pneumonia bacterial Pneumonia legionella Pneumonia viral Pneumoperitonium Portal hypertension Post procedural haemorrhage Posterior reversible encephalopathy syndrome Postoperative adhesion Postoperative ileus Postpericardiotomy Syndrome Postprocedural hematuria Presyncope Procedural dizziness Prolymphocytic leukaemia Prostate Cancer Prostatomegaly Prostrate cancer Pruritus Psychiatric disorders Pulmonary edema Pulmonary Embolism Pulmonary hypertension Pulmonary mass Pulmonary Tuberculosis Pyelonephritis Pyelonephritis acute Pyrexia	Thyroid cancer Tibia fracture Tooth abscess toxic epidermal necrolysis (prespecified) Tracheobronchitis Transient ischemic attack Transitional cell carcinoma Traumatic liver injury Troponin Increased Tuberculosis Type 2 Diabetes Mellitus Unspecified gastrointestinal bleeding Upper airway obstruction Upper gastrointestinal haemorrhage Upper limb fracture Upper respiratory tract infection Ureteric stenosis Urinary incontinence Urinary Retention Urinary tract infection Urosepsis Uterine Leiomyoma Uterovaginal prolapse Varicose ulceration Vascular disorder Vascular Stent Thrombosis Venous thrombosis limb Ventricular arrhythmia Ventricular extrasystoles Ventricular fibrillation Ventricular Tachycardia Vertebrobasilar insufficiency Vertigo Vestibular disorder VIIth nerve paralysis Viral Infection Viral pericarditis

Vaccine	Assessed Adverse Events			
Inactivated influenza (IIV; Afluria Quadrivalent, Flucelvax Quadrivalent, Fluarix Quadrivalent, Fluzone Quadrivalent, Fluad) (continued)	Chronic hepatic failure Chronic myeloid leukaemia Chronic Obstructive Pulmonary Disease Clavicle fracture Colitis Colon adenoma Colon cancer Coma hepatic Concussion Confusional state Constipation Convulsion Corneal degeneration Coronary artery disease Coronary artery restenosis	Injection Site Swelling (prespecified) Injection site tenderness Injection-site hemorrhage Interstitial lung disease Intervertebral disc degeneration Intervertebral disc disorder Intervertebral Disc Protrusion		Viterous hemorrhage Volvulus Vomiting (prespecified) Wound abscess Wound dehiscence Wrist fracture
Live attenuated influenza (LAIV; FluMist Quadrivalent)	N/A			
Measles, mumps, rubella (MMR; M-M-R II)	N/A			
Meningococcal, Quadrivalent [MenACWY-D (Menactra), MenACWY-CRM (Menveo), MenACWY-TT (MenQuadfi)]	Acute Myocardial Infarction Acute tonsillitis Arthralgia Atrial Fibrillation Benign Prostatic Hyperplasia Bile Duct Stone Biliary Colic Chills Colitis Ischaemic Completed suicide Coronary Artery Disease Cough Deep Vein Thrombosis Depression Suicidal Device Failure Device Related Infection Dizziness	Erythema Escherichia Sepsis Fatigue Foot Deformity Headache Induration Influenza Influenza-like illness Injection Site Erythema Injection Site Pain Injury Intervertebral disc protrusion Invasive Lobular Breast Carcinoma Ischaemic Stroke Joint Contracture Localised Infection Lung Adenocarcinoma	Lung Cancer Metastatic Malaise Mortality Multiple Fractures Muscle Strain Myalgia Myocardial Infarction Nasopharyngitis Nausea Non-Cardiac Chest Pain Oropharyngeal pain Osteoarthritis Osteomyelitis Pain Pain in an extremity Pancreatitis Acute	Pancreatitis Relapsing Pelvic Fracture Peripheral Vascular Disorder Pneumonia Prostate Cancer Pruritus Psychiatric disorders Pyrexia Renal cancer Sepsis Skin Ulcer Spinal Column Injury Tooth disorder Transient Ischaemic Attack Vaccination site pain Vascular disorders Vertigo

Vaccine	Assessed Adverse Events			
Meningococcal B [MenB; MenB-4C (Bexsero), MenB-FHbp (Trumenba)]	N/A			
Pneumococcal conjugate (PCV13, Prevnar 13)	Abdominal abscess Abdominal hernia Abdominal pain Abdominal pain lower Abdominal pain upper Abscess oral Accidental death Accidental overdose Acquired phimosis Actinic keratosis Acute coronary syndrome Acute disseminated encephalomyelitis Acute kidney injury Acute myocardial infarction Acute pericarditis Adenocarcinoma of colon Adverse events Ageusia Aggravated generalized joint pain Aggravated generalized muscle pain Allergic Reaction Alveolitis allergic Anaemia Anaemia postoperative Anaphylactic reaction Anaphylactic shock Anaphylaxis Angina pectoris Angina unstable Angioedema Ankle fracture Anxiety Aortic aneurysm Aortic aneurysm rupture Aortic arteriosclerosis Aortic valve stenosis	Colon cancer Colon cancer metastatic Colon neoplasm Colorectal cancer metastatic Concussion Conjunctivitis Conjunctivitis allergic Constipation Contusion Convulsion Corneal graft rejection Coronary artery disease Coronary artery dissection Coronary artery stenosis Cough Cyst Cystitis Cystitis noninfective Death Decreased appetite Deep vein thrombosis Delirium Depression Dermatitis allergic Dermatitis contact Device breakage Device dislocation Device occlusion Device related infection Diarrhea Discoloration Diverticulitis Diverticulum intestinal haemorrhagic Dizziness Drug hypersensitivity Dry skin Duodenal perforation Duodenal ulcer Dyspepsia Dyspnoea Dyspnoea exertional Ecchymosis Eczema Electrocardiogram T wave abnormal Electrolyte imbalance Endometrial adenocarcinoma Endometrial cancer Enteritis infectious Enterococcus faecalis	Joint dislocation Joint injury Joint range of motion decreased Joint stiffness Joint swelling Keratoacanthoma Kidney contusion Lactic acidosis Large intestinal stenosis Laryngeal cancer Left ventricular failure Leukaemia Ligament injury Ligament sprain Limb injury Limitation of arm move Limitation of arm movement Limitation of arm movement of the injected arm Localised infection Localized swelling Loose tooth Loss of consciousness Lower limb fracture Lower respiratory tract infection Lumbar spinal stenosis Lumbar vertebral fracture Lung adenocarcinoma metastatic Lung disorder Lung infiltration Lung neoplasm malignant Lymphadenopathy Macular fibrosis Malaise Malignant hypertension Malignant melanoma Malignant neoplasm of renal pelvis Medical device complication Melaena Melanoma recurrent Meningitis Mental status changes postoperative Mesothelioma	Prostate cancer Prostate cancer metastatic Prostate cancer recurrent Prostatitis Pruritus Pruritus generalised Psychiatric disorders Psychotic disorder Pulmonary embolism Pulmonary hypertension Pulmonary pain Pyrexia Radicular pain Radiculitis lumbosacral Radius fracture Rash Rash erythematous Rectal cancer Rectal haemorrhage Rectal prolapse Redness Renal and urinary disor Renal cancer Renal cancer recurrent Renal cell carcinoma Renal impairment Respiratory tract infection Retinal artery occlusion Retinal detachment Rhinalgia Rhinorrhoea Rib fracture Rotator cuff syndrome Sciatica Seasonal allergy Sepsis Serious adverse events Sick sinus syndrome

Vaccine	Assessed Adverse Events			
Pneumococcal conjugate (PCV13, Prevnar 13) (continued)	Aphonia Appendicitis Arrhythmia Arthralgia Arthritis Asphyxia Asthenia Asthma Atrial fibrillation Atrial flutter Atrial tachycardia Atrioventricular block Atrioventricular block complete Atrioventricular block first degree Atrioventricular block second degree Back pain Balance disorder Basal cell carcinoma Bell's palsy Benign prostatic hyperplasia Bile duct adenocarcinoma Bile duct stone Bipolar disorder Bladder adenocarcinoma stage unspecified Bladder cancer Bladder transitional cell carcinoma Blood blister Blood pressure increased Bone contusion Bone cyst Bone loss Bowen's disease Bradycardia Brain contusion Breast cancer Bronchial carcinoma Bronchiolitis Bronchitis Bronchitis chronic Bursitis Calculus bladder Cardiac arrest Cardiac asthma Cardiac disorders Cardiac failure Cardiac failure congestive	Epicondylitis Epilepsy Epistaxis Eructation Erysipelas Erythema multiforme Eye disorders Face injury Facial bones fracture Fall Fatigue Female genital tract fistula Femoral neck fracture Femur fracture Fever Fibromyalgia Finger deformity Flank pain Folliculitis Food allergy Food poisoning Foot fracture Forearm fracture Foreign body aspiration Fracture Fungal infection Fungal skin infection Gangrene Gastric cancer Gastric perforation Gastritis Gastroenteritis Gastrointestinal haemorrhage Gastrointestinal viral infection Gastrooesophageal reflux disease General disorders Gingivitis Glioblastoma Glioma Gout Groin infection Guillain-Barre Syndrome Haematoma Haematuria Haemorrhoids Hand fracture Head injury Headache Hemiparesis Hepatic adenoma Hepatic encephalopathy Hepatic enzyme increased Hepatobiliary disorder Hernia obstructive Herpes zoster	Metabolism and nutrition disor Metastasis Metastatic gastric cancer Metastatic renal cell carcinoma Micturition urgency Mild soreness Mitral valve incompetence Mobility Loss Mortality Multiple injuries Muscle aches Muscle spasms Muscle strain Muscular weakness Musculoskeletal chest pain Musculoskeletal discomfort Musculoskeletal disorder Musculoskeletal pain Musculoskeletal stiffness Myalgia Myelodysplastic syndrome Myocardial infarction Myocardial ischaemia Myositis Nasopharyngitis Nausea Neoplasm prostate Nephrolithiasis Nerve compression Nervous system disor Neuropathy peripheral New generalized joint pain New generalized muscle pain New or aggravated muscle of joint pina Non-cardiac chest pain Non-small cell lung cancer Ocular hyperaemia Oedema peripheral Oesophageal adenocarcinoma Oesophageal carcinoma recurrent Oral herpes Oral temperature Oropharyngeal pain Osteitis Osteoarthritis	Silent myocardial infarction Sinus bradycardia Sinusitis Skeletal injury Skin papilloma Skin ulcer Sleep apnoea syndrome Small cell lung cancer Sneezing Splinter Spondylolisthesis Squamous cell carcinoma of skin Staphylococcal bacteraemia Staphylococcal infection Stomach pain Subarachnoid haemorrhage Subdural haematoma Subileus Sudden cardiac death Suicidal ideation Supraventricular tachycardia Surgical failure Swelling Syncope Synovial cyst Tachycardia Temperature Temporal arteritis Tenderness Tenderness in an arm Tendon injury Tendon rupture Tendonitis Testicular pain Thermal burn Thrombocytopenia I Thrombocytopenia II Thrombophlebitis Tinea barbae Tonsil cancer Tooth abscess Tooth infection Toothache Transient global amnesia Transient ischaemic attack

Vaccine	Assessed Adverse Events			
Pneumococcal conjugate (PCV13, Prevnar 13) (continued)	Cardiac valve replacement complication Cardiogenic shock Cardiomyopathy Cardiomyopathy or heart failure Cardio-respiratory arrest Cardiovascular disease or cancer Carotid artery stenosis Cataract Cellulitis Cellulitis and infection Cerebral haemorrhage Cerebral infarction Cerebral ischaemia Cerebrovascular accident Change of bowel habit Chemical burn of skin Chemical burns of eye Chest pain Chills Cholangitis Cholangitis suppurative Cholecystitis Cholecystitis acute Cholelithiasis Chronic obstructive pulmonary disease Chronic sinusitis Circulatory collapse Clear cell renal cell carcinoma Colitis	Hiatus hernia Hip fracture Humerus fracture Hydrothorax Hypercalcaemia Hyperhidrosis Hypertension Hyperventilation Hypoglycaemia Hypopharyngeal cancer Hypotension Idiopathic thrombocytopenic purpura Ileus Ill-defined disorder Implant site fibrosis Incisional hernia Inclusion body myositis Infections and infestat Infective exacerbation of chronic obstructive airways disease Influenza Inguinal hernia, obstructive Injection site erythema Injection site exfoliation Injection site haematoma Injection site induration Injection site pain Injection site pruritus Injection site rash Injection site reaction Injection site swelling Injury Intermittent claudication International normalised ratio decreased Intervertebral disc protrusion Intestinal obstruction Intestinal perforation Investigations Iron deficiency anaemia Ischaemic stroke Itch on a leg Itching	Osteomyelitis Osteopenia Osteoporosis Otitis externa Otitis media Ovarian cancer Ovarian cyst Pain Pain in extremity Pain in jaw Pain killers Pain of skin Palpitations Pancreatic carcinoma (not prespecified and not vaccine related) Pancreatitis Pancreatitis acute Pancytopenia Paraesthesia Pelvic fracture Pelvic haematoma Pelvic pain Pericarditis Periorbital contusion Peripheral arterial occlusive disease Peripheral coldness Peripheral nerve lesion Peripheral swelling Periprosthetic fracture Peritonitis Peritonsillar abscess Peroneal nerve palsy Plantar fasciitis Plasma cell myeloma Pleural effusion Pneumonia Pneumonia legionella Pneumonia pneumococcal Pneumothorax Polymyalgia rheumatica Post laminectomy syndrome Presyncope Procedural haemorrhage Procedural intestinal perforation Procedural pain Productive cough	Transitional cell carcinoma Traumatic haemorrhage Trigeminal neuralgia Tuberculosis Type 2 diabetes mellitus Ulna fracture Umbilical hernia Upper gastrointestinal haemorrhage Upper respiratory tract infection Upper-airway cough syndrome Ureteric stenosis Urethral stenosis Urinary retention Urinary retention postoperative Urinary tract infection Urine odour abnormal Urosepsis Urticaria Vaginal prolapse Varices oesophageal Vascular graft occlusion Ventricular tachycardia Vertigo Vessel puncture site haematoma Vestibular neuronitis Viral infection Viral upper respiratory tract infection Vitreous floaters Vomiting Weight decreased Wound Wound dehiscence Wound infection Wrist fracture

Vaccine	Assessed Adverse Events			
Pneumococcal polysaccharide vaccine (PPSV23; Pneumovax)	Acute kidney injury Acute myocardial infarction Anaemia Angina pectoris Arrhythmia Arthralgia Asthma Benign prostatic hyperplasia Calcinosis Cardiac failure Cardio-respiratory arrest Carotid artery stenosis Cerebral thrombosis Chest pain Chills Chronic obstructive pulmonary disease Colon cancer metastatic	Coronary artery stenosis Coronary care unit admission Death Depression Diabetes mellitus inadequate control Erysipelas Erythema Fatigue Fever Gastrointestinal disorder Gastrointestinal infection Generalized joint pain Generalized muscle pain Headache Hospital admission Hyperhidrosis Hyperkalaemia Hypertension	Influenza-like illness Intensive care unit admission Intestinal ischaemia Intestinal malrotation Ischemic heart disease Ischemic stroke Limitation of arm movement Lower respiratory tract infection Lung infection Major swelling at the injection site (elbow joint to shoulder joint) Malaise Moderate swelling at the injections site Muscle aches Myalgia Myocardial infarction Osteoarthritis Other non-specified infection Other symptoms	Pain Pain at injection site Pneumonia Pneumonia aspiration Psychiatric disorders Rash Redness Redness at injection site Renal cancer stage ii Shingles Skin infection Squamous cell carcinoma of the oral cavity Swelling Tenderness Tuberculosis Upper respiratory tract infection Urinary tract infection Wrist fracture
Tetanus, diphtheria, & acellular pertussis (Tdap, Adecel, Boostrix)	Abdominal pain Abortion spontaneous Crohn's disease Fever (prespecified) Headache (prespecified)	Infectious mononucleosis Injection site erythema (prespecified) Injection site pain (prespecified)	Injection site swelling (prespecified) Intestinal obstruction Malaise (prespecified) Mortality Myalgia (prespecified)	Neoplasm malignant Pickwickian syndrome Tonsillar haemorrhage Upper limb fracture
Tetanus, diphtheria (TD; TDVAX, Tenicac)	N/A			
Varicella (VAR; varix)	N/A			
Zoster (recombinant, RZV [shingrix]; live ZV [Zostavax])	Abdominal abscess Abdominal adhesions Abdominal discomfort Abdominal hernia Abdominal infection Abdominal pain Abdominal pain upper Abdominal strangulated hernia Abnormal behaviour Abortion missed Abscess	Colitis Colitis ischaemic Colitis ulcerative Colon adenoma Colon cancer Colon cancer metastatic Colon neoplasm Colonic abscess Coma Completed suicide Compression fracture Concussion Confusional state Congenital cystic kidney disease Congestive cardiomyopathy Constipation	Invasive ductal breast carcinoma Invasive lobular breast carcinoma Invasive papillary breast carcinoma Iridocele Iritis Iron deficiency anaemia Irritable bowel syndrome Ischaemic cardiomyopathy Ischaemic hepatitis Ischaemic stroke Jaundice cholestatic Jaw fracture Joint dislocation	Proctitis Progressive supranuclear palsy Prostate cancer Prostate cancer metastatic Prostate cancer recurrent Prostate cancer stage iv Prostatic adenoma Prostatic obstruction Prostatitis Prostatomegaly Pseudarthrosis Pseudomembranous colitis

Vaccine	Assessed Adverse Events			
Zoster (recombinant, RZV [shingrix]; live ZV [Zostavax]) (continued)	Accident Accidental death Accidental overdose Acquired claw toe Acral lentiginous melanoma Actinic keratosis Acute coronary syndrome Acute graft versus host disease Acute hepatic failure Acute kidney injury Acute left ventricular failure Acute leukaemia Acute monocytic leukaemia Acute myeloid leukaemia Acute myocardial infarction Acute prerenal failure Acute promyelocytic leukaemia differentiation syndrome Acute psychosis Acute pulmonary oedema Acute respiratory distress syndrome Acute respiratory failure Adenocarcinoma Adenocarcinoma gastric Adenocarcinoma of colon Adenocarcinoma pancreas Administration site erythema Administration site pain Adrenal adenoma Adrenal gland cancer Adverse drug reaction Affective disorder Age-related macular degeneration Agranulocytosis	Contusion Cor pulmonale Coronary artery disease Coronary artery insufficiency Coronary artery occlusion Coronary artery reocclusion Coronary artery restenosis Coronary artery stenosis Cough Craniocerebral injury C-reactive protein increased Crohn's disease Cushingoid Cutaneous vasculitis Cyst Cystic fibrosis Cystitis Cystitis haemorrhagic Cystitis interstitial Cystitis klebsiella Cytomegalovirus infection Cytopenia Deafness neurosensory Death Decreased appetite Decubitus ulcer Deep vein thrombosis Deep vein thrombosis postoperative Dehydration Delirium Dementia Dementia alzheimer's type Dementia with lewy bodies Demyelinating polyneuropathy Depressed mood Depression Dermal cyst Dermatitis allergic Dermatitis contact Dermatomyositis Device battery issue Device deposit issue Device dislocation Device failure Device leakage Device occlusion Device related infection Diabetes mellitus Diabetes mellitus inadequate control Diabetic coma Diabetic foot	Joint effusion Joint injury Kidney contusion Kidney infection Klebsiella bacteraemia Klebsiella infection Klebsiella sepsis Kyphosis Labile hypertension Labyrinthitis Laceration Lactic acidosis Lacunar infarction Large cell lung cancer Large intestinal obstruction Large intestine benign neoplasm Large intestine perforation Large intestine polyp Laryngeal cancer Left ventricular failure Left ventricular hypertrophy Leiomyosarcoma Lens dislocation Leukaemia Lichen planus Ligament sprain Limb crushing injury Limb injury Lipoma Liver abscess Liver function test abnormal Lobar pneumonia Localised infection Loss of consciousness Lower limb fracture Lower respiratory tract infection Lower respiratory tract infection bacterial Lumbar radiculopathy Lumbar spinal stenosis Lumbar vertebral fracture Lung abscess Lung adenocarcinoma Lung adenocarcinoma metastatic Lung adenocarcinoma stage iii Lung cancer metastatic Lung disorder Lung infection Lung neoplasm Lung neoplasm malignant	Pseudomonas infection Psittacosis Psoas abscess Psoriasis Psychiatric disor Psychotic disorder Pubis fracture Pulmonary cavitation Pulmonary congestion Pulmonary embolism Pulmonary fibrosis Pulmonary haemorrhage Pulmonary mass Pulmonary oedema Pulmonary thrombosis Pulmonary tuberculosis Pulseless electrical activity Purulence Pyelonephritis Pyelonephritis acute Pyloric stenosis Pyrexia (prespecified) Radicular pain Radiculopathy Radius fracture Rash Rectal abscess Rectal adenocarcinoma Rectal adenoma Rectal cancer Rectal cancer recurrent Rectal haemorrhage Rectal perforation Rectal polypectomy Rectal prolapse Rectocele Redness (prespecified) Renal abscess Renal and urinary disor Renal cancer Renal cancer metastatic Renal cell carcinoma

Vaccine	Assessed Adverse Events			
Zoster (recombinant, RZV [shingrix]; live ZV [Zostavax]) (continued)	Alcaligenes infection Alcohol withdrawal syndrome Allergic granulomatous angiitis Amaurosis fugax Amnesia Amyloidosis Amyotrophic lateral sclerosis Anaemia Anaemia vitamin b12 deficiency Anaemia vitamin b2 deficiency Anal abscess Anal fissure Anal fistula Anal fistula infection Anal prolapse Anaphylactic reaction Anaplastic astrocytoma Anaplastic thyroid cancer Aneurysm Aneurysm ruptured Angina pectoris Angina unstable Angiocentric lymphoma Angioedema Angioimmunoblastic t-cell lymphoma Ankle fracture Anorectal cellulitis Anxiety disorder Aortic aneurysm Aortic aneurysm rupture Aortic arteriosclerosis Aortic dissection Aortic occlusion Aortic rupture Aortic stenosis Aortic valve disease Aortic valve incompetence Aortic valve stenosis Appendiceal abscess Appendicitis Appendicitis perforated	Diabetic foot infection Diabetic ketoacidosis Diaphragmatic disorder Diaphragmatic hernia Diaphragmatic hernia, obstructive Diarrhoea Diastolic dysfunction Diffuse large b-cell lymphoma Diffuse large b-cell lymphoma stage iv Diplopia Disorientation Disseminated intravascular coagulation Disturbance in attention Diverticulitis Diverticulum Diverticulum intestinal Diverticulum intestinal haemorrhagic Dizziness Drop attacks Drowning Drug eruption Drug hypersensitivity Drug use disorder Drug withdrawal syndrome Drug-induced liver injury Duodenal perforation Duodenal ulcer Duodenal ulcer haemorrhage Duodenal ulcer perforation Duodenitis Dural arteriovenous fistula Dysphagia Dyspnoea Dyspraxia Dysuria Ear and labyrinth disor Eczema Electrolyte imbalance Embolic stroke Embolism Emphysema Empyema Encephalitis Encephalitis viral Endocarditis Endocrine disorders Endometrial adenocarcinoma Endophthalmitis Enteritis Enterocolitis viral	Lymphadenitis Lymphadenopathy Lymphadenopathy mediastinal Lymphoma Macular cyst Macular hole Major depression Malaise Malignant fibrous histiocytoma of bone Malignant lymphoma unclassifiable high grade Malignant mast cell neoplasm Malignant melanoma Malignant neoplasm of ampulla of vater Malignant ovarian cyst Malignant palate neoplasm Mallory-weiss syndrome Malnutrition Mantle cell lymphoma Marasmus Marginal zone lymphoma Medical device site infection Melaena Memory impairment Meningioma Meningitis Meningitis meningococcal Meningitis pneumococcal Meningitis viral Meningoencephalitis herpetic Meniscal degeneration Meniscus injury Mental disorder Mental disorder due to a general medical condition Mental status changes Mesenteric artery embolism Mesenteric artery thrombosis Mesenteritis Mesothelioma Mesothelioma malignant Metabolic acidosis Metabolic encephalopathy	Renal cell carcinoma recurrent Renal colic Renal cyst Renal disorder Renal dysplasia Renal failure Renal hypertension Renal impairment Renal mass Renal neoplasm Renal oncocytoma Respiratory arrest Respiratory distress Respiratory failure Respiratory fume inhalation disorder Respiratory moniliasis Respiratory syncytial virus bronchitis Respiratory syncytial virus infection Respiratory tract infection Respiratory tract infection bacterial Respiratory, thoracic and mediastinal disor Restless legs syndrome Retinal artery occlusion Retinal degeneration Retinal detachment Retinal haemorrhage Retinal tear Retinal vein occlusion Retroperitoneal haemorrhage Rhabdomyolysis Rhabdomyosarcoma Rheumatoid arthritis Rib fracture Right ventricular failure Road traffic accident Rotator cuff syndrome

Vaccine	Assessed Adverse Events			
Zoster (recombinant, RZV [shingrix]; live ZV [Zostavax]) (continued)	Arrhythmia Arrhythmia supraventricular Arteriosclerosis Arteriosclerosis coronary artery Arteriosclerotic gangrene Arteriovenous fistula Arthralgia Arthritis Arthritis bacterial Arthritis infective Arthrofibrosis Arthropathy Ascites Aspergillus infection Aspiration Asthenia Asthma Asthmatic crisis Ataxia Atelectasis Atrial fibrillation Atrial flutter Atrial tachycardia Atrial thrombosis Atrioventricular block Atrioventricular block complete Atrioventricular block first degree Atrioventricular block second degree Atrophic vulvovaginitis Atypical pneumonia Autoimmune haemolytic anaemia Autoimmune pancreatitis Autoimmune thyroiditis B precursor type acute leukaemia Back injury Back pain Bacteraemia Bacterial infection Bacterial sepsis Balance disorder Barrett's oesophagus	Enterovesical fistula Epididymitis Epiglottitis Epilepsy Epistaxis Epstein-barr virus associated lymphoproliferative disorder Epstein-barrviraemia Erysipelas Erythema (prespecified) Escherichia infection Escherichia sepsis Escherichia urinary tract infection Ewing's sarcoma metastatic Extrasystoles Eye disorders Eye penetration Eyelid ptosis Face injury Facial bones fracture Facial paralysis Faecal incontinence Faecaloma Failure to thrive Fall Fallopian tube cancer Fatigue (prespecified) Fatty liver alcoholic Febrile infection Febrile neutropenia Femoral artery aneurysm Femoral artery occlusion Femoral neck fracture Femur fracture Fibula fracture Follicular thyroid cancer Foot deformity Foot fracture Forearm fracture Foreign body Fractured sacrum Functional gastrointestinal disorder Fungal pharyngitis Furuncle Gallbladder cancer Gallbladder perforation Gangrene Gastric cancer Gastric haemorrhage Gastric mucosal lesion Gastric perforation Gastric polyps Gastric ulcer Gastric ulcer haemorrhage	Metastases to adrenals Metastases to bone Metastases to central nervous system Metastases to gastrointestinal tract Metastases to liver Metastases to lung Metastases to lymph nodes Metastases to meninges Metastases to peritoneum Metastases to stomach Metastasis Metastatic carcinoma of the bladder Metastatic gastric cancer Metastatic malignant melanoma Metastatic neoplasm Metastatic renal cell carcinoma Metastatic squamous cell carcinoma Microcytic anaemia Microscopic polyangiitis Miller fisher syndrome Mitral valve incompetence Mitral valve prolapse Mitral valve stenosis Mixed connective tissue disease Mixed dementia Motion sickness Mouth ulceration Mucosal inflammation Multi-organ failure Multiple fractures Multiple injuries Multiple organ dysfunction syndrome Muscle rupture Muscular weakness Musculoskeletal pain Myalgia Myalgia (prespecified) Myasthenia gravis Mycoplasma infection Myelitis Myelodysplastic syndrome Myeloid leukaemia Myocardial infarction Myocardial ischaemia Myoclonus Myositis	Salivary gland calculus Salivary gland cancer Sarcoma Schizoaffective disorder bipolar type Schizophrenia Sciatica Seizure Senile dementia Sepsis Septic shock Serratia sepsis Shock haemorrhagic Sinus arrest Sinus node dysfunction Sinus tachycardia Sinusitis Sinusitis bacterial Sjogren's syndrome Skin cancer Skin infection Skin necrosis Skin ulcer Skin wound Skull fracture Small cell lung cancer Small cell lung cancer metastatic Small intestinal obstruction Small intestine adenocarcinoma Soft tissue infection Somatoform disorder Somnolence Spinal column stenosis Spinal compression fracture Spinal cord abscess Spinal cord compression Spinal cord injury Spinal cord injury cervical Spinal fracture Spinal osteoarthritis Spinal pain

Vaccine	Assessed Adverse Events			
Zoster (recombinant, RZV [shingrix]; live ZV [Zostavax]) (continued)	Basal cell carcinoma Basal ganglia haemorrhage Basedow's disease Basilar artery thrombosis B-cell lymphoma Benign breast neoplasm Benign neoplasm of thyroid gland Benign ovarian tumour Benign prostatic hyperplasia Bile duct cancer Bile duct obstruction Bile duct stenosis Bile duct stone Biliary colic Biliary dilatation Biliary tract infection Bladder cancer Bladder cancer recurrent Bladder neck obstruction Bladder neoplasm Bladder papilloma Bladder perforation Bladder prolapse Bladder transitional cell carcinoma Bladder transitional cell carcinoma recurrent Blood creatine phosphokinase increased Blood glucose fluctuation Blood pressure inadequately controlled Blood pressure increased Bone cancer Bone fissure Bone pain Bowen's disease Bradyarrhythmia Bradycardia Brain injury Brain neoplasm benign Brain stem infarction	Gastric ulcer perforation Gastritis Gastritis alcoholic Gastritis erosive Gastritis haemorrhagic Gastroenteritis Gastroenteritis clostridial Gastroenteritis norovirus Gastroenteritis salmonella Gastroenteritis viral Gastrointestinal angiodysplasia Gastrointestinal carcinoma Gastrointestinal disorders Gastrointestinal haemorrhage Gastrointestinal polyp haemorrhage Gastrointestinal stromal tumour Gastrointestinal tract adenoma Gastrointestinal viral infection Gastrooesophageal reflux disease General disorders General physical health deterioration Generalised oedema Generalised tonic-clonic seizure Gingival disorder Glaucoma Glioblastoma Glioblastoma multiforme Glomerulonephritis Goitre Gout Gouty arthritis Graft infection Graft versus host disease Graft versus host disease in gastrointestinal tract Graft versus host disease in liver Graft versus host disease in skin Gravitational oedema Guillain-barre syndrome Gun shot wound H1n1 influenza Haematochezia Haematoma Haematoma infection Haematotympanum Haematuria Haemoglobin decreased	Nasal septum deviation Nasopharyngitis Nausea Neck pain Necrosis ischaemic Necrotising fasciitis Necrotising fasciitis streptococcal Neoplasm malignant Neoplasm prostate Neovascular age-related macular degeneration Nephroangiosclerosis Nephrogenic anaemia Nephrolithiasis Nephropathy toxic Nerve compression Nervous system disor Neuralgia Neuroborreliosis Neurogenic bladder Neuropathy peripheral Neutropenia Neutropenic sepsis Neutrophil count decreased Non-cardiac chest pain Non-hodgkin's lymphoma Non-small cell lung cancer Non-small cell lung cancer stage iv Normochromic normocytic anaemia Ocular hypertension Ocular vascular disorder Odontogenic cyst Oedema peripheral Oesophageal achalasia Oesophageal adenocarcinoma Oesophageal adenocarcinoma metastatic Oesophageal cancer metastatic Oesophageal candidiasis Oesophageal carcinoma Oesophageal haemorrhage Oesophageal spasm Oesophageal squamous cell carcinoma Oesophageal ulcer	Splenic artery aneurysm Splenic haemorrhage Splenic infarction Splenic rupture Spondylitic myelopathy Spondyloarthropathy Spondylolisthesis Squamous cell carcinoma Squamous cell carcinoma of lung Squamous cell carcinoma of skin Squamous cell carcinoma of the oral cavity Staphylococcal abscess Staphylococcal infection Staphylococcal osteomyelitis Staphylococcal scalded skin syndrome Staphylococcal sepsis Stasis dermatitis Status epilepticus Sternal fracture Still's disease adult onset Stomatitis Strangulated hernia Streptococcal infection Streptococcal sepsis Stress cardiomyopathy Subarachnoid haemorrhage Subdural haematoma Subdural haemorrhage Subileus Sudden cardiac death Sudden death Sudden hearing loss Suicidal ideation Supraventricular tachycardia

Vaccine	Assessed Adverse Events			
Zoster (recombinant, RZV [shingrix]; live ZV [Zostavax]) (continued)	Brain stem syndrome Breast cancer Breast cancer metastatic Breast dysplasia Breathing-related sleep disorder Bronchial carcinoma Bronchiectasis Bronchiolitis Bronchitis Bronchitis bacterial Bronchitis chronic Bronchopneumonia Bronchopulmonary aspergillosis Bronchospasm Burkitt's lymphoma Bursitis Cachexia Calculus ureteric Campylobacter gastroenteritis Candida infection Candida sepsis Carbon monoxide poisoning Carcinoid tumour pulmonary Cardiac amyloidosis Cardiac arrest Cardiac death Cardiac disorders Cardiac failure Cardiac failure acute Cardiac failure chronic Cardiac failure congestive Cardiac tamponade Cardiac valve disease Cardiogenic shock Cardiomegaly Cardiomyopathy Cardiomyopathy alcoholic Cardiopulmonary failure Cardio-respiratory arrest Cardiovascular deconditioning	Haemolytic anaemia Haemoptysis Haemorrhage Haemorrhage intracranial Haemorrhagic anaemia Haemorrhagic stroke Haemorrhoidal haemorrhage Haemorrhoids Haemothorax Hairy cell leukaemia Hallucination Hand fracture Head injury Headache (prespecified) Heart rate decreased Heart valve incompetence Helicobacter infection Hemiparesis Hemiplegia Heparin-induced thrombocytopenia Hepatic cancer Hepatic cancer metastatic Hepatic cirrhosis Hepatic failure Hepatic function abnormal Hepatic neoplasm Hepatitis Hepatitis acute Hepatitis alcoholic Hepatitis b Hepatitis b reactivation Hepatitis cholestatic Hepatitis toxic Hepatobiliary disorders Hepatocellular carcinoma Hernia Hernia congenital Herpes simplex Herpes zoster Herpes zoster cutaneous disseminated Herpes zoster disseminated Herpes zoster meningitis Herpes zoster meningoencephalitis Herpes zoster oticus Hiatus hernia Hiccups Hip fracture Hodgkin's disease Hospitalisation Humerus fracture Hydrocele Hydrocephalus	Oesophageal ulcer haemorrhage Oesophageal varices haemorrhage Oesophagitis Ophthalmic herpes zoster Optic ischaemic neuropathy Optic neuritis Oral candidiasis Orchitis Organ failure Organising pneumonia Oropharyngeal candidiasis Orthostatic hypotension Osteoarthritis Osteochondritis Osteomyelitis Osteoporosis Osteoporotic fracture Otitis media Otitis media chronic Ovarian abscess Ovarian cancer Ovarian cancer recurrent Ovarian cyst Ovarian epithelial cancer Ovarian germ cell teratoma benign Overdose Pain (prespecified) Pain in extremity Palpitations Pancreatic abscess Pancreatic carcinoma Pancreatic carcinoma metastatic Pancreatic cyst Pancreatic disorder Pancreatic fistula Pancreatic mass Pancreatic neoplasm Pancreatic neuroendocrine tumour Pancreatitis Pancreatitis acute Pancreatitis necrotising Pancytopenia Panic attack Panic disorder Papillary thyroid cancer Paraganglion neoplasm Parainfluenzae virus infection Paralysis Paraplegia	Sweat gland tumour Swelling (prespecified) Syncope Synovial cyst Synovial rupture Synovitis Systemic inflammatory response syndrome Systemic lupus erythematosus Systemic scleroderma Tachyarrhythmia Tachycardia T-cell lymphoma Temporal arteritis Tendon rupture Tenosynovitis Testicular cancer metastatic Testis cancer Thalamic infarction Thalamus haemorrhage Thermal burn Thoracic vertebral fracture Throat cancer Thromboangiitis obliterans Thrombocytopenia Thrombophlebitis Thrombosis Thrombosis in device Thrombosis mesenteric vessel Thrombotic cerebral infarction Thrombotic microangiopathy Thyroid cancer Thyroiditis subacute Tibia fracture Tongue neoplasm malignant stage unspecified Tonsillar hypertrophy Tonsillitis Tooth abscess Toxic skin eruption Toxicity to various agents

Vaccine	Assessed Adverse Events			
Zoster (recombinant, RZV [shingrix]; live ZV [Zostavax]) (continued)	Cardiovascular insufficiency Carotid artery occlusion Carotid artery stenosis Carotid sinus syndrome Carpal tunnel syndrome Cataract Catheter site infection Cavernous sinus thrombosis Cellulitis Central nervous system lesion Central nervous system lymphoma Central nervous system neoplasm Cerebellar haemorrhage Cerebellar ischaemia Cerebral artery embolism Cerebral artery thrombosis Cerebral atrophy Cerebral haemorrhage Cerebral infarction Cerebral ischaemia Cerebral thrombosis Cerebrospinal fistula Cerebrospinal fluid leakage Cerebrovascular accident Cerebrovascular disorder Cervical myelopathy Cervical spinal stenosis Cervical vertebral fracture Chest discomfort Chest injury Chest pain Chills Cholangiocarcinoma Cholangitis Cholangitis acute	Hydronephrosis Hyperbilirubinaemia Hypercalcaemia Hypercholesterolaemia Hypergammaglobulinaemia benign monoclonal Hyperglycaemia Hyperkalaemia Hyperlipidaemia Hyperparathyroidism Hyperparathyroidism primary Hypersplenism Hypertension Hypertensive crisis Hypertensive emergency Hypertensive heart disease Hyperthyroidism Hypertonia Hypertrophic cardiomyopathy Hyperventilation Hypoacusis Hypoaesthesia Hypocalcaemia Hypochromic anaemia Hypoglycaemia Hypokalaemia Hyponatraemia Hypophagia Hypopituitarism Hypotension Hypothyroidism Hypovolaemia Hypoxia Hypoxic-ischaemic encephalopathy Ileus Ileus paralytic Ill-defined disorder Immune thrombocytopenic purpura Immunoglobulins decreased Impaired healing Impetigo Incarcerated hernia Incarcerated inguinal hernia Incarcerated umbilical hernia Incision site infection Incisional hernia Infected dermal cyst Infection Infectious colitis	Parapsoriasis Parathyroid tumour benign Parkinsonism Parkinson's disease Partial seizures Patella fracture Pathological fracture Pelvic fracture Peptic ulcer Peptic ulcer haemorrhage Peptic ulcer perforation Pericardial effusion Pericarditis Periodontal disease Peripheral arterial occlusive disease Peripheral artery aneurysm Peripheral artery stenosis Peripheral artery thrombosis Peripheral ischaemia Peripheral swelling Peripheral t-cell lymphoma unspecified Peripheral vascular disorder Peritoneal cyst Peritoneal haemorrhage Peritonitis Peritonitis bacterial Pernicious anaemia Pharyngeal abscess Pharyngitis Pharyngo-oesophageal diverticulum Pituitary tumour benign Plasma cell leukaemia Plasma cell myeloma Plasmacytoma Pleural effusion Pleurisy Pleuritic pain Pneumococcal sepsis Pneumocystis jirovecii pneumonia Pneumonia Pneumonia aspiration Pneumonia bacterial Pneumonia fungal Pneumonia haemophilus Pneumonia influenzal Pneumonia klebsiella Pneumonia legionella Pneumonia necrotising	Transaminases increased Transfusion reaction Transient global amnesia Transient ischaemic attack Transitional cell carcinoma Transitional cell carcinoma metastatic Traumatic fracture Traumatic intracranial haemorrhage Tricuspid valve incompetence Trigeminal neuralgia Trigger finger Tuberculosis Tubulointerstitial nephritis Tumour lysis syndrome Tumour pain Tympanic membrane perforation Type 2 diabetes mellitus Ulna fracture Umbilical hernia Upper gastrointestinal haemorrhage Upper limb fracture Upper respiratory tract infection Uraemic acidosis Urethral haemorrhage Urethral meatus stenosis Urethral neoplasm Urethral stenosis Urinary incontinence Urinary retention Urinary tract disorder Urinary tract infection Urinary tract infection bacterial Urosepsis Urticaria Uterine polyp

Vaccine	Assessed Adverse Events			
Zoster (recombinant, RZV [shingrix]; live ZV [Zostavax]) (continued)	Cholecystitis Cholecystitis acute Cholecystitis chronic Cholecystitis infective Cholelithiasis Cholestasis Cholesteatoma Chondrocalcinosis Chondropathy Choroidal effusion Chronic gastritis Chronic graft versus host disease Chronic hepatic failure Chronic kidney disease Chronic lymphocytic leukaemia Chronic myeloid leukaemia Chronic obstructive pulmonary disease Chronotropic incompetence Circulatory collapse Cirrhosis alcoholic Clavicle fracture Clostridium bacteraemia Clostridium difficile colitis Clostridium difficile infection Coagulopathy Cognitive disorder	Infective exacerbation of chronic obstructive airways disease Inferior vena caval occlusion Inflammation Influenza Influenza like illness Infusion site extravasation Inguinal hernia Inguinal hernia strangulated Injection site erythema Injection site pain Injection site swelling Injury Intermittent claudication Internal haemorrhage Interstitial lung disease Intervertebral disc disorder Intervertebral disc protrusion Intestinal adenocarcinoma Intestinal congestion Intestinal gangrene Intestinal haemorrhage Intestinal infarction Intestinal ischaemia Intestinal obstruction Intestinal perforation Intestinal polyp Intracardiac thrombus Intracranial aneurysm Intraventricular haemorrhage	Pneumonia parainfluenzae viral Pneumonia pneumococcal Pneumonia pseudomonal Pneumonia staphylococcal Pneumonia streptococcal Pneumonia viral Pneumonitis Pneumonitis chemical Pneumoperitoneum Pneumothorax Pneumothorax traumatic Polymyalgia rheumatica Polymyositis Polyneuropathy Polyp Portal hypertension Portal hypertensive gastropathy Post herpetic neuralgia Post procedural complication Post procedural haemorrhage Post procedural infection Post procedural pulmonary embolism Postoperative abscess Postoperative wound complication Postoperative wound infection Precursor t-lymphoblastic lymphoma/leukaemia Prerenal failure Presyncope Procedural intestinal perforation Procedural pain	Uterine prolapse Vaginal haemorrhage Vaginal prolapse Vaginal ulceration Varicose vein Vascular dementia Vascular disor Vascular graft occlusion Vascular pseudoaneurysm Vasculitis Venous thrombosis Venous thrombosis limb Ventricular arrhythmia Ventricular dysfunction Ventricular extrasystoles Ventricular fibrillation Ventricular tachycardia Vertebrobasilar insufficiency Vertigo Vertigo positional Vestibular disorder Vestibular neuronitis Viiith nerve lesion Viith nerve paralysis Viral infection Vith nerve paralysis Vitreous detachment Vitreous haemorrhage Volvulus Vomiting Vulval cancer Vulvitis Weight increased Wound Wound dehiscence Wound evisceration Wound haemorrhage Wound infection Wrist fracture

Note: N/A—not applicable

The next two tables show the adverse events assessed in KQ2 studies. The first table shows events that were assessed across studies that included only children.

Table C.2. Assessed adverse events for vaccines in children

Vaccine	Assessed Adverse Events			
Diphtheria, tetanus, & acellular pertussis (DTaP)	Asthma Cough Death Dehydration Diarrhoea Erythema (prespecified) Foreign Body Increased respiratory support	Injection Site Erythema Injection Site Pain Injection Site Swelling Intubation Intussusception Irritability Lymphadenitis	Nasopharyngitis Otitis Media Pain/Tenderness (prespecified) Pneumonia Pyrexia (prespecified) Rhinitis Rhinorrhoea	Seizure Sepsis evaluation Subcutaneous Abscess Swelling (prespecified) Teething Upper Respiratory Tract Infection Vomiting
Tetanus, diphtheria, & acellular pertussis (Tdap; Adacel, Boostrix)	N/A			
Hepatitis A (HepA; Havrix, Vaqta)	Anorexia nervosa Anxiety disorder Attention deficit hyperactivity disorder	Bipolar disorder Broken bone	Major depression Obsessive–compulsive disorder (OCD)	Open wound Tic disorder
Hepatitis B (HepB; Engerix-B, Recombivax HB)	Anorexia nervosa Anxiety disorder Attention deficit hyperactivity disorder Bipolar disorder Broken bone	Death Increased respiratory support Intubation	Major depression Obsessive–compulsive disorder (OCD) Open wound	Seizure Sepsis evaluation Tic disorder
Haemophilus influenzae type b (Hib; PedvaxHIB, ActHIB, Hiberix)	Death Increased respiratory support Intubation Intussusception	Seizure Sepsis evaluation		
Human papillomavirus (HPV9; Gardasil 9)	Anaemia Arthralgia Complex partial seizures Fatigue Fever Gastro-intestinal	Headache Henoch-Schonlein purpura Injection-site erythema Injection-site pain Injection-site swelling Myalgia	Nasopharyngitis Nausea Oropharyngeal pain Pain Pulmonary vasculitis Pyrexia	Rash Redness Swelling Upper abdominal pain Urticaria
Inactivated polio vaccine (IPV; IPOL)	Death Increased respiratory support Intubation Intussusception	Seizure Sepsis evaluation		

Vaccine	Assessed Adverse Events			
Inactivated influenza (IIV; Afluria Quadrivalent, Fluarix Quadrivalent, Flulaval Quadrivalent, Fluzone Quadrivalent, Flucelvax Quadrivalent)	Abscess neck Abscess Of Eyelid Accidental exposure Accidental overdose Acute disseminated encephalomyelitis (ADEM) Adenoidal hypertrophy Affective disorder Amoebic dysentery Anaphylactic Reaction Anaphylaxis Angioedema Anxiety Appendicitis Appetite lost Arthralgia Asthma Astrocytoma, low grade Autism Bacterial pyelonephritis Bell's palsy Biliary dyskinesia Bipolar Disorder Blastocystis infection Bradycardia Bronchial hyperreactivity Bronchiolitis Bronchopneumonia Cellulitis Chills (prespecified) Colitis ulcerative Conjunctivitis Convulsion Cough Craniocerebral Injury Croup infectious Crying abnormal	Decreased Appetite (prespecified) Dehydration Dengue fever Depression Diarrhea (prespecified) Diarrhoea Drowning Drowsiness (prespecified) Ecchymosis (prespecified) Encephalitis Facial bones fracture Failure to thrive Fatigue (prespecified) Febrile convulsion Febrile seizures Femur fracture Fever (prespecified) Forearm Fracture Foreign body Gastroenteritis Gastroenteritis rotavirus Gastroenteritis viral Gastrointestinal symptoms (prespecified) Grand mal convulsion Guillain–Barré syndrome (GBS) Head injury Headache (prespecified) Henoch-Schonlein Purpura Hippocampal Sclerosis Humerus Fracture Hypersensitivity Hypertension Hypovolaemia	Infections and infestations Influenza Injection Site Erythema (prespecified) Injection Site Hemorrhage Injection Site Induration (prespecified) Injection Site Pain (prespecified) Injection site pain, redness, swelling (prespecified) Injection site Swelling Injection site tenderness Intentional Self-Injury Intestinal obstruction Irritability (prespecified) Irritability/fussiness (prespecified) Joint dislocation Joint pain at other location (prespecified) Kawasaki's disease Lobar pneumonia Loss of appetite (prespecified) Lymphadenitis Major Depression Malaise Malignant melanoma Muscle aches (prespecified) Myalgia Mycoplasma infection Nasopharyngitis Nausea (prespecified) Oppositional Defiant Disorder Otitis media Otitis media acute Pain (prespecified) Partial Seizures Periorbital Cellulitis Peritonitis	Peritonsillar abscess Pharyngitis streptococcal Pneumonia Pneumonia aspiration Pneumonia viral Pyrexia Redness (prespecified) Respiratory arrest Respiratory syncytial virus bronchiolitis Respiratory syncytial virus infection Retina detachment Rhinorrhoea Rotavirus infection Seizure anoxic Septic shock Shivering (prespecified) Sleep Apnoea Syndrome Staphylococcal abscess Staphylococcal infection Status asthmaticus Suicidal Ideation Suicide Attempt Swelling (prespecified) Temperature/Fever (prespecified) Tonsillitis Transverse myelitis Traumatic brain injury Upper Respiratory Tract Infection Urticaria Uticaria Viral infection Viral upper respiratory tract infection Vitello-intestinal duct remnant Vomiting (prespecified)

Vaccine	Assessed Adverse Events			
Live attenuated influenza (LAIV; FluMist Quadrivalent)	Acute respiratory failure Appendicitis Asthma Bell's palsy Blepharitis Bronchiolitis Convulsion Cough Croup	Decreased Appetite Diaper dermatitis Encephalitis Fever (prespecified) Gastroenteritis Generalized Muscle Aches Guillain-Barre syndrome Headache Hydronephrosis Hypersensitivity	Laceration Lethargy Narcolepsy Nasopharyngitis Neuritis Osteochondrosis Peritonsillar abscess Pharyngitis/asthma Pneumonia	Renal and urinary disorders Runny/Stuffy Nose Seizures Sore Throat Thumb issue Upper respiratory infection/allergy Vasculitis Viral illness Vomiting Wheezing
Measles, mumps, rubella (MMR; M-M-R II)	Autism Intussusception Seizure			
Meningococcal, Quadrivalent [MenACWY-D (Menactra), MenACWY-CRM (Menveo), MenACWY-TT (MenQuadfi)]	Abdominal adhesions Abdominal pain Abnormal Behaviour Abscess limb Abscess neck Abscess oral Acarodermatitis Accidental drug intake by child Accidental exposure Accidental overdose Accidental Poisoning Acne Acute bronchitis Acute Disseminated Encephalomyelitis Acute myeloid leukaemia Acute sinusitis Acute Tonsilitis Adenoidal Hypertrophy Adenovirus Infection Affective disorder Aggression Allergic reactions Anaemia Angiopathy Apnoea Appendicitis Arthralgia Arthritis bacterial Ascariasis Aspergillosis	Death Dehydration Dengue fever Dermal Cys Dermatitis Atopic Dermatitis Diaper Diabetes mellitus Diabetic ketoacidosis Diarrhea Diarrhoea haemorrhagic Diarrhoea Infectious Digestive congenital anomalies Drug Abuse Drug hypersensitivity Dysentery Dyspepsia Eating Disorder Eating disorders Eczema Electrical Burn Electrocardiogram Qt Prolonged Enteritis Enteritis infectious Enterocolitis Enterovirus Infection Epilepsy Epistaxis Erythema Erythema Multiforme Escherichia Urinary Tract Infection Exanthema Subitam Eye disorders Faecaloma Failure To Thrive Fall Fallot's tetralogy Fatigue Febrile convulsion Febrile illness Febrile infection	Infected Cyst Infectious mononucleosis Influenza Ingrown nail Inguinal hernia Inguinal Hernia Repair Inguinal Hernia, Obstructive Injection Site Erythema Injection Site Induration Injection Site Pain Injection Site Swelling Injury Intestinal obstruction Intestinal operation Intussusception Iron Deficiency Anaemia Irritability Jaundice Kawasaki's Disease Klebsiella Bacteraemia Laryngospasm Leukocytosis Limb traumatic amputation Lobar Pneumonia Local tenderness Lower Respiratory Tract Infection Lung infection Lymph Node Abscess Lymphadenitis Lymphadenopathy Major Depression Malaise Malignant neoplasm Malignant neoplasm Meningitis Enteroviral Meningitis Viral Mental Status Changes	Pulmonary edema and pneumonitis Pulmonary hypertension Pulmonary Oedema Pulmonary valve stenosis Pyelonephritis Pyelonephritis Acute Pyloric stenosis Pyogenic arthritis Pyrexia Rash Renal Failure Acute Renal Mass Respiratory disorder Respiratory Distress Respiratory Failure Respiratory infection, upper Respiratory Synctial Virus Infection Respiratory Syncytial Virus Bronchiolitis Respiratory tract infection Respiratory tract infection viral Retinal Haemorrhage Rib fracture Road traffic accident Rotavirus Infection Scrotal mass Seizure-like activity and fever Sepsis Septic Shock

Vaccine	Assessed Adverse Events			
Meningococcal, Quadrivalent [MenACWY-D (Menactra), MenACWY-CRM (Menveo), MenACWY-TT (MenQuadfi)] (continued)	Asthma Asthmatic Crisis Atelectasis Atopic dermatitis Atrial septal defect Bacteraemia Bacterial diarrhoea Bacterial Tracheitis Balanitis Blepharitis Botulism Brain Death Brain neoplasm Brain stem dysfunction, Breath Holding Bronchial hyperreactivity Bronchiolitis Bronchitis Bronchitis viral Bronchomalacia Bronchopneumonia Bronchospasm Burns second degree Cardiac Arrest Cellulitis Cellulitis and abscess Cellulitis Staphylococcal Cellulitis Streptococcal Cellulitis/abscess Cerebral palsy Change in eating habit Chest Wall Abscess Chills Choking Complex partial seizures Congenital anomaly of ureter Congenital atresia Congenital cardiac condition, Conjunctivitis Constipation Contusion Convulsion	Feeding Disorder Feeding problem Fever Flatulence Food allergy Foreign body Foreign body aspiration Furuncle Gastritis Gastroenteritis Gastroenteritis Rotavirus Gastroenteritis Salmonella Gastroenteritis viral Gastrooesophageal reflux disease Genital Abscess Grand mal convulsion Groin Abscess Haematochezia Haematotympanum Haematuria Haemophilus Bacteraemia Hand-Foot-And-Mouth Disease Head injury Head injury due to a fall, Headache Hereditary spherocytosis Hernia Hernia Repair Herpangina Humerus Fracture Hydrocephalus Hydronephrosis Hypogammaglobulinaemia Hypoglycaemia Hyponatraemia Hypospadias Hypothyroidism Hypoxia Ileus Impetigo Incision Site Cellulitis Induration	Mesenteric Lymphadenopathy Metabolic Acidosis Metapneumovirus Infection Mucosal Inflammation Myalgia Nasal congestion Nasopharyngitits Nausea Nausea with vomiting Nephrotic syndrome Noninfectious gastroenteritis Nosocomial pneumonia Oedema Optic nerve hypoplasia Osteomyelitis Otalgia Other non-traumatic joint disorders Otitis externa Otitis Media Otitis Media Acute Pain in soft tissues of limb Painful respiration Palpitations Periorbital Cellulitis Peritonitis Peritonsillar Abscess Persistent crying Pertussis Pharyngitis Pharyngotonsillitis Pneumococcal bacteraemia Pneumonia Pneumonia Adenoviral Pneumonia Aspiration Pneumonia Bacterial Pneumonia Influenzal Pneumonia Primary Atypical Pneumonia Respiratory Syncytial Viral Pneumonia Viral Pneumonitis Post Procedural Complication Presyncope Psychiatric Psychiatric disorders Psychomotor skills impaired	Sickle Cell Anemia Sinusitis Skull Fracture Sleep apnoea syndrome Sleepiness Small bowel obstruction Small intestinal obstruction Somnolence Staphylococcal Abscess Staphylococcal Infection Staphylococcal Scalded Skin Syndrome Staphylococcal skin infection Status Asthmaticus Stomatitis Subarachnoid haemorrhage Subcutaneous abscess Subdural Haemorrhage Subdural Hematoma Suicidal Ideation Supraventricular Tachycardia Syncope Synostosis Tachypnoea Teething Thermal Burn Thrombocytopenia Tibia Fracture Tonic Convulsion Tonsilitis Trauma Traumatic brain injury Tremor Type 1 Diabetes Mellitus Upper Limb Fracture Upper Respiratory Tract Infection Urachal Abscess Urinary Tract Infection Urinary Tract Infection Enterococcal Urosepsis Urticaria

Vaccine	Assessed Adverse Events			
Meningococcal, Quadrivalent [MenACWY-D (Menactra), MenACWY-CRM (Menveo), MenACWY-TT (MenQuadfi)] (continued)	Cough Cow's milk intolerance Craniocerebral Injury Croup infectious Crying Cyanosis			Varicella Vasculitis Ventricular Tachycardia Vesicoureteric Reflux Viral Diarrhoea Viral Infection Viral pharyngitis Vomiting Vulval abscess Warts Wheezing Wound Infection
Meningococcal B (MenB; MenB-4C [Bexsero], MenB-FHbp (Trumenba)]	Abdominal abscess Abdominal injury Abdominal pain Abnormal behaviour Acarodermatitis Acne Acute tonsillitis Adenoidectomy Adenoma benign Alcohol poisoning Allergic conjunctivitis Allergy to animal Allergy to chemicals Alopecia Anaphylactic reaction Anaphylaxis Ankle fracture Appendicitis Appendicitis perforated Arthralgia (prespecified) Arthritis infective Arthropathy Arthropod bite Asthma Asthma exercise induced Asthmatic crisis Back injury Back pain Bengin ovarian tumour Blood iron decreased Bronchitis Burning sensation mucosal	Ear infection Ear pain Eating Disorders Eczema Eczema impetiginous Electrocardiogram QT prolonged Epilepsy Epistaxis Erythema Eye disorders Eye inflammation Eyelid cyst Factor V Leiden mutation Fainting (syncope) Fatigue Fever Fibroma Food poisoning Foot fracture Forearm fracture Foreign body Furuncle Gastritis viral Gastroenteritis Gastroenteritis rotavirus Gastroenteritis viral Gingivitis Glomerulonephritis minimal lesion Glossodynia H1N1 influenza Hand fracture Hangnail Head injury Headache (prespecified) Herpes simplex Hip fracture Histiocytic necrotising lymphadenitis Hordeolum Hydrocephalus Hypertension Hypothermia	Jaw fracture Joint dislocation Joint injury Joint sprain Juvenile idiopathic arthritis Laryngitis Ligament injury Ligament rupture Ligament sprain Limb injury Local reactions (redness, swelling, and pain) (prespecified) Lower respiratory tract infection Lymphadenitis Lymphadenopathy Lymphangitis Major depression Malaise (prespecified) Meningitis bacterlal Migraine Mononucleosis syndrome Mouth ulceration Mumps Muscle contracture Muscle Pain Myalgia (prespecified) Nasopharyngitis Nausea (prespecified) Neck pain Nervous system disorders Oropharyngeal pain Otitis media Ovarian cyst Ovarian cyst ruptured Pain Pain (bodyache) Pain at the injection site Pain in extremity Palpitations	Radius fracture Rash Redness Respiratory tract infection Respiratory tract infection viral Rheumatoid arthritis Rhinitis Rhinitis allergic Rhinorrhoea Road traffic accident Scar Scarlet fever Scoliosis Seasonal allergy Shigellain fection Sinusitis Skeletal injury Skin abrasion Skin laceration Soft tissue injury Stomatitis Subcutaneous abscess Suicide attempt Swelling Syncope Tendonitis Testicular torsion Thermal burn Tonsillectomy Tonsillitis Tonsillitis streptococcal Tooth extraction Tooth impacted Toothache Torticollis Toxicity to varlous agents Tremor Upper limb fracture

Vaccine	Assessed Adverse Events			
Meningococcal B (MenB; MenB-4C [Bexsero], MenB-FHbp (Trumenba)] (continued)	Cardiac disorders Cellulitis Cerebellar tumour Chemical burn of skin Chest injury Chest pain Chills Circumcision CNS germinoma Concussion Conjunctivitis Contusion Convulsion Costochondritis Cough Death Decreased appetite (prespecified) Dental caries Depression Dermatitis Dermatitis allergic Dermatitis atopic Dermatitis contact Diarrhea Dizziness Drug abuse Drug eruption Dysentery Dysmenorrhoea Dyspepsia Dyspnoea	Idiopathic thrombocytopenic purpura Immune system disorders Impetigo Induration Influenza Influenza like illness Ingrowing nail Inguinal hernia Injection site dermatitis Injection site erythema (prespecified) Injection site haematoma Injection site induration (prespecified) Injection site pain (prespecified) Injection site pallor Injection site paraesthesia Injection site pruritus Injection site swelling (prespecified) Injury Investigations Irritable bowel syndrome	Panic attack Parovarian cyst Penile discharge Perirectal abscess Peritonsillar abscess Pertussis Pharyngitis Photophobia Photosensitivity reaction Pilonidal cyst Pneumonia Pneumonia viral Post concussion syndrome Post procedural haematoma Premature labour Presyncope Procedural pain Psychiatric disorders Pulpitis dental Pyelonephritis Pyrexia Pyrexia/Fever (prespecified)	Upper respiratory tract infection Urinary tract infection Urticaria Use of antipyretic medications Vaccination site pallor Vertigo Vertigo positional Vessel puncture site haematoma Viral infection Viral upper respiratory tract infection Vocal cord thickening Vomiting Whiplash injury Wrist fracture
Pneumococcal polysaccharide vaccine (PPSV23; Pneumovax)	Abdominal pain Abscess Accidental poisoning Acetonaemic vomiting Acute sinusitis Acute tonsillitis Acutelymphocytic leukemia Adenoidal hypertrophy Adenoiditis Adenoviral conjunctivitis Adenovirus infection Anaemia Anal abscess Anal fissure Anal fungal infection	Diarrhoea Diet refusal Dry skin Dysentery Dyspnoea Dysuria Ear haemorrhage Ear infection Ear injury Echo virus infection Eczema Eczema asteatotic Eczema infantile Encephalopathy Endophthalmitis Enteritis infectious Epistaxis Erysipelas Erythema Erythema infectiosum Escherichia urinary tract infection	Infection Infectious mononucleosis Inflammation Influenza Influenza virus test positive Ingrowing nail Injection site dermatitis Injection site erythema Injection site induration Injection site redness Injection site swelling Injection site tenderness Intervertebral discitis Intussusception Investigations Iron deficiency anaemia Irritability (prespecified) irritability/fussiness	Pityriasis rosea Pneumococcal bacteraemia Pneumonia Pneumonia influenzal Pneumonia respiratory syncytial viral Pneumonia viral Pneumonitis Post procedural haemorrhage Posthitis Postoperative fever Postoperative wound infection Pruritus Psychiatric disorders Pulmonary artery stenosis

Vaccine	Assessed Adverse Events			
Pneumococcal polysaccharide vaccine (PPSV23; Pneumovax) Pneumococcal polysaccharide vaccine (PPSV23; Pneumovax) (continued)	Anaphylaxis Anemia Animal bite Antibiotic prophylaxis Apathy Aphthous stomatitis Apparent life threatening event Application site erythema Arthralgia Arthritis bacterial Arthropod bite Arthropod sting Asphyxiation Aspiration of food Asteatosis Asthma Bacteraemia Bacterial infection Balanoposthitis Blepharitis Body height below normal Breast swelling Breath holding Bronchial hyperreactivity Bronchiolitis Bronchitis Bronchitis viral Bronchopneumonia Brucellosis Bruise Bullous impetigo Burns second degree Candidiasis Cardiac disorders Cardiac failure congestive Cardiac failure congestive and heart disease congenital Cellulitis Cellulitis orbital Cephalhaematoma Cerebral infarction Cheilitis Chillblains	Exanthema subitum Excoriation Exposure to toxic agent External ear cellulitis Eye discharge Eye disorders Eye injury Eye movement disorder Eye pruritus Eye swelling Eyelid oedema Fall Febrile convulsion Febrile seizure Feeding disorder Femur fracture Fever (prespecified) Fever After Vaccination Fibrinous bronchitis Folliculitis Fontanelle bulging Food allergy Foreign body Fracture Frostbite Gait disturbance Gastroenteritis Gastroenteritis bacterial Gastroenteritis norovirus Gastroenteritis rotavirus Gastroenteritis viral Genital candidiasis Genital infection fungal Genital labial adhesions Gianotti-Crosti syndrome Gingivitis Grunting H1N1 influenza Haemangioma of skin Haematemesis Haematochezia Haematoma Haemoptysis Haemorrhage subcutaneous Haemorrhoidal haemorrhage Hand fracture Hand-foot-and-mouth disease Head injury Heat rash Henoch-Schonlein purpura Hepatomegaly Hepatosplenomegaly Herpangina Herpes simplex Hives (urticaria) (prespecified) Hordeolum Hyperkeratosis palmaris and plantaris Hypertension Hypotonia	Joint dislocation Kawasaki disease Keratitis Kidney enlargement Laboratory test Laceration Lactose intolerance Laryngitis Leukocytosis Leukocyturia Leukopenia Limb injury Lip swelling Localised infection Lower respiratory tract infection Lung infiltration Lymphadenitis Lymphadenopathy Medulloblastoma Melaena Meningitis Meningitis aseptic Meningitis viral Meningococcal infection Metabolic acidosis Milk allergy Molluscum contagiosum Monarthritis Mouth injury Muscular weakness Mycoplasma infection Myoclonic epilepsy Nasal obstruction Nasopharyngitis Near drowning Nervous system disorder Neuritis cranial Neutropenia Oedema peripheral Omphalitis Onychomadesis Oral candidiasis Oral disorder Oral fungal infection Oral herpes Oral infection Osteomyelitis Otitis externa Otitis media Otitis media acute Otorrhoea Overfeeding of infant Pain in extremity Papule Parainfluenzae virus infection	Pulmonary tuberculosis Pyrexia Radius fracture Rash Rash generalised Rash macular Rash maculo-papular Rash pustular Rectal haemorrhage Redness (prespecified) Respiratory distress Respiratory syncytial virus bronchiolitis Respiratory syncytial virus bronchitis Respiratory syncytial virus infection Respiratory tract infection Restlessness Rhinitis Rhinitis allergic Rhinorrhoea Rhrombocytopenia Road traffic accident Rotavirus infection Scar Scarlet fever Scratch Seborrhoeic dermatitis Septic shock and status epilepticus Sinusitis Skin candida Skin infection Skull fracture Skull fractured base Sleep apnoea syndrome Somnolence Status epilepticus Stomatitis Streptococcal bacteraemia Streptococcal infection Stridor Subcutaneous abscess Sudden death

Vaccine	Assessed Adverse Events			
Pneumococcal polysaccharide vaccine (PPSV23; Pneumovax)	Chills Choking Conjunctivitis Conjunctivitis allergic Conjunctivitis bacterial Conjunctivitis infective Conjunctivitis viral Constipation Contusion Convulsion Corneal perforation Corynebacterium infection Cough Croup infectious Cyanosis Dacryostenosis acquired Dacryostenosis congenital Deafness bilateral Death Decreased appetite (prespecified) Decreased sleep (prespecified) Dehydration Dermatitis Dermatitis atopic Dermatitis contact Dermatitis diaper Developmental delay	Hypoxia Impetigo Increased sleep (prespecified) Infantile asthma Infantile spasms Infected bites	Paronychia Parotitis Partial seizures Periorbital cellulitis Perirectal abscess Pertussis Petechiae Pharyngeal erythema Pharyngitis Pharyngotonsillitis	Swelling (prespecified) Swollen tongue Tenderness (prespecified) Testicular torsion Thermal burn Tonsillitis Tooth abscess Tooth fracture Tooth injury Tracheitis Trigger finger Tympanic membrane hyperaemia Upper respiratory tract infection Urinary tract infection Urine analysis abnormal Urticaria Urticaria and angioneurotic edema Use of antipyretic medication to treat symptoms (prespecified) Varicella Vascular disorders Ventricular septal defect Vesicoureteric reflux Viral infection Viral rash Vomiting Vulvovaginal candidiasis Weight gain poor Wheezing White blood cells urine positive Wound infection
Rotavirus (RV; Rotarix, RotaTeq)	Abdominal distention Abdominal mass Acidosis Acute gastroenteritis Acute lymphocytic leukaemia Acute tonsillitis Agranulocytosis All-cause ED visit	Deficiency anaemia Dehydration Dermatitis allergic Dermatitis atopic Dermatitis diaper Developmental delay Diabetes (prespecified) Diarrhoea (prespecified) Diarrhoea infectious Drowning Drowsiness Dyspepsia Eczema Eczema infantile	Haemorrhage intracranial Hand-foot-and-mouth disease Hematochezia Hepatic function abnormal Hernia Herpangina Herpes virus infection Histiocytosis haematophagic	Omphalitis Oral candidiasis Oral herpes Oral infection Otitis Media Overdose Pain Pallor Pharyngitis Pharyngitis bacterial Pneumonia Pneumonia klebsiella

Vaccine	Assessed Adverse Events			
Rotavirus (RV; Rotarix, RotaTeq) (continued)	All-cause hospitalization All-cause mortality Anaemia Apnea Appendicitis Asphyxia Asthma Bacterial diarrhoea Blood detected on rectal exam Blood in Stool Bloody stool Bradycardia Brain contusion Brain herniation Bronchiolitis Bronchitis Bronchitis viral Bronchopneumonia Burns second degree Burns third degree Candida infection Candidiasis Cardiomyopathy Cataract Central nervous system infection Central nervous system lesion Cerebral haematoma Congenital absence of bile ducts Conjunctivitis Constipation Convulsions (prespecified) Cough Cough/runny nose Croup infectious Crying Cytomegalovirus infection Death	Elevation in mode of ventilation Encephalitis Encephalitis/encephalopathy Enteritis Epilepsy (prespecified) Epyema Exanthema subitum Extrapyramidal disorder Eye contusion Eye disorders Febrile convulsion Febrile Convulsions Feeding intolerance Fever Food poisoning Functional gastrointestinal disorder Gastritis Gastroenteritis Gastroenteritis adenovirus Gastroenteritis bacterial Gastroenteritis rotavirus Gastroenteritis shigella Gastrointestinal (nausea, vomiting, diarrhea and/or abdominal pain Gastrointestinal disorder Gastrooesophageal reflux disease GI bleeding Gingivitis Granulocytopenia	Hospitalization due to acute lower respiratory tract infection Hydrocephalus Hydronephrosis Hypoglycaemia Hypokalaemia Hypomagnesaemia Hyponatraemia Idiopathic thrombocytopenic purpura Incarcerated inguinal hernia Increased proportion of stools defined as “loose” Infantile spasms Infantile spitting up Infection Infectious mononucleosis Influenza Inguinal hernia Inguinal hernia, obstructive Injection site reactions (redness, swelling, tenderness) Intestinal obstruction Intussusception (prespecified) Irritability Irritability/Fussiness Kawasaki disease Laryngitis Lethargy Liver function test abnormal Lobar pneumonia Loss of appetite Lymphadenitis Malnutrition Megaloblastic anaemia Meningitis Meningitis coxsackie viral Multi-organ failure Myocarditis Myoclonus (prespecified) Nasal congestion Nasopharyngitis Nonbilious emesis	Pneumonia staphylococcal Presence of feeding intolerance Psychomotor retardation Pyrexia Rash Rectal mass Redness Respiratory failure Respiratory syncytial virus bronchiolitis Respiratory syncytial virus infection Rhinitis Rhinorrhoea Rickets Rotavirus-attributable gastroenteritis Seizure Sepsis Shigella infection Sinusitis Skull fracture Subarachnoid haemorrhage Sudden death Swelling Thrombocytopenia Tonsillitis Tonsillitis bacterial Toxoplasmosis Tracheitis Tracheobronchitis Transient hypogammaglobulinaemia of infancy Type 1 diabetes mellitus (prespecified) Upper respiratory tract Upper respiratory tract infection Upper respiratory tract inflammation Ureteric stenosis Urinary tract infection Urinary tract stone Urticaria Varicella Vomiting (prespecified)

Vaccine	Assessed Adverse Events			
Varicella (VAR; Varivax)	Anorexia nervosa Anxiety disorder Attention deficit hyperactivity disorder Bipolar disorder	Broken bone Encephalitis Intussusception	Ischemic stroke Major depression Obsessive–compulsive disorder (OCD)	Open wound Seizure Tic disorder
DTap-HepB-IPV (Pediarix)	Death Increased respiratory support Intubation	Seizure Sepsis evaluation		
DTaP-IPV/Hib (Pentacel)	Alteration of consciousness (other than secondary to another diagnosis) Anaphylaxis Cardiac and circulatory congenital anomalies Certain conditions originating in the perinatal period Death Diseases of the genitourinary system Diseases of the respiratory system Diseases of the skin and subcutaneous tissue Encephalitis Encephalopathy	Fever of unknown origin Fractures Genitourinary symptoms and ill-defined conditions Guillain-Barré Syndrome Hypersensitivity reactions (urticaria, angioedema, or anaphylaxis; post-vaccination days 0–3 only) Hypovolemia	Increased respiratory support Infectious and parasitic diseases Injury and poisoning Intubation Invasive Hib disease Kawasaki disease Medically attended fever Meningitis/encephalitis/ myelitis Nausea and vomiting New-onset autoimmune disease (immune thrombocytopenic purpura [ITP], hemolytic anemia)	Other and unspecified lower respiratory disease Other and unspecified perinatal conditions Other lower respiratory disease Other perinatal conditions Pre-specified outpatient outcomes: Seizure Sepsis evaluation Serious nonanaphylactic allergic reaction Skin and subcutaneous tissue infections Skull and face fractures Symptoms; signs; and ill-defined conditions and factors influencing health status Type 1 diabetes
DTaP-IPV (Kinrix, Quadracel)	Anaphylaxis Guillain–Barré syndrome Meningitis/encephalitis	Seizures Serious allergic reactions other than	anaphylaxis Serious local reactions	Stevens–Johnson syndrome Stroke
DTaP-IPV-Hib-HepB	Abnormal crying Abnormal weight gain Abscess Accidental overdose Anal fistula Apnoeic attack Apparent life-threatening event Appetite loss	Death Decreased appetite (prespecified) Dehydration Device expulsion Diabetic ketoacidosis Diarrhea Drowsiness (prespecified) Duodenal ulcer Dyskinesia Dystonia Eczema herpeticum	Idiopathic thrombocytopenic purpura Infantile apnoeic attack Infection Influenza Injection site induration Injection site tenderness Injection-site bruising Injection-site erythema	Renal failure acute Respiratory arrest Respiratory distress Respiratory failure Respiratory syncytial virus bronchiolitis Respiratory syncytial virus infection Respiratory tract infection viral

Vaccine	Assessed Adverse Events			
DTaP-IPV-Hib-HepB (continued)	Asphyxia Aspiration Asthma Atelectasis Bacteraemia Bacterial sepsis Brain contusion Breast abscess Bronchial hyperreactivity Bronchiolitis Bronchopneumonia Cardiac arrest Cellulitis Chest wall abscess Clavicle fracture Colitis Convulsion Corona virus infection Cough Coxsackie viral infection Craniocerebral injury Crohn's disease Croup infectious Crying (prespecified) Cyanosis	Erythema Failure to thrive Febrile convulsion Febrile seizures Femur fracture Fever Fibrosarcoma Food intolerance Foreign body Gastritis viral Gastroenteritis Gastroenteritis salmonella Gastroenteritis viral Gastrooesophageal reflux disease Gatroenteritis viral Grade 3 crying abnormal Grade 3 irritability Grade 3 somnolence Groin abscess Haematemesis Hand-foot-and-mouth disease Human herpesvirus 6 infection Hydrocephalus Hydronephrosis Hypoglycaemia Hypotonia Hypoxia	Injection-site pain (prespecified) Injection-site redness (prespecified) Injection-site swelling (prespecified) Injury intussusception Irritability (prespecified) Kawasaki's disease Leukocytosis Lymphadenitis Meningitis Meningitis enteroviral Meningitis viral Metabolic acidosis Mortality Movement disorder Nasal congestion Nasopharyngitis Otitis media Periorbital cellulitis Pneumocephalus Pneumonia Pneumonia respiratory syncytial viral Pneumonitis Post concussion syndrome Post procedural infection Pyelonephritis Pyloric stenosis Pyrexia Pyrexia (prespecified)	Rhinorrhea Roseola Sepsis Sinusitis Skull fracture Skull fracture base Somnolence Staphylococcal infection Subarachnoid haemorrhage Subcutaneous abscess Subdural haemorrhage Sudden infant death syndrome Swelling Tibia fracture Tonic convulsion Type 1 diabetes mellitus Upper respiratory tract infection Urinary tract infection Urine output decreased Viral infection Viral upper respiratory tract infection Vomiting (prespecified) Vulval abscess Wheezing Wound infection staphylococcal
MMR-V (ProQuad)	Acute disseminated encephalomyelitis Anaphylaxis Arthritis/arthralgia Ataxia Bronchitis Bronchopneumonia Conjunctivitis bacterial Cough Death Diarrhoea Diphtheria	Electric shock Encephalitis/meningitis/encephalopathy Febrile convulsion Fever Gastroenteritis Gastroenteritis rotavirus Haemophilusinfluenzaetype b Hepatitis B Immune thrombocytopenia purpura Influenza	Injection site erythema Injection site pain Injection site swelling Intussusception Kawasaki disease Measles Mumps Nasopharyngitis Otitis media Poliomyelitis type 1 Poliomyelitis type 2 Poliomyelitis type 3 Pyrexia	Rash morbilliform Rhinitis Rubella Seizure Skin and subcutaneous tissue disorders Tetanus Upper respiratory tract infection Urinary tract infection Varicella Viral upper respiratory tract infection Vomiting

Note: N/A—not applicable

The collected adverse events in studies that included children as well as adults are shown in the next table. These studies also contributed to answering KQ2.

Table C.3. Assessed adverse events for vaccines in studies enrolling children and adults

Vaccine	Assessed Adverse Events			
Diphtheria, tetanus, & acellular pertussis (DTaP)	Acute disseminated encephalomyelitis	Optic neuritis	Sudden-onset sensorineural hearing loss	Transverse myelitis
Tetanus, diphtheria, & acellular pertussis (Tdap; Adacel, Boostrix)	Acute disseminated encephalomyelitis Depression Erythema (prespecified) Fatigue (prespecified)	Gastroenteritis Gastrointestinal disorder (prespecified) Headache (prespecified) Nasopharyngitis	New onset of chronic illness (prespecified) Optic neuritis Orthostatic intolerance Pain (prespecified)	Pyrexia (prespecified) Sudden-onset sensorineural hearing loss Swelling (prespecified) Transverse myelitis
Hepatitis A (HepA; Havrix, Vaqta)	Acute disseminated encephalomyelitis	Optic neuritis	Sudden-onset sensorineural hearing loss	Transverse myelitis
Hepatitis B (HepB; Engerix-B, Recombivax HB)	Acute disseminated encephalomyelitis	Optic neuritis	Sudden-onset sensorineural hearing loss	Transverse myelitis
Haemophilus influenzae type b (Hib; PedvaxHIB, ActHIB, Hiberix)	Acute disseminated encephalomyelitis	Optic neuritis	Sudden-onset sensorineural hearing loss	Transverse myelitis
Human papillomavirus (HPV9; Gardasil 9)	Abdominal pain Abdominal pain lower Abortion induced Abortion spontaneous Abortion spontaneous complete Abortion spontaneous incomplete Abscess jaw Accidental death Acute lymphocytic leukaemia Acute promyelocytic leukaemia Acute psychosis Acute tonsillitis Adenocarcinoma gastric Adenocarcinoma of the cervix Allergy to vaccine Anaemia Anal fistula	Congenital, familial and genetic disorders Conjunctivitis Craniocerebral injury Crohn's disease Cystitis haemorrhagic Cytomegalovirus infection Deep vein thrombosis Dengue fever Depression Diabetic coma Diarrhea Diverticulitis Meckel's Dizziness Dysmenorrhoea Dyspnoea Ear and labyrinth disorders Ectopic pregnancy Endometriosis Enteritis infectious Enterocolitis Ependymoma Epilepsy Facial paresis Fallopian tube cyst False labour Fatigue	Influenza Inguinal hernia Injection site erythema Injection site pain Injection site pruritus Injection site swelling Injury, poisoning and procedural complications Intracranial venous sinus thrombosis Irritable bowel syndrome Joint dislocation Labour complication Leukaemic infiltration brain Ligament injury Ligament rupture Limb injury Lower limb fracture Lumbar vertebral fracture Lymphadenopathy Major depression	Post abortion infection Post procedural haemorrhage Postoperative wound infection Postural orthostatic tachycardia syndrome Pre-eclampsia Pregnancy, puerperium and perinatal conditions Premature labour Premature rupture of membranes Presyncope Prolonged labour Psychiatric disorders Pubis fracture Pyelonephritis Pyelonephritis acute Pyrexia Renal and urinary disorders Renal colic Renal failure Renal failure acute Reproductive system and breast disorders Respiratory distress

Vaccine	Assessed Adverse Events			
Human papillomavirus (HPV9; Gardasil 9) (continued)	Anaphylactic reaction Ankle fracture Anorexia and bulimia syndrome Anorexia nervosa Aortic valve incompetence Appendicitis Asthma Asthmatic crisis Atrial fibrillation Axillary vein thrombosis Bartholinitis Benign intracranial hypertension Biliary colic Bipolar disorder Bladder injury Blighted ovum Blood and lymphatic system disorders Brain neoplasm Breast cancer Bronchitis Burns second degree Calculus ureteric Calculus urinary Cardiac disorders Cellulitis Cephalo-pelvic disproportion Cerebral haemorrhage Cervical dysplasia Cervical incompetence Cervix dystocia Cervix haemorrhage uterine Cholangitis Cholecystitis Cholecystitis infective Cholelithiasis Cholestasis of pregnancy Chronic tonsillitis Cleft lip and palate Coeliac disease Colitis Colitis ulcerative Completed suicide Concussion	Femur fracture Fibromyalgia Foetal death Foetal distress syndrome Foetal malposition Foetal malpresentation Foot fracture Foreign body in eye Fracture displacement Gastritis Gastroenteritis Gastroenteritis viral Gastrointestinal disorders Gastrointestinal infection General disorders Gestational diabetes Glioma Gun shot wound Haemorrhagic fever Haemorrhoids Hand fracture Head injury Headache Hepatobiliary disorders Humerus fracture Hydrocephalus Hyperglycaemia Hypersensitivity Hypersomnia Hypoaesthesia Hypovolaemic shock Hypoxic-ischaemic encephalopathy Immune system disorders Infections and infestations Infectious mononucleosis	Malignant melanoma Malignant palate neoplasm Metabolism and nutrition disorders Migraine Multiple injuries Multiple sclerosis Musculoskeletal and connective tissue disorders Myalgia Nasal cavity cancer Nasal polyps Nasopharyngitis Nausea Neck injury Neoplasms benign, malignant and unspecified (incl cysts and polyps) Nephrolithiasis Nervous system disorders Neuritis Non-cardiac chest pain Oligohydramnios Omental infarction Oropharyngeal pain Orthostatic intolerance Osteoarthritis Ovarian cyst Ovarian neoplasm Pancreatitis acute Paronychia Pelvic inflammatory disease Pelvic pain Pharyngitis Pharyngotonsillitis Pituitary tumour benign Pneumonia Pneumonia aspiration Pneumothorax Poisoning	Respiratory failure Respiratory papilloma Respiratory, thoracic and mediastinal disorders Road traffic accident Sarcoidosis Sciatica Sensory disturbance Septic shock Skin and subcutaneous tissue disorders Spinal compression fracture Spinal cord injury Spinal cord injury cervical Spondylitic myelopathy Sudden death Suicidal ideation Surgical and medical procedures Syncope Tension headache Thoracic vertebral fracture Thyroid cancer Tibia fracture Tongue injury Tonsillitis Tonsillitis streptococcal Trigeminal nerve disorder Ulna fracture Upper respiratory tract infection Urinary tract infection Urosepsis Urticaria Uterine contractions during pregnancy Vascular disorders Vertigo positional Viral pharyngitis Vocal cord polyp Wound infection

Vaccine	Assessed Adverse Events			
Inactivated polio vaccine (IPV; IPOL)	Acute disseminated encephalomyelitis	Optic neuritis	Sudden-onset sensorineural hearing loss	Transverse myelitis
Inactivated influenza (IIV; Afluria Quadrivalent, Fluarix Quadrivalent, Flulaval Quadrivalent, Fluzone Quadrivalent, Flucelvax Quadrivalent)	N/A			
Live attenuated influenza (LAIV; FluMist Quadrivalent)	Any hospitalization Bell's palsy Encephalitis Guillain-Barré syndrome	Hypersensitivity Lower respiratory tract infection Neuritis	Respiratory hospitalization (Respiratory hospitalizations included pneumonia, influenza, empyema, chronic obstructive pulmonary disease, chronic bronchitis, emphysema, asthma, bronchiectasis, or	other diseases of the respiratory system) Seizures/convulsions Vasculitis Wheezing
Measles, mumps, rubella (MMR; M-M-R II)	Acute disseminated encephalomyelitis Optic neuritis Sudden-onset sensorineural hearing loss Transverse myelitis			
Meningococcal, Quadrivalent [MenACWY-D (Menactra), MenACWY-CRM (Menveo), MenACWY-TT (MenQuadfi)]	Abdominal abscess Abortion spontaneous Abortion spontaneous incomplete Abscess/Cellulitis Acute disseminated encephalomyelitis Acute glomerulonephritis Alcoholic seizure Allergic urticaria Allergy to arthropod sting Anaphylaxis Appendicitis Appendicitis perforated Arrhythmia	Dehydration Delirium Depression Diabetes Diabetes mellitus inadequate control Diarrhea Disruptive mood dysregulation disorder Elective Encephalitis Encephalopathy Epilepsy Fatty Febrile Femoral Foot fracture ForeignGastroenteritis Gastroenteritis norovirus	Injury, poisoning and procedural complications Intestinal perforation Iridocyclitis (uveitis) ITP Juvenile diabetes mellitus Kyphosis Labyrinthitis Lymphocytic Major depression Malaise Meningococcal disease Metabolism and nutrition disorders Migraine Mortality Multiple sclerosis	Pneumocystosis Pneumonia Pneumonia pseudomonal Pneumothorax Poisoning/Ingestion Pregnancy Presyncope Psychiatric disorders Pulmonary embolism Pyelonephritis Renal and urinary disorders Reproductive system and breast disorders Respiratory, thoracic and mediastinal disorders Rheumatoid arthritis Scoliosis

Vaccine	Assessed Adverse Events			
Meningococcal, Quadrivalent [MenACWY-D (Menactra), MenACWY-CRM (Menveo), MenACWY-TT (MenQuadfi)] (continued)	Aseptic Aseptic meningitis Asphyxiation Asthma Autoimmune hemolytic anemia Back pain Bell's palsy Benign Blood and lymphatic system disorders Brachial neuritis Cancer Cardiac disorders Cerebellar ataxia Chest pain Chills Cholelithiasis Chronic obstructive pulmonary disease Clavicle fracture Complications Congenital Congenital, familial and genetic disorders Constipation Conversion disorder Coronary artery disease Cranial Craniocerebral injury Cyst	Gastrointestinal disorders Gastrointestinal ulcer perforation Gastrooesophageal General disorders Graves' disease Guillain-Barré syndrome Hashimoto disease Headache Henoch-Schonlein purpura Hepatobiliary disorders Hodgkin's Horner's Hydrocephalus Hypersensitivity reactions (including urticaria, angioedema, and anaphylaxis) Hypertension Idiopathic Immune system disorders Infections and infestations Inguinal Injection site erythema Injection site induration Injection site pain	Musculoskeletal and connective tissue disorders Myalgia Myasthenia gravis Nausea Neoplasms benign, malignant and unspecified (incl cysts and polyps) Nephrolithiasis Nephrotic syndrome Nervous system disorders Neuritis New-onset autoimmune disease (including idiopathic thrombocytopenic purpura, diabetes, arthritis, hemolytic anemia, and collagen-vascular disease) Non-CRC reviewed EOIs Optic neuritis Osteomyelitis Pancreatitis Pancreatitis acute Paraesthesia Pectus Pelvic Pharyngitis	Seizure Sickle Sleep Somatic symptom disorder Splenomegaly Status epilepticus Sudden-onset sensorineural hearing loss Suicidal ideation Suicide attempt Surgical and medical procedures Syncope/LOC Systemic Systemic lupus erythematosus Temporomandibular Testicular Throat tightness Thrombocytopenia Tonsillitis Tooth Transplant Transverse myelitis Trauma Type 2 diabetes mellitus Uterine leiomyoma Vascular disorders
Meningococcal B (MenB; MenB-4C [Bexsero], MenB-FHbp (Trumenba)]	Abdominal abscess Abdominal pain Abortion missed Abortion spontaneous Acute tonsillitis Allergy to arthropod sting Anaphylactic reaction Appendicitis Arthralgia Asthma Attention deficit or hyperactivity disorder Autoimmune thyroiditis Back pain Biliary dyskinesia Breast abscess Bronchitis Carbuncle	Demyelination Depression Diabetes mellitus inadequate control Diarrhoea Drug hypersensitivity Duodenal perforation Duodenal ulcer perforation Ectopic pregnancy Enteritis Fall Fatigue Fibula fracture Forearm fracture Gastroenteritis Gastrointestinal viral infection Gun shot wound Head injury Headache Heat stroke Hyperprolactinaemia	Jaw fracture Ligament sprain Lower limb fracture Major depression Meningism Meningitis enterococcal Meningitis enteroviral Meningitis viral Menorrhagia Migraine Multiple sclerosis Nasopharyngitis Nausea Neuralgia Neutropenia Oropharyngeal pain Osteochondrosis Overdose Pain in extremity Peritonsillar abscess	Radicular syndrome Rectal abscess Renal tubular necrosis Salpingitis Schizoaffective disorder Sinusitis Snake bite Spinal compression fracture Status asthmaticus Substance abuse Suicidal ideation Tension headache Testicular torsion Tick-borne viral encephalitis Tonsillitis Traumatic intracranial haemorrhage Type 1 diabetes mellitus

Vaccine	Assessed Adverse Events			
Meningococcal B (MenB; MenB-4C [Bexsero], MenB-FHbp (Trumenba)] (continued)	Cartilage injury Cellulitis Central Nervous System germinoma Clavicle fracture Concussion Constipation Contusion Convulsion Cough Craniocerebral injury Cystitis	Hyperventilation Hypothalamo-pituitary disorder Ingrowing nail Injection site erythema Injection site pain Injection site swelling Intentional overdose Intervertebral disc protrusion	Pertussis Pharyngitis Pharyngitis streptococcal Pilonidal cyst Pneumonia Postoperative wound infection Psychotic disorder Pyelonephritis Pyrexia	Upper respiratory tract infection Urinary tract infection Vaccination site pain Viral pharyngitis Vomiting
Pneumococcal polysaccharide vaccine (PPSV23; Pneumovax)	Acute disseminated encephalomyelitis	Optic neuritis	Sudden-onset sensorineural hearing loss	Transverse myelitis
Rotavirus (RV; Rotarix, RotaTeq)	Acute disseminated encephalomyelitis	Optic neuritis	Sudden-onset sensorineural hearing loss	Transverse myelitis
Varicella (VAR; Varivax)	Acute disseminated encephalomyelitis	Optic neuritis	Sudden-onset sensorineural hearing loss	Transverse myelitis
DTap-PepB-IPV (Pediarix)	Acute disseminated encephalomyelitis	Optic neuritis	Sudden-onset sensorineural hearing loss	Transverse myelitis
DTaP-IPV/Hib (Pentacel)	Acute disseminated encephalomyelitis	Optic neuritis	Sudden-onset sensorineural hearing loss	Transverse myelitis
DTaP-IPV (Kinrix, Quadracel)	Acute disseminated encephalomyelitis	Optic neuritis	Sudden-onset sensorineural hearing loss	Transverse myelitis
MMR-V (ProQuad)	Acute disseminated encephalomyelitis	Optic neuritis	Sudden-onset sensorineural hearing loss	Transverse myelitis

Note: N/A—not applicable

The next table shows assessed adverse events in studies contributing to KQ3.

Table C.4. Assessed adverse events in vaccine studies in pregnant women

Vaccine	Assessed Adverse Events		
Hepatitis B (HepB; Engerix-B, Recombivax HB)	N/A		
Inactivated influenza (IIV; Afluria Quadrivalent, Flucelvax Quadrivalent, Fluarix Quadrivalent, Flulaval Quadrivalent, Fluzone Quadrivalent)	Congenital anomalies Fatigue Fetal death Headache Myalgia Oropharyngeal pain Pain at the injection site Pneumonia Pre-eclampsia Site pruritus Spontaneous abortions Stillbirth		
Recombinant influenza (RIV; Flublok Quadrivalent)	N/A		
Tetanus, diphtheria, & acellular pertussis (Tdap; Adacel, Boostrix)	5-minute Apgar scores Aaternal neurologic disorders Abdominal discomfort Abdominal distension Abdominal pain Abnormal in fetal heart Abnormal feces Acne Acute appendicitis 19 d after delivery Adenoiditis Adjustment disorder Admission at Neonatal Intensive care Unit (NICU) Allergic reaction Altered mental status Altered state of consciousness Anemia Anemia during pregnancy and purpura Anaphylaxis Ankyloglossia Anomalies of skull and face bones Anophthalmia or microphthalmia Anotia or microtia Antenatal bleeding Any injection site symptom Any systematic symptom Apgar <8 at 5 minutes Aphonia Apnea Arthropod bite Asphyxia Atrial septum and ventricular septum defect	Injury Interstitial emphysema and related conditions Intestine anomaly, other Intestinal atresia or stenosis Intestinal haemorrhage Intrauterine growth restriction/poor fetal growth Intrauterine hypoxia Intraventricular hemorrhage Intussusception Irritability postvaccinal Jittery baby Lactation disorders (agalactia or hypogalactia) Large for gestational age infants Laryngitis Length of neonatal hospitalization Lethargy, decreased response, facial palsy, attention/sleep disturbance Limb deficiency Live birth with/without congenital anomalies Local and other reactions Local erythema Local heat Longitudinal deficiency phalanges Loss of appetite Low birth weight (LBW; birth weight under 2500 g) Lower limb anomaly, other	Preterm birth (birth before 37 weeks' gestation) Preterm contractions 33 d postvaccination Preterm delivery Preterm labor Preterm labor requiring hospitalization 18 d after placebo injection Preterm premature rupture of membranes Pulmonary embolism Pulmonary hypertension Pulmonary stenosis Pupils unequal Pyelonephritis Pyloric stenosis Pyrexia Rash Rash erythematous Rash macular Reduction deformities of brain Regurgitation Renal (Complex chronic condition) Renal agenesis or hypoplasia Renal dysplasia Respiratory (Complex chronic condition) Respiratory distress

Vaccine	Assessed Adverse Events		
Tetanus, diphtheria, & acellular pertussis (Tdap; Adacel, Boostrix) (continued)	Autism spectrum disorder Autonomic disorders Bacterial infection Bacterial sepsis of newborn, specified or unspecified Benign and innocent cardiac murmurs in newborn Bilateral pneumothoracesd Biliary atresia Birth trauma to face Bite Bladder disorder, other specified Bladder exstrophy Body temperature increased Bronchiolitis Bronchiolitis requiring hospitalization Bronchitis Campylobacter gastroenteritis Candida infection Candida nappy rash Candidiasis Cardiomyopathy Cardiomyopathy with biventricular hypertrophy Cardiovascular (Complex chronic condition) Cataracts and other lens defects Cellulitis Cesarean section Change of bowel habit Choking Choking with feeds requiring prolonged hospitalization Chorioamnionitis Chronic hypertension with superimposed pre-eclampsia Cleft lip or cleft palate Central nervous system degeneration/demyelinating Common truncus Tracheoesophageal fistula, esophageal atresia and stenosis Congenital heart anomaly, other specified Congenital pigmentary anomalies of skin Congenital anomalies (major and minor) Congenital chordee Congenital cytomegalovirus infection Congenital hydrocele Congenital hydronephrosis Congenital hypotonia Congenital pneumonia Congenital torticollis Congestive heart failure Conjunctivitis Constipation	Major birth defects Major malformations Malaise Malignancy (Complex chronic condition) Maternal cardiomyopathy Maternal death Maternal fever after labor Maternal fever during labor Meconium aspiration syndrome Meningitis Meningoencephalities Metabolic (Complex chronic condition) Microcephalus Microcephaly Mild local pain Milk allergy Mode of delivery Moderate to late preterm Movement disorders Mucous stools Myalgia Myocarditis Nail infection Nasal congestion Nasopharyngitis Nausea and/or vomiting Neonatal asphyxia/hypoxia/respiratory distress Neonatal conjunctivitis and dacryocystitis Neonatal death Neonatal erythema toxicum Neonatal hemorrhage Neonatal hypoxic-ischemic encephalopathy Neonatal jaundice Neonatal pneumonia Neonatal sepsis Neonatal skin infection Nephrolithiasis Neuromuscular (Complex chronic condition) Newborn convulsions NICU admission Obstructive defect of the renal pelvis, other Odynophagia Omphalitis Oral candidiasis Oral fungal infection Oral mucosal erythema Other conditions of integument Other congenital heart disease: septal defects, heterotaxy, partial	Respiratory distress at birth Vomiting requiring hospitalization 44 d after placebo injection Respiratory distress syndrome Respiratory distress/tachypneac Respiratory rate increase Respiratory syncytial virus bronchiolitis Respiratory tract infection Respiratory tract infection viral Respiratory tract/pneumonia Retained placenta Rhinitis Rhinorrhoea Road traffic accident Respiratory syncytial virus/bronchiolitis Sacral agenesis Sandifer's syndrome Scalp injury due to birth trauma Seborrhoeic dermatitis Second- or third-degree hypospadias Ostium secundum atrial septal defect Seizure sepsis Septal defect Severe congenital heart disease: single ventricle, tricuspid atresia, Ebstein anomaly, hypoplastic left heart,hypoplastic right heart, common truncus, transposition, atrioventricular septal defects, tetralogy of Fallot, aortic valve atresia or stenosis, coarctation, total anomalous pulmonary venous return, and anomalous coronary artery Skin anomaly, other specified Skull fracture Skull fractured base Small for gestational age (SGA) Somnolence

Vaccine	Assessed Adverse Events		
Tetanus, diphtheria, & acellular pertussis (Tdap; Adacel, Boostrix) (continued)	Cord blood pH values Cough Cranial meningocele Cranial nerve disorders Craniosynostosis Crohn's disease/colitis Croup infectious Cryptorchism Dacryostenosis acquired Dandy-walker syndrome Decreased appetite Decreased lactation Deep vein thrombosis Dehydration due to oral herpes simplex virus requiring hospitalization Dehydration of newborn Dermatitis Dermatitis atopic Dermatitis diaper Diaphragmatic hernia Diarrhoea Difficulty feeding Drowsiness Dry skin Dyshidrotic eczema Ear infection Ear malformation Eclampsia Eczema Elective termination with/without congenital anomalies Electrolyte anomalies Emotional distress Encephalocele Encephalomyelocele Encephalopathy Enteritis Enterovirus infection Epiphysiolysis Erythema Erythema infectiosum Esophageal atresia w/out tracheoesophageal fistula Exanthema subitum External hydrocephalus Eye discharge Eye infection Eye irritation Eye swelling Impetigo Induced labor Infant death Infantile colic Infantile haemangioma Infection Influenza Influenza like illness Infrequent bowel movements Injection site bruising	anomalous pulmonary venous return Other disturbances of temperature regulation of newborn Other fetal malnutrition Other neonatal jaundice Other specified birth trauma Otitis media Otitis media acute Pain in extremity Pain in limb Pallor Pancreatitis 3 mo after delivery Paralytic syndromes Pelvic fracture (motor vehicle crash) Peoteinuria Percaritis Perinatal death Perineal infection Periorbital cellulitis Peripheral coldness Peripheral neuropathy Pertussis illness Pharyngitis Pharyngotonsillitis Phimosis Placental abruption Poor feeding due to gastroesophageal reflux Positional plagiocephaly Posterior urethral valve or prune belly Post-partum endometritis Post-partum hemorrhage Posture abnormal Pre-eclampsia Pre-eclampsia with severe features Preeclampsia/Eclampsia Pregnancy hemorrhage or vaginal hemorrhage Pregnancy-induced hypertension 30 d postvaccination Pregnancy-related hypertension Pre-labor rupture of membranes Premature delivery Premature labor Premature rupture of membranes Premature uterine contraction Presence of birth defect (spina bifida, transposition of great arteries, tetralogy of	Spina bifida Spinocerebellar disease Spontaneous abortion Still birth Still birth with/ without congenital anomalies Sudden infant death syndrome Superinfection bacterial Syndactyly Syndrome of infant of a diabetic mother Syndrome of infant of mother with gestational diabetes Tachycardia or bradycardia Talipes equinovarus, metatarsus varus, other congenital deformities of feet Teething Thermal burn Thirst Thrombocytopenia Tonsillitis Toothache Torticollis Transient tachypnea of the newborn (TTN); Umbilical hernia Upper limb vessel anomaly Upper respiratory tract infection Urinary tract infection Urticaria Uterine rupture Observation for suspected genetic or metabolic condition Vaccination complication Vaccination site erythema Vaccination site pain Vaccination site swelling Vaginal or intrauterine hemorrhage Varicella Varicella zoster virus infection Venos thromboembolism Ventilation requirement Ventricular septal defect Very low birth weight Vessel puncture site bruise

Vaccine	Assessed Adverse Events		
Tetanus, diphtheria, & acellular pertussis (Tdap; Adacel, Boostrix) (continued)	Injection site erythema Injection site erythema/redness Injection site induration Injection site induration/swelling Injection site mass Injection site nodule Injection site pain Injection site pain, redness, swelling Injection site swelling Injection-site erythema and swelling	Fallot, atrioventricular septal defect, cleft palate, cleft lip, rectal and large intestinal atresia/ stenosis, reduction deformity of upper limbs, gastroschisis, or diaphragmatic hernia)	Viral infection Viral rash Viral upper respiratory tract infection Vomiting Wound haemorrhage Wound hematoma after cesarean delivery

Note: N/A—not applicable

Of note, studies collected information about the presence and absence of a variety of different events and the categories listed in the table are not an indication that the adverse event occurred.

The methods and the reporting of adverse events in the included studies varied widely. The critical appraisal result for all studies is shown in the next figure.

Table C.5. Critical appraisal adverse events reporting

Author, Year	Were the Harms PRE-DEFINED Using Standardized or Precise Definitions?	Were SERIOUS Events Precisely Defined?	Were SEVERE Events Precisely Defined?	Were the Number of DEATHS in Each Study Group Specified OR Were the Reason(s) for Not Specifying Them Given?	Was the Mode of Harms Collection Specified as ACTIVE?	Was the Mode of Harms Collection Specified as PASSIVE?	Did the Study Specify WHO Collected the Harms?	Did the Study Specify the TRAINING or BACKGROUND of Who Ascertained the Harms?	Did the Study Specify the TIMING and FREQUENCY of Collection of the Harms?	Did the Author(s) use STANDARD Scale(s) or Checklist(s) for Harms Collection?	Did the Authors Specify if the Harms Reported Encompass ALL the Events Collected or a	Was the NUMBER of Participants that Withdrew or Were Lost to Followup Specified for Each Study Group?	Was the TOTAL NUMBER of Participants Affected by Harms Specified for Each Study Arm?	Did the Author(s) Specify the NUMBER for each TYPE of Harmful Event for Each Study Group?	Did the Author(s) Specify the Type of Analyses Undertaken for Harms Data?
Abdelnour, 2014[51]	0	0	0	2	2	2	2	0	2	0	2	2	2	2	2
Acosta, 2016[52]	0	1	0	0	0	2	0	0	0	0	2	0	2	2	2
Alberer, 2015[53]	0	0	2	2	2	2	2	0	0	0	2	2	2	0	2
Alberer, 2015[54]	0	0	2	2	2	2	0	0	2	0	1	2	2	2	0
Amdekar, 2013[55]	0	0	2	2	2	2	2	0	2	0	0	2	2	2	2
Anez, 2020[56]	0	0	2	2	0	0	2	2	0	2	1	2	2	2	2
Baccarini, 2020[57]	2	0	1	0	2	2	2	0	2	0	2	2	2	2	2
Baker, 2019[58]	2	1	1	0	0	2	2	2	2	2	0	0	0	0	2
Baker, 2020[59]	2	1	1	0	0	2	0	0	2	0	0	0	2	2	2
Bart, 2016[60]	2	0	2	2	2	2	2	0	2	0	2	2	2	2	0
Baxter, 2016[62]	2	0	0	1	0	2	0	0	2	1	0	1	1	1	2
Baxter, 2016[63]	2	0	0	0	1	2	0	0	2	1	0	1	1	1	2
Baxter, 2017[61]	2	1	1	0	0	2	2	2	2	0	0	0	2	2	2
Becerra-Culqui, 2018[64]	2	1	1	0	0	2	2	2	2	0	2	0	2	2	2
Becerra-Culqui, 2020[65]	2	0	1	0	0	2	2	2	0	0	2	2	2	0	2
Beran, 2013[66]	0	0	1	0	2	2	2	0	2	0	2	2	2	2	0

Author, Year	Were the Harms PRE-DEFINED Using Standardized or Precise Definitions?	Were SERIOUS Events Precisely Defined?	Were SEVERE Events Precisely Defined?	Were the Number of DEATHS in Each Study Group Specified OR Were the Reason(s) for Not Specifying Them Given?	Was the Mode of Harms Collection Specified as ACTIVE?	Was the Mode of Harms Collection Specified as PASSIVE?	Did the Study Specify WHO Collected the Harms?	Did the Study Specify the TRAINING or BACKGROUND of Who Ascertained the Harms?	Did the Study Specify the TIMING and FREQUENCY of Collection of the Harms?	Did the Author(s) use STANDARD Scale(s) or Checklist(s) for Harms Collection?	Did the Authors Specify if the Harms Reported Encompass ALL the Events Collected or a	Was the NUMBER of Participants that Withdrew or Were Lost to Followup Specified for Each Study Group?	Was the TOTAL NUMBER of Participants Affected by Harms Specified for Each Study Arm?	Did the Author(s) Specify the NUMBER for each TYPE of Harmful Event for Each Study Group?	Did the Author(s) Specify the Type of Analyses Undertaken for Harms Data?
Berenson, 2016[67]	2	1	1	0	0	2	2	2	0	0	0	0	2	2	2
Black, 2010[68]	0	2	2	0	2	2	2	0	2	0	0	2	0	0	0
Block, 2011[71]	2	0	1	2	2	2	0	0	2	0	2	2	2	0	2
Block, 2012[69]	2	0	1	2	2	2	0	0	2	0	2	2	0	0	2
Block, 2017[70]	0	2	0	2	2	2	2	0	2	0	2	2	2	2	2
Bonten, 2015[72]	0	2	1	2	2	2	2	2	2	2	0	2	2	2	2
Briggs-Steinberg, 2019[73]	0	0	1	0	2	2	2	2	2	0	0	0	2	2	2
Burke, 2020[74]	2	1	1	0	0	2	0	0	2	0	0	0	2	2	2
Carlin, 2013[75]	2	1	1	2	0	2	2	2	2	0	0	0	2	2	2
Caspard, 2018[76]	0	1	1	0	0	2	2	2	2	0	0	0	2	0	2
Chang, 2012[80]	2	1	1	2	0	2	0	0	2	1	0	0	2	2	2
Chang, 2019[77]	0	2	1	2	2	2	2	0	2	0	2	2	2	0	2
Chang, 2020a[78]	2	2	2	2	2	2	0	0	2	1	2	2	2	2	2
Chang, 2020b[79]	0	0	1	2	2	2	0	0	2	0	2	2	2	2	2
Chen, 2012[81]	2	0	1	0	2	2	2	2	2	1	0	0	2	2	2
Chlibek, 2013[82]	0	0	2	0	2	2	2	0	2	0	2	2	2	2	2
Contopoulos-Ioannidis, 2015[83]	2	0	0	0	0	2	0	0	2	0	0	0	2	2	2

Author, Year	Were the Harms PRE-DEFINED Using Standardized or Precise Definitions?	Were SERIOUS Events Precisely Defined?	Were SEVERE Events Precisely Defined?	Were the Number of DEATHS in Each Study Group Specified OR Were the Reason(s) for Not Specifying Them Given?	Was the Mode of Harms Collection Specified as ACTIVE?	Was the Mode of Harms Collection Specified as PASSIVE?	Did the Study Specify WHO Collected the Harms?	Did the Study Specify the TRAINING or BACKGROUND of Who Ascertained the Harms?	Did the Study Specify the TIMING and FREQUENCY of Collection of the Harms?	Did the Author(s) use STANDARD Scale(s) or Checklist(s) for Harms Collection?	Did the Authors Specify if the Harms Reported Encompass ALL the Events Collected or a	Was the NUMBER of Participants that Withdrew or Were Lost to Followup Specified for Each Study Group?	Was the TOTAL NUMBER of Participants Affected by Harms Specified for Each Study Arm?	Did the Author(s) Specify the NUMBER for each TYPE of Harmful Event for Each Study Group?	Did the Author(s) Specify the Type of Analyses Undertaken for Harms Data?
Cowling, 2019[84]	0	0	2	0	2	2	0	0	2	0	0	0	0	0	0
Cunningham, 2016[85]	0	2	2	2	2	2	2	0	2	0	2	2	2	2	2
Cutland, 2018[86]	0	0	1	0	2	2	2	2	2	0	0	2	0	0	0
Dagan, 2013[87]	0	0	1	2	2	2	2	0	2	0	0	2	0	0	2
Daley, 2014[88]	2	0	1	0	0	2	0	0	2	2	0	0	2	2	2
Deichmann, 2015[89]	0	0	0	2	2	2	2	2	2	0	2	2	2	2	2
DeMeo, 2015[90]	0	0	1	2	0	2	0	0	2	0	0	0	0	0	2
DeSilva, 2017[91]	2	1	0	0	0	2	0	0	2	0	2	0	2	2	2
Dhingra, 2014[92]	0	0	0	0	2	2	2	2	2	0	2	2	2	2	2
Dhingra, 2020[93]	2	2	2	2	2	2	0	0	2	2	2	0	2	2	0
Domachowske, 2013[94]	2	0	1	2	2	2	2	0	2	0	2	0	0	0	2
Donahue, 2019[95]	2	0	1	0	0	2	0	0	2	0	2	0	2	2	2
Duffy, 2016[96]	2	1	1	0	0	2	0	0	2	0	0	0	2	2	2
Dunkle, 2017[97]	0	2	1	2	0	0	2	0	2	1	2	2	2	2	0
Dunkle, 2017[98]	1	2	1	2	0	0	0	0	0	1	2	2	2	2	0

Author, Year	Were the Harms PRE-DEFINED Using Standardized or Precise Definitions?	Were SERIOUS Events Precisely Defined?	Were SEVERE Events Precisely Defined?	Were the Number of DEATHS in Each Study Group Specified OR Were the Reason(s) for Not Specifying Them Given?	Was the Mode of Harms Collection Specified as ACTIVE?	Was the Mode of Harms Collection Specified as PASSIVE?	Did the Study Specify WHO Collected the Harms?	Did the Study Specify the TRAINING or BACKGROUND of Who Ascertained the Harms?	Did the Study Specify the TIMING and FREQUENCY of Collection of the Harms?	Did the Author(s) use STANDARD Scale(s) or Checklist(s) for Harms Collection?	Did the Authors Specify if the Harms Reported Encompass ALL the Events Collected or a	Was the NUMBER of Participants that Withdrew or Were Lost to Followup Specified for Each Study Group?	Was the TOTAL NUMBER of Participants Affected by Harms Specified for Each Study Arm?	Did the Author(s) Specify the NUMBER for each TYPE of Harmful Event for Each Study Group?	Did the Author(s) Specify the Type of Analyses Undertaken for Harms Data?
Dynavax, 2006[100]	2	2	1	0	2	2	0	0	2	2	2	2	2	2	0
Dynavax, 2015[99]	2	2	2	2	2	2	2	0	2	2	2	2	2	2	2
Eriksson, 2020[101]	0	0	0	0	2	2	0	0	2	0	0	2	2	2	0
Escolano, 2015[102]	0	1	1	0	0	2	0	0	0	0	0	0	0	0	2
Essink, 2020[103]	2	1	0	2	2	1	2	0	2	2	2	2	2	2	2
Esteves-Jaramillo, 2020[104]	0	0	0	0	2	2	0	0	2	0	0	0	0	0	0
Fernandes, 2016[106]	2	0	0	2	0	2	2	0	2	0	0	0	2	2	2
Fischer, 2015[107]	0	1	0	0	2	2	0	0	2	2	0	2	0	0	0
Fotso Kamdem, 2019[108]	2	1	1	2	0	2	2	2	0	2	0	0	2	2	2
Frenck, 2012[109]	0	0	0	0	2	2	2	0	2	0	0	2	2	2	2
Frey, 2014[110]	2	0	0	2	0	0	0	0	2	2	2	2	2	2	2
Garland, 2015[111]	0	2	2	2	2	2	2	0	2	2	2	2	2	2	0
Gasparini, 2014[112]	0	0	0	2	2	2	2	0	2	0	2	2	2	2	2
Geier, 2020[113]	2	1	1	0	0	2	0	0	2	0	2	1	2	2	2

Author, Year	Were the Harms PRE-DEFINED Using Standardized or Precise Definitions?	Were SERIOUS Events Precisely Defined?	Were SEVERE Events Precisely Defined?	Were the Number of DEATHS in Each Study Group Specified OR Were the Reason(s) for Not Specifying Them Given?	Was the Mode of Harms Collection Specified as ACTIVE?	Was the Mode of Harms Collection Specified as PASSIVE?	Did the Study Specify WHO Collected the Harms?	Did the Study Specify the TRAINING or BACKGROUND of Who Ascertained the Harms?	Did the Study Specify the TIMING and FREQUENCY of Collection of the Harms?	Did the Author(s) use STANDARD Scale(s) or Checklist(s) for Harms Collection?	Did the Authors Specify if the Harms Reported Encompass ALL the Events Collected or a	Was the NUMBER of Participants that Withdrew or Were Lost to Followup Specified for Each Study Group?	Was the TOTAL NUMBER of Participants Affected by Harms Specified for Each Study Arm?	Did the Author(s) Specify the NUMBER for each TYPE of Harmful Event for Each Study Group?	Did the Author(s) Specify the Type of Analyses Undertaken for Harms Data?
Gilca, 2018[114]	0	1	1	0	2	2	2	0	2	0	0	2	0	0	2
Glanz, 2020[115]	2	0	0	0	0	0	2	2	0	2	0	2	2	2	2
Glover, 2020[116]	0	2	1	0	2	2	2	0	2	0	2	0	2	2	2
Greenberg, 2013[118]	2	0	0	2	2	2	2	2	2	2	2	2	2	0	0
Greenberg, 2014[117]	2	0	1	2	2	2	0	0	2	2	2	2	2	0	2
Greenberg, 2014[120]	0	0	2	2	2	2	2	0	2	0	1	0	0	0	2
Greenberg, 2017[119]	2	2	2	0	2	2	2	0	2	0	2	2	2	2	2
Griffin, 2018[121]	2	0	2	2	0	2	0	0	2	0	2	0	2	2	2
Groome, 2019[122]	2	1	1	0	0	2	2	2	2	2	2	0	2	2	2
Hall, 2020[123]	2	1	1	0	0	2	0	0	2	0	0	0	2	2	2
Halperin, 2018[125]	0	0	2	0	2	2	2	0	2	0	2	2	0	0	2
Halperin, 2019[124]	2	2	2	2	2	2	2	0	2	2	2	2	2	2	2
Hansen, 2016[126]	2	0	1	0	0	2	0	0	2	0	0	0	2	2	2
Hansen, 2017[128]	0	0	1	2	0	2	0	0	2	0	0	0	0	2	2
Hansen, 2018[127]	2	1	1	2	0	2	0	0	2	0	0	0	2	2	2

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Hartvickson, 2015[129]	2	2	0	2	2	0	2	0	2	0	0	0	0	0	2
Hattori, 2018[130]	0	0	0	2	1	1	0	0	2	1	0	0	0	0	0
Hawken, 2017[131]	2	0	0	0	0	2	0	0	2	2	2	0	2	0	2
Heyward, 2013[132]	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
Hoffman, 2018[133]	2	0	0	2	0	2	2	2	2	2	2	0	2	2	2
Huang, 2015[134]	2	1	1	0	0	2	2	2	0	1	0	0	0	0	2
Huang, 2020[135]	2	1	1	0	0	2	0	0	2	0	0	0	2	2	2
Huh, 2017 [136]	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
Hung, 2010[137]	2	0	1	0	2	2	0	0	2	0	0	0	0	0	2
Hviid, 2019[138]	2	0	0	2	0	2	0	0	2	2	2	2	2	0	2
Iwata, 2013[139]	0	0	0	0	0	2	0	0	0	0	0	2	2	2	2
Jackson, 2013[140]	2	0	2	2	0	0	0	0	2	1	2	2	2	2	2
Jain, 2015[141]	2	0	0	2	0	2	2	0	0	0	2	0	2	2	2
Juergens, 2014[142]	2	2	2	0	2	2	2	0	2	2	2	2	2	2	0
Kantso, 2015[143]	0	2	0	0	0	2	0	0	2	2	2	2	2	2	2
Kharbanda, 2016[144]	2	0	0	0	0	2	0	0	2	0	0	0	0	0	2

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Kieninger, 2013[145]	2	2	2	2	2	0	2	2	2	2	2	2	2	2	2
Kim, 2013[146]	0	1	1	2	2	2	2	0	2	1	0	2	2	2	2
Kirstein, 2020[147]	0	0	1	2	2	2	2	0	2	0	0	2	0	0	2
Klein, 2010[148]	2	1	1	0	0	2	0	0	2	0	2	0	2	2	2
Klein, 2015[149]	0	0	0	0	0	2	0	0	2	1	1	0	0	0	2
Lal, 2015[150]	2	2	2	2	2	0	2	2	2	2	2	2	2	2	2
Langer-Gould, 2014[151]	2	0	0	0	0	2	0	0	0	2	0	0	2	2	2
Langley, 2013[152]	0	0	1	2	2	2	2	0	2	0	2	2	0	0	2
Langley, 2015[153]	2	2	2	0	2	0	2	2	2	2	1	0	0	0	2
Layton, 2017[154]	2	1	1	0	0	2	0	0	2	0	0	0	2	2	2
Layton, 2018[155]	2	0	1	0	0	2	0	0	2	0	0	0	0	0	2
Lee, 2014[157]	2	2	2	2	2	2	2	0	2	2	2	2	2	2	0
Lee, 2016[156]	0	0	2	0	2	2	2	0	2	0	2	2	2	2	2
Leslie, 2017[158]	2	1	1	0	0	2	0	0	0	0	0	0	2	2	2
Li, 2014[161]	0	2	1	2	2	2	0	0	2	0	2	2	2	2	2
Li, 2016[160]	2	1	1	0	0	2	0	0	2	0	0	0	0	0	2
Li, 2020[159]	2	1	1	2	2	2	0	0	2	0	0	0	0	0	2
Lombardi, 2016[162]	2	2	2	0	2	2	0	0	2	2	2	2	2	2	0

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Mallory, 2018a[164]	0	0	0	2	2	2	0	0	2	0	2	0	2	2	2
Mallory, 2020[163]	0	2	0	2	2	2	0	0	2	0	2	2	2	0	0
Marechal, 2018[165]	2	0	2	2	2	2	0	0	2	2	2	2	2	2	2
Marshall, 2015[166]	0	2	1	2	2	2	0	0	2	0	2	2	2	2	2
McClure, 2019[167]	2	1	1	0	0	2	0	0	2	0	0	0	2	2	2
McGeoch, 2020[168]	2	1	1	0	0	2	0	0	0	0	2	0	2	2	2
Mo, 2017[169]	0	0	0	2	1	1	2	0	2	1	0	2	2	0	2
Morgan, 2015[170]	0	1	1	2	0	2	0	0	0	0	0	0	2	2	2
Munnoch, 2019[171]	2	0	2	0	2	2	2	0	2	2	2	0	2	2	0
Munoz, 2014[172]	0	0	0	0	2	2	2	0	2	0	0	2	2	2	2
Naleway, 2018[173]	2	1	1	0	0	2	2	2	2	2	0	0	2	2	2
Nelson, 2013[174]	2	0	1	0	0	2	0	0	2	0	1	0	2	2	2
Novartis Vaccines and Diagnostics s.r.l, 2014[105]	2	0	0	2	2	2	0	0	2	0	0	2	2	2	0

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Oberle, 2020[175]	2	0	0	0	0	2	0	0	2	0	2	0	2	0	2
Ochoa-Gondar, 2014[176]	2	1	1	2	0	2	2	2	2	1	0	0	2	2	2
Ofori-Anyinam, 2017[177]	2	2	2	0	2	2	2	0	2	2	2	2	2	2	2
Ostergaard, 2016[178]	2	2	2	2	2	2	2	0	2	1	2	2	2	2	2
Perez, 2017[179]	0	0	0	0	2	2	2	2	2	0	0	2	2	2	0
Perez-Vilar, 2019[180]	2	1	1	0	0	2	0	0	2	0	0	0	2	2	2
Perrett, 2019[181]	2	0	1	2	2	2	2	0	2	2	2	2	2	2	2
Petousis-Harris, 2019[182]	2	1	1	2	0	2	0	0	2	0	0	0	2	2	2
Petrecz, 2016[183]	2	2	2	2	2	2	2	0	2	2	2	2	2	2	2
Pfizer, 2007[184]	2	1	2	2	2	2	2	2	2	1	1	2	2	2	2
Puig-Barbera, 2007[185]	2	1	1	0	0	2	0	0	2	1	0	0	2	2	2
Richmond, 2012[186]	0	0	2	0	2	2	2	0	2	0	2	2	2	2	2
Rivera, 2018[187]	2	0	1	0	2	1	2	0	2	2	1	2	0	0	0
Rodriguez Weber, 2014[188]	0	0	0	2	2	2	0	0	2	0	2	2	2	2	2
Rogers, 2019[189]	2	0	0	0	0	2	2	0	2	0	2	0	0	0	0

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Salas, 2019[190]	2	1	1	0	0	2	0	0	0	0	0	0	0	0	2
Sancovski, 2019[191]	0	0	1	2	0	2	0	0	0	0	2	0	2	2	2
Sanofi Pasteur, a Sanofi Company, 2019[192]	2	2	0	2	2	2	2	2	2	2	2	2	2	2	0
Santolaya, 2012[193]	0	2	2	2	2	2	2	0	2	0	2	2	2	2	2
Schwarz, 2011[195]	0	0	0	2	2	2	2	2	2	0	2	2	2	2	2
Schwarz, 2017[194]	2	2	2	2	2	2	0	0	2	1	2	2	2	0	2
Senders, 2016[196]	0	0	2	2	2	2	2	0	2	2	0	2	2	2	0
Seo, 2017[197]	2	0	0	2	2	2	2	0	2	2	2	2	2	2	2
Shakib, 2013[198]	2	1	1	0	0	2	0	0	0	0	0	0	2	2	2
Shimada, 2020[199]	0	0	0	0	2	2	2	0	2	0	0	2	0	0	2
Shiramoto, 2015[200]	2	2	2	2	2	2	0	0	2	2	2	2	2	2	2
Siriwardena, 2014[201]	2	1	1	0	0	2	0	0	2	1	0	0	2	2	2
Song, 2015a[204]	2	2	2	0	2	2	2	0	2	2	0	2	2	2	0
Song, 2015b[205]	2	2	2	0	2	2	2	0	2	2	0	2	2	2	0

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Song, 2017[202]	2	2	2	2	2	2	2	0	2	2	2	2	2	2	2
Song, 2018[203]	1	2	2	0	2	2	2	0	2	2	0	2	2	2	0
Stockwell, 2014[206]	2	1	1	0	2	2	2	2	2	0	0	0	2	2	2
Stockwell, 2017[207]	2	1	1	0	2	2	2	0	2	0	0	2	2	2	2
Stowe, 2016[208]	2	1	1	0	0	2	0	0	2	2	2	0	2	2	2
Strezova, 2019[209]	2	2	2	2	2	2	2	0	2	2	2	2	2	0	0
Svensson, 2018[210]	0	0	0	0	1	1	0	0	0	0	0	2	0	0	0
Tapiero, 2013[211]	2	0	1	2	2	2	2	0	2	0	2	2	2	2	2
Tate, 2016[213]	2	1	1	2	0	2	0	0	2	0	0	0	0	0	2
Tate, 2018[212]	2	1	1	2	2	2	2	2	2	2	2	0	2	1	2
Thompson, 2019[214]	0	0	0	2	2	2	0	0	2	0	0	2	2	2	2
Timmermann, 2015[215]	0	1	1	0	2	2	2	2	2	2	0	2	2	2	2
Tinoco, 2014[216]	0	0	0	0	2	2	2	0	2	0	1	2	0	0	2
Togashi, 2015[217]	0	0	2	0	2	2	2	0	2	0	2	2	2	2	0
Treanor, 2017[218]	0	0	1	2	2	2	2	0	2	0	2	2	2	2	2

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Tregnaghi, 2014[219]	0	0	0	2	2	2	0	0	2	0	0	2	2	2	2
Tseng, 2013[221]	2	0	0	0	0	2	2	0	2	2	2	2	2	2	2
Tseng, 2017[220]	2	0	0	0	0	2	2	2	2	2	2	0	2	2	2
Tseng, 2018[222]	2	0	0	2	0	0	2	0	2	2	2	0	2	2	2
Uhlig, 2014[223]	2	1	1	2	0	2	0	0	2	1	0	0	0	0	2
Uno, 2015[224]	2	1	1	0	0	2	0	0	2	2	0	0	0	0	2
Vaarala, 2017[225]	1	1	1	0	0	2	0	0	2	1	0	0	2	2	2
Van Damme, 2016[226]	2	2	2	2	2	2	2	0	2	1	2	2	2	2	0
Vandecasteele, 2018[227]	2	0	0	2	2	2	2	2	2	0	2	2	2	2	0
Vesikari, 2007[229]	0	0	0	0	2	2	2	0	2	2	2	2	2	2	0
Vesikari, 2015[228]	0	2	2	2	2	2	2	0	2	0	2	2	2	2	0
Vesikari, 2016[230]	0	0	0	2	2	2	2	0	2	0	2	2	2	2	2
Vila-Corcoles, 2018[231]	2	1	1	2	1	1	1	1	2	2	2	0	2	1	2
Villa, 2013[232]	2	2	0	0	0	2	2	2	2	2	0	0	2	2	2
Walter, 2020[233]	2	2	1	2	2	2	2	0	2	0	2	2	2	2	2
Wang, 2016[234]	0	0	2	2	2	2	2	0	2	2	2	2	2	2	0
Wang, 2018[235]	2	1	1	0	0	2	0	0	2	0	0	0	2	2	2

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Yih, 2014[236]	2	0	1	0	0	2	0	0	2	2	0	0	2	2	2
Yung, 2015[237]	2	1	1	2	0	2	0	0	0	2	2	0	2	2	2
Yung, 2019[238]	2	1	1	0	0	2	0	0	2	0	0	0	2	2	2
Zahid, 2012[239]	2	1	1	0	0	2	0	0	2	1	0	0	0	0	2

Table notes: 0 = High risk of bias; 1 = Unsure risk of bias; 2 = Low risk of bias

Appendix D. Evidence Tables

Given the large number of studies, the evidence tables are divided into studies addressing KQ1 (adults only), KQ 2 (children and adolescents; mixed samples), KQ 3 (pregnant women). Note: The references in this appendix can be found in the list at the end of the main report

Table D.1. KQ1 evidence table safety of vaccines in adults

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
Dynavax, 2006[100] U.S Food and Drug Administration, 2017[379] NCT00435812 Trial record RCT N=2428 Industry funded Canada, Germany	Age: 99.5% aged >=18 to <=55 years % female: 54% Ethnicity: N/A People aged 11-55 years Out of scope: Some	Hep B HEPLISAV-B 2 injections of active vaccine 4 weeks apart (then placebo for third dose at 24 weeks) Intramuscular Other : CpG adjuvant preservative NR No co-intervention Hep B Existing non-adjuvanted HepB vaccine Engerix-B 3 doses at 0, 4 weeks, 24 weeks Intramuscular adjuvant freepreservative NR Counts Prespecified AE Power NR Followup: 7 months	Angina pectoris Atrial fibrillation Supraventricular tachycardia Gastritis Pancreatitis Device dislocation Cholecystitis acute Anti-neutrophil cytoplasmic antibody positive vasculitis Liver abscess Salpingo-oophoritis Septic shock Tonsillitis Ankle fracture Femur fracture Jaw fracture Joint dislocation Meniscus injury Patella fracture Post procedural complication Sternal fracture Tendon rupture Ulna fracture Bursitis Gouty arthritis Intervertebral disc protrusion Breast cancer Breast cancer recurrent Meningioma Papillary thyroid cancer Cerebral ischaemia Guillain-barre syndrome Delirium tremens Depression Renal failure Menorrhagia Ovarian cyst Prostatitis Asthma Pneumothorax	Asthma: 22.X NA I: 0/1821, 22.X NA C: 1/607 Autoimmune disease: 10.X Granulomatosis with polyangiitis I: 1/1821, 10.X Anti-neutrophil cytoplasmic antibody positive vasculitis C: 1/607 Cardiovascular events: 2.X Angina pectoris I: 1/1821, 2.XNA C: 0/607 Death: NA Per FDA materials I: 0/1821, NA Per FDA materials C: 0/607 Guillain-Barré syndrome: 10.X NA I: 1/1821, 10.X NA C: 0/607 Herpes Zoster: 11.X NA I: 3/1821 11.X NA C: 0/607 Reproduction issues: 21.X NA I: 0/1821, 21.X Menorrhagia C: 1/607 Stroke: 17.X Cerebral ischemia I: 1/1821, 17.X Cerebral ischemia C: 0/607	From clinical trials.gov: HEPLISAV vsEngerix-B Affected / at Risk (%)Affected / at Risk (%) Total 28/1821 (1.54%) 13/607 (2.14%) Cardiac disorders Angina pectoris 1/1821 (0.05%) 0/607 (0.00%) (in AE table) Atrial fibrillation 0/1821 (0.00%) 1/607 (0.16%) Supraventricular tachycardia 0/1821 (0.00%) 1/607 (0.16%) Gastrointestinal disorders Gastritis 1/1821 (0.05%) 0/607 (0.00%) Pancreatitis 0/1821 (0.00%) 1/607 (0.16%) General disorders Device dislocation 1/1821 (0.05%) 0/607 (0.00%) Hepatobiliary disorders Cholecystitis acute 1/1821 (0.05%) 0/607 (0.00%) Immune system disorders Anti-neutrophil cytoplasmic antibody positive vasculitis 0/1821 (0.00%) 1/607 (0.16%) (in AE table) Infections and infestations Liver abscess 0/1821 (0.00%) 1/607 (0.16%) Salpingo-oophoritis 0/1821 (0.00%) 1/607 (0.16%) Septic shock 0/1821 (0.00%) 1/607 (0.16%) Tonsillitis 1/1821 (0.05%) 0/607 (0.00%) Injury, poisoning and procedural complications Ankle fracture 1/1821 (0.05%) 0/607 (0.00%) Femur fracture 0/1821 (0.00%) 1/607 (0.16%) Jaw fracture 2/1821 (0.11%) 0/607 (0.00%) Joint dislocation 0/1821 (0.00%) 1/607 (0.16%)

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
			Pneumothorax spontaneous Pulmonary embolism Granulomatosis with polyangiitis		Meniscus injury 1/1821 (0.05%) 0/607 (0.00%) Patella fracture 1/1821 (0.05%) 0/607 (0.00%) Post procedural complication 1/1821 (0.05%) 0/607 (0.00%) Sternal fracture 1/1821 (0.05%) 0/607 (0.00%) Tendon rupture 1/1821 (0.05%) 0/607 (0.00%) Ulna fracture 1/1821 (0.05%) 0/607 (0.00%) Musculoskeletal and connective tissue disorders Bursitis 1/1821 (0.05%) 0/607 (0.00%) Gouty arthritis 1/1821 (0.05%) 0/607 (0.00%) Intervertebral disc protrusion 0/1821 (0.00%) 1/607 (0.16%) Neoplasms benign, malignant and unspecified (incl cysts and polyps) Breast cancer 2/1821 (0.11%) 0/607 (0.00%) Breast cancer recurrent 1/1821 (0.05%) 0/607 (0.00%) Meningioma 1/1821 (0.05%) 0/607 (0.00%) Papillary thyroid cancer 1/1821 (0.05%) 0/607 (0.00%) Nervous system disorders Cerebral ischaemia 1/1821 (0.05%) 0/607 (0.00%) (in AE table) Guillain-Barre syndrome 1/1821 (0.05%) 0/607 (0.00%) (in AE table) Psychiatric disorders Delirium tremens 0/1821 (0.00%) 1/607 (0.16%) Depression 2/1821 (0.11%) 0/607 (0.00%) Renal and urinary disorders Renal failure 1/1821 (0.05%) 0/607 (0.00%) Reproductive system and breast disorders Menorrhagia 0/1821 (0.00%) 1/607 (0.16%)

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
					Ovarian cyst 0/1821 (0.00%) 1/607 (0.16%) Prostatitis 1/1821 (0.05%) 0/607 (0.00%) Respiratory, thoracic and mediastinal disorders Asthma 0/1821 (0.00%) 1/607 (0.16%) (in AE table) Pneumothorax 1/1821 (0.05%) 0/607 (0.00%) Pneumothorax spontaneous 1/1821 (0.05%) 0/607 (0.00%) Pulmonary embolism 3/1821 (0.16%) 0/607 (0.00%) Vascular disorders Granulomatosis with polyangiitis 1/1821 (0.05%) 0/607 (0.00%) Risk factors: No
Dynavax, 2015[99] Hyer, 2019[288]; Everett, July 28, 2017[255]; Scott, July 28, 2017[372]; U.S Food and Drug Administration, 2017[379] NCT02117934 Trial record RCT N=8374 Industry funded USA	Age: N/A % female: 49% Ethnicity: Ethnicity NR Adults 18-70 years of age, Out of scope: None	Hep B HEPLISAV-B 2 doses at weeks 0 and 4 (each dose was 0.5 mL HEPLISAV (20 mcg HBsAg and 3000 mcg 1018)) Intramuscular Other : Toll-like receipt agonist preservative free No co-intervention Hep B HepB vaccine (comparator) Engerix-B 3 doses at weeks 0, 4, 24 weeks [each 1.0 mL dose contains HBsAg/alum (20 mg HBsAg adsorbed on 500 mg aluminum hydroxide)] Intramuscular Aluminumpreservative free Counts	Anaemia Anaemia vitamin b12 deficiency Leukocytosis Microcytic anaemia Acute coronary syndrome Acute myocardial infarction Angina pectoris Angina unstable Atrial fibrillation Atrial flutter Bradycardia Cardiac arrest Cardiac failure Cardiac failure acute Cardiac failure congestive Cardiac ventricular thrombosis Cardio-respiratory arrest Cardiogenic shock Cardiomyopathy Coronary artery disease Coronary artery occlusion Coronary artery stenosis Hypertensive heart disease Myocardial infarction Myocardial ischaemia Pulseless electrical activity	Asthma: 22.X NR I: 5/5587, 22.X NR C: 1/2781 Autoimmune disease: 10.X Adjudicated by SEAC, from FDA safety materials I: 17/5587, 10.X Adjudicated by SEAC, from FDA safety materials C: 12/2781 Cardiovascular events: 2.X All cardiac disorders, from FDA safety materials I: 51/5587, 2.XAll cardiac disorders, from FDA safety materials C: 15/2781 Death: NA No deaths deemed related to study vaccine by investigator per FDA materials I: 25/5587, NA No deaths deemed related to study vaccine by investigator per FDA materials C: 7/2781 Diabetes: 14.X Type 2 diabetes mellitus I: 1/5587, 14.X Type 2 diabetes mellitus C: 1/2781 Encephalitis: 17.X Hypoxic-ischaemic encephalopathy I: 2/5587, 17.X Hypoxic-ischaemic encephalopathy C: 0/2781 Herpes Zoster: 11.X Medically attended zoster, per FDA safety materials (reported as 0.7%) I: 38/5587 11.X Medically attended	Serious AEs (fromclinical trials.gov), Intervention (HEPLISAV) vs Control (Engerix-B), Affected / at Risk (%)Affected / at Risk (%) Total 345/5587 (6.18%) 148/2781 (5.32%) Anaemia 2/5587 (0.04%) 1/2781 (0.04%) Anaemia vitamin b12 deficiency 0/5587 (0.00%) 1/2781 (0.04%) Leukocytosis 1/5587 (0.02%) 0/2781 (0.00%) Microcytic anaemia 1/5587 (0.02%) 0/2781 (0.00%) Acute coronary syndrome 1/5587 (0.02%) 0/2781 (0.00%) Acute myocardial infarction 14/5587 (0.25%) 1/2781 (0.04%) (in AE table) Angina pectoris 2/5587 (0.04%) 1/2781 (0.04%) Angina unstable 1/5587 (0.02%) 0/2781 (0.00%) Atrial fibrillation 6/5587 (0.11%) 3/2781 (0.11%) Atrial flutter 2/5587 (0.04%) 1/2781 (0.04%) Bradycardia 2/5587 (0.04%) 0/2781 (0.00%) Cardiac arrest 3/5587 (0.05%) 0/2781 (0.00%)

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
		No prespecified AE Power NR Followup: 12 months	Supraventricular tachycardia Ventricular fibrillation Ventricular tachycardia Atrial septal defect Ebstein's anomaly Sickle cell anaemia with crisis Vertigo Vertigo positional Endocrine disorders Inappropriate antidiuretic hormone secretion Pituitary-dependent cushing's syndrome Thyroid mass Abdominal hernia Abdominal pain Appendix disorder Colitis Colitis ulcerative Constipation Cyclic vomiting syndrome Diarrhoea Diverticular perforation Diverticulum intestinal haemorrhagic Duodenal ulcer haemorrhage Gastric ulcer Gastric ulcer haemorrhage Gastritis Gastritis alcoholic Gastritis alcoholic haemorrhagic Gastritis haemorrhagic Gastrointestinal haemorrhage Gastrooesophageal reflux disease Ileus Ileus paralytic Impaired gastric emptying Inguinal hernia Intestinal obstruction Large intestine perforation	zoster, per FDA safety materials (reported as 0.3%) C: 9/2781 Meningitis: 11.X NR I: 2/5587, 11.X NA C: 0/2781 Myocardial infarction: 2.X Acute myocardial infarction I: 14/5587, 2.X Acute myocardial infarction C: 1/2781 Reproduction issues: 21.X Adenomyosis I: 0/5587, 21.X Adenomyosis C: 2/2781 Seizure: 17.X Convulsion I: 4/5587, 17.X Convulsion C: 1/2781 Spontaneous abortion: 18.X NR I: 3/5587, 18.X NR C: 2/2781 Stroke: 17.X Adjudicated stroke (FDA materials) I: 11/5587, 17.X Adjudicated stroke (FDA materials) C: 4/2781	Cardiac failure 2/5587 (0.04%) 0/2781 (0.00%) Cardiac failure acute 1/5587 (0.02%) 0/2781 (0.00%) Cardiac failure congestive 6/5587 (0.11%) 3/2781 (0.11%) Cardiac ventricular thrombosis 1/5587 (0.02%) 1/2781 (0.04%) Cardio-respiratory arrest 1/5587 (0.02%) 1/2781 (0.04%) Cardiogenic shock 1/5587 (0.02%) 0/2781 (0.00%) Cardiomyopathy 0/5587 (0.00%) 1/2781 (0.04%) Coronary artery disease 6/5587 (0.11%) 2/2781 (0.07%) Coronary artery occlusion 1/5587 (0.02%) 1/2781 (0.04%) Coronary artery stenosis 2/5587 (0.04%) 0/2781 (0.00%) Hypertensive heart disease 4/5587 (0.07%) 1/2781 (0.04%) Myocardial infarction 2/5587 (0.04%) 1/2781 (0.04%) Myocardial ischaemia 1/5587 (0.02%) 0/2781 (0.00%) Pulseless electrical activity 1/5587 (0.02%) 0/2781 (0.00%) Supraventricular tachycardia 1/5587 (0.02%) 0/2781 (0.00%) Ventricular fibrillation 1/5587 (0.02%) 0/2781 (0.00%) Ventricular tachycardia 2/5587 (0.04%) 0/2781 (0.00%) Atrial septal defect 1/5587 (0.02%) 0/2781 (0.00%) Ebstein's anomaly 1/5587 (0.02%) 1/2781 (0.04%) Sickle cell anaemia with crisis 1/5587 (0.02%) 0/2781 (0.00%) Vertigo 1/5587 (0.02%) 0/2781 (0.00%) Vertigo positional 1/5587 (0.02%) 1/2781 (0.04%) Inappropriate antidiuretic hormone secretion 1/5587 (0.02%) 0/2781 (0.00%) Pituitary-dependent cushing's syndrome 0/5587 (0.00%) 1/2781 (0.04%)

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
			Lower gastrointestinal haemorrhage Oesophageal spasm Oesophagitis Pancreatitis Pancreatitis acute Rectal haemorrhage Rectal prolapse Small intestinal obstruction Upper gastrointestinal haemorrhage Varices oesophageal Chest pain Death Device failure Drug withdrawal syndrome Non-cardiac chest pain Bile duct stone Cholecystitis Cholecystitis acute Cholecystitis chronic Cholelithiasis Hepatic cirrhosis Ischaemic hepatitis Hypersensitivity Abscess limb Abscess neck Appendicitis Appendicitis perforated Arthritis bacterial Bacteraemia Bronchitis Cellulitis Cellulitis of male external genital organ Cellulitis orbital Cholecystitis infective Clostridium difficile colitis Device related infection Diabetic foot infection Diverticulitis Erysipelas Gastroenteritis Gastroenteritis viral Groin abscess Hepatitis c Infectious colitis		Thyroid mass 0/5587 (0.00%) 1/2781 (0.04%) Abdominal hernia 1/5587 (0.02%) 0/2781 (0.00%) Abdominal pain 2/5587 (0.04%) 2/2781 (0.07%) Appendix disorder 1/5587 (0.02%) 0/2781 (0.00%) Colitis 2/5587 (0.04%) 0/2781 (0.00%) Colitis ulcerative 1/5587 (0.02%) 0/2781 (0.00%) Constipation 2/5587 (0.04%) 1/2781 (0.04%) Cyclic vomiting syndrome 1/5587 (0.02%) 0/2781 (0.00%) Diarrhoea 1/5587 (0.02%) 0/2781 (0.00%) Diverticular perforation 2/5587 (0.04%) 1/2781 (0.04%) Diverticulum intestinal haemorrhagic 1/5587 (0.02%) 0/2781 (0.00%) Duodenal ulcer haemorrhage 0/5587 (0.00%) 1/2781 (0.04%) Gastric ulcer 0/5587 (0.00%) 1/2781 (0.04%) Gastric ulcer haemorrhage 1/5587 (0.02%) 0/2781 (0.00%) Gastritis 2/5587 (0.04%) 0/2781 (0.00%) Gastritis alcoholic 1/5587 (0.02%) 0/2781 (0.00%) Gastritis alcoholic haemorrhagic 1/5587 (0.02%) 0/2781 (0.00%) Gastritis haemorrhagic 1/5587 (0.02%) 0/2781 (0.00%) Gastrointestinal haemorrhage 2/5587 (0.04%) 1/2781 (0.04%) Gastrooesophageal reflux disease 3/5587 (0.05%) 1/2781 (0.04%) Ileus 1/5587 (0.02%) 0/2781 (0.00%) Ileus paralytic 1/5587 (0.02%) 0/2781 (0.00%) Impaired gastric emptying 0/5587 (0.00%) 1/2781 (0.04%) Inguinal hernia 0/5587 (0.00%) 1/2781 (0.04%) Intestinal obstruction 0/5587 (0.00%) 1/2781 (0.04%)

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
			Influenza Latent tuberculosis Lobar pneumonia Meningitis Mycobacterium avium complex infection Osteomyelitis Otitis media bacterial Periorbital cellulitis Perirectal abscess Pneumonia Pneumonia escherichia Pneumonia staphylococcal Post procedural infection Postoperative wound infection Pyelonephritis Pyelonephritis acute Sepsis Splenic abscess Staphylococcal abscess Staphylococcal osteomyelitis Upper respiratory tract infection Urinary tract infection Urinary tract infection enterococcal Urosepsis Viral sepsis Wound infection Wound infection staphylococcal Accident Accidental overdose Ankle fracture Arterial injury Cervical vertebral fracture Concussion Craniocerebral injury Facial bones fracture Femoral neck fracture Femur fracture Foot fracture Forearm fracture Gastrointestinal anastomotic leak		Large intestine perforation 1/5587 (0.02%) 1/2781 (0.04%) Lower gastrointestinal haemorrhage 0/5587 (0.00%) 1/2781 (0.04%) Oesophageal spasm 1/5587 (0.02%) 0/2781 (0.00%) Oesophagitis 1/5587 (0.02%) 0/2781 (0.00%) Pancreatitis 2/5587 (0.04%) 0/2781 (0.00%) Pancreatitis acute 1/5587 (0.02%) 2/2781 (0.07%) Rectal haemorrhage 1/5587 (0.02%) 2/2781 (0.07%) Rectal prolapse 1/5587 (0.02%) 0/2781 (0.00%) Small intestinal obstruction 6/5587 (0.11%) 2/2781 (0.07%) Upper gastrointestinal haemorrhage 2/5587 (0.04%) 0/2781 (0.00%) Varices oesophageal 1/5587 (0.02%) 0/2781 (0.00%) Chest pain 2/5587 (0.04%) 1/2781 (0.04%) Death 2/5587 (0.04%) 0/2781 (0.00%) Device failure 1/5587 (0.02%) 0/2781 (0.00%) Drug withdrawal syndrome 0/5587 (0.00%) 1/2781 (0.04%) Non-cardiac chest pain 9/5587 (0.16%) 7/2781 (0.25%) Bile duct stone 2/5587 (0.04%) 1/2781 (0.04%) Cholecystitis 5/5587 (0.09%) 2/2781 (0.07%) Cholecystitis acute 0/5587 (0.00%) 2/2781 (0.07%) Cholecystitis chronic 1/5587 (0.02%) 2/2781 (0.07%) Cholelithiasis 4/5587 (0.07%) 4/2781 (0.14%) Hepatic cirrhosis 1/5587 (0.02%) 1/2781 (0.04%) Ischaemic hepatitis 1/5587 (0.02%) 0/2781 (0.00%) Hypersensitivity 1/5587 (0.02%) 1/2781 (0.04%)

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
			Gun shot wound Hand fracture Head injury Hip fracture Humerus fracture Intentional overdose Jaw fracture Laceration Lower limb fracture Lumbar vertebral fracture Overdose Patella fracture Peripheral nerve injury Post procedural haematoma Postoperative fever Postoperative ileus Procedural intestinal perforation Procedural pain Rib fracture Scapula fracture Seroma Spinal fracture Stab wound Tibia fracture Toxicity to various agents Traumatic haemothorax Urinary retention postoperative Wrist fracture Investigations Electrophoresis protein abnormal Foetal heart rate abnormal International normalised ratio increased Dehydration Diabetes mellitus inadequate control Diabetic ketoacidosis Dyslipidaemia Hypoglycaemia Hypokalaemia Hyponatraemia Type 2 diabetes mellitus Back pain		Abscess limb 1/5587 (0.02%) 0/2781 (0.00%) Abscess neck 1/5587 (0.02%) 0/2781 (0.00%) Appendicitis 3/5587 (0.05%) 1/2781 (0.04%) Appendicitis perforated 2/5587 (0.04%) 0/2781 (0.00%) Arthritis bacterial 1/5587 (0.02%) 0/2781 (0.00%) Bacteraemia 1/5587 (0.02%) 0/2781 (0.00%) Bronchitis 3/5587 (0.05%) 0/2781 (0.00%) Cellulitis 7/5587 (0.13%) 4/2781 (0.14%) Cellulitis of male external genital organ 1/5587 (0.02%) 0/2781 (0.00%) Cellulitis orbital 0/5587 (0.00%) 1/2781 (0.04%) Cholecystitis infective 1/5587 (0.02%) 0/2781 (0.00%) Clostridium difficile colitis 1/5587 (0.02%) 0/2781 (0.00%) Device related infection 1/5587 (0.02%) 0/2781 (0.00%) Diabetic foot infection 2/5587 (0.04%) 1/2781 (0.04%) Diverticulitis 1/5587 (0.02%) 2/2781 (0.07%) Erysipelas 0/5587 (0.00%) 1/2781 (0.04%) Gastroenteritis 4/5587 (0.07%) 1/2781 (0.04%) Gastroenteritis viral 0/5587 (0.00%) 1/2781 (0.04%) Groin abscess 1/5587 (0.02%) 1/2781 (0.04%) Hepatitis c 2/5587 (0.04%) 0/2781 (0.00%) Infectious colitis 2/5587 (0.04%) 0/2781 (0.00%) Influenza 2/5587 (0.04%) 1/2781 (0.04%) Latent tuberculosis 1/5587 (0.02%) 0/2781 (0.00%) Lobar pneumonia 2/5587 (0.04%) 0/2781 (0.00%)

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
			Bursitis Costochondritis Flank pain Intervertebral disc degeneration Intervertebral disc protrusion Lumbar spinal stenosis Muscular weakness Musculoskeletal chest pain Myositis Neck pain Osteoarthritis Rhabdomyolysis Rotator cuff syndrome Spinal column stenosis Spinal osteoarthritis Spondylolisthesis Vertebral foraminal stenosis Adenocarcinoma of colon Brain neoplasm benign Breast cancer Cervix carcinoma Cholangiocarcinoma Clear cell renal cell carcinoma Colon adenoma Ductal adenocarcinoma of pancreas Endometrial cancer Hodgkin's disease Intraductal papillary mucinous neoplasm Intraductal proliferative breast lesion Invasive ductal breast carcinoma Lung adenocarcinoma Lung cancer metastatic Malignant melanoma Metastatic renal cell carcinoma Oesophageal adenocarcinoma Ovarian cancer stage iii		Mycobacterium avium complex infection 1/5587 (0.02%) 0/2781 (0.00%) Osteomyelitis 1/5587 (0.02%) 1/2781 (0.04%) Otitis media bacterial 1/5587 (0.02%) 0/2781 (0.00%) Periorbital cellulitis 1/5587 (0.02%) 0/2781 (0.00%) Perirectal abscess 1/5587 (0.02%) 1/2781 (0.04%) Pneumonia 15/5587 (0.27%) 8/2781 (0.29%) Pneumonia escherichia 1/5587 (0.02%) 0/2781 (0.00%) Pneumonia staphylococcal 1/5587 (0.02%) 0/2781 (0.00%) Post procedural infection 0/5587 (0.00%) 1/2781 (0.04%) Postoperative wound infection 0/5587 (0.00%) 1/2781 (0.04%) Pyelonephritis 2/5587 (0.04%) 1/2781 (0.04%) Pyelonephritis acute 2/5587 (0.04%) 0/2781 (0.00%) Sepsis 5/5587 (0.09%) 1/2781 (0.04%) Splenic abscess 1/5587 (0.02%) 0/2781 (0.00%) Staphylococcal abscess 1/5587 (0.02%) 1/2781 (0.04%) Staphylococcal osteomyelitis 0/5587 (0.00%) 1/2781 (0.04%) Upper respiratory tract infection 1/5587 (0.02%) 0/2781 (0.00%) Urinary tract infection 0/5587 (0.00%) 1/2781 (0.04%) Urinary tract infection enterococcal 1/5587 (0.02%) 0/2781 (0.00%) Urosepsis 4/5587 (0.07%) 2/2781 (0.07%) Viral sepsis 1/5587 (0.02%) 0/2781 (0.00%) Wound infection 0/5587 (0.00%) 1/2781 (0.04%) Wound infection staphylococcal 1/5587 (0.02%) 0/2781 (0.00%) Accident 1/5587 (0.02%) 0/2781 (0.00%)

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
			Ovarian germ cell teratoma Pancreatic carcinoma Pancreatic carcinoma metastatic Papillary thyroid cancer Pelvic neoplasm Plasma cell myeloma Prostate cancer Prostate cancer stage ii Rectal adenocarcinoma Small cell lung cancer metastatic Squamous cell carcinoma of the cervix Squamous cell carcinoma of the oral cavity Uterine leiomyoma Nervous system disorders Carotid artery stenosis Carotid sinus syndrome Cauda equina syndrome Cerebrovascular accident Cervical myelopathy Complex partial seizures Convulsion Dizziness Embolic stroke Haemorrhagic stroke Headache Hepatic encephalopathy Hypoaesthesia Hypoxic-ischaemic encephalopathy Ischaemic stroke Lacunar infarction Lumbar radiculopathy Migraine Neuropathy peripheral Radial nerve palsy Spondylitic myelopathy Subarachnoid haemorrhage Syncope Thalamic infarction Thrombotic stroke Transient global amnesia		Accidental overdose 1/5587 (0.02%) 0/2781 (0.00%) Ankle fracture 1/5587 (0.02%) 1/2781 (0.04%) Arterial injury 1/5587 (0.02%) 0/2781 (0.00%) Cervical vertebral fracture 1/5587 (0.02%) 1/2781 (0.04%) Concussion 1/5587 (0.02%) 0/2781 (0.00%) Craniocerebral injury 0/5587 (0.00%) 1/2781 (0.04%) Facial bones fracture 0/5587 (0.00%) 1/2781 (0.04%) Femoral neck fracture 0/5587 (0.00%) 2/2781 (0.07%) Femur fracture 2/5587 (0.04%) 0/2781 (0.00%) Foot fracture 1/5587 (0.02%) 0/2781 (0.00%) Forearm fracture 0/5587 (0.00%) 1/2781 (0.04%) Gastrointestinal anastomotic leak 0/5587 (0.00%) 1/2781 (0.04%) Gun shot wound 3/5587 (0.05%) 0/2781 (0.00%) Hand fracture 1/5587 (0.02%) 0/2781 (0.00%) Head injury 0/5587 (0.00%) 1/2781 (0.04%) Hip fracture 2/5587 (0.04%) 0/2781 (0.00%) Humerus fracture 2/5587 (0.04%) 0/2781 (0.00%) Intentional overdose 1/5587 (0.02%) 0/2781 (0.00%) Jaw fracture 1/5587 (0.02%) 0/2781 (0.00%) Laceration 1/5587 (0.02%) 1/2781 (0.04%) Lower limb fracture 1/5587 (0.02%) 0/2781 (0.00%) Lumbar vertebral fracture 2/5587 (0.04%) 0/2781 (0.00%) Overdose 1/5587 (0.02%) 0/2781 (0.00%)

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
			Transient ischaemic attack Abortion spontaneous Foetal growth restriction Gestational diabetes Oligohydramnios Placenta praevia Psychiatric disorders Bipolar disorder Bipolar i disorder Confusional state Delirium Depression Depression suicidal Mental status changes Schizoaffective disorder Schizophrenia Substance-induced psychotic disorder Suicidal ideation Suicide attempt Acute prerenal failure Bladder disorder Calculus ureteric Nephrolithiasis Prerenal failure Renal failure Renal failure acute Renal failure chronic Tubulointerstitial nephritis Urinary retention Adenomyosis Cystocele Dysfunctional uterine bleeding Postmenopausal haemorrhage Prostatitis Vaginal haemorrhage Acute respiratory distress syndrome Acute respiratory failure Asthma Chronic obstructive pulmonary disease Diaphragmatic paralysis Diaphragmatic rupture Dyspnoea		Patella fracture 2/5587 (0.04%) 0/2781 (0.00%) Peripheral nerve injury 1/5587 (0.02%) 0/2781 (0.00%) Post procedural haematoma 2/5587 (0.04%) 0/2781 (0.00%) Postoperative fever 1/5587 (0.02%) 1/2781 (0.04%) Postoperative ileus 1/5587 (0.02%) 1/2781 (0.04%) Procedural intestinal perforation 1/5587 (0.02%) 0/2781 (0.00%) Procedural pain 0/5587 (0.00%) 2/2781 (0.07%) Rib fracture 2/5587 (0.04%) 0/2781 (0.00%) Scapula fracture 1/5587 (0.02%) 0/2781 (0.00%) Seroma 1/5587 (0.02%) 0/2781 (0.00%) Spinal fracture 1/5587 (0.02%) 0/2781 (0.00%) Stab wound 1/5587 (0.02%) 0/2781 (0.00%) Tibia fracture 1/5587 (0.02%) 0/2781 (0.00%) Toxicity to various agents 5/5587 (0.09%) 1/2781 (0.04%) Traumatic haemothorax 0/5587 (0.00%) 1/2781 (0.04%) Urinary retention postoperative 0/5587 (0.00%) 1/2781 (0.04%) Wrist fracture 0/5587 (0.00%) 1/2781 (0.04%) Electrophoresis protein abnormal 1/5587 (0.02%) 0/2781 (0.00%) Foetal heart rate abnormal 0/5587 (0.00%) 1/2781 (0.04%) International normalised ratio increased 1/5587 (0.02%) 0/2781 (0.00%) Dehydration 1/5587 (0.02%) 3/2781 (0.11%) Diabetes mellitus inadequate control 2/5587 (0.04%) 1/2781 (0.04%) Diabetic ketoacidosis 5/5587 (0.09%) 1/2781 (0.04%) Dyslipidaemia 1/5587 (0.02%) 0/2781 (0.00%)

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
			Haemothorax Hiccups Hypoxia Lung infiltration Nasal polyps Pleural effusion Pleuritic pain Pneumonia aspiration Pneumothorax Pulmonary embolism Pulmonary oedema Respiratory arrest Respiratory failure Diabetic foot Hidradenitis Social circumstances Victim of homicide Vascular disorders Aortic aneurysm Aortic stenosis Deep vein thrombosis Hypertension Hypertensive crisis Hypotension Peripheral vascular disorder Thrombophlebitis superficial Infections and infestations Acute sinusitis Bronchitis Sinusitis Upper respiratory tract infection Urinary tract infection Metabolism and nutrition disorders Type 2 diabetes mellitus Arthralgia Back pain Musculoskeletal pain Osteoarthritis Pain in extremity Cough Hypertension		Hypoglycaemia 1/5587 (0.02%) 0/2781 (0.00%) Hypokalaemia 2/5587 (0.04%) 2/2781 (0.07%) Hyponatraemia 2/5587 (0.04%) 0/2781 (0.00%) Back pain 1/5587 (0.02%) 1/2781 (0.04%) Bursitis 1/5587 (0.02%) 0/2781 (0.00%) Costochondritis 0/5587 (0.00%) 1/2781 (0.04%) Flank pain 0/5587 (0.00%) 1/2781 (0.04%) Intervertebral disc degeneration 1/5587 (0.02%) 1/2781 (0.04%) Intervertebral disc protrusion 1/5587 (0.02%) 0/2781 (0.00%) Lumbar spinal stenosis 2/5587 (0.04%) 0/2781 (0.00%) Muscular weakness 1/5587 (0.02%) 0/2781 (0.00%) Musculoskeletal chest pain 1/5587 (0.02%) 0/2781 (0.00%) Myositis 0/5587 (0.00%) 1/2781 (0.04%) Neck pain 0/5587 (0.00%) 1/2781 (0.04%) Osteoarthritis 7/5587 (0.13%) 3/2781 (0.11%) Rhabdomyolysis 2/5587 (0.04%) 0/2781 (0.00%) Rotator cuff syndrome 0/5587 (0.00%) 1/2781 (0.04%) Spinal column stenosis 1/5587 (0.02%) 0/2781 (0.00%) Spinal osteoarthritis 2/5587 (0.04%) 0/2781 (0.00%) Spondylolisthesis 1/5587 (0.02%) 0/2781 (0.00%) Vertebral foraminal stenosis 1/5587 (0.02%) 0/2781 (0.00%) Adenocarcinoma of colon 1/5587 (0.02%) 1/2781 (0.04%) Brain neoplasm benign 1/5587 (0.02%) 0/2781 (0.00%) Breast cancer 2/5587 (0.04%) 0/2781 (0.00%)

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
					Cervix carcinoma 0/5587 (0.00%) 1/2781 (0.04%) Cholangiocarcinoma 0/5587 (0.00%) 1/2781 (0.04%) Clear cell renal cell carcinoma 1/5587 (0.02%) 0/2781 (0.00%) Colon adenoma 2/5587 (0.04%) 0/2781 (0.00%) Ductal adenocarcinoma of pancreas 1/5587 (0.02%) 0/2781 (0.00%) Endometrial cancer 1/5587 (0.02%) 0/2781 (0.00%) Hodgkin's disease 1/5587 (0.02%) 0/2781 (0.00%) Intraductal papillary mucinous neoplasm 1/5587 (0.02%) 0/2781 (0.00%) Intraductal proliferative breast lesion 2/5587 (0.04%) 0/2781 (0.00%) Invasive ductal breast carcinoma 2/5587 (0.04%) 0/2781 (0.00%) Lung adenocarcinoma 1/5587 (0.02%) 0/2781 (0.00%) Lung cancer metastatic 1/5587 (0.02%) 0/2781 (0.00%) Malignant melanoma 1/5587 (0.02%) 0/2781 (0.00%) Metastatic renal cell carcinoma 1/5587 (0.02%) 0/2781 (0.00%) Oesophageal adenocarcinoma 0/5587 (0.00%) 1/2781 (0.04%) Ovarian cancer stage iii 0/5587 (0.00%) 1/2781 (0.04%) Ovarian germ cell teratoma 0/5587 (0.00%) 1/2781 (0.04%) Pancreatic carcinoma 1/5587 (0.02%) 0/2781 (0.00%) Pancreatic carcinoma metastatic 1/5587 (0.02%) 1/2781 (0.04%) Papillary thyroid cancer 0/5587 (0.00%) 1/2781 (0.04%) Pelvic neoplasm 1/5587 (0.02%) 0/2781 (0.00%) Plasma cell myeloma 1/5587 (0.02%) 0/2781 (0.00%) Prostate cancer 3/5587 (0.05%) 4/2781 (0.14%)

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
					Prostate cancer stage ii 1/5587 (0.02%) 0/2781 (0.00%) Rectal adenocarcinoma 1/5587 (0.02%) 0/2781 (0.00%) Small cell lung cancer metastatic 1/5587 (0.02%) 0/2781 (0.00%) Squamous cell carcinoma of the cervix 1/5587 (0.02%) 0/2781 (0.00%) Squamous cell carcinoma of the oral cavity 1/5587 (0.02%) 0/2781 (0.00%) Uterine leiomyoma 1/5587 (0.02%) 2/2781 (0.07%) Carotid artery stenosis 2/5587 (0.04%) 1/2781 (0.04%) Carotid sinus syndrome 0/5587 (0.00%) 1/2781 (0.04%) Cauda equina syndrome 1/5587 (0.02%) 0/2781 (0.00%) Cerebrovascular accident 7/5587 (0.13%) 3/2781 (0.11%) Cervical myelopathy 1/5587 (0.02%) 1/2781 (0.04%) Complex partial seizures 1/5587 (0.02%) 1/2781 (0.04%) Dizziness 2/5587 (0.04%) 0/2781 (0.00%) Embolic stroke 1/5587 (0.02%) 0/2781 (0.00%) Haemorrhagic stroke 0/5587 (0.00%) 1/2781 (0.04%) Headache 1/5587 (0.02%) 0/2781 (0.00%) Hepatic encephalopathy 1/5587 (0.02%) 0/2781 (0.00%) Hypoaesthesia 0/5587 (0.00%) 1/2781 (0.04%) Hypoxic-ischaemic encephalopathy (in AE table) Ischaemic stroke 2/5587 (0.04%) 1/2781 (0.04%) Lacunar infarction 1/5587 (0.02%) 0/2781 (0.00%) Lumbar radiculopathy 1/5587 (0.02%) 0/2781 (0.00%) Migraine 1/5587 (0.02%) 0/2781 (0.00%) Neuropathy peripheral 1/5587 (0.02%) 0/2781 (0.00%)

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
					Radial nerve palsy 1/5587 (0.02%) 0/2781 (0.00%) Spondylitic myelopathy 0/5587 (0.00%) 1/2781 (0.04%) Subarachnoid haemorrhage 1/5587 (0.02%) 0/2781 (0.00%) Syncope 2/5587 (0.04%) 4/2781 (0.14%) Thalamic infarction 1/5587 (0.02%) 0/2781 (0.00%) Thrombotic stroke 0/5587 (0.00%) 1/2781 (0.04%) Transient global amnesia 1/5587 (0.02%) 0/2781 (0.00%) Transient ischaemic attack 4/5587 (0.07%) 1/2781 (0.04%) Abortion spontaneous 3/5587 (0.05%) 2/2781 (0.07%) (in AE table) Foetal growth restriction 1/5587 (0.02%) 0/2781 (0.00%) Gestational diabetes 1/5587 (0.02%) 0/2781 (0.00%) Oligohydramnios 0/5587 (0.00%) 1/2781 (0.04%) Placenta praevia 1/5587 (0.02%) 0/2781 (0.00%) Bipolar disorder 3/5587 (0.05%) 1/2781 (0.04%) Bipolar i disorder 4/5587 (0.07%) 0/2781 (0.00%) Confusional state 0/5587 (0.00%) 1/2781 (0.04%) Delirium 1/5587 (0.02%) 0/2781 (0.00%) Depression 5/5587 (0.09%) 1/2781 (0.04%) Depression suicidal 1/5587 (0.02%) 0/2781 (0.00%) Mental status changes 3/5587 (0.05%) 1/2781 (0.04%) Schizoaffective disorder 1/5587 (0.02%) 0/2781 (0.00%) Schizophrenia 1/5587 (0.02%) 0/2781 (0.00%) Substance-induced psychotic disorder 0/5587 (0.00%) 1/2781 (0.04%) Suicidal ideation 3/5587 (0.05%) 1/2781 (0.04%)

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
					Suicide attempt 3/5587 (0.05%) 1/2781 (0.04%) Acute prerenal failure 1/5587 (0.02%) 0/2781 (0.00%) Bladder disorder 0/5587 (0.00%) 1/2781 (0.04%) Calculus ureteric 4/5587 (0.07%) 2/2781 (0.07%) Nephrolithiasis 0/5587 (0.00%) 1/2781 (0.04%) Prerenal failure 1/5587 (0.02%) 0/2781 (0.00%) Renal failure 0/5587 (0.00%) 1/2781 (0.04%) Renal failure acute 4/5587 (0.07%) 3/2781 (0.11%) Renal failure chronic 2/5587 (0.04%) 0/2781 (0.00%) Tubulointerstitial nephritis 1/5587 (0.02%) 0/2781 (0.00%) Urinary retention 0/5587 (0.00%) 2/2781 (0.07%) Adenomyosis 0/5587 (0.00%) 2/2781 (0.07%) (in AE table) Cystocele 1/5587 (0.02%) 0/2781 (0.00%) Dysfunctional uterine bleeding 1/5587 (0.02%) 0/2781 (0.00%) Postmenopausal haemorrhage 0/5587 (0.00%) 1/2781 (0.04%) Prostatitis 0/5587 (0.00%) 1/2781 (0.04%) Respiratory, thoracic and mediastinal disorders Acute respiratory distress syndrome 1/5587 (0.02%) 1/2781 (0.04%) Acute respiratory failure 6/5587 (0.11%) 1/2781 (0.04%) Chronic obstructive pulmonary disease 9/5587 (0.16%) 3/2781 (0.11%) Diaphragmatic paralysis 1/5587 (0.02%) 0/2781 (0.00%) Diaphragmatic rupture 1/5587 (0.02%) 0/2781 (0.00%) Dyspnoea 2/5587 (0.04%) 0/2781 (0.00%)

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
					Haemothorax 1/5587 (0.02%) 0/2781 (0.00%) Hiccups 1/5587 (0.02%) 0/2781 (0.00%) Hypoxia 2/5587 (0.04%) 0/2781 (0.00%) Lung infiltration 1/5587 (0.02%) 0/2781 (0.00%) Nasal polyps 1/5587 (0.02%) 0/2781 (0.00%) Pleural effusion 2/5587 (0.04%) 0/2781 (0.00%) Pleuritic pain 1/5587 (0.02%) 0/2781 (0.00%) Pneumonia aspiration 1/5587 (0.02%) 1/2781 (0.04%) Pneumothorax 4/5587 (0.07%) 1/2781 (0.04%) Pulmonary embolism 3/5587 (0.05%) 2/2781 (0.07%) Pulmonary oedema 1/5587 (0.02%) 0/2781 (0.00%) Respiratory arrest 0/5587 (0.00%) 1/2781 (0.04%) Respiratory failure 1/5587 (0.02%) 2/2781 (0.07%) Diabetic foot 1/5587 (0.02%) 2/2781 (0.07%) Hidradenitis 1/5587 (0.02%) 0/2781 (0.00%) Victim of homicide 1/5587 (0.02%) 0/2781 (0.00%) Aortic aneurysm 2/5587 (0.04%) 0/2781 (0.00%) Aortic stenosis 0/5587 (0.00%) 1/2781 (0.04%) Deep vein thrombosis 4/5587 (0.07%) 3/2781 (0.11%) Hypertension 5/5587 (0.09%) 3/2781 (0.11%) Hypertensive crisis 2/5587 (0.04%) 0/2781 (0.00%) Hypotension 2/5587 (0.04%) 2/2781 (0.07%) Peripheral vascular disorder 1/5587 (0.02%) 0/2781 (0.00%) Thrombophlebitis superficial 1/5587 (0.02%) 0/2781 (0.00%)

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
					Risk factors: Subgroup analysis (in people aged 60-70 years with diabetes mellitus, from related study of risk group): Medically attended AE grade 3 or 4: Intervention 77/327 (23.5%) vs Control 34/153 (22.2%) No serious AEs related to the study treatment were reported in either group. Immune-mediated AE: Intervention 1/327 (0.3%) (polymyalgia rheumatica) vs Control 0/153 (0%) Deaths: Intervention 3/327 (0.9%) vs Control 1/153 (0.6%) Adverse events and deaths were comparable between groups
Heyward, 2013[132] Dynavax Technologies Corporation, 2010[252]; Hyer, 2018[287]; Euctr, 2014[253]; U.S Food and Drug Administration, 2017[379] NCT01005407 Article RCT N=2452 Industry funded Canada, USA	Age: 54.0 % female: 52 Ethnicity: 82% White, 18% Non-white Healthy participants 40–70 years old with no clinically significant illness who were seronegative for HBsAg, anti-has, antibody against hepatitis B core antigen (anti-abc) and HIV. Out of scope: None	Hep B HEPLISAV-B 20 ug of yeast-derived recombinant HBsAg and 3000 mcg of 1018 adjuvant per 0.5 mL dose each times 2 doses (3rd dose was placebo) Intramuscular Other : 1018 adjuvant preservative free No co-intervention Hep B HBsAg-Eng (Engerix-B) Engerix-B 20 mcg of recombinant HBsAg combined with 500 mcg aluminum hydroxide adjuvant per 1.0 mL dose times 3 doses Intramuscular Aluminumpreservative free Counts	Anaemia Acute myocardial infarction Angina pectoris Angina unstable Atrial fibrillation Cardiac failure Cardiomyopathy Coronary artery disease Coronary artery stenosis Vertigo Abdominal hernia Barrett's oesophagus Erosive oesophagitis Gastric haemorrhage Gastric ulcer Gastrooesophageal reflux disease Haematemesis Inguinal hernia Small intestinal obstruction Chest pain Non-cardiac chest pain Cholecystitis Cavernous sinus thrombosis Diverticulitis Gastroenteritis salmonella Localised infection Perirectal abscess Pneumonia Post procedural infection	Asthma: 22.X NR I: 2/1968, 22.X Reactive airway disease (mentioned in article only) C: 1/481 Autoimmune disease: 10.2 Autoimmune hypothyroidism (n=2), vitiligo (n=1); new onset, and mild to moderate in severity (not serious; mentioned in article only) I: 3/1968, 10.X NA C: 0/481 Cardiovascular events: 2.X Acute myocardial infarction I: 2/1968, 2.XAcute myocardial infarction C: 1/481 Death: NA Death from pulmonary embolism I: 1/1968, NA Death from heart failure C: 1/481 Herpes Zoster: 11.X From FDA materials I: 4/1968 11.X From FDA materials C: 1/481 Myocardial infarction: 2.X Acute myocardial infarction I: 2/1968, 2.X Acute myocardial infarction C: 1/481 Reproduction issues: 21.X Endometriosis I: 1/1968, 21.X Endometriosis C: 0/481	Serious AEs (from clinicaltrials.gov) Intervention (HEPLISAV and/or Placebo) vs Control (Engerix-B) Affected / at Risk (%)Affected / at Risk (%) Total 78/1968 (3.96%) 23/481 (4.78%) Blood and lymphatic system disorders Anaemia 0/1968 (0.00%) 1/481 (0.21%) Cardiac disorders Acute myocardial infarction(in AE table) Angina pectoris1/1968 (0.05%) 0/481 (0.00%) Angina unstable 0/1968 (0.00%) 1/481 (0.21%) Atrial fibrillation 1/1968 (0.05%) 0/481 (0.00%) Cardiac failure 0/1968 (0.00%) 1/481 (0.21%) Cardiomyopathy 1/1968 (0.05%) 0/481 (0.00%) Coronary artery disease 2/1968 (0.10%) 1/481 (0.21%) Coronary artery stenosis 0/1968 (0.00%) 1/481 (0.21%) Ear and labyrinth disorders Vertigo 1/1968 (0.05%) 0/481 (0.00%) Gastrointestinal disorders Abdominal hernia 1/1968 (0.05%) 0/481 (0.00%) Barrett's oesophagus 0/1968 (0.00%) 1/481 (0.21%)

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
		No prespecified AE Power other outcome Followup: 12 months	Staphylococcal infection Alcohol poisoning Ankle fracture Contusion Delayed recovery from anaesthesia Fall Fibula fracture Foot fracture Gun shot wound Joint injury Meniscus injury Muscle strain Thermal burn Tibia fracture Dehydration Diabetic ketoacidosis Hyperglycaemia Hypokalaemia Hyponatraemia Water intoxication Bursitis Intervertebral disc degeneration Intervertebral disc protrusion Loose body in joint Lumbar spinal stenosis Musculoskeletal chest pain Neck pain Osteoarthritis Spinal column stenosis Spondylolisthesis Brain neoplasm Breast cancer Colon adenoma Colon cancer stage iv Inflammatory carcinoma of the breast Invasive ductal breast carcinoma Non-small cell lung cancer metastatic Prostate cancer Uterine leiomyoma Benign intracranial hypertension		Erosive oesophagitis 1/1968 (0.05%) 0/481 (0.00%) Gastric haemorrhage 0/1968 (0.00%) 1/481 (0.21%) Gastric ulcer 1/1968 (0.05%) 0/481 (0.00%) Gastrooesophageal reflux disease 1/1968 (0.05%) 0/481 (0.00%) Haematemesis 1/1968 (0.05%) 0/481 (0.00%) Inguinal hernia 1/1968 (0.05%) 0/481 (0.00%) Small intestinal obstruction 1/1968 (0.05%) 0/481 (0.00%) General disorders Chest pain 0/1968 (0.00%) 1/481 (0.21%) Non-cardiac chest pain 3/1968 (0.15%) 1/481 (0.21%) Hepatobiliary disorders Cholecystitis 1/1968 (0.05%) 0/481 (0.00%) Infections and infestations Cavernous sinus thrombosis 1/1968 (0.05%) 0/481 (0.00%) Diverticulitis 1/1968 (0.05%) 0/481 (0.00%) Gastroenteritis salmonella 0/1968 (0.00%) 1/481 (0.21%) Localised infection 1/1968 (0.05%) 0/481 (0.00%) Perirectal abscess 1/1968 (0.05%) 0/481 (0.00%) Pneumonia 1/1968 (0.05%) 0/481 (0.00%) Post procedural infection 1/1968 (0.05%) 0/481 (0.00%) Staphylococcal infection 1/1968 (0.05%) 0/481 (0.00%) Injury, poisoning and procedural complications Alcohol poisoning 2/1968 (0.10%) 0/481 (0.00%) Ankle fracture 2/1968 (0.10%) 0/481 (0.00%) Contusion 1/1968 (0.05%) 0/481 (0.00%)

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
			Spondylitic myelopathy Subarachnoid haemorrhage Major depression Endometriosis Haemorrhagic ovarian cyst Menstruation irregular Asthma Bronchial hyperreactivity Chronic obstructive pulmonary disease Hypoxia Pulmonary embolism Deep vein thrombosis Hypertension Nasopharyngitis Injection site pain Redness Swelling Fever Malaise Headache Myalgia Fatigue Hypothyroidism Vitiligo		Delayed recovery from anaesthesia 0/1968 (0.00%) 1/481 (0.21%) Fall 1/1968 (0.05%) 0/481 (0.00%) Fibula fracture 1/1968 (0.05%) 0/481 (0.00%) Foot fracture 1/1968 (0.05%) 0/481 (0.00%) Gun shot wound 1/1968 (0.05%) 0/481 (0.00%) Joint injury 1/1968 (0.05%) 1/481 (0.21%) Meniscus injury 1/1968 (0.05%) 1/481 (0.21%) Muscle strain 1/1968 (0.05%) 0/481 (0.00%) Thermal burn 1/1968 (0.05%) 0/481 (0.00%) Tibia fracture 1/1968 (0.05%) 0/481 (0.00%) Metabolism and nutrition disorders Dehydration 0/1968 (0.00%) 1/481 (0.21%) Diabetic ketoacidosis 1/1968 (0.05%) 0/481 (0.00%) Hyperglycaemia 1/1968 (0.05%) 0/481 (0.00%) Hypokalaemia 1/1968 (0.05%) 0/481 (0.00%) Hyponatraemia 2/1968 (0.10%) 0/481 (0.00%) Water intoxication 1/1968 (0.05%) 0/481 (0.00%) Musculoskeletal and connective tissue disorders Bursitis 0/1968 (0.00%) 1/481 (0.21%) Intervertebral disc degeneration 1/1968 (0.05%) 1/481 (0.21%) Intervertebral disc protrusion 4/1968 (0.20%) 0/481 (0.00%) Loose body in joint 1/1968 (0.05%) 0/481 (0.00%) Lumbar spinal stenosis 1/1968 (0.05%) 1/481 (0.21%) Musculoskeletal chest pain 1/1968 (0.05%) 0/481 (0.00%) Neck pain 1/1968 (0.05%) 0/481 (0.00%)

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
					Osteoarthritis 9/1968 (0.46%) 2/481 (0.42%) Spinal column stenosis 2/1968 (0.10%) 0/481 (0.00%) Spondylolisthesis 1/1968 (0.05%) 0/481 (0.00%) Neoplasms benign, malignant and unspecified (incl cysts and polyps) Brain neoplasm 1/1968 (0.05%) 0/481 (0.00%) Breast cancer 1/1968 (0.05%) 1/481 (0.21%) Colon adenoma 2/1968 (0.10%) 0/481 (0.00%) Colon cancer stage iv 1/1968 (0.05%) 0/481 (0.00%) Inflammatory carcinoma of the breast 1/1968 (0.05%) 0/481 (0.00%) Invasive ductal breast carcinoma 0/1968 (0.00%) 1/481 (0.21%) Non-small cell lung cancer metastatic 1/1968 (0.05%) 0/481 (0.00%) Prostate cancer 1/1968 (0.05%) 3/481 (0.62%) Uterine leiomyoma 1/1968 (0.05%) 0/481 (0.00%) Nervous system disorders Benign intracranial hypertension † 1 0/1968 (0.00%) 1/481 (0.21%) Spondylitic myelopathy 1/1968 (0.05%) 0/481 (0.00%) Subarachnoid haemorrhage 1/1968 (0.05%) 0/481 (0.00%) Psychiatric disorders Major depression 1/1968 (0.05%) 0/481 (0.00%) Reproductive system and breast disorders Endometriosis 1/1968 (0.05%) 0/481 (0.00%) Haemorrhagic ovarian cyst 0/1968 (0.00%) 1/481 (0.21%) Menstruation irregular (in AE table) Respiratory, thoracic and mediastinal disorders Asthma (in AE table)

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
					Bronchial hyperreactivity 0/1968 (0.00%) 1/481 (0.21%) Chronic obstructive pulmonary disease 1/1968 (0.05%) 1/481 (0.21%) Hypoxia 1/1968 (0.05%) 0/481 (0.00%) Pulmonary embolism 2/1968 (0.10%) 0/481 (0.00%) Vascular disorders Deep vein thrombosis2/1968 (0.10%) 1/481 (0.21%) Hypertension1/1968 (0.05%) 0/481 (0.00%) Risk factors: NR
Huang, 2015[134] Article Cohort study N=15316 Not industry funded USA	Age: 49 years (18) % female: 52% Ethnicity: 18% Mexican-American, 8% Other Hispanic, 46% Non-Hispanic White, 18% Non-Hispanic Black, 4% Others Adults 20 years and older who participated in the National Health and Nutrition Examination Survey (NHANES) study between 2005 and 2010 Out of scope: None	Hep B Brand NR Presumed to be non-recombinant HepB (i.e., not Heplisav given timeframe) Three doses (some received fewer) Route NR adjuvant NR preservative NR No co-intervention No intervention Analytic study Prespecified AE Power NR Followup: months	Diabetes	Diabetes: 10.X NR I: 472/4063, 10.X NR C: 2154/11253	HepB Vaccination (by self-report) 472 (11.62%) vs 2,154 (19.14%); Model 1 0.56 (0.50–0.62); Model 2 1.01 (0.89–1.14); Model 3 1.03 (0.91–1.16); Model 4 1.08 (0.96–1.23) HepB Immunization (by serology) 156 (6.72%) vs 2,470 (19.01%); Model 1 0.31 (0.26–0.36); Model 2 0.68 (0.56–0.95); Model 3 (0.58–0.83); Model 4 (0.62–0.90) HepB Successful vaccination (by both self-report and serology) 85 (5.36%) vs 2,541 (18.51%); Model 1 0.25 (0.20–0.31); Model 2 0.57 (0.45–0.72); Model 3 0.59 (0.46–0.75); Model 4 0.67 (0.52–0.84) Model 1: unadjusted Model 2: adjusted for gender, age, and BMI Model 3: adjusted for gender, age, BMI, and ethnic/racial group Model 4: adjusted for gender, age, BMI, ethnic/race group, active smoker, active alcohol consumption, family history of diabetes, poverty index, and education Risk factors: No
Langer-Gould, 2014[151] Article Case-Control N=4665	Age: Mean(range): Cases: 39.3 (2.2-85.8); controls: 39.3 (2.2-85.9)	Hep B Engerix-B,Recombivax HB Route NR adjuvant NR preservative NR No co-intervention	Acquired central nervous system demyelinating syndromes (CNS ADS) Multiple sclerosis (MS) Clinically isolated syndrome (CIS)	NA	No significant OR for single-antigen Hep B vaccine and any of the demyelinating disorders (from eTable) Cases N vaccinated [N=780](%)/Control N vaccinated [N=3885](%) All acquired central nervous system demyelinating syndromes (CNS ADS):

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
Not industry funded USA	% female: 69% Ethnicity: Cases: 43% White, 18% Black, 30% Hispanic, <1% Native American/Alaskan, 4% Asian/Pacific Islander, 5% Multiple/other/unknown; Controls: 32% White, 11% Black, 37% Hispanic, <1% Native American/Alaskan, 9%Asian/Pacific Islander, 11% Multiple/other/unknown Cases were newly diagnosed multiple sclerosis or any other central nervous system acquired demyelinating syndrome and controls matched on date of birth, sex, zip code at time of case patient's symptoms onset date. Out of scope: None	No intervention No Hep B vaccine Analytic study Insufficient power Followup: 36 months	Acute disseminated encephalomyelitis (ADEM)		2 weeks: 0(0.0)/0(0.0); OR NA 30 days: 0(0.00)/1(0.0); OR NA 42 days: 0(0.0)/1(0.0); OR NA 90 days: 1(0.1)/2(0.1); OR 2.5(0.2,27.6) 180 days: 2(0.3)/4(0.1); OR 2.5(0.5,13.7) 1 year: 2(0.3)/13(0.3); OR 0.8(0.2,3.5) 3 years: 8(1.0)/46(1.2); OR 0.8(0.4,2.0) Multiple sclerosis (MS): 2 weeks: 0(0.0)/0(0.0), OR NA 30 days: 0(0.0)/0(0.0), OR NA 42 days: 0(0.0)/0(0.0), OR NA 90 days: 1(0.2)/0(0.0), OR NA 180 days: 1(0.2)/2(0.1), OR 2.5(0.2,27.6) 1 year: 1(0.2)/7(0.3), OR 0.7(0.1,6.4) 3 years: 2(0.5)/22(1.0), OR 0.4(0.1,1.9) (primary result) Clinically isolated syndrome (CIS): 2 weeks: 0(0.0)/0(0.0), OR NA 30 days: 0(0.0)/0(0.0), OR NA 42 days: 0(0.0)/0(0.0), OR NA 90 days: 0(0.0)/1(0.1), OR NA 180 days: 1(0.3)/1(0.1), OR 5.0(0.3,80.0) 1 year: 1(0.3)/5(0.3), OR 1.0(0.1,8.6) 3 years: 4(1.2)/16(1.0), OR 1.3(0.4,4.2) Acute Disseminated Encephalomyelitis (ADEM): 2 weeks: 0(0.0)/0(0.0), OR NA 30 days: 0(0.0)/1(1.0), OR NA 42 days: 0(0.0)/1(1.0), OR NA 90 days: 0(0.0)/1(1.0), OR NA 180 days: 0(0.0)/1(1.0), OR NA 1 year: 0(0.0)/1(1.0), OR NA 3 years: 2(9.5)/8(7.8), OR 1.5 (0.2-12.1) (primary result) Risk factors: NR
Bart, 2016[60] Novartis Vaccines, 2014[330] NCT01992094	Age: 57.3 (17.9) % female: 57% Ethnicity: <1% Asian, 1% American Indian,	IIV Flucelvax Quadrivalent 15 µg of purified viral HA antigens for each of the 4 influenza strains	Injection-site pain Severe pain Injection-site hemorrhage Myalgia Bronchitis Sinusitis	ALS: 17.X NR I: 1/1324, 17.X NA C: 0/1338 Anaphylaxis: 10.X Anaphylactic reaction I: 0/1324, 10.3 Anaphylactic reaction C: 1/1338	Severe AEs, Intervention (Flucelvax Quadrivalent QIVc) vs Control (trivalent TIV1c) vs Control (trivalent TIV2c): Injection-site pain: 33.6% vs 27.8% vs 29.4%

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
Article RCT N=2680 Industry funded USA	13% African-American, 0.1% Native Hawaiian, 9% Hispanic, 77% Caucasian Individuals 18 years of age and older in the US from November 2013 to July 2014 Out of scope: None	recommended by the World Health Organization (WHO) for the 2013/14 influenza vaccine composition for the Northern Hemisphere season: A/Brisbane/10/2010 (H1N1), A/ Texas/50/2012 (H3N2), B/Massachusetts/2/ 2012, and B/Brisbane/ 60/2008. 60 µg in 0.5 ml as one dose Intramuscular adjuvant NR preservative NR No co-intervention IIV TIV1c (B/Yamagata lineage) and TIV2c (B/Victoria lineage) 45 µg in 0.5 ml as one dose Intramuscular adjuvant NRpreservative NR Counts No prespecified AE Power other outcome Followup: 6 months	Death Fever Acute myeloid leukemia and worsening of diabetes Histiocytosis haematophagic Iron deficiency anaemia Angina pectoris Arteriosclerosis coronary artery Atrial fibrillation Cardiac arrest Cardiac failure acute Cardiac failure congestive Coronary artery disease Mitral valve incompetence Myocardial infarction Myocardial ischaemia Ventricular fibrillation Abdominal pain Gastrointestinal haemorrhage Lower gastrointestinal haemorrhage Small intestinal obstruction Chest discomfort Chest pain Coronary artery restenosis Death Non-cardiac chest pain Strangulated hernia Anaphylactic reaction Appendicitis Bronchitis Cellulitis Diverticulitis Escherichia sepsis Gastroenteritis Gastroenteritis viral Meningitis viral Pneumonia Pneumonia legionella Pyelonephritis Sepsis Urinary tract infection Head injury Hip fracture	Cardiovascular events: 2.X Cardiac failure, congestive I: 5/1324, 2.XCardiac failure, congestive C: 2/1338 Death: NA Unrelated to vaccine; none <65 years I: 5/1324, NA Unrelated to vaccine; 1 <65 years C: 7/1338 Diabetes: 14.X Diabetes mellitus I: 0/1324, 14.X Diabetes mellitus C: 1/1338 Meningitis: 11.X Meningitis viral I: 1/1324, 11.X Meningitis viral C: 0/1338 Myocardial infarction: 2.X NR I: 4/1324, 2.X NR C: 1/1338 Reproduction issues: 21.X Endometriosis I: 0/1324, 21.X Endometriosis C: 1/1338 Seizure: 17.X Generalized tonic-clonic seizure I: 0/1324, 17.X Generalized tonic-clonic seizure C: 2/673	Injection-site pain, severe pain: 3/1319 0.2% vs 1/670 0.1% vs NR for TIV2c Headache 14.0% vs 13.4% vs 13.4% Serious AEs (from clinical trials.gov) Intervention (Flucelvax Quadrivalent ≥18 Years)Control 1 (TIV1c ≥ 18 Years) Control 2 (TIV2c ≥ 18 Years) Affected / at Risk (%)Affected / at Risk (%) Total 52/1324 (3.93%) 22/673 (3.27%) Histiocytosis hematophagic 1/1324 (0.08%) 0/673 (0.00%) 0/665 (0.00%) Iron deficiency anemia 1/1324 (0.08%) 0/673 (0.00%) 0/665 (0.00%) Angina pectoris1/1324 (0.08%) 0/673 (0.00%) 0/665 (0.00%) 0/665 (0.00%) Arteriosclerosis coronary artery 0/1324 (0.00%) 1/673 (0.15%) 0/665 (0.00%) Atrial fibrillation3/1324 (0.23%) 1/673 (0.15%) 1/665 (0.15%) Cardiac arrest0/1324 (0.00%) 2/673 (0.30%) 1/665 (0.15%) Cardiac failure acute1/1324 (0.08%) 0/673 (0.00%) 0/665 (0.00%) Cardiac failure congestive5/1324 (0.38%) 0/673 (0.00%) 2/665 (0.30%) Coronary artery disease2/1324 (0.15%) 2/673 (0.30%) 1/665 (0.15%) Mitral valve incompetence 1/1324 (0.08%) 0/673 (0.00%) 0/665 (0.00%) Myocardial ischemia 1/1324 (0.08%) 1/673 (0.15%) 0/665 (0.00%) Ventricular fibrillation1/1324 (0.08%) 0/673 (0.00%) 0/665 (0.00%) Abdominal pain1/1324 (0.08%) 0/673 (0.00%) 0/665 (0.00%) Gastrointestinal hemorrhage1/1324 (0.08%) 0/673 (0.00%) 0/665 (0.00%) Lower gastrointestinal hemorrhage1/1324 (0.08%) 0/673 (0.00%) 0/665 (0.00%) Small intestinal obstruction0/1324 (0.00%) 0/673 (0.00%) 2/665 (0.30%) Chest discomfort0/1324 (0.00%) 0/673 (0.00%) 1/665 (0.15%) Chest pain1/1324 (0.08%) 0/673 (0.00%) 0/665 (0.00%)

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
			Lumbar vertebral fracture Postoperative ileus Subdural haematoma Tendon rupture Diabetes mellitus Hyponatraemia Hypovolaemia Arthralgia Muscle haemorrhage Muscular weakness Osteoarthritis Pain in extremity Rotator cuff syndrome Acute myeloid leukaemia Basal cell carcinoma Cervix carcinoma Endometrial adenocarcinoma Endometrial cancer Metastases to lung Ovarian adenoma Squamous cell carcinoma Transitional cell carcinoma Amyotrophic lateral sclerosis Dizziness Generalised tonic-clonic seizure Presyncope Transient ischaemic attack Psychiatric disorders Alcoholism Bipolar disorder Depression Benign prostatic hyperplasia Endometriosis Acute respiratory failure Chronic obstructive pulmonary disease Hypoxia Pulmonary embolism Respiratory failure Implantable defibrillator insertion Arteriosclerosis Hypertension		Coronary artery restenosis0/1324 (0.00%) 0/673 (0.00%) 1/665 (0.15%) Death 0/1324 (0.00%) 1/673 (0.15%) 0/665 (0.00%) Non-cardiac chest pain 1/1324 (0.08%) 1/673 (0.15%) 0/665 (0.00%) Strangulated hernia1/1324 (0.08%) 0/673 (0.00%) 0/665 (0.00%) Appendicitis 0/1324 (0.00%) 1/673 (0.15%) 0/665 (0.00%) Bronchitis 1/1324 (0.08%) 0/673 (0.00%) 0/665 (0.00%) Cecllulitis 3/1324 (0.23%) 1/673 (0.15%) 0/665 (0.00%) Diverticulitis 2/1324 (0.15%) 0/673 (0.00%) 0/665 (0.00%) Escherichia sepsis 1/1324 (0.08%) 0/673 (0.00%) 0/665 (0.00%) Gastroenteritis 1/1324 (0.08%) 0/673 (0.00%) 0/665 (0.00%) Gastroenteritis viral 1/1324 (0.08%) 0/673 (0.00%) 0/665 (0.00%) Pneumonia 2/1324 (0.15%) 0/673 (0.00%) 3/665 (0.45%) Pneumonia Legionella 0/1324 (0.00%) 0/673 (0.00%) 1/665 (0.15%) Pyelonephritis 2/1324 (0.15%) 0/673 (0.00%) 0/665 (0.00%) Sepsis 1/1324 (0.08%) 1/673 (0.15%) 0/665 (0.00%) Urinary tract infection1/1324 (0.08%) 0/673 (0.00%) 0/665 (0.00%) Injury, poisoning and procedural complications Head injury 0/1324 (0.00%) 1/673 (0.15%) 0/665 (0.00%) Hip fracture0/1324 (0.00%) 0/673 (0.00%) 1/665 (0.15%) Lumbar vertebral fracture 1/1324 (0.08%) 0/673 (0.00%) 0/665 (0.00%) Postoperative ileus 0/1324 (0.00%) 0/673 (0.00%) 1/665 (0.15%) Subdural hematoma 1/1324 (0.08%) 0/673 (0.00%) 0/665 (0.00%) Tendon rupture 0/1324 (0.00%) 1/673 (0.15%) 0/665 (0.00%)

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
			Diarrhoea Nausea Chills Fatigue Injection site erythema Injection site haemorrhage Injection site induration Injection site pain Decreased appetite Arthralgia Myalgia Headache		Hyponatremia 1/1324 (0.08%) 0/673 (0.00%) 0/665 (0.00%) Hypovolemia 1/1324 (0.08%) 0/673 (0.00%) 0/665 (0.00%) Musculoskeletal and connective tissue disorders Arthralgia 0/1324 (0.00%) 1/673 (0.15%) 0/665 (0.00%) Muscle hemorrhage 0/1324 (0.00%) 1/673 (0.15%) 0/665 (0.00%) Muscular weakness 1/1324 (0.08%) 0/673 (0.00%) 0/665 (0.00%) Osteoarthritis 3/1324 (0.23%) 0/673 (0.00%) 0/665 (0.00%) Pain in extremity0/1324 (0.00%) 1/673 (0.15%) 0/665 (0.00%) Rotator cuff syndrome 1/1324 (0.08%) 0/673 (0.00%) 0/665 (0.00%) Neoplasms benign, malignant and unspecified (incl cysts and polyps) Acute myeloid leukemia1/1324 (0.08%) 0/673 (0.00%) 0/665 (0.00%) Basal cell carcinoma1/1324 (0.08%) 0/673 (0.00%) 0/665 (0.00%) Cervix carcinoma 0/1324 (0.00%) 1/673 (0.15%) 0/665 (0.00%) Endometrial adenocarcinoma 0/1324 (0.00%) 1/673 (0.15%) 0/665 (0.00%) Endometrial cancer 1/1324 (0.08%) 0/673 (0.00%) 0/665 (0.00%) Metastases to lung1/1324 (0.08%) 0/673 (0.00%) 0/665 (0.00%) Ovarian adenoma1/1324 (0.08%) 0/673 (0.00%) 0/665 (0.00%) Squamous cell carcinoma1/1324 (0.08%) 0/673 (0.00%) 1/665 (0.15%) Transitional cell carcinoma0/1324 (0.00%) 0/673 (0.00%) 1/665 (0.15%) Amyotrophic lateral sclerosis(in AE table) Dizziness 0/1324 (0.00%) 0/673 (0.00%) 1/665 (0.15%) Generalized tonic-clonic seizure (in AE table) Presyncope 0/1324 (0.00%) 0/673 (0.00%) 1/665 (0.15%) Transient ischemic attack 0/1324 (0.00%) 1/673 (0.15%) 0/665 (0.00%)

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
					Alcoholism0/1324 (0.00%) 1/673 (0.15%) 0/665 (0.00%) Bipolar disorder1/1324 (0.08%) 0/673 (0.00%) 0/665 (0.00%) Derepression0/1324 (0.00%) 0/673 (0.00%) 1/665 (0.15%) Acute respiratory failure 1/1324 (0.08%) 1/673 (0.15%) 0/665 (0.00%) Chronic obstructive pulmonary disease 1/1324 (0.08%) 0/673 (0.00%) 0/665 (0.00%) Hypoxia 0/1324 (0.00%) 0/673 (0.00%) 1/665 (0.15%) Pulmonary embolism 1/1324 (0.08%) 1/673 (0.15%) 0/665 (0.00%) Respiratory failure 0/1324 (0.00%) 2/673 (0.30%) 0/665 (0.00%) Implantable defibrillator insertion0/1324 (0.00%) 0/673 (0.00%) 1/665 (0.15%) Arteriosclerosis 0/1324 (0.00%) 0/673 (0.00%) 1/665 (0.15%) Hypertension 2/1324 (0.15%) 0/673 (0.00%) 1/665 (0.15%) Risk factors: Sub-group analyses, Intervention (Flucelvax Quadrivalent QIVc) vs Control (trivalent TIV1c) vs Control (trivalent TIV2c):: Rates of any solicited AEs were higher in the >=18 to <65 y age cohort (61.8% in QIVc, 56.7% in TIV1c, 59.6% in TIV2c) than in the >=65 y age cohort (41.3% in QIVc, 39.1% in TIV1c, 43.2% in TIV2c). Rates of any solicited AE were higher among females (57.9% in QIVc, 54.1% in TIV1c, 54.2% in TIV2c) than among male subjects (43.9% in QIVc, 38.9% in TIV1c, 47.1% in TIV2c). Any SAE (>=18 to <65 y): 11/665 (1.7%) vs 6/330 (1.8%) vs 5/328 (1.5%), Any SAE (>=65 y): 41/659 (6.2%) vs 16/343 (4.7%) vs 16/337 (4.7%) Medically attended AE (>=18 to <65 y): 141/665 (21.2%) vs 58/330 (17.6%) vs 67/328 (20.4%), Medically attended AE (>=65 y): 203/659 (30.8%) vs 114/343 (33.3%) vs 99/337 (29.4%)

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
					New onset chronic diseases (>=18 to <65 y): 24/665 (3.6%) vs 10/330 (3.0%) vs 12/328 (3.7%), New onset chronic diseases (>=65 y): 38/659 (5.8%) vs 15/343 (4.4%) vs 17/337 (5.0%)
Beran, 2013[66] GlaxoSmithKline, 2008[259] NCT00714285 Article RCT N=420 Industry funded Czech Republic	Age: 37.6 (12.4) % female: 60% Ethnicity: 100% White Healthy adults 18-60 years old Out of scope: None	IIV Fluarix Quadrivalent 0.5 mL in one dose Intramuscular adjuvant free preservative NR No co-intervention IIV Trivalent inactivated influenza vaccine Fluarix 0.5 mL in one dose Intramuscular adjuvant freepreservative NR Counts No prespecified AE Power NR Followup: 6 months	Mortality Haemorrhage (following tonsillectomy) Pain (prespecified) Redness (prespecified) Swelling (prespecified) Arthalgia (prespecified) Fatigue (prespecified) Headache (prespecified) Myalgia (prespecified) Nausea(prespecified) Shivering (prespecified) Fever (prespecified) Potentially immune-mediated diseases	Autoimmune disease: 10.X Potentially immune-mediated diseases I: 0/105, 10.X Potentially immune-mediated diseases C: 0/105 Death: NA NA I: 0/105, NA NA C: 0/105	Severe AEs within 7 days, Intervention (Fluarix Quadrivalent) % (5% CI) vs Control (Fluarix) % (95% CI) Any Symptoms Grade 3: 3.8 (1.0–9.5) vs 1.9 (0.2–6.7) Local Symptoms Grade 3: 0 (0–3.5) vs 0 (0–3.5) Pain Grade 3: 0 (0–3.5) vs 0 (0–3.5) Redness >100 mm: 0 (0–3.5) vs 0 (0–3.5) Swelling >100 mm: 0 (0–3.5) vs 0 (0–3.5) General Symptoms Grade 3: 3.8 (1.0–9.5) vs 1.9 (0.2–6.7) Arthralgia Grade 3: 1.0 (0–5.2) vs 0 (0–3.5) Fatigue Grade 3: 1.9 (0.2–6.7) vs 1.0 (0–5.2) Headache Grade 3: 2.9 (0.6–8.1) vs 0 (0–3.5) Myalgia Grade 3: 1.0 (0–5.2) vs 1.0 (0–5.2) Nausea Grade 3: 1.9 (0.2–6.7) vs 1.0 (0–5.2) Shivering Grade 3: 1.0 (0–5.2) vs 0 (0–3.5) Fever >39°C: 0 (0–3.5) vs 0 (0–3.5) Serious AEs: Intervention 0/105 vs Control 1/105 (prolonged hospitalization for hemorrhage after tonsillectomy) up to 6 months later No potentially immune-mediated diseases were reported in any group up to 6 months later Risk factors: NR
Chang, 2019[77] Sanofi Pasteur a Sanofi Company, 2017[368] NCT03282240	Age: 73.0 (5.6) % female: 58% Ethnicity: 91% White, 7% Black, 0.5% American Indian or Alaska	IIV Fluzone High Dose Quadrivalent 60 µg hemagglutinin each of A/Michigan/45/2015	Mortality Haemorrhagic anaemia Acute myocardial infarction Angina pectoris Atrial fibrillation	Cardiovascular events: 2.X Coronary artery disease I: 2/1777, 2.XCoronary artery disease C: 3/893 Death: NA All cause mortality, 1 death due to Sudden Death per clinicaltrials.gov I: 3/1777, NA All	Severe AEs, Intervention (QIV-HD) vs Controls pooled (TIV-HD1 and TIV-HD2) Grade 3 solicited reactions: <1% vs <1% (numbers not specified) AEs of special interest: 1/1777 (<0.1%) vs 2/893 (0.2%)

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
Article RCT N=2670 Industry funded USA	Native, 0.5% Asian, 0.5% Multiple, 0.5% Not Reported; 3% Hispanic or Latino Healthy adults 65 years and older Out of scope: None	X-275, A/Hong Kong/4801/2014 [NYMC X-263B], B/Brisbane/60/2008 (Victoria lineage), and B/Phuket/3073/2013 (Yamagata lineage) per 0.7-mL dose 240 µg in 0.7 mL as one dose Intramuscular adjuvant NR preservative NR No co-intervention IIV TIV-HD1 (B/Victoria, licensed) and TIV-HD2 (B/Yamagata, investigational) Fluzone High-Dose and TIV-HD2 180 µg in 0.5 mL as one dose Intramuscular adjuvant NRpreservative NR Counts No prespecified AE Power other outcome Followup: 6 months	Atrioventricular block complete Cardiac failure congestive Coronary artery disease Myocardial infarction Pericarditis Sinus bradycardia Stress cardiomyopathy Ventricular tachycardia Colitis Constipation Diverticulum intestinal haemorrhagic Gastritis Gastrointestinal haemorrhage Gastrointestinal ulcer haemorrhage Inguinal hernia Pancreatitis Small intestinal obstruction Non-cardiac chest pain Pyrexia Sudden death Vascular stent thrombosis Cholangitis Cholecystitis Cholecystitis acute Cholelithiasis Bacteraemia Bronchitis Diverticulitis Endocarditis Influenza Parainfluenzae viral laryngotracheobronchitis Pneumonia Respiratory tract infection Septic shock Staphylococcal infection Streptococcal infection Urinary tract infection Viral infection Anaesthetic complication Ankle fracture Bone contusion Femur fracture	cause mortality, Both in Licensed TIV group C: 2/893 Diabetes: 14.X Type 2 diabetes mellitus I: 0/1777, 14.X Type 2 diabetes mellitus C: 1/893 Myocardial infarction: 2.X Myocardial infarction I: 2/1777, 2.X Myocardial infarction C: 2/893 Reproduction issues: 21.X Prostate cancer I: 2/1777, 21.X Prostate cancer C: 1/893 Seizure: 17.X N/A I: 0/1777, 17.X NR C: 1/893 Stroke: 17.X Ischaemic cerebral infarction I: 0/1777, 17.X Ischaemic cerebral infarction C: 1/893	*AEs of special interest were new onset of Guillain-Barré syndrome, encephalitis/myelitis (including transverse myelitis), Bell's palsy, optic neuritis, and brachial neuritis. SAE within 28 days: 19/1777 (1.1%) vs 12/893 (1.3%) Serious AEs within 6 months (from clinicaltrials.gov) Intervention (QIV-HD)Control (TIV-HD1)Control (Investigational TIV-HD2) Affected / at Risk (%)# EventsAffected / at Risk (%)# EventsAffected / at Risk (%)# Events Total 80/1777 (4.50%) 29/443 (6.55%) 19/450 (4.22%) Blood and lymphatic system disorders Haemorrhagic Anaemia 1/1777 (0.06%) 0/443 (0.00%) 0/450 (0.00%) Cardiac disorders Acute Myocardial Infarction 3/1777 (0.17%) 0/443 (0.00%) 0/450 (0.00%) Angina Pectoris 2/1777 (0.11%) 0/443 (0.00%) 1/450 (0.22%) Atrial Fibrillation 2/1777 (0.11%) 0/443 (0.00%) 1/450 (0.22%) Atrioventricular Block Complete 1/1777 (0.06%) 0/443 (0.00%) 0/450 (0.00%) Cardiac Failure Congestive 2/1777 (0.11%) 1/443 (0.23%) 1/450 (0.22%) Coronary Artery Disease 2/1777 (0.11%) 3/443 (0.68%) 0/450 (0.00%) (in AE table) Myocardial Infarction 2/1777 (0.11%) 1/443 (0.23%) 1/450 (0.22%) (in AE table) Pericarditis 1/1777 (0.06%) 0/443 (0.00%) 0/450 (0.00%) Sinus Bradycardia 1/1777 (0.06%) 0/443 (0.00%) 0/450 (0.00%) Stress Cardiomyopathy 0/1777 (0.00%) 1/443 (0.23%) 0/450 (0.00%) Ventricular Tachycardia 1/1777 (0.06%) 10/443 (0.00%) 00/450 (0.00%) Gastrointestinal disorders Colitis 1/1777 (0.06%) 0/443 (0.00%) 0/450 (0.00%)

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
			Incisional hernia Postpericardiotomy syndrome Rib fracture Road traffic accident Spinal compression fracture Tendon rupture Investigati Troponin increased Type 2 diabetes mellitus Back pain Groin pain Intervertebral disc protrusion Lumbar spinal stenosis Osteoarthritis Pain in extremity Rotator cuff syndrome Spinal osteoarthritis Bladder cancer Brain neoplasm Breast cancer Cholangiocarcinoma Invasive ductal breast carcinoma Malignant melanoma Neoplasm malignant Pancreatic carcinoma Prostate cancer Uterine leiomyoma Nervous system disorder Carotid artery occlusion Carotid artery stenosis Cerebrospinal fluid leakage Cerebrovascular accident Facial paralysis Ischaemic cerebral infarction Seizure Small fibre neuropathy Syncope Transient ischaemic attack Mental status changes Nephrolithiasis Nephropathy		Constipation 1/1777 (0.06%) 0/443 (0.00%) 0/450 (0.00%) Diverticulum Intestinal Haemorrhagic 0/1777 (0.00%) 1/443 (0.23%) 0/450 (0.00%) Gastritis 0/1777 (0.00%) 0/443 (0.00%) 1/450 (0.22%) Gastrointestinal Haemorrhage 0/1777 (0.00%) 1/443 (0.23%) 0/450 (0.00%) Gastrointestinal Ulcer Haemorrhage 1/1777 (0.06%) 0/443 (0.00%) 0/450 (0.00%) Inguinal Hernia 1/1777 (0.06%) 0/443 (0.00%) 0/450 (0.00%) Pancreatitis 3/1777 (0.17%) 0/443 (0.00%) 0/450 (0.00%) Small Intestinal Obstruction 2/1777 (0.11%) 1/443 (0.23%) 0/450 (0.00%) General disorders Non-Cardiac Chest Pain 1/1777 (0.06%) 143 (0.23%) /450 (0.00%) Pyrexia 0/1777 (0.00%) 0/443 (0.00%) 1/450 (0.22%) Sudden Death 1/1777 (0.06%) 10/443 (0.00%) 00/450 (0.00%) Vascular Stent Thrombosis 1/1777 (0.06%) 0/443 (0.00%) 0/450 (0.00%) Hepatobiliary disorders Cholangitis 0/1777 (0.00%) 0/443 (0.00%) 1/450 (0.22%) Cholecystitis 1/1777 (0.06%) 1/443 (0.23%) 0/450 (0.00%) Cholecystitis Acute 1/1777 (0.06%) 10/443 (0.00%) 00/450 (0.00%) Cholelithiasis 0/1777 (0.00%) 0/443 (0.00%) 1/450 (0.22%) Infections and infestations Bacteraemia 2/1777 (0.11%) 0/443 (0.00%) 0/450 (0.00%) Bronchitis 0/1777 (0.00%) 01/443 (0.23%) 10/450 (0.00%) Diverticulitis 2/1777 (0.11%) 0/443 (0.00%) 0/450 (0.00%) Endocarditis 1/1777 (0.06%) 0/443 (0.00%) 0/450 (0.00%) Influenza 0/1777 (0.00%) 1/443 (0.23%) 0/450 (0.00%)

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
			Urinary retention Benign prostatic hyperplasia Chronic obstructive pulmonary disease Dyspnoea Pulmonary embolism Respiratory failure Skin ulcer Vascular disorder Aortic stenosis Deep vein thrombosis Peripheral vascular disorder Chills Injection site erythema (prespecified) Injection site pain (prespecified) Injection site swelling (prespecified) Malaise (prespecified) Myalgia (prespecified) Headache (prespecified) Fever (prespecified) Headache (prespecified)		Parainfluenzae Viral Laryngotracheobronchitis 0/1777 (0.00%) 0/443 (0.00%) 1/450 (0.22%) Pneumonia 6/1777 (0.34%) 2/443 (0.45%) 0/450 (0.00%) Respiratory Tract Infection 1/1777 (0.06%) 0/443 (0.00%) 0/450 (0.00%) Septic Shock 1/1777 (0.06%) 0/443 (0.00%) 0/450 (0.00%) Staphylococcal Infection 1/1777 (0.06%) 0/443 (0.00%) 0/450 (0.00%) Streptococcal Infection 1/1777 (0.06%) 0/443 (0.00%) 0/450 (0.00%) Urinary Tract Infection 2/1777 (0.11%) 0/443 (0.00%) 0/450 (0.00%) Viral Infection 1/1777 (0.06%) 0/443 (0.00%) 0/450 (0.00%) Injury, poisoning and procedural complications Anaesthetic Complication 1/1777 (0.06%) 0/443 (0.00%) 0/450 (0.00%) Ankle Fracture 0/1777 (0.00%) 0/443 (0.00%) 1/450 (0.22%) Bone Contusion 0/1777 (0.00%) 1/443 (0.23%) 0/450 (0.00%) Femur Fracture 1/1777 (0.06%) 0/443 (0.00%) 0/450 (0.00%) Incisional Hernia 1/1777 (0.06%) 0/443 (0.00%) 0/450 (0.00%) Postpericardiotomy Syndrome 1/1777 (0.06%) 0/443 (0.00%) 0/450 (0.00%) Rib Fracture 0/1777 (0.00%) 1/443 (0.23%) 1/450 (0.22%) Road Traffic Accident 1/1777 (0.06%) 0/443 (0.00%) 0/450 (0.00%) Spinal Compression Fracture 0/1777 (0.00%) 0/443 (0.00%) 1/450 (0.22%) Tendon Rupture 0/1777 (0.00%) 1/443 (0.23%) 0/450 (0.00%) Investigations Troponin Increased 1/1777 (0.06%) 0/443 (0.00%) 0/450 (0.00%) Metabolism and nutrition disorders Type 2 Diabetes Mellitus (in AE table) Musculoskeletal and connective tissue disorders

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
					Back Pain 2/1777 (0.11%) 0/443 (0.00%) 0/450 (0.00%) Groin Pain 1/1777 (0.06%) 0/443 (0.00%) 0/450 (0.00%) Intervertebral Disc Protrusion 0/1777 (0.00%) 0/443 (0.00%) 1/450 (0.22%) Lumbar Spinal Stenosis 0/1777 (0.00%) 0/443 (0.00%) 1/450 (0.22%) Osteoarthritis 6/1777 (0.34%) 4/443 (0.90%) 0/450 (0.00%) Pain In Extremity 1/1777 (0.06%) 0/443 (0.00%) 0/450 (0.00%) Rotator Cuff Syndrome 0/1777 (0.00%) 1/443 (0.23%) 0/450 (0.00%) Spinal Osteoarthritis 1/1777 (0.06%) 0/443 (0.00%) 0/450 (0.00%) Neoplasms benign, malignant and unspecified (incl cysts and polyps) Bladder Cancer 1/1777 (0.06%) 1/443 (0.23%) 0/450 (0.00%) Brain Neoplasm 1/1777 (0.06%) 0/443 (0.00%) 0/450 (0.00%) Breast Cancer 1/1777 (0.06%) 0/443 (0.00%) 1/450 (0.22%) Cholangiocarcinoma 1/1777 (0.06%) 0/443 (0.00%) 0/450 (0.00%) Invasive Ductal Breast Carcinoma 1/1777 (0.06%) 0/443 (0.00%) 0/450 (0.00%) Malignant Melanoma 1/1777 (0.06%) 0/443 (0.00%) 0/450 (0.00%) Neoplasm Malignant 0/1777 (0.00%) 1/443 (0.23%) 0/450 (0.00%) Pancreatic Carcinoma 0/1777 (0.00%) 1/443 (0.23%) 0/450 (0.00%) Prostate Cancer 2/1777 (0.11%) 1/443 (0.23%) 0/450 (0.00%) Uterine Leiomyoma 0/1777 (0.00%) 1/443 (0.23%) 0/450 (0.00%) Nervous system disorders Carotid Artery Occlusion 0/1777 (0.00%) 0/443 (0.00%) 1/450 (0.22%) Carotid Artery Stenosis 2/1777 (0.11%) 0/443 (0.00%) 0/450 (0.00%) Cerebrospinal Fluid Leakage 1/1777 (0.06%) 0/443 (0.00%) 0/450 (0.00%)

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
					Cerebrovascular Accident 1/1777 (0.06%) 0/443 (0.00%) 0/450 (0.00%) Facial Paralysis 1/1777 (0.06%) 0/443 (0.00%) 2/450 (0.44%) Ischaemic Cerebral Infarction (in AE table) Seizure (in AE table) Small Fibre Neuropathy 1/1777 (0.06%) 0/443 (0.00%) 0/450 (0.00%) Syncope 3/1777 (0.17%) 0/443 (0.00%) 2/450 (0.44%) Transient Ischaemic Attack 3/1777 (0.17%) 0/443 (0.00%) 0/450 (0.00%) Psychiatric disorders Mental Status Changes 1/1777 (0.06%) 0/443 (0.00%) 0/450 (0.00%) Renal and urinary disorders Nephrolithiasis 1/1777 (0.06%) 0/443 (0.00%) 0/450 (0.00%) Nephropathy 1/1777 (0.06%) 0/443 (0.00%) 0/450 (0.00%) Urinary Retention 1/1777 (0.06%) 0/443 (0.00%) 0/450 (0.00%) Reproductive system and breast disorders Benign Prostatic Hyperplasia (in AE table) Respiratory, thoracic and mediastinal disorders Chronic Obstructive Pulmonary Disease 1/1777 (0.06%) 1/443 (0.23%) 0/450 (0.00%) Dyspnoea 1/1777 (0.06%) 0/443 (0.00%) 0/450 (0.00%) Pulmonary Embolism 4/1777 (0.23%) 0/443 (0.00%) 0/450 (0.00%) Respiratory Failure 1/1777 (0.06%) 0/443 (0.00%) 0/450 (0.00%) Skin and subcutaneous tissue disorders Skin Ulcer 0/1777 (0.00%) 0/443 (0.00%) 1/450 (0.22%) Vascular disorders Aortic Stenosis 2/1777 (0.11%) 1/443 (0.23%) 0/450 (0.00%) Deep Vein Thrombosis 0/1777 (0.00%) 0/443 (0.00%) 1/450 (0.22%)

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
					Peripheral Vascular Disorder 1/1777 (0.06%) 0/443 (0.00%) 0/450 (0.00%) Risk factors: NR
Greenberg, 2013[118] Sanofi Pasteur a Sanofi Company, 2009[360] NCT00988143 Article RCT N=590 Industry funded USA	Age: 55.6 (17.7) % female: 67 Ethnicity: 88% White, 10% Black, 1% Other, 1% Asian or Hispanic Healthy adults 18 years and older Out of scope: None	IIV Fluzone Quadrivalent QIV: 15 µg hemagglutinin each of A/Brisbane/59/2007 (H1N1), A/Uruguay/716/2007 (H3N2; an A/Brisbane/10/2007 - like virus), B/Brisbane/60/2008 (Victoria lineage), and B/Florida/04/2006 (Yamagata lineage) per 0.5-mL dose 0.5 mL (60 µg) in one dose Intramuscular adjuvant free preservative free No co-intervention IIV 2008-2009 trivalent IIV and 2009-2010 trivalent IIV Fluzone (2008-2009 and 2009-2010) 45 µg in 0.5 mL as one dose Intramuscular adjuvant freepreservative free Counts No prespecified AE Power other outcome Followup: 1 months	Myalgia Headache Malaise Fever Pain Swelling Cough Oropharyngeal pain Unspecified gastrointestinal bleeding Vertigo positional Chest pain Shivering Appetite lost Drowsiness Crying abnormal Irritability Rhinorrhoea Rash	Death: NA NA I: 0/190, NA NA C: 0/380	Solicited injection-site reactions occurring within 3 days: QIV 47.9% vs 2009–2010 TIV 53.2% vs 2008–2009 TIV 44.2% Grade 3 reactions (pain only): QIV 1/190 vs 2009–2010 TIV 1/190 vs 2008–2009 TIV 0/190 Solicited systemic reactions occurring within 3 days: QIV 33.7% vs 2009–2010 TIV 38.4% vs 2008–2009 TIV 28.9% Grade 3 reactions headache: QIV 1/190 vs 2009–2010 TIV 1/190 vs 2008–2009 TIV 0/190 Grade 3 malaise: QIV 2/190 vs 2009–2010 TIV 2/190 vs 2008–2009 TIV 1/190 Serious AEs: QIV 1/190 (chest pain) vs 2009–2010 TIV 0/190 vs 2008–2009 TIV 1/190 (gastrointestinal bleeding) *Note that clinical trials.gov entry includes an additional AE for QIV which is Vertigo positional (QIV 1/190 vs 2009–2010 TIV 0/190 vs 2008–2009 TIV 0/190) but does not note the gastrointestinal bleeding as an SAE) Risk factors: Solicited systemic reactions were reported more frequently by participants 18–60 years of age than by participants ≥61 years of age
Greenberg, 2017[119] Sanofi Pasteur a	Age: 70.4 (9.8) % female: 54%	IIV Fluzone Quadrivalent A/California/07/200	Retina detachment Cellulitis Malignant melanoma	Encephalitis: 17.X Encephalitis/myelitis I: 0/225, 17.X Encephalitis/myelitis C: 0/225	Severe AEs, Intervention (Fluzone Quadrivalent) % (95% CI) vs Control

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
Sanofi Company, 2010[362] NCT01218646 Article RCT N=675 Industry funded USA	Ethnicity: Ethnicity NR Healthy older adults (65 y of age and older) were recruited for the randomized, double-blind cohort trial (healthy younger adults 18–64 y of age were recruited for the open-label cohort, but not included in this abstraction) Out of scope: None	9 (H1N1), A/Victoria/210/ 2009 (H3N2), B/Brisbane/60/2008 (Victoria lineage), and B/Florida/04/2006 (Yamagata lineage) strains 60 µg in 0.5 mL as one dose Intramuscular adjuvant NR preservative NR No co-intervention IIV TIV (include only licensed, not investigational) Fluzone 45 µg in 0.5 mL as one dose Intramuscular adjuvant NRpreservative NR Counts No prespecified AE Power other outcome Followup: 6 months	Injection site pain (prespecified) Injection site swelling Erythema (prespecified) Malaise (prespecified) Fever (prespecified) Myalgia(prespecified) Headache (prespecified) Guillain-Barre syndrome (prespecified) Bell's palsy (prespecified) encephalitis/myelitis (prespecified) optic neuritis (prespecified) Stevens-Johnson syndrome (prespecified) toxic epidermal necrolysis (prespecified)	Guillain-Barré syndrome: 10.X NA I: 0/225, 10.X NA C: 0/225 Optic neuritis: 17.X NA I: 0/225, 17.X NA C: 0/225	(Licensed Trivalent Influenza Vaccine) % (95% CI): Any solicited reaction grade 3: 0.9 (0.1; 3.2) vs 0.0 (0.0; 1.6) Solicited injection site reaction grade 3: 0.9 (0.1; 3.2) vs 0.0 (0.0; 1.6) Solicited systemic reaction grade 3: 0.4 (0.0; 2.5) vs 0.0 (0.0; 1.6) Injection-site pain grade 3: 0.9 (0.1; 3.2) vs 0.0 (0.0; 1.6) Injection-site erythema grade 3: 0.0 (0.0; 1.6) vs 0.0 (0.0; 1.6) vs 0.0 (0.0; 1.6) Injection-site swelling grade 3: 0.0 (0.0; 1.6) vs 0.0 (0.0; 1.6) vs 0.0 (0.0; 1.6) Fever grade 3: 0.4 (0.0; 2.5) vs 0.0 (0.0; 1.6) Headache grade 3: 0.4 (0.0; 2.5) vs 0.0 (0.0; 1.6) Malaise grade 3: 0.4 (0.0; 2.5) vs 0.0 (0.0; 1.6) Myalgia grade 3: 0.4 (0.0; 2.5) vs 0.0 (0.0; 1.6) Serious AEs (from clinicaltrials.gov): Intervention (Fluzone Quadrivalent) vs Control (Licensed Trivalent Influenza Vaccine) Affected / at Risk (%)# EventsAffected / at Risk (%)# Event Total 0/225 (0.00%) 2/225 (0.89%) Retina detachment 0/225 (0.00%) 1/225 (0.44%) Cellulitis * 0/225 (0.00%) 0/64 (0.00%) Malignant melanoma 0/225 (0.00%) 0/225 (0.00%) No AEs of special interest were reported, which include Guillain-Barr e syndrome (in AE table), Bell's palsy, encephalitis/myelitis (in AE table under encephalitis), optic neuritis (in AE table), Stevens-Johnson syndrome, and toxic epidermal necrolysis. Risk factors: NR
Kieninger, 2013[145] GlaxoSmithKline, 2010[262]	Age: 58.0 (17.75) % female: 57%	IIV Fluarix Quadrivalent Two influenza A strains (A/California/ 7/2009 [H1N1] and	Anaemia Acute myocardial infarction Arteriosclerosis coronary artery Atrial fibrillation	Asthma: 22.X NR I: 1/3036, 22.X NR C: 1/1010	Adverse events day 0-20: subjects with more than 1 Grade 3 event: QIV: 39/3036 (1.3%); TIV-Vic: 7/1010 (0.7%); TIV-Yam 2/610 (0.3%)

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
NCT01204671 Article RCT N=4659 Industry funded Germany, Romania, Spain, Korea, Taiwan, USA	Ethnicity: QIV: 68% European Caucasian, 1% Arabic/north American heritage/Caucasian, 27% Asian, 3% African/African American, <1% American Indian or Native Alaskan, <1% Native Hawaiian or other pacific islander, 1% Other; 4% Hispanic. Subjects aged 18 years and older and in stable health without significant pulmonary, cardiovascular, hepatic, or renal disease. Out of scope: None	A/Victoria/210/2009 [H3N2], an A/Perth/16/2009-like strain) and one influenza B strain (B/Brisbane/60/2008 [Victoria-lineage]) recommended for the influenza season 2010–2011 in the Northern Hemisphere, and one influenza B strain from the B/ Yamagata lineage (B/Brisbane/3/2007, a B/Florida/4/ 2006 like strain previously recommended for the 2008–2009 influenza season) 60 µg in one 0.5 mL dose Intramuscular adjuvant free preservative free No co-intervention IIV TIV-Vic or TIV-Yam Fluarix (trivalent) or TIV-Yam 45 µg in one 0.5 mL dose Intramuscular adjuvant freepreservative free Counts No prespecified AE Power other outcome Followup: 6 months	Cardiac arrest Cardiac disorder Cardiac failure Cardiac failure congestive Cardio-respiratory arrest Cardiopulmonary failure Coronary artery disease Myocardial infarction Myocardial ischaemia Vertigo Vestibular disorder Diplopia Abdominal hernia Acute abdomen Gastric ulcer Gastric ulcer haemorrhage Inguinal hernia Intestinal infarction Oesophagitis Upper gastrointestinal haemorrhage General disorders Death Non-cardiac chest pain Sudden death Cholelithiasis Jaundice Bronchiolitis Central nervous system infection Device related infection Erysipelas Gastroenteritis Groin abscess Osteomyelitis Pneumonia Pyelonephritis acute Respiratory tract infection Tooth abscess Urinary tract infection Foot fracture Head injury Hip fracture Joint dislocation Ligament rupture Lumbar vertebral fracture Pelvic fracture	Cardiovascular events: 2.X Myocardial infarction I: 5/3036, 2.X Myocardial infarction C: 1/1010 Death: NA None of the deaths were considered by the investigator to be related to vaccination - 2 cardiac disorders, 1 neoplasm, 1 intestinal infarction, 2 sudden deaths, 1 hepatic coma, 1 cerebrovascular accident, 1 pulmonary hypertension I: 9/3036, NA None of the deaths were considered by the investigator to be related to vaccination - All deaths due to cardiac disorders C: 3/1010 Diabetes: 14.X Diabetes mellitus I: 0/3036, 14.X Diabetes mellitus C: 1/1010 Myocardial infarction: 2.X Myocardial infarction I: 5/3036, 2.X Myocardial infarction C: 1/1010 Reproduction issues: 21.X Benign prostatic hyperplasia I: 1/3036, 21.X Benign prostatic hyperplasia C: 0/1010 Stroke: 17.X Cerebrovascular accident I: 5/3036, 17.X Cerebrovascular accident C: 2/1010	Medically-attended adverse events day 0-20: QIV: 193/3036 (6.4%); TIV-Vic: 60/1010 (5.9%); TIV_Yam: 47/610 (7.7%) Medically-attended adverse events day 0-180: QIV: 688/3036 (22.7%); TIV-Vic: 216/1010 (21.4%); TIV-Yam NA (only followed for 21 days) Serious AEs (from clinicaltrials.gov): (TIV-Yam not included as only followed to 21 days) Intervention Lot 1 Intervention Lot 2Intervention Lot 3Fluarix Group (TIV-Vic) Affected / at Risk (%)Affected / at Risk (%)Affected / at Risk (%)Affected / at Risk (%)Affected / at Risk (%). Risk (%)Affected / at Risk (%) Total 28/1012 (2.77%) 20/1013 (1.97%) 22/1011 (2.18%) 26/1010 (2.57%) Blood and lymphatic system disorders Anaemia0/1012 (0.00%) 1/1013 (0.10%) 0/1011 (0.00%) 0/1010 (0.00%) Cardiac disorders Acute myocardial infarction 0/1012 (0.00%) 0/1013 (0.00%) 1/1011 (0.10%) 0/1010 (0.00%) Arteriosclerosis coronary artery 0/1012 (0.00%) 0/1013 (0.00%) 1/1011 (0.10%) 0/1010 (0.00%) Atrial fibrillation 0/1012 (0.00%) 0/1013 (0.00%) 0/1011 (0.00%) 1/1010 (0.10%) Cardiac arrest 0/1012 (0.00%) 0/1013 (0.00%) 0/1011 (0.00%) 1/1010 (0.10%) Cardiac disorder 0/1012 (0.00%) 0/1013 (0.00%) 0/1011 (0.00%) 1/1010 (0.10%) Cardiac failure 2/1012 (0.20%) 0/1013 (0.00%) 0/1011 (0.00%) 0/1010 (0.00%) Cardiac failure congestive 1/1012 (0.10%) 1/1013 (0.10%) 1/1011 (0.10%) 0/1010 (0.00%) Cardio-respiratory arrest 0/1012 (0.00%) 0/1013 (0.00%) 0/1011 (0.00%) 1/1010 (0.10%) Cardiopulmonary failure 1/1012 (0.10%) 0/1013 (0.00%) 0/1011 (0.00%) 0/1010 (0.00%)

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
			Radius fracture Tendon rupture Investigations Ammonia increased Dehydration Diabetes mellitus Arthralgia Intervertebral disc disorder Intervertebral disc protrusion Muscular weakness Rotator cuff syndrome Breast cancer Colon cancer Gastric adenoma Gastric cancer Hepatic neoplasm malignant Rectal cancer (Renal cell carcinoma Small cell lung cancer stage unspecified Thyroid cancer Nervous system disorders Carotid artery stenosis Cerebrovascular accident Coma hepatic Depressed level of consciousness Dizziness Headache Intracranial aneurysm Ischaemic stroke Subarachnoid haemorrhage Transient ischaemic attack Psychiatric disorders Confusional state Renal and urinary disorders Nephrolithiasis Ureteric stenosis Urinary incontinence Benign prostatic hyperplasia Acute respiratory failure Asthma		Coronary artery disease 0/1012 (0.00%) 0/1013 (0.00%) 0/1011 (0.00%) 1/1010 (0.10%) Myocardial infarction (in AE table) Myocardial ischaemia 1/1012 (0.10%) 0/1013 (0.00%) 0/1011 (0.00%) 0/1010 (0.00%) Ear and labyrinth disorders Vertigo 0/1012 (0.00%) 1/1013 (0.10%) 0/1011 (0.00%) 1/1010 (0.10%) Vestibular disorder 0/1012 (0.00%) 0/1013 (0.00%) 1/1011 (0.10%) 0/1010 (0.00%) Eye disorders Diplopia 0/1012 (0.00%) 1/1013 (0.10%) 0/1011 (0.00%) 0/1010 (0.00%) Gastrointestinal disorders Abdominal hernia 0/1012 (0.00%) 0/1013 (0.00%) 0/1011 (0.00%) 1/1010 (0.10%) Acute abdomen 0/1012 (0.00%) 0/1013 (0.00%) 0/1011 (0.00%) 1/1010 (0.10%) Gastric ulcer 0/1012 (0.00%) 1/1013 (0.10%) 0/1011 (0.00%) 0/1010 (0.00%) Gastric ulcer haemorrhage 1/1012 (0.10%) 0/1013 (0.00%) 1/1011 (0.10%) 0/1010 (0.00%) Inguinal hernia 0/1012 (0.00%) 0/1013 (0.00%) 1/1011 (0.10%) 1/1010 (0.10%) Intestinal infarction 1/1012 (0.10%) 0/1013 (0.00%) 0/1011 (0.00%) 0/1010 (0.00%) Oesophagitis 1/1012 (0.10%) 0/1013 (0.00%) 0/1011 (0.00%) 0/1010 (0.00%) Upper gastrointestinal haemorrhage 0/1012 (0.00%) 0/1013 (0.00%) 0/1011 (0.00%) 1/1010 (0.10%) General disorders Non-cardiac chest pain 0/1012 (0.00%) 0/1013 (0.00%) 1/1011 (0.10%) 0/1010 (0.00%) Sudden death 1/1012 (0.10%) 0/1013 (0.00%) 0/1011 (0.00%) 0/1010 (0.00%) Hepatobiliary disorders Cholelithiasis 1/1012 (0.10%) 1/1013 (0.10%) 0/1011 (0.00%) 0/1010 (0.00%)

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
			Atelectasis Bronchospasm Pleurisy Pneumonia aspiration Pulmonary hypertension Respiratory failure Pruritus Aortic aneurysm Arteriosclerosis Pain Fatigue Gastrointestinal symptoms Headache Joint pain Muscle aches		Jaundice 1/1012 (0.10%) 0/1013 (0.00%) 0/1011 (0.00%) 0/1010 (0.00%) Infections and infestations Bronchiolitis 0/1012 (0.00%) 0/1013 (0.00%) 1/1011 (0.10%) 1/1010 (0.10%) Central nervous system infection 1/1012 (0.10%) 0/1013 (0.00%) 0/1011 (0.00%) 0/1010 (0.00%) Device related infection 1/1012 (0.10%) 0/1013 (0.00%) 0/1011 (0.00%) 0/1010 (0.00%) Erysipelas 1/1012 (0.10%) 0/1013 (0.00%) 0/1011 (0.00%) 0/1010 (0.00%) Gastroenteritis 1/1012 (0.10%) 0/1013 (0.00%) 0/1011 (0.00%) 1/1010 (0.10%) Groin abscess 0/1012 (0.00%) 0/1013 (0.00%) 0/1011 (0.00%) 1/1010 (0.10%) Osteomyelitis 0/1012 (0.00%) 0/1013 (0.00%) 0/1011 (0.00%) 1/1010 (0.10%) Pneumonia 0/1012 (0.00%) 0/1013 (0.00%) 3/1011 (0.30%) 2/1010 (0.20%) Pyelonephritis acute 0/1012 (0.00%) 1/1013 (0.10%) 0/1011 (0.00%) 0/1010 (0.00%) Respiratory tract infection 0/1012 (0.00%) 1/1013 (0.10%) 1/1011 (0.10%) 0/1010 (0.00%) Tooth abscess 1/1012 (0.10%) 0/1013 (0.00%) 0/1011 (0.00%) 0/1010 (0.00%) Urinary tract infection 2/1012 (0.20%) 0/1013 (0.00%) 0/1011 (0.00%) 0/1010 (0.00%) Injury, poisoning and procedural complications Foot fracture 0/1012 (0.00%) 0/1013 (0.00%) 0/1011 (0.00%) 1/1010 (0.10%) Head injury 0/1012 (0.00%) 0/1013 (0.00%) 0/1011 (0.00%) 1/1010 (0.10%) Hip fracture 1/1012 (0.10%) 0/1013 (0.00%) 0/1011 (0.00%) 0/1010 (0.00%) Joint dislocation 0/1012 (0.00%) 1/1013 (0.10%) 0/1011 (0.00%) 0/1010 (0.00%) Ligament rupture 0/1012 (0.00%) 1/1013 (0.10%) 0/1011 (0.00%) 0/1010 (0.00%) Lumbar vertebral fracture 0/1012 (0.00%) 0/1013 (0.00%) 1/1011 (0.10%) 0/1010 (0.00%)

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
					Pelvic fracture 1/1012 (0.10%) 0/1013 (0.00%) 0/1011 (0.00%) 0/1010 (0.00%) Radius fracture 1/1012 (0.10%) 0/1013 (0.00%) 0/1011 (0.00%) 0/1010 (0.00%) Tendon rupture 0/1012 (0.00%) 1/1013 (0.10%) 0/1011 (0.00%) 0/1010 (0.00%) Investigations Ammonia increased 0/1012 (0.00%) 0/1013 (0.00%) 1/1011 (0.10%) 0/1010 (0.00%) Metabolism and nutrition disorders Dehydration 0/1012 (0.00%) 1/1013 (0.10%) 0/1011 (0.00%) 0/1010 (0.00%) Diabetes mellitus (in AE table) Musculoskeletal and connective tissue disorders Arthralgia 1/1012 (0.10%) 0/1013 (0.00%) 0/1011 (0.00%) 0/1010 (0.00%) Intervertebral disc disorder 0/1012 (0.00%) 0/1013 (0.00%) 1/1011 (0.10%) 0/1010 (0.00%) Intervertebral disc protrusion 0/1012 (0.00%) 0/1013 (0.00%) 2/1011 (0.20%) 0/1010 (0.00%) Muscular weakness 0/1012 (0.00%) 0/1013 (0.00%) 1/1011 (0.10%) 0/1010 (0.00%) Rotator cuff syndrome 0/1012 (0.00%) 0/1013 (0.00%) 0/1011 (0.00%) 1/1010 (0.10%) Neoplasms benign, malignant and unspecified (incl cysts and polyps) Breast cancer 1/1012 (0.10%) 0/1013 (0.00%) 1/1011 (0.10%) 0/1010 (0.00%) Colon cancer 0/1012 (0.00%) 1/1013 (0.10%) 0/1011 (0.00%) 0/1010 (0.00%) Gastric adenoma 2/1012 (0.20%) 0/1013 (0.00%) 1/1011 (0.10%) 0/1010 (0.00%) Gastric cancer 0/1012 (0.00%) 0/1013 (0.00%) 0/1011 (0.00%) 1/1010 (0.10%) Hepatic neoplasm malignant 1/1012 (0.10%) 0/1013 (0.00%) 0/1011 (0.00%) 0/1010 (0.00%) Rectal cancer 0/1012 (0.00%) 1/1013 (0.10%) 0/1011 (0.00%) 0/1010 (0.00%)

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
					Renal cell carcinoma 0/1012 (0.00%) 1/1013 (0.10%) 0/1011 (0.00%) 0/1010 (0.00%) Small cell lung cancer stage unspecified 0/1012 (0.00%) 0/1013 (0.00%) 1/1011 (0.10%) 0/1010 (0.00%) Thyroid cancer 0/1012 (0.00%) 1/1013 (0.10%) 0/1011 (0.00%) 0/1010 (0.00%) Nervous system disorders Carotid artery stenosis 1/1012 (0.10%) 0/1013 (0.00%) 0/1011 (0.00%) 0/1010 (0.00%) Cerebrovascular accident 3/1012 (0.30%) 0/1013 (0.00%) 2/1011 (0.20%) 2/1010 (0.20%) Coma hepatic 0/1012 (0.00%) 0/1013 (0.00%) 1/1011 (0.10%) 0/1010 (0.00%) Depressed level of consciousness 0/1012 (0.00%) 0/1013 (0.00%) 1/1011 (0.10%) 0/1010 (0.00%) Dizziness 1/1012 (0.10%) 0/1013 (0.00%) 0/1011 (0.00%) 0/1010 (0.00%) Headache 0/1012 (0.00%) 1/1013 (0.10%) 0/1011 (0.00%) 0/1010 (0.00%) Intracranial aneurysm 1/1012 (0.10%) 0/1013 (0.00%) 0/1011 (0.00%) 0/1010 (0.00%) Ischaemic stroke (in AE table) Subarachnoid haemorrhage 1/1012 (0.10%) 0/1013 (0.00%) 0/1011 (0.00%) 0/1010 (0.00%) Transient ischaemic attack 1/1012 (0.10%) 0/1013 (0.00%) 0/1011 (0.00%) 0/1010 (0.00%) Psychiatric disorders Confusional state 0/1012 (0.00%) 0/1013 (0.00%) 1/1011 (0.10%) 0/1010 (0.00%) Renal and urinary disorders Nephrolithiasis 0/1012 (0.00%) 0/1013 (0.00%) 0/1011 (0.00%) 2/1010 (0.20%) Ureteric stenosis 0/1012 (0.00%) 1/1013 (0.10%) 0/1011 (0.00%) 0/1010 (0.00%) Urinary incontinence 1/1012 (0.10%) 0/1013 (0.00%) 0/1011 (0.00%) 0/1010 (0.00%)

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
					Reproductive system and breast disorders Benign prostatic hyperplasia (in AE table) Respiratory, thoracic and mediastinal disorders Acute respiratory failure 0/1012 (0.00%) 1/1013 (0.10%) 0/1011 (0.00%) 0/1010 (0.00%) Asthma (in AE table) Atelectasis 0/1012 (0.00%) 1/1013 (0.10%) 0/1011 (0.00%) 0/1010 (0.00%) Bronchospasm 0/1012 (0.00%) 0/1013 (0.00%) 1/1011 (0.10%) 0/1010 (0.00%) Pleurisy 0/1012 (0.00%) 0/1013 (0.00%) 1/1011 (0.10%) 0/1010 (0.00%) Pneumonia aspiration 0/1012 (0.00%) 1/1013 (0.10%) 0/1011 (0.00%) 0/1010 (0.00%) Pulmonary hypertension 0/1012 (0.00%) 1/1013 (0.10%) 0/1011 (0.00%) 0/1010 (0.00%) Respiratory failure0/1012 (0.00%) 0/1013 (0.00%) 1/1011 (0.10%) 0/1010 (0.00%) Skin and subcutaneous tissue disorders Pruritus 1/1012 (0.10%) 0/1013 (0.00%) 0/1011 (0.00%) 0/1010 (0.00%) Vascular disorders Aortic aneurysm 0/1012 (0.00%) 1/1013 (0.10%) 0/1011 (0.00%) 0/1010 (0.00%) Arteriosclerosis 0/1012 (0.00%) 0/1013 (0.00%) 0/1011 (0.00%) 0/1010 (0.00%) Risk factors: NR
Tinoco, 2014[216] GlaxoSmithKline, 2010[264] NCT01196975 Article RCT N=1703 Industry funded Canada, Mexico, USA	Age: 50.1 (19.3) % female: 61 Ethnicity: 60% European heritage/Caucasian, 1% Arabic/north American heritage/Caucasian, 3% Asian, 3% African heritage/African American, <1%	IIV Flulaval Quadrivalent Contained 15 60 µg in 0.5 mL as one dose Intramuscular adjuvant free preservative free No co-intervention IIV TIV with either Victoria and Yamagata strains Flulaval 45 µg in	Angina unstable Cardiac failure Cardiac failure congestive Cardiogenic shock Cardiopulmonary failure Coronary artery disease Mitral valve incompetence Myocardial infarction Myocardial ischaemia Nodal rhythm Dyspepsia Dysphagia Gastrointestinal mucosal disorder	Asthma: 22.X NA I: 0/1272, 22.3 Asthmatic crisis C: 1/431 Cardiovascular events: 2.X Myocardial infarction I: 2/1272, 2.XMyocardial infarction C: 0/431 Myocardial infarction: 2.X Myocardial infarction I: 2/1272, 2.X Myocardial infarction C: 0/431 Reproduction issues: 21.X Cystocele I: 1/1272, 21.X Cystocele C: 0/431 Spontaneous abortion: 18.X NR I: 1/1272, 18.X NA C: 0/431	Severe AEs, Intervention Lot 1 (Flulaval) Intervention Lot 2 (Flulaval)Intervention Lot32 (Flulaval)Control (Victoria Strain FluLaval)Control (Yamagata Strain FluLaval): Grade 3 Pain: 9/417 (2.2%) 5/421 (1.2%) 8/422 (1.9%) 2/208 (1.0%) 3/216 (1.4%) Grade 3 Redness: 0/417 (0.0%) 0/421 (0.0%) 0/422 (0.0%) 0/208 (0.0%) 0/216 (0.0%) Grade 3 Swelling: 0/417 (0.0%) 0/421 (0.0%) 0/422 (0.0%) 0/208 (0.0%) 0/216 (0.0%)

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
	American Indian or native Alaskan, 34% Other; 37% Hispanic Adults aged ≥18 years, in stable health, and had not received any non-registered drug or vaccine within 30 days or any investigational or approved influenza vaccine within six months of the first visit Out of scope: None	0.5 mL as one dose Intramuscular adjuvant freeThimerisol Counts No prespecified AE Power other outcome Followup: 6 months	Pancreatitis acute Upper gastrointestinal haemorrhage Gait disturbance Pain Cholecystitis Cholecystitis acute Cholecystitis chronic Hepatic cirrhosis Portal hypertension Abscess limb Bronchitis Diverticulitis Pneumonia Urinary tract infection Anaemia postoperative Animal bite Ankle fracture Fracture displacement Hip fracture Humerus fracture Multiple injuries Patella fracture Stab wound Cervical spinal stenosis Malignant melanoma Metastatic neoplasm Non-small cell lung cancer Parathyroid tumour benign Prostate cancer Rectal cancer Cerebrovascular accident Cerebrovascular disorder Hypoaesthesia Ischaemic stroke Abortion spontaneous Renal and urinary disorders Calculus bladder Renal failure chronic Cystocele Asthmatic crisis Dyspnoea Pulmonary embolism Sleep apnoea syndrome Arteriosclerosis Venous thrombosis limb	Stroke: 17.X Cerebrovascular accident I: 1/1272, 17.X Cerebrovascular accident C: 0/431	Grade 3 Fatigue: 6/417 (1.4%)2/421 (0.5%)2/422 (0.5%)2/208 (1.0%)4/216 (1.9%) Grade 3 Headache: 4/417 (1.0%)3/421 (0.7%)4/422 (0.9%)1/208 (0.5%)0/216 (0.0%) Grade 3 Muscle Ache: 2/417 (0.5%)4/421 (1.0%)4/422 (0.9%)1/208 (0.5%)3/216 (1.4%) Grade 3 Shivering: 4/417 (1.0%)2/421 (0.5%)2/422 (0.5%)1/208 (0.5%)2/216 (0.9%) Grade 3 Temperature: 0/417 (0.0%)3/421 (0.7%)2/422 (0.5%)0/208 (0.0%)1/216 0.5)% Grade 3 Joint Pain: 1/196 (0.5%)3/199 (1.5%)1/201 (0.5%)1/102 (1.0%)3/103 (2.9%) Grade 3 Gastr.: 5/417 (1.2%)1/421 (0.2%) 4/422 (0.9%)4/208 (1.9%)1/216 (0.5%) Any Grade 3 unsolicited AEs: 26/1300 (2.0%) (all QIV) 6/214 (2.8%) 7/219 (3.2%) Medically attended events: 330/1272 (25.9%) (all QIV) 51/213 (23.9%) 64/218 (29.4%) Serious AEs (from clinicaltrials.gov): Intervention Lot 1 (Flulaval) Intervention Lot 2 (Flulaval)Intervention Lot32 (Flulaval)Control (Victoria Strain FluLaval)Control (Yamagata Strain FluLaval) Affected / at Risk (%)Affected / at Risk (%)Affected / at Risk (%)Affected / at Risk (%)Affected / at Risk (%) Total 15/423 (3.55%) 13/424 (3.07%) 7/425 (1.65%) 3/213 (1.41%) 7/218 (3.21%) Cardiac disorders Angina unstable 1/423 (0.24%) 0/424 (0.00%) 0/425 (0.00%) 1/213 (0.47%) 0/218 (0.00%) Cardiac failure 1/423 (0.24%) 0/424 (0.00%) 0/425 (0.00%) 0/213 (0.00%) 0/218 (0.00%)

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
			Fatigue (prespecified) Gastrointestinal adverse event(s) (prespecified) Headache (prespecified) Muscle aches Shivering (prespecified) Joint pain at other location than injection site Redness Pain (prespecified) Redness (prespecified) Swelling (prespecified) Oropharyngeal pain Cough Nasopharyngitis Sinusitis Upper respiratory tract infection Myalgia (prespecified) Arthralgia (prespecified) Fever (prespecified)		Cardiac failure congestive 1/423 (0.24%) 0/424 (0.00%) 0/425 (0.00%) 0/213 (0.00%) 0/218 (0.00%) Cardiogenic shock 1/423 (0.24%) 0/424 (0.00%) 0/425 (0.00%) 0/213 (0.00%) 0/218 (0.00%) Cardiopulmonary failure 0/423 (0.00%) 1/424 (0.24%) 0/425 (0.00%) 0/213 (0.00%) 0/218 (0.00%) Coronary artery disease 0/423 (0.00%) 0/424 (0.00%) 1/425 (0.24%) 0/213 (0.00%) 1/218 (0.46%) Mitral valve incompetence 0/423 (0.00%) 0/424 (0.00%) 1/425 (0.24%) 0/213 (0.00%) 0/218 (0.00%) Myocardial infarction (in AE table) Myocardial ischaemia 1/423 (0.24%) 0/424 (0.00%) 0/425 (0.00%) 0/213 (0.00%) 0/218 (0.00%) Nodal rhythm 0/423 (0.00%) 1/424 (0.24%) 0/425 (0.00%) 0/213 (0.00%) 0/218 (0.00%) Gastrointestinal disorders Dyspepsia 1/423 (0.24%) 0/424 (0.00%) 0/425 (0.00%) 0/213 (0.00%) 0/218 (0.00%) Dysphagia 0/423 (0.00%) 1/424 (0.24%) 0/425 (0.00%) 0/213 (0.00%) 0/218 (0.00%) Gastrointestinal mucosal disorder 0/423 (0.00%) 0/424 (0.00%) 0/425 (0.00%) 1/213 (0.47%) 0/218 (0.00%) Pancreatitis acute 1/423 (0.24%) 0/424 (0.00%) 0/425 (0.00%) 0/213 (0.00%) 0/218 (0.00%) Upper gastrointestinal haemorrhage 0/423 (0.00%) 0/424 (0.00%) 0/425 (0.00%) 1/213 (0.47%) 0/218 (0.00%) General disorders Gait disturbance 0/423 (0.00%) 1/424 (0.24%) 0/425 (0.00%) 0/213 (0.00%) 0/218 (0.00%) Pain 0/423 (0.00%) 1/424 (0.24%) 0/425 (0.00%) 0/213 (0.00%) 0/218 (0.00%) Hepatobiliary disorders

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
					Cholecystitis 0/423 (0.00%) 1/424 (0.24%) 0/425 (0.00%) 0/213 (0.00%) 0/218 (0.00%) Cholecystitis acute 1/423 (0.24%) 0/424 (0.00%) 0/425 (0.00%) 0/213 (0.00%) 0/218 (0.00%) Cholecystitis chronic 1/423 (0.24%) 0/424 (0.00%) 0/425 (0.00%) 0/213 (0.00%) 0/218 (0.00%) Hepatic cirrhosis 0/423 (0.00%) 0/424 (0.00%) 0/425 (0.00%) 0/213 (0.00%) 1/218 (0.46%) Portal hypertension 0/423 (0.00%) 0/424 (0.00%) 0/425 (0.00%) 0/213 (0.00%) 1/218 (0.46%) Infections and infestations Abscess limb 0/423 (0.00%) 0/424 (0.00%) 0/425 (0.00%) 0/213 (0.00%) 1/218 (0.46%) Bronchitis 0/423 (0.00%) 0/424 (0.00%) 0/425 (0.00%) 0/213 (0.00%) 1/218 (0.46%) Diverticulitis 1/423 (0.24%) 0/424 (0.00%) 0/425 (0.00%) 0/213 (0.00%) 0/218 (0.00%) Pneumonia 1/423 (0.24%) 0/424 (0.00%) 0/425 (0.00%) 0/213 (0.00%) 0/218 (0.00%) Urinary tract infection 0/423 (0.00%) 1/424 (0.24%) 1/425 (0.24%) 0/213 (0.00%) 0/218 (0.00%) Injury, poisoning and procedural complications Anaemia postoperative 1/423 (0.24%) 0/424 (0.00%) 0/425 (0.00%) 0/213 (0.00%) 0/218 (0.00%) Animal bite 0/423 (0.00%) 0/424 (0.00%) 1/425 (0.24%) 0/213 (0.00%) 0/218 (0.00%) Ankle fracture 1/423 (0.24%) 0/424 (0.00%) 0/425 (0.00%) 0/213 (0.00%) 0/218 (0.00%) Fracture displacement 0/423 (0.00%) 0/424 (0.00%) 0/425 (0.00%) 1/213 (0.47%) 0/218 (0.00%)

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
					Hip fracture 0/423 (0.00%) 0/424 (0.00%) 0/425 (0.00%) 1/213 (0.47%) 1/218 (0.46%) Humerus fracture 0/423 (0.00%) 1/424 (0.24%) 0/425 (0.00%) 0/213 (0.00%) 0/218 (0.00%) Multiple injuries 0/423 (0.00%) 0/424 (0.00%) 0/425 (0.00%) 0/213 (0.00%) 1/218 (0.46%) Patella fracture 0/423 (0.00%) 1/424 (0.24%) 0/425 (0.00%) 0/213 (0.00%) 0/218 (0.00%) Stab wound 0/423 (0.00%) 1/424 (0.24%) 0/425 (0.00%) 0/213 (0.00%) 0/218 (0.00%) Musculoskeletal and connective tissue disorders Cervical spinal stenosis 0/423 (0.00%) 0/424 (0.00%) 1/425 (0.24%) 0/213 (0.00%) 0/218 (0.00%) Neoplasms benign, malignant and unspecified (incl cysts and polyps) Malignant melanoma 0/423 (0.00%) 1/424 (0.24%) 0/425 (0.00%) 0/213 (0.00%) 0/218 (0.00%) Metastatic neoplasm 0/423 (0.00%) 1/424 (0.24%) 0/425 (0.00%) 0/213 (0.00%) 0/218 (0.00%) Non-small cell lung cancer 1/423 (0.24%) 0/424 (0.00%) 0/425 (0.00%) 0/213 (0.00%) 0/218 (0.00%) Parathyroid tumour benign 0/423 (0.00%) 1/424 (0.24%) 0/425 (0.00%) 0/213 (0.00%) 0/218 (0.00%) Prostate cancer 0/423 (0.00%) 0/424 (0.00%) 0/425 (0.00%) 0/213 (0.00%) 1/218 (0.46%) Rectal cancer 0/423 (0.00%) 0/424 (0.00%) 1/425 (0.24%) 0/213 (0.00%) 0/218 (0.00%) Nervous system disorders Cerebrovascular accident 0/423 (0.00%) 1/424 (0.24%) 0/425 (0.00%) 0/213 (0.00%) 0/218 (0.00%) Cerebrovascular disorder 1/423 (0.24%) 0/424 (0.00%) 1/425 (0.24%) 0/213 (0.00%) 0/218 (0.00%)

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
					Hypoaesthesia 0/423 (0.00%) 0/424 (0.00%) 0/425 (0.00%) 1/213 (0.47%) 0/218 (0.00%) Ischaemic stroke (in AE table) Pregnancy, puerperium and perinatal conditions Abortion spontaneous (in AE table) Renal and urinary disorders Calculus bladder 0/423 (0.00%) 0/424 (0.00%) 1/425 (0.24%) 0/213 (0.00%) 0/218 (0.00%) Renal failure chronic 1/423 (0.24%) 1/424 (0.24%) 0/425 (0.00%) 0/213 (0.00%) 0/218 (0.00%) Reproductive system and breast disorders Cystocele (in AE table) Respiratory, thoracic and mediastinal disorders Asthmatic crisis (in AE table) Dyspnoea 1/423 (0.24%) 0/424 (0.00%) 0/425 (0.00%) 0/213 (0.00%) 0/218 (0.00%) Pulmonary embolism 1/423 (0.24%) 0/424 (0.00%) 0/425 (0.00%) 0/213 (0.00%) 0/218 (0.00%) Sleep apnoea syndrome 0/423 (0.00%) 1/424 (0.24%) 0/425 (0.00%) 0/213 (0.00%) 0/218 (0.00%) Vascular disorders Arteriosclerosis 0/423 (0.00%) 1/424 (0.24%) 0/425 (0.00%) 0/213 (0.00%) 0/218 (0.00%) Venous thrombosis limb 0/423 (0.00%) 0/424 (0.00%) 1/425 (0.24%) 0/213 (0.00%) 0/218 (0.00%) Risk factors: NR
Treanor, 2017[218] Seqirus, 2014[374] NCT02214225 Article RCT N=3484	Age: 58 (18) % female: 57% Ethnicity: 82% White, 16% Black or African American, 1% Asian, 1% Other	IIV Afluria Quandrivalent 15 µg hemagglutinin for each influenza virus strain (four strains) 60 µg in 0.5 mL dose as one dose Intramuscular adjuvant NR preservative NR	Atrial fibrillation Myocardial infarction Cardiac failure congestive Acute myocardial infarction Atrioventricular block second degree Bundle branch block left Cardiac failure Coronary artery disease Sick sinus syndrome	Asthma: 22.X NR I: 1/1721, 22.X NA C: 0/1728 Autoimmune disease: 10.X Granulomatosis with polyangiitis I: 1/1721, 10.X Granulomatosis with polyangiitis C: 0/1728 Cardiovascular events: 2.X Atrial fibrillation I: 3/1721, 2.XAtrial fibrillation C: 3/1728	Intervention (QIV)Control (TIV-1)Control (TIV-2) Any Grade 3 AE: 107/1721 (6.2%) 42/864 (4.9%)52/864 (6.0%) Severe (grade 3) solicited AEs: 42/1721 (2.4%) 15/864 (1.7%) 24/864 (2.8%) Severe (grade 3) unsolicited AE: 39/1721 (2.3%) 14/864 (1.6%) 13/864 (1.2%) AEs of special interest: 0/1721 (0.0%) 0/864 (0%) 0/864 (0%)

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
Industry funded Australia	Healthy men and women aged 18 years and older Out of scope: None	No co-intervention IIV IIV3-YAM or IIV-VIC Afluria and not reported 45 µg in 0.5 mL as one dose Intramuscular adjuvant NRpreservative free Counts No prespecified AE Power other outcome Followup: 6 months	Ventricular arrhythmia Abominable pain upper Colitis Diverticulum intestinal Pancreatitis acute Small intestinal obstruction Chest pain Asthenia Pyrexia Bronchitis Pneumonia Sepsis Atypical pneumonia Cellulitis Diverticulitis Pelvic inflammatory disease Urinary tract infection Esophageal injury Postprocedural hematuria Road traffic accident Upper limb fracture Investigatio Oxygen saturation decreased Dehydration Osteoarthritis Joint swelling Musculoskeletal chest pain Lung neoplasm malignant Adenocarcinoma of colon Parathyroid tumor benign Prostate cancer Renal cell carcinoma Cerebrovascular accident Transient ischemic attack Carotid artery disease Carotid artery stenosis Hemorrhage intracranial Ischemic stroke Posterior reversible encephalopathy syndrome Spasmodic dysphonia Syncope Thalamic infarction Psychiatric disorde Bipolar I disorder	Death: NA One death due to pneumonia considered related to vaccine I: 5/1721, NA No related to vaccine. Occurred in TIV1 C: 1/1728 Myocardial infarction: 2.X Myocardial infarction I: 1/1721, 2.X Myocardial infarction (1 each from TIV1 and TIV2) C: 2/1728 Stroke: 17.X Cerebrovascular accident I: 2/1721, 17.X Cerebrovascular accident C: 1/1728	Serious AEs (from clinicaltrials.gov): Intervention (QIV)Control (TIV-1)Control (TIV-2) Affected / at Risk (%)Affected / at Risk (%) Affected / at Risk (%) Total 39/1721 (2.27%) 14/864 (1.62%) 13/864 (1.50%) Cardiac disorders Atrial fibrillation 3/1721 (0.17%) 0/864 (0.00%) 3/864 (0.35%) Myocardial infarction 1/1721 (0.06%) 1/864 (0.12%) 1/864 (0.12%) (in AE table) Cardiac failure congestive 1/1721 (0.06%) 0/864 (0.00%) 1/864 (0.12%) (in AE table) Acute myocardial infarction 1/1721 (0.06%) 0/864 (0.00%) 0/864 (0.00%) Atrioventricular block second degree 1/1721 (0.06%) 0/864 (0.00%) 0/864 (0.00%) Bundle branch block left 1/1721 (0.06%) 1 (0.00%) 064 (0.00%) Cardiac failure 1/1721 (0.06%) 0/864 (0.00%) 0/864 (0.00%) Coronary artery disease 1/1721 (0.06%) 0/864 (0.00%) 0/864 (0.00%) Sick sinus syndrome 0/1721 (0.00%) 1/864 (0.12%) 0/864 (0.00%) Ventricular arrhythmia 1/1721 (0.06%) 0/864 (0.00%) 0/864 (0.00%) Gastrointestinal disorders Abominable pain upper 1/1721 (0.06%) 0/864 (0.00%) 0/864 (0.00%) Colitis 1/1721 (0.06%) 0/864 (0.00%) 0/864 (0.00%) Diverticulum intestinal 1/1721 (0.06%) 0/864 (0.00%) 0/864 (0.00%) Pancreatitis acute 1/1721 (0.06%) 0/864 (0.00%) 0/864 (0.00%) Small intestinal obstruction 1/1721 (0.06%) 0/864 (0.00%) 0/864 (0.00%) General disorders Chest pain 1/1721 (0.06%) 0/864 (0.00%) 1/864 (0.12%) Asthenia 1/1721 (0.06%) 0/864 (0.00%) 0/864 (0.00%)

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
			Bipolar disorder Hydronephrosis Renal failure Renal failure acute Renal impairment Pulmonary embolism Acute respiratory failure Asthma Chronic obstructive pulmonary disease Hypoxia Respiratory failure Diabetic foot Accelerated hypertension Deep vein thrombosis Granulomatosis with polyangiitis Hypertension Pain Myalgia Headache Malaise		Pyrexia 1/1721 (0.06%) 0/864 (0.00%) 0/864 (0.00%) Infections and infestations Bronchitis 0/1721 (0.00%) 1/864 (0.12%) 0/864 (0.00%) Pneumonia 2/1721 (0.12%) 2/864 (0.23%) 1/864 (0.12%) Sepsis 0/1721 (0.00%) 2/864 (0.23%) 1/864 (0.12%) Atypical pneumonia 0/1721 (0.00%) 1/864 (0.12%) 0/864 (0.00%) Cellulitis 0/1721 (0.00%) 1/864 (0.12%) 0/864 (0.00%) Diverticulitis 0/1721 (0.00%) 1/864 (0.12%) 0/864 (0.00%) Pelvic inflammatory disease 0/1721 (0.00%) 1/864 (0.12%) 0/864 (0.00%) Urinary tract infection 1/1721 (0.06%) 0/864 (0.00%) 0/864 (0.00%) Injury, poisoning and procedural complications Esophageal injury 0/1721 (0.00%) 0/864 (0.00%) 1/864 (0.12%) Postprocedural hematuria 1/1721 (0.06%) 0/864 (0.00%) 0/864 (0.00%) Road traffic accident 1/1721 (0.06%) 0/864 (0.00%) 0/864 (0.00%) Upper limb fracture 1/1721 (0.06%) 0/864 (0.00%) 0/864 (0.00%) Investigations Oxygen saturation decreased 0/1721 (0.00%) 1/864 (0.12%) 0/864 (0.00%) Metabolism and nutrition disorders Dehydration 1/1721 (0.06%) 0/864 (0.00%) 0/864 (0.00%) Musculoskeletal and connective tissue disorders Osteoarthritis 2/1721 (0.12%) 0/864 (0.00%) 0/864 (0.00%) Joint swelling 0/1721 (0.00%) 01/864 (0.12%) 0/864 (0.00%) Musculoskeletal chest pain 0/1721 (0.00%) 0/864 (0.00%) 1/864 (0.12%) Neoplasms benign, malignant and unspecified (incl cysts and polyps) Lung neoplasm malignant 2/1721 (0.12%) 0/864 (0.00%) 1/864 (0.12%)

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
					Adenocarcinoma of colon 0/1721 (0.00%) 1/864 (0.12%) 0/864 (0.00%) Parathyroid tumor benign 0/1721 (0.00%) 0/864 (0.00%) 1/864 (0.12%) Prostate cancer 1/1721 (0.06%) 0/864 (0.00%) 0/864 (0.00%) Renal cell carcinoma 1/1721 (0.06%) 0/864 (0.00%) 0/864 (0.00%) Nervous system disorders Cerebrovascular accident 2/1721 (0.12%) 0/864 (0.00%) 1/864 (0.12%) (in AE table) Transient ischemic attack 1/1721 (0.06%) 0/864 (0.00%) 1/864 (0.12%) Carotid artery disease 0/1721 (0.00%) 1/864 (0.12%) 0/864 (0.00%) Carotid artery stenosis 1/1721 (0.06%) 0/864 (0.00%) 0/864 (0.00%) Hemorrhage intracranial 1/1721 (0.06%) 0/864 (0.00%) 0/864 (0.00%) Ischemic stroke 1/1721 (0.06%) 10/864 (0.00%) 0/864 (0.00%) Posterior reversible encephalopathy syndrome 1/1721 (0.06%) 0/864 (0.00%) 0/864 (0.00%) Spasmodic dysphonia 1/1721 (0.06%) 0/864 (0.00%) 0/864 (0.00%) Syncope 0/1721 (0.00%) 1/864 (0.12%) 0/864 (0.00%) Thalamic infarction 1/1721 (0.06%) 0/864 (0.00%) 0/864 (0.00%) Psychiatric disorders Bipolar I disorder 0/1721 (0.00%) 0/864 (0.00%) 1/864 (0.12%) Bipolar disorder 0/1721 (0.00%) 0/864 (0.00%) 1/864 (0.12%) Renal and urinary disorders Hydronephrosis 1/1721 (0.06%) 0/864 (0.00%) 0/864 (0.00%) Renal failure 0/1721 (0.00%) 1/864 (0.12%) 0/864 (0.00%) Renal failure acute 0/1721 (0.00%) 1/864 (0.12%) 0/864 (0.00%) Renal impairment 0/1721 (0.00%) 1/864 (0.12%) 0/864 (0.00%) Respiratory, thoracic and mediastinal disorders

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
					Pulmonary embolism 0/1721 (0.00%) 0/864 (0.00%) 2/864 (0.23%) Acute respiratory failure 0/1721 (0.00%) 0/864 (0.00%) 1/864 (0.12%) Asthma (in AE table) Chronic obstructive pulmonary disease 1/1721 (0.06%) 0/864 (0.00%) 0/864 (0.00%) Hypoxia 1/1721 (0.06%) 0/864 (0.00%) 0/864 (0.00%) Respiratory failure 0/1721 (0.00%) 0/864 (0.00%) 1/864 (0.12%) Skin and subcutaneous tissue disorders Diabetic foot 0/1721 (0.00%) 1/864 (0.12%) 0/864 (0.00%) Vascular disorders Accelerated hypertension 1/1721 (0.06%) 0/864 (0.00%) 0/864 (0.00%) Deep vein thrombosis 1/1721 (0.06%) 0/864 (0.00%) 0/864 (0.00%) Granulomatosis with polyangiitis 1/1721 (0.06%) 0/864 (0.00%) 0/864 (0.00%) (in AE table) Hypertension 1/1721 (0.06%) 0/864 (0.00%) 0/864 (0.00%) Risk factors: NR
Essink, 2020[103] Seqirus [373] NCT03314662 Article RCT N=1778 Industry funded USA	Age: 72.5 (5.5) % female: 57% Ethnicity: 92% Caucasian, 7% African American, <1% Native Hawaiian or Pacific Islander, <1% Native American, <1% Other Men or women >=65 years of age who were healthy or had comorbidities that increased their risk of	Influenza aIIV Fluad Quadrivalent Contained strains compliant with recommendations by the World Health Organization (WHO) for the 2017–2018 Northern Hemisphere influenza season for quadrivalent vaccines: A/Michigan/45/2015 (H1N1)-like virus; A/Hong Kong/4801/2014 (H3N2)-like virus; B/Phuket/3073/2013-like virus	Mortality Anaemia Thrombocytopenia Coronary artery disease Atrial fibrillation Angina pectoris Angina unstable Arteriosclerosis coronary artery Myocardial infarction Sinus node dysfunction Vertigo Abdominal pain Diverticular perforation Enteritis Gastrointestinal perforation Gastrooesophageal reflux disease Haematochezia Ileus paralytic Intestinal obstruction	ALS: 17.X NR I: 0/888, 17.X Occurred in aTIV1 C: 1/888 Asthma: 22.X NA I: 0/888, 22.X Unrelated to vaccine C: 1/888 Autoimmune disease: 10.X Polymyalgia rheumatica I: 1/888, 10.X Addison's disease in aTIV1 C: 1/888 Cardiovascular events: 2.X Coronary artery disease I: 1/888, 2.XCoronary artery disease (1 in aTIV1, 2 in aTIV2) C: 3/888 Death: NA Unrelated to vaccine I: 2/888, NA NA (combined aTIV1 and aTIV2) C: 0/888 Encephalitis: 17.X Encephalopathy I: 0/888, Encephalopathy (in aTIV2) C: 1/888 Myocardial infarction: 2.X Myocardial Infarction I: 0/888, 2.X Myocardial Infarction C: 1/888	Severe AEs, Intervention (aQIV), Control Group 1 (aTIV-1), Control Group 2 (aTIV-2): Fever >=39 C: 1/888 (0.1%) vs 0/444 (0%) vs 0/444 (0%) New onset of chronic disease: 23/888 (2.6%), 16/444 (3.6%), 14/444 (3.2%) Serious AEs (from clinicaltrials.gov), Intervention (aQIV) vs Control (aTIV1) vs Control (aTIV2), Affected / at Risk (%) Affected / at Risk (%) Affected / at Risk (%) Total 37/888 (4.17%) 28/444 (6.31%) 18/444 (4.05%) Anaemia 1/888 (0.11%) 0/444 (0.00%) 0/444 (0.00%) Thrombocytopenia0/888 (0.00%) 1/444 (0.23%) 0/444 (0.00%) Coronary artery disease1/888 (0.11%) 1/444 (0.23%) 2/444 (0.45%) (in AE table)

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
	influenza complications Out of scope: None	(Yamagata lineage); B/Brisbane/60/2008 -like virus (Victoria lineage) 60 µg in 0.5 mL given as one dose Route NR Other : MF-59 preservative NR No co-intervention IIV Routine adjuvanted TIV vaccine (one of two types) Fluad (aTIV-1) and not reported (aTIV-2) 45 µg in 0.5 mL given as one dose route NR Other : MF-59preservative NR Counts No prespecified AE Power other outcome Followup: 6 months	Large intestinal obstruction Pancreatitis acute Upper gastrointestinal haemorrhage Chest pain Non-cardiac chest pain Cholelithiasis Cholangitis acute Hepatic failure Pneumonia Influenza Sepsis Abscess intestinal Cellulitis Pneumonia bacterial Pyelonephritis Respiratory syncytial virus infection Urinary tract infection Viral pericarditis Femur fracture Humerus fracture Lower limb fracture Overdose Procedural dizziness Road traffic accident Scapula fracture Skin abrasion Spinal compression fracture Subdural haematoma Hyperglycaemia Dehydration Osteoarthritis Lumbar spinal stenosis Spinal column stenosis Bladder cancer Breast cancer Breast cancer in situ Non-small cell lung cancer Ovarian cancer stage IV Pituitary tumour benign Skin cancer Carotid artery stenosis Amyotrophic lateral sclerosis Encephalopathy	Seizure: 17.X NR I: 1/888, 17.X Combined aTIV1 and aTIV2 C: 0/888 Stroke: 17.X Ischaemic cerebral infarction I: 0/888, 17.X Ischaemic cerebral infarction in aTIV1 C: 1/888	Atrial fibrillation 1/888 (0.11%) 0/444 (0.00%) 1/444 (0.23%) Angina pectoris 0/888 (0.00%) 0/444 (0.00%) 1/444 (0.23%) Angina unstable 1/888 (0.11%) 0/444 (0.00%) 0/444 (0.00%) Arteriosclerosis coronary artery 1/888 (0.11%) 0/444 (0.00%) 0/444 (0.00%) Myocardial infarction 0/888 (0.00%) 1/444 (0.23%) 0/444 (0.00%) Sinus node dysfunction0/888 (0.00%) 1/444 (0.23%) 0/444 (0.00%) Vertigo 0/888 (0.00%) 1/444 (0.23%) 0/444 (0.00%) Abdominal pain 1/888 (0.11%) 0/444 (0.00%) 0/444 (0.00%) Diverticular perforation1/888 (0.11%) 0/444 (0.00%) 0/444 (0.00%) Enteritis 0/888 (0.00%) 0/444 (0.00%) 1/444 (0.23%) Gastrointestinal perforation 0/888 (0.00%) 0/444 (0.00%) 1/444 (0.23%) Gastrooesophageal reflux disease 0/888 (0.00%) 1/444 (0.23%) 0/444 (0.00%) Haematochezia 0/888 (0.00%) 0/444 (0.00%) 1/444 (0.23%) Ileus paralytic 0/888 (0.00%) 0/444 (0.00%) 1/444 (0.23%) Intestinal obstruction 1/888 (0.11%) 0/444 (0.00%) 0/444 (0.00%) Large intestinal obstruction 0/888 (0.00%) 1/444 (0.23%) 0/444 (0.00%) Pancreatitis acute 1/888 (0.11%) 0/444 (0.00%) 0/444 (0.00%) Upper gastrointestinal haemorrhage 0/888 (0.00%) 0/444 (0.00%) 1/444 (0.23%) Chest pain1/888 (0.11%) 0/444 (0.00%) 0/444 (0.00%) Non-cardiac chest pain 0/888 (0.00%) 1/444 (0.23%) 0/444 (0.00%) Cholelithiasis 0/888 (0.00%) 1/444 (0.23%) 1/444 (0.23%) Cholangitis acute 0/888 (0.00%) 1/444 (0.23%) 0/444 (0.00%) Hepatic failure 0/888 (0.00%) 1/444 (0.23%) 0/444 (0.00%)

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
			Ischaemic cerebral infarction Loss of consciousness Presyncope Seizure Syncope Confusional state Acute kidney injury Renal mass Dyspnoea Chronic obstructive pulmonary disease Thrombosis Accelerated hypertension Aortic aneurysm Aortic dissection Hypotension Diarrhea (prespecified) Redness Swelling Pain Fatigue Ecchymosis Myalgia (prespecified) Arthralgia (prespecified) Headache (prespecified) Fever (prespecified) Loss of appetite (prespecified) Nausea (prespecified) Chills (prespecified) Vomiting (prespecified)		Pneumonia 7/888 (0.79%) 4/444 (0.90%) 1/444 (0.23%) Influenza 1/888 (0.11%) 0/444 (0.00%) 2/444 (0.45%) Sepsis 1/888 (0.11%) 1/444 (0.23%) 0/444 (0.00%) Abscess intestinal 0/888 (0.00%) 0/444 (0.00%) 1/444 (0.23%) Cellulitis 1/888 (0.11%) 0/444 (0.00%) 0/444 (0.00%) Pneumonia bacterial 1/888 (0.11%) 0/444 (0.00%) 0/444 (0.00%) Pyelonephritis 1/888 (0.11%) 0/444 (0.00%) 0/444 (0.00%) Respiratory syncytial virus infection 0/888 (0.00%) 1/444 (0.23%) 0/444 (0.00%) Urinary tract infection 1/888 (0.11%) 0/444 (0.00%) 0/444 (0.00%) Viral pericarditis 0/888 (0.00%) 1/444 (0.23%) 0/444 (0.00%) Femur fracture 1/888 (0.11%) 0/444 (0.00%) 0/444 (0.00%) Humerus fracture 0/888 (0.00%) 1/444 (0.23%) 0/444 (0.00%) Lower limb fracture 1/888 (0.11%) 0/444 (0.00%) 0/444 (0.00%) Overdose 0/888 (0.00%) 1/444 (0.23%) 0/444 (0.00%) Procedural dizziness 0/888 (0.00%) 1/444 (0.23%) 0/444 (0.00%) Road traffic accident 0/888 (0.00%) 1/444 (0.23%) 0/444 (0.00%) Scapula fracture 1/888 (0.11%) 0/444 (0.00%) 0/444 (0.00%) Skin abrasion 1/888 (0.11%) 0/444 (0.00%) 0/444 (0.00%) Spinal compression fracture 1/888 (0.11%) 0/444 (0.00%) 0/444 (0.00%) Subdural haematoma 1/888 (0.11%) 0/444 (0.00%) 0/444 (0.00%) Hyperglycaemia 1/888 (0.11%) 1/444 (0.23%) 0/444 (0.00%) Dehydration 1/888 (0.11%) 0/444 (0.00%) 0/444 (0.00%) Osteoarthritis 3/888 (0.34%) 3/444 (0.68%) 0/444 (0.00%)

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
					Lumbar spinal stenosis 0/888 (0.00%) 1/444 (0.23%) 0/444 (0.00%) Spinal column stenosis 0/888 (0.00%) 0/444 (0.00%) 1/444 (0.23%) Neoplasms benign, malignant and unspecified (incl cysts and polyps) Bladder cancer 0/888 (0.00%) 0/444 (0.00%) 1/444 (0.23%) Breast cancer 0/888 (0.00%) 1/444 (0.23%) 0/444 (0.00%) Breast cancer in situ 0/888 (0.00%) 1/444 (0.23%) 0/444 (0.00%) Non-small cell lung cancer 0/888 (0.00%) 0/444 (0.00%) 1/444 (0.23%) Ovarian cancer stage IV 1/888 (0.11%) 0/444 (0.00%) 0/444 (0.00%) Pituitary tumour benign 0/888 (0.00%) 1/444 (0.23%) 0/444 (0.00%) Skin cancer 1/888 (0.11%) 0/444 (0.00%) 0/444 (0.00%) Carotid artery stenosis 1/888 (0.11%) 2/444 (0.45%) 0/444 (0.00%) Amyotrophic lateral sclerosis (in AE table) Loss of consciousness 0/888 (0.00%) 1/444 (0.23%) 0/444 (0.00%) Presyncope 1/888 (0.11%) 0/444 (0.00%) 0/444 (0.00%) Syncope 0/888 (0.00%) 1/444 (0.23%) 0/444 (0.00%) Confusional state 1/888 (0.11%) 0/444 (0.00%) 0/444 (0.00%) Acute kidney injury 1/888 (0.11%) 1/444 (0.23%) 0/444 (0.00%) Renal mass 1/888 (0.11%) 0/444 (0.00%) 0/444 (0.00%) Respiratory, thoracic and mediastinal disorders Dyspnoea 0/888 (0.00%) 1/444 (0.23%) 1/444 (0.23%) Chronic obstructive pulmonary disease0/888 (0.00%) 0/444 (0.00%) 1/444 (0.23%) Thrombosis0/888 (0.00%) 1/444 (0.23%) 1/444 (0.23%) Accelerated hypertension 0/888 (0.00%) 1/444 (0.23%) 0/444 (0.00%)

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
					Aortic aneurysm 0/888 (0.00%) 0/444 (0.00%) 1/444 (0.23%) Aortic dissection 1/888 (0.11%) 0/444 (0.00%) 0/444 (0.00%) Hypotension 0/888 (0.00%) 0/444 (0.00%) 1/444 (0.23%) Risk factors: When analyzed by age subgroups, the rates of any solicited AEs were higher in the >=65–74 year age subgroup (55.2% [337/611] in aQIV, 51.9% [161/310] in aTIV-1, and 50.8% [151/297] in aTIV-2) than in the >=75–84year age subgroup (44.3% [109/246] in aQIV, 39.2% [47/120] in aTIV-1, and 44.4% [59/133] in aTIV-2). No notable differences were observed in the subgroups by gender and race.
Frey, 2014[110] Novartis Vaccines, 2010[329] NCT01162122 Article RCT N=7104 Industry funded Panama, Columbia, Philippines, USA	Age: 71.9 (5.3) % female: 65% Ethnicity: 53% Asian, 1% Black, 28% Caucasian, 18% Hispanic, <1% Native American/Hawaii and <1% Other Adults aged 65 years or older Out of scope: None	Influenza aIIV Fluad (trivalent) 15 45 µg in 05 mL as one dose Intramuscular Other : MF-59 preservative free No co-intervention IIV Non-adjuvanted TIV Agriflu 45 µg in 05 mL as one dose Intramuscular adjuvant freepreservative free Counts No prespecified AE Power other outcome Followup: 12 months	Anemia Disseminated intravascular coagulation Idiopathic Thrombocytopenic coagulation Leukocytosis Sideroblastic anaemia Acute coronary syndrome Acute myocardial infarction Angina pectoris Angina unstable Arrhythmia Arteriosclerosis coronary artery Atrial Fibrillation Atrial tachycardia Bradycardia Cardiac arrest Cardiac disorder Cardiac failure Cardiac failure congestive Cardio-respiratory arrest Cardiogenic shock Coronary artery disease Dressler's syndrome Hypertensive heart disease Hypertrophic cardiomyopathy	Angioedema: 10.X NR I: 1/3545, 10.X NA C: 0/3537 Asthma: 22.X Asthma I: 1/3545, 22.3 Asthmatic crisis C: 1/3537 Cardiovascular events: 2.X Cardiac failure congestive I: 8/3545, 2.X Cardiac failure congestive C: 16/3537 Death: NA None related to vaccine, 3 of the deaths due to influenza I: 52/3479, NA 4 of the deaths due to influenza, q death of TIV vaccine considered possibly vaccine-related (cause of death respiratory depression secondary to Guillain–Barré syndrome) C: 46/3482 Diabetes: 14.X Diabetes mellitus I: 5/3545, 14.X Diabetes mellitus C: 2/3537 Guillain-Barré syndrome: 17.X NA I: 0/3545, 17.4 Severe, possibly vaccine related C: 1/3537 Herpes Zoster: 11.X NA I: 0/3545 11.X NR C: 1/3537 Immune Thrombocytopenia Purpura: 2.X Idiopathic thrombocytopenic coagulation I: 1/3545, 2.X Idiopathic thrombocytopenic coagulation C: 0/3537	Percentage of subjects experiencing the following, in the order of Intervention Group (aTIV) and Control Group (TIV): Solicited local AEs: 32% vs 17% Solicited systemic AEs: 32% vs 26%) New-onset chronic diseases: 6% vs 6% Serious AEs (from clinicaltrials.gov) Intervention (aTIV-all lots)Control (licensed TIV) Affected / at Risk (%)Affected / at Risk (%) Total 264/3545 (7.45%) 243/3537 (6.87%) Blood and lymphatic system disorders Anemia 2/3545 (0.06%) 5/3537 (0.14%) Disseminated intravascular coagulation 1/3545 (0.03%) 0/3537 (0.00%) Idiopathic Thrombocytopenic coagulation (in AE table) Leukocytosis 0/3545 (0.00%) 1/3537 (0.03%) Sideroblastic anaemia 1/3545 (0.03%) 0/3537 (0.00%) Cardiac disorders Acute coronary syndrome 2/3545 (0.06%) 0/3537 (0.00%) Acute myocardial infarction 11/3545 (0.31%) 7/3537 (0.20%) Angina pectoris 1/3545 (0.03%) 2/3537 (0.06%)

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
			Myocardial infarction Myocardial Ischemia Nodal arrythmia Pericarditis Sinus Tachycardia Ventricular extrasystoles Ventricular tachycardia Hydrocele Vertigo Vertigo positional Eye disor Blindness unilateral Corneal degeneration Retinal neovascularisation Viterous hemorrhage Abdominal hernia Abdominal pain Abdominal pain upper Abdominal wall hematoma Ascites Colitis Diverticular perforation Diverticulum Duodenal ulcer perforation Dyspepsia Erosive oesophagitis Femoral hernia obstructive Gastric ulcer perforation Gastritis Gastrointestinal haemorrhage Hiatus hernia Ileus Ileus paralytic Inguinal hernia, obstructive Intestinal perforation Irritable bowel syndrome Large intestine perforation Lower gastrointestinal haemorrhage Oesophagitis Pancreatic mass Pancreatitis Pancreatitis acute Peptic ulcer Peptic ulcer perforation Pneumoperitonium	Meningitis: 11.X Meningitis aseptic I: 0/3545, 11.X Meningitis aseptic C: 1/3537 Myocardial infarction: 2.X Myocardial infarction I: 10/3545, 2.X Myocardial infarction C: 9/3537 Reproduction issues: 21.X Endometriosis I: 1/3545, 21.X Endometriosis C: 0/3537 Seizure: 17.X Convulsion I: 2/3545, 17.X Convulsion C: 0/3537 Stroke: 17.X Cerebral infarction I: 3/3545, 17.X Cerebral infarction C: 2/3537	Angina unstable 3/3545 (0.08%) 1/3537 (0.03%) Arrhythmia 0/3545 (0.00%) 2/3537 (0.06%) Arteriosclerosis coronary artery 2/3545 (0.06%) 0/3537 (0.00%) Atrial Fibrillation 4/3545 (0.11%) 8/3537 (0.23%) Atrial tachycardia 1/3545 (0.03%) 0/3537 (0.00%) Bradycardia 2/3545 (0.06%) 0/3537 (0.00%) Cardiac arrest 0/3545 (0.00%) 2/3537 (0.06%) Cardiac disorder 2/3545 (0.06%) 0/3537 (0.00%) Cardiac failure 3/3545 (0.08%) 4/3537 (0.11%) Cardiac failure congestive 8/3545 (0.23%) 16/3537 (0.45%) Cardio-respiratory arrest 3/3545 (0.08%) 1/3537 (0.03%) Cardiogenic shock 0/3545 (0.00%) 1/3537 (0.03%) Coronary artery disease 7/3545 (0.20%) 6/3537 (0.17%) Dressler's syndrome 1/3545 (0.03%) 0/3537 (0.00%) Hypertensive heart disease 2/3545 (0.06%) 1/3537 (0.03%) Hypertrophic cardiomyopathy 0/3545 (0.00%) 1/3537 (0.03%) Myocardial infarction (in AE table) Myocardial Ischemia 3/3545 (0.08%) 2/3537 (0.06%) Nodal arrythmia 1/3545 (0.03%) 0/3537 (0.00%) Pericarditis 1/3545 (0.03%) 0/3537 (0.00%) Sinus Tachycardia 1/3545 (0.03%) 0/3537 (0.00%) Ventricular extrasystoles 2/3545 (0.06%) 0/3537 (0.00%) Ventricular tachycardia 1/3545 (0.03%) 1/3537 (0.03%) Congenital, familial and genetic disorders

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
			Rectal haemorrhage Small intestinal obstruction Upper gastrointestinal haemorrhage Volvulus Chest pain Hernia obstructive Multi-organ failure Non-cardiac chest pain Pyrexia Hepatobiliary disor Bile duct stone Cholecystitis Cholecystitis chronic Cholelithiasis Chronic hepatic failure Hepatic cirrhosis Jaundice Immune system disor Drug hypersensitivity Infections and infestat Appendicitis Arthritis bacterial Arthritis infective Bronchitis Cellulitis Cellulitis staphylococcal Cystitis Diverticulitis Escherichia sepsis Gastroenteritis Gastroenteritis viral Herpes zoster Incision site infection Infected skin ulcer Infectious peritonitis Laryngitis Leptospirosis Lobar pneumonia Lower respiratory tract infection Meningitis aseptic Peritonsillar abscess Pneumonia Pneumonia viral Pulmonary Tuberculosis Pyelonephritis acute		Hydrocele 1/3545 (0.03%) 1/3537 (0.03%) Ear and labyrinth disorders Vertigo 1/3545 (0.03%) 1/3537 (0.03%) Vertigo positional 2/3545 (0.06%) 1/3537 (0.03%) Eye disorders Blindness unilateral 0/3545 (0.00%) 1/3537 (0.03%) Corneal degeneration 0/3545 (0.00%) 1/3537 (0.03%) Retinal neovascularisation 0/3545 (0.00%) 1/3537 (0.03%) Viterous hemorrhage 0/3545 (0.00%) 1/3537 (0.03%) Gastrointestinal disorders Abdominal hernia 1/3545 (0.03%) 0/3537 (0.00%) Abdominal pain 0/3545 (0.00%) 1/3537 (0.03%) Abdominal pain upper 0/3545 (0.00%) 1/3537 (0.03%) Abdominal wall hematoma 0/3545 (0.00%) 1/3537 (0.03%) Ascites 1/3545 (0.03%) 0/3537 (0.00%) Colitis 0/3545 (0.00%) 1/3537 (0.03%) Diverticular perforation 0/3545 (0.00%) 1/3537 (0.03%) Diverticulum 1/3545 (0.03%) 2/3537 (0.06%) Duodenal ulcer perforation 0/3545 (0.00%) 1/3537 (0.03%) Dyspepsia 0/3545 (0.00%) 1/3537 (0.03%) Erosive oesophagitis 1/3545 (0.03%) 0/3537 (0.00%) Femoral hernia,obstructive 1/3545 (0.03%) 0/3537 (0.00%) Gastric ulcer perforation 0/3545 (0.00%) 1/3537 (0.03%) Gastritis 1/3545 (0.03%) 1/3537 (0.03%) Gastrointestinal haemorrhage 2/3545 (0.06%) 1/3537 (0.03%) Hiatus hernia 1/3545 (0.03%) 1/3537 (0.03%) Ileus 0/3545 (0.00%) 1/3537 (0.03%)

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
			Sepsis Septic shock Staphylococcal infection Streptococcal sepsis Tetanus Tracheobronchitis Tuberculosis Upper respiratory tract infection Urinary tract infection Urosepsis Wound abscess Back injury Brain herniation Clavicle fracture Concussion Craniocerebral injury Facial bones fracture Fall Femoral neck fracture Femur fracture Foot fracture Forearm Fracture Hip fracture Humerus Fracture Incisional hernia Jaw fracture Laceration Lower limb fracture Multiple injuries Nerve injury Pelvic fracture Perirenal haematoma Post procedural haemorrhage Postoperative adhesion Radius fracture Seroma Spinal compression fracture Spinal cord injury Subdural haematoma Thoracic vertebral fracture Tibia fracture Traumatic liver injury Wound dehiscence Wrist fracture		Ileus paralytic 0/3545 (0.00%) 1/3537 (0.03%) Inguinal hernia, obstructive 0/3545 (0.00%) 1/3537 (0.03%) Intestinal perforation 1/3545 (0.03%) 0/3537 (0.00%) Irritable bowel syndrome 1/3545 (0.03%) 0/3537 (0.00%) Large intestine perforation 1/3545 (0.03%) 0/3537 (0.00%) Lower gastrointestinal haemorrhage 1/3545 (0.03%) 1/3537 (0.03%) Oesophagitis 1/3545 (0.03%) 0/3537 (0.00%) Pancreatic mass 1/3545 (0.03%) 0/3537 (0.00%) Pancreatitis 4/3545 (0.11%) 0/3537 (0.00%) Pancreatitis acute 1/3545 (0.03%) 1/3537 (0.03%) Peptic ulcer 0/3545 (0.00%) 4/3537 (0.11%) Peptic ulcer perforation 1/3545 (0.03%) 0/3537 (0.00%) Pneumoperitonium 0/3545 (0.00%) 1/3537 (0.03%) Rectal haemorrhage 1/3545 (0.03%) 1/3537 (0.03%) Small intestinal obstruction 0/3545 (0.00%) 4/3537 (0.11%) Upper gastrointestinal haemorrhage 4/3545 (0.11%) 7/3537 (0.20%) Volvulus 1/3545 (0.03%) 0/3537 (0.00%) General disorders Chest pain 7/3545 (0.20%) 3/3537 (0.08%) Hernia obstructive 0/3545 (0.00%) 1/3537 (0.03%) Multi-organ failure 3/3545 (0.08%) 1/3537 (0.03%) Non-cardiac chest pain 1/3545 (0.03%) 1/3537 (0.03%) Pyrexia 1/3545 (0.03%) 2/3537 (0.06%) Hepatobiliary disorders Bile duct stone 1/3545 (0.03%) 0/3537 (0.00%)

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
			Dehydration Diabetes Mellitus Diabetes mellitus inadequate control Diabetic foot Diabetic ketoacidosis Electrolyte imbalance Hyperglycaemia Hypocalcaemia Hypoglycaemia Hypokalaemia Hypomagnesaemia Hyponatraemia Malnutrition Type 2 diabetes mellitus Arthropathy Arthralgia Arthritis Costochondritis Gouty arthritis Intervertebral disc degeneration Intervertebral disc protrusion Lumbar spinal stenosis Osteoarthritis Rhabdomyolysis Spinal column stenosis Spondylolisthesis Acute leukaemia Acute myeloid leukaemia Adenocarcinoma B-cell lymphoma Basal cell carcinoma Bladder adenocarcinoma stage unspecified Bladder cancer Bladder transitional cell carcinoma Brain neoplasm malignant Breast cancer Breast cancer stage II Chronic myeloid leukaemia Colon adenoma Colon cancer Gastric cancer		Cholecystitis 7/3545 (0.20%) 2/3537 (0.06%) Cholecystitis chronic 1/3545 (0.03%) 0/3537 (0.00%) Cholelithiasis 4/3545 (0.11%) 4/3537 (0.11%) Chronic hepatic failure 1/3545 (0.03%) 0/3537 (0.00%) Hepatic cirrhosis 1/3545 (0.03%) 0/3537 (0.00%) Jaundice 0/3545 (0.00%) 1/3537 (0.03%) Immune system disorders Drug hypersensitivity 1/3545 (0.03%) 0/3537 (0.00%) Infections and infestations Appendicitis 1/3545 (0.03%) 2/3537 (0.06%) Arthritis bacterial 0/3545 (0.00%) 1/3537 (0.03%) Arthritis infective 0/3545 (0.00%) 1/3537 (0.03%) Bronchitis 5/3545 (0.14%) 1/3537 (0.03%) Cellulitis 2/3545 (0.06%) 3/3537 (0.08%) Cellulitis staphylococcal 1/3545 (0.03%) 0/3537 (0.00%) Cystitis 0/3545 (0.00%) 1/3537 (0.03%) Diverticulitis 1/3545 (0.03%) 2/3537 (0.06%) Escherichia sepsis 1/3545 (0.03%) 0/3537 (0.00%) Gastroenteritis 5/3545 (0.14%) 6/3537 (0.17%) Gastroenteritis viral 0/3545 (0.00%) 1/3537 (0.03%) Herpes zoster 0/3545 (0.00%) 1/3537 (0.03%) Incision site infection 0/3545 (0.00%) 1/3537 (0.03%) Infected skin ulcer 1/3545 (0.03%) 0/3537 (0.00%) Infectious peritonitis 1/3545 (0.03%) 1/3537 (0.03%) Laryngitis 1/3545 (0.03%) 0/3537 (0.00%)

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
			Gastrointestinal stromal tumor Lung adenocarcinoma Lung cancer metastatic Lung carcinoma cell type unspecified stage IV Lung neoplasm malignant Lung squamous cell carcinoma stage unspecified Malignant melanoma Meningioma Metastases to lung Metastatic neoplasm Neoplasm malignant Non-small cell lung cancer Oesophageal carcinoma Ovarian adenoma Pancreatic neoplasm Prolymphocytic leukaemia Prostrate cancer Rectal cancer Sarcoma Squamous cell carcinoma of the cervix Transitional cell carcinoma Nervous system disor Ovarian cancer Pancreatic carcinoma Carotid artery disease Carotid artery stenosis Cerebellar infraction Cerebral haemorrhage Cerebral infraction Cerebral ischaemia Cerebrovascular accident Cerebrovascular disorder Cervical myelopathy Cervicobrachial syndrome Convulsion Dementia alzheimer's type Dementia with lewy bodies Embolic stroke Guillain-barre syndrome Haemorrhage intracranial Headcahe Hemiplegia		Leptospirosis 1/3545 (0.03%) 0/3537 (0.00%) Lobar pneumonia 2/3545 (0.06%) 1/3537 (0.03%) Lower respiratory tract infection 0/3545 (0.00%) 1/3537 (0.03%) Meningitis aseptic (in AE table) Peritonsillar abscess 0/3545 (0.00%) 1/3537 (0.03%) Pneumonia 32/3545 (0.90%) 35/3537 (0.99%) Pneumonia viral 1/3545 (0.03%) 0/3537 (0.00%) Pulmonary Tuberculosis 2/3545 (0.06%) 2/3537 (0.06%) Pyelonephritis acute 0/3545 (0.00%) 1/3537 (0.03%) Sepsis 3/3545 (0.08%) 2/3537 (0.06%) Septic shock 3/3545 (0.08%) 3/3537 (0.08%) Staphylococcal infection 0/3545 (0.00%) 1/3537 (0.03%) Streptococcal sepsis 1/3545 (0.03%) 1/3537 (0.03%) Tetanus 0/3545 (0.00%) 1/3537 (0.03%) Tracheobronchitis 1/3545 (0.03%) 0/3537 (0.00%) Tuberculosis 1/3545 (0.03%) 0/3537 (0.00%) Upper respiratory tract infection 1/3545 (0.03%) 0/3537 (0.00%) Urinary tract infection 8/3545 (0.23%) 6/3537 (0.17%) Urosepsis 0/3545 (0.00%) 1/3537 (0.03%) Wound abscess 0/3545 (0.00%) 1/3537 (0.03%) Injury, poisoning and procedural complications Back injury 1/3545 (0.03%) 0/3537 (0.00%) Brain herniation 0/3545 (0.00%) 1/3537 (0.03%) Clavicle fracture 0/3545 (0.00%) 1/3537 (0.03%)

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
			Ishaemic stroke Metabolic encephalopathy Radiculopathy Ruptured cerebral aneurysm Stroke in evolution Subarachnoid hemorrhage Syncope Transient ischemic attack Vertebrobasilar insufficiency VIIth nerve paralysis Confusional state Psychiatric disor Mental status change Renal and urinary disor Azotemia Calculus ureteric Nephropathy Obstructive uropathy Renal Failure Renal Failure acute Renal failure chronic Benign prostatic hyperplasia Endometriosis Prostatomegaly Uterovaginal prolapse Acute respiratory failure Asthma Asthmatic crisis Chronic obstructive pulmonary disease Dyspnea Hypoxia Interstitial lung disease Pleural effusion Pneumonia aspiration Pulmonary embolism Pulmonary hypertension Pulmonary mass Pulmonary edema Respiratory arrest Respiratory failure Upper airway obstruction Angioedema Vascular disor		Concussion 1/3545 (0.03%) 0/3537 (0.00%) Craniocerebral injury 0/3545 (0.00%) 1/3537 (0.03%) Facial bones fracture 0/3545 (0.00%) 1/3537 (0.03%) Fall 1/3545 (0.03%) 0/3537 (0.00%) Femoral neck fracture 2/3545 (0.06%) 1/3537 (0.03%) Femur fracture 3/3545 (0.08%) 4/3537 (0.11%) Foot fracture 0/3545 (0.00%) 1/3537 (0.03%) Forearm Fracture 0/3545 (0.00%) 1/3537 (0.03%) Hip fracture 1/3545 (0.03%) 3/3537 (0.08%) Humerus Fracture 0/3545 (0.00%) 1/3537 (0.03%) Incisional hernia 0/3545 (0.00%) 1/3537 (0.03%) Jaw fracture 0/3545 (0.00%) 1/3537 (0.03%) Laceration 0/3545 (0.00%) 1/3537 (0.03%) Lower limb fracture 1/3545 (0.03%) 0/3537 (0.00%) Multiple injuries 1/3545 (0.03%) 0/3537 (0.00%) Nerve injury 1/3545 (0.03%) 0/3537 (0.00%) Pelvic fracture 0/3545 (0.00%) 1/3537 (0.03%) Perirenal haematoma 0/3545 (0.00%) 1/3537 (0.03%) Post procedural haemorrhage 1/3545 (0.03%) 0/3537 (0.00%) Postoperative adhesion 0/3545 (0.00%) 1/3537 (0.03%) Radius fracture 0/3545 (0.00%) 1/3537 (0.03%) Seroma 0/3545 (0.00%) 1/3537 (0.03%) Spinal compression fracture 1/3545 (0.03%) 0/3537 (0.00%) Spinal cord injury 0/3545 (0.00%) 1/3537 (0.03%)

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
			Aneurysm ruptured Aortic aneurysm Aortic dissection Aortic stenosis Arteriosclerosis Hypertension Hypertensive crisis Hypotension Peripheral artery aneurysm Varicose ulceration Gastrointestinal disorder Diarrhoea (prespecified) Chills (prespecified) Fatigue (prespecified) Injection site erythema (prespecified) Injection site pain (prespecified) Arthralgia (prespecified) Myalgia (prespecified) Headache (prespecified) Fever (prespecified) Vomiting (prespecified) Tenderness (prespecified)		Subdural haematoma 1/3545 (0.03%) 0/3537 (0.00%) Thoracic vertebral fracture 0/3545 (0.00%) 1/3537 (0.03%) Tibia fracture 1/3545 (0.03%) 0/3537 (0.00%) Traumatic liver injury 0/3545 (0.00%) 1/3537 (0.03%) Wound dehiscence 0/3545 (0.00%) 1/3537 (0.03%) Wrist fracture 2/3545 (0.06%) 0/3537 (0.00%) Metabolism and nutrition disorders Dehydration 1/3545 (0.03%) 1/3537 (0.03%) Diabetes Mellitus (in AE table) Diabetes mellitus inadequate control 2/3545 (0.06%) 2/3537 (0.06%) Diabetic foot 2/3545 (0.06%) 1/3537 (0.03%) Diabetic ketoacidosis 0/3545 (0.00%) 1/3537 (0.03%) Electrolyte imbalance 1/3545 (0.03%) 0/3537 (0.00%) Hyperglycaemia 2/3545 (0.06%) 1/3537 (0.03%) Hypocalcaemia 0/3545 (0.00%) 1/3537 (0.03%) Hypoglycaemia 2/3545 (0.06%) 0/3537 (0.00%) Hypokalaemia 0/3545 (0.00%) 1/3537 (0.03%) Hypomagnesaemia 0/3545 (0.00%) 1/3537 (0.03%) Hyponatraemia 0/3545 (0.00%) 1/3537 (0.03%) Malnutrition 0/3545 (0.00%) 1/3537 (0.03%) Type 2 diabetes mellitus 3/3545 (0.08%) 0/3537 (0.00%) Arthropathy 1/3545 (0.03%) 0/3537 (0.00%) Musculoskeletal and connective tissue disorders Arthralgia 3/3545 (0.08%) 3/3537 (0.08%) Arthritis 3/3545 (0.08%) 0/3537 (0.00%)

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
					Costochondritis 1/3545 (0.03%) 0/3537 (0.00%) Gouty arthritis 1/3545 (0.03%) 0/3537 (0.00%) Intervertebral disc degeneration 0/3545 (0.00%) 1/3537 (0.03%) Intervertebral disc protrusion 0/3545 (0.00%) 3/3537 (0.08%) Lumbar spinal stenosis 1/3545 (0.03%) 1/3537 (0.03%) Osteoarthritis 7/3545 (0.20%) 12/3537 (0.34%) Rhabdomyolysis 0/3545 (0.00%) 1/3537 (0.03%) Spinal column stenosis 1/3545 (0.03%) 0/3537 (0.00%) Spondylolisthesis 1/3545 (0.03%) 0/3537 (0.00%) Neoplasms benign, malignant and unspecified (incl cysts and polyps) Acute leukaemia 1/3545 (0.03%) 0/3537 (0.00%) Acute myeloid leukaemia 1/3545 (0.03%) 1/3537 (0.03%) Adenocarcinoma 0/3545 (0.00%) 1/3537 (0.03%) B-cell lymphoma 0/3545 (0.00%) 1/3537 (0.03%) Basal cell carcinoma 1/3545 (0.03%) 0/3537 (0.00%) Bladder adenocarcinoma stage unspecified 0/3545 (0.00%) 1/3537 (0.03%) Bladder cancer 1/3545 (0.03%) 0/3537 (0.00%) Bladder transitional cell carcinoma 2/3545 (0.06%) 0/3537 (0.00%) Brain neoplasm malignant 1/3545 (0.03%) 0/3537 (0.00%) Breast cancer 1/3545 (0.03%) 3/3537 (0.08%) Breast cancer stage II 1/3545 (0.03%) 0/3537 (0.00%) Chronic myeloid leukaemia 1/3545 (0.03%) 0/3537 (0.00%) Colon adenoma 0/3545 (0.00%) 1/3537 (0.03%)

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
					Colon cancer 2/3545 (0.06%) 1/3537 (0.03%) Gastric cancer 0/3545 (0.00%) 1/3537 (0.03%) Gastrointestinal stromal tumor 0/3545 (0.00%) 1/3537 (0.03%) Lung adenocarcinoma 1/3545 (0.03%) 1/3537 (0.03%) Lung cancer metastatic 1/3545 (0.03%) 0/3537 (0.00%) Lung carcinoma cell type unspecified stage IV 1/3545 (0.03%) 0/3537 (0.00%) Lung neoplasm malignant 0/3545 (0.00%) 1/3537 (0.03%) Lung squamous cell carcinoma stage unspecified 0/3545 (0.00%) 1/3537 (0.03%) Malignant melanoma 1/3545 (0.03%) 0/3537 (0.00%) Meningioma 1/3545 (0.03%) 0/3537 (0.00%) Metastases to lung 0/3545 (0.00%) 1/3537 (0.03%) Metastatic neoplasm 1/3545 (0.03%) 0/3537 (0.00%) Neoplasm malignant 0/3545 (0.00%) 1/3537 (0.03%) Non-small cell lung cancer 1/3545 (0.03%) 0/3537 (0.00%) Oesophageal carcinoma 0/3545 (0.00%) 1/3537 (0.03%) Ovarian adenoma 0/3545 (0.00%) 1/3537 (0.03%) Pancreatic neoplasm 0/3545 (0.00%) 2/3537 (0.06%) Prolymphocytic leukaemia 0/3545 (0.00%) 1/3537 (0.03%) Prostrate cancer 2/3545 (0.06%) 4/3537 (0.11%) Rectal cancer 1/3545 (0.03%) 0/3537 (0.00%) Sarcoma 1/3545 (0.03%) 0/3537 (0.00%) Squamous cell carcinoma of the cervix 0/3545 (0.00%) 1/3537 (0.03%)

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
					Transitional cell carcinoma 2/3545 (0.06%) 0/3537 (0.00%) Nervous system disorders Ovarian cancer 0/3545 (0.00%) 1/3537 (0.03%) Pancreatic carcinoma 0/3545 (0.00%) 1/3537 (0.03%) Carotid artery disease 0/3545 (0.00%) 1/3537 (0.03%) Carotid artery stenosis 1/3545 (0.03%) 1/3537 (0.03%) Cerebellar infraction 1/3545 (0.03%) 1/3537 (0.03%) Cerebral haemorrhage 3/3545 (0.08%) 2/3537 (0.06%) Cerebral infarction (in AE table) Cerebral ischaemia 0/3545 (0.00%) 1/3537 (0.03%) Cerebrovascular accident 4/3545 (0.11%) 10/3537 (0.28%) Cerebrovascular disorder 8/3545 (0.23%) 3/3537 (0.08%) Cervical myelopathy 0/3545 (0.00%) 1/3537 (0.03%) Cervicobrachial syndrome 0/3545 (0.00%) 1/3537 (0.03%) Convulsion (in AE table) Dementia alzheimer's type 1/3545 (0.03%) 1/3537 (0.03%) Dementia with lewy bodies 1/3545 (0.03%) 0/3537 (0.00%) Embolic stroke 0/3545 (0.00%) 1/3537 (0.03%) Guillain-barre syndrome (in AE table) Haemorrhage intracranial 1/3545 (0.03%) 1/3537 (0.03%) Headcahe 0/3545 (0.00%) 1/3537 (0.03%) Hemiplegia 1/3545 (0.03%) 0/3537 (0.00%) Ishaemic stroke 0/3545 (0.00%) 3/3537 (0.08%) Metabolic encephalopathy 0/3545 (0.00%) 1/3537 (0.03%) Radiculopathy 1/3545 (0.03%) 0/3537 (0.00%)

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
					Ruptured cerebral aneurysm 1/3545 (0.03%) 0/3537 (0.00%) Stroke in evolution 0/3545 (0.00%) 1/3537 (0.03%) Subarachnoid hemorrhage 1/3545 (0.03%) 1/3537 (0.03%) Syncope 4/3545 (0.11%) 4/3537 (0.11%) Transient ischemic attack 3/3545 (0.08%) 2/3537 (0.06%) Vertebrobasilar insufficiency 0/3545 (0.00%) 1/3537 (0.03%) VIIth nerve paralysis 1/3545 (0.03%) 0/3537 (0.00%) Confusional state 0/3545 (0.00%) 1/3537 (0.03%) Psychiatric disorders Mental status change 1/3545 (0.03%) 0/3537 (0.00%) Renal and urinary disorders Azotemia 1/3545 (0.03%) 0/3537 (0.00%) Calculus ureteric 1/3545 (0.03%) 0/3537 (0.00%) Nephropathy 1/3545 (0.03%) 0/3537 (0.00%) Obstructive uropathy 1/3545 (0.03%) 0/3537 (0.00%) Renal Failure 2/3545 (0.06%) 0/3537 (0.00%) Renal Failure acute 3/3545 (0.08%) 2/3537 (0.06%) Renal failure chronic 2/3545 (0.06%) 2/3537 (0.06%) Reproductive system and breast disorders Benign prostatic hyperplasia (in AE table) Endometriosis (in AE table) Prostatomegaly 0/3545 (0.00%) 1/3537 (0.03%) Uterovaginal prolapse 0/3545 (0.00%) 1/3537 (0.03%) Respiratory, thoracic and mediastinal disorders Acute respiratory failure 0/3545 (0.00%) 1/3537 (0.03%)

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
					Asthma (in AE table) Asthmatic crisis (in AE table) Chronic obstructive pulmonary disease 10/3545 (0.28%) 14/3537 (0.40%) Dyspnea 2/3545 (0.06%) 2/3537 (0.06%) Hypoxia 1/3545 (0.03%) 0/3537 (0.00%) Interstitial lung disease 1/3545 (0.03%) 0/3537 (0.00%) Pleural effusion 1/3545 (0.03%) 2/3537 (0.06%) Pneumonia aspiration 2/3545 (0.06%) 0/3537 (0.00%) Pulmonary embolism 3/3545 (0.08%) 0/3537 (0.00%) Pulmonary hypertension 1/3545 (0.03%) 0/3537 (0.00%) Pulmonary mass 1/3545 (0.03%) 0/3537 (0.00%) Pulmonary edema 1/3545 (0.03%) 1/3537 (0.03%) Respiratory arrest 1/3545 (0.03%) 0/3537 (0.00%) Respiratory failure 2/3545 (0.06%) 3/3537 (0.08%) Upper airway obstruction 1/3545 (0.03%) 0/3537 (0.00%) Angioedema (in AE table) Vascular disorders Aneurysm ruptured 0/3545 (0.00%) 1/3537 (0.03%) Aortic aneurysm 3/3545 (0.08%) 1/3537 (0.03%) Aortic dissection 0/3545 (0.00%) 1/3537 (0.03%) Aortic stenosis 0/3545 (0.00%) 1/3537 (0.03%) Arteriosclerosis 1/3545 (0.03%) 1/3537 (0.03%) Hypertension 8/3545 (0.23%) 8/3537 (0.23%) Hypertensive crisis 4/3545 (0.11%) 2/3537 (0.06%) Hypotension 2/3545 (0.06%) 1/3537 (0.03%)

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
					Peripheral artery aneurysm 1/3545 (0.03%) 1/3537 (0.03%) Varicose ulceration 1/3545 (0.03%) 0/3537 (0.00%) Risk factors: NR
Perez-Vilar, 2019[180] Article Pre-post N=1464577 Not industry funded USA	Age: 75.8 years (7.6) % female: 58% Ethnicity: NR U.S. Medicare beneficiaries enrolled in Fee-for-Service (FFS) Medicare Parts A (hospitalization) and B (outpatient medical care) Out of scope: None	Influenza aIIV Fluad (trivalent) NR Route NR Other : MF59 preservative NR Co-intervention Some received concomitant PCV13 or PPSV23 No intervention Analytic study Prespecified AE Power NR Followup: 3 months	Guillain-Barré syndrome (GBS)	NA	For aIIV3, there were 5 GBS claims in the primary risk window and four in the control window, resulting in an increased GBS risk (OR: 3.75 (95% CI: 1.01, 13.96); AR: 2.50 (95% CI: 0.02, 3.75) per million vaccinations). This result, however, was not robust after multiplicity adjustment (q = 0.15). Risk factors: No
Puig-Barbera, 2007[185] Article Case-Control N=1301 Funding unclear Spain	Age: Acute coronary syndrome (ACS) cases 75.7 (6.8) and controls 78.8 (7.6); Cerebrovascular accident (CVA) cases 76.9 (6.7) and controls 76.9 (6.7); Pneumonia cases 78.5 (7.3) and controls 78.5 (7.4) % female: N/A Ethnicity: NR Elderly (>64 years of age) population from three health districts in the Valencia	Influenza aIIV Fluad (trivalent) Route NR Other : MF59 preservative NR No co-intervention No intervention Analytic study Prespecified AE Power NR Followup: 5 months	Acute coronary syndrome Cerebrovascular accident Pneumonia	NA	Acute coronary syndrome (hospitalizations in epidemiological weeks 7-14, 2005): OR 0.89 (0.37–2.08); aOR 0.13 (0.03–0.65) Cerebrovascular accident (hospitalizations in epidemiological weeks 3-10, 2005): OR 0.66 (0.31–1.40); aOR 0.07 (0.01–0.48) Pneumonia (hospitalizations in epidemiological weeks 3-12, 2005): OR 0.73 (0.40–1.35); aOR 0.31 (0.14–0.71) Risk factors: No

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
	Autonomous Region, Spain; cases were those with ACS, CVA or pneumonia and controls were matched for hospital and gender Out of scope: None				
Song, 2015a[204] Korea University Guro Hospital, 2013[296]; Song, 2015b[204] NCT02225327 Article RCT N=224 Industry funded South Korea	Age: Intervention (Fluad+PPV23 from Group 2 and Group 3): 71.2 (4.6) and 71.0 (4.1); Control (PPV23) 71.9 (4.5) % female: Intervention: 69%; Control 64% Ethnicity: N/A Adults aged ≥65 years old who were healthy as well as those with stable underlying diseases (≥6 weeks) were included Out of scope: None	Influenza aIIV Fluad (trivalent) Contained 15µ 45 µg in 0.5 mL as one dose Route NR Other : MF59 adjuvant preservative NR Co-intervention PPV23 (Pneumovax) Base treatment Polysaccharide pneumococcal vaccine (PPV23) Pneumovax 0.5 mL in one dose route NR adjuvant NRpreservative NR Counts Prespecified AE Power NR Followup: 1 months	Pain Tenderness Redness Swelling Fever Headache Malaise Fatigue Chill Muscle aches Arthralgia	NA	Severe AEs, Intervention (Fluad+PPV23) vs Control (PPV23 only) Pain, Severe: 0/107 (0%), 0/55 (0%) Tenderness, Severe: 0/107 (0%), 1/55 (1.9%) Redness diameter ≥5 mm: 9/107 (8.4%), 2/55 (3.8%) Swelling diameter ≥5 mm 5/107 (4.7%), 0/55 (0%) Headache, Severe: 0/107 (0%), 0/55 (0%) Malaise, Severe: 0/107 (0%), 0/55 (0%) Fatigue, Severe: 0/107 (0%), 0/55 (0%) Chills, Severe: 0/107 (0%), 0/55 (0%) Muscle aches, Severe: 0/107 (0%), 0/55 (0%) Arthralgia, Severe: 0/107 (0%), 0/55 (0%) No vaccine-related serious adverse events occurred. Risk factors: NR
Villa, 2013[232] Article Cohort study N=107661 Author COI Italy	Age: aIIV 76.5 years, TIV 74.9 years % female: N/A Ethnicity: NR Residents aged ≥65 years seeking	Influenza aIIV Fluad (trivalent) Route NR Other : MF59 preservative NR No co-intervention	Anaphylaxis Autoimmune hepatitis Bell's palsy Convulsions Demyelinating disorders Encephalitis Guillain-Barré syndrome	Anaphylaxis: 10.3 Hospitalized I: 1/88449, 10.3 NA C: 0/82539 Autoimmune disease: 10.X Autoimmune hepatitis I: 0/88449, 10.X Autoimmune hepatitis C: 0/82539 Encephalitis: 11.X NA I: 0/88449, 11.3 Hospitalized C: 1/82539	Numbers of "Definite," "Probable," and "Possible" Cases of Adverse Events of Special Interest Arising During the 6-Month Time Window Following Receipt, excess risk per 100,000 people (95% CI) Anaphylaxis (in AE table) 1.13 (−1.09, 3.35)

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
	influenza vaccination at local health authorities' district offices or the offices of participating general practitioners Out of scope: None	IIV Trivalent IIV Agrippal (Novartis) route NR adjuvant NRpreservative NR Counts Prespecified AE Power NR Followup: 6 months	Immune thrombocytopenic purpura Vasculitis	Encephalomyelitis: 17.X No demyelinating events (ICD-9 code for specific AE included) I: 0/88449, 17.X No demyelinating events (ICD-9 code for specific AE included) C: 0/82539 Guillain-Barré syndrome: 10.3 Hospitalized I: 1/88449, 10.3 Hospitalized C: 4/82539 Immune Thrombocytopenia Purpura: 1.3 Hospitalized I: 3/88449, 1.3 Hospitalized C: 1/82539 Multiple sclerosis: 17.X No demyelinating events (ICD-9 code for specific AE included) I: 0/88449, 17.X No demyelinating events (ICD-9 code for specific AE included) C: 0/82539 Optic neuritis: 17.X No demyelinating events (ICD-9 code for specific AE included) I: 0/88449, 17.X No demyelinating events (ICD-9 code for specific AE included), C: 0/82539 Seizure: 17.3 Convulsions; hospitalized I: 39/88449, 17.3 Convulsions; hospitalized C: 41/82539 Transverse myelitis: 17.X No demyelinating events (ICD-9 code for specific AE included) I: 0/88449, 17.X No demyelinating events (ICD-9 code for specific AE included) C: 0/82539	Autoimmune hepatitis (in AE table) 0.00 (N/A) Bell's palsy 2/88449 vs 1/82539, excess risk 1.05 (−2.88, 4.98) Convulsions (in AE table) −5.58 (−26.12, 14.97) Demyelinating disorders* (in AE table) 0.00 (N/A) Encephalitis (in AE table) −1.21 (−3.59, 1.16) Guillain-Barré syndrome (in AE table) −3.72 (−8.96, 1.53) Immune thrombocytopenic purpura (in AE table) 2.18 (−2.33, 6.69) Vasculitis 5/88449 vs 1/82539, excess risk 4.44 (−1.05, 9.94) Numbers of "Definite," "Probable," and "Possible" Cases of Adverse Events of Special Interest Arising During the Biologically Plausible Time Windows Following Receipt, , excess risk per 100,000 people (95% CI) Anaphylaxis 0/88449 vs 0/82539, 0.00 (N/A) Autoimmune hepatitis 0/88449 vs 0/82539, 0.00 (N/A) Bell's palsy 1/88449 vs 0/82539, 1.13 (−1.09, 3.35) Convulsions 4/88449 vs 6/82539, −2.75 (−10.06, 4.57) Demyelinating disorders* 0/88449 vs 0/82539, 0.00 (N/A) Encephalitis 0/88449 vs 0/82539, 0.00 (N/A) Guillain-Barré syndrome 0/88449 vs 0/82539, 0.00 (N/A) Immune thrombocytopenic purpura 2/88449 vs 1/82539, 1.05 (−2.88, 4.98) Vasculitis 2/88449 vs 0/82539, 2.26 (−0.87, 5.39) Sensitivity analyses that included "Cannot Be Ruled Out" cases also showed no significant findings *ICD-9 codes included: Acute disseminated encephalomyelitis, multiple sclerosis, Schilder's disease, transverse

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
					myelitis, CNS demyelination not otherwise specified, optic neuritis Risk factors: No
Block, 2011[71] MedImmune LLC, 2009[305] NCT00860067 Article RCT N=1800 Industry funded USA	Age: Median age 32.0 years (range 18–49) % female: 55% Ethnicity: White 76.3%, Black 20.9%, Asian 0.8%, American Indian/Alaskan Native 0.6%, Pacific Islander 0.4%, Other race or multiracial 0.9% Adults aged 18-49 years Out of scope: None	Influenza LAIV FluMist Quadrivalent 0.1mL into each nostril (10^7.0 ± 0.5 fluorescent focus units [FFU] of each viral strain) Intranasal adjuvant NR preservative NR No co-intervention Other : Trivalent LAIV Trivalent LAIV FluMist 0.1mL into each nostril (10^7.0 ± 0.5 fluorescent focus units [FFU] of each viral strain) Intranasal adjuvant NRpreservative NR Counts Prespecified AE Power other outcome Followup: 6 months	Arteriospasm coronary Cardiac failure congestive Myocardial infarction Cholecystitis acute Cholelithiasis Hypersensitivity Appendicitis Bacteraemia Clostridium difficile colitis Diverticulitis Gas gangrene Lobar pneumonia Fibula fracture Foot fracture Fracture displacement Ilium fracture Tibia fracture Traumatic fracture Uterine leiomyoma Psychotic disorder Menorrhagia Asthma Fever (prespecified) Runny/stuffy nose (prespecified) Sore throat (prespecified) Cough (prespecified) Headache (prespecified) Generalized muscle aches (prespecified) Decreased activity level or tiredness/weakness (prespecified) Decreased appetite (prespecified) Sneezing Oropharyngeal pain Upper respiratory tract infection Allergic reaction with bronchospasm	Anaphylaxis: 22.X NA I: 0/1198, 22.2 Allergic reaction with bronchospasm, considered treatment-related. Throat tightening and dyspnea occurring 26h after T/LAIV C: 1/598 Asthma: 22.X NA I: 0/1198, 22.X Occurred on day 24 in patient with known asthma (history not previously revealed) C: 1/598 Cardiovascular events: 2.X Cardiac failure congestive I: 0/1198, 2.XCardiac failure congestive C: 1/598 Death: NA NA I: 0/1198, NA NA C: 0/598 Myocardial infarction: 2.X NA I: 0/1198, 2.X NA C: 1/598 Reproduction issues: 21.X Uterine leiomyoma I: 0/1198, 21.X Uterine leiomyoma C: 2/598	Serious AEs (from clinicaltrials.gov): Intervention [Q/LAIV (MEDI3250)] vsControl [All FluMist] Affected / at Risk (%)# EventsAffected / at Risk (%)# Events Total 12/1198 (1.00%) 6/598 (1.00%) Cardiac disorders ARTERIOSPASM CORONARY 1/1198 (0.08%) 0/598 (0.00%) CARDIAC FAILURE CONGESTIVE 0/1198 (0.00%) 1/598 (0.17%) (in AE table) MYOCARDIAL INFARCTION0/1198 (0.00%) 1/598 (0.17%) (in AE table) Hepatobiliary disorders CHOLECYSTITIS ACUTE 1/1198 (0.08%) 0/598 (0.00%) CHOLELITHIASIS 1/1198 (0.08%) 0/598 (0.00%) Immune system disorders HYPERSENSITIVITY 0/1198 (0.00%) 1/598 (0.17%) (in AE table) Infections and infestations APPENDICITIS 1/1198 (0.08%) 0/598 (0.00%) BACTERAEMIA 1/1198 (0.08%) 0/598 (0.00%) CLOSTRIDIUM DIFFICILE COLITIS 1/1198 (0.08%) 0/598 (0.00%) DIVERTICULITIS 2/1198 (0.17%) 0/598 (0.00%) GAS GANGRENE 1/1198 (0.08%) 0/598 (0.00%) LOBAR PNEUMONIA 1/1198 (0.08%) 0/598 (0.00%) Injury, poisoning and procedural complications FIBULA FRACTURE 1/1198 (0.08%) 0/598 (0.00%) FOOT FRACTURE 1/1198 (0.08%) 0/598 (0.00%) FRACTURE DISPLACEMENT 1/1198 (0.08%) 0/598 (0.00%)

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
					ILIUM FRACTURE 1/1198 (0.08%) 0/598 (0.00%) TIBIA FRACTURE 1/1198 (0.08%) 0/598 (0.00%) TRAUMATIC FRACTURE 1/1198 (0.08%) 0/598 (0.00%) Neoplasms benign, malignant and unspecified (incl cysts and polyps) UTERINE LEIOMYOMA 0/1198 (0.00%) 2/598 (0.33%) (in AE table) Psychiatric disorders PSYCHOTIC DISORDER 1/1198 (0.08%) 0/598 (0.00%) Reproductive system and breast disorders MENORRHAGIA 0/1198 (0.00%) 1/598 (0.17%) Respiratory, thoracic and mediastinal disorders ASTHMA 0/1198 (0.00%) 1/598 (0.17%) (in AE table) Risk factors: No
Cowling, 2019[84] The University of Hong Kong, 2017[378]; Cowling, 2020[249] NCT03330132 Article RCT N=1861 Not industry funded Hong Kong	Age: Intervention (RIV Quadrivalent): 51% 65-70 years, 24% 71-76 year, 24% 77-82 years; Control (QIV) 53% 65-70 years, 26% 71-76 year, 21% 77-82 years % female: Intervention 58%, Control 59% Ethnicity: Ethnicity NR Community-dwelling older adults who were: 65–82 years of age; residing in Hong Kong; and	Influenza RIV Flublok Quadrivalent Included 45 µg of each of the strains recommended for the Northern hemisphere 2017–2018 formulation: namely, the A/Michigan/45/2015 (H1N1)-like virus (clade 6B.1), A/Hong Kong/4801/2014(H3N2)-like virus (clade 3C.2a), and B/ Brisbane/60/2008-like virus (Victoria lineage; clade 1A), and the quadrivalent vaccines also included the	Injection site tenderness Injection site pain Injection site swelling	Cardiovascular events: 2.X NA I: 0/335, 2.XNA C: 0/508 Myocardial infarction: 2.X NA I: 0/335, 2.X NA C: 0/508	Overall hospitalizations: 22/335 (6.6%) vs 41/508 (8.1%) Time since vaccination <1 month: 2/335 (0.6%) vs 7/508 (1.4%) Time since vaccination 1-3 months: 4/335 (1.2%) vs 9/508 (1.8%) Time since vaccination 4-6 months: 14/335 (4.2%) vs 20/508 (3.9%) Time since vaccination >6 months: 0/335 (0.0%) vs 1/508 (0.2%) Did not identify any potentially vaccine-related serious adverse events. No MIs per personal communication from author (BC). Risk factors: NR

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
	had not already received the Northern hemisphere 2017–2018 formulation of the influenza vaccine Out of scope: None	B/Phuket/3073/2013- like virus (Yamagata lineage; clade 3) 180 µg in 0.5mL given as one dose Route NR adjuvant NR preservative NR No co-intervention IIV Standard QIV FluQuadri 60 µg in 0.5mL given as one dose route NR adjuvant NRpreservative NR Counts Prespecified AE Power other outcome Followup: 1 months			
Dunkle, 2017[97] Dunkle, 2015[351]; Protein Sciences Corporation, 2015[351] NCT02285998 Article RCT N=9003 Industry funded USA	Age: 63 (range 50-96) % female: 58% Ethnicity: 80% White, 18% Black, 2% Other Adults 50 years of age or older who were living independently without clinically significant acute illness, who were not receiving ongoing immu-nosuppressive therapy, and who had no contra-indications to trial vaccines Out of scope: None	Influenza RIV Flublok Quadrivalent Syringe with recombinant hemagglutinin One 0.5 mL dose containing 45 µg of recombinant HA per strain (180 µg of protein per dose) Intramuscular adjuvant free preservative free No co-intervention IIV Standard-dose IIV4 Fluarix Quadrivalent One 0.5 mL dose containing 15 µg of HA per strain (60 µg of protein per dose) Intramuscular	Anaemia Leukocytosis Microcytic anaemia Thrombocytosis Cardiac disorders Atrial fibrillation Myocardial infarction Angina pectoris Cardiac failure congestive Angina unstable Coronary artery disease Cardiac arrest Cardiac failure Acute myocardial infarction Arrhythmia Atrial flutter Cardiac tamponade Cardio-respiratory arrest Cardiogenic shock Cardiovascular disorder Coronary artery insufficiency Coronary artery stenosis Coronary artery thrombosis	Cardiovascular events: 2.X All cardiac disorders (from appendix) I: 23/4328, 2.XAll cardiac disorders (from appendix) C: 19/4344 Death: NA Not related to vaccine I: 8/4328, NA Not related to vaccine C: 12/4344 Encephalitis: 17.X Encephalopathy I: 0/4328, 17.X Encephalopathy C: 1/4344 Myocardial infarction: 2.X Myocardial infarction I: 4/4328, 2.X Myocardial infarction C: 3/4344 Reproduction issues: 21.X All reproductive system disorders (from appendix) I: 1/4328, 21.X All reproductive system disorders (from appendix) C: 3/4344 Stillbirth: 17.X Convulsion I: 1/4328, 17.X Convulsion C: 1/4344 Stroke: 17.X Cerebrovascular accident I: 5/4328, 17.X Cerebrovascular accident C: 6/4344	No serious AEs were considered by the trial team to be related to a trial vaccine. Intervention (Flublok) vs Control (Fluarix) Affected / at Risk (%)Affected / at Risk (%) Total 145/4328 (3.35%) 132/4344 (3.04%) Blood and lymphatic system disorders Anaemia 1/4328 (0.02%) 0/4344 (0.00%) Leukocytosis 1/4328 (0.02%) 0/4344 (0.00%) Microcytic anaemia 1/4328 (0.02%) 0/4344 (0.00%) Thrombocytosis 1/4328 (0.02%) 0/4344 (0.00%) Cardiac disorders (summarized in AE table as group, specific disorders are below) Atrial fibrillation 6/4328 (0.14%) 3/4344 (0.07%) Myocardial infarction 4/4328 (0.09%) 3/4344 (0.07%) Angina pectoris 2/4328 (0.05%) 2/4344 (0.05%)

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
		adjuvant freepreservative free Counts No prespecified AE Power other outcome Followup: 6 months	Ischaemic cardiomyopathy Sick sinus syndrome Supraventricular tachycardia Vertigo Gastrointestinal haemorrhage Small intestinal obstruction Upper gastrointestinal haemorrhage Diverticulum intestinal haemorrhagic Dysphagia Intestinal obstruction Pancreatitis Abdominal pain Colitis ischaemic Cyclic vomiting syndrome Diverticulum Food poisoning Gastric ulcer Haemorrhoids Hiatus hernia Ileus Inguinal hernia Intestinal perforation Volvulus Chest pain Death Non-cardiac chest pain Asthenia Drug withdrawal syndrome Hernia obstructive Oedema peripheral Pain Cholelithiasis Cholecystitis Hepatic cirrhosis Hepatic haemorrhage Hepatitis alcoholic Pneumonia Bronchitis Diverticulitis Influenza Urinary tract infection Cellulitis Appendicitis		Cardiac failure congestive 2/4328 (0.05%) 2/4344 (0.05%) Angina unstable 2/4328 (0.05%) 1/4344 (0.02%) Coronary artery disease 2/4328 (0.05%) 1/4344 (0.02%) Cardiac arrest 1/4328 (0.02%) 1/4344 (0.02%) Cardiac failure 0/4328 (0.00%) 2/4344 (0.05%) Acute myocardial infarction 1/4328 (0.02%) 0/4344 (0.00%) Arrhythmia 1/4328 (0.02%) 0/4344 (0.00%) Atrial flutter 1/4328 (0.02%) 0/4344 (0.00%) Cardiac tamponade 0/4328 (0.00%) 1/4344 (0.02%) Cardio-respiratory arrest 0/4328 (0.00%) 1/4344 (0.02%) Cardiogenic shock 1/4328 (0.02%) 0/4344 (0.00%) Cardiovascular disorder 0/4328 (0.00%) 1/4344 (0.02%) Coronary artery insufficiency 1/4328 (0.02%) 0/4344 (0.00%) Coronary artery stenosis 1/4328 (0.02%) 0/4344 (0.00%) Coronary artery thrombosis 1/4328 (0.02%) 0/4344 (0.00%) Ischaemic cardiomyopathy 1/4328 (0.02%) 0/4344 (0.00%) Sick sinus syndrome 0/4328 (0.00%) 1/4344 (0.02%) Supraventricular tachycardia 1/4328 (0.02%) 0/4344 (0.00%) Ear and labyrinth disorders Vertigo 0/4328 (0.00%) 1/4344 (0.02%) Gastrointestinal disorders Gastrointestinal haemorrhage 4/4328 (0.09%) 1/4344 (0.02%) Small intestinal obstruction 2/4328 (0.05%) 1/4344 (0.02%) Upper gastrointestinal haemorrhage 1/4328 (0.02%) 2/4344 (0.05%) Diverticulum intestinal haemorrhagic 1/4328 (0.02%) 1/4344 (0.02%)

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
			Lung Infection Osteomyelitis Pyelonephritis Abscess intestinal Device related infection Endocarditis staphylococcal Erysipelas Eye abscess Gangrene Osteomyelitis acute Osteomyelitis chronic Otitis media Pneumonia bacterial Salmonellosis Urinary tract infection fungal Urosepsis Viral upper respiratory tract infection Craniocerebral injury Toxicity to various agents Upper limb fracture Cervical vertebral fracture Head injury Hip fracture Lower limb fracture Overdose Procedural pain Road traffic accident Spinal compression fracture Stab wound Tendon rupture Tibia fracture Wound complication Haematocrit decreased International normalised ratio increased Troponin increased Hyponatraemia Dehydration Diabetes mellitus inadequate control Diabetic ketoacidosis Failure to thrive Gout		Dysphagia 2/4328 (0.05%) 0/4344 (0.00%) Intestinal obstruction 1/4328 (0.02%) 1/4344 (0.02%) Pancreatitis 2/4328 (0.05%) 0/4344 (0.00%) Abdominal pain 1/4328 (0.02%) 0/4344 (0.00%) Colitis ischaemic 0/4328 (0.00%) 1/4344 (0.02%) Cyclic vomiting syndrome 1/4328 (0.02%) 0/4344 (0.00%) Diverticulum 1/4328 (0.02%) 0/4344 (0.00%) Food poisoning 1/4328 (0.02%) 0/4344 (0.00%) Gastric ulcer 1/4328 (0.02%) 0/4344 (0.00%) Haemorrhoids 1/4328 (0.02%) 0/4344 (0.00%) Hiatus hernia 0/4328 (0.00%) 1/4344 (0.02%) Ileus 1/4328 (0.02%) 0/4344 (0.00%) Inguinal hernia 1/4328 (0.02%) 0/4344 (0.00%) Intestinal perforation 1/4328 (0.02%) 0/4344 (0.00%) Volvulus 0/4328 (0.00%) 1/4344 (0.02%) General disorders Chest pain 7/4328 (0.16%) 6/4344 (0.14%) Death 2/4328 (0.05%) 1/4344 (0.02%) Non-cardiac chest pain 3/4328 (0.07%) 0/4344 (0.00%) Asthenia 0/4328 (0.00%) 1/4344 (0.02%) Drug withdrawal syndrome 0/4328 (0.00%) 1/4344 (0.02%) Hernia obstructive 0/4328 (0.00%) 1/4344 (0.02%) Oedema peripheral 1/4328 (0.02%) 0/4344 (0.00%) Pain 1/4328 (0.02%) 0/4344 (0.00%) Hepatobiliary disorders Cholelithiasis 1/4328 (0.02%) 1/4344 (0.02%) Cholecystitis 0/4328 (0.00%) 1/4344 (0.02%)

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
			Hyperglycaemia Hypoglycaemia Lactic acidosis Obesity Osteoarthritis Intervertebral disc protrusion Arthralgia Back pain Intervertebral disc degeneration Musculoskeletal pain Neck pain Spinal column stenosis Arthritis Intervertebral disc compression Lumbar spinal stenosis Muscular weakness Pain in extremity Rhabdomyolysis Rotator cuff syndrome Tenosynovitis stenosans Neoplasms benign, malignant and unspecified (incl cysts and polyps) Breast cancer Prostate cancer Bladder cancer Hepatic cancer Squamous cell carcinoma of lung Abdominal wall neoplasm B-cell lymphoma Bladder neoplasm Colorectal cancer Colorectal cancer recurrent Invasive ductal breast carcinoma Metastases to liver Oesophageal carcinoma Pancreatic carcinoma metastatic Renal cancer Rhabdomyoma Testis cancer		Hepatic cirrhosis 1/4328 (0.02%) 0/4344 (0.00%) Hepatic haemorrhage 0/4328 (0.00%) 1/4344 (0.02%) Hepatitis alcoholic 0/4328 (0.00%) 1/4344 (0.02%) Infections and infestations Pneumonia 6/4328 (0.14%) 6/4344 (0.14%) Bronchitis 2/4328 (0.05%) 3/4344 (0.07%) Diverticulitis 2/4328 (0.05%) 2/4344 (0.05%) Influenza 1/4328 (0.02%) 3/4344 (0.07%) Urinary tract infection 2/4328 (0.05%) 2/4344 (0.05%) Cellulitis 0/4328 (0.00%) 3/4344 (0.07%) Appendicitis 1/4328 (0.02%) 1/4344 (0.02%) Lung Infection 1/4328 (0.02%) 1/4344 (0.02%) Osteomyelitis 1/4328 (0.02%) 1/4344 (0.02%) Pyelonephritis 1/4328 (0.02%) 1/4344 (0.02%) Abscess intestinal 1/4328 (0.02%) 0/4344 (0.00%) Device related infection 1/4328 (0.02%) 0/4344 (0.00%) Endocarditis staphylococcal 1/4328 (0.02%) 0/4344 (0.00%) Erysipelas 0/4328 (0.00%) 1/4344 (0.02%) Eye abscess 1/4328 (0.02%) 0/4344 (0.00%) Gangrene 0/4328 (0.00%) 1/4344 (0.02%) Osteomyelitis acute 0/4328 (0.00%) 1/4344 (0.02%) Osteomyelitis chronic 0/4328 (0.00%) 1/4344 (0.02%) Otitis media 0/4328 (0.00%) 1/4344 (0.02%) Pneumonia bacterial 1/4328 (0.02%) 0/4344 (0.00%) Salmonellosis 1/4328 (0.02%) 0/4344 (0.00%)

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
			Thyroid cancer Thyroid neoplasm Transitional cell carcinoma Cerebrovascular accident Transient ischaemic attack Syncope Convulsion Embolic stroke Cerebral haemorrhage Encephalopathy Haemorrhagic stroke Lacunar infarction Loss of consciousness Lumbar radiculopathy Myelomalacia Sinus headache Subarachnoid haemorrhage Thalamic infarction Suicidal ideation Anxiety Renal failure acute Urinary retention Bladder outlet obstruction Calculus ureteric Renal necrosis Benign prostatic hyperplasia Cystocele Menorrhagia Uterine disorder Chronic obstructive pulmonary disease Pulmonary embolism Acute respiratory failure Respiratory failure Aspiration Epistaxis Pleural effusion Hyperhidrosis Knee arthroplasty Abdominal hernia repair Alcohol detoxification Drug detoxification Gastric bypass Hernia repair Hip arthroplasty		Urinary tract infection fungal 0/4328 (0.00%) 1/4344 (0.02%) Urosepsis 0/4328 (0.00%) 1/4344 (0.02%) Viral upper respiratory tract infection 0/4328 (0.00%) 1/4344 (0.02%) Injury, poisoning and procedural complications Craniocerebral injury 1/4328 (0.02%) 1/4344 (0.02%) Toxicity to various agents 0/4328 (0.00%) 2/4344 (0.05%) Upper limb fracture 1/4328 (0.02%) 1/4344 (0.02%) Cervical vertebral fracture 1/4328 (0.02%) 0/4344 (0.00%) Head injury 1/4328 (0.02%) 0/4344 (0.00%) Hip fracture 1/4328 (0.02%) 0/4344 (0.00%) Lower limb fracture 0/4328 (0.00%) 1/4344 (0.02%) Overdose 1/4328 (0.02%) 0/4344 (0.00%) Procedural pain 0/4328 (0.00%) 1/4344 (0.02%) Road traffic accident 1/4328 (0.02%) 0/4344 (0.00%) Spinal compression fracture 1/4328 (0.02%) 0/4344 (0.00%) Stab wound 1/4328 (0.02%) 0/4344 (0.00%) Tendon rupture 0/4328 (0.00%) 1/4344 (0.02%) Tibia fracture 0/4328 (0.00%) 1/4344 (0.02%) Wound complication 0/4328 (0.00%) 1/4344 (0.02%) Investigations Haematocrit decreased 0/4328 (0.00%) 1/4344 (0.02%) International normalised ratio increased 1/4328 (0.02%) 0/4344 (0.00%) Troponin increased 1/4328 (0.02%) 0/4344 (0.00%) Metabolism and nutrition disorders

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
			Inguinal hernia repair Intestinal resection Joint surgery Rotator cuff repair Hypertensive crisis Aortic aneurysm Aortic aneurysm rupture Aortic dissection Arteriosclerosis Circulatory collapse Haemorrhage Hypotension Peripheral arterial occlusive disease Thrombosis Influenza like illness Fatigue Upper respiratory tract infection Myalgia Nervous system disorders Headache Cough Oropharyngeal pain Productive cough		Hyponatraemia 2/4328 (0.05%) 1/4344 (0.02%) Dehydration 2/4328 (0.05%) 0/4344 (0.00%) Diabetes mellitus inadequate control 1/4328 (0.02%) 1/4344 (0.02%) Diabetic ketoacidosis 1/4328 (0.02%) 0/4344 (0.00%) Failure to thrive 0/4328 (0.00%) 1/4344 (0.02%) Gout 0/4328 (0.00%) 1/4344 (0.02%) Hyperglycaemia 1/4328 (0.02%) 0/4344 (0.00%) Hypoglycaemia 0/4328 (0.00%) 1/4344 (0.02%) Lactic acidosis 0/4328 (0.00%) 1/4344 (0.02%) Obesity 0/4328 (0.00%) 1/4344 (0.02%) Musculoskeletal and connective tissue disorders Osteoarthritis 8/4328 (0.18%) 7/4344 (0.16%) Intervertebral disc protrusion 1/4328 (0.02%) 4/4344 (0.09%) Arthralgia 2/4328 (0.05%) 0/4344 (0.00%) Back pain 2/4328 (0.05%) 0/4344 (0.00%) Intervertebral disc degeneration 1/4328 (0.02%) 1/4344 (0.02%) Musculoskeletal pain 1/4328 (0.02%) 1/4344 (0.02%) Neck pain 2/4328 (0.05%) 0/4344 (0.00%) Spinal column stenosis 1/4328 (0.02%) 1/4344 (0.02%) Arthritis 0/4328 (0.00%) 1/4344 (0.02%) Intervertebral disc compression 1/4328 (0.02%) 0/4344 (0.00%) Lumbar spinal stenosis 0/4328 (0.00%) 1/4344 (0.02%) Muscular weakness 0/4328 (0.00%) 1/4344 (0.02%) Pain in extremity 1/4328 (0.02%) 0/4344 (0.00%) Rhabdomyolysis 1/4328 (0.02%) 0/4344 (0.00%)

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
					Rotator cuff syndrome 1/4328 (0.02%) 0/4344 (0.00%) Tenosynovitis stenosans 0/4328 (0.00%) 1/4344 (0.02%) Neoplasms benign, malignant and unspecified (incl cysts and polyps) Breast cancer 1/4328 (0.02%) 4/4344 (0.09%) Prostate cancer 2/4328 (0.05%) 2/4344 (0.05%) Bladder cancer 1/4328 (0.02%) 1/4344 (0.02%) Hepatic cancer 0/4328 (0.00%) 2/4344 (0.05%) Squamous cell carcinoma of lung 0/4328 (0.00%) 2/4344 (0.05%) Abdominal wall neoplasm 1/4328 (0.02%) 0/4344 (0.00%) B-cell lymphoma 0/4328 (0.00%) 1/4344 (0.02%) Bladder neoplasm 0/4328 (0.00%) 1/4344 (0.02%) Colorectal cancer 0/4328 (0.00%) 1/4344 (0.02%) Colorectal cancer recurrent 1/4328 (0.02%) 0/4344 (0.00%) Invasive ductal breast carcinoma 1/4328 (0.02%) 0/4344 (0.00%) Metastases to liver 0/4328 (0.00%) 1/4344 (0.02%) Oesophageal carcinoma 1/4328 (0.02%) 0/4344 (0.00%) Pancreatic carcinoma metastatic 1/4328 (0.02%) 0/4344 (0.00%) Renal cancer 0/4328 (0.00%) 1/4344 (0.02%) Rhabdomyoma 0/4328 (0.00%) 1/4344 (0.02%) Testis cancer 1/4328 (0.02%) 0/4344 (0.00%) Thyroid cancer 0/4328 (0.00%) 1/4344 (0.02%) Thyroid neoplasm 0/4328 (0.00%) 1/4344 (0.02%) Transitional cell carcinoma 0/4328 (0.00%) 1/4344 (0.02%) Nervous system disorders

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
					Cerebrovascular accident (in AE table) Transient ischaemic attack 3/4328 (0.07%) 2/4344 (0.05%) Syncope 1/4328 (0.02%) 3/4344 (0.07%) Convulsion (in AE table) Embolic stroke 2/4328 (0.05%) 0/4344 (0.00%) Cerebral haemorrhage 1/4328 (0.02%) 0/4344 (0.00%) Encephalopathy (in AE table) Haemorrhagic stroke 0/4328 (0.00%) 1/4344 (0.02%) Lacunar infarction 1/4328 (0.02%) 0/4344 (0.00%) Loss of consciousness 1/4328 (0.02%) 0/4344 (0.00%) Lumbar radiculopathy 0/4328 (0.00%) 1/4344 (0.02%) Myelomalacia 1/4328 (0.02%) 0/4344 (0.00%) Sinus headache 1/4328 (0.02%) 0/4344 (0.00%) Subarachnoid haemorrhage 1/4328 (0.02%) 0/4344 (0.00%) Thalamic infarction 1/4328 (0.02%) 0/4344 (0.00%) Psychiatric disorders Suicidal ideation 0/4328 (0.00%) 2/4344 (0.05%) Anxiety 0/4328 (0.00%) 1/4344 (0.02%) Renal and urinary disorders Renal failure acute 3/4328 (0.07%) 1/4344 (0.02%) Urinary retention 2/4328 (0.05%) 0/4344 (0.00%) Bladder outlet obstruction 1/4328 (0.02%) 0/4344 (0.00%) Calculus ureteric 1/4328 (0.02%) 0/4344 (0.00%) Renal necrosis 1/4328 (0.02%) 0/4344 (0.00%) Reproductive system and breast disorders (summarized in AE table as group, specific disorders are below) Benign prostatic hyperplasia 1/4328 (0.02%) 0/4344 (0.00%)

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
					Cystocele 0/4328 (0.00%) 1/4344 (0.02%) Menorrhagia 0/4328 (0.00%) 1/4344 (0.02%) Uterine disorder 0/4328 (0.00%) 1/4344 (0.02%) Respiratory, thoracic and mediastinal disorders Chronic obstructive pulmonary disease 5/4328 (0.12%) 5/4344 (0.12%) Pulmonary embolism 3/4328 (0.07%) 1/4344 (0.02%) Acute respiratory failure 2/4328 (0.05%) 0/4344 (0.00%) Respiratory failure 1/4328 (0.02%) 1/4344 (0.02%) Aspiration 0/4328 (0.00%) 1/4344 (0.02%) Epistaxis 0/4328 (0.00%) 1/4344 (0.02%) Pleural effusion 0/4328 (0.00%) 1/4344 (0.02%) Skin and subcutaneous tissue disorders Hyperhidrosis 0/4328 (0.00%) 1/4344 (0.02%) Surgical and medical procedures Knee arthroplasty 2/4328 (0.05%) 0/4344 (0.00%) Abdominal hernia repair 1/4328 (0.02%) 0/4344 (0.00%) Alcohol detoxification 0/4328 (0.00%) 1/4344 (0.02%) Drug detoxification 0/4328 (0.00%) 1/4344 (0.02%) Gastric bypass 1/4328 (0.02%) 0/4344 (0.00%) Hernia repair 1/4328 (0.02%) 0/4344 (0.00%) Hip arthroplasty 0/4328 (0.00%) 1/4344 (0.02%) Inguinal hernia repair 0/4328 (0.00%) 1/4344 (0.02%) Intestinal resection 1/4328 (0.02%) 0/4344 (0.00%) Joint surgery 1/4328 (0.02%) 0/4344 (0.00%) Rotator cuff repair 1/4328 (0.02%) 0/4344 (0.00%)

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
					Vascular disorders Hypertensive crisis 1/4328 (0.02%) 1/4344 (0.02%) Aortic aneurysm 1/4328 (0.02%) 0/4344 (0.00%) Aortic aneurysm rupture 0/4328 (0.00%) 1/4344 (0.02%) Aortic dissection 0/4328 (0.00%) 1/4344 (0.02%) Arteriosclerosis 1/4328 (0.02%) 0/4344 (0.00%) Circulatory collapse 0/4328 (0.00%) 1/4344 (0.02%) Haemorrhage 1/4328 (0.02%) 0/4344 (0.00%) Hypotension 0/4328 (0.00%) 1/4344 (0.02%) Peripheral arterial occlusive disease 0/4328 (0.00%) 1/4344 (0.02%) Thrombosis 1/4328 (0.02%) 0/4344 (0.00%) Risk factors: NR
Dunkle, 2017[98] Protein Sciences Corporation, 2015[352] NCT02290509 Article RCT N=1350 Industry funded USA	Age: Intervention (FluBlok) 33 years, Control (IIV4) 34 years % female: Intervention: 67%, Control 64% Ethnicity: Intervention: 59% Caucasian, 38% Black, 1% American Indian or Native Alaskan, 1% Native Hawaiian/Pacific Islander, <1% Asian, 1% Other; Control: 61% Caucasian, 34% Black, 1% American Indian or Native	Influenza RIV Flublok Quadrivalent 180 µg of rHA (4 × 45 µg) derived from H1N1: A/California/07/2009, H3N2: A/Texas/50/2012, B/Massachusetts/2/2012 (B/ Yamagata-lineage) and B/Brisbane/60/2008 (B/Victoria- lineage) 180 µg in 1 dose Intramuscular adjuvant free preservative free No co-intervention IIV Quadrivalent inactivated influenza vaccine (IIV4) Fluarix	Mortality Myocardial infarction Gastrointestinal haemorrhage Pancreatitis Small intestinal obstruction Hepatobiliary disorders Cholecystitis Appendicitis Periumbilical abcess Road traffic accident Neck pain Metabolic encephalopathy Abortion spontaneous Ovarian cyst Arm amputation Nasophayngitis Upper respiratory tract infection Sinusitis Headache Cough	Cardiovascular events: 2.X All cardiac disorders (only myocardial infarction was reported) I: 2/998, 2.XAll cardiac disorders (only myocardial infarction was reported) C: 0/332 Death: NA NA I: 0/998, NA NA C: 0/332 Encephalitis: 17.X Metabolic encephalopathy I: 1/998, 17.X NA C: 0/332 Myocardial infarction: 2.X Myocardial infarction I: 2/998, 2.X Myocardial infarction C: 0/332 Reproduction issues: 21.X Ovarian cyst I: 1/998, 21.X Ovarian cyst C: 0/332 Spontaneous abortion: 18.X NR I: 1/998, 18.X NA C: 0/332	Severe AEs: Any injection site reaction Grade 3/4: RIV 1.1% vs IIV4 1.5% Local pain Grade 3/4: RIV 0.9% vs IIV4 0.9% Local tenderness Grade 3/4: RIV 0.9% vs IIV4 1.2% Redness Grade 3/4: RIV 0% vs IIV4 0% Firmness/swelling Grade 3/4: RIV 0% vs IIV4 0% Any systemic reaction Grade 3/4: RIV 2.3% vs IIV4 3.0% Fatigue Grade 3/4: RIV 0.5% vs IIV4 1.2% Shivering/chills Grade 3/4: RIV 0.5% vs IIV4 1.2% Joint pain Grade 3/4: RIV 0.9% vs IIV4 0.6% Muscle pain Grade 3/4: RIV 0.9% vs IIV4 0.9% Headache Grade 3/4: RIV 1.3% vs IIV4 2.1% Nausea Grade 3/4: RIV 0.7% vs IIV4 1.2% Fever Grade 3/4: RIV 0.4% vs IIV4 0.3%

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
	Alaskan, 1% Native Hawaiian/Pacific Islander, 1% Asian, Medically stable adults aged 18–49 years with no contraindications to either study vaccine Out of scope: None	Quadrivalent 60 µg in 1 dose Intramuscular adjuvant freepreservative free Counts No prespecified AE Power NR Followup: 6 months			Serious AEs (from clinical trials.gov): Intervention (RIV-Flublok Quadrivalent) vs Control (IIV4-Fluarix Quadrivalent) Affected / at Risk (%)Affected / at Risk (%) Total 10/998 (1.00%) 2/332 (0.60%) Cardiac disorders Myocardial infarction (in AE table) Gastrointestinal disorders Gastrointestinal haemorrhage0/998 (0.00%) 1/332 (0.30%) Pancreatitis 0/998 (0.00%) 1/332 (0.30%) Small intestinal obstruction 1/998 (0.10%) 0/332 (0.00%) Hepatobiliary disorders Cholecystitis 0/998 (0.00%) 1/332 (0.30%) Infections and infestations Appendicitis 1/998 (0.10%) 0/332 (0.00%) Periumbilical abcess 1/998 (0.10%) 0/332 (0.00%) Injury, poisoning and procedural complications Road traffic accident 1/998 (0.10%) 0/332 (0.00%) Musculoskeletal and connective tissue disorders Neck pain 1/998 (0.10%) 0/332 (0.00%) Nervous system disorders Metabolic encephalopathy (in AE table) Pregnancy, puerperium and perinatal conditions Abortion spontaneous (in AE table) Reproductive system and breast disorders Ovarian cyst (in AE table) Surgical and medical procedures Arm amputation 1/998 (0.10%) 0/332 (0.00%) Risk factors: NR
Sanofi Pasteur, a Sanofi	Age: 42.6 (26.97) % female: 63%	Influenza RIV Flublok Quadrivalent 0.5 mL in 1 dose Intramuscular	Vomiting Crying Injection site erythema Injection site pain Injection site swelling	Death: NA NA I: 0/61, NA NA C: 0/59	Serious AEs: Intervention (Flublok Quadrivalent) 0/61 (0.00%) vs Control (Fluzone Quadrivalent) 0/59 (0.00%) Risk factors: NR

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
Company, 2019[192] NCT03617523 Trial record RCT N=240 Industry funded USA	Ethnicity: 75% White, 22% Black / African-American, 2% More than one race Adults aged 18 to <65 years Out of scope: None	adjuvant free preservative free No co-intervention IIV IIV4 Fluzone Quadrivalent 0.5 mL in 1 dose Intramuscular adjuvant freepreservative free Counts No prespecified AE Power NR Followup: 1 months	Malaise Pyrexia Gastroenteritis viral Decreased appetite Myalgia Headache Somnolence Irritability Cough Rash		
Alberer, 2015[53] Novartis, 2011[322] NCT01466387 Article RCT N=301 Author COI Germany, Czech Republic	Age: Intervention: 35 years (11), Control: 37 (11) % female: 47% Ethnicity: 97% White, 1% Asian, 1% Black or African American, 1% Other Adults between 18 and 60 years Out of scope: Some	Men quadrivalent Menveo [MenACWY-CRM] One 0.5 mL dose containing 10µg of meningococcal serogroup A and 5µg each of capsular polysaccharide of serogroups C, W-135, and Y, and 32.7 to 64.1 µg of CRM, without adjuvant, 25 µg purified Vi polysaccharide, 0.5 mL dose contained not less than 1,000LD Intramuscular adjuvant free preservative free Co-intervention Typhoid Fever vaccine and Yellow Fever vaccine Base treatment Typhoid Fever vaccine and Yellow	Headache Pain in an extremity Tooth disorder Pneumonia Injection site pain Influenza-like illness Fatigue Acute tonsillitis Injury Intervertebral disc protrusion Nasopharyngitis	Death: NA NA I: 0/99, NA NA C: 0/100	There were no AEs leading to premature withdrawal, SAEs, or deaths reported in any of the study groups. Severe AEs: Intervention 3/99 (one subject with a headache and pain in an extremity, one with a tooth disorder, and one with a headache) vs Control 2/100 (pneumonia) Serious AEs (from clinicaltrials.gov): Intervention (TF+YF+MenACWY-CRM197) vs Control (TF+YF) Total sAE0/100 (0.00%) vs 0/101 (0.00%) Injury 0/100 (0.00%) vs 0/101 (0.00%) Intervertebral disc protrusion 0/100 (0.00%) vs 0/101 (0.00%) Risk factors: NR

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
		Fever vaccine only Typhim Vi, Stamaril 0.5 mL dose of TF vaccine (Typhim Vi® , Sanofi Pasteur MSD) contained 25 µg purified Vi polysaccha- ride and 0.5 mL dose of YF vaccine (Stamaril®, Sanofi Pasteur MSD) powder was reconstituted by adding the provided sol- vent to the vial followed by subcut Intramuscular,Other : Subcutaneous adjuvant freepreservative free Counts No prespecified AE Power other outcome Followup: 1 months			
Alberer, 2015[54] Novartis Vaccines, 2011[324] NCT01453348 Article RCT N=252 Industry funded Germany	Age: Hep A/B 39.0 (12.3) HepA/B+MenACWY-CRM 39.9 (12.6) MenACWY-CRM 39.7 (11.0) % female: 54% Ethnicity: Asian 1.0%, Black 1.0%, Caucasian 98% Healthy adults Out of scope: Some	Men quadrivalent Menveo [MenACWY-CRM] MenACWY-CRM 0.5 mL 1 dose Intramuscular adjuvant NR preservative NR Co-intervention Either one dose of Twinrix (if booster) or if primary series, one dose of Twinrix followed by 2 doses of Hep A (Havrix) and/or Hep B (Engerix-B)	Headache Nasopharyngitis Fatigue Influenza-like illness Injection site pain Vaccination site pain Cough Myalgia Erythema Pain Chills Oropharyngeal pain Pruritus Pyrexia Arthralgia Induration Nausea Vertigo	Death: NA NA I: 0/85, NA NA C: 0/84	Serious AEs (from clinicaltrials.gov) Total: Intervention 0/85 (0.00%); Control 1/84 (1.19%) Renal cancer: Intervention 0/85 (0.00%); Control 1/84 (1.19%) Completed suicide: Intervention: 0/85 (0.00%); Control 0/84 (0.00%) Risk factors: NR

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
		depending on prior vaccination status Base treatment Either one dose of Twinrix (if booster) or if primary series, one dose of Twinrix followed by 2 doses of Hep A (Havrix) and/or Hep B (Engerix-B) depending on prior vaccination status Twinrix, Havrix, Engerix-B Dose amount not specified except for Havrix; schedule was either one dose of Twinrix (if booster) or if primary series, one dose of Twinrix followed by 2 doses of Hep A (Havrix) and/or Hep B (Engerix-B) depending on prior vaccination status Intramuscular adjuvant freepreservative free Counts No prespecified AE Power other outcome Followup: 2 months	Renal cancer Completed suicide Mortality Dizziness		
Esteves-Jaramillo, 2020[104] Sanofi Pasteur, 2016[367]; Jeanfreau, 2018[289]	Age: N/A % female: N/A Ethnicity: Ethnicity NR Healthy adults ≥ 56 years of age	Men quadrivalent MenQuadFi [MenACWY-TT] Single dose of MenACWY-TT Intramuscular	Acute Myocardial Infarction Atrial Fibrillation Coronary Artery Disease Myocardial Infarction Colitis Ischaemic Pancreatitis Acute	Cardiovascular events: 2.X Acute myocardial infarction I: 0/448, 2.XAcute myocardial infarction C: 2/453 Death: NA NA I: 0/448, NA There were two deaths during the study; both	Most unsolicited adverse events were of Grade 1 or Grade 2 intensity. No vaccine related serious adverse events were reported per authors Serious AEs (from clinicaltrial.gov):

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
NCT02842866 Article RCT N=907 Industry funded USA	in the United States Out of scope: None	adjuvant free preservative free No co-intervention Meningococcal polysaccaride MPSV4 vaccine Menomune Single dose of MPSV4 vaccine Other : Subcutaneous adjuvant freepreservative free Counts No prespecified AE Power NR Followup: 6 months	Pancreatitis Relapsing Non-Cardiac Chest Pain Bile Duct Stone Biliary Colic Device Related Infection Escherichia Sepsis Influenza Localised Infection Osteomyelitis Pneumonia Sepsis Multiple Fractures Muscle Strain Pelvic Fracture Spinal Column Injury Foot Deformity Joint Contracture Osteoarthritis Invasive Lobular Breast Carcinoma Lung Adenocarcinoma Lung Cancer Metastatic Prostate Cancer Ischaemic Stroke Transient Ischaemic Attack Device Failure Psychiatric disorders Depression Suicidal Benign Prostatic Hyperplasia Skin Ulcer Vascular disorders Deep Vein Thrombosis Peripheral Vascular Disorder Injection Site Erythema Injection Site Pain Malaise Myalgia Headache	occurred in the MPSV4 group and were considered unrelated to vaccination (metastatic lung cancer and spinal column injury due to road traffic accident, respectively). C: 2/453 Myocardial infarction: 2.X Acute myocardial infarction I: 0/448, 2.X Acute myocardial infarction C: 2/453 Reproduction issues: 21.X Benign prostatic hyperplasia I: 1/448, 21.X Benign prostatic hyperplasia C: 0/453 Stroke: 17.X NA I: 0/448, 17.X Ischaemic stroke C: 1/453	Intervention (MenACYW Conjugate Vaccine) vs Control (Menomune Vaccine) Affected / at Risk (%)# EventsAffected / at Risk (%)# Events Total 15/448 (3.35%) 15/453 (3.31%) Cardiac disorders Acute Myocardial Infarction 0/448 (0.00%) 2/453 (0.44%) (in AE table) Atrial Fibrillation 1/448 (0.22%) 0/453 (0.00%) Coronary Artery Disease 0/448 (0.00%) 1/453 (0.22%) Myocardial Infarction 0/448 (0.00%) 1/453 (0.22%) Gastrointestinal disorders Colitis Ischaemic 1/448 (0.22%) 0/453 (0.00%) Pancreatitis Acute 0/448 (0.00%) 1/453 (0.22%) Pancreatitis Relapsing 0/448 (0.00%) 1/453 (0.22%) General disorders Non-Cardiac Chest Pain 1/448 (0.22%) 0/453 (0.00%) Hepatobiliary disorders Bile Duct Stone 1/448 (0.22%) 10/453 (0.00%) Biliary Colic 1/448 (0.22%) 10/453 (0.00%) Infections and infestations Device Related Infection 0/448 (0.00%) 01/453 (0.22%) 1 Escherichia Sepsis 1/448 (0.22%) 10/453 (0.00%) 0 Influenza 0/448 (0.00%) 01/453 (0.22%) 1 Localised Infection 1/448 (0.22%) 10/453 (0.00%) 0 Osteomyelitis 0/448 (0.00%) 01/453 (0.22%) 1 Pneumonia 0/448 (0.00%) 01/453 (0.22%) 1 Sepsis 1/448 (0.22%) 11/453 (0.22%) 1 Injury, poisoning and procedural complications

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
					Multiple Fractures 0/448 (0.00%) 01/453 (0.22%) 1 Muscle Strain 1/448 (0.22%) 10/453 (0.00%) 0 Pelvic Fracture 0/448 (0.00%) 01/453 (0.22%) 1 Spinal Column Injury 0/448 (0.00%) 01/453 (0.22%) 1 Musculoskeletal and connective tissue disorders Foot Deformity 1/448 (0.22%) 10/453 (0.00%) 0 Joint Contracture 1/448 (0.22%) 10/453 (0.00%) 0 Osteoarthritis 2/448 (0.45%) 20/453 (0.00%) 0 Neoplasms benign, malignant and unspecified (incl cysts and polyps) Invasive Lobular Breast Carcinoma1/448 (0.22%) 10/453 (0.00%) 0 Lung Adenocarcinoma 1/448 (0.22%) 10/453 (0.00%) 0 Lung Cancer Metastatic 0/448 (0.00%) 01/453 (0.22%) 1 Prostate Cancer 1/448 (0.22%) 10/453 (0.00%) 0 Nervous system disorders Transient Ischaemic Attack 0/448 (0.00%) 01/453 (0.22%) 1 Product Issues Device Failure 1/448 (0.22%) 10/453 (0.00%) 0 Psychiatric disorders Depression Suicidal 0/448 (0.00%) 01/453 (0.22%) 1 Skin and subcutaneous tissue disorders Skin Ulcer0/448 (0.00%) 01/453 (0.22%) 1 Risk factors: NR
Kirstein, 2020[147] Sanofi Pasteur, 2012[369] NCT01732627 Article	Age: 65.9 (6.96) % female: 58.5% Ethnicity: 95% White, 3% Black or African American, 0.3% American Indian	Men quadrivalent MenQuadFi [MenACWY-TT] Single 0.5 mL dose Intramuscular adjuvant NR preservative NR	Injection Site Erythema (prespecified) Injection Site Pain (prespecified) Injection Site Swelling (prespecified) Malaise (prespecified) Myalgia (prespecified)	Death: NA NA I: 0/199, NA NA C: 0/100	No SAE in either group: MenACWY-TT 0/199, MPSV4 0/100 Risk factors: The safety profile was generally comparable between 56–64-year-old and the ≥65-year-old subsets, apart from the small difference in the solicited injection site reac- tions.

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
RCT N=301 Industry funded USA	or Alaska Native, 1.3% More than one race Adults aged 56 years and older Out of scope: None	No co-intervention Meningococcal polysaccaride MPSV4 alone Not specified Single 0.5 mL dose Intramuscular adjuvant NRpreservative NR Counts Prespecified AE Power calculation Followup: 1 months	Headache (prespecified)		
Bonten, 2015[72] Pfizer, 2008[343]; Werkhoven, 2015[383] NCT00744263 Article RCT N=84496 Industry funded Netherlands	Age: 72.8 (5.7) % female: 44% Ethnicity: 98% White 1% Asian 1% Other/Unknown Adults 65 years and older (included entire sample, as well as a N = 2011 for safety sub-analysis) Out of scope: None	Pneumococcal PCV13 Prevnar 13 0.5 mL in one dose Intramuscular Aluminum preservative NR No co-intervention Placebo Placebo (see formulation) 0.5 mL in one dose Intramuscular Aluminumpreservative NR Counts No prespecified AE Power calculation Followup: 6 months	Mortality Anaemia Idiopathic thrombocytopenic purpura Iron deficiency anaemia Pancytopenia Cardiac disorders Angina pectoris Atrial fibrillation Myocardial infarction Cardiac failure Atrial flutter Coronary artery disease Acute coronary syndrome Cardiac asthma Angina unstable Cardiac arrest Sick sinus syndrome Aortic valve stenosis Atrioventricular block Atrioventricular block complete Myocardial ischaemia Pericarditis Supraventricular tachycardia Acute myocardial infarction Arrhythmia Atrial tachycardia Bradycardia Cardio-respiratory arrest Coronary artery dissection	Anaphylaxis: 10.X NA I: 0/42237, 10.3 NR C: 2/42255 Autoimmune disease: 10.X Polymyalgia rheumatica I: 0/42237, 10.X Polymyalgia rheumatica C: 0/42255 Cardiovascular events: 2.X All cardiac disorders (from supplementary material) I: 72/42237, 2.XAll cardiac disorders (from supplementary material) C: 74/42255 Death: NA NA I: 3006/42237, NA NA C: 3005/42255 Encephalomyelitis: 17.X ADEM I: 1/42237, 17.X ADEM C: 0/42255 Herpes Zoster: 11.X NR I: 1/42237 11.X NA C: 0/42255 Immune Thrombocytopenia Purpura: 1.X NA I: 0/42237, 1.X NR C: 1/42255 Meningitis: 11.X NR I: 1/42237, 11.X NA C: 0/42255 Myocardial infarction: 2.X NR I: 12/42237, 2.X NR C: 6/42255 Reproduction issues: 21.X All reproductive disorders (from supplementary material) I: 0/42237, 21.X All reproductive disorders (from supplementary material) C: 3/42255 Seizure: 17.X Convulsion I: 1/42237, 17.X Epilepsy C: 2/42255	Severe AEs with 7 days, PCV13 vs Placebo (safety subset) (%, 95% CI): Redness: Severe (n = 881, 859) 0.5 (0.1 to 1.2) vs 0.1 (0.0 to 0.6) Swelling: Severe (n = 881, 859) 0.1 (0.0 to 0.6) vs 0.1 (0.0 to 0.6) Pain: Severe (n = 881, 860) 0.3 (0.1 to 1.0) vs 0.1 (0.0 to 0.6) Limitation of arm movement: Severe (n = 882, 861) 1.2 (0.6 to 2.2) vs 0.7 (0.3 to 1.5) Fever: >40 degrees C (n = 882, 860) 0.8 (0.3 to 1.6) vs 0.3 (0.1 to 1.0) Fatigue: Severe (n = 883, 863) 1.4 (0.7 to 2.4) vs 0.9 (0.4 to 1.8) Headache: Severe (n = 881, 861) 0.6 (0.2 to 1.3) vs 0.6 (0.2 to 1.3) Vomiting: Severe (n = 881, 860) 0.2 (0.0 to 0.8) vs 0.1 (0.0 to 0.6) Diarrhea: Severe (n = 881, 862) 0.7 (0.3 to 1.5) vs 0.5 (0.1 to 1.2) New muscle pain: Severe (n = 882, 860) 0.7 (0.3 to 1.5) vs 0.5 (0.1 to 1.2) Aggravated muscle pain: Severe (n = 882, 860) 0.7 (0.3 to 1.5) vs 0.1 (0.0 to 0.6) New joint pain: Severe (n = 882, 860) 0.3 (0.1 to 1.0) vs 0.3 (0.1 to 1.0) Aggravated joint pain: Severe (n = 882, 860) 0.3 (0.1 to 1.0) vs 0.3 (0.1 to 1.0) Chronic medical condition diagnosed 1–6 mo after vaccination (n=106, 1005)

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
			Left ventricular failure Mitral valve incompetence Palpitations Silent myocardial infarction Sinus bradycardia Ventricular tachycardia Atrioventricular block second degree Cardiac failure congestive Coronary artery stenosis Vertigo positional Vertigo Retinal detachment Retinal artery occlusion Macular fibrosis Ileus Constipation Rectal haemorrhage Colitis Diarrhoea Gastrooesophageal reflux disease Pancreatitis acute Abdominal pain Duodenal perforation Duodenal ulcer Gastric perforation Gastritis Inguinal hernia, obstructive Intestinal obstruction Intestinal perforation Melaena Pancreatitis Subileus Upper gastrointestinal haemorrhage Varices oesophageal Abdominal hernia Diverticulum intestinal haemorrhagic Large intestinal stenosis Umbilical hernia General disor Non-cardiac chest pain Chest pain Device dislocation Accidental death	Stroke: 17.X Cerebrovascular accident I: 9/42237, 17.X Cerebrovascular accident C: 8/42255	17/1005 (1.7%) vs 12/1005 (1.2%), p=0.46 Serious AEs (from clinicaltrials.gov, with AE table taken from safety set only): 13vPnC Safety SetPlacebo Safety Set13vPnC Immunogenicity SubsetPlacebo Immunogenicity Subset Affected / at Risk (%)Affected / at Risk (%)Affected / at Risk (%)Affected / at Risk (%) Total 327/42237 (0.77%) 314/42255 (0.74%) 55/1006 (5.47%) 48/1005 (4.78%) Blood and lymphatic system disorders Anaemia 2/42237 (0.00%) 0/42255 (0.00%) 1/1006 (0.10%) 0/1005 (0.00%) Idiopathic thrombocytopenic purpura (in AE table) 0/1006 (0.00%) 0/1005 (0.00%) Iron deficiency anaemia 1/42237 (0.00%) 0/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%) Pancytopenia 0/42237 (0.00%) 1/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%) Cardiac disorders Angina pectoris 19/42237 (0.04%) 19/42255 (0.04%) 3/1006 (0.30%) 1/1005 (0.10%) Atrial fibrillation 13/42237 (0.03%) 9/42255 (0.02%) 3/1006 (0.30%) 1/1005 (0.10%) Myocardial infarction 12/42237 (0.03%) 6/42255 (0.01%) 0/1006 (0.00%) 1/1005 (0.10%) Cardiac failure 7/42237 (0.02%) 10/42255 (0.02%) 4/1006 (0.40%) 0/1005 (0.00%) Atrial flutter 5/42237 (0.01%) 2/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%) Coronary artery disease 3/42237 (0.01%) 4/42255 (0.01%) 0/1006 (0.00%) 0/1005 (0.00%) Acute coronary syndrome 2/42237 (0.00%) 3/42255 (0.01%) 1/1006 (0.10%) 0/1005 (0.00%)

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
			Death Device occlusion Hernia obstructive Malaise Medical device complication Pyrexia Sudden cardiac death Implant site fibrosis Hepatobiliary disorder Cholecystitis Bile duct stone Cholangitis Cholecystitis acute Cholelithiasis Anaphylactic reaction Anaphylactic shock Corneal graft rejection Infections and infestat Pneumonia Appendicitis Device related infection Urinary tract infection Urosepsis Gastroenteritis Pneumonia pneumococcal Diverticulitis Pneumonia legionella Wound infection Bronchiolitis Cholangitis suppurative Cystitis Erysipelas Herpes zoster Infective exacerbation of chronic obstructive airways disease Meningitis Peritonitis Peritonsillar abscess Respiratory tract infection Staphylococcal bacteraemia Staphylococcal infection Tuberculosis Upper respiratory tract infection		Cardiac asthma 2/42237 (0.00%) 3/42255 (0.01%) 0/1006 (0.00%) 0/1005 (0.00%) Angina unstable 2/42237 (0.00%) 2/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%) Cardiac arrest 2/42237 (0.00%) 1/42255 (0.00%) 0/1006 (0.00%) 1/1005 (0.10%) Sick sinus syndrome 1/42237 (0.00%) 2/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%) Aortic valve stenosis 1/42237 (0.00%) 1/42255 (0.00%) 1/1006 (0.10%) 0/1005 (0.00%) Atrioventricular block 1/42237 (0.00%) 1/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%) Atrioventricular block complete 1/42237 (0.00%) 1/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%) Myocardial ischaemia 1/42237 (0.00%) 1/42255 (0.00%) 1/1006 (0.10%) 0/1005 (0.00%) Pericarditis 1/42237 (0.00%) 1/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%) Supraventricular tachycardia 0/42237 (0.00%) 2/42255 (0.00%) 0/1006 (0.00%) 1/1005 (0.10%) Acute myocardial infarction 1/42237 (0.00%) 0/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%) Arrhythmia 0/42237 (0.00%) 1/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%) Atrial tachycardia 0/42237 (0.00%) 1/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%) Bradycardia 0/42237 (0.00%) 1/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%) Cardio-respiratory arrest 0/42237 (0.00%) 1/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%) Coronary artery dissection 1/42237 (0.00%) 0/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%)

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
			Vestibular neuronitis Viral infection Viral upper respiratory tract infection Abdominal abscess Femur fracture Hip fracture Femoral neck fracture Humerus fracture Brain contusion Radius fracture Ankle fracture Contusion Head injury Rib fracture Subdural haematoma Tendon rupture Fracture Pelvic fracture Ulna fracture Wrist fracture Accidental overdose Anaemia postoperative Cardiac valve replacement complication Concussion Facial bones fracture Forearm fracture Foreign body aspiration Incisional hernia Injury Joint dislocation Kidney contusion Ligament injury Lower limb fracture Mental status changes postoperative Multiple injuries Periprosthetic fracture Post laminectomy syndrome Procedural intestinal perforation Procedural pain Tendon injury Thermal burn		Left ventricular failure 0/42237 (0.00%) 1/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%) Mitral valve incompetence 0/42237 (0.00%) 1/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%) Palpitations 0/42237 (0.00%) 1/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%) Silent myocardial infarction 0/42237 (0.00%) 1/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%) Sinus bradycardia 0/42237 (0.00%) 1/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%) Ventricular tachycardia 0/42237 (0.00%) 1/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%) Atrioventricular block second degree 0/42237 (0.00%) 0/42255 (0.00%) 1/1006 (0.10%) 0/1005 (0.00%) Cardiac failure congestive 0/42237 (0.00%) 0/42255 (0.00%) 0/1006 (0.00%) 1/1005 (0.10%) Coronary artery stenosis 0/42237 (0.00%) 0/42255 (0.00%) 1/1006 (0.10%) 0/1005 (0.00%) Ear and labyrinth disorders Vertigo positional 0/42237 (0.00%) 1/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%) Vertigo 0/42237 (0.00%) 0/42255 (0.00%) 1/1006 (0.10%) 0/1005 (0.00%) Eye disorders Retinal detachment 1/42237 (0.00%) 1/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%) Retinal artery occlusion 1/42237 (0.00%) 0/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%) Macular fibrosis 0/42237 (0.00%) 0/42255 (0.00%) 0/1006 (0.00%) 1/1005 (0.10%) Gastrointestinal disorders Ileus 2/42237 (0.00%) 4/42255 (0.01%) 0/1006 (0.00%) 0/1005 (0.00%) Constipation 4/42237 (0.01%) 1/42255 (0.00%) 0/1006 (0.00%) 1/1005 (0.10%)

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
			Urinary retention postoperative Vascular graft occlusion Wound dehiscence Procedural haemorrhage Weight decreased Metabolism and nutrition disor Electrolyte imbalance Hypoglycaemia Finger deformity Intervertebral disc protrusion Lumbar spinal stenosis Osteoarthritis Arthralgia Bone cyst Polymyalgia rheumatica Rotator cuff syndrome Spondylolisthesis Basal cell carcinoma Prostate cancer Colon cancer Breast cancer Malignant melanoma Transitional cell carcinoma Gastric cancer Adenocarcinoma of colon Bladder cancer Colon cancer metastatic Endometrial adenocarcinoma Non-small cell lung cancer Plasma cell myeloma Rectal cancer Bladder adenocarcinoma stage unspecified Bowen's disease Bronchial carcinoma Clear cell renal cell carcinoma Colorectal cancer metastatic Glioblastoma Glioma Hepatic adenoma Hypopharyngeal cancer		Rectal haemorrhage 1/42237 (0.00%) 2/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%) Colitis 1/42237 (0.00%) 1/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%) Diarrhoea 1/42237 (0.00%) 1/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%) Gastrooesophageal reflux disease 1/42237 (0.00%) 1/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%) Pancreatitis acute 2/42237 (0.00%) 0/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%) Abdominal pain 0/42237 (0.00%) 1/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%) Duodenal perforation 1/42237 (0.00%) 0/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%) Duodenal ulcer 1/42237 (0.00%) 0/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%) Gastric perforation 0/42237 (0.00%) 1/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%) Gastritis 0/42237 (0.00%) 1/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%) Inguinal hernia, obstructive 0/42237 (0.00%) 1/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%) Intestinal obstruction 0/42237 (0.00%) 1/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%) Intestinal perforation 1/42237 (0.00%) 0/42255 (0.00%) 1/1006 (0.10%) 0/1005 (0.00%) Melaena 0/42237 (0.00%) 1/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%) Pancreatitis 0/42237 (0.00%) 1/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%) Subileus 1/42237 (0.00%) 0/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%) Upper gastrointestinal haemorrhage 0/42237 (0.00%) 1/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%)

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
			Laryngeal cancer Leukaemia Lung adenocarcinoma metastatic Lung neoplasm malignant Malignant neoplasm of renal pelvis Melanoma recurrent Mesothelioma Metastasis Metastatic gastric cancer Metastatic renal cell carcinoma Myelodysplastic syndrome Neoplasm prostate Oesophageal adenocarcinoma Oesophageal carcinoma recurrent Prostate cancer metastatic Prostate cancer recurrent Renal cancer Renal cell carcinoma Small cell lung cancer Squamous cell carcinoma Squamous cell carcinoma of skin Tonsil cancer Bile duct adenocarcinoma Bladder transitional cell carcinoma Colon neoplasm Endometrial cancer Renal cancer recurrent Nervous system disor Cerebrovascular accident Cerebral infarction Transient ischaemic attack Syncope Presyncope Cerebral haemorrhage Subarachnoid haemorrhage Dizziness Epilepsy Loss of consciousness Transient global amnesia		Varices oesophageal 1/42237 (0.00%) 0/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%) Abdominal hernia 0/42237 (0.00%) 0/42255 (0.00%) 1/1006 (0.10%) 0/1005 (0.00%) Diverticulum intestinal haemorrhagic 0/42237 (0.00%) 0/42255 (0.00%) 1/1006 (0.10%) 0/1005 (0.00%) Large intestinal stenosis 0/42237 (0.00%) 0/42255 (0.00%) 1/1006 (0.10%) 0/1005 (0.00%) Umbilical hernia 0/42237 (0.00%) 0/42255 (0.00%) 1/1006 (0.10%) 0/1005 (0.00%) General disorders Non-cardiac chest pain 12/42237 (0.03%) 2/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%) Chest pain 5/42237 (0.01%) 1/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%) Device dislocation 2/42237 (0.00%) 0/42255 (0.00%) 1/1006 (0.10%) 0/1005 (0.00%) Accidental death 0/42237 (0.00%) 1/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%) Death 0/42237 (0.00%) 1/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%) Device occlusion 0/42237 (0.00%) 1/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%) Hernia obstructive 0/42237 (0.00%) 1/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%) Malaise 1/42237 (0.00%) 0/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%) Medical device complication 1/42237 (0.00%) 0/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%) Pyrexia 1/42237 (0.00%) 0/42255 (0.00%) 1/1006 (0.10%) 0/1005 (0.00%) Sudden cardiac death 1/42237 (0.00%) 0/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%)

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
			Acute disseminated encephalomyelitis Cerebral ischaemia Convulsion Hemiparesis Peroneal nerve palsy Radicular pain Radiculitis lumbosacral Trigeminal neuralgia Carotid artery stenosis Hepatic encephalopathy Ischaemic stroke Peripheral nerve lesion Psychiatric disor Bipolar disorder Delirium Psychotic disorder Suicidal ideation Renal and urinary disor Calculus bladder Haematuria Cystitis noninfective Nephrolithiasis Renal impairment Ureteric stenosis Urethral stenosis Urinary retention Reproductive disorders Benign prostatic hyperplasia Acquired phimosis Female genital tract fistula Vaginal prolapse Chronic obstructive pulmonary disease Pulmonary embolism Pneumothorax Epistaxis Dyspnoea exertional Sleep apnoea syndrome Alveolitis allergic Asphyxia Dyspnoea Hydrothorax Lung infiltration Pleural effusion Skin ulcer		Implant site fibrosis 0/42237 (0.00%) 0/42255 (0.00%) 1/1006 (0.10%) 0/1005 (0.00%) Hepatobiliary disorders Cholecystitis 2/42237 (0.00%) 2/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%) Bile duct stone 0/42237 (0.00%) 2/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%) Cholangitis 2/42237 (0.00%) 0/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%) Cholecystitis acute 0/42237 (0.00%) 1/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%) Cholelithiasis 0/42237 (0.00%) 1/42255 (0.00%) 0/1006 (0.00%) 1/1005 (0.10%) Immune system disorders Anaphylactic reaction (in AE table) 0/1006 (0.00%) 0/1005 (0.00%) Anaphylactic shock 0/42237 (0.00%) 1/42255 (0.00%) 0/1006 (0.00%) 1/1005 (0.10%) Corneal graft rejection 0/42237 (0.00%) 1/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%) Infections and infestations Pneumonia 14/42237 (0.03%) 6/42255 (0.01%) 4/1006 (0.40%) 1/1005 (0.10%) Appendicitis 2/42237 (0.00%) 4/42255 (0.01%) 0/1006 (0.00%) 0/1005 (0.00%) Device related infection 3/42237 (0.01%) 2/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%) Urinary tract infection 2/42237 (0.00%) 3/42255 (0.01%) 0/1006 (0.00%) 0/1005 (0.00%) Urosepsis 1/42237 (0.00%) 3/42255 (0.01%) 0/1006 (0.00%) 0/1005 (0.00%) Gastroenteritis 0/42237 (0.00%) 3/42255 (0.01%) 1/1006 (0.10%) 0/1005 (0.00%) Pneumonia pneumococcal 1/42237 (0.00%) 2/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%) Diverticulitis 1/42237 (0.00%) 1/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%)

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
			Rash Vascular disor Circulatory collapse Aortic aneurysm Aortic aneurysm rupture Hypertension Hypotension Deep vein thrombosis Haematoma Intermittent claudication Peripheral arterial occlusive disease Temporal arteritis Thrombophlebitis Malignant hypertension Cardiac disor Angina pectoris Atrial fibrillation Cardiac failure Mitral valve incompetence Palpitations Tachycardia Vertigo Eye disor Conjunctivitis Cataract Conjunctivitis allergic Ocular hyperaemia Vitreous floaters Nausea Abdominal pain upper Gastrooesophageal reflux disease Change of bowel habit Eructation Gastritis Haemorrhoids Vomiting General disor Injection site erythema Injection site pain Injection site pruritus Injection site swelling Malaise Injection site haematoma Injection site exfoliation Pyrexia		Pneumonia legionella 1/42237 (0.00%) 1/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%) Wound infection 0/42237 (0.00%) 2/42255 (0.00%) 2/1006 (0.20%) 1/1005 (0.10%) Bronchiolitis 0/42237 (0.00%) 1/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%) Cholangitis suppurative 0/42237 (0.00%) 1/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%) Cystitis 0/42237 (0.00%) 1/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%) Erysipelas 1/42237 (0.00%) 0/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%) Herpes zoster (in AE table) 0/1006 (0.00%) 0/1005 (0.00%) Infective exacerbation of chronic obstructive airways disease 1/42237 (0.00%) 0/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%) Meningitis (in AE table) 0/1006 (0.00%) 0/1005 (0.00%) Peritonitis 1/42237 (0.00%) 0/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%) Peritonsillar abscess 0/42237 (0.00%) 1/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%) Respiratory tract infection 1/42237 (0.00%) 0/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%) Staphylococcal bacteraemia 0/42237 (0.00%) 1/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%) Staphylococcal infection 1/42237 (0.00%) 0/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%) Tuberculosis 0/42237 (0.00%) 1/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%) Upper respiratory tract infection 0/42237 (0.00%) 1/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%) Vestibular neuronitis 0/42237 (0.00%) 1/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%) Viral infection 1/42237 (0.00%) 0/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%)

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
			Cyst Device breakage Ill-defined disorder Injection site rash Injection site reaction Oedema peripheral Vaccination site erythema Vessel puncture site haematoma Fever Fatigue Headache Chills Rash Vomiting Decreased appetite Diarrhea New generalized muscle Aggravated generalized muscle New generalized joint Aggravated generalized joint Cholelithiasis Infections and infestat Nasopharyngitis Upper respiratory tract infection Cystitis Gastroenteritis Bronchitis Influenza Herpes zoster Pneumonia Sinusitis Fungal infection Urinary tract infection Wound infection Abscess oral Enteritis infectious Folliculitis Fungal skin infection Lower respiratory tract infection Oral herpes Otitis externa Otitis media		Viral upper respiratory tract infection 0/42237 (0.00%) 1/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%) Abdominal abscess 0/42237 (0.00%) 0/42255 (0.00%) 1/1006 (0.10%) 0/1005 (0.00%) Injury, poisoning and procedural complications Femur fracture 5/42237 (0.01%) 4/42255 (0.01%) 0/1006 (0.00%) 1/1005 (0.10%) Hip fracture 3/42237 (0.01%) 3/42255 (0.01%) 1/1006 (0.10%) 0/1005 (0.00%) Femoral neck fracture 3/42237 (0.01%) 2/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%) Humerus fracture 1/42237 (0.00%) 4/42255 (0.01%) 0/1006 (0.00%) 0/1005 (0.00%) Brain contusion 2/42237 (0.00%) 2/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%) Radius fracture 1/42237 (0.00%) 3/42255 (0.01%) 0/1006 (0.00%) 0/1005 (0.00%) Ankle fracture 2/42237 (0.00%) 1/42255 (0.00%) 0/1006 (0.00%) 2/1005 (0.20%) Contusion 0/42237 (0.00%) 3/42255 (0.01%) 0/1006 (0.00%) 0/1005 (0.00%) Head injury 1/42237 (0.00%) 2/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%) Rib fracture 3/42237 (0.01%) 0/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%) Subdural haematoma 2/42237 (0.00%) 1/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%) Tendon rupture 0/42237 (0.00%) 3/42255 (0.01%) 0/1006 (0.00%) 0/1005 (0.00%) Fracture 0/42237 (0.00%) 2/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%) Pelvic fracture 1/42237 (0.00%) 1/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%) Ulna fracture 1/42237 (0.00%) 1/42255 (0.00%) 0/1006 (0.00%) 1/1005 (0.10%)

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
			Tinea barbae Limb injury Contusion Procedural pain Bone contusion Concussion Epicondylitis Face injury Muscle strain Periorbital contusion Traumatic haemorrhage International normalised ratio decreased Decreased appetite Gout Back pain Myalgia Arthralgia Musculoskeletal stiffness Pain in extremity Tendonitis Intervertebral disc protrusion Fibromyalgia Inclusion body myositis Joint range of motion decreased Joint stiffness Muscle spasms Muscular weakness Musculoskeletal chest pain Musculoskeletal discomfort Musculoskeletal disorder Musculoskeletal pain Myositis Osteitis Pain in jaw Keratoacanthoma Nervous system disor Headache Dizziness Ageusia Aphonia Cerebrovascular accident Neuropathy peripheral Paraesthesia Sciatica		Wrist fracture 1/42237 (0.00%) 1/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%) Accidental overdose 0/42237 (0.00%) 1/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%) Anaemia postoperative 0/42237 (0.00%) 1/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%) Cardiac valve replacement complication 0/42237 (0.00%) 1/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%) Concussion 1/42237 (0.00%) 0/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%) Facial bones fracture 1/42237 (0.00%) 0/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%) Forearm fracture 0/42237 (0.00%) 1/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%) Foreign body aspiration 1/42237 (0.00%) 0/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%) Incisional hernia 1/42237 (0.00%) 0/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%) Injury 0/42237 (0.00%) 1/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%) Joint dislocation 0/42237 (0.00%) 1/42255 (0.00%) 0/1006 (0.00%) 1/1005 (0.10%) Kidney contusion 0/42237 (0.00%) 1/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%) Ligament injury 1/42237 (0.00%) 0/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%) Lower limb fracture 0/42237 (0.00%) 1/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%) Mental status changes postoperative 1/42237 (0.00%) 0/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%) Multiple injuries 0/42237 (0.00%) 1/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%)

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
			Syncope Transient ischaemic attack Haematuria Nephrolithiasis Urinary retention Epistaxis Cough Productive cough Chronic obstructive pulmonary disease Dyspnoea Hyperventilation Lung disorder Rhinalgia Rhinorrhoea Sneezing Dermatitis allergic Dry skin Blood blister Eczema Pruritus Pruritus generalised Skin ulcer Urticaria Redness Swelling Pain Limitation of arm move Hypertension Peripheral coldness		Periprosthetic fracture 0/42237 (0.00%) 1/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%) Post laminectomy syndrome 0/42237 (0.00%) 1/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%) Procedural intestinal perforation 0/42237 (0.00%) 1/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%) Procedural pain 0/42237 (0.00%) 1/42255 (0.00%) 0/1006 (0.00%) 1/1005 (0.10%) Tendon injury 0/42237 (0.00%) 1/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%) Thermal burn 1/42237 (0.00%) 0/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%) Urinary retention postoperative 0/42237 (0.00%) 1/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%) Vascular graft occlusion 1/42237 (0.00%) 0/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%) Wound dehiscence 1/42237 (0.00%) 0/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%) Procedural haemorrhage 0/42237 (0.00%) 0/42255 (0.00%) 1/1006 (0.10%) 0/1005 (0.00%) Investigations Weight decreased 1/42237 (0.00%) 0/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%) Metabolism and nutrition disorders Electrolyte imbalance 0/42237 (0.00%) 1/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%) Hypoglycaemia 1/42237 (0.00%) 0/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%) Musculoskeletal and connective tissue disorders Finger deformity 1/42237 (0.00%) 0/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%) Intervertebral disc protrusion 1/42237 (0.00%) 0/42255 (0.00%) 2/1006 (0.20%) 1/1005 (0.10%)

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
					Lumbar spinal stenosis 1/42237 (0.00%) 0/42255 (0.00%) 0/1006 (0.00%) 1/1005 (0.10%) Osteoarthritis 1/42237 (0.00%) 0/42255 (0.00%) 2/1006 (0.20%) 10/1005 (1.00%) Arthralgia 0/42237 (0.00%) 0/42255 (0.00%) 2/1006 (0.20%) 0/1005 (0.00%) Bone cyst 0/42237 (0.00%) 0/42255 (0.00%) 0/1006 (0.00%) 1/1005 (0.10%) Polymyalgia rheumatica 0/42237 (0.00%) 0/42255 (0.00%) 0/1006 (0.00%) 1/1005 (0.10%) Rotator cuff syndrome 0/42237 (0.00%) 0/42255 (0.00%) 0/1006 (0.00%) 1/1005 (0.10%) Spondylolisthesis 0/42237 (0.00%) 0/42255 (0.00%) 1/1006 (0.10%) 0/1005 (0.00%) Neoplasms benign, malignant and unspecified (incl cysts and polyps) Basal cell carcinoma 22/42237 (0.05%) 16/42255 (0.04%) 0/1006 (0.00%) 0/1005 (0.00%) Prostate cancer 10/42237 (0.02%) 7/42255 (0.02%) 0/1006 (0.00%) 2/1005 (0.20%) Colon cancer 7/42237 (0.02%) 6/42255 (0.01%) 2/1006 (0.20%) 1/1005 (0.10%) Breast cancer 2/42237 (0.00%) 3/42255 (0.01%) 0/1006 (0.00%) 1/1005 (0.10%) Malignant melanoma 2/42237 (0.00%) 3/42255 (0.01%) 0/1006 (0.00%) 1/1005 (0.10%) Transitional cell carcinoma 2/42237 (0.00%) 2/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%) Gastric cancer 2/42237 (0.00%) 1/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%) Adenocarcinoma of colon 0/42237 (0.00%) 2/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%) Bladder cancer 1/42237 (0.00%) 1/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%)

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
					Colon cancer metastatic 1/42237 (0.00%) 1/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%) Endometrial adenocarcinoma 1/42237 (0.00%) 1/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%) Non-small cell lung cancer 2/42237 (0.00%) 0/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%) Plasma cell myeloma 2/42237 (0.00%) 0/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%) Rectal cancer 2/42237 (0.00%) 0/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%) Bladder adenocarcinoma stage unspecified 0/42237 (0.00%) 1/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%) Bowen's disease 0/42237 (0.00%) 1/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%) Bronchial carcinoma 1/42237 (0.00%) 0/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%) Clear cell renal cell carcinoma 0/42237 (0.00%) 1/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%) Colorectal cancer metastatic 0/42237 (0.00%) 1/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%) Glioblastoma 1/42237 (0.00%) 0/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%) Glioma 0/42237 (0.00%) 1/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%) Hepatic adenoma 1/42237 (0.00%) 0/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%) Hypopharyngeal cancer 1/42237 (0.00%) 0/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%) Laryngeal cancer 0/42237 (0.00%) 1/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%) Leukaemia 1/42237 (0.00%) 0/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%) Lung adenocarcinoma metastatic 0/42237 (0.00%) 1/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%)

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
					Lung neoplasm malignant 1/42237 (0.00%) 0/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%) Malignant neoplasm of renal pelvis 1/42237 (0.00%) 0/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%) Melanoma recurrent 1/42237 (0.00%) 0/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%) Mesothelioma 0/42237 (0.00%) 1/42255 (0.00%) 0/1006 (0.00%) 1/1005 (0.10%) Metastasis 0/42237 (0.00%) 1/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%) Metastatic gastric cancer 0/42237 (0.00%) 1/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%) Metastatic renal cell carcinoma 0/42237 (0.00%) 1/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%) Myelodysplastic syndrome 0/42237 (0.00%) 1/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%) Neoplasm prostate 0/42237 (0.00%) 1/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%) Oesophageal adenocarcinoma 1/42237 (0.00%) 0/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%) Oesophageal carcinoma recurrent 1/42237 (0.00%) 0/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%) Prostate cancer metastatic 0/42237 (0.00%) 1/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%) Prostate cancer recurrent 0/42237 (0.00%) 1/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%) Renal cancer 1/42237 (0.00%) 0/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%) Renal cell carcinoma 0/42237 (0.00%) 1/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%) Small cell lung cancer 1/42237 (0.00%) 0/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%)

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
					Squamous cell carcinoma 1/42237 (0.00%) 0/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%) Squamous cell carcinoma of skin 1/42237 (0.00%) 0/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%) Tonsil cancer 1/42237 (0.00%) 0/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%) Bile duct adenocarcinoma 0/42237 (0.00%) 0/42255 (0.00%) 1/1006 (0.10%) 0/1005 (0.00%) Bladder transitional cell carcinoma 0/42237 (0.00%) 0/42255 (0.00%) 0/1006 (0.00%) 1/1005 (0.10%) Colon neoplasm 0/42237 (0.00%) 0/42255 (0.00%) 1/1006 (0.10%) 0/1005 (0.00%) Endometrial cancer 0/42237 (0.00%) 0/42255 (0.00%) 0/1006 (0.00%) 1/1005 (0.10%) Renal cancer recurrent 0/42237 (0.00%) 0/42255 (0.00%) 0/1006 (0.00%) 1/1005 (0.10%) Nervous system disorders Cerebrovascular accident (in AE table) 3/1006 (0.30%) 1/1005 (0.10%) Cerebral infarction 4/42237 (0.01%) 9/42255 (0.02%) 0/1006 (0.00%) 0/1005 (0.00%) Transient ischaemic attack 8/42237 (0.02%) 5/42255 (0.01%) 0/1006 (0.00%) 0/1005 (0.00%) Syncope 3/42237 (0.01%) 3/42255 (0.01%) 0/1006 (0.00%) 0/1005 (0.00%) Presyncope 1/42237 (0.00%) 3/42255 (0.01%) 0/1006 (0.00%) 0/1005 (0.00%) Cerebral haemorrhage 2/42237 (0.00%) 1/42255 (0.00%) 1/1006 (0.10%) 0/1005 (0.00%) Subarachnoid haemorrhage 1/42237 (0.00%) 2/42255 (0.00%) 1/1006 (0.10%) 0/1005 (0.00%) Dizziness 1/42237 (0.00%) 1/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%) Epilepsy (in AE table) 0/1006 (0.00%) 0/1005 (0.00%)

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
					Loss of consciousness 1/42237 (0.00%) 1/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%) Transient global amnesia 0/42237 (0.00%) 2/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%) Acute disseminated encephalomyelitis 1/42237 (0.00%) 0/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%) (in AE table) Cerebral ischaemia 1/42237 (0.00%) 0/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%) Convulsion (in AE table combined with epilepsy) Hemiparesis 1/42237 (0.00%) 0/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%) Peroneal nerve palsy 0/42237 (0.00%) 1/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%) Radicular pain 0/42237 (0.00%) 1/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%) Radiculitis lumbosacral 0/42237 (0.00%) 1/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%) Trigeminal neuralgia 1/42237 (0.00%) 0/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%) Carotid artery stenosis 0/42237 (0.00%) 0/42255 (0.00%) 1/1006 (0.10%) 0/1005 (0.00%) Hepatic encephalopathy 0/42237 (0.00%) 0/42255 (0.00%) 0/1006 (0.00%) 1/1005 (0.10%) Ischaemic stroke 0/42237 (0.00%) 0/42255 (0.00%) 1/1006 (0.10%) 0/1005 (0.00%) Peripheral nerve lesion 0/42237 (0.00%) 0/42255 (0.00%) 0/1006 (0.00%) 1/1005 (0.10%) Psychiatric disorders Bipolar disorder 1/42237 (0.00%) 0/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%) Delirium 0/42237 (0.00%) 1/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%)

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
					Psychotic disorder 0/42237 (0.00%) 1/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%) Suicidal ideation 1/42237 (0.00%) 0/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%) Renal and urinary disorders Calculus bladder 2/42237 (0.00%) 0/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%) Haematuria 2/42237 (0.00%) 0/42255 (0.00%) 1/1006 (0.10%) 0/1005 (0.00%) Cystitis noninfective 0/42237 (0.00%) 1/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%) Nephrolithiasis 1/42237 (0.00%) 0/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%) Renal impairment 1/42237 (0.00%) 0/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%) Ureteric stenosis 0/42237 (0.00%) 1/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%) Urethral stenosis 0/42237 (0.00%) 0/42255 (0.00%) 0/1006 (0.00%) 1/1005 (0.10%) Urinary retention 0/42237 (0.00%) 0/42255 (0.00%) 1/1006 (0.10%) 0/1005 (0.00%) Reproductive system and breast disorders Benign prostatic hyperplasia 0/42237 (0.00%) 2/42255 (0.00%) 1/1006 (0.10%) 1/1005 (0.10%) Acquired phimosis 0/42237 (0.00%) 1/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%) Female genital tract fistula 0/42237 (0.00%) 0/42255 (0.00%) 1/1006 (0.10%) 0/1005 (0.00%) Vaginal prolapse 0/42237 (0.00%) 0/42255 (0.00%) 0/1006 (0.00%) 1/1005 (0.10%) Respiratory, thoracic and mediastinal disorders

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
					Chronic obstructive pulmonary disease 13/42237 (0.03%) 8/42255 (0.02%) 2/1006 (0.20%) 1/1005 (0.10%) Pulmonary embolism 3/42237 (0.01%) 2/42255 (0.00%) 1/1006 (0.10%) 0/1005 (0.00%) Pneumothorax 1/42237 (0.00%) 3/42255 (0.01%) 0/1006 (0.00%) 0/1005 (0.00%) Epistaxis 2/42237 (0.00%) 1/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%) Dyspnoea exertional 0/42237 (0.00%) 2/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%) Sleep apnoea syndrome 1/42237 (0.00%) 1/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%) Alveolitis allergic 1/42237 (0.00%) 0/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%) Asphyxia 0/42237 (0.00%) 1/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%) Dyspnoea 0/42237 (0.00%) 1/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%) Hydrothorax 1/42237 (0.00%) 0/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%) Lung infiltration 0/42237 (0.00%) 1/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%) Pleural effusion 0/42237 (0.00%) 0/42255 (0.00%) 0/1006 (0.00%) 1/1005 (0.10%) Skin and subcutaneous tissue disorders Skin ulcer 0/42237 (0.00%) 2/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%) Rash 1/42237 (0.00%) 0/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%) Vascular disorders Circulatory collapse 3/42237 (0.01%) 2/42255 (0.00%) 1/1006 (0.10%) 0/1005 (0.00%) Aortic aneurysm 2/42237 (0.00%) 1/42255 (0.00%) 2/1006 (0.20%) 0/1005 (0.00%) Aortic aneurysm rupture 3/42237 (0.01%) 0/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%)

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
					Hypertension 1/42237 (0.00%) 1/42255 (0.00%) 0/1006 (0.00%) 1/1005 (0.10%) Hypotension 2/42237 (0.00%) 0/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%) Deep vein thrombosis 1/42237 (0.00%) 0/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%) Haematoma 0/42237 (0.00%) 1/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%) Intermittent claudication 0/42237 (0.00%) 1/42255 (0.00%) 2/1006 (0.20%) 1/1005 (0.10%) Peripheral arterial occlusive disease 0/42237 (0.00%) 1/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%) Temporal arteritis 1/42237 (0.00%) 0/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%) Thrombophlebitis 1/42237 (0.00%) 0/42255 (0.00%) 0/1006 (0.00%) 0/1005 (0.00%) Malignant hypertension 0/42237 (0.00%) 0/42255 (0.00%) 1/1006 (0.10%) 0/1005 (0.00%) Risk factors: NR
Eriksson, 2020[101] Helsinki University Central Hospital, 2013[285] NCT01781871 Article RCT N=133 Industry funded Finland	Age: PCV13 55.9 (± 11.7); PPSV23 52.4 (± 12.6) % female: PCV13 36%; PPSV23 33% Ethnicity: NR Adult patients with CKD Stage 5 who were beginning dialysis (hemodialysis or peritoneal dialysis) and were being considered as kidney transplant candidates	Pneumococcal PCV13 Prevnar 13 Note that study examined two doses, but only dose 1 abstracted here Single dose adjuvant NR preservative NR No co-intervention PPSV PPSV23 alone Pneumovax Single dose route NR adjuvant NRpreservative NR Counts No prespecified AE Power NR Followup: 2 months	Pain at the injection site Pain, redness, swelling, functional disability of the arm Gastrointestinal discomfort Raised temperature Rash	NA	Reported SAE within a week of first vaccine: PCV13 7/66; PPSV23 1/66 SAE related to vaccination within a week of first vaccine: PCV 0/66; PPSV23 0/66 No vaccine-related allograft rejection was detected. Risk factors: No

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
	Out of scope: None				
Frenck, 2012[109] Pfizer, 2007[341] NCT00521586 Article RCT N=1158 Industry funded USA	Age: 54.6 (2.8) % female: 58% Ethnicity: 91% White, 7% Black, 1% Asian, 1% Other Healthy men and women aged 50 to 59 years at the time of enrollment. Adults with underlying diseases that were stable for 6 or more weeks prior to vaccination were included. Out of scope: None	Pneumococcal PCV13 Prevnar 13 1 dose Intramuscular Aluminum preservative NR Co-intervention Trivalent IIV (Fluarix) Placebo,Base treatment : Trivalent IIV Trivalent IIV and placebo Fluarix 1 dose Intramuscular adjuvant NRpreservative NR Counts Power other outcome Followup: 1 months	Cardiac failure congestive Coronary artery disease Myocardial infarction Palpitations Ventricular fibrillation Abdominal mass Abdominal pain Small intestinal obstruction Gastrointestinal haemorrhage Ileus Large intestine perforation Small intestinal obstruction Non-cardiac chest pain Cholecystitis Appendicitis Diverticulitis Abdominal abscess Cellulitis Pelvic abscess Peridiverticular abscess Tuberculosis Clostridium difficile infection Thermal burn Overdose Blood glucose increased Pain in extremity Back pain Musculoskeletal chest pain Osteoarthritis Arthritis Rotator cuff syndrome Spinal column stenosis Arthralgia Neck pain Spinal column stenosis Squamous cell carcinoma Basal cell carcinoma Prostate cancer Breast cancer Leiomyosarcoma Lung neoplasm malignant Malignant melanoma Bone cancer	Cardiovascular events: 2.X Coronary artery disease I: 0/551, 2.XCoronary artery disease, not vaccine-related C: 1/560 Encephalitis: 17.X Hepatic encephalopathy I: 0/551, 17.X Hepatic encephalopathy C: 0/560 Myocardial infarction: 2.X NR I: 0/551, 2.X Not vaccine-related C: 1/560 Reproduction issues: 21.X Uterine prolapse I: 0/551, 21.X Uterine prolapse C: 0/560 Stroke: 17.X Cerebrovascular accident I: 0/551, 17.X Cerebrovascular accident C: 0/560	Intervention (13vPnC+TIV): Dose 1 (Year 0) vsControl (Placebo+TIV): Dose 1 (Year 0) Systemic events: 417/484 (86.2%) vs 326/430 (75.8%), P < 0.001 Serious AEs (from clinicaltrials.gov): Intervention (13vPnC+TIV): Dose 1 (Year 0) vsControl (Placebo+TIV): Dose 1 (Year 0) Affected / at Risk (%)Affected / at Risk (%) Total 4/551 (0.73%) 5/560 (0.89%) Cardiac disorders Cardiac failure congestive0/551 (0.00%) 0/560 (0.00%) (in AE table) Coronary artery disease 0/551 (0.00%) 1/560 (0.18%) Myocardial infarction0/551 (0.00%) 1/560 (0.18%) (in AE table) Palpitations0/551 (0.00%) 0/560 (0.00%) Ventricular fibrillation0/551 (0.00%) 0/560 (0.00%) Gastrointestinal disorders Abdominal mass1/551 (0.18%) 0/560 (0.00%) Abdominal pain 0/551 (0.00%) 0/560 (0.00%) Small intestinal obstruction 0/551 (0.00%) 0/560 (0.00%) Gastrointestinal haemorrhage 0/551 (0.00%) 0/560 (0.00%) Ileus 0/551 (0.00%) 0/560 (0.00%) Large intestine perforation 0/551 (0.00%) 0/560 (0.00%) Small intestinal obstruction 0/551 (0.00%) 0/560 (0.00%) General disorders Non-cardiac chest pain 1/551 (0.18%) 1/560 (0.18%) Hepatobiliary disorders Cholecystitis 0/551 (0.00%) 1/560 (0.18%) Infections and infestations Appendicitis 0/551 (0.00%) 1/560 (0.18%)

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
			Lung cancer metastatic Metastatic malignant melanoma Pancreatic carcinoma Plasma cell myeloma Renal cell carcinoma Thyroid cancer metastatic Colon cancer Hepatic encephalopathy Syncope Cerebrovascular accident Transient ischaemic attack Anxiety Depression Renal colic Uterine prolapse Pulmonary embolism Haemoptysis Thrombosis Redness (prespecified) Swelling (prespecified) Pain (prespecified) Limitation of arm movement (prespecified) Fever (oral temperature of 38°C or 100.4°F) (prespecified) Chills (prespecified) Fatigue (prespecified) Headache (prespecified) Vomiting (prespecified) Decreased appetite (prespecified) Fash (prespecified) New generalized muscle pain (prespecified) Aggravated generalized muscle pain, new generalized joint pain (prespecified) Aggravated generalized joint pain (prespecified) Use of antipyretic and pain medications to treat symptoms (prespecified)		Diverticulitis 0/551 (0.00%) 0/560 (0.00%) Abdominal abscess 0/551 (0.00%) 0/560 (0.00%) Cellulitis 0/551 (0.00%) 0/560 (0.00%) Pelvic abscess 0/551 (0.00%) 0/560 (0.00%) Peridiverticular abscess 0/551 (0.00%) 0/560 (0.00%) Tuberculosis 0/551 (0.00%) 0/560 (0.00%) Clostridium difficile infection 0/551 (0.00%) 0/560 (0.00%) Injury, poisoning and procedural complications Thermal burn 0/551 (0.00%) 0/560 (0.00%) Overdose 0/551 (0.00%) 0/560 (0.00%) Investigations Blood glucose increased 1/551 (0.18%) 0/560 (0.00%) Musculoskeletal and connective tissue disorders Pain in extremity 1/551 (0.18%) 0/560 (0.00%) Back pain 0/551 (0.00%) 0/560 (0.00%) Musculoskeletal chest pain 0/551 (0.00%) 0/560 (0.00%) Osteoarthritis 0/551 (0.00%) 0/560 (0.00%) Arthritis 0/551 (0.00%) 0/560 (0.00%) Rotator cuff syndrome 0/551 (0.00%) 0/560 (0.00%) Spinal column stenosis 0/551 (0.00%) 0/560 (0.00%) Arthralgia 0/551 (0.00%) 0/560 (0.00%) Neck pain 0/551 (0.00%) 0/560 (0.00%) Spinal column stenosis 0/551 (0.00%) 0/560 (0.00%) Neoplasms benign, malignant and unspecified (incl cysts and polyps) Squamous cell carcinoma 1/551 (0.18%)0/560 (0.00%) Basal cell carcinoma 0/551 (0.00%) 0/560 (0.00%) Prostate cancer 0/551 (0.00%) 0/560 (0.00%)

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
					Breast cancer 0/551 (0.00%) 0/560 (0.00%) Leiomyosarcoma 0/551 (0.00%) 0/560 (0.00%) Lung neoplasm malignant 0/551 (0.00%) 0/560 (0.00%) Malignant melanoma 0/551 (0.00%)0/560 (0.00%) Bone cancer 0/551 (0.00%) 0/560 (0.00%) Lung cancer metastatic 0/551 (0.00%) 0/560 (0.00%) Metastatic malignant melanoma 0/551 (0.00%) 0/560 (0.00%) Pancreatic carcinoma 0/551 (0.00%) 0/560 (0.00%) Plasma cell myeloma 0/551 (0.00%) 0/560 (0.00%) Renal cell carcinoma 0/551 (0.00%) 0/560 (0.00%) Thyroid cancer metastatic 0/551 (0.00%) 0/560 (0.00%) Colon cancer 0/551 (0.00%) 0/560 (0.00%) Nervous system disorders Hepatic encephalopathy 0/551 (0.00%) 0/560 (0.00%) (in AE table) Syncope 0/551 (0.00%) 0/560 (0.00%) Cerebrovascular accident 0/551 (0.00%) 0/560 (0.00%) (in AE table) Transient ischaemic attack 0/551 (0.00%) 0/560 (0.00%) Psychiatric disorders Anxiety 0/551 (0.00%) 0/560 (0.00%) Depression 0/551 (0.00%) 0/560 (0.00%) Renal and urinary disorders Renal colic 0/551 (0.00%) 0/560 (0.00%) Reproductive system and breast disorders Uterine prolapse 0/551 (0.00%) 0/560 (0.00%) (in AE table) Respiratory, thoracic and mediastinal disorders Pulmonary embolism 0/551 (0.00%) 0/560 (0.00%)

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
					Haemoptysis 0/551 (0.00%) 0/560 (0.00%) Vascular disorders Thrombosis 1/551 (0.18%) 0/560 (0.00%) Risk factors: Local reactions associated with the concomitant administration of PCV13 and TIV were comparable to those associated with PCV13 given a month after TIV. More systemic adverse events were seen with the concomitant administration of PCV13 and TIV than with the single administration of either vaccine. Given that two vaccines were administered concomitantly, the higher rate of systemic events does not appear to be unusual and is not considered clinically meaningful.
Greenberg, 2014[120] Pfizer, 2007[387] NCT00574548 Article RCT N=720 Industry funded USA	Age: 61.7 (1.4) % female: 58% Ethnicity: PCV13 95% White, 4% Black, 1% Other, 1% American Indian or Alaska Native, <1% Asian, <1% Native Hawaiian or Other Pacific Islander; PPSV23 97% White, 3% Black, 0% Other, 0% American Indian or Alaska Native, 0% Asian, 0% Native Hawaiian or Other Pacific Is Pneumococcal vaccine–naïve adults 60 through 64 years of age, conducted at 21 medical centers	Pneumococcal PCV13 Prevnar 13 1 dose Intramuscular Aluminum preservative NR No co-intervention PPSV PPSV23 alone Pneumovax 1 dose Intramuscular adjuvant NRPhenol Counts No prespecified AE Power other outcome Followup: 6 months	Fever (Severe) Fever (Potentially life threatening) Redness (Severe) Swelling (Severe) Pain (Severe) Limitation of arm movement (Severe) Angina unstable Arrhythmia Myocardial infarction Angina pectoris Coronary artery disease Vertigo positional Goitre Gastrointestinal haemorrhage Intestinal infarction Pancreatitis Small intestinal obstruction Non-cardiac chest pain Cholecystitis acute Appendicitis Cellulitis orbital Perirectal abscess Staphylococcal abscess Fall Post procedural bile leak Hip fracture	Cardiovascular events: 2.X Myocardial infarction, not vaccine-related (at month 0) I: 1/478, 2.XMyocardial infarction, not vaccine-related (at 6 month follow-up) C: 1/237 Death: NA NA I: 0/478, NA NA C: 0/237 Myocardial infarction: 2.X Not vaccine-related (at month 0) I: 1/478, 2.X Not vaccine-related (at 6 month follow-up) C: 1/237 Reproduction issues: 21.X Ovarian adhesion, not vaccine-related I: 1/478, 21.X Ovarian adhesion C: 0/237	Severe AEs (from clinicaltrials.gov): Intervention (13vPnC [Year 0]) vs Control (23vPS [Year 0]) Affected / at Risk (%) Affected / at Risk (%) Fever (Severe)1/259 (0.39%) 1/127 (0.79%) Fever (Potentially life threatening)1/258 (0.39%) 0/127 (0.00%) Redness (Severe)3/259 (1.16%) 1/127 (0.79%) Swelling (Severe)0/258 (0.00%) 0/127 (0.00%) Pain (Severe)6/261 (2.30%) 1/127 (0.79%) Limitation of arm movement (Severe)3/261 (1.15%) 3/128 (2.34%) Serious AEs (from clinicaltrials.gov): Intervention (13vPnC [Year 0]) vs Control (23vPS [Year 0]) vs Intervention F/U (13vPnC: 6 Month Follow-up After Vax 1 [Year 0]) vs Control (23vPS: 6 Month Follow-up After Vax 1 [Year 0]) Affected / at Risk (%)Affected / at Risk (%)Affected / at Risk (%)Affected / at Risk (%) Total 2/478 (0.42%) 1/237 (0.42%) 15/478 (3.14%) 6/237 (2.53%) Cardiac disorders

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
	in the United States Out of scope: None		Accidental overdose Foot fracture Hypokalaemia Intervertebral disc degeneration Lumbar spinal stenosis Breast cancer Squamous cell carcinoma of skin Malignant melanoma Basal cell carcinoma Gastrointestinal stromal tumour Prostate cancer Benign neoplasm of skin Uterine cancer Renal failure Endometriosis Ovarian adhesion Uterine Haemothorax Chronic obstructive pulmonary disease Pleural effusion Dyspnoea Deep vein thrombosis		Angina unstable0/478 (0.00%) 1/237 (0.42%) 0/478 (0.00%) 0/237 (0.00%) Arrhythmia0/478 (0.00%) 1/237 (0.42%) 0/478 (0.00%) 0/237 (0.00%) Myocardial infarction0/478 (0.00%) 1/237 (0.42%) 1/478 (0.21%) 0/237 (0.00%) (in AE table) Angina pectoris0/478 (0.00%) 0/237 (0.00%) 1/478 (0.21%) 0/237 (0.00%) Coronary artery disease0/478 (0.00%) 0/237 (0.00%) 0/478 (0.00%) 0/237 (0.00%) Ear and labyrinth disorders Vertigo positional 0/478 (0.00%) 0/237 (0.00%) 1/478 (0.21%) 0/237 (0.00%) Endocrine disorders Goitre 0/478 (0.00%) 0/237 (0.00%) 0/478 (0.00%) 0/237 (0.00%) Gastrointestinal disorders Gastrointestinal haemorrhage 0/478 (0.00%) 0/237 (0.00%) 1/478 (0.21%) 0/237 (0.00%) Intestinal infarction 0/478 (0.00%) 0/237 (0.00%) 1/478 (0.21%) 0/237 (0.00%) Pancreatitis0/478 (0.00%) 0/237 (0.00%) 1/478 (0.21%) 0/237 (0.00%) Small intestinal obstruction0/478 (0.00%) 0/237 (0.00%) 0/478 (0.00%) 0/237 (0.00%) General disorders Non-cardiac chest pain0/478 (0.00%) 0/237 (0.00%) 0/478 (0.00%) 1/237 (0.42%) Hepatobiliary disorders Cholecystitis acute 0/478 (0.00%) 0/237 (0.00%) 1/478 (0.21%) 0/237 (0.00%) Infections and infestations Appendicitis0/478 (0.00%) 0/237 (0.00%) 1/478 (0.21%) 0/237 (0.00%) Cellulitis orbital 0/478 (0.00%) 0/237 (0.00%) 1/478 (0.21%) 0/237 (0.00%) Perirectal abscess 0/478 (0.00%) 0/237 (0.00%) 1/478 (0.21%) 0/237 (0.00%) Staphylococcal abscess0/478 (0.00%) 0/237 (0.00%) 0/478 (0.00%) 1/237 (0.42%)

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
					Injury, poisoning and procedural complications Fall0/478 (0.00%) 0/237 (0.00%) 1/478 (0.21%) 0/237 (0.00%) Post procedural bile leak 0/478 (0.00%) 0/237 (0.00%) 1/478 (0.21%) 0/237 (0.00%) Hip fracture 0/478 (0.00%) 0/237 (0.00%) 0/478 (0.00%) 0/237 (0.00%) Accidental overdose 0/478 (0.00%) 0/237 (0.00%) 0/478 (0.00%) 0/237 (0.00%) Foot fracture 0/478 (0.00%) 0/237 (0.00%) 0/478 (0.00%) 0/237 (0.00%) Metabolism and nutrition disorders Hypokalaemia 0/478 (0.00%) 0/237 (0.00%) 1/478 (0.21%) 0/237 (0.00%) Musculoskeletal and connective tissue disorders Intervertebral disc degeneration 0/478 (0.00%) 0/237 (0.00%) 0/478 (0.00%) 0/237 (0.00%) Lumbar spinal stenosis 0/478 (0.00%) 0/237 (0.00%) 0/478 (0.00%) 0/237 (0.00%) Neoplasms benign, malignant and unspecified (incl cysts and polyps) Breast cancer 1/478 (0.21%) 0/237 (0.00%) 0/478 (0.00%) 0/237 (0.00%) Squamous cell carcinoma of skin 1/478 (0.21%) 0/237 (0.00%) 1/478 (0.21%) 0/237 (0.00%) Malignant melanoma 0/478 (0.00%) 0/237 (0.00%) 1/478 (0.21%) 1/237 (0.42%) Basal cell carcinoma 0/478 (0.00%) 0/237 (0.00%) 1/478 (0.21%) 0/237 (0.00%) Gastrointestinal stromal tumour 0/478 (0.00%) 0/237 (0.00%) 1/478 (0.21%) 0/237 (0.00%) Prostate cancer 0/478 (0.00%) 0/237 (0.00%) 0/478 (0.00%) 1/237 (0.42%) Benign neoplasm of skin 0/478 (0.00%) 0/237 (0.00%) 0/478 (0.00%) 0/237 (0.00%)

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
					Uterine cancer 0/478 (0.00%) 0/237 (0.00%) 0/478 (0.00%) 0/237 (0.00%) Renal and urinary disorders Renal failure 0/478 (0.00%) 0/237 (0.00%) 1/478 (0.21%) 0/237 (0.00%) Reproductive system and breast disorders Endometriosis 0/478 (0.00%) 0/237 (0.00%) 1/478 (0.21%) 0/237 (0.00%) Ovarian adhesion 0/478 (0.00%) 0/237 (0.00%) 1/478 (0.21%) 0/237 (0.00%) (in AE table) Uterine polyp 0/478 (0.00%) 0/237 (0.00%) 1/478 (0.21%) 0/237 (0.00%) Respiratory, thoracic and mediastinal disorders Haemothorax 0/478 (0.00%) 0/237 (0.00%) 1/478 (0.21%) 0/237 (0.00%) Chronic obstructive pulmonary disease 0/478 (0.00%) 0/237 (0.00%) 0/478 (0.00%) 1/237 (0.42%) Pleural effusion 0/478 (0.00%) 0/237 (0.00%) 0/478 (0.00%) 1/237 (0.42%) Dyspnoea 0/478 (0.00%) 0/237 (0.00%) 0/478 (0.00%) 0/237 (0.00%) Vascular disorders Deep vein thrombosis 0/478 (0.00%) 0/237 (0.00%) 0/478 (0.00%) 0/237 (0.00%) Risk factors: No
Jackson, 2013[140] Article RCT N=1303 Industry funded USA	Age: Intervention (PCV13) 61.8 (1.4), Control (PPSV23) 61.7 (1.4), Open-abel group (not abstracted here) 54.4 (2.9) % female: Intervention 54%, Control 61%, Open-label 62% Ethnicity: 95% Caucasian, 2% African	Pneumococcal PCV13 Prevnar 13 0.5 mL in one dose Intramuscular Aluminum preservative free No co-intervention PPSV Pneumococcal polysaccharide vaccine Pneumovax 23 0.5 mL in one dose Intramuscular	Redness Swelling Pain Limitation of arm movement of the injected arm Chills Fatigue Headache Vomiting Decreased appetite Rash New generalized muscle pain Aggravated generalized muscle pain New generalized joint pain	Death: NA Not considered related to vaccination I: 1/418, NA C: 0/417	Severe AEs within 14 days of vaccination: Redness, Severe: 1.7% vs 0%, p=0.095 Swelling, Severe: 0.6% vs 1.1%, p=0.689 Pain, Severe: 1.7% vs 8.6%, p=0.003 Limitation of arm movement, Severe: 1.7% vs 4.3%, p=0.147 Fever, Severe (≥39C but ≤40C): 0.0% vs 0.0%, p=>0.99 Fever >40C: 0.0% vs 0.0%, p=>0.99 Risk factors: NR

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
	American, 1% Asian, 1% American Indian or Alaska Native, <1% Native Hawaiian or Other Pacific Islander, 1% Other; 2% Hispanic or Latino Adults 60–64 years of age (also included open-label study of adults aged 50-59 years, not abstracted here) Out of scope: None	adjuvant freePhenol Counts Prespecified AE Power other outcome Followup: 12 months	Aggravated generalized joint pain Oral temperature Death		
Juergens, 2014[142] Pfizer, 2005[386] NCT00269672 Article RCT N=915 Industry funded South Africa	Age: 70.7 (no SD) % female: 57% Ethnicity: 62% White, 38% Other (Year 0) Adults aged ≥65 y who were not previously vaccinated with PPSV23 Out of scope: None	Pneumococcal PCV13 Prevnar 13 0.5 mL in one dose Intramuscular Aluminum preservative free No co-intervention PPSV Pneumococcal polysaccharide vaccine (PPSV23) Pneumovax 23 0.5 mL in one dose Intramuscular adjuvant freePhenol Counts No prespecified AE Power other outcome Followup: 2 months	Myocardial infarction Cardiovascular disease or cancer Redness Swelling Pain Rash Fever	NA	Serious AEs within 29-43 days: 0.6% vs 0.3% (none deemed related to the study vaccines) Severe AEs: Fever ≥39C but ≤40C: 2.9% vs 3.4% Fever >40C: 0% vs 0.4% Risk factors: NR
Kantso, 2015[143] Statens	Age: 44 (14) % female: 56%	Pneumococcal PCV13 Prevnar 13	Mild soreness Fever Headache	NA	Serious AEs: PCV13 0/74, PPV23 2/77 (infection with Enterococcus faecalis, sinusitis)

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
Serum Institut, 2013[377]; Statens Serum Institut, 2013[376]; Kantso, 2015[291] NCT01947010 ; EudraCT 2012- 002867-86 Article RCT N=157 Industry funded Denmark	Ethnicity: N/A Adults (above 18 years of age) diagnosed with Crohn's disease, non-pregnant, with no previous pneumococcal vaccination Out of scope: None	Not reported Route NR adjuvant NR preservative NR No co-intervention PPSV Polysaccharide pneumococcal vaccine Pneumovax Not reported route NR adjuvant NRpreservative NR Counts No prespecified AE Power NR Followup: 1 months	Stomach pain Nausea Tenderness in an arm Enterococcus faecalis Sinusitis Itch on a leg Pneumonia		Risk factors: NR
Lombardi, 2016[162] University of Siena, 2011[382] NCT02123433 Article CCT N=100 Not industry funded Italy	Age: Intervention: 44 (9), Control: 46 (11) % female: 28% Ethnicity: 92% Caucasian HIV-infected adult outpatients who had never been vaccinated with any pneumococcal vaccine Out of scope: None	Pneumococcal PCV13 Prevnar 13 Route NR adjuvant NR preservative NR No co-intervention PPSV Routine vaccine alone Pneumovax route NR adjuvant NRpreservative NR Counts No prespecified AE Power other outcome Followup: 12 months	Fatigue Itching	NA	No severe AEs reported in either group. Risk factors: No but study is of a subgroup (people with HIV)
Pfizer, 2007[184] NCT00427895 Trial record RCT N=2141	Age: 100% were 60-64 years in Cohort 1 % female: Intervention 64%, Control 61%	Pneumococcal PCV13 Prevnar 13 1 dose Intramuscular adjuvant NR preservative NR No co-intervention	Myocardial infarction Coronary artery disease Angina pectoris Abdominal mass Crohn's disease Gastrooesophageal reflux Rectal haemorrhage Pancreatitis	Autoimmune disease: 7.X Crohn's disease I: 0/417, 7.X Crohn's disease C: 1/414 Cardiovascular events: 2.X Myocardial infarction I: 1/417, 2.XMyocardial infarction C: 1/414 Myocardial infarction: 2.X NR I: 1/417, 2.X NR C: 1/414	Serious AEs (from clinicaltrials.gov) Intervention (13vPnC, Cohort 1)Interevntion F/U (13vPnC: 6 Month Follow-up After Vax 1) Control (23vPS) Control (23vPS: 6 Month Follow-up After Vax 1) Affected / at Risk (%)# EventsAffected / at Risk (%)# EventsAffected / at Risk

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
Industry funded USA	Ethnicity: NR Healthy male and female adults 60 to 64 years of age at time of enrollment. Out of scope: None	PPSV PPSV23 Pneumovax 1 dose Intramuscular adjuvant NRpreservative NR Counts Unclear Power NR Followup: 6 months	Non-cardiac chest pain Pyrexia Bile duct obstruction Cholecystitis Cholecystitis acute Cholelithiasis Cellulitis Pneumonia Pneumonia bacterial Bronchitis Procedural pain Ligament rupture Lumbar vertebral fracture Rib fracture Femur fracture Hip fracture Osteoarthritis Intervertebral disc protrusion Spinal column stenosis Haemangioma Malignant melanoma Ovarian cancer Endometrial cancer metastatic Prostate cancer Breast cancer Hepatic neoplasm malignant Pancreatic carcinoma Meningioma Basal cell carcinoma Nystagmus Migraine Bipolar disorder Depression Suicidal ideation Ovarian cyst ruptured Chronic obstructive pulmonary disease Erythema multiforme Lymphadenectomy Vascular disorders Thrombosis Fever Chills Rash	Reproduction issues: 21.X Ovarian cyst ruptured I: 0/417, 21.X Ovarian cyst ruptured C: 0/414	(%)# EventsAffected / at Risk (%)# Events Total 1/417 (0.24%) 12/417 (2.88%) 2/414 (0.48%) 10/414 (2.42%) Cardiac disorders Myocardial infarction0/417 (0.00%) 1/417 (0.24%) 1/414 (0.24%) 0/414 (0.00%) (in AE table) Coronary artery disease0/417 (0.00%) 1/417 (0.24%) 0/414 (0.00%) 0/414 (0.00%) Angina pectoris 0/417 (0.00%) 0/417 (0.00%) 0/414 (0.00%) 1/414 (0.24%) Gastrointestinal disorders Abdominal mass 0/417 (0.00%) 0/417 (0.00%) 0/414 (0.00%) 1/414 (0.24%) Crohn's disease 0/417 (0.00%) 0/417 (0.00%) 0/414 (0.00%) 1/414 (0.24%) (in AE table) Gastrooesophageal reflux 0/417 (0.00%) 1/417 (0.24%) 0/414 (0.00%) 0/414 (0.00%) Rectal haemorrhage 0/417 (0.00%) 0/417 (0.00%) 0/414 (0.00%) 1/414 (0.24%) Pancreatitis0/417 (0.00%) 0/417 (0.00%) 0/414 (0.00%) 0/414 (0.00%) General disorders Non-cardiac chest pain0/417 (0.00%) 0/417 (0.00%) 0/414 (0.00%) 1/414 (0.24%) Pyrexia 0/417 (0.00%) 0/417 (0.00%) 0/414 (0.00%) 0/414 (0.00%) Hepatobiliary disorders Bile duct obstruction0/417 (0.00%) 0/417 (0.00%) 0/414 (0.00%) 1/414 (0.24%) Cholecystitis 0/417 (0.00%) 0/417 (0.00%) 0/414 (0.00%) 1/414 (0.24%) Cholecystitis acute0/417 (0.00%) 1/417 (0.24%) 0/414 (0.00%) 0/414 (0.00%) Cholelithiasis 0/417 (0.00%) 1/417 (0.24%) 0/414 (0.00%) 0/414 (0.00%) Infections and infestations Cellulitis 0/417 (0.00%) 0/417 (0.00%) 1/414 (0.24%) 0/414 (0.00%) Pneumonia0/417 (0.00%) 1/417 (0.24%) 0/414 (0.00%) 0/414 (0.00%)

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
			Vomiting Decreased appetite New generalized muscle pain Aggravated generalized muscle pain New generalized joint pain Aggravated generalized joint pain Lymphadenitis Leukocytosis Lymphadenopathy Iron deficiency anaemia Lymph node pain Tachycardia Deafness bilateral Ear congestion Ear discomfort Vertigo Ear pain Cerumen impaction Hypothyroidism Cataract Visual impairment Eye irritation Eye pruritus Vision blurred Lacrimation increased Constipation Diverticulum Gastrooesophageal reflux disease Nausea Diarrhoea Dyspepsia Abdominal discomfort Chapped lips Vomiting Abdominal pain lower Toothache Haemorrhoids Inguinal hernia Colonic polyp Gastritis Abdominal pain Abdominal pain upper Fatigue		Pneumonia bacterial 0/417 (0.00%) 1/417 (0.24%) 0/414 (0.00%) 0/414 (0.00%) Bronchitis 0/417 (0.00%) 0/417 (0.00%) 0/414 (0.00%) 0/414 (0.00%) Injury, poisoning and procedural complications Procedural pain 0/417 (0.00%) 0/417 (0.00%) 1/414 (0.24%) 0/414 (0.00%) Ligament rupture0/417 (0.00%) 0/417 (0.00%) 0/414 (0.00%) 0/414 (0.00%) Lumbar vertebral fracture0/417 (0.00%) 0/417 (0.00%) 0/414 (0.00%) 0/414 (0.00%) Rib fracture0/417 (0.00%) 0/417 (0.00%) 0/414 (0.00%) 0/414 (0.00%) Femur fracture0/417 (0.00%) 0/417 (0.00%) 0/414 (0.00%) 0/414 (0.00%) Hip fracture 0/417 (0.00%) 0/417 (0.00%) 0/414 (0.00%) 0/414 (0.00%) Musculoskeletal and connective tissue disorders Osteoarthritis 0/417 (0.00%) 1/417 (0.24%) 0/414 (0.00%) 0/414 (0.00%) Intervertebral disc protrusion0/417 (0.00%) 1/417 (0.24%) 0/414 (0.00%) 0/414 (0.00%) Spinal column stenosis 0/417 (0.00%) 1/417 (0.24%) 0/414 (0.00%) 0/414 (0.00%) Neoplasms benign, malignant and unspecified (incl cysts and polyps) Haemangioma 1/417 (0.24%) 0/417 (0.00%) 0/414 (0.00%) 0/414 (0.00%) Malignant melanoma0/417 (0.00%) 0/417 (0.00%) 1/414 (0.24%) 0/414 (0.00%) Ovarian cancer0/417 (0.00%) 0/417 (0.00%) 0/414 (0.00%) 0/414 (0.00%) Endometrial cancer metastatic 0/417 (0.00%) 0/417 (0.00%) 0/414 (0.00%) 0/414 (0.00%) Prostate cancer0/417 (0.00%) 1/417 (0.24%) 0/414 (0.00%) 2/414 (0.48%) Breast cancer 0/417 (0.00%) 0/417 (0.00%) 0/414 (0.00%) 1/414 (0.24%)

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
			Non-cardiac chest pain Oedema peripheral Pyrexia Injection site pain Injection site pruritus Adverse drug reaction Axillary pain Chills Influenza like illness Injection site haematoma Injection site injury Injury associated with device Malaise Mass Injection site erythema Injection site reaction Vessel puncture site haematoma Injection site pallor Injection site rash Injection site swelling Injection site warmth Pain Injection site irritation Injection site induration Seasonal allergy Allergy to vaccine Drug hypersensitivity Herpes simplex Sinusitis Upper respiratory tract infection Nasopharyngitis Gastroenteritis Bronchitis Lower respiratory tract infection Localised infection Oral herpes Bacterial infection Cellulitis Gingival infection Herpes zoster Influenza Laryngitis Otitis media		Hepatic neoplasm malignant 0/417 (0.00%) 1/417 (0.24%) 0/414 (0.00%) 0/414 (0.00%) Pancreatic carcinoma 0/417 (0.00%) 1/417 (0.24%) 0/414 (0.00%) 0/414 (0.00%) Meningioma0/417 (0.00%) 0/417 (0.00%) 0/414 (0.00%) 0/414 (0.00%) Basal cell carcinoma0/417 (0.00%) 0/417 (0.00%) 0/414 (0.00%) 0/414 (0.00%) Nervous system disorders Nystagmus0/417 (0.00%) 0/417 (0.00%) 0/414 (0.00%) 0/414 (0.00%) Migraine 0/417 (0.00%) 0/417 (0.00%) 0/414 (0.00%) 0/414 (0.00%) Psychiatric disorders Bipolar disorder 0/417 (0.00%) 0/417 (0.00%) 0/414 (0.00%) 1/414 (0.24%) Depression 0/417 (0.00%) 0/417 (0.00%) 0/414 (0.00%) 1/414 (0.24%) Suicidal ideation 0/417 (0.00%) 0/417 (0.00%) 0/414 (0.00%) 1/414 (0.24%) Reproductive system and breast disorders Ovarian cyst ruptured 0/417 (0.00%) 0/417 (0.00%) 0/414 (0.00%) 0/414 (0.00%) (in AE table) Respiratory, thoracic and mediastinal disorders Chronic obstructive pulmonary disease0/417 (0.00%) 0/417 (0.00%) 0/414 (0.00%) 0/414 (0.00%) Skin and subcutaneous tissue disorders Erythema multiforme 0/417 (0.00%) 0/417 (0.00%) 0/414 (0.00%) 0/414 (0.00%) Surgical and medical procedures Lymphadenectomy0/417 (0.00%) 0/417 (0.00%) 0/414 (0.00%) 0/414 (0.00%) Vascular disorders Thrombosis0/417 (0.00%) 1/417 (0.24%) 0/414 (0.00%) 0/414 (0.00%) Risk factors: No

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
			Pharyngitis Pharyngitis streptococcal Pneumonia Staphylococcal infection Urinary tract infection Vaginal infection Viral upper respiratory tract infection Acarodermatitis Fungal infection Gastroenteritis viral Clostridial infection Diverticulitis Hordeolum Pyelonephritis Skin candida Tooth abscess Tinea infection Viral infection Vulvovaginal mycotic infection Injury, poisoning and procedural complications Head injury Procedural dizziness Joint injury Arthropod bite Skin laceration Lower limb fracture Rib fracture Arthropod sting Skin injury Tendon rupture Muscle strain Contusion Fall Ligament rupture Ligament sprain Upper limb fracture Limb injury Laceration Hand fracture Procedural pain Investigations Prostatic specific antigen increased Weight decreased		

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
			Heart rate increased Metabolism and nutrition disorders Hypercholesterolaemia Hypokalaemia Gout Hyperlipidaemia Hyperglycaemia Polydipsia Decreased appetite Musculoskeletal and connective tissue disorders Tendonitis Joint stiffness Muscle tightness Myalgia Back pain Arthralgia Pain in extremity Musculoskeletal pain Musculoskeletal stiffness Arthritis Musculoskeletal chest pain Neck pain Pain in jaw Rotator cuff syndrome Muscle spasms Tenosynovitis Medial tibial stress syndrome Muscle twitching Neoplasms benign, malignant and unspecified (incl cysts and polyps) Benign breast neoplasm Melanocytic naevus Nervous system disorders Aphonia Dementia Headache Hypoaesthesia Dizziness Sciatica Paraesthesia Somnolence Neuralgia		

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
			Nerve compression Neuritis Tension headache Psychiatric disorders Generalised anxiety disorder Anxiety Depressive symptom Insomnia Mood altered Bipolar disorder Depression Renal and urinary disorders Renal failure chronic Nephrolithiasis Renal failure Nephrolithiasis Reproductive system and breast disorders Breast mass Atrophic vulvovaginitis Testicular pain Vaginal discharge Nipple exudate bloody Atrophic vulvovaginitis Respiratory, thoracic and mediastinal disorders Cough Rhinorrhoea Oropharyngeal pain Nasal congestion Asthma Diaphragmalgia Paranasal sinus hypersecretion Sneezing Dyspnoea Pulmonary congestion Rhinitis allergic Sinus congestion Upper-airway cough syndrome Bronchial hyperreactivity Epistaxis Upper respiratory tract congestion		

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
			Dermatitis allergic Skin and subcutaneous tissue disorders Redness (Any) Redness (Mild) Redness (Moderate) Redness (Severe) Swelling (Any) Swelling (Mild) Swelling (Moderate) Swelling (Severe) Pain (Any) Pain (Mild) Pain (Moderate) Pain (Severe) Limitation of arm movement (Any) Limitation of arm movement (Mild) Limitation of arm movement (Moderate) Limitation of arm movement (Severe) Rosacea Rash pruritic Dermatitis contact Eczema Erythema Rash Acne Dermatitis Petechiae Precancerous skin lesion Swelling face Urticaria Erythema multiforme Skin irritation Vascular disorders Venous insufficiency Hypertension Haematoma Hot flush Hypotension		
Schwarz, 2011[195] Pfizer, 2007[342]	Age: 72.0 (5.4) % female: 50%	Pneumococcal PCV13 Prevnar 13 1 dose Intramuscular	Angina pectoris Cardiac failure Myocardial infarction Atrial fibrillation	Asthma: 22.1 NA I: 0/576, 22.1 NA C: 0/575	Serious AEs (from clinical trials.gov) Intervention (13vPnC+TIV) vs Control (Placebo+TIV)

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
NCT00492557 Article RCT N=1190 Industry funded Germany, The Netherlands, Belgium, and Hungary	Ethnicity: 99% White, <1% Asian, <1% Black or African-American, <1% Other Generally healthy male or female adults 65 years of age or older. Out of scope: None	Aluminum preservative NR Co-intervention Trivalent IIV (Fluarix) Placebo,Base treatment : Trivalent IIV (Fluarix) Trivalent IIV plus placebo Fluarix 1 dose Intramuscular adjuvant NRpreservative NR Counts Prespecified AE Power other outcome Followup: 1 months	Gastric ulcer Duodenal ulcer perforation Gastrointestinal haemorrhage Peritonitis Cholecystitis Pneumonia Femoral neck fracture Sternal fracture Endoscopy small intestine Electrocardiogram ST segment elevation Spinal column stenosis Basal cell carcinoma Bladder neoplasm Malignant melanoma Chronic obstructive pulmonary disease Cardiac pacemaker insertion Fever > 40.0 degrees C (prespecified) Redness (severe) (prespecified) Swelling (severe) (prespecified) Pain (severe) (prespecified) Limitation of arm movement (severe) (prespecified) Chills (prespecified) Headache (prespecified) Fatigue (prespecified) Vomiting (prespecified) Decreased appetite (prespecified) Rash (prespecified) New and aggravated generalized muscle of joint pain (prespecified) Use of antipyretic and pain (prespecified)	Cardiovascular events: 2.X Angina pectoris, not vaccine-related I: 1/576, 2.XAngina pectoris C: 0/575 Death: NA NA I: 0/576, NA NA C: 0/575 Herpes Zoster: 11.1 NA I: 0/576 11.1 NA C: 0/575 Myocardial infarction: 2.X Myocardial infarction, not vaccine-related I: 1/576, 2.X Myocardial infarction C: 0/575	Affected / at Risk (%)Affected / at Risk (%) Total 4/576 (0.69%) 0/575 (0.00%) Cardiac disorders Angina pectoris 1/576 (0.17%) 0/575 (0.00%) (in AE table) Cardiac failure 1/576 (0.17%) 0/575 (0.00%) Myocardial infarction 1/576 (0.17%) 0/575 (0.00%) (in AE table) Atrial fibrillation 0/576 (0.00%) 0/575 (0.00%) Gastrointestinal disorders Gastric ulcer 1/576 (0.17%) 0/575 (0.00%) Duodenal ulcer perforation 0/576 (0.00%) 0/575 (0.00%) Gastrointestinal haemorrhage 0/576 (0.00%) 0/575 (0.00%) Peritonitis 0/576 (0.00%) 0/575 (0.00%) Hepatobiliary disorders Cholecystitis 0/576 (0.00%) 0/575 (0.00%) Infections and infestations Pneumonia 1/576 (0.17%) 0/575 (0.00%) Injury, poisoning and procedural complications Femoral neck fracture 0/576 (0.00%) 0/575 (0.00%) Sternal fracture 0/576 (0.00%) 0/575 (0.00%) Investigations Endoscopy small intestine 1/576 (0.17%) 0/575 (0.00%) Electrocardiogram ST segment elevation 0/576 (0.00%) 0/575 (0.00%) Musculoskeletal and connective tissue disorders Spinal column stenosis 1/576 (0.17%) 0/575 (0.00%) Neoplasms benign, malignant and unspecified (incl cysts and polyps) Basal cell carcinoma 0/576 (0.00%) 0/575 (0.00%) Bladder neoplasm 0/576 (0.00%) 0/575 (0.00%)

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
					Malignant melanoma 0/576 (0.00%) 0/575 (0.00%) Respiratory, thoracic and mediastinal disorders Chronic obstructive pulmonary disease 0/576 (0.00%) 0/575 (0.00%) Surgical and medical procedures Cardiac pacemaker insertion 0/576 (0.00%) 0/575 (0.00%) Other (not including Serious AEs) (from clinical trials.gov): Herpes zoster 0/576 (0.00%) 0/575 (0.00%) Asthma 0/576 (0.00%) 0/575 (0.00%) Severe AEs: Fever > 40.0 degrees C 6/429 (1.40%) 10/438 (2.28%) Redness (severe) 3/429 (0.70%) 0/431 (0.00%) Swelling (severe) 1/428 (0.23%) 1/431 (0.23%) Pain (severe) 6/429 (1.40%) 0/431 (0.00%) Limitation of arm movement (severe) 8/429 (1.86%) 0/431 (0.00%) Risk factors: No
Seo, 2017[197] Korea University Guro Hospital, 2012[294] NCT02582047 Article RCT N=224 Not industry funded Republic of Korea	Age: Intervention: 72, Control: 73 % female: Intervention: 54%, Control: 54% Ethnicity: Ethnicity NR Healthy men and women aged 65 years or older who were naïve to the 2012/2013 season influenza vaccine and any pneumococcal vaccine	Pneumococcal PCV13 Prevnar 13 Contained polysaccharides of pneumococcal sero- types 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19F, 19A, and 23F conjugated to a nontoxic mutant form of diphtheria toxin cross-reactive material 1972.2 Each dose contained 2.2 µg of each serotype, except type 6B, which was included at 4.4 µg 0.5 mL	Pain Tenderness Redness Swelling Fever Headache Malaise Fatigue Chill Muscle aches Arthralgia	NA	Local adverse effects within 7 days, Intervention (PCV13+TIV) vs Control (PPSV23+TIV): Pain, Severe: 0/110 (0%) vs 0/110 (0%) Tenderness, Severe: 0/110 (0%) vs 0/110 (0%) Redness diameter, ≥5mm: 1/110 (0.9%) vs 0/110 (0%) Swelling diameter, ≥5mm: 0/110 (0%) vs 0/110 (0%) Systemic adverse effects within 7 days, Intervention (PCV13+TIV) vs Control (PPSV23+TIV): Fever, temperature ≥ 38°C: 0/110 (0%) vs 0/110 (0%) Headache, Severe: 0/110 (0%) vs 0/110 (0%) Malaise, Severe: 0/110 (0%) vs 0/110 (0%) Fatigue, Severe: 0/110 (0%) vs 0/110 (0%)

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
	Out of scope: None	dose once Intramuscular adjuvant NR preservative NR Co-intervention IIV3 (GCflu, Green Cross Corp., Yongin, Korea) Base treatment,PPSV Pneumococcal polysaccharide vaccine and trivalent influenza vaccine Pneumovax 23 and GCflu 0.5 mL of each vaccine Intramuscular adjuvant NRpreservative NR Counts Prespecified AE Power NR Followup: 1 months			Chills, Severe: 0/110 (0%) vs 0/110 (0%) Muscle aches, Severe: 0/110 (0%) vs 0/110 (0%) Arthralgia, Severe: 0/110 (0%) vs 0/110 (0%) Risk factors: NR
Shiramoto, 2015[200] Article RCT N=1194 Industry funded Japan	Age: 70 (4) % female: 50% Ethnicity: 100% Japanese Healthy Japanese men and women 65 years of age and older who provided informed consent and would be available for the duration of the study. Adults with underlying chronic conditions that	Pneumococcal PCV13 Prevnar 13 Single 0.5 mL dose (pneumococcal serotypes 1, 3, 4, 5, 6A, 6B, 7F,9V, 14, 18C, 19A, 19F, and 23F (containing 2.2mg of eachsaccharide, except for 4.4mg of serotype 6B) individually conju-gated to a nontoxic form of diphtheria toxin cross-reactive mate-rial Intramuscular Aluminum preservative free	Redness Swelling Pain Limitation of arm movement Temperature Chills Fatigue Headache Vomiting Rash Decreased appetite New or aggravated muscle of joint pina Pancreatic carcinoma (not prespecified and not vaccine related)	Death: NA NA I: 0/367, NA NA C: 0/370	Local reactions: PCV13 211/367 (57.5&) vs PPSV23 166/370 (44.9%) Serious AEs: PCV13 1/367 (0.3%) (pancreatic carcinoma, not considered vaccine related) vs PPSV23 0/370 (0%) Risk factors: NR

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
	were stable for !12 weeks prior to vaccination were included. Subjects were ineligible if they were immunocompromised, had severe acute/chronic medical or psychiatric conditions, had a history of severe vaccine associated adverse reactions, had S. pneumoniae infection within the last 5 years, were vaccinated with a diphtheria-containing vaccine or toxoid within 6 months, received a blood product within the last 3 months, or had previously received a pneumococcal vaccination. Out of scope: None	No co-intervention PPSV PPSV23 alone Pneumovax Single 0.5 mL dose of purified capsular polysaccha-ride from 12 of the serotypes included in PCV13 (all except 6A),as well as 11 additional serotypes (2, 8, 9N, 10A, 11A, 12F, 15B,17F, 20, 22F, and 33F). The vaccine contains 25mg of each ofthe 23 purified Intramuscular adjuvant freePhenol Counts Prespecified AE Power other outcome Followup: 2 months			
Song, 2017[202] Korea University Guro Hospital, 2014[297] NCT02215863 Article	Age: Intervention (Fluad+PCV13) 65.4 (95% CI 64.9–65.9), Control (Fluad) 65.9 (95% CI 65.5–66.4)	Pneumococcal PCV13 Prevnar 13 Contains polysaccharides from pneumococcal serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and	Pain Tenderness Redness Headache Swelling Malaise Chills Muscle aches	NA	Severe AEs (from supplemental material), Intervention (Fluad+PCV13) vs Control (Fluad): Pain, severe: 8/373 (2.1%) vs 1/382 (0.3%) Redness diameter >=5 mm: 13/373 (3.5%) vs 2/382 (0.5%)

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
RCT N=1194 Industry funded Korea	% female: Intervention 66%, Control 70% Ethnicity: Ethnicity NR Healthy adults >=60 years of age with stable underlying diseases (>=6 weeks) Out of scope: None	23F individually conjugated to nontoxic diphtheria toxin cross-reactive material 197 (CRM197). The vaccine is formulated to contain 2.2 µg of each saccharide, except for 4.4 µg of 6B per 0.5-mL dose. The vaccine also contains 0.125 mg aluminum as aluminum phosphate per 0.5 mL dose. 0.5 mL in one dose Route NR Aluminum preservative NR Co-intervention Fluad Base treatment Adjuvanted TIV Fluad 45 µg in 0.5-mL dose given once route NR Other : MF59 adjuvantpreservative NR Counts Prespecified AE Power other outcome Followup: 1 months	Arthralgia Limitation of arm movement Fever Fatigue		Swelling diameter >=5 mm: 13/373 (3.5%) vs 3/382 (0.8%) Limitation of arm movement, severe: 7/373 (1.9%) vs 2/382 (0.5%) Fever, temp (≥38℃): 3/373 (0.8%) vs 1/382 (0.3%) Headache, severe: 3/373 (0.8%) vs 1/382 (0.3%) Fatigue, severe: 3/373 (0.8%) vs 1/382 (0.3%) Chills, severe: 2/373 (0.5%) vs 0/382 (0.0%) Muscle aches, severe: 6/373 (1.6%) vs 0/382 (0.0%) Arthralgia, severe: 1/373 (0.3%) vs 0/382 (0.0%) No serious AEs related to vaccines occurred (no other serious AEs reported). Risk factors: NR
Song, 2018[203] Korea University Guro Hospital, 2013[295] NCT03552445 Article RCT	Age: Intervention: 57.5 (NA); Control: 57.8(NA) % female: Intervention:	Pneumococcal PCV13 Prevnar 13 0.5 mL in 1 dose (ontains polysaccha- rides from pneumococcal serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9 V, 14, 18C, 19A, 19F, and	Pain Tenderness Redness Swelling Headache Fatigue Chills Myalgia Arthralgia	NA	Serious AEs: None in either groups Severe AEs (PCV13 + Td versus Td alone): Pain (severe): Intervention 0/151 (0%) vs Control 1/148 Tenderness (severe): Intervention 0/151 (0%) vs Control 0/148 (0%) Redness (>=10 mm): Intervention 40/151 (26.%) vs Control 22/148 (14.9%)

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
N=462 Industry funded South Korea	73%; Control 76% Ethnicity: Ethnicity NR Healthy adults aged 50 years and older with stable underlying diseases (>= 6 weeks) Out of scope: None	23F individually conjugated to nontoxic diphtheria toxin cross-reactive material 197 (CRM197). The vaccine is formulated at pH 5.8 Intramuscular Aluminum preservative free Co-intervention Td vaccine (SK Chemical Td-pur) Base treatment Td vaccine (as does intervention) Td-pur (SK Chemical) 0.5 mL in 1 dose Intramuscular Aluminumpreservative free Counts Prespecified AE Power other outcome Followup: 1 months			Swelling diameter (>=10 mm): Intervention 26/151 (17.2%) vs Control 16/148 (10.8%) Risk factors: NR
Svensson, 2018[210] Karolinska University Hospital, 2013[292] NCT01892618 Article RCT N=128 Industry funded Sweden	Age: Median 69 (range 46-87) % female: 49% Ethnicity: N/A Treatment naïve CLL patients, 18 years or older in all clinical stages (Rai 0-IV), from eight hematology units in Sweden, were enrolled prospectively in the study between	Pneumococcal PCV13 Prevnar 13 0.5 mL in one dose Intramuscular Aluminum preservative free No co-intervention PPSV Pneumococcal polysaccharide vaccine (PPSV23) Pneumovax 0.5 mL in one dose Intramuscular adjuvant freePhenol Counts	Adverse events Serious adverse events Vaccine-related adverse events	NA	Vaccine-related severe AEs: 0/63 (0%) vs 0/65 (0%) Disease progression during study period: PCV13 5/63 (6%), PPSV23 2/65 (3.1%) Risk factors: NR

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
	September 2013 to June 2015 Out of scope: None	No prespecified AE Power other outcome Followup: 6 months			
Thompson, 2019[214] Pfizer, 2015[349] NCT02124161 Article RCT N=882 Industry funded USA	Age: 67 (9) % female: 55% Ethnicity: 89% White Eligible subjects were ≥50 years old and had received ≥1 dose of PPSV23 at least 1 year before enrollment. Subjects with chronic, nonserious, stable disease not requiring substantial change in therapy or hospitalization 6 weeks before vaccination were eligible Out of scope: None	Pneumococcal PCV13 Prevnar 13 2.2 µg of each polysaccharide [from pneumococcal serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F individually conjugated to nontoxic diphtheria toxin cross-reactive material 197 (CRM197)], except for 4.4 µg for 6B, 5 mM succinate buffer, 0.85% sodium chloride, 0.02% polysorbate 80, and 0.125 mg aluminum as aluminum phosphate 0.5 mL dose once Route NR Aluminum preservative free Co-intervention QIV (Fluzone Quadrivalent) Placebo,Base treatment QIV + Placebo Fluzone Quadrivalent and Placebo Counts No prespecified AE Power other outcome Followup: 1 months	Myocardial infarction Cardiac failure congestive Cardiogenic shock Coronary artery disease Acute coronary syndrome Acute myocardial infarction Atrial fibrillation Colitis Diverticulum intestinal haemorrhagic Dyspepsia Hiatus hernia Vomiting Gastrointestinal haemorrhage Chest pain Surgical failure Cellulitis Gangrene Localised infection Osteomyelitis Pneumonia Influenza Incisional hernia Femur fracture Hypercalcaemia Musculoskeletal chest pain Osteoarthritis Bone loss Ovarian cancer Syncope Acute kidney injury Bronchitis chronic Hyperhidrosis Lymphadenopathy Cardiac disorders Angina pectoris Cardiac failure congestive Atrioventricular block first degree Cardiomyopathy Eye disorders	Cardiovascular events: 2.X Cardiac disorders I: 0/439, 2.XCardiac disorders C: 0/437 Death: NA no SAE was related to study vaccines. 1 death cardiogenic shock 35 days after PCV13+QIV. I: 1/421, NA NA C: 0/441 Myocardial infarction: 2.X Myocardial infarction I: 0/439, 2.X Myocardial infarction C: 0/437 Reproduction issues: 21.X Ovarian cancer I: 1/439, 21.X Ovarian cancer C: 0/437	Serious AEs (from clinicaltrials.gov): Intervention (13vPnC+QIV/Placebo: After Vaccination 1) vs Control (Placebo+QIV/13vPnC: After Vaccination 1) Affected / at Risk (%) Affected / at Risk (%) Total 6/439 (1.37%) 0/437 (0.00%) Myocardial infarction (in AE table) Cardiac failure congestive 0/439 (0.00%) 0/437 (0.00%) Cardiogenic shock 0/439 (0.00%) 0/437 (0.00%) Coronary artery disease 0/439 (0.00%) 0/437 (0.00%) Acute coronary syndrome 0/439 (0.00%) 0/437 (0.00%) Acute myocardial infarction 0/439 (0.00%) 0/437 (0.00%) Atrial fibrillation 0/439 (0.00%) 0/437 (0.00%) Gastrointestinal disorders Colitis 1/439 (0.23%) 0/437 (0.00%) Diverticulum intestinal haemorrhagic 0/439 (0.00%) 0/437 (0.00%) Dyspepsia 0/439 (0.00%) 0/437 (0.00%) Hiatus hernia 0/439 (0.00%) 0/437 (0.00%) Vomiting 0/439 (0.00%) 0/437 (0.00%) Gastrointestinal haemorrhage 0/439 (0.00%) 0/437 (0.00%) General disorders Chest pain 1/439 (0.23%) 0/437 (0.00%) Surgical failure 0/439 (0.00%) 0/437 (0.00%) Infections and infestations Cellulitis 1/439 (0.23%) 0/437 (0.00%) Gangrene 1/439 (0.23%) 0/437 (0.00%) Localised infection 1/439 (0.23%) 0/437 (0.00%)

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
			Vitreous floaters Diarrhoea Abdominal pain lower Gastritis Gastrooesophageal reflux disease Hiatus hernia Nausea Rectal haemorrhage Rectal prolapse Toothache Vomiting Dyspepsia Food poisoning Loose tooth General disorders Injection site pain Pyrexia Injection site erythema Injection site induration Injection site swelling Vaccination site pain Asthenia Peripheral swelling Vaccination site reaction Vaccination site induration Chills Injection site haematoma Oedema peripheral Fatigue Cholelithiasis Drug hypersensitivity Seasonal allergy Food allergy Upper respiratory tract infection Bronchitis Nasopharyngitis Urinary tract infection Sinusitis Gastroenteritis Tooth abscess Viral upper respiratory tract infection Abdominal abscess Cellulitis Fungal infection		Osteomyelitis 0/439 (0.00%) 0/437 (0.00%) Pneumonia 0/439 (0.00%) 0/437 (0.00%) Influenza 0/439 (0.00%) 0/437 (0.00%) Injury, poisoning and procedural complications Incisional hernia 0/439 (0.00%) 0/437 (0.00%) Femur fracture 0/439 (0.00%) 0/437 (0.00%) Metabolism and nutrition disorders Hypercalcaemia 0/439 (0.00%) 0/437 (0.00%) Musculoskeletal and connective tissue disorders Musculoskeletal chest pain 0/439 (0.00%) 0/437 (0.00%) Osteoarthritis 0/439 (0.00%) 0/437 (0.00%) Bone loss 0/439 (0.00%) 0/437 (0.00%) Neoplasms benign, malignant and unspecified (incl cysts and polyps) Ovarian cancer 1/439 (0.23%) 0/437 (0.00%) Nervous system disorders Syncope 1/439 (0.23%) 0/437 (0.00%) Renal and urinary disorders Acute kidney injury 0/439 (0.00%) 0/437 (0.00%) Respiratory, thoracic and mediastinal disorders Bronchitis chronic 0/439 (0.00%) 0/437 (0.00%) Skin and subcutaneous tissue disorders Hyperhidrosis 0/439 (0.00%) 0/437 (0.00%) Risk factors: NR

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
			Gastrointestinal viral infection Gingivitis Groin infection Herpes zoster Tooth infection Sepsis Staphylococcal infection Chronic sinusitis Foot fracture Chemical burn of skin Chemical burns of eye Contusion Fall Joint injury Ligament sprain Skeletal injury Splinter Tendon rupture Hand fracture Lumbar vertebral fracture Muscle strain Radius fracture Wound Investigations Blood pressure increased Electrocardiogram T wave abnormal Hepatic enzyme increased Decreased appetite Lactic acidosis Type 2 diabetes mellitus Myalgia Pain in extremity Musculoskeletal pain Arthritis Bursitis Plantar fasciitis Synovial cyst Arthralgia Back pain Rotator cuff syndrome Flank pain Joint swelling Osteoporosis Osteopenia Bladder cancer		

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
			Skin papilloma Squamous cell carcinoma of skin Headache Dizziness Nerve compression Neuropathy peripheral Sciatica Balance disorder Psychiatric disorders Depression Anxiety Nephrolithiasis Urine odour abnormal Micturition urgency Benign prostatic hyperplasia Prostatitis Pelvic pain Testicular pain Ovarian cyst Pelvic haematoma Cough Oropharyngeal pain Asthma Dyspnoea exertional Epistaxis Pulmonary pain Rhinorrhoea Pulmonary hypertension Upper-airway cough syndrome Sleep apnoea syndrome Pruritus generalised Pain of skin Rash Urticaria Actinic keratosis Angioedema Dermatitis contact Ecchymosis Pruritus Rash erythematous Haematoma Hypertension Hypotension Aortic arteriosclerosis		

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
Tseng, 2018[222] Article Cohort study N=545727 Not industry funded USA	Age: 50% within 65-69, 20% within 70-74, 14% within 75-79, and 17% older than 80 % female: 54% Ethnicity: N/A Patients 65+ enrolled in managed care organizations Out of scope: None	Pneumococcal PCV13 Prevnar 13 Not reported Route NR adjuvant NR preservative NR Co-intervention (Sometimes concomitant vaccines not specified PPSV Pneumococcal polysaccharide vaccine (PPSV23) (and sometimes concomitant vaccines not specified) Pneumonax (and sometimes concomitant vaccines not specified) Not reported route NR adjuvant NRpreservative NR Analytic study Prespecified AE Power NR Followup: 8 months	Acute myocardial infarction Acute pericarditis Atrial fibrillation Cardiomyopathy or heart failure Bell's palsy Syncope Erythema multiforme Thrombocytopenia I Thrombocytopenia II Cellulitis and infection Allergic Reaction Anaphylaxis Guillain-Barre Syndrome	NA	Serious AEs, Intervention (PCV13) vs Control (PPSV23), event rates, Inverse Probability of Treatment Weighting (IPTW) relative incidence (RI) (95% CI) Acute myocardial infarction: 534/13024960 vs 375/9572008, RI 0.73 (0.61, 0.88) Acute pericarditis 6/13024960 vs 8/9572008, IPW RI 0.90 (0.27, 2.94) Atrial fibrillation 702/13024960 vs 430/9572008, RI 0.67 (0.57, 0.80) Cardiomyopathy or heart failure 838/13024960 vs 566/9572008, RI 0.62 (0.54, 0.72) Bell's palsy (69/13024960 vs 57/9572008, RI 0.69 (0.41 1.15) Guillain-Barre syndrome 4/13024950 vs 8/9572008, RI 0.21 (0.05, 0.78) Syncope 22/313136 vs 75/232591 control, RI 0.13 (0.07, 0.25) Erythema multiforme 2/13024960 vs 2/9572008, RI 0.94 (0.13, 6.71) Thrombocytopenia I 17/8718620 vs 21/6428155, RI 0.66 (0.25, 1.76) Thrombocytopenia II 96/8718620 vs 100/6428155, RI 0.44 (0.31, 0.61) Cellulitis and infection 1915/2188604 vs 1393/1621515, RI 0.89 (0.91, 0.98) Allergic Reaction 49/2188604 vs 70/1621515, RI 0.47 (0.30, 0.73) Anaphylaxis 5/626152 vs 4/464888, RI 1.32 (0.30, 5.79) Risk factors: Stratified analyses age group (65–69, ≥70 years) were consistent with the findings from the main analysis
Vandecasteele, 2018[227] AZ Sint-Jan AV, 2013[242] NCT02492438 Article RCT N=155	Age: 72.4 (11.1) % female: 43% Ethnicity: N/A Patients were eligible if (a) treated with chronic haemodialysis, (b) !50 years of age, (c) not	Pneumococcal PCV13 Prevnar 13 0.5 mL in one dose Intramuscular adjuvant NR preservative NR No co-intervention PPSV Pneumococcal polysaccharide	Pain killers Fatigue Muscle aches Headache Itching Pain Mobility Loss Death Redness Discoloration Localized swelling	Death: NA NR I: 2/40, NA NR C: 8/40	Renal transplant: 4/40 (10%) vs 4/40 (10%) Pneumonia: 3/40 (10%) vs 3/40 (10%) Risk factors: NR

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
Unrestricted industry grant Belgium	pregnant, (d) without immediate life-threatening conditions, (e) without allergy to the vaccines, (f) with pneumococcal vaccination status documented in the medical files, and (g) gave their informed consent. Out of scope: None	vaccine (PPSV23) Pneumovax 0.5 mL in one dose Intramuscular adjuvant NRpreservative NR Counts Prespecified AE Power NR Followup: 12 months			
Vila-Corcoles, 2018[231] Article Cohort study N=2025730 Not industry funded Spain	Age: 66.0 (11.5) % female: 54% Ethnicity: N/A Adults assigned to the 274 Primary Health Care Centres (PHCCs) managed by the Catalonian Health Institute (Institut Catala de la Salut, ICS) who were aged 50 years or older at December 31, 2014. Out of scope: None	Pneumococcal PCV13 Prevnar 13 Not reported Intramuscular adjuvant NR preservative NR No co-intervention No intervention No PCV13 vaccine Counts Prespecified AE Power other outcome Followup: 12 months	Pneumonia Death	Death: NA NA I: 420/5010, NA NA C: 46845/2020720	AEs, PCV13 versus no vaccine, multivariable-adjusted HR (95% CI): Death: 1.07 (95% CI 0.97-1.18), p=0.190 Pneumococcal pneumonia: 1.17 (0.75-1.83), p=0.493 All cause pneumonia: 1.69 (1.48-1.94), p<0.001 Risk factors: After multivariable adjustments, PCV13 did not shown any significant effect against pneumococcal pneumonia and all-cause death. However, significantly associated with increased risk of all-cause pneumonia among elderly people (mHR: 1.76; 95% CI: 1.52–2.04; p < 0.001), immunocompromised persons (mHR: 1.51; 95% CI: 1.24–1.83; p < 0.001) and immunocompetent subjects (mHR: 1.86; 95% CI: 1.55–2.25; p < 0.001).
Chang, 2012[80] Article Cohort study N=43399 Not industry funded	Age: PPSV23+IIV 80.1 years (4.2); IIV alone 80.5 years (4.5) % female: PPSV23+IIV	Pneumococcal PSV23 Pneumovax Route NR adjuvant NR preservative NR Co-intervention IIV	All-cause deaths Hospitalization for pneumonia and influenza Hospitalization for respiratory diseases Hospitalization for COPD Hospitalization for CHF	Cardiovascular events: 2.3 Hospitalization for CHF I: 11/8142, 2.3 Hospitalization for CHF C: 17/8142 Death: NA NR I: 13/8142, NA NR C: 17/8142	PPSV23 + IIV vs IIV alone in propensity-score matched samples (incidence; RR based on multivariate logistic regression) All-causes death (incidence in AE table); aRR 0.74 (0.57, 0.96) Hospitalization for pneumonia and influenza 21/8142 vs 24/8142; aRR 0.85 (0.69, 1.05)

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
Taiwan	55%; IIV alone 52% Ethnicity: NR Taiwanese adults aged 75 years and older Out of scope: None	Base treatment : IIV IIV alone route NR adjuvant NRpreservative NR Counts Prespecified AE Power NR Followup: 6 months	Hospitalization for all diseases		Hospitalization for respiratory diseases 39/8142 vs 48/8142; aRR 0.77 (0.66, 0.91) Hospitalization for COPD 17/8142 vs 23/8142; aRR 0.72 (0.57, 0.90) Hospitalization for CHF (incidence in AE table); aRR 0.71 (0.54, 0.92) Hospitalization for all diseases 44/8142 vs 55/8142; aRR 0.77 (0.67, 0.90) Risk factors: No
Chen, 2012[81] Article Analytic study N=17510 Not industry funded Taiwan	Age: 75 years and older % female: N/A Ethnicity: NR Individuals aged 75 or more between 2008 and 2009 (the larger paper is of younger individuals also, but does not pertain) Out of scope: None	Pneumococcal PSV23 Pneumovax Route NR adjuvant NR preservative NR No co-intervention No intervention Analytic study Prespecified AE Power NR Followup: months	Stroke	NA	Adjusted hazard ratios of stroke events among the individuals aged 75 or more with vaccination and those without vaccination Multivariate adjusted HR (95% CI): 0.57(0.31-1.03), p=0.061 Risk factors: No
Fischer, 2015[107] Article Cohort study N=201 Not industry funded Switzerland	Age: Median 53.9 (range 43.3-65.7) % female: 58% Ethnicity: N/A Patients aged 18 years and older with a diagnosis of immune-mediated inflammatory disorder and ongoing treatment with high-dose systemic corticosteroids (≥20 mg/day for ≥1 month)	Pneumococcal PSV23 Pneumovax One dose Intramuscular adjuvant NR preservative NR No co-intervention No intervention No intervention Counts No prespecified AE Power NR Followup: 12 months	Upper respiratory tract infection Lower respiratory tract infection Urinary tract infection Gastrointestinal infection Shingles Tuberculosis Skin infection Other non specified infection	Herpes Zoster: 11.X Shingles at follow-up I: 1/56 11.X Shingles at follow-up C: 3/138	Disease activity according to Physician Global Assessment (PGA) score: Vaccination group decreased from 1.2±0.56 to 0.91±0.88 (p = 0.025) in the vaccination group; Observation group decreased from 1.12±0.77 to 0.93±0.76 (p = 0.004) Risk factors: NR

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
	and/or immunosuppressive drugs (classical immunosuppressive drugs and/or biologic immunomodulatory agents Out of scope: None				
Hung, 2010[137] Article Cohort study N=36636 Not industry funded Hong Kong	Age: Median age in years: Unvaccinated 75; PPV-TIV: 77; TIV alone: 75; PPV alone: 75 % female: Unvaccinated 53%, PPV-TIV 60%, TIV alone 55%, PPV alone group 55% Ethnicity: N/A All patients aged >=65 years with chronic illness Out of scope: None	Pneumococcal PSV23 Pneumovax 0.5 mL as one dose Intramuscular adjuvant NR preservative NR Co-intervention TIV (Vaxigrip) Base treatment TIV alone Vaxigrip 45 µg in 0.5 mL as one dose Intramuscular adjuvant NRpreservative NR Counts Prespecified AE Power NR Followup: 7 months	Pneumonia Chronic obstructive pulmonary disease Asthma Influenza-like illness Ischemic stroke Acute myocardial infarction Cardiac failure Hospital admission Intensive care unit admission Coronary care unit admission Ischemic heart disease Death	NA	AEs at week 64, Pneumovax-TIV versus TIV-alone: Pneumonia: 24% reduction, P=0.008 Acute myocardial infarction: 38% reduction, P=0.06 Hospitalization for pneumonia: 73 vs 95 hospitalizations per 1000 person-years; P=0.003 Hospitalization for influenza-like illness: 10 vs 15 hospitalizations per 1000 person-years; P=0.005 Hospitalizations for ischemic stroke: 22 vs 30 hospitalizations per 1000 person-years; P=0.007 Hospitalizations for ischemic heart disease: 32 vs 58 hospitalizations per 1000 person-years; P<=0.001 Hospitalizations for acute myocardial infarction: 10 vs 19 hospitalizations per 1000 person-years; P=<0.009 Risk factors: NR
Li, 2020[159] Article Cohort study N=4376 Not industry funded Taiwan	Age: 81 years ± 4 % female: NR Ethnicity: NR Patients with prostate cancer Out of scope: None	Pneumococcal PSV23 Brand NR NR NR Route NR adjuvant NR preservative NR Co-intervention unclear No intervention Analytic study Prespecified AE Power NR Followup: 84 months	Pneumonia	NA	Overall survival rate was significantly higher in the PPSV23-vaccinated group than in the unvaccinated group (log-rank test, P =0.0003) 7-year overall survival rates for the PPSV23- vaccinated and unvaccinated groups were 47.5% vs 42.3%. Risk factors: No

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
Munnoch, 2019[171] University of Newcastle, 2015[381] ACTRN12615000536561 Article RCT N=4725 Not industry funded Australia	Age: Median 58.1 (range 55-61) % female: 48% Ethnicity: N/A Adults aged 55 to 60 years who resided within a 25 km radius of one of six study sites in Australia by Medicare, Australia's national health insurance provider Out of scope: None	Pneumococcal PSV23 Pneumovax Not reported Intramuscular adjuvant NR preservative NR No co-intervention Placebo Saline placebo Counts Prespecified AE Power NR Followup: 22 months	Redness at injection site Moderate swelling at the injections site Major swelling at the injection site (elbow joint to shoulder joint) Pain at injection site Limitation of arm movement Fever Fatigue Headache Chills Rash Generalized muscle pain Generalized joint pain Other symptoms	NA	Extensive arm swelling: PPV23 13/2340 (0.55%) vs Saline 0/2332 (0.0%), p<0.001 Medical advice sought (symptomatic patients): PPV23 15/2340 (1.9%) vs Saline 18/2332 (7.5%), p<0.001 Risk factors: Sub-group analysis PPV23: Female 10/1138 (0.88%) vs Male 3/1202 (0.25%) p=0.04, Saline Female/1139 0 (0.0%) vs Male 0/1193 (0.0%), p=NA
Ochoa-Gondar, 2014[176] Vila-Corcoles, 2014[384]; Vila-Corcoles, 2012[385] Article Cohort study N=27204 Not industry funded Spain	Age: 71.7 years (8.6) % female: 55% Ethnicity: NR Individuals ≥60 years- old in Tarragona, Spain, who were prospectively followed from 01/12/2008 until 30/11/2011 Out of scope: None	Pneumococcal PSV23 Pneumovax Route NR adjuvant NR preservative NR No co-intervention No intervention Analytic study Prespecified AE Power NR Followup: 36 months	Acute myocardial infarction (AMI) Ischemic stroke Death from AMI Death from any cause Death from stroke	NA	Acute myocardial infarction (all are vaccinated versus unvaccinated): Unadjusted incidence rate per 1000 person-years 4.74 (4.01–5.61) vs 4.75 (4.17–5.42) Unadjusted hazard ratio 1.01 (0.82–1.25) Age, gender adjusted hazard ratio 1.02 (0.83–1.27) Propensity-adjusted hazard ratio 1.04 (0.83–1.31) Multivariate hazard ratio 0.95 (0.76–1.18) Death from AMI: Unadjusted incidence rate per 1000 person-years 0.86 (0.58–1.27) vs 0.64 (0.45–0.91) Unadjusted hazard ratio 1.34 (0.79–2.29) Age, gender adjusted hazard ratio 1.45 (0.85–2.47) Propensity-adjusted hazard ratio 1.30 (0.74–2.27) Multivariate hazard ratio 1.32 (0.76–2.28) Ischemic stroke: Unadjusted incidence rate per 1000 person-years 4.60 (3.88-5.46) vs 4.49 (3.92-5.14) Unadjusted hazard ratio 1.03 (0.83-1.28)

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
					Age, gender adjusted hazard ratio 1.08 (0.87-1.34) Propensity-adjusted hazard ratio 0.97 (0.77-1.23) Multivariate hazard ratio 1.04 (0.83-1.30) Death from stroke: Unadjusted incidence rate per 1000 person-years 0.55 (0.34-0.90) vs 0.62 (0.43-0.89) Unadjusted hazard ratio 0.88 (0.48-1.62) Age, gender adjusted hazard ratio 1.02 (0.55-1.89) Propensity-adjusted hazard ratio 1.11 (0.59-2.08) Multivariate hazard ratio 1.14 (0.61-2.13) All-cause death: Unadjusted incidence rate per 1000 person-years 28.38 (26.51–30.39) vs 34.92 (33.27–36.65) Unadjusted hazard ratio 0.81 (0.74–0.88) Age, gender adjusted hazard ratio 0.90 (0.83–0.98) Propensity-adjusted hazard ratio 0.92 (0.84–1.00) Multivariate hazard ratio 0.97 (0.89–1.05) Among those with and without history of prior coronary artery disease: Myocardial infarction, Multivariable hazard ratio 0.78 (0.54–1.14) and 1.07 (0.80–1.41) Death from AMI, Multivariable hazard ratio 1.00 (0.40–2.47) and 1.58 (0.79–3.16) Death from any cause, Multivariable hazard ratio 0.68 (0.52–0.89) and 1.03 (0.94–1.12) Among those without a history of cerebrovascular disease and then those with a history of cerebrovascular disease: Ischemic stroke, Multivariable hazard ratio 0.94 (0.61-1.44) and 1.07 (0.82-1.40) Death from stroke, Multivariable hazard ratio 0.77 (0.14-4.35) and 1.20 (0.61-2.36)

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
					Death from any cause, Multivariable hazard ratio 0.79 (0.61-1.04) and 1.00 (0.91-1.09) Risk factors: Yes; see results above (stratified by history of CVD or CAD)
Ofori-Anyinam, 2017[177] GlaxoSmithKline, 2015[273] NCT02218697 Article RCT N=356 Industry funded France, Belgium	Age: 68.3 (no SD) % female: 43% Ethnicity: 98% White Caucasian/European, 1% White Arabic/North African, 1% African/African American Adults ≥50 years of age at risk of complications from influenza or pneumococcal infections who met their country's recommendations for vaccination Out of scope: None	Pneumococcal PSV23 Pneumovax 25 µg each of 23 purified capsular polysaccharides from S. pneumoniae types 1, 2, 3, 4, 5, 6B, 7F, 8, 9N, 9V, 10A, 11A, 12F, 14, 15B, 17F, 18C, 19F, 19A, 20, 22F, 23F, and 33F 0.5 mL in one dose Intramuscular adjuvant NR preservative NR Co-intervention IIV4 (Influsplit Tetra) Base treatment IIV4 Influsplit Tetra 0.5 mL in one dose Intramuscular adjuvant NRpreservative NR Counts No prespecified AE Power other outcome Followup: 6 months	Anaemia Angina pectoris Arrhythmia Cardiac failure Cardio-respiratory arrest Coronary artery stenosis Myocardial infarction Intestinal malrotation Intestinal ischaemia Calcinosis Chest pain Erysipelas Lung infection Wrist fracture Diabetes mellitus inadequate control Hyperkalaemia Osteoarthritis Colon cancer metastatic Renal cancer stage ii Squamous cell carcinoma of the oral cavity Carotid artery stenosis Cerebral thrombosis Psychiatric disorders Depression Acute kidney injury Benign prostatic hyperplasia Pneumonia aspiration Hypertension Gastrointestinal disorder Chills Fatigue Pain Swelling Arthralgia Myalgia Headache Erythema Hyperhidrosis	NA	Solicited general symptoms during 7-day post-vaccination period after dose 1, Intervention (PPSV23+IIV4) vs Control (IIV4 alone) Grade 3 Fatigue, Dose 1: 2/173 vs 1/176 Grade 3 GI symptoms, Dose 1: 1/173 vs 1/176 Grade 3 Headache, Dose 1: 2/173 vs 0/176 Grade 3 Joint pain, Dose 1: 0/173 vs 0/176 Grade 3 Muscle aches, Dose 1: 1/173 vs 0/176 Grade 3 Shivering, Dose 1: 1/173 vs 0/176 Grade 3 Sweating, Dose 1: 1/173 vs 0/176 Grade 3 Fever, Dose 1: 1/173 vs 0/176 Injection site symptoms reported during the 7-day post-vaccination period, Intervention (PPSV23+IIV4) vs Control (IIV4 alone) Grade 3 Pain: 6/173 (3.5%) vs 0/177 Redness >100 mm: 0/176 vs 0/177 Swelling >100 mm: 0/173 vs 0/177 No vaccine-related serious adverse events occurred. Risk factors: Yes, study itself is subgroup of patients who receive IIV4 with PPSV23

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
Shimada, 2020[199] Article RCT N=41 Industry funded Japan	Age: Intervention 66 years ± 8; Control 67 years ± 8 % female: Intervention 89%; Control 86% Ethnicity: NR Patients with stable coronary artery disease (CAD), who requested influenza vaccination at regular check-up in the outpatient clinic at Juntendo University Hospital, to participate this study from November 2013 to December 2013 Out of scope: None	Pneumococcal PSV23 Pneumovax 0.5 mL in one dose Intramuscular adjuvant NR preservative NR Co-intervention Trivalent IIV Placebo,Base treatment : Trivalent IIV Trivalent IIV plus saline placebo NR 0.5 mL Intramuscular adjuvant NRpreservative NR Counts Prespecified AE Power NR Followup: 3 months	Injection site pain Injection site swelling Injection site reddening Coronary artery disease	Cardiovascular events: 2.X NA I: 0/19, 2.XNA C: 0/21 Death: NA NA I: 0/19, NA NA C: 0/21	No influenza infection, other vaccine related-serious adverse reactions, cardiovascular events, or other inflammatory diseases were observed during 12 weeks. No serious injection-related reactions observed. Risk factors: No
Siriwardena, 2014[201] Article Case-Control N=94022 Not industry funded United Kingdom	Age: 23% <65 years; 67% >=65 years % female: 52% Ethnicity: NR Cases were patients aged 18 years and over, recorded with standard computer codes for stroke or transient ischemic attack (TIA); each case	Pneumococcal PSV23 Brand NR Not reported but Pneumovax was in use in UK during this time period NR Route NR adjuvant NR preservative NR No co-intervention No intervention Analytic study Prespecified AE Power NR Followup: months	Stroke Transient ischemic attack	NA	Pneumococcal vaccination and stroke (all): Unadjusted OR 1.10 (1.05, 1.14) Adjusted (but not for influenza vaccination) OR 0.86 (0.81, 0.90) Adjusted (including for influenza vaccination) OR 0.94 (0.89 to 1.00) Multiply imputed adjusted (including for influenza vaccination) OR 0.96 (0.92, 1.02) Pneumococcal vaccination and transient ischemic attack (all): Unadjusted OR 1.51 (1.44, 1.59) Adjusted (but not for influenza vaccination) OR 1.14 (1.08, 1.20)

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
	of stroke or TIA was matched to one control according to age, sex, general practice attended and calendar time (controls were patients registered at the same practice during the study period identified at the same index date as the corresponding case) Out of scope: None				Adjusted (including for influenza vaccination) OR 1.15 (1.08, 1.23) Multiply imputed adjusted (including for influenza vaccination) OR 1.16 (1.09, 1.23) Pneumococcal vaccination and stroke (<65 years): Unadjusted OR 2.49 (2.29, 2.74) Adjusted (but not for influenza vaccination) OR 0.82 (0.69, 0.98) Adjusted (including for influenza vaccination) OR 0.91 (0.75, 1.10) Multiply imputed adjusted (including for influenza vaccination) OR 0.88 (0.74, 1.05) Pneumococcal vaccination and stroke (>=65 years): Unadjusted OR 0.86 (0.82, 0.90) Adjusted (but not for influenza vaccination) OR 0.86 (0.81, 0.90) Adjusted (including for influenza vaccination) OR 0.96 (0.90, 1.02) Multiply imputed adjusted (including for influenza vaccination) OR 1.00 (0.94, 1.05) Pneumococcal vaccination and transient ischemic attack (<65 years): Unadjusted OR 2.63 (2.34, 2.92) Adjusted (but not for influenza vaccination) OR 1.54 (1.36, 1.77) Adjusted (including for influenza vaccination) OR 1.61 (1.40, 1.84) Multiply imputed adjusted (including for influenza vaccination) OR 1.61 (1.40, 1.85) Pneumococcal vaccination and transient ischemic attack (>=65 years): Unadjusted OR 1.27 (1.20, 1.35) Adjusted (but not for influenza vaccination) OR 1.03 (0.97, 1.09) Adjusted (including for influenza vaccination) OR (1.02 0.95, 1.10) Multiply imputed adjusted (including for influenza vaccination) OR 1.03 (0.96, 1.10) Risk factors: Yes; by age <65 years and age >=65 years (see results)

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
Song, 2015b[205] Korea University Guro Hospital, 2013[296]; Song, 2015a[204] NCT02225327 Article RCT N=224 Industry funded South Korea	Age: Intervention (Fluad+PPV23 from Group 2 and Group 3): 71.2 (4.6) and 71.0 (4.1); Control (Fluad): 71.0 ± 4.2 % female: Intervention: 69%; Control 59% Ethnicity: N/A Adults aged ≥65 years old who were healthy as well as those with stable underlying diseases (≥6 weeks) were included Out of scope: None	Pneumococcal PSV23 Pneumovax 0.5 mL in one dose Route NR adjuvant NR preservative NR Co-intervention MF59-adjuvanted IIV (Fluad) Base treatment MF59-adjuvanted IIV Fluad 0.5 mL in one dose route NR adjuvant NRpreservative NR Counts Prespecified AE Power NR Followup: 1 months	Pain Tenderness Redness Swelling Fever Headache Malaise Fatigue Chill Muscle aches Arthralgia	NA	Severe AEs, Intervention (Fluad+PPV23) vs Control (Fluad only) Pain, Severe: 0/107 (0%), 0/56 (0%) Tenderness, Severe: 0/107 (0%), 0/56 (0%) Redness diameter ≥5 mm: 9/107 (8.4%), 0/56 (0%) Swelling diameter ≥5 mm 5/107 (4.7%), 0/56 (0%) Headache, Severe: 0/107 (0%), 0/56 (0%) Malaise, Severe: 0/107 (0%), 0/56 (0%) Fatigue, Severe: 0/107 (0%), 0/56 (0%) Chills, Severe: 0/107 (0%), 0/56 (0%) Muscle aches, Severe: 0/107 (0%), 0/56 (0%) Arthralgia, Severe: 0/107 (0%), 0/56 (0%) No vaccine-related serious adverse events occurred. Risk factors: NR
Zahid, 2012[239] Article Cohort study N=1436 Not industry funded USA	Age: 67.3 years (11.8) % female: 2% Ethnicity: 78% White Patients admitted to the VA Pittsburgh Healthcare System with suspected ACS/NSTEMI on the basis of chest pain, suspected unstable angina or anginal-equivalent between	Pneumococcal PSV23 Pneumovax Route NR adjuvant NR preservative NR No co-intervention No intervention Counts Prespecified AE Power NR Followup: 6 months	Myocardial infarction Death	Cardiovascular events: 2.X Myocardial infarction I: 30/857, 2.X Myocardial infarction C: 37/499 Death: NA NR I: 71/857, NA NR C: 134/499 Myocardial infarction: 2.X NR I: 30/857, 2.X NR C: 37/499	Mortality: PPSV23 (+ IIV or no IIV) prior to admission versus no PPSV23 (IIV or no IIV): see AE table, p<0.001 PPSV23 + no IIV prior to admission versus no vaccines prior to admission: 11/247 (4.5%) vs 75/301 (24.9%), p<0.001 Myocardial infarction: PPSV23 (+ IIV or no IIV) prior to admission versus no PPSV23 (IIV or no IIV): see AE table, p<0.001 PPSV23 + no IIV prior to admission versus no vaccines prior to admission: 10/247 (4.0%) vs 23/301 (7.6%), p=0.32 Univariate models (Unadjusted): Mortality HR 0.31 (0.23, 0.41) Myocardial infarction HR 0.50 (0.31, 0.80) Main effects model (Unadjusted): Mortality HR 0.25 (0.19, 0.34)

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
	January 2001 and April 2006. Out of scope: None				Myocardial infarction HR 0.52 (0.32, 0.84) Interaction model (Unadjusted): Mortality HR 0.13 (0.07, 0.23) Myocardial infarction HR 0.58 (0.32, 1.03) Interaction model (Covariate adjusted): Mortality HR 0.11 (0.06, 0.20) Myocardial infarction HR 0.69 (0.38, 1.23) Interaction model (Propensity score adjustment for pneumococcal vaccination): Mortality HR 0.12 (0.06, 0.21) Myocardial infarction HR 0.60 (0.32, 1.10) Interaction model (Propensity score adjustment for influenza vaccination): Mortality HR 0.11 (0.06, 0.20) Myocardial infarction HR 0.46 (0.25, 0.85) Risk factors: No
Halperin, 2019[124] Sanofi Pasteur a Sanofi Company, 2011[364] NCT01439165 Article RCT N=1330 Industry funded Canada, USA	Age: Tdap: 28.9 years (10.0); Td: 29.2 years (10.6) % female: 65% Ethnicity: 95% White, 2% Black, 2% Mixed, 1% Asian Healthy adults 18-64 years old who had received a dose of Tdap 10 years prior Out of scope: None	Tdap Adacel 0.5 mL in 1 dose (contained 5 limit of flocculation units (Lf) of tetanus toxoid, 2 Lf diphtheria toxoid, 2.5 µg pertussis toxoid (PT), 5 µg filamentous hemagglutinin (FHA), 3 µg pertactin (PRN), 5 µg fimbriae 2 and 3 (FIM), 1.5 mg aluminum phosphate, and Intramuscular Aluminum preservative free No co-intervention Td Td vaccine Tenivac 0.5 mL in 1 dose (ontained 5 Lf	Mortality Abdominal pain Crohn's disease Intestinal obstruction Infectious mononucleosis Upper limb fracture Neoplasm malignant Abortion spontaneous Pickwickian syndrome Tonsillar haemorrhage Injection site pain (prespecified) Injection site erythema (prespecified) Injection site swelling (prespecified) Malaise (prespecified) Myalgia (prespecified) Headache (prespecified) Fever (prespecified)	Autoimmune disease: 7.X Crohn's disease - considered unrelated to vaccine I: 1/999, 7.X Crohn's disease C: 0/328 Death: NA NA I: 0/999, NA NA C: 0/328 Spontaneous abortion: 18.2 Became pregnant ~12 days after her Tdap vaccination, and experienced a spontaneous abortion 38 days after vaccination; not considered vaccine-related I: 1/999, 18.X NA C: 0/328	Severe AEs within 7 days of vaccination: Adacel VaccineTd Adsorbed Vaccine Grade 3 Injection site Pain: 38/982, 3.6% (2.5–4.9) vs 9/325, 2.8% (1.3–5.2) Grade 3 Injection site Erythema: 2/982, 0.2% (0.0–0.7) vs 0/325, 0% (0.0–1.1) Grade 3 Injection site Swelling: 3/981, 0.3% (0.1–0.9) vs 0/325, 0% (0.0–1.1) Grade 3 Fever: 2/978, 0.2% 0.2 (0.0–0.7) vs 1/325, 0.3% (0.0–1.7) Grade 3 Headache: 26/982, 2.6% (1.7–3.9) vs 13/325, 4.0% (2.1–6.7) Grade 3 Malaise: 29/982, 3.0% (2.0–4.2) vs 12/325, 3.7% (1.9-6.4) Grade 3 Myalgia: 29/982, 3.0% (2.0–4.2) vs 10/325, 3.1% (1.5–5.6) Mortality (from clinical trials.gov): Adacel VaccineTd Adsorbed Vaccine Total: 0/999 (0.00%) 0/328 (0.00%) Serious AEs (from clinicaltrials.gov) Adacel VaccineTd Adsorbed Vaccine Affected / at Risk (%)Affected / at Risk (%) Total 8/999 (0.80%) 1/328 (0.30%) Gastrointestinal disorders

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
		tetanus toxoid, 2 Lf diphtheria toxoid, 1.5 mg aluminum phosphate, and 0.5% (vol/vol) 2-phenoxyethanol) Intramuscular Aluminumpreservative free Counts No prespecified AE Power other outcome Followup: 6 months			Abdominal pain 1/999 (0.10%) 0/328 (0.00%) Crohn's disease (in AE table) Intestinal obstruction 1/999 (0.10%) 0/328 (0.00%) Infections and infestations Infectious mononucleosis 1/999 (0.10%) 0/328 (0.00%) Injury, poisoning and procedural complications Upper limb fracture 0/999 (0.00%) 1/328 (0.30%) Neoplasms benign, malignant and unspecified (incl cysts and polyps) Neoplasm malignant 1/999 (0.10%) 0/328 (0.00%) Abortion spontaneous (in AE table) Respiratory, thoracic and mediastinal disorders Pickwickian syndrome 1/999 (0.10%) 0/328 (0.00%) Tonsillar haemorrhage 1/999 (0.10%) 0/328 (0.00%) Risk factors: NR
Chlibek, 2013[82] GlaxoSmithKline, 2009[260] NCT00802464 Article RCT N=410 Industry funded Czech Republic, Spain, USA	Age: 65.0 (9.2) % female: 57% Ethnicity: 2% African Heritage / African American, 1% American Indian or Alaskan Native, <1% Other , <1% White - Arabic / North African Heritage, 97% White - Caucasian / European Heritage, Adults 50 years and older Out of scope: None	ZosterAdj Shingrix Two doses, mont 0 and month 2 Intramuscular Other : AS01B preservative NR No co-intervention Placebo Saline placebo Counts No prespecified AE Power NR Followup: 14 months	Acute myocardial infarction Atrial fibrillation Bradycardia Cardiac failure Coronary artery occlusion Myocardial infarction Myocardial ischaemia Sinus node dysfunction Hiatus hernia Ileus Pancreatic mass Subileus Upper gastrointestinal haemorrhage Chest pain Hernia Bile duct obstruction Cholelithiasis Appendicitis Diverticulitis Escherichia sepsis Pneumonia Femur fracture	Cardiovascular events: 2.X One participant reported myocardial infarction and withdrew from the study prior to receiving the second dose. The investigator considered this SAE to be unrelated to the study vaccine. I: 1/150, 2.XNA C: 0/38 Death: NA All-cause mortality I: 1/150, NA NA C: 0/38 Herpes Zoster: 11.X NA I: 0/142 11.X NA C: 0/38 Myocardial infarction: 2.X NR I: 1/150, 2.X NR C: 0/38	Severe AEs: Grade 3 Pain, Dose 1: 0/150 (0%) vs 0/38 (0%) Grade 3 Redness, Dose 1: 2/150 vs 0/38 (0%) Grade 3 Swelling, Dose 1: 0/150 (0%) vs 0/38 (0%) Grade 3 Pain, Dose 2: 6/143 (4.2%) vs 0/37 (0%) Grade 3 Redness, Dose 2: 1/143 (0.7%) vs 0/37 (0%) Grade 3 Swelling, Dose 2: 1/143 (0.7%) vs 0/37 (0%) Grade 3 Pain, Any Dose: 6/150 (4.0%) vs 0/38 (0%) Grade 3 Redness, Any Dose: 2/150 (1.3%) vs 0/38 (0%) Grade 3 Swelling, Any Dose: 1/150 (0.7%) vs 0/38 (0%) Grade 3 Fatigue, Dose 1: 2/150 (1.3%) vs 0/38 (0%) Grade 3 Gastr. sympt., Dose 1: 0/150 (0%) vs 1/38 (2.6%)

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
			Osteoarthritis Bladder cancer Plasma cell myeloma Cerebrovascular disorder Syncope Transient ischaemic attack Depression Acute kidney injury Renal failure Pulmonary embolism Respiratory failure Haematoma Gastrointestinal disorder Chills Fatigue Pain Pyrexia Swelling Myalgia Headache Erythema		Grade 3 Headache, Dose 1: 1/150 (0.7%) vs 0/38 (0%) Grade 3 Myalgia, Dose 1: 2/150 (1.3%) vs 0/38 (0%) Grade 3 Temperature, Dose 1: 0/150 (0%) vs 0/38 (0%) Grade 3 Fatigue, Dose 2: 7/143 (4.9%) 1/37 (2.7%) Grade 3 Gastr. sympt., Dose 2: 0/143 (0%) vs 0/37 (0%) Grade 3 Headache, Dose 2: 4/143 (2.8%) vs 0/37 (0%) Grade 3 Myalgia, Dose 2: 6/143 (4.2%) vs 1/37 (2.7%) Grade 3 Temperature, Dose 2: 0/143 (0%) vs 0/37 (0%) Grade 3 Fatigue, Any Dose: 9/150 (6.0%) vs 1/38 (2.6%) Grade 3 Gastr. sympt., Any Dose: 0/150 (0%) vs 1/38 (2.6%) Grade 3 Headache, Any Dose: 5/15 (3.3%) vs 0/38 (0%) Grade 3 Myalgia, Any Dose: 7/150 (4.7%) vs 1/38 (2.6%) Grade 3 Temperature, Any Dose: 0/143 (0%) vs 0/38 (0%) Serious AEs (from clinicaltrials.gov): Intervention (Shingrix) vs Placebo Group Affected / at Risk (%)# EventsAffected / at Risk (%)# Events Total 10/150 (6.67%) 3/38 (7.89%) Cardiac disorders Acute myocardial infarction 0/150 (0.00%) 0/38 (0.00%) Atrial fibrillation 1/150 (0.67%) 0/38 (0.00%) Bradycardia 1/150 (0.67%) 0/38 (0.00%) Cardiac failure 0/150 (0.00%) 0/38 (0.00%) Coronary artery occlusion 0/150 (0.00%) 0/38 (0.00%) Myocardial infarction (in AE table) Myocardial ischaemia 1/150 (0.67%) 0/38 (0.00%) Sinus node dysfunction 1/150 (0.67%) 0/38 (0.00%)

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
					Gastrointestinal disorders Hiatus hernia 0/150 (0.00%) 1/38 (2.63%) Ileus 1/150 (0.67%) 0/38 (0.00%) Pancreatic mass 1/150 (0.67%) 0/38 (0.00%) Subileus 0/150 (0.00%) 0/38 (0.00%) Upper gastrointestinal haemorrhage 0/150 (0.00%) 0/38 (0.00%) General disorders Chest pain 1/150 (0.67%) 0/38 (0.00%) Hernia 0/150 (0.00%) 0/38 (0.00%) Hepatobiliary disorders Bile duct obstruction 0/150 (0.00%) 0/38 (0.00%) Cholelithiasis 0/150 (0.00%) 1/38 (2.63%) Infections and infestations Appendicitis 0/150 (0.00%) 0/38 (0.00%) Diverticulitis 0/150 (0.00%) 0/38 (0.00%) Escherichia sepsis 0/150 (0.00%) 0/38 (0.00%) Pneumonia 1/150 (0.67%) 0/38 (0.00%) Injury, poisoning and procedural complications Femur fracture 0/150 (0.00%) 0/38 (0.00%) Musculoskeletal and connective tissue disorders Osteoarthritis 0/150 (0.00%) 1/38 (2.63%) Neoplasms benign, malignant and unspecified (incl cysts and polyps) Bladder cancer 1/150 (0.67%) 0/38 (0.00%) Plasma cell myeloma 0/150 (0.00%) 0/38 (0.00%) Nervous system disorders Cerebrovascular disorder 1/150 (0.67%) 0/38 (0.00%) Syncope 0/150 (0.00%) 0/38 (0.00%) Transient ischaemic attack 0/150 (0.00%) 0/38 (0.00%) Psychiatric disorders Depression 0/150 (0.00%) 0/38 (0.00%) Renal and urinary disorders

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
					Acute kidney injury 0/150 (0.00%) 0/38 (0.00%) Renal failure 0/150 (0.00%) 0/38 (0.00%) Respiratory, thoracic and mediastinal disorders Pulmonary embolism 1/150 (0.67%) 0/38 (0.00%) Respiratory failure1/150 (0.67%) 0/38 (0.00%) Vascular disorders Haematoma 0/150 (0.00%) 0/38 (0.00%) Risk factors: NR
Cunningham, 2016[85] Lopez-Fauqed, 2019[301]; Oostvogels, 2019[334]; GlaxoSmithKline, 2017[277] NCT01165229 Article RCT N=14816 Industry funded Australia, Brazil, Canada, Czechia, Estonia, Finland, France, Germany, Hong Kong, Italy, Japan, Republic of Korea, Mexico, Spain, Sweden, Taiwan, United Kingdom, USA	Age: 75.6 (4.7) % female: 55% Ethnicity: 77% White, 1% Black, 18% Asian, 4% Other Adults 70 years of age or older were eligible for inclusion in the trial unless they had a history of herpes zoster, had previously been vaccinated against varicella or herpes zoster, or had an immunosuppressive condition Out of scope: None	ZosterAdj Shingrix Two 0.5 mL doses 2 months apart. Each dose contained 50 µg of recombinant VZV glyco- protein E and the liposome-based AS01B adjuvant system (which contains 50 µg of 3-O-desacyl-4′- monophosphoryl lipid A [MPL] and 50 µg of Quillaja saponaria Molina, fract Intramuscular Other : AS01B adjuvant system preservative free No co-intervention Placebo Saline placebo in two 0.5 mL doses 2 months apart Counts No prespecified AE Power other outcome Followup: 48 months	Anaemia Anaemia vitamin b12 deficiency Coagulopathy Disseminated intravascular coagulation Haemorrhagic anaemia Hypersplenism Immune thrombocytopenic purpura Iron deficiency anaemia Lymphadenitis Lymphadenopathy Microcytic anaemia Nephrogenic anaemia Normochromic normocytic anaemia Pancytopenia Pernicious anaemia Thrombocytopenia Acute coronary syndrome Acute left ventricular failure Acute myocardial infarction Angina pectoris Angina unstable Aortic valve disease Aortic valve incompetence Aortic valve stenosis Arrhythmia Arrhythmia supraventricular Arteriosclerosis coronary artery	ALS: 17.X NR I: 2/6950, 17.X NR C: 0/6950 Anaphylaxis: 10.3 Anaphylactic reaction I: 1/6950, 10.3 Anaphylactic reaction C: 1/6950 Angioedema: 10.X NR I: 1/6950, 10.X NR C: 0/6950 Asthma: 22.X NR I: 2/6950, 22.X NR C: 4/6950 Ataxia: 17.X NR I: 0/6950, 17.X NR C: 1/6950 Autoimmune disease: 10.X Potential immune-mediated disease I: 92/6950, 10.X Potential immune-mediated disease C: 97/6950 Autoimmune thyroiditis: 10.X Autoimmune thyroiditis I: 0/6950, 10.X Autoimmune thyroiditis C: 1/6950 Cardiovascular events: 2.X Cardiac events (from GSK website) I: 268/6950, 2.XCardiac events (from GSK website) C: 315/6950 Death: NA All-cause mortality; 1 death considered related, died from neutropenic sepsis 97 days after vaccination I: 426/6950, NA All-cause mortality C: 459/6950 Diabetes: 14.X Type 2 diabetes mellitus I: 5/6950, 14.X Type 2 diabetes mellitus C: 6/6950 Encephalitis: 17.X Hypoxic-ischaemic encephalopathy I: 0/6950, 17.X	Injection-site reactions Grade 3 within 7 days: Intervention 8.5%, Control 0.2% System reactions Grade 3 within 7 days: Intervention 6.0%, Control 2.0% Potential immune-mediated diseases: Intervention 1.3% vs Control 1.4% Severe AEs (Grade 3 or higher) Dose 1 Fatigue, 8/501, 5/503 Gastrointestinal, 3/501, 2/503 Headache, 2/501, 4/503 Myalgia, 6/501, 2/503 Shivering, 1/501, 1/503 Temperature, 0/501, 2/503 Fatigue, 9/492, 0/489 Dose 2 Gastrointestinal, 3/492, 1/489 Headache, 4/492, 0/489 Myalgia, 7/492, 0/489 Shivering, 5/492, 1/489 Temperature, 0/492, 2/489 Across doses Fatigue, 16/504, 4/505 Gastrointestinal, 5/504, 2/505 Headache, 5/504, 4/505 Myalgia, 12/504, 2/505 Shivering, 6/504, 2/505 Temperature, 0/504, 2/505 Serious AEs at 48 months (from clinicaltrials.gov) Intervention vs Control (Placebo)

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
			Atrial fibrillation Atrial flutter Atrioventricular block Atrioventricular block complete Atrioventricular block first degree Atrioventricular block second degree Bradyarrhythmia Bradycardia Cardiac arrest Cardiac disorder Cardiac failure Cardiac failure acute Cardiac failure chronic Cardiac failure congestive Cardiac tamponade Cardiac valve disease Cardio-respiratory arrest Cardiogenic shock Cardiomegaly Cardiomyopathy Cardiopulmonary failure Chronotropic incompetence Congestive cardiomyopathy Cor pulmonale Coronary artery disease Coronary artery insufficiency Coronary artery occlusion Coronary artery stenosis Diastolic dysfunction Extrasystoles Heart valve incompetence Hypertensive heart disease Ischaemic cardiomyopathy Left ventricular failure Left ventricular hypertrophy Mitral valve incompetence Myocardial infarction Myocardial ischaemia Palpitations	Hypoxic-ischaemic encephalopathy C: 1/6950 Guillain-Barré syndrome: 10.X NR I: 1/6950, 10.X NR C: 2/6950 Herpes Zoster: 11.X From article (by 3.7 years follow-up) I: 23/6950 11.X From article (by 3.7 years follow-up) C: 223/6950 Immune Thrombocytopenia Purpura: 1.X NR I: 1/6950, 1.X NR C: 0/6950 Meningitis: 11.X Herpes zoster meningitis I: 0/6950, 11.X Herpes zoster meningitis C: 1/6950 Myocardial infarction: 2.X Acute myocardial infarction I: 21/6950, 2.X Acute myocardial infarction C: 28/6950 Reproduction issues: 21.X Reproductive system and breast disorders I: 16/6950, 21.X Reproductive system and breast disorders C: 18/6950 Seizure: 17.X NR I: 2/6950, 17.X NR C: 0/6950 Stroke: 17.X Ischaemic stroke I: 7/6950, 17.X Ischaemic stroke C: 6/6950	Total 1153/6950 (16.59%) 1214/6950 (17.47%) Anaemia 6/6950, 13/6950 Anaemia vitamin b12 deficiency 1/6950, 0/6950 Coagulopathy 0/6950, 2/6950 Disseminated intravascular coagulation 1/6950, 1/6950 Haemorrhagic anaemia 1/6950, 1/6950 Hypersplenism 1 0/6950, 1/6950 Immune thrombocytopenic purpura (in AE table) Iron deficiency anaemia 5/6950, 4/6950 Lymphadenitis 1/6950, 0/6950 Lymphadenopathy 1/6950, 1/6950 Microcytic anaemia 0/6950, 1/6950 Nephrogenic anaemia 1/6950, 0/6950 Normochromic normocytic anaemia 0/6950, 1/6950 Pancytopenia 1/6950, 0/6950 Pernicious anaemia 1/6950, 0/6950 Thrombocytopenia 0/6950, 3/6950 Acute coronary syndrome 3/6950, 4/6950 Acute left ventricular failure 0/6950, 1/6950 Acute myocardial infarction 21/6950, 28/6950 Angina pectoris 13/6950, 6/6950 Angina unstable 7/6950, 7/6950 Aortic valve disease 1/6950, 0/6950 Aortic valve incompetence 0/6950, 1/6950 Aortic valve stenosis 1/6950, 3/6950 Arrhythmia 5/6950, 9/6950 Arrhythmia supraventricular 0/6950, 1/6950 Arteriosclerosis coronary artery 1/6950, 3/6950 Atrial fibrillation 40/6950, 54/6950 Atrial flutter 6/6950, 5/6950 Atrioventricular block 0/6950, 4/6950 Atrioventricular block complete 4/6950, 2/6950 Atrioventricular block first degree 1/6950, 1/6950

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
			Pericarditis Right ventricular failure Sinus arrest Sinus node dysfunction Sinus tachycardia Supraventricular tachycardia Tachyarrhythmia Tachycardia Tricuspid valve incompetence Ventricular arrhythmia Ventricular extrasystoles Ventricular fibrillation Ventricular tachycardia Congenital cystic kidney disease Hypertrophic cardiomyopathy Pyloric stenosis Renal dysplasia Sudden hearing loss Vertigo Vertigo positional Vestibular disorder Autoimmune thyroiditis Cushingoid Goitre Hyperparathyroidism primary Hyperthyroidism Hypothyroidism Age-related macular degeneration Amaurosis fugax Cataract Choroidal effusion Diplopia Glaucoma Iridocele Iritis Ocular hypertension Ocular vascular disorder Optic ischaemic neuropathy Retinal degeneration Retinal detachment		Atrioventricular block second degree 1/6950, 3/6950 Bradyarrhythmia 1/6950, 1/6950 Bradycardia 4/6950, 8/6950 Cardiac arrest 23/6950, 17/6950 Cardiac disorder 0/6950, 1/6950 Cardiac failure 51/6950, 57/6950 Cardiac failure acute 0/6950, 1/6950 Cardiac failure chronic 3/6950, 6/6950 Cardiac failure congestive 23/6950, 33/6950 Cardiac tamponade 1/6950, 0/6950 Cardiac valve disease 2/6950, 1/6950 Cardio-respiratory arrest 3/6950, 5/6950 Cardiogenic shock 6/6950, 2/6950 Cardiomegaly 0/6950, 2/6950 Cardiomyopathy 1/6950, 2/6950 Cardiopulmonary failure 0/6950, 2/6950 Chronotropic incompetence 0/6950, 1/6950 Congestive cardiomyopathy 2/6950, 1/6950 Cor pulmonale 1/6950, 0/6950 Coronary artery disease 28/6950, 25/6950 Coronary artery insufficiency 2/6950, 0/6950 Coronary artery occlusion 1/6950, 0/6950 Coronary artery stenosis 3/6950, 6/6950 Diastolic dysfunction 0/6950, 1/6950 Extrasystoles 2/6950, 0/6950 Heart valve incompetence 0/6950, 2/6950 Hypertensive heart disease 0/6950, 1/6950 Ischaemic cardiomyopathy 0/6950, 4/6950 Left ventricular failure 1/6950, 0/6950 Left ventricular hypertrophy 1/6950, 0/6950 Mitral valve incompetence 2/6950, 3/6950 Myocardial infarction 41/6950, 45/6950 Myocardial ischaemia 5/6950, 16/6950 Palpitations 1/6950, 3/6950 Pericarditis 1/6950, 0/6950

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
			Retinal haemorrhage Abdominal adhesions Abdominal discomfort Abdominal hernia Abdominal pain Abdominal pain upper Abdominal strangulated hernia Anal prolapse Ascites Autoimmune pancreatitis Barrett's oesophagus Chronic gastritis Colitis Colitis ischaemic Colitis ulcerative Constipation Crohn's disease Diaphragmatic hernia Diaphragmatic hernia, obstructive Diarrhoea Diverticulum Diverticulum intestinal Diverticulum intestinal haemorrhagic Duodenal ulcer Duodenal ulcer haemorrhage Duodenal ulcer perforation Enteritis Enterovesical fistula Faecal incontinence Gastric haemorrhage Gastric perforation Gastric ulcer Gastric ulcer haemorrhage Gastric ulcer perforation Gastritis Gastritis haemorrhagic Gastrointestinal angiodysplasia Gastrointestinal haemorrhage Gastrooesophageal reflux disease Haematochezia		Right ventricular failure 2/6950, 1/6950 Sinus arrest 0/6950, 1/6950 Sinus node dysfunction 5/6950, 6/6950 Sinus tachycardia 0/6950, 1/6950 Supraventricular tachycardia 3/6950, 0/6950 Tachyarrhythmia 0/6950, 1/6950 Tachycardia 3/6950, 2/6950 Tricuspid valve incompetence 2/6950, 0/6950 Ventricular arrhythmia 1/6950, 0/6950 Ventricular extrasystoles 1/6950, 1/6950 Ventricular fibrillation 2/6950, 3/6950 Ventricular tachycardia 2/6950, 6/6950 Congenital, familial and genetic disorders , Congenital cystic kidney disease 0/6950, 1/6950 Hypertrophic cardiomyopathy 1/6950, 0/6950 Pyloric stenosis 1/6950, 0/6950 Renal dysplasia 1/6950, 0/6950 Ear and labyrinth disorders , Sudden hearing loss 1/6950, 1/6950 Vertigo 3/6950, 4/6950 Vertigo positional 2/6950, 1/6950 Vestibular disorder 0/6950, 3/6950 Autoimmune thyroiditis (in AE table) Cushingoid 0/6950, 1/6950 Goitre 1/6950, 1/6950 Hyperparathyroidism primary 1/6950, 0/6950 Hyperthyroidism 1/6950, 1/6950 Hypothyroidism 0/6950, 3/6950 Age-related macular degeneration 0/6950, 1/6950 Amaurosis fugax 1/6950, 1/6950 Cataract 7/6950, 7/6950 Choroidal effusion 0/6950, 1/6950 Diplopia 1/6950, 0/6950 Glaucoma 0/6950, 1/6950 Iridocele 1/6950, 0/6950 Iritis 0/6950, 1/6950 Ocular hypertension 0/6950, 1/6950 Ocular vascular disorder 1/6950, 0/6950 Optic ischaemic neuropathy 2/6950, 0/6950

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
			Haemorrhoids Hiatus hernia Ileus Incarcerated inguinal hernia Incarcerated umbilical hernia Inguinal hernia Inguinal hernia strangulated Intestinal haemorrhage Intestinal infarction Intestinal ischaemia Intestinal obstruction Intestinal perforation Large intestinal obstruction Large intestine perforation Large intestine polyp Mallory-weiss syndrome Melaena Mesenteric artery embolism Mesenteric artery thrombosis Mesenteritis Mouth ulceration Nausea Oesophageal haemorrhage Oesophageal spasm Oesophageal ulcer Oesophageal ulcer haemorrhage Oesophagitis Pancreatic disorder Pancreatitis Pancreatitis acute Peptic ulcer haemorrhage Pharyngo-oesophageal diverticulum Proctitis Rectal haemorrhage Rectal perforation Rectal polyp Rectal prolapse Retroperitoneal haemorrhage		Retinal degeneration 1/6950, 0/6950 Retinal detachment 0/6950, 4/6950 Retinal haemorrhage 0/6950, 1/6950 Abdominal adhesions 0/6950, 1/6950 Abdominal discomfort 1/6950, 1/6950 Abdominal hernia 2/6950, 2/6950 Abdominal pain 1/6950, 7/6950 Abdominal pain upper 2/6950, 2/6950 Abdominal strangulated hernia 0/6950, 1/6950 Anal prolapse 0/6950, 1/6950 Ascites 1/6950, 0/6950 Autoimmune pancreatitis 1/6950, 0/6950 Barrett's oesophagus 1/6950, 0/6950 Chronic gastritis 0/6950, 2/6950 Colitis 0/6950, 1/6950 Colitis ischaemic 3/6950, 1/6950 Colitis ulcerative 1/6950, 0/6950 Constipation 3/6950, 2/6950 Crohn's disease 1/6950, 1/6950 Diaphragmatic hernia 0/6950, 1/6950 Diaphragmatic hernia, obstructive 1/6950, 0/6950 Diarrhoea 0/6950, 4/6950 Diverticulum 3/6950, 3/6950 Diverticulum intestinal 1/6950, 2/6950 Diverticulum intestinal haemorrhagic 0/6950, 1/6950 Duodenal ulcer 1/6950, 1/6950 Duodenal ulcer haemorrhage 1/6950, 1/6950 Duodenal ulcer perforation 1/6950, 1/6950 Enteritis 1/6950, 0/6950 Enterovesical fistula 1/6950, 0/6950 Faecal incontinence 1/6950, 0/6950 Gastric haemorrhage 0/6950, 1/6950 Gastric perforation 1/6950, 0/6950 Gastric ulcer 4/6950, 6/6950 Gastric ulcer haemorrhage 2/6950, 4/6950 Gastric ulcer perforation 1/6950, 0/6950 Gastritis 3/6950, 6/6950 Gastritis haemorrhagic 1/6950, 1/6950 Gastrointestinal angiodysplasia 0/6950, 1/6950

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
			Salivary gland calculus Small intestinal obstruction Subileus Thrombosis mesenteric vessel Umbilical hernia Upper gastrointestinal haemorrhage Vomiting Accidental death Administration site erythema Administration site pain Adverse drug reaction Asthenia Cardiac death Chest discomfort Chest pain Chills Cyst Death Device battery issue Device deposit issue Device dislocation Device leakage Device occlusion Drowning Fatigue General physical health deterioration Generalised oedema Ill-defined disorder Incarcerated hernia Inflammation Malaise Multi-organ failure Non-cardiac chest pain Oedema peripheral Organ failure Peripheral swelling Pyrexia Sudden cardiac death Sudden death Systemic inflammatory response syndrome Thrombosis in device Acute hepatic failure		Gastrointestinal haemorrhage 3/6950, 4/6950 Gastrooesophageal reflux disease 3/6950, 2/6950 Haematochezia 0/6950, 2/6950 Haemorrhoids 2/6950, 1/6950 Hiatus hernia 1/6950, 1/6950 Ileus 6/6950, 7/6950 Incarcerated inguinal hernia 2/6950, 0/6950 Incarcerated umbilical hernia 0/6950, 2/6950 Inguinal hernia 5/6950, 10/6950 Inguinal hernia strangulated 1/6950, 0/6950 Intestinal haemorrhage 1/6950, 0/6950 Intestinal infarction 0/6950, 2/6950 Intestinal ischaemia 2/6950, 2/6950 Intestinal obstruction 6/6950, 6/6950 Intestinal perforation 1/6950, 2/6950 Large intestinal obstruction 2/6950, 0/6950 Large intestine perforation 3/6950, 2/6950 Large intestine polyp 3/6950, 4/6950 Mallory-weiss syndrome 1/6950, 1/6950 Melaena 0/6950, 1/6950 Mesenteric artery embolism 0/6950, 1/6950 Mesenteric artery thrombosis 1/6950, 0/6950 Mesenteritis 1/6950, 0/6950 Mouth ulceration 0/6950, 1/6950 Nausea 2/6950, 0/6950 Oesophageal haemorrhage 1/6950, 0/6950 Oesophageal spasm 2/6950, 0/6950 Oesophageal ulcer 1/6950, 0/6950 Oesophageal ulcer haemorrhage 0/6950, 1/6950 Oesophagitis 1/6950, 0/6950 Pancreatic disorder 0/6950, 1/6950 Pancreatitis 3/6950, 8/6950 Pancreatitis acute 5/6950, 4/6950 Peptic ulcer haemorrhage 0/6950, 1/6950

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
			Bile duct obstruction Bile duct stone Biliary colic Biliary dilatation Cholangitis Cholangitis acute Cholecystitis Cholecystitis acute Cholecystitis chronic Cholelithiasis Cholestasis Chronic hepatic failure Cirrhosis alcoholic Drug-induced liver injury Gallbladder perforation Hepatic cirrhosis Hepatic failure Hepatic function abnormal Hepatitis acute Hepatitis alcoholic Hyperbilirubinaemia Ischaemic hepatitis Jaundice cholestatic Allergic granulomatous angiitis Amyloidosis Anaphylactic reaction Drug hypersensitivity Abdominal abscess Abdominal infection Abdominal infection Alcaligenes infection Anal abscess Anal fistula infection Anorectal cellulitis Appendiceal abscess Appendicitis Appendicitis perforated Arteriosclerotic gangrene Arthritis bacterial Arthritis infective Atypical pneumonia Bacteraemia Bacterial sepsis Biliary tract infection Bronchitis Bronchitis bacterial		Pharyngo-oesophageal diverticulum 1/6950, 0/6950 Proctitis 0/6950, 1/6950 Rectal haemorrhage 2/6950, 3/6950 Rectal perforation 0/6950, 1/6950 Rectal polyp 1/6950, 0/6950 Rectal prolapse 1/6950, 0/6950 Retroperitoneal haemorrhage 0/6950, 2/6950 Salivary gland calculus 1/6950, 0/6950 Small intestinal obstruction 2/6950, 4/6950 Subileus 1/6950, 0/6950 Thrombosis mesenteric vessel 1/6950, 0/6950 Umbilical hernia 2/6950, 2/6950 Upper gastrointestinal haemorrhage 2/6950, 2/6950 Vomiting 0/6950, 1/6950 Accidental death 1/6950, 0/6950 Administration site erythema 1/6950, 0/6950 Administration site pain 1/6950, 0/6950 Adverse drug reaction 1/6950, 1/6950 Asthenia 2/6950, 0/6950 Cardiac death 0/6950, 1/6950 Chest discomfort 0/6950, 3/6950 Chest pain 20/6950, 19/6950 Chills 1/6950, 0/6950 Cyst 1/6950, 0/6950 Death 17/6950, 29/6950 Device battery issue 0/6950, 1/6950 Device deposit issue 0/6950, 1/6950 Device dislocation 1/6950, 2/6950 Device leakage 1/6950, 0/6950 Device occlusion 0/6950, 1/6950 Drowning 0/6950, 1/6950 Fatigue 1/6950, 0/6950 General physical health deterioration 1/6950, 2/6950 Generalised oedema 0/6950, 1/6950 Ill-defined disorder 1/6950, 0/6950 Incarcerated hernia 1/6950, 1/6950 Inflammation 1/6950, 0/6950 Malaise 1/6950, 0/6950 Multi-organ failure 9/6950, 12/6950 Non-cardiac chest pain 0/6950, 4/6950

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
			Bronchopneumonia Candida infection Candida sepsis Cavernous sinus thrombosis Cellulitis Cholecystitis infective Clostridium bacteraemia Clostridium difficile colitis Clostridium difficile infection Colonic abscess Cystitis Cystitis klebsiella Device related infection Diabetic foot infection Diverticulitis Empyema Encephalitis Encephalitis viral Endocarditis Enterocolitis viral Epididymitis Erysipelas Escherichia infection Escherichia sepsis Escherichia urinary tract infection Gangrene Gastroenteritis Gastroenteritis clostridial Gastroenteritis norovirus Gastroenteritis salmonella Gastroenteritis viral Graft infection Haematoma infection Helicobacter infection Herpes simplex Herpes zoster Herpes zoster disseminated Herpes zoster meningitis Herpes zoster oticus Incision site infection Infected dermal cyst Infection Infectious colitis		Oedema peripheral 1/6950, 1/6950 Organ failure 2/6950, 1/6950 Peripheral swelling 1/6950, 2/6950 Pyrexia 2/6950, 1/6950 Sudden cardiac death 2/6950, 3/6950 Sudden death 13/6950, 4/6950 Systemic inflammatory response syndrome 1/6950, 1/6950 Thrombosis in device 1/6950, 0/6950 Acute hepatic failure 0/6950, 1/6950 Bile duct obstruction 1/6950, 0/6950 Bile duct stone 3/6950, 3/6950 Biliary colic 1/6950, 1/6950 Biliary dilatation 0/6950, 1/6950 Cholangitis 5/6950, 5/6950 Cholangitis acute 0/6950, 2/6950 Cholecystitis 7/6950, 15/6950 Cholecystitis acute 7/6950, 4/6950 Cholecystitis chronic 0/6950, 1/6950 Cholelithiasis 14/6950, 14/6950 Cholestasis 1/6950, 0/6950 Chronic hepatic failure 0/6950, 1/6950 Cirrhosis alcoholic 2/6950, 0/6950 Drug-induced liver injury 0/6950, 1/6950 Gallbladder perforation 0/6950, 1/6950 Hepatic cirrhosis 2/6950, 3/6950 Hepatic failure 2/6950, 1/6950 Hepatic function abnormal 1/6950, 0/6950 Hepatitis acute 0/6950, 1/6950 Hepatitis alcoholic 1/6950, 0/6950 Hyperbilirubinaemia 1/6950, 0/6950 Ischaemic hepatitis 0/6950, 1/6950 Jaundice cholestatic 2/6950, 0/6950 Allergic granulomatous angiitis 1/6950, 0/6950 Amyloidosis 1/6950, 1/6950 Anaphylactic reaction (in AE table) Drug hypersensitivity 0/6950, 2/6950 Infections and infestations , Abdominal abscess 1/6950, 1/6950 Abdominal infection 1/6950, 0/6950 Acarodermatitis 0/6950, 1/6950 Alcaligenes infection 1/6950, 0/6950 Anal abscess 1/6950, 0/6950 Anal fistula infection 0/6950, 1/6950 Anorectal cellulitis 0/6950, 1/6950

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
			Infective exacerbation of chronic obstructive airways disease Influenza Intestinal gangrene Kidney infection Klebsiella bacteraemia Klebsiella sepsis Labyrinthitis Liver abscess Lobar pneumonia Localised infection Lower respiratory tract infection Lung abscess Lung infection Medical device site infection Meningitis Nasopharyngitis Necrotising fasciitis Necrotising fasciitis streptococcal Neuroborreliosis Neutropenic sepsis Oesophageal candidiasis Ophthalmic herpes zoster Orchitis Oropharyngeal candidiasis Osteomyelitis Ovarian abscess Pancreatic abscess Peritonitis Peritonitis bacterial Pharyngitis Pneumonia Pneumonia bacterial Pneumonia influenzal Pneumonia klebsiella Pneumonia pneumococcal Pneumonia streptococcal Pneumonia viral Post procedural infection Postoperative abscess Postoperative wound infection Pseudomembranous colitis		Appendiceal abscess 0/6950, 1/6950 Appendicitis 5/6950, 5/6950 Appendicitis perforated 0/6950, 1/6950 Arteriosclerotic gangrene 0/6950, 1/6950 Arthritis bacterial 1/6950, 1/6950 Arthritis infective 0/6950, 2/6950 Atypical pneumonia 1/6950, 0/6950 Bacteraemia 1/6950, 0/6950 Bacterial sepsis 2/6950, 2/6950 Biliary tract infection 1/6950, 0/6950 Bronchitis 8/6950, 7/6950 Bronchitis bacterial 0/6950, 1/6950 Bronchopneumonia 1/6950, 4/6950 Candida infection 0/6950, 1/6950 Candida sepsis 0/6950, 1/6950 Cavernous sinus thrombosis 0/6950, 1/6950 Cellulitis 8/6950, 14/6950 Cholecystitis infective 1/6950, 1/6950 Clostridium bacteraemia 0/6950, 1/6950 Clostridium difficile colitis 1/6950, 5/6950 Clostridium difficile infection 1/6950, 1/6950 Colonic abscess 1/6950, 0/6950 Cystitis 4/6950, 0/6950 Cystitis klebsiella 1/6950, 0/6950 Device related infection 1/6950, 1/6950 Diabetic foot infection 0/6950, 1/6950 Diverticulitis 5/6950, 11/6950 Empyema 1/6950, 2/6950 Encephalitis 1/6950, 1/6950 Encephalitis viral 1/6950, 1/6950 Endocarditis 3/6950, 0/6950 Enterocolitis viral 1/6950, 0/6950 Epididymitis 1/6950, 0/6950 Erysipelas 3/6950, 7/6950 Escherichia infection 1/6950, 0/6950 Escherichia sepsis 1/6950, 2/6950 Escherichia urinary tract infection 0/6950, 1/6950 Gangrene 1/6950, 0/6950 Gastroenteritis 8/6950, 8/6950 Gastroenteritis clostridial 0/6950, 2/6950 Gastroenteritis norovirus 1/6950, 1/6950

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
			Pseudomonas infection Psittacosis Psoas abscess Pulmonary tuberculosis Purulence Pyelonephritis Pyelonephritis acute Rectal abscess Renal abscess Respiratory moniliasis Respiratory tract infection Sepsis Septic shock Sinusitis Soft tissue infection Staphylococcal infection Staphylococcal osteomyelitis Staphylococcal sepsis Streptococcal sepsis Tonsillitis Tooth abscess Tuberculosis Upper respiratory tract infection Urinary tract infection Urinary tract infection bacterial Urosepsis Vestibular neuronitis Viral infection Vulvitis Wound infection Accident Accidental overdose Ankle fracture Back injury Bone fissure Carbon monoxide poisoning Cervical vertebral fracture Chest injury Clavicle fracture Compression fracture Concussion Contusion		Gastroenteritis salmonella 1/6950, 0/6950 Gastroenteritis viral 2/6950, 2/6950 Graft infection 1/6950, 0/6950 Haematoma infection 0/6950, 1/6950 Helicobacter infection 0/6950, 1/6950 Herpes simplex 0/6950, 1/6950 Herpes zoster (in AE table) Herpes zoster disseminated 0/6950, 1/6950 Herpes zoster meningitis (in AE table) Herpes zoster oticus 1/6950, 0/6950 Incision site infection 0/6950, 1/6950 Infected dermal cyst 1/6950, 0/6950 Infection 1/6950, 1/6950 Infectious colitis 1/6950, 1/6950 Infective exacerbation of chronic obstructive airways disease 2/6950, 1/6950 Influenza 2/6950, 1/6950 Intestinal gangrene 2/6950, 0/6950 Kidney infection 1/6950, 0/6950 Klebsiella bacteraemia 0/6950, 1/6950 Klebsiella sepsis 0/6950, 1/6950 Labyrinthitis 1/6950, 1/6950 Liver abscess 2/6950, 1/6950 Lobar pneumonia 4/6950, 8/6950 Localised infection 1/6950, 0/6950 Lower respiratory tract infection 1/6950, 1/6950 Lung abscess 0/6950, 1/6950 Lung infection 1/6950, 2/6950 Medical device site infection 0/6950, 1/6950 Meningitis 0/6950, 1/6950 Nasopharyngitis 0/6950, 1/6950 Necrotising fasciitis 1/6950, 1/6950 Necrotising fasciitis streptococcal 0/6950, 1/6950 Neuroborreliosis 1/6950, 0/6950 Neutropenic sepsis 1/6950, 0/6950 Oesophageal candidiasis 0/6950, 2/6950 Ophthalmic herpes zoster 0/6950, 1/6950 Orchitis 0/6950, 3/6950

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
			Coronary artery reocclusion Coronary artery restenosis Craniocerebral injury Deep vein thrombosis postoperative Eye penetration Face injury Facial bones fracture Fall Femoral neck fracture Femur fracture Fibula fracture Foot fracture Forearm fracture Foreign body Fractured sacrum Gun shot wound Hand fracture Head injury Hip fracture Humerus fracture Incisional hernia Injury Jaw fracture Joint dislocation Joint injury Kidney contusion Laceration Ligament sprain Limb crushing injury Limb injury Lower limb fracture Lumbar vertebral fracture Meniscus injury Multiple fractures Multiple injuries Muscle rupture Overdose Patella fracture Pelvic fracture Pneumothorax traumatic Post procedural complication Post procedural haemorrhage		Oropharyngeal candidiasis 0/6950, 1/6950 Osteomyelitis 1/6950, 1/6950 Ovarian abscess 0/6950, 1/6950 Pancreatic abscess 1/6950, 0/6950 Peritonitis 4/6950, 4/6950 Peritonitis bacterial 0/6950, 1/6950 Pharyngitis 0/6950, 1/6950 Pneumonia 70/6950, 81/6950 Pneumonia bacterial 3/6950, 0/6950 Pneumonia influenzal 2/6950, 0/6950 Pneumonia klebsiella 1/6950, 2/6950 Pneumonia pneumococcal 1/6950, 0/6950 Pneumonia streptococcal 1/6950, 0/6950 Pneumonia viral 0/6950, 1/6950 Post procedural infection 0/6950, 3/6950 Postoperative abscess 3/6950, 0/6950 Postoperative wound infection 0/6950, 2/6950 Pseudomembranous colitis 0/6950, 1/6950 Pseudomonas infection 1/6950, 0/6950 Psittacosis 1/6950, 0/6950 Psoas abscess 0/6950, 1/6950 Pulmonary tuberculosis 1/6950, 1/6950 Purulence 1/6950, 0/6950 Pyelonephritis 3/6950, 4/6950 Pyelonephritis acute 4/6950, 0/6950 Rectal abscess 1/6950, 0/6950 Renal abscess 1/6950, 0/6950 Respiratory moniliasis 0/6950, 1/6950 Respiratory tract infection 1/6950, 3/6950 Sepsis 26/6950, 17/6950 Septic shock 11/6950, 14/6950 Sinusitis 2/6950, 0/6950 Soft tissue infection 1/6950, 0/6950 Staphylococcal infection 4/6950, 1/6950 Staphylococcal osteomyelitis 0/6950, 1/6950 Staphylococcal sepsis 1/6950, 1/6950 Streptococcal sepsis 0/6950, 1/6950 Tonsillitis 0/6950, 1/6950 Tooth abscess 1/6950, 0/6950 Tuberculosis 2/6950, 0/6950

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
			Post procedural pulmonary embolism Postoperative wound complication Procedural intestinal perforation Procedural pain Pubis fracture Radius fracture Respiratory fume inhalation disorder Rib fracture Road traffic accident Skin wound Skull fracture Spinal compression fracture Spinal cord injury Spinal cord injury cervical Spinal fracture Splenic rupture Subdural haematoma Subdural haemorrhage Synovial rupture Tendon rupture Thermal burn Thoracic vertebral fracture Tibia fracture Toxicity to various agents Traumatic fracture Traumatic intracranial haemorrhage Ulna fracture Upper limb fracture Vascular graft occlusion Vascular pseudoaneurysm Wound Wound dehiscence Wound evisceration Wound haemorrhage Wrist fracture Blood creatine phosphokinase increased Blood glucose fluctuation Blood pressure increased C-reactive protein increased		Upper respiratory tract infection 0/6950, 3/6950 Urinary tract infection 28/6950, 24/6950 Urinary tract infection bacterial 2/6950, 0/6950 Urosepsis 7/6950, 9/6950 Vestibular neuronitis 0/6950, 3/6950 Viral infection 2/6950, 2/6950 Vulvitis 1/6950, 0/6950 Wound infection 3/6950, 2/6950 Accident 1/6950, 0/6950 Accidental overdose 1/6950, 0/6950 Ankle fracture 3/6950, 5/6950 Back injury 2/6950, 0/6950 Bone fissure 0/6950, 1/6950 Carbon monoxide poisoning 1/6950, 1/6950 Cervical vertebral fracture 0/6950, 2/6950 Chest injury 1/6950, 0/6950 Clavicle fracture 0/6950, 1/6950 Compression fracture 1/6950, 0/6950 Concussion 4/6950, 3/6950 Contusion 4/6950, 5/6950 Coronary artery reocclusion 1/6950, 0/6950 Coronary artery restenosis 0/6950, 1/6950 Craniocerebral injury 0/6950, 2/6950 Deep vein thrombosis postoperative 1/6950, 0/6950 Eye penetration 1/6950, 0/6950 Face injury 1/6950, 0/6950 Facial bones fracture 2/6950, 4/6950 Fall 8/6950, 5/6950 Femoral neck fracture 2/6950, 6/6950 Femur fracture 10/6950, 15/6950 Fibula fracture 0/6950, 1/6950 Foot fracture 2/6950, 2/6950 Forearm fracture 1/6950, 0/6950 Foreign body 0/6950, 1/6950 Fractured sacrum 0/6950, 1/6950 Gun shot wound 0/6950, 1/6950 Hand fracture 2/6950, 1/6950 Head injury 5/6950, 4/6950 Hip fracture 7/6950, 2/6950 Humerus fracture 3/6950, 6/6950

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
			Haemoglobin decreased Heart rate decreased Liver function test abnormal Weight increased Cachexia Decreased appetite Dehydration Diabetes mellitus Diabetes mellitus inadequate control Diabetic ketoacidosis Electrolyte imbalance Failure to thrive Gout Hypercholesterolaemia Hyperglycaemia Hyperkalaemia Hyperlipidaemia Hypocalcaemia Hypoglycaemia Hypokalaemia Hyponatraemia Hypophagia Hypovolaemia Lactic acidosis Malnutrition Marasmus Type 2 diabetes mellitus Uraemic acidosis Acquired claw toe Arthralgia Arthritis Arthrofibrosis Arthropathy Back pain Bursitis Cervical spinal stenosis Chondrocalcinosis Chondropathy Foot deformity Gouty arthritis Intervertebral disc disorder Intervertebral disc protrusion Joint effusion Lumbar spinal stenosis		Incisional hernia 0/6950, 1/6950 Injury 0/6950, 1/6950 Jaw fracture 0/6950, 1/6950 Joint dislocation 3/6950, 0/6950 Joint injury 2/6950, 2/6950 Kidney contusion 1/6950, 0/6950 Laceration 1/6950, 2/6950 Ligament sprain 2/6950, 0/6950 Limb crushing injury 1/6950, 0/6950 Limb injury 0/6950, 1/6950 Lower limb fracture 1/6950, 0/6950 Lumbar vertebral fracture 2/6950, 2/6950 Meniscus injury 3/6950, 2/6950 Multiple fractures 1/6950, 0/6950 Multiple injuries 1/6950, 2/6950 Muscle rupture 0/6950, 2/6950 Overdose 2/6950, 0/6950 Patella fracture 3/6950, 1/6950 Pelvic fracture 2/6950, 4/6950 Pneumothorax traumatic 1/6950, 0/6950 Post procedural complication 1/6950, 2/6950 Post procedural haemorrhage 0/6950, 3/6950 Post procedural pulmonary embolism 1/6950, 0/6950 Postoperative wound complication 1/6950, 0/6950 Procedural intestinal perforation 1/6950, 0/6950 Procedural pain 1/6950, 0/6950 Pubis fracture 2/6950, 3/6950 Radius fracture 5/6950, 5/6950 Respiratory fume inhalation disorder 0/6950, 1/6950 Rib fracture 6/6950, 7/6950 Road traffic accident 1/6950, 1/6950 Skin wound 1/6950, 0/6950 Skull fracture 3/6950, 0/6950 Spinal compression fracture 6/6950, 1/6950 Spinal cord injury 0/6950, 1/6950 Spinal cord injury cervical 1/6950, 0/6950 Spinal fracture 1/6950, 1/6950 Splenic rupture 0/6950, 1/6950

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
			Meniscal degeneration Mixed connective tissue disease Muscular weakness Musculoskeletal pain Myositis Osteoarthritis Osteochondritis Osteoporosis Osteoporotic fracture Pain in extremity Pathological fracture Polymyalgia rheumatica Polymyositis Pseudarthrosis Rhabdomyolysis Rheumatoid arthritis Rotator cuff syndrome Sjogren's syndrome Spinal column stenosis Spinal osteoarthritis Spinal pain Spondyloarthropathy Spondylolisthesis Still's disease adult onset Synovial cyst Synovitis Systemic lupus erythematosus Tenosynovitis Trigger finger Acral lentiginous melanoma Acute monocytic leukaemia Acute myeloid leukaemia Adenocarcinoma Adenocarcinoma gastric Adenocarcinoma of colon Adenocarcinoma pancreas Adrenal adenoma Adrenal gland cancer Anaplastic astrocytoma Anaplastic thyroid cancer B precursor type acute leukaemia B-cell lymphoma		Subdural haematoma 9/6950, 6/6950 Subdural haemorrhage 0/6950, 1/6950 Synovial rupture 0/6950, 1/6950 Tendon rupture 4/6950, 4/6950 Thermal burn 0/6950, 1/6950 Thoracic vertebral fracture 0/6950, 1/6950 Tibia fracture 2/6950, 3/6950 Toxicity to various agents 4/6950, 2/6950 Traumatic fracture 0/6950, 1/6950 Traumatic intracranial haemorrhage 1/6950, 1/6950 Ulna fracture 0/6950, 1/6950 Upper limb fracture 4/6950, 4/6950 Vascular graft occlusion 1/6950, 1/6950 Vascular pseudoaneurysm 1/6950, 0/6950 Wound 1/6950, 0/6950 Wound dehiscence 0/6950, 1/6950 Wound evisceration 0/6950, 1/6950 Wound haemorrhage 1/6950, 0/6950 Wrist fracture 0/6950, 2/6950 Blood creatine phosphokinase increased 0/6950, 1/6950 Blood glucose fluctuation 1/6950, 0/6950 Blood pressure increased 0/6950, 1/6950 C-reactive protein increased 0/6950, 1/6950 Haemoglobin decreased 0/6950, 1/6950 Heart rate decreased 1/6950, 0/6950 Liver function test abnormal 0/6950, 1/6950 Weight increased 1/6950, 0/6950 Cachexia 2/6950, 2/6950 Decreased appetite 0/6950, 2/6950 Dehydration 8/6950, 8/6950 Diabetes mellitus 2/6950, 3/6950 Diabetes mellitus inadequate control 0/6950, 2/6950 Diabetic ketoacidosis 1/6950, 1/6950 Electrolyte imbalance 1/6950, 1/6950 Failure to thrive 0/6950, 2/6950 Gout 2/6950, 0/6950 Hypercholesterolaemia 0/6950, 1/6950

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
			Basal cell carcinoma Benign neoplasm of thyroid gland Benign ovarian tumour Bile duct cancer Bladder cancer Bladder cancer recurrent Bladder neoplasm Bladder papilloma Bladder transitional cell carcinoma Bladder transitional cell carcinoma recurrent Bone cancer Bowen's disease Brain neoplasm benign Breast cancer Breast cancer metastatic Bronchial carcinoma Carcinoid tumour pulmonary Central nervous system neoplasm Cholangiocarcinoma Cholesteatoma Chronic lymphocytic leukaemia Chronic myeloid leukaemia Colon adenoma Colon cancer Colon cancer metastatic Colon neoplasm Diffuse large b-cell lymphoma Diffuse large b-cell lymphoma stage iv Endometrial adenocarcinoma Fallopian tube cancer Follicular thyroid cancer Gallbladder cancer Gastric cancer Gastrointestinal carcinoma Gastrointestinal stromal tumour Gastrointestinal tract adenoma		Hyperglycaemia 1/6950, 2/6950 Hyperkalaemia 0/6950, 2/6950 Hyperlipidaemia 1/6950, 1/6950 Hypocalcaemia 0/6950, 1/6950 Hypoglycaemia 6/6950, 4/6950 Hypokalaemia 7/6950, 2/6950 Hyponatraemia 2/6950, 5/6950 Hypophagia 1/6950, 0/6950 Hypovolaemia 0/6950, 1/6950 Lactic acidosis 0/6950, 1/6950 Malnutrition 1/6950, 2/6950 Marasmus 0/6950, 1/6950 Type 2 diabetes mellitus (in AE table) Uraemic acidosis 0/6950, 1/6950 Acquired claw toe 0/6950, 1/6950 Arthralgia 0/6950, 1/6950 Arthritis 1/6950, 1/6950 Arthrofibrosis 0/6950, 1/6950 Arthropathy 0/6950, 1/6950 Back pain 2/6950, 5/6950 Bursitis 2/6950, 0/6950 Cervical spinal stenosis 0/6950, 1/6950 Chondrocalcinosis 0/6950, 1/6950 Chondropathy 0/6950, 1/6950 Foot deformity 1/6950, 1/6950 Gouty arthritis 2/6950, 1/6950 Intervertebral disc disorder 1/6950, 0/6950 Intervertebral disc protrusion 5/6950, 4/6950 Joint effusion 0/6950, 1/6950 Lumbar spinal stenosis 0/6950, 1/6950 Meniscal degeneration 0/6950, 1/6950 Mixed connective tissue disease 0/6950, 1/6950 Muscular weakness 0/6950, 1/6950 Musculoskeletal pain 2/6950, 1/6950 Myositis 1/6950, 0/6950 Osteoarthritis 26/6950, 17/6950 Osteochondritis 1/6950, 0/6950 Osteoporosis 0/6950, 2/6950 Osteoporotic fracture 1/6950, 0/6950 Pain in extremity 0/6950, 1/6950 Pathological fracture 1/6950, 1/6950 Polymyalgia rheumatica 5/6950, 4/6950 Polymyositis 0/6950, 1/6950 Pseudarthrosis 0/6950, 1/6950

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
			Glioblastoma Glioblastoma multiforme Hepatic cancer Hepatic cancer metastatic Hepatic neoplasm Hepatocellular carcinoma Hypergammaglobulinaemia benign monoclonal Intestinal adenocarcinoma Invasive ductal breast carcinoma Invasive lobular breast carcinoma Invasive papillary breast carcinoma Large cell lung cancer Large intestine benign neoplasm Laryngeal cancer Lung adenocarcinoma Lung adenocarcinoma metastatic Lung adenocarcinoma stage iii Lung cancer metastatic Lung neoplasm Lung neoplasm malignant Lymphoma Malignant fibrous histiocytoma of bone Malignant lymphoma unclassifiable high grade Malignant mast cell neoplasm Malignant melanoma Malignant melanoma in situ Malignant neoplasm of ampulla of vater Malignant palate neoplasm Meningioma Mesothelioma Metastases to adrenals Metastases to bone Metastases to central nervous system		Rhabdomyolysis 0/6950, 2/6950 Rheumatoid arthritis 2/6950, 1/6950 Rotator cuff syndrome 3/6950, 2/6950 Sjogren's syndrome 1/6950, 0/6950 Spinal column stenosis 6/6950, 6/6950 Spinal osteoarthritis 3/6950, 5/6950 Spinal pain 0/6950, 1/6950 Spondyloarthropathy 2/6950, 0/6950 Spondylolisthesis 1/6950, 0/6950 Still's disease adult onset 1/6950, 0/6950 Synovial cyst 0/6950, 1/6950 Synovitis 0/6950, 1/6950 Systemic lupus erythematosus 0/6950, 2/6950 Tenosynovitis 1/6950, 0/6950 Trigger finger 0/6950, 2/6950 Acral lentiginous melanoma 0/6950, 1/6950 Acute monocytic leukaemia 0/6950, 1/6950 Acute myeloid leukaemia 2/6950, 0/6950 Adenocarcinoma 1/6950, 3/6950 Adenocarcinoma gastric 3/6950, 1/6950 Adenocarcinoma of colon 4/6950, 4/6950 Adenocarcinoma pancreas 1/6950, 1/6950 Adrenal adenoma 1/6950, 0/6950 Adrenal gland cancer 0/6950, 1/6950 Anaplastic astrocytoma 0/6950, 1/6950 Anaplastic thyroid cancer 1/6950, 0/6950 B precursor type acute leukaemia 1/6950, 0/6950 B-cell lymphoma 1/6950, 2/6950 Basal cell carcinoma 5/6950, 3/6950 Benign neoplasm of thyroid gland 0/6950, 1/6950 Benign ovarian tumour 1/6950, 0/6950 Bile duct cancer 2/6950, 0/6950 Bladder cancer 6/6950, 13/6950 Bladder cancer recurrent 2/6950, 1/6950 Bladder neoplasm 3/6950, 4/6950 Bladder papilloma 1/6950, 1/6950

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
			Metastases to gastrointestinal tract Metastases to liver Metastases to lung Metastases to lymph nodes Metastases to peritoneum Metastases to stomach Metastasis Metastatic carcinoma of the bladder Metastatic gastric cancer Metastatic malignant melanoma Metastatic neoplasm Metastatic renal cell carcinoma Metastatic squamous cell carcinoma Myelodysplastic syndrome Neoplasm malignant Neoplasm prostate Non-hodgkin's lymphoma Non-small cell lung cancer Non-small cell lung cancer stage iv Oesophageal adenocarcinoma Oesophageal adenocarcinoma metastatic Oesophageal cancer metastatic Oesophageal carcinoma Oesophageal squamous cell carcinoma Ovarian cancer Ovarian cancer recurrent Ovarian epithelial cancer Ovarian germ cell teratoma benign Pancreatic carcinoma Pancreatic carcinoma metastatic Pancreatic neoplasm Pancreatic neuroendocrine tumour		Bladder transitional cell carcinoma 1/6950, 2/6950 Bladder transitional cell carcinoma recurrent 1/6950, 0/6950 Bone cancer 1/6950, 0/6950 Bowen's disease 0/6950, 2/6950 Brain neoplasm benign 1/6950, 0/6950 Breast cancer 5/6950, 4/6950 Breast cancer metastatic 0/6950, 2/6950 Bronchial carcinoma 1/6950, 0/6950 Carcinoid tumour pulmonary 0/6950, 1/6950 Central nervous system neoplasm 0/6950, 1/6950 Cholangiocarcinoma 2/6950, 3/6950 Cholesteatoma 1/6950, 0/6950 Chronic lymphocytic leukaemia 0/6950, 1/6950 Chronic myeloid leukaemia 1/6950, 0/6950 Colon adenoma 0/6950, 1/6950 Colon cancer 9/6950, 6/6950 Colon cancer metastatic 3/6950, 3/6950 Colon neoplasm 0/6950, 2/6950 Diffuse large b-cell lymphoma 1/6950, 0/6950 Diffuse large b-cell lymphoma stage iv 0/6950, 1/6950 Endometrial adenocarcinoma 0/6950, 2/6950 Fallopian tube cancer 0/6950, 1/6950 Follicular thyroid cancer 0/6950, 1/6950 Gallbladder cancer 1/6950, 0/6950 Gastric cancer 6/6950, 3/6950 Gastrointestinal carcinoma 2/6950, 0/6950 Gastrointestinal stromal tumour 1/6950, 0/6950 Gastrointestinal tract adenoma 1/6950, 0/6950 Glioblastoma 0/6950, 1/6950 Glioblastoma multiforme 1/6950, 0/6950 Hepatic cancer 2/6950, 6/6950 Hepatic cancer metastatic 1/6950, 0/6950 Hepatic neoplasm 0/6950, 2/6950

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
			Papillary thyroid cancer Paraganglion neoplasm Parathyroid tumour benign Pituitary tumour benign Plasma cell myeloma Prostate cancer Prostate cancer metastatic Prostate cancer recurrent Prostate cancer stage iv Prostatic adenoma Rectal adenocarcinoma Rectal adenoma Rectal cancer Rectal cancer recurrent Renal cancer Renal cancer metastatic Renal cell carcinoma Renal cell carcinoma recurrent Renal oncocytoma Salivary gland cancer Sarcoma Skin cancer Small cell lung cancer Small cell lung cancer metastatic Small intestine adenocarcinoma Squamous cell carcinoma Squamous cell carcinoma of lung Squamous cell carcinoma of skin Squamous cell carcinoma of the oral cavity Sweat gland tumour T-cell lymphoma Throat cancer Thyroid cancer Tongue neoplasm malignant stage unspecified Transitional cell carcinoma Transitional cell carcinoma metastatic Urethral neoplasm Vulval cancer		Hepatocellular carcinoma 2/6950, 1/6950 Hypergammaglobulinaemia benign monoclonal 0/6950, 1/6950 Intestinal adenocarcinoma 1/6950, 0/6950 Invasive ductal breast carcinoma 2/6950, 2/6950 Invasive lobular breast carcinoma 0/6950, 2/6950 Invasive papillary breast carcinoma 0/6950, 1/6950 Large cell lung cancer 0/6950, 1/6950 Large intestine benign neoplasm 1/6950, 0/6950 Laryngeal cancer 1/6950, 0/6950 Lung adenocarcinoma 1/6950, 6/6950 Lung adenocarcinoma metastatic 1/6950, 2/6950 Lung adenocarcinoma stage iii 0/6950, 1/6950 Lung cancer metastatic 6/6950, 4/6950 Lung neoplasm 1/6950, 3/6950 Lung neoplasm malignant 22/6950, 13/6950 Lymphoma 2/6950, 3/6950 Malignant fibrous histiocytoma of bone 1/6950, 0/6950 Malignant lymphoma unclassifiable high grade 0/6950, 1/6950 Malignant mast cell neoplasm 0/6950, 1/6950 Malignant melanoma 3/6950, 4/6950 Malignant melanoma in situ 1/6950, 1/6950 Malignant neoplasm of ampulla of vater 2/6950, 0/6950 Malignant palate neoplasm 1/6950, 0/6950 Meningioma 0/6950, 2/6950 Mesothelioma 1/6950, 0/6950 Metastases to adrenals 1/6950, 0/6950 Metastases to bone 2/6950, 4/6950 Metastases to central nervous system 4/6950, 2/6950 Metastases to gastrointestinal tract 0/6950, 1/6950

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
			Amnesia Amyotrophic lateral sclerosis Ataxia Balance disorder Basal ganglia haemorrhage Basilar artery thrombosis Brain injury Brain stem infarction Brain stem syndrome Carotid artery occlusion Carotid artery stenosis Carotid sinus syndrome Carpal tunnel syndrome Central nervous system lesion Cerebellar haemorrhage Cerebellar ischaemia Cerebral artery embolism Cerebral artery thrombosis Cerebral atrophy Cerebral haemorrhage Cerebral infarction Cerebral ischaemia Cerebrospinal fluid leakage Cerebrovascular accident Cerebrovascular disorder Cervical myelopathy Cognitive disorder Coma Dementia Dementia alzheimer's type Dementia with lewy bodies Diabetic coma Dizziness Drop attacks Dural arteriovenous fistula Dyspraxia Epilepsy Generalised tonic-clonic seizure Guillain-barre syndrome Haemorrhage intracranial Haemorrhagic stroke Headache		Metastases to liver 5/6950, 5/6950 Metastases to lung 2/6950, 1/6950 Metastases to lymph nodes 1/6950, 1/6950 Metastases to peritoneum 3/6950, 0/6950 Metastases to stomach 1/6950, 0/6950 Metastasis 0/6950, 1/6950 Metastatic carcinoma of the bladder 2/6950, 1/6950 Metastatic gastric cancer 1/6950, 2/6950 Metastatic malignant melanoma 2/6950, 2/6950 Metastatic neoplasm 1/6950, 2/6950 Metastatic renal cell carcinoma 1/6950, 1/6950 Metastatic squamous cell carcinoma 0/6950, 2/6950 Myelodysplastic syndrome 1/6950, 1/6950 Neoplasm malignant 2/6950, 3/6950 Neoplasm prostate 0/6950, 1/6950 Non-hodgkin's lymphoma 0/6950, 3/6950 Non-small cell lung cancer 1/6950, 1/6950 Non-small cell lung cancer stage iv 0/6950, 2/6950 Oesophageal adenocarcinoma 0/6950, 2/6950 Oesophageal adenocarcinoma metastatic 1/6950, 0/6950 Oesophageal cancer metastatic 2/6950, 1/6950 Oesophageal carcinoma 6/6950, 1/6950 Oesophageal squamous cell carcinoma 1/6950, 1/6950 Ovarian cancer 4/6950, 0/6950 Ovarian cancer recurrent 0/6950, 1/6950 Ovarian epithelial cancer 0/6950, 1/6950 Ovarian germ cell teratoma benign 1/6950, 0/6950 Pancreatic carcinoma 7/6950, 10/6950 Pancreatic carcinoma metastatic 3/6950, 2/6950 Pancreatic neoplasm 3/6950, 0/6950

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
			Hemiplegia Hydrocephalus Hypertonia Hypoaesthesia Hypoxic-ischaemic encephalopathy Intracranial aneurysm Intraventricular haemorrhage Ischaemic stroke Lacunar infarction Loss of consciousness Lumbar radiculopathy Memory impairment Miller fisher syndrome Mixed dementia Myasthenia gravis Myoclonus Nerve compression Neuralgia Neuropathy peripheral Paralysis Parkinson's disease Parkinsonism Partial seizures Polyneuropathy Post herpetic neuralgia Presyncope Progressive supranuclear palsy Radiculopathy Restless legs syndrome Sciatica Seizure Senile dementia Somnolence Spondylitic myelopathy Status epilepticus Subarachnoid haemorrhage Syncope Thalamic infarction Thalamus haemorrhage Thrombotic cerebral infarction Transient global amnesia Transient ischaemic attack		Pancreatic neuroendocrine tumour 1/6950, 0/6950 Papillary thyroid cancer 0/6950, 1/6950 Paraganglion neoplasm 1/6950, 0/6950 Parathyroid tumour benign 1/6950, 0/6950 Pituitary tumour benign 1/6950, 1/6950 Plasma cell myeloma 1/6950, 1/6950 Prostate cancer 19/6950, 18/6950 Prostate cancer metastatic 3/6950, 2/6950 Prostate cancer recurrent 3/6950, 0/6950 Prostate cancer stage iv 0/6950, 1/6950 Prostatic adenoma 0/6950, 1/6950 Rectal adenocarcinoma 4/6950, 1/6950 Rectal adenoma 0/6950, 1/6950 Rectal cancer 1/6950, 2/6950 Rectal cancer recurrent 1/6950, 0/6950 Renal cancer 1/6950, 2/6950 Renal cancer metastatic 0/6950, 1/6950 Renal cell carcinoma 3/6950, 4/6950 Renal cell carcinoma recurrent 0/6950, 1/6950 Renal oncocytoma 1/6950, 0/6950 Salivary gland cancer 1/6950, 0/6950 Sarcoma 0/6950, 1/6950 Skin cancer 0/6950, 1/6950 Small cell lung cancer 1/6950, 1/6950 Small cell lung cancer metastatic 0/6950, 2/6950 Small intestine adenocarcinoma 1/6950, 0/6950 Squamous cell carcinoma 2/6950, 3/6950 Squamous cell carcinoma lung 2/6950, 0/6950 Squamous cell carcinoma skin 0/6950, 2/6950 Squamous cell carcinoma oral cavity 1/6950, 10/6950 Sweat gland tumour 1/6950, 0/6950 T-cell lymphoma 0/6950, 1/6950 Throat cancer 1/6950, 1/6950 Thyroid cancer 2/6950, 0/6950 Tongue neoplasm malignant stage unspecified 1/6950, 0/6950

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
			Trigeminal neuralgia Vascular dementia Vertebrobasilar insufficiency Viiith nerve lesion Viith nerve paralysis Abnormal behaviour Acute psychosis Affective disorder Alcohol withdrawal syndrome Anxiety disorder Breathing-related sleep disorder Completed suicide Confusional state Delirium Depressed mood Depression Disorientation Hallucination Major depression Mental disorder Mental disorder due to a general medical condition Mental status changes Panic attack Panic disorder Psychotic disorder Schizoaffective disorder bipolar type Schizophrenia Somatoform disorder Suicidal ideation Acute kidney injury Acute prerenal failure Bladder neck obstruction Bladder perforation Bladder prolapse Calculus ureteric Chronic kidney disease Cystitis haemorrhagic Cystitis interstitial Dysuria Glomerulonephritis Haematuria Hydronephrosis		Transitional cell carcinoma 2/6950, 0/6950 Transitional cell carcinoma metastatic 0/6950, 1/6950 Urethral neoplasm 1/6950, 0/6950 Vulval cancer 1/6950, 0/6950 Nervous system disorders , Amnesia 1/6950, 0/6950 Amyotrophic lateral sclerosis (in AE table) Ataxia (in AE table) Balance disorder 0/6950, 2/6950 Basal ganglia haemorrhage 1/6950, 0/6950 Basilar artery thrombosis 0/6950, 1/6950 Brain injury 0/6950, 1/6950 Brain stem infarction 0/6950, 1/6950 Brain stem syndrome 1/6950, 0/6950 Carotid artery occlusion 1/6950, 0/6950 Carotid artery stenosis 1/6950, 1/6950 Carotid sinus syndrome 0/6950, 1/6950 Carpal tunnel syndrome 1/6950, 0/6950 Central nervous system lesion 0/6950, 1/6950 Cerebellar haemorrhage 0/6950, 2/6950 Cerebellar ischaemia 0/6950, 1/6950 Cerebral artery embolism 1/6950, 1/6950 Cerebral artery thrombosis 1/6950, 0/6950 Cerebral atrophy 0/6950, 1/6950 Cerebral haemorrhage 6/6950, 7/6950 Cerebral infarction 16/6950, 17/6950 Cerebral ischaemia 2/6950, 3/6950 Cerebrospinal fluid leakage 0/6950, 1/6950 Cerebrovascular accident 34/6950, 31/6950 Cerebrovascular disorder 3/6950, 1/6950 Cervical myelopathy 1/6950, 0/6950 Cognitive disorder 1/6950, 1/6950 Coma 0/6950, 1/6950 Dementia 4/6950, 2/6950 Dementia alzheimer's type 2/6950, 0/6950

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
			Nephroangiosclerosis Nephrolithiasis Nephropathy toxic Neurogenic bladder Prerenal failure Renal cyst Renal disorder Renal failure Renal hypertension Renal mass Tubulointerstitial nephritis Urethral haemorrhage Urethral meatus stenosis Urethral stenosis Urinary incontinence Urinary retention Urinary tract disorder Atrophic vulvovaginitis Benign prostatic hyperplasia Breast dysplasia Ovarian cyst Prostatic obstruction Prostatitis Prostatomegaly Rectocele Uterine polyp Uterine prolapse Vaginal haemorrhage Vaginal prolapse Vaginal ulceration Acute pulmonary oedema Acute respiratory failure Aspiration Asthma Atelectasis Bronchiectasis Bronchitis chronic Bronchospasm Chronic obstructive pulmonary disease Diaphragmatic disorder Dyspnoea Emphysema Epistaxis Haemoptysis Haemothorax		Dementia with lewy bodies 0/6950, 1/6950 Diabetic coma 1/6950, 0/6950 Dizziness 1/6950, 5/6950 Drop attacks 0/6950, 1/6950 Dural arteriovenous fistula 0/6950, 1/6950 Dyspraxia 1/6950, 0/6950 Epilepsy 2/6950, 4/6950 Generalised tonic-clonic seizure 2/6950, 0/6950 Guillain-barre syndrome (in AE table) , Haemorrhage intracranial 1/6950, 2/6950 Haemorrhagic stroke 0/6950, 4/6950 Headache 0/6950, 1/6950 Hemiplegia 1/6950, 0/6950 Hydrocephalus 1/6950, 1/6950 Hypertonia 0/6950, 1/6950 Hypoaesthesia 2/6950, 0/6950 Hypoxic-ischaemic encephalopathy , Intracranial aneurysm 0/6950, 1/6950 Intraventricular haemorrhage 1/6950, 0/6950 Ischaemic stroke (in AE table) Lacunar infarction 2/6950, 2/6950 Loss of consciousness 1/6950, 1/6950 Lumbar radiculopathy 0/6950, 2/6950 Memory impairment 0/6950, 1/6950 Miller fisher syndrome 0/6950, 1/6950 Mixed dementia 1/6950, 1/6950 Myasthenia gravis 0/6950, 1/6950 Myoclonus 1/6950, 0/6950 Nerve compression 0/6950, 1/6950 Neuralgia 0/6950, 1/6950 Neuropathy peripheral 0/6950, 1/6950 Paralysis 1/6950, 0/6950 Parkinson's disease 1/6950, 0/6950 Parkinsonism 0/6950, 2/6950 Partial seizures 0/6950, 1/6950 Polyneuropathy 0/6950, 1/6950 Post herpetic neuralgia 0/6950, 1/6950 Presyncope 1/6950, 2/6950 Progressive supranuclear palsy 0/6950, 1/6950 Radiculopathy 0/6950, 1/6950 Restless legs syndrome 0/6950, 1/6950

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
			Hyperventilation Hypoxia Interstitial lung disease Lung disorder Nasal septum deviation Pleural effusion Pleurisy Pleuritic pain Pneumonia aspiration Pneumothorax Pulmonary cavitation Pulmonary congestion Pulmonary embolism Pulmonary fibrosis Pulmonary mass Pulmonary oedema Respiratory arrest Respiratory distress Respiratory failure Actinic keratosis Angioedema Decubitus ulcer Dermal cyst Dermatitis allergic Dermatitis contact Dermatomyositis Diabetic foot Drug eruption Eczema Lichen planus Skin necrosis Skin ulcer Stasis dermatitis Urticaria Hospitalisation Rectal polypectomy Aneurysm Aneurysm ruptured Aortic aneurysm Aortic aneurysm rupture Aortic arteriosclerosis Aortic dissection Aortic occlusion Aortic rupture Aortic stenosis Arteriosclerosis Arteriovenous fistula		Sciatica 4/6950, 4/6950 Seizure (in AE table) Senile dementia 0/6950, 2/6950 Somnolence 0/6950, 1/6950 Spondylitic myelopathy 0/6950, 1/6950 Status epilepticus 0/6950, 1/6950 Subarachnoid haemorrhage 5/6950, 7/6950 Syncope 11/6950, 20/6950 Thalamic infarction 0/6950, 1/6950 Thalamus haemorrhage 1/6950, 0/6950 Thrombotic cerebral infarction 0/6950, 2/6950 Transient global amnesia 1/6950, 1/6950 Transient ischaemic attack 20/6950, 14/6950 Trigeminal neuralgia 1/6950, 0/6950 Vascular dementia 0/6950, 1/6950 Vertebrobasilar insufficiency 1/6950, 0/6950 Viiith nerve lesion 1/6950, 0/6950 Viith nerve paralysis 2/6950, 2/6950 Abnormal behaviour 0/6950, 1/6950 Acute psychosis 0/6950, 1/6950 Affective disorder 1/6950, 0/6950 Alcohol withdrawal syndrome 0/6950, 1/6950 Anxiety disorder 1/6950, 0/6950 Breathing-related sleep disorder 0/6950, 1/6950 Completed suicide 1/6950, 1/6950 Confusional state 2/6950, 0/6950 Delirium 2/6950, 3/6950 Depressed mood 2/6950, 0/6950 Depression 4/6950, 3/6950 Disorientation 1/6950, 0/6950 Hallucination 0/6950, 2/6950 Major depression 0/6950, 2/6950 Mental disorder 1/6950, 0/6950 Mental disorder due to a general medical condition 0/6950, 1/6950 Mental status changes 0/6950, 2/6950 Panic attack 0/6950, 1/6950 Panic disorder 1/6950, 0/6950 Psychotic disorder 1/6950, 0/6950

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
			Blood pressure inadequately controlled Circulatory collapse Deep vein thrombosis Embolism Femoral artery aneurysm Femoral artery occlusion Haematoma Haemorrhage Hypertension Hypertensive crisis Hypertensive emergency Hypotension Inferior vena caval occlusion Intermittent claudication Internal haemorrhage Labile hypertension Microscopic polyangiitis Necrosis ischaemic Orthostatic hypotension Peripheral arterial occlusive disease Peripheral artery aneurysm Peripheral artery stenosis Peripheral ischaemia Peripheral vascular disorder Shock haemorrhagic Temporal arteritis Thromboangiitis obliterans Thrombophlebitis Thrombosis Varicose vein Vasculitis Venous thrombosis Venous thrombosis limb Chills Fatigue Injection site erythema Injection site pain Injection site swelling Pain Pyrexia Myalgia Headache		Schizoaffective disorder bipolar type 0/6950, 1/6950 Schizophrenia 0/6950, 1/6950 Somatoform disorder 1/6950, 0/6950 Suicidal ideation 0/6950, 1/6950 Renal and urinary disorders , Acute kidney injury 18/6950, 19/6950 Acute prerenal failure 1/6950, 1/6950 Bladder neck obstruction 1/6950, 0/6950 Bladder perforation 0/6950, 2/6950 Bladder prolapse 0/6950, 2/6950 Calculus ureteric 0/6950, 1/6950 Chronic kidney disease 4/6950, 11/6950 Cystitis haemorrhagic 1/6950, 0/6950 Cystitis interstitial 0/6950, 1/6950 Dysuria 1/6950, 0/6950 Glomerulonephritis 0/6950, 1/6950 Haematuria 3/6950, 2/6950 Hydronephrosis 1/6950, 0/6950 Nephroangiosclerosis 1/6950, 0/6950 Nephrolithiasis 6/6950, 2/6950 Nephropathy toxic 0/6950, 1/6950 Neurogenic bladder 0/6950, 1/6950 Prerenal failure 0/6950, 2/6950 Renal cyst 2/6950, 1/6950 Renal disorder 1/6950, 0/6950 Renal failure 11/6950, 11/6950 Renal hypertension 0/6950, 1/6950 Renal mass 1/6950, 0/6950 Tubulointerstitial nephritis 0/6950, 4/6950 Urethral haemorrhage 1/6950, 0/6950 Urethral meatus stenosis 1/6950, 0/6950 Urethral stenosis 2/6950, 2/6950 Urinary incontinence 1/6950, 0/6950 Urinary retention 3/6950, 3/6950 Urinary tract disorder 1/6950, 1/6950 Reproductive system and breast disorders , Atrophic vulvovaginitis 1/6950, 0/6950 Benign prostatic hyperplasia 9/6950, 7/6950 Breast dysplasia 1/6950, 0/6950 Ovarian cyst 1/6950, 0/6950 Prostatic obstruction 0/6950, 2/6950 Prostatitis 1/6950, 2/6950 Prostatomegaly 1/6950, 0/6950

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
					Rectocele 1/6950, 1/6950 Uterine polyp 0/6950, 1/6950 Uterine prolapse 0/6950, 4/6950 Vaginal haemorrhage 1/6950, 0/6950 Vaginal prolapse 0/6950, 1/6950 Vaginal ulceration 0/6950, 1/6950 Acute pulmonary oedema 2/6950, 3/6950 Acute respiratory failure 2/6950, 4/6950 Aspiration 0/6950, 1/6950 Asthma (in AE table) Atelectasis 0/6950, 1/6950 Bronchiectasis 1/6950, 0/6950 Bronchitis chronic 0/6950, 2/6950 Bronchospasm 0/6950, 1/6950 Chronic obstructive pulmonary disease 21/6950, 18/6950 Diaphragmatic disorder 0/6950, 1/6950 Dyspnoea 2/6950, 4/6950 Emphysema 0/6950, 1/6950 Epistaxis 1/6950, 3/6950 Haemoptysis 3/6950, 0/6950 Haemothorax 0/6950, 1/6950 Hyperventilation 1/6950, 0/6950 Hypoxia 0/6950, 2/6950 Interstitial lung disease 1/6950, 1/6950 Lung disorder 0/6950, 2/6950 Nasal septum deviation 1/6950, 1/6950 Pleural effusion 5/6950, 8/6950 Pleurisy 1/6950, 0/6950 Pleuritic pain 0/6950, 1/6950 Pneumonia aspiration 10/6950, 3/6950 Pneumothorax 0/6950, 2/6950 Pulmonary cavitation 1/6950, 0/6950 Pulmonary congestion 1/6950, 1/6950 Pulmonary embolism 15/6950, 21/6950 Pulmonary fibrosis 0/6950, 3/6950 Pulmonary mass 0/6950, 1/6950 Pulmonary oedema 2/6950, 4/6950 Respiratory arrest 3/6950, 0/6950 Respiratory distress 2/6950, 2/6950 Respiratory failure 15/6950, 15/6950 Actinic keratosis 1/6950, 0/6950 Angioedema (in AE table) Decubitus ulcer 1/6950, 2/6950 Dermal cyst 0/6950, 1/6950 Dermatitis allergic 1/6950, 0/6950

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
					Dermatitis contact 1/6950, 1/6950 Dermatomyositis 0/6950, 1/6950 Diabetic foot 0/6950, 5/6950 Drug eruption 0/6950, 1/6950 Eczema 2/6950, 1/6950 Lichen planus 1/6950, 0/6950 Skin necrosis 0/6950, 2/6950 Skin ulcer 1/6950, 1/6950 Stasis dermatitis 1/6950, 0/6950 Urticaria 1/6950, 0/6950 Hospitalisation 0/6950, 1/6950 Rectal polypectomy 1/6950, 0/6950 Aneurysm 0/6950, 1/6950 Aneurysm ruptured 1/6950, 1/6950 Aortic aneurysm 6/6950, 2/6950 Aortic aneurysm rupture 4/6950, 4/6950 Aortic arteriosclerosis 0/6950, 1/6950 Aortic dissection 1/6950, 2/6950 Aortic occlusion 1/6950, 0/6950 Aortic rupture 0/6950, 1/6950 Aortic stenosis 0/6950, 8/6950 Arteriosclerosis 1/6950, 5/6950 Arteriovenous fistula 1/6950, 0/6950 Blood pressure inadequately controlled 0/6950, 1/6950 Circulatory collapse 5/6950, 3/6950 Deep vein thrombosis 6/6950, 9/6950 Embolism 1/6950, 1/6950 Femoral artery aneurysm 1/6950, 0/6950 Femoral artery occlusion 0/6950, 1/6950 Haematoma 1/6950, 6/6950 Haemorrhage 1/6950, 3/6950 Hypertension 22/6950, 25/6950 Hypertensive crisis 7/6950, 6/6950 Hypertensive emergency 0/6950, 1/6950 Hypotension 6/6950, 5/6950 Inferior vena caval occlusion 0/6950, 1/6950 Intermittent claudication 0/6950, 2/6950 Internal haemorrhage 2/6950, 0/6950 Labile hypertension 1/6950, 0/6950 Microscopic polyangiitis 0/6950, 1/6950 Necrosis ischaemic 1/6950, 0/6950 Orthostatic hypotension 2/6950, 4/6950 Peripheral arterial occlusive disease 6/6950, 6/6950

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
					Peripheral artery aneurysm 0/6950, 1/6950 Peripheral artery stenosis 0/6950, 1/6950 Peripheral ischaemia 1/6950, 0/6950 Peripheral vascular disorder 1/6950, 0/6950 Shock haemorrhagic 1/6950, 0/6950 Temporal arteritis 1/6950, 1/6950 Thromboangiitis obliterans 0/6950, 1/6950 Thrombophlebitis 1/6950, 0/6950 Thrombosis 1/6950, 2/6950 Varicose vein 0/6950, 1/6950 Vasculitis 1/6950, 0/6950 Venous thrombosis 1/6950, 0/6950 Risk factors: Unsolicited AEs least common among people who were Black, most common among people who were Asian, more common among women, very slightly more common among 50-69 than 70+. Solicited reactions tended to be less frequent among those 80 years of age compared to 70-79 yrs of age
Lal, 2015[150] McElhaney, 2016[304]; GlaxoSmithKline, 2010[266] NCT01165177 Article RCT N=15411 Industry funded Australia, Belgium, Czech republic, Spain, Taiwan, Finland, Japan, São Paulo	Age: 62.3(9.0) % female: 61% Ethnicity: 72% White; 2% Black; 19% Asian; 7% Other Participants 50 years of age or older unless history of zoster, previously vaccinated against varicella or zoster, or immunosuppressive condition Out of scope: None	ZosterAdj Shingrix 100 50 µg in 2 doses (each dose 50 µg of recombinant VZV glycoprotein E and the liposome-based AS01B adjuvant system containing 50 µg of 3-O-desacyl-4′-monophosphoryl lipid A (MPL) and 50 µg of Quillaja Saponaria Molina, fraction 21 (QS21)) Intramuscular Other : AS01B adjuvant system preservative NR No co-intervention	Anaemia Anaemia vitamin b2 deficiency Disseminated intravascular coagulation Haemorrhagic anaemia Heparin-induced thrombocytopenia Hypochromic anaemia Immune thrombocytopenic purpura Iron deficiency anaemia Lymphadenopathy Lymphadenopathy mediastinal Splenic haemorrhage Splenic infarction Thrombocytopenia Cardiac disorders Acute coronary syndrome Acute myocardial infarction Angina pectoris	ALS: 17.X NR I: 2/7695, 17.X NR C: 1/7710 Anaphylaxis: 10.4 Anaphylactic reaction I: 1/7695, 10.X Anaphylactic reaction C: 0/7710 Asthma: 22.X NR I: 6/7695, 22.X NR C: 5/7710 Autoimmune disease: 10.X Potential immune-mediated diseases I: 78/7698, 10.X Potential immune-mediated diseases C: 97/7710 Cardiovascular events: 2.X Cardiac disorders I: 145/7698, 2.X Cardiac disorders C: 147/7710 Death: NA no SAE (except for 4, and none were deaths) were considered related to study vaccines I: 167/7698, NA no SAE (except for 4, and none were deaths) were considered related to study vaccines C: 174/7713	Any unsolicited grade 3 AE within 30 days: 208/4460, 151/4466 Any solicited or unsolicited grade 3 AE within 7 days: 760/4460, 145/4466 Grade 3 solicited report of injection-site reaction within 7 days: 417/4382, 16/4377 Grade 3 solicited report of systemic reaction within 7 days; 498/4375, 106/4378 Serious adverse events within 30 days after vaccination: 87/7698,97/7713 Potential immune-mediated diseases: 78/7698,97/7713 (overlaps with Guillain-Barre syndrome, some AEs on clinicaltrials.gov) Serious AEs (from clinicaltrials.gov): Total 727/7695 (9.45%) 731/7710 (9.48%)

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
		Placebo Saline placebo Counts No prespecified AE Power NR Followup: 60 months	Angina unstable Aortic valve disease Aortic valve stenosis Arrhythmia Atrial fibrillation Atrial flutter Atrial tachycardia Atrioventricular block Atrioventricular block complete Atrioventricular block second degree Bradyarrhythmia Bradycardia Cardiac arrest Cardiac failure Cardiac failure acute Cardiac failure chronic Cardiac failure congestive Cardiac valve disease Cardio-respiratory arrest Cardiogenic shock Cardiomyopathy alcoholic Cardiopulmonary failure Cardiovascular deconditioning Cardiovascular insufficiency Cor pulmonale Coronary artery disease Coronary artery insufficiency Coronary artery occlusion Coronary artery stenosis Intracardiac thrombus Left ventricular failure Mitral valve prolapse Mitral valve stenosis Myocardial infarction Myocardial ischaemia Palpitations Pericardial effusion Pericarditis Right ventricular failure Sinus node dysfunction Stress cardiomyopathy	Diabetes: 14.X NR I: 3/7695, 14.X NR C: 2/7710 Encephalitis: 17.X Encephalopathy I: 0/7695, 17.X Encephalopathy C: 1/7710 Encephalomyelitis: 11.X Encephalomyelitis I: 0/7695, 11.X Encephalomyelitis C: 1/7710 Guillain-Barré syndrome: 10.X NR I: 1/7695, 10.X NR C: 1/7710 Herpes Zoster: 11.X NR I: 9/7695 11.X NR C: 235/7713 Immune Thrombocytopenia Purpura: 1.X NR I: 3/7695, 1.X NR C: 1/7710 Meningitis: 11.X Pneumococcal meningitis I: 0/7695, 11.X Pneumococcal meningitis C: 1/7710 Myocardial infarction: 2.X Myocardial infarction I: 28/7695, 2.X Myocardial infarction C: 27/7710 Reproduction issues: 21.X NR I: 10/7698, 21.X NR C: 7/7710 Seizure: 17.X NR I: 3/7695, 17.X NR C: 3/7710 Stroke: 17.X Cerebrovascular accident I: 19/7695, 17.X Cerebrovascular accident C: 12/7710	Anaemia 6/7695, 4/7710 Anaemia vitamin b12 deficiency 0/7695, 1/7710 Disseminated intravascular coagulation 2/7695, 0/7710 Haemorrhagic anaemia 1/7695, 0/7710 Heparin-induced thrombocytopenia 0/7695, 1/7710 Hypochromic anaemia 1/7695, 0/7710 Immune thrombocytopenic purpura (in AE table), Iron deficiency anaemia 2/7695, 1/7710 Lymphadenopathy 0/7695, 1/7710 Lymphadenopathy mediastinal 0/7695, 1/7710 Splenic haemorrhage 0/7695, 1/7710 Splenic infarction 0/7695, 1/7710 Thrombocytopenia 0/7695, 1/7710 Cardiac disorders (entire captured in AE table, from CSR at GSK website) Acute coronary syndrome 4/7695, 2/7710 Acute myocardial infarction 8/7695, 19/7710 Angina pectoris 3/7695, 3/7710 Angina unstable 2/7695, 4/7710 Aortic valve disease 1/7695, 0/7710 Aortic valve stenosis 1/7695, 2/7710 Arrhythmia 6/7695, 0/7710 Atrial fibrillation 19/7695, 6/7710 Atrial flutter 4/7695, 4/7710 Atrial tachycardia 1/7695, 0/7710 Atrioventricular block 1/7695, 1/7710 Atrioventricular block complete 1/7695, 2/7710 Atrioventricular block second degree 2/7695, 0/7710 Bradyarrhythmia 0/7695, 1/7710 Bradycardia 2/7695, 2/7710 Cardiac arrest 8/7695, 8/7710 Cardiac failure 20/7695, 24/7710 Cardiac failure acute 0/7695, 3/7710 Cardiac failure chronic 2/7695, 1/7710 Cardiac failure congestive 14/7695, 10/7710 Cardiac valve disease 2/7695, 0/7710 Cardio-respiratory arrest 0/7695, 2/7710

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
			Supraventricular tachycardia Tachycardia Ventricular extrasystoles Ventricular fibrillation Ventricular tachycardia Hypertrophic cardiomyopathy Odontogenic cyst Cystic fibrosis Hernia congenital Hydrocele Deafness neurosensory Motion sickness Vertigo Vertigo positional Endocrine disorders Basedow's disease Goitre Hypopituitarism Thyroiditis subacute Eye disorders Amaurosis fugax Cataract Eyelid ptosis Glaucoma Lens dislocation Macular cyst Macular hole Neovascular age-related macular degeneration Retinal artery occlusion Retinal detachment Retinal tear Vitreous detachment Vitreous haemorrhage Gastrointestinal disorders Abdominal hernia Abdominal pain Abdominal pain upper Abdominal strangulated hernia Ascites Colitis Colitis ischaemic Constipation Crohn's disease		Cardiogenic shock 3/7695, 1/7710 Cardiomyopathy alcoholic 1/7695, 0/7710 Cardiopulmonary failure 1/7695, 1/7710 Cardiovascular deconditioning 0/7695, 1/7710 Cardiovascular insufficiency 1/7695, 0/7710 Cor pulmonale 0/7695, 1/7710 Coronary artery disease 11/7695, 17/7710 Coronary artery insufficiency 1/7695, 0/7710 Coronary artery occlusion 1/7695, 0/7710 Coronary artery stenosis 4/7695, 0/7710 Intracardiac thrombus 2/7695, 0/7710 Left ventricular failure 3/7695, 0/7710 Mitral valve prolapse 1/7695, 0/7710 Mitral valve stenosis 0/7695, 1/7710 Myocardial infarction 28/7695, 27/7710 Myocardial ischaemia 7/7695, 11/7710 Palpitations 1/7695, 0/7710 Pericardial effusion 1/7695, 0/7710 Pericarditis 0/7695, 1/7710 Right ventricular failure 1/7695, 0/7710 Sinus node dysfunction 2/7695, 0/7710 Stress cardiomyopathy 2/7695, 1/7710 Supraventricular tachycardia 3/7695, 0/7710 Tachycardia 0/7695, 1/7710 Ventricular extrasystoles 0/7695, 1/7710 Ventricular fibrillation 1/7695, 1/7710 Ventricular tachycardia 1/7695, 0/7710 Hypertrophic cardiomyopathy 0/7695, 1/7710 Odontogenic cyst 0/7695, 1/7710 Deafness neurosensory 0/7695, 1/7710 Motion sickness 0/7695, 1/7710 Vertigo 4/7695, 3/7710 Vertigo positional 0/7695, 1/7710 Basedow’s disease 0/7695, 1/7710 Goitre 1/7695, 0/7710 Hypopituitarism 1/7695, 0/7710 Thyroiditis subacute 1/7695, 0/7710 Amaurosis fugax 1/7695, 0/7710 Cataract 2/7695, 5/7710

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
			Diarrhoea Diverticulum Diverticulum intestinal Duodenal perforation Duodenal ulcer haemorrhage Duodenitis Enteritis Enterovesical fistula Functional gastrointestinal disorder Gastric haemorrhage Gastric mucosal lesion Gastric polyps Gastric ulcer Gastric ulcer haemorrhage Gastritis Gastritis alcoholic Gastrointestinal angiodysplasia Gastrointestinal haemorrhage Gastrointestinal polyp haemorrhage Gastrooesophageal reflux disease Gingival disorder Haemorrhoidal haemorrhage Haemorrhoids Hiatus hernia Ileus Incarcerated umbilical hernia Inguinal hernia Intestinal congestion Intestinal obstruction Intestinal polyp Irritable bowel syndrome Large intestine polyp Mallory-weiss syndrome Melaena Nausea Oesophageal ulcer Oesophageal varices haemorrhage Oesophagitis		Eyelid ptosis 1/7695, 0/7710 Glaucoma 1/7695, 0/7710 Lens dislocation 0/7695, 1/7710 Macular cyst 0/7695, 1/7710 Macular hole 0/7695, 1/7710 Neovascular age-related macular degeneration 0/7695, 1/7710 Retinal artery occlusion 0/7695, 1/7710 Retinal detachment 1/7695, 4/7710 Retinal tear 0/7695, 1/7710 Vitreous detachment 1/7695, 0/7710 Vitreous haemorrhage 1/7695, 1/7710 Abdominal hernia 1/7695, 0/7710 Abdominal pain 2/7695, 2/7710 Abdominal pain upper 1/7695, 0/7710 Abdominal strangulated hernia 1/7695, 0/7710 Ascites 1/7695, 0/7710 Colitis 0/7695, 1/7710 Colitis ischaemic 1/7695, 3/7710 Constipation 1/7695, 2/7710 Crohn's disease 1/7695, 0/7710 Diarrhoea 4/7695, 1/7710 Diverticulum 3/7695, 1/7710 Diverticulum intestinal 0/7695, 1/7710 Duodenal perforation 1/7695, 0/7710 Duodenal ulcer haemorrhage 0/7695, 1/7710 Duodenitis 1/7695, 0/7710 Enteritis 0/7695, 2/7710 Enterovesical fistula 1/7695, 0/7710 Functional gastrointestinal disorder 1/7695, 1/7710 Gastric haemorrhage 1/7695, 0/7710 Gastric mucosal lesion 0/7695, 1/7710 Gastric polyps 1/7695, 0/7710 Gastric ulcer 3/7695, 3/7710 Gastric ulcer haemorrhage 0/7695, 2/7710 Gastritis 5/7695, 4/7710 Gastritis alcoholic 1/7695, 0/7710 Gastrointestinal angiodysplasia 1/7695, 0/7710 Gastrointestinal haemorrhage 3/7695, 4/7710 Gastrointestinal polyp haemorrhage 0/7695, 1/7710

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
			Pancreatic cyst Pancreatic fistula Pancreatitis Pancreatitis acute Pancreatitis necrotising Peptic ulcer Peptic ulcer perforation Periodontal disease Peritoneal cyst Peritoneal haemorrhage Pneumoperitoneum Portal hypertensive gastropathy Rectal haemorrhage Rectal polyp Retroperitoneal haemorrhage Small intestinal obstruction Splenic artery aneurysm Subileus Thrombosis mesenteric vessel Upper gastrointestinal haemorrhage Volvulus Vomiting General disorders Asthenia Chest discomfort Chest pain Death Device dislocation Device failure Drowning Drug withdrawal syndrome General physical health deterioration Gravitational oedema Hernia Impaired healing Influenza like illness Malaise Multi-organ failure Non-cardiac chest pain Pain Peripheral swelling Polyp		Gastrooesophageal reflux disease 1/7695, 2/7710 Gingival disorder 1/7695, 0/7710 Haemorrhoidal haemorrhage 0/7695, 1/7710 Haemorrhoids 1/7695, 4/7710 Hiatus hernia 0/7695, 3/7710 Ileus 1/7695, 3/7710 Incarcerated umbilical hernia 0/7695, 1/7710 Inguinal hernia 3/7695, 8/7710 Intestinal congestion 0/7695, 1/7710 Intestinal obstruction 3/7695, 3/7710 Intestinal polyp 0/7695, 1/7710 Irritable bowel syndrome1/7695, 2/7710 Large intestine polyp 1/7695, 4/7710 Mallory-weiss syndrome 1/7695, 1/7710 Melaena 1/7695, 0/7710 Nausea 1/7695, 0/7710 Oesophageal ulcer1/7695, 0/7710 Oesophageal varices haemorrhage 0/7695, 1/7710 Oesophagitis 2/7695, 0/7710 Pancreatic cyst 0/7695, 1/7710 Pancreatic fistula 0/7695, 1/7710 Pancreatitis 4/7695, 0/7710 Pancreatitis acute 5/7695, 6/7710 Pancreatitis necrotising 1/7695, 0/7710 Peptic ulcer 0/7695, 1/7710 Peptic ulcer perforation 2/7695, 0/7710 Periodontal disease 1/7695, 0/7710 Peritoneal cyst 1/7695, 1/7710 Peritoneal haemorrhage 0/7695, 1/7710 Pneumoperitoneum 0/7695, 1/7710 Portal hypertensive gastropathy 0/7695, 1/7710 Rectal haemorrhage 0/7695, 1/7710 Rectal polyp 0/7695, 1/7710 Retroperitoneal haemorrhage 0/7695, 1/7710 Small intestinal obstruction 2/7695, 3/7710 Splenic artery aneurysm 0/7695, 1/7710 Subileus 1/7695, 0/7710 Thrombosis mesenteric vessel 0/7695, 1/7710

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
			Pyrexia Strangulated hernia Sudden cardiac death Sudden death Systemic inflammatory response syndrome Hepatobiliary disorders Bile duct obstruction Bile duct stenosis Bile duct stone Biliary colic Cholangitis Cholangitis acute Cholecystitis Cholecystitis acute Cholelithiasis Fatty liver alcoholic Gallbladder polyp Hepatic cirrhosis Hepatic failure Hepatotoxicity Jaundice cholestatic Biliary dyskinesia Anaphylactic reaction Drug hypersensitivity Hypersensitivity Sarcoidosis Abdominal infection Abdominal sepsis Abscess Abscess neck Anal abscess Appendiceal abscess Appendicitis Appendicitis perforated Atypical pneumonia Bacteraemia Bacterial infection Bacteriuria Biliary sepsis Breast abscess Bronchitis Bronchitis bacterial Bronchopneumonia Candiduria Catheter site infection Cellulitis		Upper gastrointestinal haemorrhage 2/7695, 1/7710 Volvulus 0/7695, 1/7710 Vomiting 1/7695, 0/7710 Asthenia 3/7695, 0/7710 Chest discomfort 0/7695, 1/7710 Chest pain 12/7695, 10/7710 Death (in AE table), Device dislocation 0/7695, 1/7710 Device failure 0/7695, 1/7710 Drowning 1/7695, 1/7710 Drug withdrawal syndrome 1/7695, 0/7710 General physical health deterioration 1/7695, 1/7710 Gravitational oedema 1/7695, 0/7710 Hernia 0/7695, 1/7710 Impaired healing 1/7695, 0/7710 Influenza like illness 0/7695, 1/7710 Malaise 2/7695, 0/7710 Multi-organ failure 6/7695, 2/7710 Non-cardiac chest pain 2/7695, 1/7710 Pain 1/7695, 2/7710 Peripheral swelling 1/7695, 0/7710 Polyp 1/7695, 0/7710 Pyrexia 2/7695, 1/7710 Strangulated hernia 0/7695, 1/7710 Sudden cardiac death 0/7695, 3/7710 Sudden death 5/7695, 7/7710 Systemic inflammatory response syndrome 1/7695, 0/7710 Bile duct obstruction 0/7695, 1/7710 Bile duct stenosis 1/7695, 0/7710 Bile duct stone 0/7695, 3/7710 Biliary colic 0/7695, 1/7710 Cholangitis 0/7695, 1/7710 Cholangitis acute 1/7695, 0/7710 Cholecystitis 5/7695, 6/7710 Cholecystitis acute 6/7695, 4/7710 Cholelithiasis 7/7695, 10/7710 Fatty liver alcoholic 0/7695, 1/7710 Gallbladder polyp 1/7695, 0/7710 Hepatic cirrhosis 1/7695, 0/7710 Hepatic failure 1/7695, 1/7710 Hepatotoxicity 1/7695, 0/7710 Jaundice cholestatic 1/7695, 0/7710 Biliary dyskinesia 1/7695, 0/7710

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
			Cellulitis orbital Cellulitis streptococcal Chronic sinusitis Clostridium difficile colitis Clostridium difficile infection Cystitis Cystitis klebsiella Dengue fever Diabetic gangrene Diverticulitis Encephalomyelitis Endocarditis Endometritis Erysipelas Fungaemia Gangrene Gastroenteritis Gastroenteritis caliciviral Gastroenteritis clostridial Gastroenteritis salmonella Gastroenteritis viral Gastrointestinal infection Helicobacter gastritis Hepatitis a Herpes zoster Infected dermal cyst Infected skin ulcer Infection Infectious colitis Influenza Klebsiella sepsis Labyrinthitis Leptospirosis Liver abscess Lobar pneumonia Localised infection Lower respiratory tract infection Lung infection Lymph node tuberculosis Meningitis pneumococcal Mycobacterial infection Nasal abscess Nasopharyngitis Neuroborreliosis Osteomyelitis		Anaphylactic reaction (in AE table), Drug hypersensitivity 0/7695, 1/7710 Hypersensitivity 2/7695, 1/7710 Sarcoidosis 0/7695, 1/7710 Abdominal infection 0/7695, 1/7710 Abdominal sepsis 1/7695, 0/7710 Abscess 1/7695, 0/7710 Abscess neck 1/7695, 0/7710 Anal abscess 0/7695, 1/7710 Appendiceal abscess 0/7695, 1/7710 Appendicitis 3/7695, 6/7710 Appendicitis perforated 1/7695, 0/7710 Atypical pneumonia 0/7695, 1/7710 Bacteraemia 1/7695, 0/7710 Bacterial infection 0/7695, 2/7710 Bacteriuria 1/7695, 0/7710 Biliary sepsis 0/7695, 1/7710 Breast abscess 1/7695, 0/7710 Bronchitis 3/7695, 4/7710 Bronchitis bacterial 0/7695, 1/7710 Bronchopneumonia 2/7695, 0/7710 Candiduria 0/7695, 1/7710 Catheter site infection 0/7695, 1/7710 Cellulitis 8/7695, 6/7710 Cellulitis orbital 0/7695, 1/7710 Cellulitis streptococcal 1/7695, 0/7710 Chronic sinusitis 1/7695, 0/7710 Clostridium difficile colitis 2/7695, 0/7710 Clostridium difficile infection 0/7695, 3/7710 Cystitis 1/7695, 0/7710 Cystitis klebsiella 0/7695, 1/7710 Dengue fever 0/7695, 1/7710 Diabetic gangrene 0/7695, 1/7710 Diverticulitis 4/7695, 6/7710 Encephalomyelitis (in AE table), Endocarditis 1/7695, 1/7710 Endometritis 1/7695, 0/7710 Erysipelas 2/7695, 3/7710 Fungaemia 0/7695, 1/7710 Gangrene 3/7695, 0/7710 Gastroenteritis 3/7695, 4/7710 Gastroenteritis caliciviral 1/7695, 0/7710 Gastroenteritis clostridial 0/7695, 1/7710 Gastroenteritis salmonella 1/7695, 1/7710

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
			Osteomyelitis chronic Otitis media chronic Periodontitis Peritonitis Peritonsillar abscess Pertussis Pharyngitis Pharyngotonsillitis Pneumonia Pneumonia bacterial Pneumonia mycoplasmal Pneumonia pneumococcal Post procedural infection Pseudomembranous colitis Pyelonephritis Pyelonephritis acute Respiratory tract infection Sepsis Septic shock Serratia infection Shigella infection Sinusitis Sinusitis fungal Soft tissue infection Staphylococcal infection Subcutaneous abscess Subdiaphragmatic abscess Superinfection Testicular abscess Toxic shock syndrome Tracheobronchitis Tularaemia Upper respiratory tract infection Upper respiratory tract infection bacterial Urethritis Urinary tract infection Urosepsis Vestibular neuronitis Viral sepsis Viral upper respiratory tract infection Visceral leishmaniasis Wound infection Wound infection pseudomonas		Gastroenteritis viral 2/7695, 0/7710 Gastrointestinal infection 1/7695, 0/7710 Helicobacter gastritis 0/7695, 1/7710 Hepatitis a 1/7695, 0/7710 Herpes zoster (used from paper not from clinicaltrials.gov)0/7695, 1/7710 Infected dermal cyst 1/7695, 0/7710 Infected skin ulcer 1/7695, 0/7710 Infection 1/7695, 1/7710 Infectious colitis 0/7695, 1/7710 Influenza 1/7695, 0/7710 Klebsiella sepsis 1/7695, 0/7710 Labyrinthitis 1/7695, 0/7710 Leptospirosis 1/7695, 0/7710 Liver abscess 1/7695, 0/7710 Lobar pneumonia 1/7695, 2/7710 Localised infection 1/7695, 0/7710 Lower respiratory tract infection 1/7695, 6/7710 Lung infection 1/7695, 0/7710 Lymph node tuberculosis 1/7695, 0/7710 Meningitis pneumococcal (in AE table), Mycobacterial infection 0/7695, 1/7710 Nasal abscess 1/7695, 0/7710 Nasopharyngitis 0/7695, 1/7710 Neuroborreliosis 1/7695, 0/7710 Osteomyelitis 4/7695, 2/7710 Osteomyelitis chronic 0/7695, 1/7710 Otitis media chronic 1/7695, 0/7710 Periodontitis 1/7695, 0/7710 Peritonitis 1/7695, 2/7710 Peritonsillar abscess 1/7695, 0/7710 Pertussis 0/7695, 1/7710 Pharyngitis 1/7695, 0/7710 Pharyngotonsillitis 1/7695, 0/7710 Pneumonia 40/7695, 26/7710 Pneumonia bacterial 1/7695, 0/7710 Pneumonia mycoplasmal 2/7695, 0/7710 Pneumonia pneumococcal 0/7695, 1/7710 Post procedural infection 0/7695, 3/7710 Pseudomembranous colitis 2/7695, 1/7710 Pyelonephritis 6/7695, 3/7710 Pyelonephritis acute 1/7695, 2/7710

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
			Wound infection staphylococcal Accident Acetabulum fracture Anastomotic leak Aneurysm perforation Ankle fracture Burns second degree Burns third degree Cataract operation complication Chemical poisoning Chest injury Clavicle fracture Comminuted fracture Concussion Contusion Craniocerebral injury Electrical burn Eye penetration Facial bones fracture Fall Femoral neck fracture Femur fracture Fibula fracture Flail chest Foot fracture Forearm fracture Fractured sacrum Gun shot wound Hand fracture Head injury Hip fracture Humerus fracture Incarcerated incisional hernia Incisional hernia Joint dislocation Joint injury Laceration Ligament rupture Ligament sprain Limb injury Lower limb fracture Lumbar vertebral fracture Meniscus injury Multiple fractures		Respiratory tract infection 3/7695, 2/7710 Sepsis 7/7695, 13/7710 Septic shock 1/7695, 14/7710 Serratia infection 1/7695, 0/7710 Shigella infection 1/7695, 10/7710 Sinusitis 0/7695, 1/7710 Sinusitis fungal 1/7695, 0/7710 Soft tissue infection 0/7695, 1/7710 Staphylococcal infection 2/7695, 1/7710 Subcutaneous abscess 0/7695, 1/7710 Subdiaphragmatic abscess 0/7695, 1/7710 Superinfection 1/7695, 0/7710 Testicular abscess 1/7695, 0/7710 Toxic shock syndrome 1/7695, 0/7710 Tracheobronchitis 0/7695, 1/7710 Tularaemia 0/7695, 1/7710 Upper respiratory tract infection 2/7695, 2/7710 Upper respiratory tract infection bacterial 2/7695, 0/7710 Urethritis 0/7695, 1/7710 Urinary tract infection 10/7695, 10/7710 Urosepsis 2/7695, 3/7710 Vestibular neuronitis 0/7695, 1/7710 Viral sepsis 1/7695, 0/7710 Viral upper respiratory tract infection 0/7695, 1/7710 Visceral leishmaniasis 0/7695, 1/7710 Wound infection 2/7695, 0/7710 Wound infection pseudomonas 1/7695, 1/7710 Wound infection staphylococcal 0/7695, 1/7710 Accident 1/7695, 1/7710 Acetabulum fracture 0/7695, 1/7710 Anastomotic leak 0/7695, 1/7710 Aneurysm perforation 1/7695, 0/7710 Ankle fracture 7/7695, 4/7710 Burns second degree 1/7695, 0/7710 Burns third degree 1/7695, 0/7710 Cataract operation complication 0/7695, 1/7710 Chemical poisoning 2/7695, 0/7710 Chest injury 1/7695, 0/7710 Clavicle fracture 0/7695, 1/7710

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
			Multiple injuries Muscle rupture Muscle strain Nerve root injury cervical Open fracture Overdose Patella fracture Pelvic fracture Pneumothorax traumatic Poisoning Post procedural haemorrhage Procedural pain Pubis fracture Radius fracture Respiratory fume inhalation disorder Rib fracture Road traffic accident Seroma Skin abrasion Skull fracture Snake bite Soft tissue injury Spinal compression fracture Spinal cord injury Spinal fracture Splenic rupture Sternal fracture Subdural haematoma Spinal cord injury cervical Subdural haemorrhage Tendon injury Tendon rupture Tibia fracture Toxicity to various agents Traumatic intracranial haemorrhage Traumatic shock Ulna fracture Upper limb fracture Vascular pseudoaneurysm ruptured Wound Wound dehiscence Wrist fracture		Comminuted fracture 1/7695, 2/7710 Concussion 2/7695, 0/7710 Contusion 1/7695, 2/7710 Craniocerebral injury 1/7695, 0/7710 Electrical burn 1/7695, 0/7710 Eye penetration 1/7695, 0/7710 Facial bones fracture 2/7695, 1/7710 Fall 2/7695, 2/7710 Femoral neck fracture 5/7695, 4/7710 Femur fracture 7/7695, 3/7710 Fibula fracture 3/7695, 0/7710 Flail chest 0/7695, 1/7710 Foot fracture 1/7695, 1/7710 Forearm fracture 1/7695, 1/7710 Fractured sacrum 1/7695, 1/7710 Gun shot wound 1/7695, 0/7710 Hand fracture 1/7695, 2/7710 Head injury 3/7695, 4/7710 Hip fracture 2/7695, 6/7710 Humerus fracture 2/7695, 2/7710 Incarcerated incisional hernia 1/7695, 1/7710 Incisional hernia 1/7695, 0/7710 Joint dislocation 3/7695, 1/7710 Joint injury 0/7695, 1/7710 Laceration 1/7695, 4/7710 Ligament rupture 1/7695, 1/7710 Ligament sprain 1/7695, 2/7710 Limb injury 0/7695, 1/7710 Lower limb fracture 1/7695, 3/7710 Lumbar vertebral fracture 1/7695, 1/7710 Meniscus injury 3/7695, 1/7710 Multiple fractures 0/7695, 2/7710 Multiple injuries 1/7695, 3/7710 Muscle rupture 0/7695, 1/7710 Muscle strain 1/7695, 0/7710 Nerve root injury cervical 1/7695, 0/7710 Open fracture 0/7695, 1/7710 Overdose 2/7695, 0/7710 Patella fracture 1/7695, 1/7710 Pelvic fracture 1/7695, 1/7710 Pneumothorax traumatic 0/7695, 1/7710 Poisoning 1/7695, 0/7710 Post procedural haemorrhage 1/7695, 2/7710 Procedural pain 3/7695, 1/7710

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
			Investigations Anticoagulation drug level above therapeutic Blood heavy metal increased Haemoglobin decreased Metabolism and nutrition disorders Decreased appetite Dehydration Diabetes mellitus Diabetes mellitus inadequate control Diabetic ketoacidosis Electrolyte imbalance Gout Hyperammonaemia Hyperglycaemia Hyperkalaemia Hyperlipidaemia Hypertriglyceridaemia Hypoglycaemia Hypokalaemia Hyponatraemia Ketoacidosis Malnutrition Metabolic acidosis Obesity Type 1 diabetes mellitus Type 2 diabetes mellitus Arthritis Arthropathy Back pain Costochondritis Fasciitis Foot deformity Intervertebral disc degeneration Intervertebral disc disorder Intervertebral disc protrusion Joint destruction Lumbar spinal stenosis Muscle spasms Musculoskeletal chest pain Musculoskeletal pain Myalgia		Pubis fracture 0/7695, 1/7710 Radius fracture 7/7695, 7/7710 Respiratory fume inhalation disorder 1/7695, 0/7710 Rib fracture 3/7695, 1/7710 Road traffic accident 1/7695, 5/7710 Seroma 0/7695, 1/7710 Skin abrasion 0/7695, 1/7710 Skull fracture 1/7695, 0/7710 Snake bite 2/7695, 0/7710 Soft tissue injury 0/7695, 1/7710 Spinal compression fracture 2/7695, 1/7710 Spinal cord injury 0/7695, 1/7710 Spinal fracture 0/7695, 1/7710 Splenic rupture 1/7695, 1/7710 Sternal fracture 0/7695, 1/7710 Subdural haematoma 2/7695, 1/7710 Spinal cord injury cervical 0/7695, 1/7710 Subdural haemorrhage 1/7695, 1/7710 Tendon injury 0/7695, 1/7710 Tendon rupture 2/7695, 0/7710 Tibia fracture 3/7695, 1/7710 Toxicity to various agents 3/7695, 1/7710 Traumatic intracranial haemorrhage 1/7695, 1/7710 Traumatic shock 0/7695, 1/7710 Ulna fracture 1/7695, 0/7710 Upper limb fracture 4/7695, 1/7710 Vascular pseudoaneurysm ruptured 0/7695, 1/7710 Wound 1/7695, 2/7710 Wound dehiscence 0/7695, 1/7710 Wrist fracture 1/7695, 0/7710 Anticoagulation drug level above therapeutic 0/7695, 1/7710 Blood heavy metal increased 1/7695, 0/7710 Haemoglobin decreased 0/7695, 1/7710 Decreased appetite 1/7695, 0/7710 Dehydration 4/7695, 2/7710 Diabetes mellitus (in AE table), Diabetes mellitus inadequate control 1/7695, 1/7710 Diabetic ketoacidosis 1/7695, 1/7710 Electrolyte imbalance 1/7695, 1/7710

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
			Neck pain Osteitis Osteoarthritis Osteochondrosis Osteolysis Osteonecrosis Periarthritis Polyarthritis Polymyalgia rheumatica Rhabdomyolysis Rheumatoid arthritis Rotator cuff syndrome Soft tissue mass Spinal column stenosis Spinal disorder Spinal osteoarthritis Spondylolisthesis Still's disease adult onset Synovial cyst Systemic lupus erythematosus Tendonitis Abdominal neoplasm Acute leukaemia Acute myeloid leukaemia Acute promyelocytic leukaemia Adenocarcinoma Adenocarcinoma gastric Adenocarcinoma of colon Adenocarcinoma pancreas Adult t-cell lymphoma/leukaemia Angioimmunoblastic t-cell lymphoma Basal cell carcinoma Benign neoplasm of bladder Benign neoplasm of orbit Benign neoplasm of thyroid gland Benign renal neoplasm Benign soft tissue neoplasm Bile duct adenocarcinoma Bile duct cancer Bladder cancer		Gout 1/7695, 0/7710 Hyperammonaemia 1/7695, 0/7710 Hyperglycaemia 1/7695, 2/7710 Hyperkalaemia 1/7695, 0/7710 Hyperlipidaemia 3/7695, 1/7710 Hypertriglyceridaemia 1/7695, 1/7710 Hypoglycaemia 3/7695, 0/7710 Hypokalaemia 2/7695, 1/7710 Hyponatraemia 2/7695, 2/7710 Ketoacidosis 0/7695, 1/7710 Malnutrition 0/7695, 1/7710 Metabolic acidosis 0/7695, 1/7710 Obesity 0/7695, 1/7710 Type 1 diabetes mellitus 0/7695, 2/7710 Type 2 diabetes mellitus 2/7695, 4/7710 Arthritis 1/7695, 0/7710 Arthropathy 2/7695, 0/7710 Back pain 2/7695, 1/7710 Costochondritis 0/7695, 1/7710 Fasciitis 1/7695, 0/7710 Foot deformity 0/7695, 2/7710 Intervertebral disc degeneration 0/7695, 1/7710 Intervertebral disc disorder 0/7695, 1/7710 Intervertebral disc protrusion 1/7695, 7/7710 Joint destruction 0/7695, 1/7710 Lumbar spinal stenosis 1/7695, 0/7710 Muscle spasms 0/7695, 1/7710 Musculoskeletal chest pain 1/7695, 0/7710 Musculoskeletal pain 1/7695, 0/7710 Myalgia 1/7695, 0/7710 Neck pain 1/7695, 0/7710 Osteitis 0/7695, 1/7710 Osteoarthritis 8/7695, 11/7710 Osteochondrosis 1/7695, 0/7710 Osteolysis 1/7695, 0/7710 Osteonecrosis 4/7695, 0/7710 Periarthritis 0/7695, 1/7710 Polyarthritis 1/7695, 0/7710 Polymyalgia rheumatica 1/7695, 1/7710 Rhabdomyolysis 1/7695, 0/7710 Rheumatoid arthritis 1/7695, 2/7710 Rotator cuff syndrome 1/7695, 2/7710 Soft tissue mass 0/7695, 1/7710

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
			Bladder neoplasm Bowen's disease Brain cancer metastatic Brain neoplasm Brain neoplasm malignant Breast cancer Breast cancer female Breast cancer in situ Breast cancer metastatic Bronchial carcinoma Bronchial neoplasm Carcinoid tumour of the small bowel Cervix carcinoma Cervix carcinoma recurrent Cholangiocarcinoma Chronic lymphocytic leukaemia Chronic myeloid leukaemia Colon adenoma Colon cancer Diffuse large b-cell lymphoma Endometrial adenocarcinoma Extranodal marginal zone b-cell lymphoma (malt type) Fallopian tube cancer Gallbladder cancer Gastric cancer Gastrointestinal neoplasm Gastrointestinal stromal tumour Glioblastoma Glioblastoma multiforme Glioma Glomus tumour Hepatic cancer Hepatic cancer metastatic Hepatic neoplasm Hepatocellular carcinoma Hypopharyngeal cancer Intraductal proliferative breast lesion Invasive ductal breast carcinoma		Spinal column stenosis 1/7695, 2/7710 Spinal disorder 1/7695, 0/7710 Spinal osteoarthritis 1/7695, 3/7710 Spondylolisthesis 3/7695, 0/7710 Still's disease adult onset 1/7695, 0/7710 Synovial cyst 1/7695, 1/7710 Systemic lupus erythematosus 1/7695, 0/7710 Tendonitis 1/7695, 0/7710 Abdominal neoplasm 1/7695, 0/7710 Acute leukaemia 0/7695, 1/7710 Acute myeloid leukaemia 0/7695, 2/7710 Acute promyelocytic leukaemia 1/7695, 0/7710 Adenocarcinoma 1/7695, 1/7710 Adenocarcinoma gastric2/7695, 2/7710 Adenocarcinoma of colon 2/7695, 1/7710 Adenocarcinoma pancreas 0/7695, 1/7710 Adult t-cell lymphoma/leukaemia 1/7695, 0/7710 Angioimmunoblastic t-cell lymphoma 1/7695, 0/7710 Basal cell carcinoma 4/7695, 1/7710 Benign neoplasm of bladder 0/7695, 1/7710 Benign neoplasm of orbit 0/7695, 1/7710 Benign neoplasm of thyroid gland 1/7695, 0/7710 Benign renal neoplasm 1/7695, 0/7710 Benign soft tissue neoplasm 0/7695, 1/7710 Bile duct adenocarcinoma 1/7695, 0/7710 Bile duct cancer 1/7695, 0/7710 Bladder cancer 3/7695, 5/7710 Bladder neoplasm 0/7695, 4/7710 Bowen's disease 0/7695, 1/7710 Brain cancer metastatic 0/7695, 1/7710 Brain neoplasm 1/7695, 0/7710 Brain neoplasm malignant 0/7695, 2/7710 Breast cancer 8/7695, 6/7710 Breast cancer female 1/7695, 0/7710 Breast cancer in situ 0/7695, 1/7710

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
			Invasive papillary breast carcinoma Laryngeal cancer Laryngeal neoplasm Leukaemia Lip and/or oral cavity cancer Lip squamous cell carcinoma Lipoma Lung adenocarcinoma Lung adenocarcinoma metastatic Lung adenocarcinoma stage i Lung cancer metastatic Lung neoplasm Lung neoplasm malignant Lymphoma Malignant melanoma Malignant neoplasm of pleura metastatic Malignant neoplasm of unknown primary site Malignant pleural effusion Melanocytic naevus Meningioma benign Metastases to central nervous system Metastases to liver Metastases to lung Metastases to lymph Metastases to peritoneum Metastases to pleura Metastasis Metastatic carcinoma of the bladder Metastatic malignant melanoma Metastatic neoplasm Metastatic squamous cell carcinoma Nasopharyngeal cancer Neoplasm malignant Neoplasm skin Neuroendocrine carcinoma Non-small cell lung cancer		Breast cancer metastatic 1/7695, 0/7710 Bronchial carcinoma 1/7695, 2/7710 Bronchial neoplasm 1/7695, 0/7710 Carcinoid tumour of the small bowel 0/7695, 1/7710 Cervix carcinoma 1/7695, 1/7710 Cervix carcinoma recurrent 0/7695, 1/7710 Cholangiocarcinoma 3/7695, 3/7710 Chronic lymphocytic leukaemia 1/7695, 0/7710 Chronic myeloid leukaemia 2/7695, 0/7710 Colon adenoma 1/7695, 0/7710 Colon cancer 7/7695, 11/7710 Diffuse large b-cell lymphoma 0/7695, 1/7710 Endometrial adenocarcinoma 1/7695, 0/7710 Extranodal marginal zone b-cell lymphoma (malt type) 1/7695, 0/7710 Fallopian tube cancer 1/7695, 0/7710 Gallbladder cancer 1/7695, 1/7710 Gastric cancer 4/7695, 4/7710 Gastrointestinal neoplasm 1/7695, 0/7710 Gastrointestinal stromal tumour 0/7695, 1/7710 Glioblastoma 0/7695, 1/7710 Glioblastoma multiforme 0/7695, 1/7710 Glioma 1/7695, 1/7710 Glomus tumour 0/7695, 1/7710 Hepatic cancer 4/7695, 1/7710 Hepatic cancer metastatic 1/7695, 0/7710 Hepatic neoplasm 0/7695, 1/7710 Hepatocellular carcinoma 1/7695, 2/7710 Hypopharyngeal cancer 1/7695, 0/7710 Intraductal proliferative breast lesion 3/7695, 2/7710 Invasive ductal breast carcinoma 5/7695, 4/7710 Invasive papillary breast carcinoma 2/7695, 0/7710 Laryngeal cancer 1/7695, 0/7710 Laryngeal neoplasm 0/7695, 1/7710

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
			Oesophageal adenocarcinoma Oesophageal carcinoma Oesophageal squamous cell carcinoma Ovarian cancer Ovarian fibroma Ovarian neoplasm Pancreatic carcinoma Pancreatic carcinoma metastatic Pancreatic neoplasm Phaeochromocytoma Plasma cell myeloma Pleural mesothelioma Prostate cancer Prostate cancer metastatic Prostate cancer recurrent Prostatic adenoma Rectal adenocarcinoma Rectal adenoma Rectal cancer Renal cancer Renal cancer metastatic Renal neoplasm Renal oncocytoma Skin cancer Small intestine adenocarcinoma Spinal cord neoplasm Squamous cell carcinoma Squamous cell carcinoma of lung Squamous cell carcinoma of skin Squamous cell carcinoma of the oral cavity Testicular neoplasm Thyroid adenoma Thyroid cancer Thyroid neoplasm Tongue neoplasm malignant stage unspecified Tumour haemorrhage Uterine cancer Uterine leiomyoma		Leukaemia 1/7695, 1/7710 Lip and/or oral cavity cancer 1/7695, 0/7710 Lip squamous cell carcinoma 1/7695, 0/7710 Lipoma 0/7695, 2/7710 Lung adenocarcinoma 4/7695, 3/7710 Lung adenocarcinoma metastatic 0/7695, 2/7710 Lung adenocarcinoma stage i 1/7695, 0/7710 Lung cancer metastatic 3/7695, 1/7710 Lung neoplasm 1/7695, 0/7710 Lung neoplasm malignant 11/7695, 6/7710 Lymphoma 1/7695, 4/7710 Malignant melanoma 2/7695, 1/7710 Malignant neoplasm of pleura metastatic 0/7695, 1/7710 Malignant neoplasm of unknown primary site 1/7695, 0/7710 Malignant pleural effusion 0/7695, 1/7710 Melanocytic naevus 1/7695, 0/7710 Meningioma benign 0/7695, 1/7710 Metastases to central nervous system 1/7695, 0/7710 Metastases to liver 3/7695, 3/7710 Metastases to lung 1/7695, 3/7710 Metastases to lymph 1/7695, 2/7710 Metastases to peritoneum 2/7695, 0/7710 Metastases to pleura 1/7695, 0/7710 Metastasis 0/7695, 1/7710 Metastatic carcinoma of the bladder 1/7695, 0/7710 Metastatic malignant melanoma 1/7695, 1/7710 Metastatic neoplasm 1/7695, 0/7710 Metastatic squamous cell carcinoma 2/7695, 0/7710 Nasopharyngeal cancer 0/7695, 1/7710 Neoplasm malignant 1/7695, 1/7710 Neoplasm skin 1/7695, 0/7710 Neuroendocrine carcinoma 1/7695, 0/7710

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
			Vulval cancer Nervous system disorders Amyotrophic lateral sclerosis Aphasia Basal ganglia haemorrhage Basal ganglia infarction Brain injury Carotid artery disease Carotid artery stenosis Carotid artery thrombosis Cerebral haemorrhage Cerebral infarction Cerebral ischaemia Cerebrovascular accident Cerebrovascular disorder Cerebrovascular insufficiency Cervicobrachial syndrome Chronic inflammatory demyelinating polyradiculoneuropathy Coma Dementia alzheimer's type Demyelinating polyneuropathy Diabetic neuropathy Dizziness Encephalopathy Epilepsy Generalised tonic-clonic seizure Guillain-barre syndrome Haemorrhage intracranial Haemorrhagic transformation stroke Headache Hemiparesis Hydrocephalus Hypoaesthesia Intracranial aneurysm Ischaemic stroke Ivth nerve paralysis Lacunar infarction Loss of consciousness Lumbar radiculopathy		Non-small cell lung cancer 1/7695, 1/7710 Oesophageal adenocarcinoma 0/7695, 1/7710 Oesophageal carcinoma 0/7695, 1/7710 Oesophageal squamous cell carcinoma 1/7695, 0/7710 Ovarian cancer 3/7695, 0/7710 Ovarian fibroma 1/7695, 0/7710 Ovarian neoplasm 0/7695, 1/7710 Pancreatic carcinoma 6/7695, 8/7710 Pancreatic carcinoma metastatic 3/7695, 2/7710 Pancreatic neoplasm 0/7695, 1/7710 Phaeochromocytoma 1/7695, 0/7710 Plasma cell myeloma 3/7695, 2/7710 Pleural mesothelioma 0/7695, 1/7710 Prostate cancer 7/7695, 9/7710 Prostate cancer metastatic 3/7695, 0/7710 Prostate cancer recurrent 1/7695, 0/7710 Prostatic adenoma 0/7695, 1/7710 Rectal adenocarcinoma 0/7695, 1/7710 Rectal adenoma 0/7695, 1/7710 Rectal cancer 0/7695, 2/7710 Renal cancer 1/7695, 3/7710 Renal cancer metastatic 0/7695, 1/7710 Renal neoplasm 1/7695, 2/7710 Renal oncocytoma 1/7695, 0/7710 Skin cancer 1/7695, 0/7710 Small intestine adenocarcinoma 1/7695, 0/7710 Spinal cord neoplasm 0/7695, 1/7710 Squamous cell carcinoma 0/7695, 1/7710 Squamous cell carcinoma of lung 1/7695, 1/7710 Squamous cell carcinoma of skin 1/7695, 0/7710 Squamous cell carcinoma of the oral cavity 0/7695, 1/7710 Testicular neoplasm 0/7695, 1/7710 Thyroid adenoma 1/7695, 0/7710 Thyroid cancer 0/7695, 1/7710 Thyroid neoplasm 0/7695, 1/7710

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
			Metabolic encephalopathy Migraine Mononeuritis Myasthenia gravis Myelopathy Nerve compression Nervous system disorder Neuritis cranial Paraesthesia Paraneoplastic neurological syndrome Post polio syndrome Presyncope Radiculopathy Reversible ischaemic neurological deficit Ruptured cerebral aneurysm Sciatica Seizure Spinal claudication Subarachnoid haemorrhage Syncope Transient global amnesia Transient ischaemic attack Trigeminal neuralgia Vascular encephalopathy Vasculitis cerebral Viith nerve paralysis Psychiatric disorders Abnormal behaviour Adjustment disorder Completed suicide Delirium Delirium febrile Depression Generalised anxiety disorder Korsakoff's syndrome Major depression Mental status changes Psychotic disorder Somatoform disorder Suicidal ideation Suicide attempt		Tongue neoplasm malignant stage unspecified 1/7695, 0/7710 Tumour haemorrhage 1/7695, 0/7710 Uterine cancer 0/7695, 2/7710 Uterine leiomyoma 1/7695, 0/7710 Vulval cancer 1/7695, 0/7710 Amyotrophic lateral sclerosis (in AE table), Aphasia 1/7695, 0/7710 Basal ganglia haemorrhage 0/7695, 1/7710 Basal ganglia infarction 1/7695, 0/7710 Brain injury 0/7695, 1/7710 Carotid artery disease 1/7695, 0/7710 Carotid artery stenosis 1/7695, 1/7710 Carotid artery thrombosis 0/7695, 1/7710 Cerebral haemorrhage 2/7695, 4/7710 Cerebral infarction 8/7695, 6/7710 Cerebral ischaemia 0/7695, 2/7710 Cerebrovascular accident (in AE table)19/7695, 12/7710 Cerebrovascular disorder 0/7695, 1/7710 Cerebrovascular insufficiency 1/7695, 0/7710 Cervicobrachial syndrome 1/7695, 0/7710 Chronic inflammatory demyelinating polyradiculoneuropathy 0/7695, 1/7710 Coma 0/7695, 1/7710 Dementia alzheimer's type 0/7695, 1/7710 Demyelinating polyneuropathy 1/7695, 0/7710 Diabetic neuropathy 1/7695, 0/7710 Dizziness 3/7695, 4/7710 Encephalopathy (in AE table), Epilepsy 1/7695, 4/7710 Generalised tonic-clonic seizure 1/7695, 0/7710 Guillain-barre syndrome (in AE table), Haemorrhage intracranial 0/7695, 1/7710 Haemorrhagic transformation stroke 1/7695, 0/7710 Headache 4/7695, 0/7710 Hemiparesis 1/7695, 0/7710

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
			Renal and urinary disorders Acute kidney injury Azotaemia Bladder prolapse Calculus bladder Calculus ureteric Calculus urinary Chronic kidney disease Diabetic nephropathy Haematuria Nephrolithiasis Renal artery arteriosclerosis Renal artery occlusion Renal colic Renal cyst Renal failure Renal impairment Stress urinary incontinence Tubulointerstitial nephritis Urethral polyp Urinary incontinence Urinary retention Benign prostatic hyperplasia Cystocele Endometrial hypertrophy Fibrocystic breast disease Ovarian cyst Postmenopausal haemorrhage Prostatitis Prostatomegaly Rectocele Uterine enlargement Uterine prolapse Uterovaginal prolapse Dyspnoea Acute pulmonary oedema Acute respiratory failure Aspiration Asthma Bronchiectasis Bronchitis chronic		Hydrocephalus 0/7695, 1/7710 Hypoaesthesia 0/7695, 1/7710 Intracranial aneurysm 1/7695, 0/7710 Ischaemic stroke 1/7695, 3/7710 Ivth nerve paralysis 0/7695, 1/7710 Lacunar infarction 0/7695, 1/7710 Loss of consciousness 1/7695, 0/7710 Lumbar radiculopathy 1/7695, 0/7710 Metabolic encephalopathy 0/7695, 2/7710 Migraine 0/7695, 1/7710 Mononeuritis 0/7695, 1/7710 Myasthenia gravis 0/7695, 1/7710 Myelopathy 0/7695, 1/7710 Nerve compression 1/7695, 0/7710 Nervous system disorder 1/7695, 0/7710 Neuritis cranial 1/7695, 0/7710 Paraesthesia 1/7695, 0/7710 Paraneoplastic neurological syndrome 0/7695, 1/7710 Post polio syndrome 0/7695, 1/7710 Presyncope 1/7695, 1/7710 Radiculopathy 0/7695, 2/7710 Reversible ischaemic neurological deficit 1/7695, 0/7710 Ruptured cerebral aneurysm 0/7695, 1/7710 Sciatica 2/7695, 1/7710 Seizure (in AE table), Spinal claudication 0/7695, 1/7710 Subarachnoid haemorrhage 2/7695, 4/7710 Syncope 8/7695, 8/7710 Transient global amnesia 1/7695, 0/7710 Transient ischaemic attack 8/7695, 6/7710 Trigeminal neuralgia 1/7695, 0/7710 Vascular encephalopathy 1/7695, 0/7710 Vasculitis cerebral 1/7695, 0/7710 Viith nerve paralysis 0/7695, 1/7710 Abnormal behaviour 0/7695, 1/7710 Adjustment disorder 0/7695, 1/7710 Completed suicide 4/7695, 4/7710 Delirium 0/7695, 1/7710 Delirium febrile 1/7695, 0/7710

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
			Chronic obstructive pulmonary disease Emphysema Epistaxis Haemoptysis Hypoxia Idiopathic pulmonary fibrosis Lung disorder Nasal polyps Nasal septum deviation Nasal turbinate hypertrophy Paranasal cyst Pickwickian syndrome Pleural calcification Pleural effusion Pleurisy Pneumonia aspiration Pneumothorax Pulmonary bulla Pulmonary congestion Pulmonary embolism Pulmonary fibrosis Pulmonary oedema Respiratory acidosis Respiratory arrest Respiratory distress Respiratory failure Sleep apnoea syndrome Decubitus ulcer Dermal cyst Dermatitis Diabetic foot Eczema Erythema multiforme Hyperkeratosis Leukoplakia Psoriasis Skin ulcer Cardiac pacemaker replacement Vascular disorders Aneurysm Angiodysplasia Aortic aneurysm Aortic dilatation		Depression 3/7695, 4/7710 Generalised anxiety disorder 1/7695, 0/7710 Korsakoff's syndrome 0/7695, 1/7710 Major depression 1/7695, 0/7710 Mental status changes 0/7695, 1/7710 Psychotic disorder 1/7695, 3/7710 Somatoform disorder 2/7695, 0/7710 Suicidal ideation 1/7695, 0/7710 Suicide attempt 4/7695, 0/7710 Acute kidney injury 8/7695, 4/7710 Azotaemia 0/7695, 1/7710 Bladder prolapse 0/7695, 1/7710 Calculus bladder 1/7695, 0/7710 Calculus ureteric 4/7695, 0/7710 Calculus urinary 1/7695, 0/7710 Chronic kidney disease 2/7695, 6/7710 Diabetic nephropathy 2/7695, 0/7710 Haematuria 1/7695, 0/7710 Nephrolithiasis 1/7695, 2/7710 Renal artery arteriosclerosis 0/7695, 1/7710 Renal artery occlusion 1/7695, 1/7710 Renal colic 0/7695, 1/7710 Renal cyst 0/7695, 2/7710 Renal failure 0/7695, 3/7710 Renal impairment 1/7695, 1/7710 Stress urinary incontinence 1/7695, 0/7710 Tubulointerstitial nephritis 2/7695, 0/7710 Urethral polyp 0/7695, 1/7710 Urinary incontinence 1/7695, 0/7710 Urinary retention 1/7695, 4/7710 Reproductive system and breast disorders (category in AE table, supplementary material) Benign prostatic hyperplasia 3/7695, 2/7710 Cystocele 3/7695, 0/7710 Endometrial hypertrophy 0/7695, 1/7710 Fibrocystic breast disease 0/7695, 1/7710 Ovarian cyst 1/7695, 0/7710 Postmenopausal haemorrhage 1/7695, 0/7710 Prostatitis 1/7695, 0/7710

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
			Aortic dissection Aortic rupture Aortic stenosis Arterial disorder Arterial thrombosis Arteriosclerosis Bleeding varicose vein Circulatory collapse Deep vein thrombosis Diabetic vascular disorder Essential hypertension Haematoma Haemodynamic instability Haemorrhage Hypertension Hypertensive crisis Hypertensive emergency Hypotension Hypovolaemic shock Intermittent claudication Orthostatic hypertension Orthostatic hypotension Peripheral arterial occlusive disease Peripheral artery stenosis Peripheral artery thrombosis Peripheral embolism Peripheral ischaemia Peripheral vascular disorder Peripheral venous disease Polyarteritis nodosa Shock haemorrhagic Superior vena cava syndrome Temporal arteritis Thrombophlebitis Varicose ulceration Varicose vein Gastrointestinal disorders Gastrointestinal disorder General disorders Chills Fatigue Injection site erythema Injection site pain		Prostatomegaly 0/7695, 1/7710 Rectocele 1/7695, 0/7710 Uterine enlargement 1/7695, 0/7710 Uterine prolapse 0/7695, 1/7710 Uterovaginal prolapse 0/7695, 1/7710 Dyspnoea 3/7695, 0/7710 Acute pulmonary oedema 0/7695, 2/7710 Acute respiratory failure 2/7695, 3/7710 Aspiration 1/7695, 0/7710 Asthma (see AE table), Bronchiectasis 0/7695, 1/7710 Bronchitis chronic 1/7695, 1/7710 Chronic obstructive pulmonary disease 8/7695, 8/7710 Emphysema 1/7695, 0/7710 Epistaxis 0/7695, 1/7710 Haemoptysis 1/7695, 1/7710 Hypoxia 2/7695, 0/7710 Idiopathic pulmonary fibrosis 1/7695, 1/7710 Lung disorder 2/7695, 0/7710 Nasal polyps 1/7695, 0/7710 Nasal septum deviation 0/7695, 1/7710 Nasal turbinate hypertrophy 0/7695, 1/7710 Paranasal cyst 1/7695, 0/7710 Pickwickian syndrome 0/7695, 1/7710 Pleural calcification 1/7695, 0/7710 Pleural effusion 3/7695, 4/7710 Pleurisy 0/7695, 2/7710 Pneumonia aspiration 1/7695, 4/7710 Pneumothorax 1/7695, 1/7710 Pulmonary bulla 0/7695, 1/7710 Pulmonary congestion 1/7695, 0/7710 Pulmonary embolism 6/7695, 13/7710 Pulmonary fibrosis 1/7695, 0/7710 Pulmonary oedema 2/7695, 1/7710 Respiratory acidosis 1/7695, 0/7710 Respiratory arrest 0/7695, 1/7710 Respiratory distress 1/7695, 0/7710 Respiratory failure 7/7695, 12/7710 Sleep apnoea syndrome 1/7695, 0/7710 Decubitus ulcer 0/7695, 1/7710 Dermal cyst 1/7695, 0/7710 Dermatitis 0/7695, 1/7710 Diabetic foot 1/7695, 0/7710

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
			Injection site swelling Pain Pyrexia Swelling Myalgia Headache Erythema		Eczema 0/7695, 1/7710 Erythema multiforme 0/7695, 1/7710 Hyperkeratosis 1/7695, 0/7710 Leukoplakia 0/7695, 1/7710 Psoriasis 0/7695, 1/7710 Skin ulcer 4/7695, 0/7710 Cardiac pacemaker replacement 0/7695, 1/7710 Aneurysm 0/7695, 1/7710 Angiodysplasia 1/7695, 0/7710 Aortic aneurysm 0/7695, 3/7710 Aortic dilatation 0/7695, 1/7710 Aortic dissection 1/7695, 0/7710 Aortic rupture 0/7695, 1/7710 Aortic stenosis 0/7695, 3/7710 Arterial disorder 1/7695, 0/7710 Arterial thrombosis 0/7695, 1/7710 Arteriosclerosis 1/7695, 2/7710 Bleeding varicose vein 1/7695, 0/7710 Circulatory collapse 2/7695, 3/7710 Deep vein thrombosis 3/7695, 5/7710 Diabetic vascular disorder 1/7695, 0/7710 Essential hypertension 1/7695, 0/7710 Haematoma 1/7695, 3/7710 Haemodynamic instability 0/7695, 1/7710 Haemorrhage 1/7695, 1/7710 Hypertension 8/7695, 10/7710 Hypertensive crisis 2/7695, 3/7710 Hypertensive emergency 0/7695, 1/7710 Hypotension 2/7695, 2/7710 Hypovolaemic shock 0/7695, 3/7710 Intermittent claudication 0/7695, 2/7710 Orthostatic hypertension 0/7695, 1/7710 Orthostatic hypotension 2/7695, 2/7710 Peripheral arterial occlusive disease 2/7695, 4/7710 Peripheral artery stenosis 2/7695, 0/7710 Peripheral artery thrombosis 0/7695, 1/7710 Peripheral embolism 0/7695, 1/7710 Peripheral ischaemia 0/7695, 1/7710 Peripheral vascular disorder 1/7695, 1/7710

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
					Peripheral venous disease 2/7695, 0/7710 Polyarteritis nodosa 0/7695, 1/7710 Shock haemorrhagic 0/7695, 1/7710 Superior vena cava syndrome 0/7695, 1/7710 Temporal arteritis 1/7695, 0/7710 Thrombophlebitis 2/7695, 0/7710 Varicose ulceration 1/7695, 0/7710 Varicose vein 0/7695, 1/7710 Risk factors: NR
Marechal, 2018[165] Dezure, 2018[251]; GlaxoSmithKline, 2015[274] NCT02045836 Article RCT N=865 Industry funded USA, Canada, Estonia	Age: Co-Ad: 63.2 (8.4); Control: 63.2 (8.4) % female: Co-Ad: 61%, Control 58% Ethnicity: Co-ad: 94% Caucasian, 3% African American, 3% Others; Control: Co-ad: 94% Caucasian, 2% African American, 4% Others Adults who are 50 years of age or older at the time of first intervention Out of scope: None	ZosterAdj Shingrix 100 µg in 2 doses (50 µg per 0.5ml of VZV in 2 doses) Intramuscular Other : AS01b adjuvant system (50 ug MPL and 50 ug QS-21 preservative free Co-intervention PPSV23 (one dose) (also later received 2 doses of RZV but not counted here Base treatment PPSV23 vaccine Pneumovax 23 0.5 mL dose once Intramuscular adjuvant freePhenol Counts No prespecified AE Power unclear Followup: 12 months	Leukocytosis Acute myocardial infarction Atrial fibrillation Cardiac failure congestive Tachycardia Ventricular tachycardia Colitis ulcerative Gastric ulcer Asthenia Chest pain Sarcoidosis Bacteraemia Cellulitis Escherichia urinary tract infection Gastroenteritis salmonella Pelvic abscess Pneumonia Limb traumatic amputation Gout Hyperlipidaemia Osteoarthritis Angiomyolipoma Bladder transitional cell carcinoma stage iv Breast cancer Chronic lymphocytic leukaemia Glioblastoma multiforme Invasive ductal breast carcinoma Carotid artery stenosis Central nervous system lesion Cerebral infarction Dizziness	Herpes Zoster: 11.X NR (from article only) I: 0/429 11.X NR (from article only) C: 0/432	Zoster occurred in Co-Ad group but 302 days later. Not counted in above table, which compares the 2 months post-RZV+PPSV23 versus PPSV23 alone Solicited local symptoms: RZV+PPSV23 84.1% (12.6% grade 3), PPSV23 alone 41.3% (1.6% grade 3) Solicited general symptoms: RZV+PPSV23 64.4% (12.2% grade 3), PPSV23 alone 37.0% (2.1% grade 3) After the second dose of RZV, which was always administered as a standalone vaccine, fatigue was the most frequent solicited general symptom, reported by 46.0% and 41.5% of participants in the Co-Ad and Control groups. Proportions of participants reporting at least 1 general or local solicited reaction after the second RZV dose were similar in the 2 study groups Below AEs are from the follow-up period and cannot be used as by that time all participants received both vaccines (RZV and PPSV23) Serious AEs (from clinicaltrials.gov), Affected / at Risk (%) vs Affected / at Risk (%) Total 17/432 (3.94%) vs 19/433 (4.39%) Leukocytosis 0/432 (0.00%) vs 1/433 (0.23%) Cardiac disorders Acute myocardial infarction 3/432 (0.69%) 1/433 (0.23%) (in AE table) Atrial fibrillation 2/432 (0.46%) 1/433 (0.23%)

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
			Embolic stroke Lumbosacral radiculopathy Syncope Transient ischaemic attack Vertebral artery dissection Delirium Calculus urinary Chronic obstructive pulmonary disease Dyspnoea Pneumonia aspiration Vascular disorders Aortic dissection Arteriosclerosis Deep vein thrombosis Gastrointestinal disorders Chills (prespecified) Fatigue (prespecified) Pain (prespecified) Pyrexia (prespecified) Swelling (prespecified) Erythema (prespecified) Myalgia (prespecified) Headache(prespecified) Gastrointestinal symptoms (prespecified)		Cardiac failure congestive 1/432 (0.23%) 2/433 (0.46%) Tachycardia 1/432 (0.23%) 0/433 (0.00%) Ventricular tachycardia 0/432 (0.00%) 1/433 (0.23%) Colitis ulcerative 0/432 (0.00%) vs 1/433 (0.23%) (in AE table) Gastric ulcer 1/432 (0.23%) vs0/433 (0.00%) Asthenia 1/432 (0.23%) vs 0/433 (0.00%) Chest pain 0/432 (0.00%) vs2/433 (0.46%) Sarcoidosis 1/432 (0.23%) vs 0/433 (0.00%) (in AE table) Bacteraemia 0/432 (0.00%) vs 1/433 (0.23%) Cellulitis 0/432 (0.00%) vs1/433 (0.23%) Escherichia urinary tract infection 0/432 (0.00%) vs 1/433 (0.23%) Gastroenteritis salmonella 1/432 (0.23%) vs 0/433 (0.00%) Pelvic abscess 0/432 (0.00%) vs1/433 (0.23%) Pneumonia 1/432 (0.23%) vs 3/433 (0.69%) Limb traumatic amputation 1/432 (0.23%) vs 0/433 (0.00%) Gout 1/432 (0.23%) vs 0/433 (0.00%) Hyperlipidaemia 0/432 (0.00%) vs 1/433 (0.23%) Osteoarthritis 1/432 (0.23%) vs 0/433 (0.00%) Angiomyolipoma 1/432 (0.23%) vs0/433 (0.00%) Bladder transitional cell carcinoma stage iv 1/432 (0.23%) vs 0/433 (0.00%) Breast cancer 1/432 (0.23%) vs 0/433 (0.00%) Chronic lymphocytic leukaemia 0/432 (0.00%) vs 1/433 (0.23%) Glioblastoma multiforme 0/432 (0.00%) vs 1/433 (0.23%) Invasive ductal breast carcinoma 1/432 (0.23%) vs 0/433 (0.00%) Carotid artery stenosis 0/432 (0.00%) vs 1/433 (0.23%)

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
					Central nervous system lesion 0/432 (0.00%) vs 1/433 (0.23%) Cerebral infarction 0/432 (0.00%) vs2/433 (0.46%) (in AE table) Dizziness 1/432 (0.23%) vs 0/433 (0.00%) Embolic stroke 1/432 (0.23%) vs 0/433 (0.00%) Lumbosacral radiculopathy 0/432 (0.00%) vs 1/433 (0.23%) Syncope 1/432 (0.23%) vs 0/433 (0.00%) Transient ischaemic attack 0/432 (0.00%) vs1/433 (0.23%) Vertebral artery dissection 0/432 (0.00%) vs 1/433 (0.23%) Delirium 0/432 (0.00%) vs 1/433 (0.23%) Calculus urinary 0/432 (0.00%) vs 1/433 (0.23%) Chronic obstructive pulmonary disease 1/432 (0.23%) vs 0/433 (0.00%) Dyspnoea 1/432 (0.23%) vs0/433 (0.00%) Pneumonia aspiration 0/432 (0.00%) vs 1/433 (0.23%) Risk factors: Solicited local symptoms after the first RZV dose were reported by similar percentages of participants in both groups. Solicited general symptoms were more frequently reported when the first dose of RZV and PPSV23 were co-administered. No differences were apparent between groups after the second RZV dose.
Schwarz, 2017[194] GlaxoSmithKline, 2014[271] NCT01954251 Article RCT N=828 Industry funded	Age: Intervention: 63.4 (8.3), Control: 63.4 (8.8) % female: Intervention: 51%, Control: 53% Ethnicity: Intervention: 92% White/European,	ZosterAdj Shingrix Dose 1 was 0.5 mL containing 50 µg VZV gE and the AS01B Adjuvant System con-taining 50 µg of MPL (3-O-desacyl-4'-monophosphoryl lipid A; produced by GSK) and 50 µg of QS-21 (Quillaja sapon-aria Molina,	Hypochromic anaemia Cardiac disorders Coronary artery disease Atrial fibrillation Acute myocardial infarction Angina unstable Cardiac failure congestive Aortic valve stenosis Atrial flutter Cardiac failure Congestive cardiomyopathy Myocardial infarction Vertigo	Death: NA none of the deaths were considered to be related to the vaccine, and that all but 1 death in intervention group occurred after 90 days (metastatic hepatocellular cancer) I: 2/413, NA all deaths occurred after 90 days after 2nd dose C: 5/415 Herpes Zoster: 11.X Within 2 months I: 0/415 11.X Within 2 months C: 2/413	Intervention (HZ/su first dose + IIV) vs Control (IIV alone) Solicited general reactions, Grade 3: Intervention 8.8% vs Control 2.7% Risk factors: NR

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
Canada, Germany, USA	2% African/African American, 4% Asian/Southeast Asian, 1% Other, Control: 92% White/European, 1% African/African American, 5% Asian/Southeast Asian, 1% Other Adults Aged 50 Years or Older Out of scope: None	fraction 21; licensed by GSK Route NR Other : AS01B preservative free Co-intervention IIV (Fluarix) Base treatment Same influenza vaccine as received by Fluarix Quadrivalent or Influsplit Tetra IIV4 (Influsplit Tetra in Germany, Fluarix Quadrivalent in Canada and USA contained 15 µg of hemagglutinin from each of 4 strains (Northern Hemisphere formulation for 2013–2014) per 0.5-mL monodose syringe. The 4 strains w route NR adjuvant freepreservative free Counts No prespecified AE Power other outcome Followup: 12 months	Vestibular disorder Endocrine disorders Hypothyroidism Eye disorders Blindness Hiatus hernia Intestinal obstruction Pancreatitis Colitis ulcerative Diarrhoea Ileus Inguinal hernia Lower gastrointestinal haemorrhage Nausea Small intestinal obstruction Gastric ulcer Asthenia Pain Pyrexia Death (unknown causes) Hepatobiliary disorders Cholelithiasis Cholecystitis Cholecystitis acute Pneumonia Urinary tract infection Urosepsis Anal abscess Appendicitis Breast cellulitis Cellulitis Cellulitis pharyngeal Cystitis Diverticulitis Erysipelas Lung infection Subcutaneous abscess Abscess Ankle fracture Femoral neck fracture Femur fracture Patella fracture Road traffic accident Tendon injury Traumatic lung injury Hypokalaemia		

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
			Osteoarthritis Foot deformity Intervertebral disc disorder Intervertebral disc protrusion Musculoskeletal discomfort Rheumatoid arthritis Spinal osteoarthritis Lumbar spinal stenosis Pancreatic carcinoma Adrenal adenoma Bladder cancer Breast cancer metastatic Breast cancer Hepatic cancer Hepatic cancer metastatic Lung adenocarcinoma metastatic Cerebrovascular accident Syncope Acquired syringomyelia Brain stem infarction Carotid artery stenosis Cerebrovascular disorder Dementia Lumbar radiculopathy Occipital neuralgia Presyncope Transient ischaemic attack Transitional cell carcinoma Myasthenia gravis Psychiatric disorders Depression Renal and urinary disorders Calculus urethral Pulmonary embolism Respiratory failure Vascular disorders Hypertension Peripheral arterial occlusive disease Thrombosis Pain (prespecified) Redness (prespecified) Swelling (prespecified) Arthralgia (prespecified)		

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
			Fatigue (prespecified) Gastrointestinal symptoms (prespecified) Headache Myalgia Shivering Temperature/(Oral) Nasopharyngitis Fever Nausea (prespecified) Vomiting (prespecified) Diarrhea (prespecified) Abdominal pain (prespecified)		
Strezova, 2019[209] GlaxoSmithKline, 2015[272] NCT02052596 Article RCT N=903 Industry funded USA	Age: 63.2 (8.7) % female: 54% Ethnicity: 11% African Heritage/African American, <1% American Indian or Alaskan Native, <1% Asian - Central/South Asian Heritage, <1% Asian - East Asian Heritage, <1% Asian - Japanese Heritage, <1% White - Arabic/North African Heritage, 87% White - Caucasian/Europe Adults aged 50 years and older at the time of first vaccination, who provided written informed consent before study start, and,	ZosterAdj Shingrix 0.5 mL in one dose (study examined three doses, but only first dose is abstracted due to comparator) Intramuscular Other : AS01B preservative free Co-intervention Tdap (Boostrix) Base treatment Tdap Boostrix 0.5 mL in 1 dose Intramuscular Aluminumpreservative free Counts No prespecified AE Power calculation Followup: 12 months	Anaemia Acute myocardial infarction Atrial fibrillation Cardiac arrest Cardiac failure Cardiac failure congestive Congenital cystic kidney disease Endocrine disorders Hyperthyroidism Gastrointestinal disorders Duodenal ulcer haemorrhage Gastrooesophageal reflux disease Hiatus hernia Upper gastrointestinal haemorrhage General disorders Chest pain Surgical failure Cholecystitis chronic Cholelithiasis Bacterial sepsis Breast cellulitis Cellulitis Clostridium difficile colitis Diverticulitis Gastroenteritis viral Osteomyelitis Perirectal abscess Pneumonia Sepsis	NA	Severe AEs within 7 days (from clinicaltrials.gov): Intervention (RZV+Tdap) Control (Tdap alone) Grade 3 Pain, Dose 1: 26/407 (6.4%) vs 3/409 (0.7%) Grade 3 Redness, Dose 1: 1/407 (0.2%) vs 1/409 (0.2%) Grade 3 Swelling, Dose 1: 1/407 (0.2%) vs 1/409 (0.2%) Grade 3 Fatigue, Dose 1: 12/407 (2.9%) vs 7/409 (1.7%) Grade 3 Gastrointestinal, Dose 1: 2/407 (0.5%) vs 3/409 (0.7%) Grade 3 Headache, Dose 1: 7/407 (1.7%) vs 3/409 (0.7%) Grade 3 Myalgia, Dose 1: 12/407 (2.9%) vs 4/409 (1.0%) Grade 3 Shivering, Dose 1: 6/407 (1.5%) vs 3/409 (0.7%) Grade 3 Temperature, Dose 1: 2/407 (0.5%) vs 0/409 (0.0%) Risk factors: NR

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
	in the opinion of the investigator, were able to comply with the requirements of the protocol. Out of scope: None		Burns second degree Burns third degree Fall Multiple injuries Postoperative wound complication Spinal fracture Investigations Staphylococcus test positive Arthralgia Intervertebral disc protrusion Myalgia Osteoarthritis Pain in extremity Bladder cancer Breast cancer Colon cancer Lung cancer metastatic Metastatic malignant melanoma Tumour necrosis Carotid artery disease Carotid artery stenosis Dizziness Device failure Haematuria Acute respiratory failure Chronic obstructive pulmonary disease Lung disorder Pulmonary embolism Respiratory failure Vascular disorders Deep vein thrombosis Hypovolaemic shock Gastrointestinal disorder Chills (prespecified) Fatigue (prespecified) Pain (prespecified) Pyrexia (prespecified) Swelling (prespecified) Myalgia (prespecified) Headache (prespecified) Erythema (prespecified)		

Table D.2. KQ2 evidence table safety of vaccines in children

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
Petrecz, 2016[183] Merck Sharp, 2006[310] NCT00289913 Article RCT N=1271 Industry funded USA	Age: Intervention: 15 months (0), Control: 15 months (0) % female: Intervention: 44%, Control: 48% Ethnicity: Intervention: 65% White, 13% Black, 20% Hispanic, 2% Other; Control: 61% White, 18% Black, 14% Hispanic, 7% Other Healthy subjects 15 months of age with a negative clinical history of hepatitis A had no immune impairment or deficiency, neoplastic disease, or depressed immunity including those resulting from corticosteroid use, and no history of allergy or anaphylactoid reaction to any component of the vaccines. Out of scope: None	DTap Infanrix One dose of 0.5 mL. One dose inactivated pertussis PT, FHA, and pertactin (69 kiloDalton outer membrane protein) approved for the active immunization against diphtheria, tetanus, and pertussis. Each antigen is individually adsorbed onto aluminum hydroxide. Each 0.5 mL dose is formulated to contain 25 Lf of diphtheria toxoid, 10 Lf of tetanus toxoid, 25 mg of inactivated pertussis PT, 25 mg of FHA, and 8 mg of pertactin. Intramuscular Aluminum preservative free Co-intervention Hep A (Vaqta) and Hib (Pedvax) Base treatment Hep A and Hib vaccines Vaqta, PedvaxHIB 0.5 mL of HepA in each of two doses. 0.5 mL of	Lymphadenitis Vomiting Pyrexia (prespecified) Otitis Media Pneumonia Subcutaneous Abscess Foreign Body Dehydration Asthma Diarrhoea Teething Vomiting Injection Site Erythema Injection Site Pain Injection Site Swelling Irritability Nasopharyngitis Rhinitis Upper Respiratory Tract Infection Cough Rhinorrhoea Erythema (prespecified) Pain/Tenderness (prespecified) Swelling (prespecified)	Asthma: 22.X Severity NR I: 1/145, 22.X Severity NR C: 0/146 Death: NA From article but restricted to N from clinical trials.gov groups I: 0/145, NA From article but restricted to N from clinical trials.gov groups C: 0/146	Serious AEs (from clinical trials.gov) PedvaxHIB and Infanrix/ VAQTA™/ VAQTA™ (Stage 1) vs PedvaxHIB/ VAQTA/ VAQTA (Stage I) Affected / at Risk (%)vs Affected / at Risk (%) Total 2/145 (1.38%) vs 2/146 (1.37%) Lymphadenitis 0/145 (0.00%) vs 0/146 (0.00%) Vomiting 0/145 (0.00%) vs 1/146 (0.68%) Pyrexia 0/145 (0.00%) vs 1/146 (0.68%) Otitis media 0/145 (0.00%) vs 1/146 (0.68%) Pneumonia 0/145 (0.00%) vs 1/146 (0.68%) Subcutaneous abscess 1/145 (0.69%) vs 0/146 (0.00%) Foreign body 0/145 (0.00%) vs 0/146 (0.00%) Dehydration 0/145 (0.00%) vs 1/146 (0.68%) Risk factors: NR

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
		Pedvax in one dose Intramuscular Aluminumpreservative free Counts No prespecified AE Power other outcome Followup: 1 months			
Duffy, 2016[96] Article Other design N=596 Not industry funded USA	Age: Patients with a febrile seizure (FS) during risk interval: 75% were 12-23 months (remainder 6-11 months); Patients with FS during control interval: 83% were 12-23 months % female: FS during risk interval: 49%; FS during control interval: 42% Ethnicity: FS during risk interval: 34% Hispanic; 34% White, 16% Black, 11% Asian, 1% Native Hawaiian/Pacific Islander, 21% Other, 6% >=2 Races, 11%	DTap,Hib,Hep A,Hep B,MMR,Pneumococcal PCV13,Pneumococcal PSV23,Polio inactivated,RV,Varicella,DTaP-HepB-IPV,DTaP-IPV-Hib,MMR-V Pediarix,Pentacel, RotaTeq Most brands not specified; risk intervals is 0-1 days after vaccination Base treatment Control interval is 14-20 days after vaccination Analytic study Prespecified AE Power NR Followup: 1 months	Febrile seizures	NA	IRR of FS During the 0 to 1 Days After Vaccination for Each Type of Vaccine Estimated Using Self-controlled Risk Interval Analysis: DTaP aIRR 1.17; 0.52 to 2.60 Hib aIRR 1.53; 0.87 to 2.72 HepA aIRR 0.88; 0.56 to 1.38 HepB aIRR 1.17; 0.31 to 4.40 IPV aIRR 1.41; 0.08 to 24.53 MMR aIRR 0.78; 0.44 to 1.40 PCV13 aIRR 1.41; 0.08 to 24.53 PPSV23 could not be defined RV5 aIRR 1.18 (0.47 to 2.99 VAR aIRR 0.80; 0.45 to 1.42 DTaP-HepB-IPV aIRR 1.64 (0.62 to 4.35 DTaP-IPV/Hib aIRR 0.72; 0.13 to 3.85 MMRV aIRR 1.12; 0.49 to 2.54 Risk factor analyses: IRR of FS during the 0 to 1 Day After Vaccination for Each Unique Combination of IIV3, PCV, and DTaP-Containing Vaccines Estimated Using Self- controlled Risk Interval Analysis (Note that IIV3, PCV not included in report; DTaP here is all DTaP-containing vaccines) For 2006–2007 to 2010–2011 IIV3: aIRR 0.46 (0.21 to 1.02) PCV: aIRR 1.81 (0.97 to 3.38) DTaP: aIRR 1.04 (0.47 to 2.28)

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
	Missing; FS during control interval: 36% Hispanic; 32% White, 10% Black, 1% American Indian/Alaska Native, 17% Asian, 1% Native Hawaiian/Pacific Islander, 15% Other, 6% >= 2 Race, 18% Unknown Vaccine Safety Datalink members aged 6 through 23 months who had a febrile seizure during prespecified time intervals after receipt of one or more vaccines of any type Out of scope: None				PCV + DTaP: aIRR 2.33 (1.45 to 3.76) (not significant in 2010-2011 period) IIV3 + DTaP: aIRR 3.50 (1.52 to 8.07) (not significant in 2010-2011 period) IIV3 + PCV: aIRR 3.50 (1.52 to 8.07) (not significant in 2006-7 to 2009-2010 period or 2010-2011 periods separately) IIV3 + PCV + DTaP: aIRR 5.00 (2.53 to 9.90) (not significant in 2010-2011 period) Any vaccination event not involving IIV3, PCV, or DTaP: aIRR 0.58 (0.28 to 1.23) Measures of Effect-Measure Modification (Interaction) Between All Unique Combinations of IIV3, PCV, and DTaP-Containing Vaccines (compared to vaccine alone given on separate days), Ratio of IRRs (95% CI): PCV + DTaP: PCV 1.29 (0.59 to 2.83), DTaP 2.25 (0.89 to 5.66) IIV3 + DTaP: IIV3 7.57 (2.40 to 23.89), DTaP 3.38 (1.07 to 10.65) IIV3 + PCV: IIV3 7.57 (1.91 to 30.07), PCV 1.93 (0.53 to 7.04) IIV3 + PCV + DTaP : PCV+DTaP 2.14 (0.93 to 4.93), IIV3 10.82 (3.81 to 30.69), IIV3+DTaP 1.43 (0.49 to 4.20), PCV 2.76 (1.10 to 6.96), IIV3+PCV 1.43 (0.38 to 5.36), DTaP 4.82 (1.70 to 13.69) Risk factors: Yes; risk of vaccines given together
Wang, 2018[235] Hambidge, 2014[282] Article Other design N=2610 Not industry funded USA	Age: NR % female: NR Ethnicity: NR Children aged 11-23 months Out of scope: None	DTap,Hib,Hep A,Hep B,MMR,Pneumococcal PCV13,Polio inactivated,RV,Varicella Other : Not reported (administrative data from VSD) NR NR Route NR adjuvant NR preservative NR Co-intervention Routine vaccines Base treatment : Routine vaccines	Seizures	NA	Results from Wang et al., 2018 (self-controlled risk interval design; VSD data from 1995-2015, 11-23 month-olds) (risk period 7-10 days post-vaccine): Univariate analyses: -Naiive cases: DTAP IRR 2.5 (2.1, 2.9) Hib IRR 2.5 (2.2, 3.0) HepA IRR 1.8 (1.5, 2.2) HepB IRR 1.7 (1.0, 2.8) MMR IRR 3.6 (3.1, 4.1) IPV IRR 2.6 (1.9, 3.4) PCV13 IRR 2.1 (1.5, 2.8) VAR IRR 3.0 (2.6, 3.4) -Restricted to single vaccine DTAP 1.3 (0.8, 2.3) Hib IRR 0.9 (0.1, 6.7)

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
		Compares risk interval to control interval Analytic study Prespecified AE Power NR Followup: 2 months			HepA IRR 1.0 (0.6, 1.8) HepB IRR - MMR IRR 3.5 (1.4, 8.8) IPV IRR - PCV13 IRR - VAR IRR 1.9 (0.7, 5.0) -Restrict—no MMR DTAP IRR 1.2 (0.9, 1.5) Hib IRR 1.2 (0.9, 1.7) HepA IRR 1.1 (0.8, 1.5) HepB IRR 0.6 (0.2, 1.7) MMR IRR N/A IPV IRR 1.0 (0.5, 1.8) PCV13 IRR 1.2 (0.6, 2.2) VAR IRR 1.0 (0.6, 1.8) Multivariate analyses: -All concomitant vaccines: **DTAP IRR 1.4 (1.1, 1.7) Hib IRR 1.0 (0.8, 1.2) HepA IRR 0.9 (0.7, 1.2) HepB IRR 0.8 (0.4, 1.3) **MMR IRR 3.8 (2.9, 5.1) IPV IRR 1.0 (0.7, 1.4) PCV13 IRR 0.9 (0.6, 1.3) VAR IRR 0.8 (0.6, 1.0) -Adjust for MMR **DTAP IRR 1.3 (1.1, 1.6) Hib IRR 1.1 (0.9, 1.3) HepA IRR 0.9 (0.7, 1.1) HepB IRR 0.9 (0.5, 0.14) MMR IRR N/A IPV IRR 1.1 (0.8, 1.5) PCV13 IRR 0.8 (0.6, 1.1) VAR IRR 0.8 (0.6, 1.0) Evaluate departure from multiplicity: No other adjustment: MMR IRR 2.9 (2.4, 3.5), DTaP 1.2 (0.9, 1.5) Adjusted for concomitant vaccines: MMR IRR 3.5 (2.5, 4.8), DTaP 1.2 (0.9, 1.6) Adjusted for concomitant vaccines and age: MMR 12 mo IRR 2.9 (2.1, 4.1), 15 mo IRR 4.3 (3.2, 5.9), 18 mo IRR 6.4 (4.4, 9.3); DTaP IRR 1.2 (0.9, 1.6) Age-adjusted attributable risk: DTaP (no MMR same day): <1 per 10,000 vaccinations

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
					MMR (not DTaP): 3 per 10,000 vaccinations Results from Hambidge et al., 2014 (self-controlled case series; VSD data from 2004-2008, 0-23 month-olds) : Vaccine and age at receipt, IRR (CI) is risk of seizure comparing vaccination period (0-7 days for all vaccines by MMR, MMRV which was 7-10 days) with control period: DTaP 1.26 (0.65–2.45) [38-92 days] vs 1.56 (0.19–12.92) [93-730 days] HIB 1.04 (0.50–2.16) [38-92 days] vs 1.56 (0.19–12.92) [93-730 days] IPV 1.26 (0.65–2.45) [38-92 days] vs 1.56 (0.19–12.92) [93-730 days] Rotavirus 1.17 (0.57–2.39) [38-92 days] vs 0.70 (0.08–5.99) [93-730 days] MMR 2.65 (1.99–3.55) [361–488 days] vs MMR 6.53 (3.15–13.53) [489-730 days] VAR (2.05–3.70) [361–488 days] vs 3.64 (1.86–7.12) [489-730 days] MMRV 4.95 (3.68–6.66) [361–488 days] vs 9.80 (4.35–22.06) [489-730 days] Risk factors: Age at receipt, left implicit (no effects found, all IRR 95% confidence intervals included 1 (Hambidge). Pre-term vs term. (McClure).
DeMeo, 2015[90] Article Pre-post N=13926 Not industry funded USA	Age: Median age at immunization was 64 days (interquartile range, 60-72 days) % female: 51% Ethnicity: 41% White, 31% Black, 19% Hispanic, 6% Other Infants discharged from January 1, 2007, through December 31, 2012, with the	DTap,Hib,Hep B,Polio inactivated,DTaP-HepB-IPV,DTaP-IPV-Hib Brands not specified Route NR adjuvant NR preservative NR Co-intervention May have received multiple vaccines at once No intervention Control period is three days prior to vaccine Analytic study	Sepsis evaluation Increased respiratory support Intubation Seizure Death	NA	Sepsis evaluation incidence before and after vaccines, adjusted rate ratio (95% CI) DTaP, IPV, and HiB (combination vaccine) 4.0 (2.3-6.9) IPV 3.0 (2.1-4.2) DTaP 3.2 (2.2-4.5) HepB 3.1 (2.3-4.1) DTaP, IPV, and HepB (combination vaccine) 4.3 (3.6-5.3) HiB 4.0 (3.3-4.8) Increased respiratory support before and after vaccines, adjusted rate ratio (95% CI) DTaP, IPV, and HiB (combination vaccine) 2.3 (1.3-4.0) IPV 2.1 (1.5-2.9) DTaP 1.9 (1.4-2.6) HepB 2.1 (1.6-2.8)

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
	following characteristics: (1) birth weight of 1000 g or less, (2) gestational age at birth of 28 weeks or less, and (3) receipt of at least one immunization (diphtheria, tetanus toxoids, and acellular pertussis [DTaP]; inactivated polio virus [IPV]; hepatitis B [HepB]; Haemophilus influenzae type B [HiB]; 7-valent and 13-valent pneumococcal conjugate; combination DTaP, IPV, and HepB; combination DTaP, IPV, and HiB; or combination HepB and HiB) between the ages of 53 and 110 days. Out of scope: None	Prespecified AE Power NR Followup: 1 months			DTaP, IPV, and HepB (combination vaccine) 2.6 (2.1-3.1) HiB 2.1 (1.8-2.5) Intubated before and after vaccines, adjusted relative rate ratio (95% CI) DTaP, IPV, and HiB (combination vaccine) 2.6 (0.8-7.9) IPV 2.5 (1.3-4.9) DTaP 2.5 (1.3-4.8) HepB 1.5 (0.9-2.6) DTaP, IPV, and HepB (combination vaccine) 1.8 (1.3-2.6) HiB 1.6 (1.2-2.7) Risk factors: No, not stratified by vaccine

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
Daley, 2014[88] Article Pre-post N=201116 Not industry funded USA	Age: 53 months % female: N/A Ethnicity: Ethnicity NR Children 4 through 6 years of age who received DTaP–IPV vaccine between January 4, 2009 and May 26, 2012, and were enrolled at four of the 8 MCOs that participate in the VSD project compared with historical cohorts Out of scope: None	DTaP-IPV Kinrix Route NR adjuvant NR preservative NR Co-intervention Routine vaccines Base treatment Cohort prior to DTaP-IPV vaccine (some had received DTaP and IPV on the same day) Analytic study Prespecified AE Power NR Followup: 2 months	Meningitis/encephalitis Seizures Stroke Guillain–Barré syndrome Stevens–Johnson syndrome Anaphylaxis Serious allergic reactions other than anaphylaxis Serious local reactions	NA	Observed AE after DTaP-IPV versus Expected based on historical controls: Meningitis, encephalitis, and myelitis: Observed events 0, Expected events, 4.85; RR 0 Seizures: Observed events 18, Expected events, 22.23; RR 0.81 Stroke: Observed events 1, Expected events 2.25; RR 0.44 Guillain–Barré syndrome: Observed events 1, Expected events 0.34; RR 2.98 Stevens-Johnson syndrome: Observed events 0, Expected events 0.49; RR 0 Anaphylaxis: Observed events 1, Expected events 0.24; RR 4.15 Angioneurotic edema and other non-anaphylactic allergic reactions: Observed events 330, Expected events 362.06; RR 0.91 Serious local reactions: Observed events 376, Expected events 492.61; RR 0.76 Risk factors: NR
Hansen, 2016[126] Sanofi Pasteur a Sanofi Company, 2008[359] NCT00804284 Article Other design N=14042 Industry funded USA	Age: N/A % female: N/A Ethnicity: Ethnicity NR Infants vaccinated with either DTaP-IPV/Hib or another DTaP-containing vaccine Out of scope: None	DTaP-IPV-Hib Pentacel Route NR adjuvant NR preservative NR Co-intervention Routine vaccines, including rotavirus for some No intervention Compared risk interval (0-30 days) to comparison interval (31-60 days) (self-controlled) Analytic study Prespecified AE Power NR Followup: 2 months	Guillain-Barré Syndrome Encephalopathy Encephalitis Alteration of consciousness (other than secondary to another diagnosis) Meningitis Hypersensitivity reactions (urticaria, angioedema, or anaphylaxis; post-vaccination days 0–3 only) New-onset autoimmune disease (immune thrombocytopenic purpura [ITP], hemolytic anemia) Type 1 diabetes Kawasaki disease Infectious and parasitic diseases Hypovolemia Diseases of the respiratory system	NA	AE of interest, IRR (95% CI) Infectious and parasitic diseases, Hospital setting, dose 2: NE (1.12, NE) Hypovolemia, Hospital setting, dose 1: NE (1.69, NE), Hypovolemia, Hospital setting, any dose: 4.70 (1.15, 31.57) Diseases of the respiratory system, Hospital setting, dose 1: 2.17 (1.20, 4.08) Other lower respiratory disease, Hospital setting, dose 1: 10.86 (1.88, 234.21) Other and unspecified lower respiratory disease, Hospital setting, dose 1: 10.86 (1.88, 234.21) Diseases of the genitourinary system, ED setting, dose 4: NE (1.50, NE) Genitourinary symptoms and ill-defined conditions, ED setting, any dose: NE (1.45, NE) Genitourinary symptoms and ill-defined conditions, ED setting, first 3 doses: NE (1.44, NE) Diseases of the skin and subcutaneous tissue, ED setting, dose 4: 3.57 (1.06, 15.95)

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
			Other lower respiratory disease Other and unspecified lower respiratory disease Diseases of the genitourinary system Genitourinary symptoms and ill-defined conditions Diseases of the skin and subcutaneous tissue Skin and subcutaneous tissue infections Cardiac and circulatory congenital anomalies Certain conditions originating in the perinatal period Other perinatal conditions Other and unspecified perinatal conditions Injury and poisoning Fractures Skull and face fractures Symptoms; signs; and ill-defined conditions and factors influencing health status Fever of unknown origin Nausea and vomiting		Skin and subcutaneous tissue infections, ED setting, dose 4: NE (1.50, NE) Cardiac and circulatory congenital anomalies, Hospital setting, dose 2: NE (1.42, NE) Certain conditions originating in the perinatal period, ED setting, dose 1: 2.87 (1.18, 7.84), Certain conditions originating in the perinatal period, ED setting, any dose: 3.01 (1.14, 9.19) Other perinatal conditions, ED setting, dose 1: 2.87 (1.18, 7.84) Other perinatal conditions, ED setting, any dose: 3.01 (1.14, 9.19) Other and unspecified perinatal conditions, ED setting, dose 1: 3.62 (1.09, 15.99), Other and unspecified perinatal conditions, ED setting, any dose: NE (2.69, NE) Other and unspecified perinatal conditions, Hospital setting, any dose: NE (1.15, NE), Other and unspecified perinatal conditions, ED setting, first 3 doses: NE (2.05, NE) Injury and poisoning, Hospital setting, dose 2: 7.36 (1.18, 164.60), Injury and poisoning, Hospital setting, dose 4: NE (1.19, NE), Injury and poisoning, Hospital setting, any dose: 3.39 (1.31, 10.22) Fractures, Hospital setting, any dose: NE (1.45, NE), Fractures, Hospital setting, first 3 doses: NE (1.14, NE) Skull and face fractures, ED setting, any dose: NE (1.15, NE), Skull and face fractures, Hospital setting, any dose: NE (1.15, NE) Symptoms; signs; and ill-defined conditions and factors influencing health status, ED setting, dose 2: 1.61 (1.14, 2.28) Symptoms; signs; and ill-defined conditions, ED setting, dose 2: 1.82 (1.26, 2.67), Fever of unknown origin, ED setting, dose 2: 1.84 (1.15, 3.02), Nausea and vomiting, ED setting, dose 1: 2.89 (1.10, 8.83) Risk factors: NR

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
Nelson, 2013[174] Article Cohort study N=149337 Not industry funded USA	Age: N/A % female: N/A Ethnicity: Ethnicity NR Children aged 6 weeks–2 years (i.e., <36 months) who received DTaP-IPV-Hib vaccine or another DTaP-containing comparator vaccine during the study period and were enrolled at one of 7 VSD MCOs Out of scope: None	DTaP-IPV-Hib Pentacel 4 doses Route NR adjuvant NR preservative NR Co-intervention Routine vaccines Other : DTaP-containing vaccines from prior to introduction of Pentacel DTaP-containing vaccines from pre- Pentacel route NR adjuvant NRpreservative NR Counts Prespecified AE Power calculation Followup: 1 months	Medically attended fever Seizure Meningitis/encephalitis/myelitis Serious nonanaphylactic allergic reaction Anaphylaxis Guillain-Barré syndrome Invasive Hib disease	NA	No cases of Guillain-Barré syndrome, anaphylaxis, or invasive Hib disease occurred among DTaP-IPV-Hib recipients during the study period. In historical controls (per doses): Medically Attended Fever: Intervention 348/72,651, Historical controls (expected) 317.7 (RR 1.10, p=0.06) Seizure: Intervention 9/72,651; Historical control (expected) 8.6 (RR 1.04, p=0.50) Meningitis, encephalitis, myelitis: Intervention 5/149,337; Historical controls (expected) 8.8 (RR 0.57, p=0.93) Nonanaphylactic serious allergic reaction: Intervention 5/149,337; Historical controls (expected) 6.1 (RR 0.82, p=0.64) In concurrent controls (per doses): Medically Attended Fever: Intervention 545/149,337; Concurrent controls 2045/813,325 (OR 0.98, 95% CI 0.87, 1.11) Seizure: Intervention 17/149,337; Concurrent control 168/813,325 (OR 0.91, 95% CI 0.52, 1.57) Meningitis, encephalitis, myelitis: Intervention 5/149,337; Concurrent controls 24/813,325 (OR 0.78, 95% CI 0.23, 2.69) Nonanaphylactic serious allergic reaction: Intervention 5/149,337; Concurrent controls 38/813,325 (OR 1.00, 95% CI 0.34, 2.99) Any Hospitalization: Intervention Group 192/149,337; Concurrent controls 1124/813,325 (OR 0.87, 95% CI 0.73, 1.04) Risk factors: Medically attended fever (historical controls)" <1 year old: RR 0.83, 95% confidence interval: 0.73, 0.94 1-2-year-olds: RR 1.83, 95% confidence interval: 1.34, 2.50 Medically attended fever (concurrent controls): <1 year old: Intervention 433/130,073; Concurrent controls 1517/583,663 (OR 0.83, 95% CI 0.71, 0.96)

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
					1-2 years-olds: Intervention 112/19,264; Concurrent controls 528/229,662 (OR 1.75, 95% CI 1.38, 2.22)
Block, 2017[70] Merck Sharp, 2011[317] NCT01340937 Article RCT N=2808 Industry funded USA	Age: Mean age in days (SD): Intervention (HV Lot A, Lot B, Lot C): 64.6 (6.7), 64.4 (6.2), 64.7 (6.6); Control: 64.3 (6.6) % female: Lot A 47%; Lot B 46%; Lot C 47%; Control 54% Ethnicity: Lot A 67% White, 8% Black, 7% American Indian, 4% Asian, 12% Other; Lot B 68% White, 10% Black, 7% American Indian, 4% Asian, 10% Other; 68% White, 7% Black, 6% American Indian, 5% Asian, 12% Other; Control 67% White, 10% Black, 7%	DTaP-IPV-Hib-HepB Vaxelis DTaP-IPV-Hib-HepB: PRP, OMPC (3 µg, 50 µg), HBsAg (10 µg), Diphtheria toxoid (15 Lf), Tetanus toxoid (5 Lf), PT (20 µg), FHA (20 µg), PRN (3 µg), FIM-2,3 (5 µg), IPV Type 1 (Mahoney) (40 DU), IPV Type 2 (MEF-1) (8 DU), IPV Type 3 (Saukett) (32 DU), and aluminum (319 µg) 2.0 mL in 4 doses (0.5-mL doses of DTaP-IPV-Hib-HepB at 2, 4, and 6 months Intramuscular Aluminum preservative NR Co-intervention Pentacel at 15 months; Prevnar 13 (PCV 13) at 2,	Mortality Idiopathic thrombocytopenic purpura Lymphadenitis Cyanosis Colitis Crohn's disease Diarrhoea Duodenal ulcer Gastrooesophageal reflux disease Haematemesis intussusception Vomiting Death Irritability Pyrexia Sudden infant death syndrome Bacteraemia Bacterial sepsis Breast abscess Bronchiolitis Cellulitis Chest wall abscess Corona virus infection Coxsackie viral infection Croup infectious Eczema herpeticum Gatroenteritis viral Gastroenteritis	Asthma: 22.X NR I: 1/2390, 22.X NA C: 0/397 Autoimmune disease: 7.X Crohn's disease I: 1/2390, 7.X Crohn's disease C: 0/397 Death: NA 1 due to obstructive hydrocephalus 1 day after dose 2; 1 death of unknown cause 44 days after dose 1; 1 group A streptococcal sepsis 2 days after dose 1; 2 sudden infant death syndrome 10 days after dose 2 and 49 days after dose 1, respectively. None of the deaths were considered to be vaccine related by the investigator. I: 5/2390, NA NR C: 0/397 Diabetes: 14.X Type 1 diabetes I: 1/2390, 14.X NA C: 0/397 Febrile seizures: 17.X NR I: 4/2390, 17.X NA C: 0/397 Immune Thrombocytopenia Purpura: 1.X NR I: 1/2390, 1.X NA C: 0/397 Intussusception: 7.X One participant reported ileocolic intussusception, which the investigator considered to be related to third dose of RV5. I: 1/2390, 7.X NA C: 0/397 Meningitis: 11.X NR I: 1/2390, 11.X NR C: 0/397	Any fever >=38.0: Intervention 1135/2308 (49.2%) vs Control 134/378 (35.4%), Percent Difference Estimate (95% CI) 13.7 (8.4, 18.8) Serious AEs (from clinical trials.gov): Intervention (Vaexlis V419 Lots A, B, and C Combined) vs Control Affected / at Risk (%)# EventsAffected / at Risk (%)# Events Total 94/2390 (3.93%) 15/397 (3.78%) Blood and lymphatic system disorders Idiopathic thrombocytopenic purpura (in AE table) Lymphadenitis 1/2390 (0.04%) 1/397 (0.25%) Cardiac disorders Cyanosis 1/2390 (0.04%) 0/397 (0.00%) Gastrointestinal disorders Colitis 1/2390 (0.04%) 0/397 (0.00%) 0 (in AE table) Crohn's disease 1/2390 (0.04%) 0/397 (0.00%) Diarrhoea 2/2390 (0.08%) 0/397 (0.00%) Duodenal ulcer 1/2390 (0.04%) 0/397 (0.00%) Gastrooesophageal reflux disease 2/2390 (0.08%) 0/397 (0.00%) Haematemesis 1/2390 (0.04%) 0/397 (0.00%) intussusception 1/2390 (0.04%) 0/397 (0.00%)

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
	American Indian, 5% Asian, 12% Other Healthy infants 46–89 days old who had previously received 1 dose of hepatitis B vaccine (outside of the study) by 1 month of age Out of scope: None	4, 6, 15 months; RotaTeq (RV5) at 2, 4, 6 months Base treatment,Hep B,DTaP-IPV/Hib Pentacel and Recombivax HB (plus Prevnar 13 at 2, 4, 6, 15 months and RV5 at 2, 4, 6 months) Pentacel, Recombivax HB (plus Prevnar 13 and RotaTeq) 3.0 mL in 6 doses (0.5-mL doses of Pentacel at 2, 4, 6, and 15 months; 0.5-mL doses of Recombivax HB at 2 and 6 months) Intramuscular Aluminumpreservative NR Counts No prespecified AE Power other outcome Followup: 12 months	Groin abscess Hand-foot-and-mouth disease Infection Influenza Meningitis Otitis media Periorbital cellulitis Pneumonia Pneumonia respiratory syncytial viral Post procedural infection Respiratory syncytial virus bronchiolitis Respiratory syncytial virus infection Respiratory tract infection viral Sepsis Sinusitis Staphylococcal infection Subcutaneous abscess Upper respiratory tract infection Urinary tract infection Viral infection Viral upper respiratory tract infection Vulval abscess Brain contusion Clavicle fracture Craniocerebral injury Femur fracture Skull fracture Subdural haemorrhage Tibia fracture Dehydration Diabetic ketoacidosis Failure to thrive Food intolerance Metabolic acidosis Type 1 diabetes mellitus Febrile convulsion Hydrocephalus Pneumocephalus Subarachnoid haemorrhage		Vomiting 1/2390 (0.04%) 0/397 (0.00%) General disorders Death 1/2390 (0.04%) 0/397 (0.00%) Irritability 1/2390 (0.04%) 0/397 (0.00%) Pyrexia 4/2390 (0.17%) 1/397 (0.25%) Sudden infant death syndrome 2/2390 (0.08%) 0/397 (0.00%) Infections and infestations Bacteraemia 2/2390 (0.08%) 0/397 (0.00%) Bacterial sepsis 1/2390 (0.04%) 0/397 (0.00%) Breast abscess 1/2390 (0.04%) 0/397 (0.00%) Bronchiolitis 9/2390 (0.38%) 3/397 (0.76%) Cellulitis 1/2390 (0.04%) 0/397 (0.00%) Chest wall abscess 1/2390 (0.04%) 0/397 (0.00%) Corona virus infection 1/2390 (0.04%) 0/397 (0.00%) Coxsackie viral infection 1/2390 (0.04%) 0/397 (0.00%) Croup infectious 3/2390 (0.13%) 0/397 (0.00%) Eczema herpeticum 1/2390 (0.04%) 0/397 (0.00%) Gatroenteritis viral 3/2390 (0.13%) 0/397 (0.00%) Gastroenteritis 5/2390 (0.21%) 0/397 (0.00%) Groin abscess 1/2390 (0.04%) 0/397 (0.00%) Hand-foot-and-mouth disease 2/2390 (0.08%) 0/397 (0.00%) Infection 1/2390 (0.04%) 0/397 (0.00%) Influenza 2/2390 (0.08%) 0/397 (0.00%) Meningitis (in AE table) Otitis media 0/2390 (0.00%) 1/397 (0.25%) Periorbital cellulitis 1/2390 (0.04%) 0/397 (0.00%) Pneumonia 5/2390 (0.21%) 0/397 (0.00%) Pneumonia respiratory syncytial viral 1/2390 (0.04%) 0/397 (0.00%) Post procedural infection 1/2390 (0.04%) 0/397 (0.00%)

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
			Hydronephrosis Apnoeic attack Asthma Atelectasis Bronchial hyperreactivity Hypoxia Pneumonitis Respiratory distress Diarrhoea Vomiting Crying Irritability Pyrexia Injection-site bruising Injection-site erythema Injection-site pain Injection-site swelling Otitis media Upper respiratory tract infection Decreased appetite Somnolence		Respiratory syncytial virus bronchiolitis 12/2390 (0.50%) 4/397 (1.01%) Respiratory syncytial virus infection 1/2390 (0.04%) 0/397 (0.00%) Respiratory tract infection viral 1/2390 (0.04%) 0/397 (0.00%) Sepsis 1/2390 (0.04%) 1/397 (0.25%) Sinusitis 0/2390 (0.00%) 1/397 (0.25%) Staphylococcal infection 1/2390 (0.04%) 0/397 (0.00%) Subcutaneous abscess 4/2390 (0.17%) 1/397 (0.25%) Upper respiratory tract infection 3/2390 (0.13%) 1.39/ (0.25%) Urinary tract infection 1/2390 (0.04%) 1/397 (0.25%) Viral infection 3/2390 (0.13%) 0/397 (0.00%) Viral upper respiratory tract infection 0/2390 (0.00%) 2/397 (0.50%) Vulval abscess 1/2390 (0.04%) 0/397 (0.00%) Injury, poisoning and procedural complications Brain contusion 1/2390 (0.04%) 0/397 (0.00%) Clavicle fracture 1/2390 (0.04%) 0/397 (0.00%) Craniocerebral injury 1/2390 (0.04%) 0/397 (0.00%) Femur fracture 0/2390 (0.00%) 1/397 (0.25%) Skull fracture 3/2390 (0.13%) 1/397 (0.25%) Subdural haemorrhage 1/2390 (0.04%) 0/397 (0.00%) Tibia fracture 0/2390 (0.00%) 1/397 (0.25%) Metabolism and nutrition disorders Dehydration 7/2390 (0.29%) 1/397 (0.25%) Diabetic ketoacidosis 1/2390 (0.04%) 0/397 (0.00%) Failure to thrive 2/2390 (0.08%) 1/397 (0.25%) Food intolerance 1/2390 (0.04%) 0/397 (0.00%)

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
					Metabolic acidosis 1/2390 (0.04%) 0/397 (0.00%) Type 1 diabetes mellitus (in AE table) Nervous system disorders Febrile convulsion (in AE table) Hydrocephalus 1/2390 (0.04%) 0/397 (0.00%) Pneumocephalus 1/2390 (0.04%) 0/397 (0.00%) Subarachnoid haemorrhage 1/2390 (0.04%) 0/397 (0.00%) Renal and urinary disorders Hydronephrosis 1/2390 (0.04%) 0/397 (0.00%) Respiratory, thoracic and mediastinal disorders Apnoeic attack 1/2390 (0.04%) 0/397 (0.00%) Asthma (in AE table) Atelectasis 1/2390 (0.04%) 0/397 (0.00%) Bronchial hyperreactivity 2/2390 (0.08%) 1/397 (0.25%) Hypoxia 1/2390 (0.04%) 0/397 (0.00%) Pneumonitis 0/2390 (0.00%) 1/397 (0.25%) Respiratory distress 2/2390 (0.08%) 1/397 (0.25%) Risk factors: NR
Marshall, 2015[166] Merck Sharp, 2011[318] NCT01337167 Article RCT N=1473 Industry funded USA	Age: Intervention 65.6 days (7.5); Control 65.0 days (6.9) % female: Intervention 49%; Control 44% Ethnicity: Intervention: 78% White, 16% Black, 1$ Asian, 6% Other, 8% Hispanic; Control: 82% White, 11% Black, 1% Asian,	DTaP-IPV-Hib-HepB Vaxelis DTaP5-IPV-Hib-HepB, PCV13, and RV5 at 2, 4, and 6 months of age followed by DTaP5, Hib-OMP, and PCV13 at 15 months of age Intramuscular Aluminum preservative free Co-intervention PCV13 (Prevnar 13) and RV5 (Rotateq); at 15 months Daptacel,	Leukocytosis Lymphadenitis Cardiac arrest Pyloric stenosis Anal fistula Gastrooesophageal reflux disease Vomiting Device expulsion Pyrexia Abscess Bronchiolitis Bronchopneumonia Croup infectious Gastritis viral Gastroenteritis Gastroenteritis salmonella Gastroenteritis viral	Asthma: 22.X NR I: 2/983, 22.X NR C: 1/480 Death: NA Death not considered by investigator to be related to study vaccinations I: 1/980, NA Death not considered by investigator to be related to study vaccinations C: 1/483 Febrile seizures: 17.X mild I: 2/980, 17.X mild C: 2/483 Kawasaki Disease: 10.X NA I: 0/980, 10.X NR C: 1/483 Meningitis: 11.X Viral meningitis (enterovirus) I: 1/980, 11.X Viral meningitis C: 1/483	Intervention vsControl Affected / at Risk (%)# EventsAffected / at Risk (%)# Events Total 58/980 (5.92%) 32/483 (6.63%) Blood and lymphatic system disorders Leukocytosis 0/980 (0.00%) 01/483 (0.21%) 1 Lymphadenitis 0/980 (0.00%) 02/483 (0.41%) 2 Cardiac disorders Cardiac arrest 1/980 (0.10%) 11/483 (0.21%) 1 Congenital, familial and genetic disorders Pyloric stenosis 0/980 (0.00%) 01/483 (0.21%) 1 Gastrointestinal disorders Anal fistula 1/980 (0.10%) 10/483 (0.00%) 0

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
	6% Other, 6% Hispanic Healthy infants 46 to 89 days of age who had received 1 dose of hepatitis B vaccine (outside of study) before or at 1 month of age Out of scope: None	Prevnar 13, PedvaxHib Base treatment,Hep B,DTaP-IPV/Hib DTAP5-IPV/Hib plus HepB plus base treatment PCV13 and RV5 (as with intervention) Pentacel, Recombivax, Prevnar 13, Rotateq; at 15 months Daptacel, Prevnar 13, ActHib DTaP5-IPV/Hib,PCV13, and RV5 at 2, 4, and 6 months of age, with HepB at 2 and 6 months of age, followed by DTaP5,Hib-TT, and PCV13 at 15 months of age Intramuscular adjuvant freepreservative free Counts No prespecified AE Power other outcome Followup: 6 months	Human herpesvirus 6 infection Influenza Meningitis enteroviral Meningitis viral Otitis media Pneumonia Pyelonephritis Respiratory syncytial virus bronchiolitis Respiratory syncytial virus infection Roseola Subcutaneous abscess Upper respiratory tract infection Urinary tract infection Viral upper respiratory tract infection Vulval abscess Wound infection staphylococcal Accidental overdose Foreign body Injury Post concussion syndrome Skull fracture Skull fracture base Tibia fracture Urine output decreased Abnormal weight gain Dehydration Failure to thrive Hypoglycaemia Convulsion Dyskinesia Dystonia Febrile convulsion Movement disorder Tonic convulsion Renal failure acute Apparent life threatening event Asphyxia Aspiration Asthma Bronchial hyperreactivity		Gastrooesophageal reflux disease † 1 4/980 (0.41%) 40/483 (0.00%) 0 Vomiting 1/980 (0.10%) 10/483 (0.00%) 0 General disorders Device expulsion 1/980 (0.10%) 10/483 (0.00%) 0 Pyrexia 0/980 (0.00%) 01/483 (0.21%) 1 Infections and infestations Abscess 1/980 (0.10%) 10/483 (0.00%) 0 Bronchiolitis 6/980 (0.61%) 65/483 (1.04%) 5 Bronchopneumonia 0/980 (0.00%) 01/483 (0.21%) 1 Croup infectious 4/980 (0.41%) 53/483 (0.62%) 3 Gastritis viral 1/980 (0.10%) 10/483 (0.00%) 0 Gastroenteritis 5/980 (0.51%) 50/483 (0.00%) 0 Gastroenteritis salmonella 1/980 (0.10%) 10/483 (0.00%) 0 Gastroenteritis viral 2/980 (0.20%) 20/483 (0.00%) 0 Human herpesvirus 6 infection † 1 1/980 (0.10%) 10/483 (0.00%) 0 Influenza0/980 (0.00%) 01/483 (0.21%) 1 Meningitis enteroviral (in AE table) Meningitis viral (in AE table) Otitis media 1/980 (0.10%) 11/483 (0.21%) 1 Pneumonia 5/980 (0.51%) 52/483 (0.41%) 2 Pyelonephritis 1/980 (0.10%) 10/483 (0.00%) 0 Respiratory syncytial virus bronchiolitis 6/980 (0.61%) 64/483 (0.83%) 4 Respiratory syncytial virus infection 1/980 (0.10%) 10/483 (0.00%) 0 Roseola 1/980 (0.10%) 10/483 (0.00%) 0 Subcutaneous abscess 2/980 (0.20%) 20/483 (0.00%) 0 Upper respiratory tract infection 1/980 (0.10%) 10/483 (0.00%) 0 Urinary tract infection 2/980 (0.20%) 21/483 (0.21%) 1 Viral upper respiratory tract infection 1/980 (0.10%) 10/483 (0.00%) 0

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
			Cough Hypoxia Infantile apnoeic attack Respiratory arrest Respiratory distress Respiratory failure Wheezing Kawasaki's disease Grade 3 crying abnormal Grade 3 somnolence Grade 3 irritability Diarrhoea Vomiting (prespecified) Crying (prespecified) Irritability (prespecified) Pyrexia (prespecified) Injection-site bruising Injection-site erythema Injection-site pain (prespecified) Injection-site swelling (prespecified) Injection-site redness (prespecified) Drowsiness (prespecified) Otitis media Upper respiratory tract infection Decreased appetite (prespecified) Somnolence		Vulval abscess 0/980 (0.00%) 01/483 (0.21%) 1 Wound infection staphylococcal 0/980 (0.00%) 01/483 (0.21%) 1 Injury, poisoning and procedural complications Accidental overdose 0/980 (0.00%) 01/483 (0.21%) 1 Foreign body 1/980 (0.10%) 10/483 (0.00%) 0 Injury 0/980 (0.00%) 01/483 (0.21%) 1 Post concussion syndrome 1/980 (0.10%) 10/483 (0.00%) 0 Skull fracture 1/980 (0.10%) 10/483 (0.00%) 0 Skull fracture base 1/980 (0.10%) 10/483 (0.00%) 0 Tibia fracture 1/980 (0.10%) 10/483 (0.00%) 0 Investigations Urine output decreased 1/980 (0.10%) 10/483 (0.00%) 0 Metabolism and nutrition disorders Abnormal weight gain 1/980 (0.10%) 10/483 (0.00%) 0 Dehydration12/980 (1.22%) 122/483 (0.41%) 2 Failure to thrive0/980 (0.00%) 01/483 (0.21%) 1 Hypoglycaemia 1/980 (0.10%) 10/483 (0.00%) 0 Nervous system disorders Convulsion 1/980 (0.10%) 11/483 (0.21%) 1 Dyskinesia 1/980 (0.10%) 10/483 (0.00%) 0 Dystonia 0/980 (0.00%) 01/483 (0.21%) 1 Febrile convulsion (in AE table; note numbers are from article) Movement disorder 0/980 (0.00%) 01/483 (0.21%) 1 Tonic convulsion 0/980 (0.00%) 01/483 (0.21%) 1 Renal and urinary disorders Renal failure acute 1/980 (0.10%) 10/483 (0.00%) 0

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
					Respiratory, thoracic and mediastinal disorders Apparent life threatening event 1/980 (0.10%) 10/483 (0.00%) 0 Asphyxia 1/980 (0.10%) 10/483 (0.00%) 0 Aspiration 0/980 (0.00%) 01/483 (0.21%) 1 Asthma (in AE table) Bronchial hyperreactivity 1/980 (0.10%) 20/483 (0.00%) 0 Cough 1/980 (0.10%) 10/483 (0.00%) 0 Hypoxia 1/980 (0.10%) 11/483 (0.21%) 1 Infantile apnoeic attack 1/980 (0.10%) 10/483 (0.00%) 0 Respiratory arrest 0/980 (0.00%) 02/483 (0.41%) 2 Respiratory distress 1/980 (0.10%) 11/483 (0.21%) 1 Respiratory failure 1/980 (0.10%) 10/483 (0.00%) 0 Wheezing 1/980 (0.10%) 10/483 (0.00%) 0 Vascular disorders Kawasaki's disease (in AE table) Intervention (N=981) vs Control (N=484) All routes >=39.5°C, severe2.0%; 1.1% Rectal >=39.5°C, severe2.0%; 0.9% Intervention (N=981) vs Control (N=484) Grade 3 injection-site pain5.9%; 4.6% Grade 3 injection-site erythema0.2%; 0.6% Grade 3 injection-site swelling0.3%; 0.4% Grade 3 pyrexia1.5%; 1.2% Grade 3 vomiting0.4%; 0.6% Grade 3 crying abnormal7.9%; 8.3% Grade 3 somnolence3.5%; 2.9% Grade 3 decreased appetite1.3%; 0.4% Grade 3 irritability7.7%; 5.8% Risk factors: NR

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
Tapiero, 2013[211] Sanofi Pasteur a Sanofi Company, 2006[356] NCT00362427 Article RCT N=460 Industry funded Canada	Age: 63.2 days (9.1) % female: 50% Ethnicity: 80% White Healthy full-term infants 42-89 days old Out of scope: None	DTaP-IPV-Hib-HepB Vaxelis 0.5 ml in each of 3 doses at 2, 4, and 6months Intramuscular Aluminum preservative free Co-intervention PCV7 (Prevnar) Base treatment,Hep B,DTaP-IPV/Hib DTaP-IPV/Hib and Hep B and same base treatment (PCV7) Pentacel, Engerix-B, Prevnar 0.5 ml of each vaccine in each of 3 doses at 2, 4, and 6months Intramuscular Aluminumpreservative free Counts No prespecified AE Power other outcome Followup: 1 months	Injection site tenderness Injection site induration Erythema Swelling Fever Vomiting Abnormal crying Drowsiness Appetite loss Irritability Nasopharyngitis Diarrhea Nasal congestion Cough Rhinorrhea Hypotonia Fibrosarcoma Febrile seizures	Death: NA NA I: 0/151, NA NA C: 0/149 Febrile seizures: 17.X NA I: 0/151, 17.X NA C: 0/150	Rates of solicited injection site reactions and solicited systemic reactions were generally similar across groups. 24 serious adverse events were reported in the study; only 1 (hypotonia in the DtaP-IPV-Hib-HepB + PCV7 group) was considered related to the vaccine. Intervention (Vaxelis + PCV7) vs Control (Pentacel + HepB + PC7) Severe tenderness after any dose: Intervention 3.2% (95% CI 1.0-7.3) vs Control 6.5% (95% CI 3.2-11.7) Severe erythema or swelling after any dose: Rare and similar among the groups Severe fever (temperature >39.5C): Intervention 0.6% (95% CI 0.0-3.5) vs Control 2.0% (95% CI 0.4-5.6) Serious AEs: Intervention 8/151 (95% CI 5.1%) vs Control 6/150 (95% CI 3.9%) Risk factors: NR

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
Leslie, 2017[158] Article Case-Control N=170302 Funding unclear USA	Age: 11.1 (2.7) to 12.3 (2.6) % female: 33-87% Ethnicity: Ethnicity NR Children and adolescents aged 6–15 years with neuropsychiatric disorders that were newly diagnosed Out of scope: None	Hep A,Hep B,Varicella Route NR adjuvant NR preservative NR Co-intervention unclear No intervention Control without the outcome of interest (the AE of interest) Analytic study Prespecified AE Power NR Followup: 12 months	Broken bone Open wound Obsessive–compulsive disorder (OCD) Anorexia nervosa Anxiety disorder Tic disorder Attention deficit hyperactivity disorder Major depression Bipolar disorder	NA	Bivariate associations between hazards and vaccines after vaccination expressed in Hazard Ratios (HR) (95% CI) [* are significant] Broken bone (N=85151) HepA 3 months: 1.02 (0.94, 1.12), HepA 6 months: 1.05 (0.98,,1.12), HepA 12 months: 1.08 (1.02, 1.13) HepB 3 months: 1.08 (0.93, 1.25), HepB 6 months: 1.02 (0.92, 1.13), HepB 12 months: 1.03 (0.95, 1.11) Varicella 3 months: 0.88 (0.79, 0.99)*, Varicella 6 months: 0.97 (0.88, 1.06), Varicella 12 months: 1.00 (0.93, 1.08) Open wound (N=73290) HepA 3 months: 0.97 (0.88, 1.07), HepA 6 months: 0.99 (0.92, 1.07), HepA 12 months: 0.99 (0.93, 1.05) HepB 3 months: 1.05 (0.89, 1.24), HepB 6 months: 1.02 (0.91, 1.15), HepB 12 months: 1.00 (0.91, 1.09) Varicella 3 months: 0.90 (0.79, 1.03), Varicella 6 months: 0.96 (0.87, 1.07), Varicella 12 months: 0.93(0.85, 1.01) OCD (N=3222) HepA 3 months: 1.47 (0.92 2.33), HepA 6 months: 1.43 (1.02, 2.01)*, HepA 12 months: 1.40 (1.07, 1.82)* HepB 3 months: 0.71 (0.32, 1.61), HepB 6 months: 0.80 (0.45, 1.44), HepB 12 months: 0.93 (0.60, 1.44) Varicella 3 months: 1.33 0.79, 2.26), Varicella 6 months: 1.38 (0.89, 2.15), Varicella 12 months: 1.36 (0.92, 1.99) Anorexia nervosa (N=551) HepA 3 months: 1.60 (0.52, 4.89), HepA 6 months: 1.09 (0.48, 2.51), HepA 12 months: 1.73 (0.89, 3.37) HepB 3 months: 3.00 (0.61, 14.86), HepB 6 months: 1.71 (0.68, 4.35), HepB 12 months: 1.55 (0.72, 3.30) Varicella 3 months: 1.00 (0.20, 4.96), Varicella 6 months: 2.66 (0.71, 10.04), Varicella 12 months: 1.29 (0.48, 3.45) Anxiety disorder (N=23462)

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
					HepA 3 months: 1.00 (0.85, 1.18), HepA 6 months: 1.08 (0.95, 1.22), HepA 12 months: 1.00 (0.91, 1.10) HepB 3 months: 1.01 (0.76, 1.34), HepB 6 months: 1.01 (0.83, 1.23), HepB 12 months: 1.01 (0.89, 1.16) Varicella 3 months: 1.06 (0.85, 1.31), Varicella 6 months: 1.17 (0.99, 1.38), Varicella 12 months: 1.11 (0.97, 1.28) Tic disorder (N=2547) HepA 3 months: 1.13 (0.70, 1.83), HepA 6 months: 1.35 (0.92, 1.98), HepA 12 months: 1.17 (0.88, 1.56) HepB 3 months: 1.40 (0.44, 4.41), HepB 6 months: 1.17 (0.54, 2.52), HepB 12 months: 1.19 (0.61, 2.31) Varicella 3 months: 0.73 (0.42, 1.27), Varicella 6 months: 0.91 (0.59, 1.40), Varicella 12 months: 0.97 (0.67, 1.40) ADHD (N=46640) HepA 3 months: 1.03 (0.92, 1.17), HepA 6 months: 1.05 (0.96, 1.15), HepA 12 months: 1.09 (1.02, 1.18)* HepB 3 months: 1.13 (0.91, 1.39), HepB 6 months: 1.07 (0.92, 1.24), HepB 12 months: 1.06 (0.95, 1.18) Varicella 3 months: 1.06 (0.90, 1.24), Varicella 6 months: 1.09 (0.97, 1.23), Varicella 12 months: 1.06 (0.95, 1.17) Major depression (N=13295) HepA 3 months: 0.86 (0.68, 1.08), HepA 6 months: 0.95 (0.81, 1.13), HepA 12 months: 0.97 (0.86, 1.11) HepB 3 months: 1.05 (0.77, 1.43), HepB 6 months: 0.89 (0.71, 1.11), HepB 12 months: 1.00 (0.85, 1.18) Varicella 3 months: 0.85 (0.58, 1.24), Varicella 6 months: 0.85 (0.64, 1.14), Varicella 12 months: 0.84 (0.66, 1.06) Bipolar disorder (N=5892) HepA 3 months: 1.03 (0.73, 1.47), HepA 6 months: 0.79 (0.60, 1.03), HepA 12 months: 0.81 (0.66, 1.00) HepB 3 months: 0.97 (0.61, 1.56), HepB 6 months: 0.91 (0.64, 1.29), HepB 12 months: 1.07 (0.83, 1.38)

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
					Varicella 3 months: 1.08 (0.63, 1.87), Varicella 6 months: 0.79 (0.52, 1.21), Varicella 12 months: 0.74 (0.53, 1.05) Risk factors: NR
Gilca, 2018[114] Laval University, 2015[298] NCT02567955 Article RCT N=371 Not industry funded Canada	Age: 9.6 (0.3) % female: 50% Ethnicity: 92% White; 8% Not white Healthy girls and boys aged 9–10 years living in the Quebec City area Out of scope: None	HPV Gardasil 9 1 dose of 0.5 mL (study was for two doses, but comparison between HPV9 and HPV2 is just after dose 1) Intramuscular Aluminum preservative free No co-intervention HPV HPV2 Cervarix 0.5 mL per dose Intramuscular ASO 4preservative NR Counts No prespecified AE Power other outcome Followup: 6 months	Pain Redness Swelling Fever Fatigue Headache Gastro-intestinal Arthralgia Myalgia Rash Urticaria	Death: NA NA I: 0/274, NA NA C: 0/93	Intervention HPV9 (N=274) %(95% CI) vs Control HPV2 (N=93) %(95% CI) At least one local AE: Intervention 67.4% (61.4–72.9) vs Control 87.1% (78.5–93.1) At least one systemic AE: Intervention 66.7% (56.1–76.1) vs Control 49.8% (43.7–55.9) Severe AE Pain grade 3: Intervention 7.5% (3.1–14.9) vs Control 7.5% (3.1–14.9) Redness &/or Swelling > 50 mm: Intervention 0.0% vs Control 1.1% (0.03–5.9) At least one local grade 3 AE: Intervention 1.8% (0.6–4.2) vs Control 8.6% (3.8–16.2) Fatigue: Intervention 2.2% (0.8–4.7) vs Control 2.2% (0.3–7.6) Headache: Intervention 1.8% (0.6–4.2) vs Control 0.0% Gastro-intestinal: Intervention 0.4% (0.01–2.0) vs Control 0.0% Arthralgia: Intervention 0.0% vs Control 0.0% Myalgia: Intervention 0.7% (0.1–2.6) vs Control 3.2% (0.7–9.1) Rash &/or Urticaria: Intervention 0.8% (0.01–2.0) vs Control 0.0% At least one systemic grade 3 AE: Intervention 4.0% (2.0–7.1) vs Control 4.3% (1.2–10.6) Risk factors: NR

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
Vesikari, 2015[228] Merck Sharp, 2011[315] NCT01304498 Article RCT N=600 Industry funded Belgium, Denmark, Finland, Italy, Spain and Sweden	Age: 12.6 (1.9) % female: 100% Ethnicity: Ethnicity NR Females aged ≥9 to <16 years in good physical health, virgin, and with no intention to become sexually active through month 7 of the study. Out of scope: None	HPV Gardasil 9 3 doses of 0.5 mL each on day 1, and in month 2 and month 6 Intramuscular Aluminum preservative NR No co-intervention HPV Quadrivalent HPV Gardasil 3 doses of 0.5 mL each on day 1, and in month 2 and month 6 Intramuscular Aluminumpreservative free Counts No prespecified AE Power other outcome Followup: 6 months	Fatigue Upper abdominal pain Anaemia Complex partial seizures Pulmonary vasculitis Henoch-Schonlein purpura Nausea Injection-site erythema Injection-site pain Injection-site swelling Pyrexia Nasopharyngitis Headache Oropharyngeal pain	Autoimmune disease: 10.X Henoch-Schonlein purpura I: 0/299, 10.X Henoch-Schonlein purpura, 46 days after dose 2 C: 1/300 Death: NA NR I: 0/299, NA NR C: 0/300 Seizure: 17.X Complex partial seizures I: 0/299, 17.X Complex partial seizures, 36 days after dose 1 C: 1/300	Infection-site swelling (days 1-5): Intervention 143/299 (47.8%) vs Control 108/300 (36.0%), P = 0.003 Severe injection-site swelling (>5cm) (days 1-5): Intervention 6.0% vs Control (6.3%) Intervention (HPV9) vs Control (HPV4) Affected / at Risk (%)# EventsAffected / at Risk (%)# Events Total 1/299 (0.33%) 2/300 (0.67%) Anaemia 1/299 (0.33%) 10/300 (0.00%) 0 Complex partial seizures (in AE table) Pulmonary vasculitis 1/299 (0.33%) 10/300 (0.00%) 0 Henoch-Schonlein purpura (in AE table) Risk factors: NR
Domachowske, 2013[94] GlaxoSmithKline, 2010[267] NCT01196988 Article RCT N=3027 Industry funded Czech Republic, France, Germany, Philippines, USA	Age: Intervention 7.8 years (3.69); TIV-Vic 7.8 years (3.78); TIV-Yam 7.8 years (3.69) % female: 48% Ethnicity: Intervention 10% Hispanic, 54% European heritage/ Caucasian, 12% African heritage/African American, 29% Asian/Southeast heritage, 5% Other; TIV-Vic Intervention 10%	IIV Fluarix Quadrivalent 1-2 doses (depending on priming) Intramuscular adjuvant NR preservative free No co-intervention Other : Fluarix trivalent Trivalent inactivated influenza vaccine (one of two types) Fluarix (one control was not branded, but by same manufacturer) 1-2 doses depending	Pain (prespecified) Redness (prespecified) Swelling (prespecified) Drowsiness (prespecified) Irritability (prespecified) Loss of appetite (prespecified) Temperature >39°C (prespecified) Fatigue (prespecified) Gastrointestinal symptoms (prespecified) Headache (prespecified) Joint Pain (prespecified) Muscle aches (prespecified) Shivering (prespecified) Lymphadenitis Atrioventricular block first degree	Cardiovascular events: 2.X Myocarditis, not considered vaccine-related I: 1/915, 2.X Myocarditis C: 0/1823 Diabetes: 14.X Type 1 diabetes mellitus I: 0/915, 14.X Type 1 diabetes mellitus, not considered vaccine-related C: 1/1823 Febrile seizures: 17.X Febrile convulsion I: 0/915, 17.X Febrile convulsion C: 0/1823 Seizure: 17.X Epilepsy I: 0/915, 17.X Epilepsy C: 0/1823	Severe AEs (from clinicaltrials.gov): Intervention (GSK2321138A 1 Group) Control 1 (Fluarix) Control 2 (GSK2604409A) Grade 3 Pain20/903 (2.2%)21/902 (2.3%)13/906 (1.4%) Grade 3 Redness12/903 (1.3%)3/902 (0.3%) 6/906 (0.7%) Grade 3 Swelling11/903 (1.2%)10/902 (1.1%) 3/906 (0.3%) Intervention (GSK2321138A 1 Group) Control 1 (Fluarix) Control 2 (GSK2604409A) Grade 3 Drowsiness5/291 (1.7%) 3/314 (1.0%) 2/280 (0.7%) Grade 3 Irritability4/291 (1.4%) 2/314 (0.6%) 3/280 (1.1%)

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	Hispanic, 53% European heritage/ Caucasian, 13% African heritage/African American, 29% Asian/Southeast heritage, 5% Other; TIV-Yam Intervention 10% Hispanic, 53% European heritage/ Caucasian, 12% African heritage/African American, 29% Asian/Southeast heritage, 6% Other Children were eligible for inclusion if they were aged 6 months to 17 years and were in stable health; children with chronic illness were eligible for inclusion unless there was evidence of significant pulmonary, cardiovascular, hepatic, or renal functional abnormalities. Children aged 6-35 months excluded from this abstraction as no	on priming Intramuscular adjuvant NRpreservative free Counts Prespecified AE Power other outcome Followup: 6 months	Myocarditis Amoebiasis Appendicitis Bronchiolitis Bronchitis Bronchopneumonia Dengue fever Gastroenteritis Gastroenteritis bacterial Gastroenteritis rotavirus Gastroenteritis viral Infectious mononucleosis Otitis media acute Peritonsillar abscess Pneumococcal sepsis Pneumonia Respiratory syncytial virus infection Tonsillitis Abdominal injury Concussion Road traffic accident Diabetic ketoacidosis Type 1 diabetes mellitus Epilepsy Febrile convulsion Suicidal ideation Rash Diabetes Seizure Death		Grade 3 Loss of appetite3/291 (1.0%) 3/314 (1.0%) 3/280 (1.1%) Temperature >39°C4/291 (1.4%) 2/314 (0.6%) 3/280 (1.1%) Intervention (GSK2321138A 1 Group) Control 1 (Fluarix) Control 2 (GSK2604409A) Grade 3 Fatigue9/613 (1.5%)8/589 (1.4%)4/626 (0.6%) Grade 3 Gastro.7/613 (1.1%)4/589 (0.7%)2/626 (0.3%) Grade 3 Headache8/613 (1.3%)4/589 (0.7%) 5/626 (0.8%) Grade 3 Joint Pain2/613 (0.3%)4/589 (0.7%)2/626 (0.3%) Grade 3 Muscle aches4/613 (0.7%)8/589 (1.4%) 3/626 (0.5%) Grade 3 Shivering3/613 (0.5%)3/589 (0.5%)1/626 (0.2%) Temperature >39°C7/613 (1.1%) 5/589 (0.8%)3/626 (0.5%) Intervention (GSK2321138A 1 Group) Control 1 (Fluarix) Control 2 (GSK2604409A) Subjects with grade 3 AE(s)20/915 (2.2%)37/912 (4.1%)26/911 (2.9%) Serious AEs (from clinicaltrials.gov): Intervention (GSK2321138A 1 Group) Control 1 (Fluarix) Control 2 (GSK2604409A) Affected / at Risk (%)Affected / at Risk (%)Affected / at Risk Total 8/915 (0.87%) 6/912 (0.66%) 7/911 (0.77%) Blood and lymphatic system disorders Lymphadenitis 1/915 (0.11%) 0/912 (0.00%) 0/911 (0.00%) Cardiac disorders Atrioventricular block first degree 1/915 (0.11%) 0/912 (0.00%) 0/911 (0.00%)

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	comparison group. Out of scope: None				Myocarditis 1/915 (0.11%) 0/912 (0.00%) 0/911 (0.00%) (in AE table) Infections and infestations Amoebiasis 0/915 (0.00%) 0/912 (0.00%) 0/911 (0.00%) Appendicitis 0/915 (0.00%) 0/912 (0.00%) 1/911 (0.11%) Bronchiolitis 0/915 (0.00%) 0/912 (0.00%) 0/911 (0.00%) Bronchitis 0/915 (0.00%) 0/912 (0.00%) 0/911 (0.00%) Bronchopneumonia 0/915 (0.00%) 0/912 (0.00%) 0/911 (0.00%) Dengue fever 0/915 (0.00%) 2/912 (0.22%) 0/911 (0.00%) Gastroenteritis 0/915 (0.00%) 0/912 (0.00%) 0/911 (0.00%) Gastroenteritis bacterial 1/915 (0.11%) 0/912 (0.00%) 0/911 (0.00%) Gastroenteritis rotavirus 0/915 (0.00%) 0/912 (0.00%) 1/911 (0.11%) Gastroenteritis viral 0/915 (0.00%) 0/912 (0.00%) 0/911 (0.00%) Infectious mononucleosis 1/915 (0.11%) 0/912 (0.00%) 0/911 (0.00%) Otitis media acute 1/915 (0.11%) 0/912 (0.00%) 0/911 (0.00%) Peritonsillar abscess 1/915 (0.11%) 0/912 (0.00%) 0/911 (0.00%) Pneumococcal sepsis 0/915 (0.00%) 0/912 (0.00%) 0/911 (0.00%) Pneumonia 0/915 (0.00%) 2/912 (0.22%) 0/911 (0.00%) Respiratory syncytial virus infection 0/915 (0.00%) 0/912 (0.00%) 0/911 (0.00%) Tonsillitis 1/915 (0.11%) 0/912 (0.00%) 0/911 (0.00%) Injury, poisoning and procedural complications Abdominal injury 0/915 (0.00%) 1/912 (0.11%) 0/911 (0.00%) Concussion 3/915 (0.33%) 0/912 (0.00%) 2/911 (0.22%) Road traffic accident 0/915 (0.00%) 1/912 (0.11%) 0/911 (0.00%) Metabolism and nutrition disorders

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
					Diabetic ketoacidosis 0/915 (0.00%) 0/912 (0.00%) 1/911 (0.11%) Type 1 diabetes mellitus 0/915 (0.00%) 0/912 (0.00%) 1/911 (0.11%) (in AE table) Nervous system disorders Epilepsy 0/915 (0.00%) 0/912 (0.00%) 0/911 (0.00%) (in AE table) Febrile convulsion 0/915 (0.00%) 0/912 (0.00%) 0/911 (0.00%) (in AE table) Psychiatric disorders Suicidal ideation 1/915 (0.11%) 0/912 (0.00%) 1/911 (0.11%) Skin and subcutaneous tissue disorders Rash 0/915 (0.00%) 1/912 (0.11%) 1/911 (0.11%) None of the SAEs were considered to be vaccine-related by the investigator. There was 1 death due to a motor vehicle accident (group not specified). Risk factors: No
Greenberg, 2014[117] Sanofi Pasteur a Sanofi Company, 2010[361] NCT01240746 Article RCT N=4363 Industry funded USA	Age: QIV 49.8 (29.7); TIV: 49.6 (29.0) months % female: 49 Ethnicity: QIV: 58% White, 20% Black, 14% Hispanic, 1% Asian, <1% American Indian/Alaska Native/Native Hawaiian/Pacific Islander, 6% Other; TIV: 59% White, 20% Black, 13% Hispanic, 1% Asian, <1% American Indian/Alaska Native/Native Hawaiian/Pacific Islander, 7% Other	IIV Fluzone Quadrivalent A/California/07/2009 (H1N1), A/Victoria/210/2009 (H3N2), B/Brisbane/60/2008 (B Victoria lineage) and B/Florida/04/2006 (B Yamagata lineage) strains; 30 µg HA/strain/mL 0.25 mL or 0.5 mL per dose depending on age; 1-2 doses depending on vaccination history Intramuscular adjuvant free preservative NR No co-intervention IIV Licensed TIV 2010-2011 Fluzone (licensed	Bradycardia Drowning Pyrexia Appendicitis Croup infectious Gastroenteritis Gastroenteritis viral Mycoplasma infection Otitis media Periorbital cellulitis Peritonsillar abscess Pneumonia Respiratory syncytial vrus bronchiolitis Respiratory syncytial vrus infection Staphylococcal abscess Staphylococcal infection Viral infection Viral upper respiratory tract infection Accidental exposure Femur fracture Dehydration Hypovolaemia Astrocytoma, low grade Autism	Asthma: 22.X Not considered related to vaccine I: 8/2892, 22.4 NA C: 0/734 Autism: 17.X Not considered related to vaccine I: 1/2892, 17.X NA C: 0/734 Cardiovascular events: 2.X Bradycardia; Not considered related to vaccine I: 1/2892, 2.X Bradycardia C: 0/734 Death: NA NA I: 0/2892, NA Death from drowning; considered vaccination-unrelated by the investigator C: 1/734 Febrile seizures: 17.2 No participant reported what the investigator considered to be vaccine-related febrile seizure I: 8/2892, 17.2 One participant reported what the investigator assessed as vaccine-related febrile seizure (one day after first dose; resolved) C: 2/734 Kawasaki Disease: 10.X Not considered related to vaccine I: 3/2892, 10.X NA C: 0/734 Seizure: 17.X Seizure anoxic I: 1/2892, 17.X Seizure anoxic C: 0/734	Study Group 1 (Trivalent Influenza Vaccine)Study Group 3 (Investigational Quadrivalent Influenza Vaccine) Affected / at Risk (%)# EventsAffected / at Risk (%)# Events Total 7/734 (0.95%) 41/2892 (1.42%) Cardiac disorders Bradycardia (in AE table) General disorders Drowning 0/2892 (0.00%) 0 1/225 (0.44%) 1 Pyrexia 1/2892 (0.03%) 1 0/734 (0.00%) 0 Infections and infestations Appendicitis 0/2892 (0.00%) 0 0/734 (0.00%) 0 Croup infectious 1/2892 (0.03%) 1 0/734 (0.00%) 0 Gastroenteritis 2/2892 (0.07%) 2 0/734 (0.00%) 0 Gastroenteritis viral 1/2892 (0.03%) 1 0/734 (0.00%) 0 Mycoplasma infection 0/2892 (0.00%) 0 0/734 (0.00%) 0 Otitis media 0/2892 (0.00%) 0 0/734 (0.00%) 0

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
	Healthy children 6 months to <9 years of age (if 6 -23 months, had to be born full term >=37 weeks and birth weight >=2.5 kg) Out of scope: None	trivalent) 0.25 mL or 0.5 mL per dose depending on age; 1-2 doses depending on vaccination history Intramuscular adjuvant freepreservative NR Counts No prespecified AE Power other outcome Followup: 6 months	Febrile convulsion Seizure anoxic Psychiatric disorders Affective disorder Adenoidal hypertrophy Asthma Bronchial hrperreactivity Respiratory arrest Status asthmaticus Vascular disorders Kawasaki's disease Vomiting (prespecified) Diarrhoea Vomiting General disorders Injection site pain Injection site swelling (prespecified) Malaise (prespecified) Injection site tenderness (prespecified) Injection site erythema (prespecified) Fever (prespecified) Pyrexia Appetite lost (prespecified) Myalgia (prespecified) Headache (prespecified) Drowsiness (prespecified) Crying abnormal (prespecified) Irritability Cough Rhinorrhoea		Periorbital cellulitis 1/2892 (0.03%) 1 0/734 (0.00%) 0 Peritonsillar abscess 0/2892 (0.00%) 0 0/734 (0.00%) 0 Pneumonia 1/2892 (0.03%) 1 1/734 (0.14%) 1 Respiratory syncytial vrus bronchiolitis 12/2892 (0.07%) 2 1/734 (0.14%) Respiratory syncytial vrus infection 1/2892 (0.03%) 1 0/734 (0.00%) 0 Staphylococcal abscess 0/2892 (0.00%) 0 1/734 (0.14%) 1 Staphylococcal infection 1/2892 (0.03%) 1 0/734 (0.00%) 0 Viral infection 1/2892 (0.03%) 1 0/734 (0.00%) 0 Viral upper respiratory tract infection 1/2892 (0.03%) 1 0/734 (0.00%) 0 Injury, poisoning and procedural complications Accidental exposure 1/2892 (0.03%) 1 0/734 (0.00%) 0 Femur fracture 2/2892 (0.07%) 2 0/734 (0.00%) 0 Metabolism and nutrition disorders Dehydration 1/2892 (0.03%) 1 0/734 (0.00%) 0 Hypovolaemia 1/2892 (0.03%) 1 0/734 (0.00%) 0 Neoplasms benign, malignant and unspecified (incl cysts and polyps) Astrocytoma, low grade 1/2892 (0.03%) 1 0/734 (0.00%) 0 Nervous system disorders Autism (in AE table) Febrile convulsion (in AE table) Seizure anoxic (in AE table) Psychiatric disorders Affective disorder 0/2892 (0.00%) 0 0/734 (0.00%) 0 Respiratory, thoracic and mediastinal disorders Adenoidal hypertrophy 0/2892 (0.00%) 0 0/734 (0.00%) 0 Asthma (in AE table) Bronchial hyperreactivity 1/2892 (0.03%) 1 0/734 (0.00%) 0

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
					Respiratory arrest 1/2892 (0.03%) 1. 0/734 (0.00%) 0 Status asthmaticus 0/2892 (0.00%) 0 1/734 (0.14%) 1 Vascular disorders Kawasaki's disease (in AE table) Risk factors: NR
Hartvickson, 2015[129] Novartis Vaccines, 2014[331] NCT01992107 Article RCT N=2333 Industry funded USA	Age: Intervention (QIVc): 9.5(3.8); Control (TIV1c and TIV2c): 9.4 (3.8) % female: Intervention 48%; Control 49% Ethnicity: Intervention: 1% Asian, <1% American Indian, 22% Black, 53% Caucasian, 20% Hispanic, <1% Native Hawaiian, 4% Other; Control: <1% Asian, 1% American Indian, 21% Black, 54% Caucasian, 20% Hispanic, 1% Native Hawaiian, 3% Other Children aged 4 to 17 years, and excluded if: a recent body	IIV Flucelvax Quadrivalent 15 µg of HA for each of the four influenza strains recommended by the WHO for the 2013/ 14 influenza vaccine composition for the Northern Hemisphere season: A/Brisbane/10/2010 (H1N1), A/Texas/50/2012 (H3N2), B/Massachusetts/ 2/2012, and B/Brisbane/60/2008 0.5 mL in one dose Intramuscular adjuvant free preservative free No co-intervention IIV One of two comparison cell-derived trivalent influenza vaccines	Anaphylactic Reaction Abscess Of Eyelid Appendicitis Gastroenteritis Periorbital Cellulitis Craniocerebral Injury Forearm Fracture Humerus Fracture Hippocampal Sclerosis Partial Seizures Bipolar Disorder Depression Intentional Self-Injury Major Depression Oppositional Defiant Disorder Suicidal Ideation Suicide Attempt Sleep Apnoea Syndrome Henoch-Schonlein Purpura Diarrhea (prespecified) Nausea (prespecified) Vomiting (prespecified) Chills (prespecified) Fatigue Injection Site Erythema (prespecified) Injection Site Hemorrhage Ecchymosis (prespecified) Injection Site Induration (prespecified)	Anaphylaxis: 10.3 Anaphylactic reaction I: 1/1149, 10.3 Anaphylactic reaction C: 0/1149 Autoimmune disease: 10.X Henoch-Schonlein purpura I: 0/1149, 10.X Henoch-Schonlein purpura C: 1/1149 Death: NA NA I: 0/1149, NA NA C: 0/1149 Seizure: 17.X Partial seizures I: 1/1149, 17.X Partial seizures C: 0/1149	Study AEs, QIVc vs TIV1c vs TIV2c Unsolicited AEs: 24% vs 24% vs 27% Medically attended AEs: 27% vs 27% vs 27% New onset of chronic disease: 2% vs 2% vs 2% Serious AEs (from clinicaltrials.gov) Intervention (QIVc) vsControl 1 (TIV1c) vs Control 2(TIV2c) Affected / at Risk (%)Affected / at Risk (%)Affected / at Risk Total 6/1149 (0.52%) 7/579 (1.21%) 2/570 (0.35%) Anaphylactic reaction (in AE table) Abscess of eyelid 0/1149 (0.00%) 1/579 (0.17%) 0/570 (0.00%) Appendicits 0/1149 (0.00%) 1/579 (0.17%) 0/570 (0.00%) Gastroenteritis 0/1149 (0.00%) 1/579 (0.17%) 1/570 (0.18%) Periorbital cellulitis 0/1149 (0.00%) 1/579 (0.17%) 0/570 (0.00%) Craniocerebral injury 1/1149 (0.09%) 0/579 (0.00%) 0/570 (0.00%) Forearm fracture 0/1149 (0.00%) 1/579 (0.17%) 0/570 (0.00%) Humerus fracture 0/1149 (0.00%) 1/579 (0.17%) 0/570 (0.00%) Hippocampal sclerosis1/1149 (0.09%) 0/579 (0.00%) 0/570 (0.00%) Partial seizures (in AE table)

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	temperature 38 8C (within 3 days prior to vaccination); a history of any significant ongoing chronic/acute illness that would interfere with their ability to comply with study-related procedures and or interfere in the evaluation of the study vaccine; females of child-bearing potential who had not used any of the acceptable contraceptive methods for at least 2 months prior to study entry and/or were not willing to do so through day 60; females who were pregnant or breast-feeding; those of childbearing potential with a positive or indeterminate pregnancy test; history of any bleeding disorder; history of anaphylaxis to previous influenza vaccination, serious vaccine	with B strains of opposite lineages 0.5 mL in one dose Intramuscular adjuvant freepreservative free Counts No prespecified AE Power NR Followup: 3 months	Injection Site Pain (prespecified) Upper Respiratory Tract Infection Decreased Appetite (prespecified) Arthralgia Myalgia Headache Cough		Bipolar disorder1/1149 (0.09%) 0/579 (0.00%) 0/570 (0.00%) Depression 1/1149 (0.09%) 0/579 (0.00%) 0/570 (0.00%) Intentional self-injury 0/1149 (0.00%) 1/579 (0.17%) 0/570 (0.00%) Major depression 0/1149 (0.00%) 1/579 (0.17%) 0/570 (0.00%) Oppositional defiant disorder 1/1149 (0.09%) 0/579 (0.00%) 0/570 (0.00%) Suicidal ideation 0/1149 (0.00%) 1/579 (0.17%) 0/570 (0.00%) Suicide attempt 0/1149 (0.00%) 1/579 (0.17%) 0/570 (0.00%) Sleep apnea syndrome 0/1149 (0.00%) 0/579 (0.00%) 1/570 (0.18%) Henoch-Schonlein purpura (in AE table) Risk factors: Yes, stratified by age (4-6, 6-9, 9-18) for non-serious and non-severe AEs. 6, 7, and 8 year olds were the most likely to have reactions.

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	reactions, or hypersensitivity to any of the vaccine components, or on exposure to latex; received any influenza vaccination or had documented influenza disease within the prior 6 months; history of known or suspected congenital or acquired immunodeficiency or receipt of immunosuppressive therapy; history of known Guillain–Barre´ syndrome Out of scope: None				
Langley, 2013[152] GlaxoSmithKline, 2010[263] NCT01198756 Article RCT N=3094 Industry funded USA, Canada, Mexico, Spain, Taiwan	Age: Mean age in years (SD; median; range) QIV 8.9 (4.21; 8.0; 3–17) TIV-Vic 8.9 (4.23; 9.0; 2–17) TIV-Yam 8.9 (4.17; 9.0; 3–17) % female: QIV 47%, TIV-Vic 49%, TIV-Yam 50% Ethnicity: QIV: 64% Caucasian, 13% Asian, 9% African American, 1% American Indian / Native Alaskan,	IIV Fluarix Quadrivalent 0.5mL per dose for either 1 or 2 doses (28 days apart) depending on prior influenza vaccination Intramuscular adjuvant free preservative free No co-intervention IIV Trivalent IIV, one with Victoria strain and one with Yamagata strain Fluarix trivalent 0.5mL per dose for either 1 or 2 doses (28	Lymphadenitis Vitello-intestinal duct remnant Conjunctivitis Biliary dyskinesia Anaphylactic reaction Hypersensitivity Gastroenteritis Bronchopneumonia Gastroenteritis rotavirus Influenza Lobar pneumonia Pneumonia Pneumonia viral Respiratory syncytial virus infection Accidental overdose Facial bones fracture Foreign body Head injury	Anaphylaxis: 10.X Anaphylactic reaction I: 0/932, 10.3 Anaphylactic reaction C: 1/1861 Angioedema: 10.X NA I: 0/932, 10.X NR C: 2/1861 Asthma: 22.X NA I: 0/932, 22.X NA C: 0/1861 Cardiovascular events: 26.X Hypertension I: 1/932, 26.X Hypertension C: 0/1861 Death: NA NA I: 0/932, NA NA C: 0/1861 Febrile seizures: 17.X NA I: 0/932, 17.X NA C: 0/1861 Seizure: 17.X NA I: 0/932, 17.X NA C: 0/1861	Severe AEs among children aged 5-17 years: Grade 3 fatigue: QIV 6/727 (23.8%; 20.7-27.1) vs TIV1c 13/724 (24.4%; 21.3, 27.7) vs TIV2c 177/725 (24.4%; 21.3 27.7) Grade 3 gastrointestinal: QIV 9/727 (1.2%; 0.6, 2.3) vs TIV1c 8/724 (1.1%; 0.5, 2.2) vs TIV2c 6/725 (0.8%; 0.3, 1.6) Grade 3 headache: QIV 8/727 (1.1%; 0.5, 2.2) vs TIV1c 9/724 (1.2%; 0.6, 2.3) vs TIV2c 10/725 (1.4%; 0.7, 2.5) Grade 3 joint pain: QIV 4/727 (0.6%; 0.2, 1.4) vs TIV1c 5/724 (0.7%; 0.2, 1.6) vs TIV2c 1/725 (0.1%; 0.0, 0.8) Grade 3 muscle aches: QIV 6/727 (0.8%; 0.3, 1.8) vs TIV1c 5/724 (0.7%; 0.2, 1.6) vs TIV2c 9/725 (1.2%; 0.6, 2.3) Grade 3 shivering: QIV 4/727 (0.6% 0.2, 1.4) vs TIV1c 10/724 (1.4%; 0.7, 2.5) vs TIV2c 4/725 (0.6%; 0.2, 1.4)

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
	0% Pacific Islander/Native Hawaiian, 13% Other, TIV-Vic, 62% Caucasian, 14% Asian, 9% African American, 0% American Indian / Native Alaskan, 0% Pacific Islander/Native Hawaiian, 15% Other, TIV-Yam 62% Caucasian, 13% Asian, 9% African American, 0% American Indian / Native Alaskan, 0% Pacific Islander/Native Hawaiian, 15% Other, (Yes TIV-Vic and TIV-Yam are identical at that level) Children in stable health between 6 months and 17 years of age and not pregnant Out of scope: None	days apart) depending on prior influenza vaccination Intramuscular adjuvant freepreservative free Counts No prespecified AE Power other outcome Followup: 6 months	Joint dislocation Traumatic brain injury Hypovolaemia Febrile convulsion Grand mal convulsion Depression Anxiety Suicidal ideation Asthma Angioedema Urticaria Hypertension Diarrhoea Pain (prespecified) Redness (prespecified) Swelling (prespecified) Drowsiness (prespecified) Irritability (prespecified) Loss of appetite (prespecified) Temperature/Fever (prespecified) Fatigue (prespecified) Gastrointestinal symptoms (prespecified) Headache (prespecified) Joint pain at other location (prespecified) Muscle aches (prespecified) Shivering (prespecified) Pyrexia Upper respiratory tract infection Nasopharyngitis Cough Rhinorrhoea		Serious AEs (from clinicaltrials.gov): Intervention (Fluarix Quadrivalent) vs Control 1 (Fluarix Trivalent Victoria Strain) vs Control 2 (Fluarix Trivalent Yamagata Strain) Note combined Control 1 and 2 in table Affected / at Risk (%)Affected / at Risk (%)Affected / at Risk Total 3/932 (0.32%) 6/929 (0.65%) 5/932 (0.54%) Blood and lymphatic system disorders Lymphadenitis 1/932 (0.11%) 0/929 (0.00%) 0/932 (0.00%) Congenital, familial and genetic disorders Vitello-intestinal duct remnant 0/932 (0.00%) 1/929 (0.11%) 0/932 (0.00%) Eye disorders Conjunctivitis 0/932 (0.00%) 0/929 (0.00%) 1/932 (0.11%) Hepatobiliary disorders Biliary dyskinesia 0/932 (0.00%) 1/929 (0.11%) 0/932 (0.00%) Immune system disorders Anaphylactic reaction (in AE table) Hypersensitivity 0/932 (0.00%) 1/929 (0.11%) 0/932 (0.00%) Infections and infestations Gastroenteritis 0/932 (0.00%) 1/929 (0.11%) 0/932 (0.00%) Bronchopneumonia 0/932 (0.00%) 0/929 (0.00%) 1/932 (0.11%) Gastroenteritis rotavirus 0/932 (0.00%) 0/929 (0.00%) 1/932 (0.11%) Influenza 0/932 (0.00%) 0/929 (0.00%) 1/932 (0.11%) Lobar pneumonia 0/932 (0.00%) 0/929 (0.00%) 0/932 (0.00%) Pneumonia 0/932 (0.00%) 1/929 (0.11%) 0/932 (0.00%) Pneumonia viral 0/932 (0.00%) 0/929 (0.00%) 0/932 (0.00%) Respiratory syncytial virus infection 0/932 (0.00%) 0/929 (0.00%) 0/932 (0.00%) Injury, poisoning and procedural complications Accidental overdose 1/932 (0.11%) 0/929 (0.00%) 0/932 (0.00%)

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
					Facial bones fracture0/932 (0.00%) 0/929 (0.00%) 1/932 (0.11%) Foreign body 0/932 (0.00%) 0/929 (0.00%) 0/932 (0.00%) Head injury 0/932 (0.00%) 0/929 (0.00%) 1/932 (0.11%) Joint dislocation 0/932 (0.00%) 0/929 (0.00%) 1/932 (0.11%) Traumatic brain injury 0/932 (0.00%) 1/929 (0.11%) 0/932 (0.00%) Metabolism and nutrition disorders Hypovolaemia 0/932 (0.00%) 0/929 (0.00%) 1/932 (0.11%) Nervous system disorders Febrile convulsion (in AE table) Grand mal convulsion (in AE table) Psychiatric disorders Depression 1/932 (0.11%) 1/929 (0.11%) 0/932 (0.00%) Anxiety 0/932 (0.00%) 1/929 (0.11%) 0/932 (0.00%) Suicidal ideation * 0/932 (0.00%) 1/929 (0.11%) 0/932 (0.00%) Respiratory, thoracic and mediastinal disorders Asthma (in AE table) Skin and subcutaneous tissue disorders Angioedema (in AE table) Urticaria 0/932 (0.00%) 1/929 (0.11%) 0/932 (0.00%) Vascular disorders Hypertension 1/932 (0.11%) 0/929 (0.00%) 0/932 (0.00%) Risk factors: NR

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
Langley, 2015[153] GlaxoSmithKline, 2012[268] NCT01711736 Article RCT N=601 Industry funded Canada, Dominican Republic, Honduras	Age: Month: 18.1 (8.25) % female: 50% Ethnicity: 16% European heritage/Caucasian, 5% Asian, 1% African heritage/African American Children in stable health between 6 to 35 months of age at time of first vaccination Out of scope: None	IIV Flulaval Quadrivalent 15 µg of hemagglutinin (HA) from 4 strains recommended for the 2012–2013 season [10]: A/California/7/2009(H1N1)pdm09, A/Victoria/361/2011(H3N2), B/Brisbane/60/2008 (Victoria lineage), and B/Hubei-Wujiagang/158/2009 (Yamagata lineage). 0.5 mL, either 1 or 2 doses depending on vaccination history Intramuscular adjuvant free preservative free No co-intervention IIV Trivalent IIV Fluarix 0.5 mL, either 1 or 2 doses depending on vaccination history Intramuscular adjuvant freepreservative free Counts No prespecified AE Power other outcome Followup: 6 months	Colitis ulcerative Diarrhoea Intestinal obstruction Bronchiolitis Gastroenteritis rotavirus Amoebic dysentery Bacterial pyelonephritis Blastocystis infection Dengue fever Otitis media acute Peritonitis Pharyngitis streptococcal Respiratory syncytial virus bronchiolitis Rotavirus infection Septic shock Tonsillitis Dehydration Febrile convulsion Asthma Bronchial hyperreactivity Pneumonia aspiration Pain (prespecified) Drowsiness (prespecified) Redness (prespecified) Swelling (prespecified) Irritability/fussiness (prespecified) Loss of appetite (prespecified) Fever (prespecified) Infections and infestations Nasopharyngitis	Asthma: 22.X NA I: 0/299, 22.X NR C: 1/302 Autoimmune disease: 7.X Ulcerative colitis I: 0/299, 7.X Ulcerative colitis C: 1/302 Febrile seizures: 17.1 Simple partial febrile seizure 6 hours after dose 1, resolved without sequelae I: 1/299, 17.X NA C: 0/302	Injection-site pain: QIV 32.6% vs TIV 30.6% Grade 3 pain: 2.4% vs 1.0% Irritability/fussiness: QIV 40.7% vs TIV 41.6% Grade 3 irritability/fussiness: QIV 5.2% vs TIV 4.7% Temperature 39.0C or higher: QIV 3.8% (95% CI 1.9-6.7) vs TIV 3.0% (95% CI 1.4-5.7) At least 1 unsolicited grade 3 AE: QIV 3.0% vs TIV 1.7% Serious AEs (from clinicaltrials.gov) Intervention (Fluarix Quadrivalent) vs (Fluarix) Affected / at Risk (%)Affected / at Risk (%) Total 9/299 (3.01%) 8/302 (2.65%) Gastrointestinal disorders Colitis ulcerative (in AE table) Diarrhoea 1/299 (0.33%) 0/302 (0.00%) Intestinal obstruction 0/299 (0.00%) 1/302 (0.33%) Infections and infestations Bronchiolitis 0/299 (0.00%) 2/302 (0.66%) Gastroenteritis rotavirus 0/299 (0.00%) 2/302 (0.66%) Amoebic dysentery 1/299 (0.33%) 0/302 (0.00%) Bacterial pyelonephritis 1/299 (0.33%) 0/302 (0.00%) Blastocystis infection 0/299 (0.00%) 1/302 (0.33%) Dengue fever 1/299 (0.33%) 0/302 (0.00%) Otitis media acute 0/299 (0.00%) 1/302 (0.33%) Peritonitis 0/299 (0.00%) 1/302 (0.33%) Pharyngitis streptococcal 1/299 (0.33%) 0/302 (0.00%) Respiratory syncytial virus bronchiolitis 0/299 (0.00%) 1/302 (0.33%) Rotavirus infection1/299 (0.33%) 0/302 (0.00%) Septic shock 0/299 (0.00%) 1/302 (0.33%) Tonsillitis 0/299 (0.00%) 1/302 (0.33%) Metabolism and nutrition disorders Dehydration 1/299 (0.33%) 1/302 (0.33%)

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
					Nervous system disorders Febrile convulsion (in AE table) Respiratory, thoracic and mediastinal disorders Asthma (in AE table) Bronchial hyperreactivity 0/299 (0.00%) 1/302 (0.33%) Pneumonia aspiration 1/299 (0.33%) 0/302 (0.00%) Risk factors: NR
Li, 2016[160] Article Other design N=275261 Not industry funded USA	Age: Ages 6-23 months (for analysis of interest) % female: N/A Ethnicity: Ethnicity NR Members of integrated healthcare systems with 6 to 23 month-old children Out of scope: None	IIV Not reported Route NR adjuvant NR preservative NR Co-intervention Other routine vaccines, including PCV13 (Prevnar) Base treatment Control was comparison interval compared to risk interval Analytic study Prespecified AE Power calculation Followup: 2 months	Acute disseminated encephalomyelitis (ADEM) Anaphylaxis Bell's palsy Encephalitis Guillain–Barré syndrome (GBS) Febrile seizures Transverse myelitis	NA	End of season analysis for febrile seizures following IIV3 for the combined two seasons and IIV4 for the 2014–2015 season among 6- to 23- month-old children: IIV4 with PCV 13 and other vaccines: 12.3, (95% CI 2.50 – 58.90) IIV4 without PCV13: 0.6. (95% CI 0.07 – 4.85) IIV alone (no other concomitant vaccines): 1.2 (0.12-11.20) Study states that found no evidence of statistically significant relationship between IIV4 and seven predefined AE (ADEM, Anaphylaxis, Bell's palsy, Encephalitis, GBS, Seizure, Transverse myelitis) across all age groups, but no risk estimates were provided. Risk factors: Yes, by PCV13 and other concomitant vaccine and by other concomitant vaccines

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
Rodriguez Weber, 2014[188] GlaxoSmithKline, 2009[261] NCT00985790 Article RCT N=599 Industry funded Mexico	Age: Median age 33 months (range 18-47 months) % female: 48% Ethnicity: Ethnicity NR Children who received 2 0.5 mL doses of thimerosal-free TIV in prior season at age 6-5 months (primed cohort), and children from same community who had received 1 or no doses in the past (unprimed cohort) Out of scope: None	IIV Fluarix Quadrivalent 1-2 0.5 mL doses depending on prior vaccination status Intramuscular adjuvant free preservative free No co-intervention IIV IIV3 Fluarix 1-2 0.5 mL doses depending on prior vaccination status Intramuscular adjuvant freepreservative free Counts Prespecified AE Power other outcome Followup: 6 months	Pain (prespecified) Redness (prespecified) Swelling (prespecified) Fever (prespecified) Irritability/fussiness (prespecified) Drowsiness (prespecified) Loss of appetite (prespecified) Bronchopneumonia Uticaria	Death: NA NA I: 0/293, NA NA C: 0/298	Severe AEs (from clinicaltrials.gov), Grade 3 Pain 4/293 (1.4%) 1/298 (0.3%) Redness >50 mm 0/293 (0.0%) 0/298 (0.0%) Swelling >50 mm 0/293 (0.0%) 0/298 (0.0%) Severe AEs (from article), Any Grade 3 unsolicited event 10/298 (3.4%) 12/301 (4.0%) Serious AEs (from clinicaltrials.gov), Intervention (Fluarix Quadrivalent) vs Control (Fluarix), Affected / at Risk (%)Affected / at Risk (%) Total 0/298 (0.00%) 2/301 (0.66%) Bronchopneumonia 0/298 (0.00%) 1/301 (0.33%) Urticaria 0/298 (0.00%) 1/301 (0.33%) Risk factors: NR
Walter, 2020[233] Duke University, 2018[380] NCT03165981 Article RCT N=221 Not industry funded USA	Age: 14.6 months (range 12-16.9) % female: 50% Ethnicity: 8% American Indian/Alaskan Native, 8%Asian only, 1% Native Hawaiian or other Pacific Islander only, 8% Black only, 53% White only, 18% >1 race, 4% Unknown or not reported Children aged 12-16 months	IIV Fluzone Quadrivalent 0.25 mL Intramuscular adjuvant free preservative free Co-intervention PCV13 (Prevnar 13) and DtaP (Infanrix) Base treatment PCV13 and DTaP (later received IIV4 as well, but not part of comparison of interest) Prevnar 13, Infanrix 0.5 mL PCV13 and 0.5 mLDTaP	Dehydration	Death: NA NA I: 0/99, NA NA C: 0/107	Intervention (IIV4+PCV13+DTaP) vs Control (PCV13+DTaP) Days 1-2, any fever after visit 1: 91/99 (91.9%) vs 98/107 (91.6%), RR 0.97 (95% CI 0.39-2.40), p=0.94 Days 1-2, Grade 2 or 3 fever after visit 1: 95/99 (96%) vs 102/107 (95.3%), RR 0.87 (0.24-3.13), p=0.832 Days 3-8, any fever after visit 1: 93/99 (93.9%) vs 99/107 (92.5%), RR 0.81 (0.29-2.25), p=0.684 Days 3-8, Grade 2 or 3 fever after visit 1: 96/99 (97%) vs 102/107 (95.3%), RR 0.65 (0.16-2.64), p=0.544 Serious AE (dehydration): 0/99 (0%) vs 1/107 (0.93%), no p-value reported Days 1-2, antipyretic use after visit 1: 37.4% vs 22.4%, p=0.020 Risk factors: NR

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
	and current with Advisory Committee on Immunization Practices immunizations Out of scope: None	Counts No prespecified AE Power calculation Followup: 1 months			
Wang, 2016[234] GlaxoSmithKline, 2014[270] NCT01974895 Article RCT N=316 Industry funded USA	Age: 19.7 months (8.9) % female: 50% Ethnicity: 55% White (Caucasian or European heritage), 36% African/African American, 0% Native Hawaiian or other Pacific Islander, <1% American Indian or Alaskan Native, 1% Asian, <1% White (Arabic or North African), 8% Other, Healthy children aged 6-35 months and those with chronic illness who were not acutely ill at the time of enrollment at 12 centers across	IIV Flulaval Quadrivalent 15 µg HA of each of 4 strains (A/California/7/2009 [A/H1N1], A/Texas/50/2012 [A/H3N2], B/Brisbane/60/2008 [B/Victoria], and B/Massachusetts/2/2012 [B/Yamagata]) 60% received 1.0 mL in 2 doses; 40% received 0.5 mL in 1 dose, depending on vaccination history Intramuscular adjuvant free preservative free No co-intervention IIV Trivalent IIV covering three of the four strains of the investigational vaccine Fluzone 59% received 1.0 mL in 2 doses;	Injection site pain, redness, swelling (prespecified) Respiratory syncytial virus infection Abscess neck Respiratory syncytial virus bronchiolitis Viral infection Dehydration Failure to thrive Convulsion Sleep apnoea syndrome Vomiting Diarrhoea Pain Drowsiness Irritability/fussiness Loss of appetite Fever Otitis media Upper respiratory tract infection Nasopharyngitis Cough Rhinorrhoea	Death: NA NA I: 0/158, NA NA C: 0/156 Seizure: 17.X NA I: 0/158, 17.X Not considered related to vaccination C: 1/156	Severe AEs (Grade 3 AEs, defined as severe enough to prevent everyday activity): Intervention 2/158 (1.26%) vs Control 1/156 (0.64%) Serious AEs (from clinical trials.gov): Intervention (FluLaval Quadrivalent) vs Control (Fluzone) Affected / at Risk (%)Affected / at Risk (%) Total 5/158 (3.16%) 4/156 (2.56%) Infections and infestations Respiratory syncytial virus infection 2/158 (1.27%) 0/156 (0.00%) Abscess neck 0/158 (0.00%) 1/156 (0.64%) Respiratory syncytial virus bronchiolitis 0/158 (0.00%) 1/156 (0.64%) Viral infection 1/158 (0.63%) 0/156 (0.00%) Metabolism and nutrition disorders Dehydration 1/158 (0.63%) 0/156 (0.00%) Failure to thrive 0/158 (0.00%) 1/156 (0.64%) Nervous system disorders Convulsion (in AE table) Respiratory, thoracic and mediastinal disorders Sleep apnoea syndrome * 1/158 (0.63%) 0/156 (0.00%) Risk factors: NR

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
	the United States during the fall and winter of 2013–2014. Out of scope: None	41% received 0.5 mL in 1 dose, depending on vaccination history Intramuscular adjuvant freepreservative free Counts No prespecified AE Power other outcome Followup: 6 months			
Block, 2012[69] MedImmune LLC, 2010[306] NCT01091246 Article RCT N=2312 Industry funded USA	Age: Intervention 6.7 years (3.8); Control 6.8 years (3.8) % female: 51% Ethnicity: Intervention 70% White, 18% Black, <1% Asian, <1% American Indian/Alaska Native, <1% Pacific Islander, 10% Other race or multiracial; Control 72% White, 18% Black, <1% Asian, <1% American Indian/Alaska Native, <1% Pacific Islander, 9% Other race or multiracial Children aged 2-17 years (subjects <2 years of age	Influenza LAIV FluMist Quadrivalent 1-2 doses depending on prior vaccination status Intranasal adjuvant NR preservative NR No co-intervention Other : Trivalent LAIV Trivalent LAIV FluMist 1-2 doses depending on prior vaccination status Intranasal adjuvant NR preservative NR Counts Unclear Power other outcome Followup: 6 months	Pyrexia Headache Orophyaryngeal pain Vomiting Diarrhea Appendicitis Salmonella gastroenteritis with dehydration Major depression New-onset chronic disease Fever Appendicitis Cellulitis Gastroenteritis salmonella Sepsis Urinary tract infection Head injury Humerus fracture Lung injury Dehydration Diabetic ketoacidosis Type 1 diabetes mellitus Cerebrovascular accident Pelvi-ureteric obstruction Pneumothorax	Death: NA No life-threatening or fatal AEs I: 0/1382, NA No life-threatening or fatal AEs C: 0/923 Diabetes: 14.X Type 1 diabetes, not thought to be due to vaccine I: 1/1382, 14.X Type 1 diabetes, not thought to be due to vaccine C: 0/923 Stroke: 17.X Cerebrovascular accident, not thought to be due to vaccine I: 0/1382, 17.X Cerebrovascular accident, not thought to be due to vaccine C: 1/923	New-onset chronic diseases: Q-LAIV 1.4% vs T-LAIV 0.8% Fever after dose 1 subjects 2–8 years of age: Q-LAIV 5.1% vs T-LAIV 3.1% Serious AEs (from clinicaltrials.gov): Intervention (Q/LAIV [MEDI3250]) vs Control (FluMist) Affected / at Risk (%)# EventsAffected / at Risk (%)# Events Total 6/1382 (0.43%) 5/923 (0.54%) Infections and infestations Appendicitis 1/1382 (0.07%) 0/923 (0.00%) Cellulitis 1/1382 (0.07%) 0/923 (0.00%) Gastroenteritis salmonella 1/1382 (0.07%) 0/923 (0.00%) Sepsis 0/1382 (0.00%) 1/923 (0.11%) Urinary tract infection 0/1382 (0.00%) 2/923 (0.22%) Injury, poisoning and procedural complications Head injury 0/1382 (0.00%) 1/923 (0.11%) Humerus fracture 1/1382 (0.07%) 0/923 (0.00%) Lung injury 0/1382 (0.00%) 1/923 (0.11%) Metabolism and nutrition disorders Dehydration 1/1382 (0.07%) 0/923 (0.00%) Diabetic ketoacidosis 1/1382 (0.07%) 0/923 (0.00%)

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
	were excluded because trivalent LAIV is not indicated in that population based on existing safety data; children with a history of asthma and children <5 years of age with recurrent wheezing were excluded to be consistent with US dosing recommendations for trivalent LAIV) Out of scope: None				Type 1 diabetes mellitus 1/1382 (0.07%) 0/923 (0.00%) (in AE table) Nervous system disorders Cerebrovascular accident 0/1382 (0.00%) 1/923 (0.11%) (in AE table) Psychiatric disorders Major depression 0/1382 (0.00%) 1/923 (0.11%) Renal and urinary disorders Pelvi-ureteric obstruction 0/1382 (0.00%) 1/923 (0.11%) Respiratory, thoracic and mediastinal disorders Pneumothorax 0/1382 (0.00%) 1/923 (0.11%) *No SAEs thought to be study vaccine-related Risk factors: Yes, stratifies analyses by age 2-8 years. Solicited symptoms occurring after the first dose in the subset of subjects who were 2–8 years of age are presented. In this age group, there was a small (2.0 percentage points) but statistically significant increase in fever ≥38°C (100.4°F) in the Q/LAIV group (5.1%) compared with the T/LAIV group (3.1%). In subjects 2–8 years of age who received 2 doses, fewer subjects had AEs after the second dose than after the first (Q/LAIV doses 1 and 2, 20% and 13%; T/LAIV 23% and 17%, respectively).
Caspard, 2018[76] EUPAS18527 Article Pre-post N=33646 Industry funded UK	Age: 2014-2015 season (when LAIV4 used): 12% aged 2-3 years, 37% aged 4-8 years, 51% aged 9-17 years % female: 42% Ethnicity: Ethnicity NR Children and adolescents aged 2-17 years with asthma and high-risk	Influenza LAIV FluMist Quadrivalent Intranasal adjuvant NR preservative NR No co-intervention No intervention Matched unvaccinated controls (matched on age, calendar date , healthcare utilization in past 12 months,	Hypersensitivity Seizures/convulsions Vasculitis Asthma Croup Wheezing Bronchiolitis Pneumonia Acute respiratory failure Guillain-Barre syndrome Bell's palsy Encephalitis Neuritis Narcolepsy	Seizure: 17.X 2014-2015 season I: 22/6745, 17.X 2014-2015 season; seizures in matched TIV was 52/6738 C: 36/20163	LAIV vs no vaccine, 2014-2015 season (RR, 95% CI): Any hospitalization within 42 days: RR 0.90 (0.76 to 1.07); Hospitalization for lower respiratory event within 42 days: RR 0.85 (0.65 to 1.10) Any hospitalization within 6 months: RR 1.08 (0.97 to 1.20); Hospitalization for lower respiratory event within 6 months: RR 1.01 (0.87 to 1.18) LAIV vs IIV, 2014-2015 season (RR, 95% CI): Any hospitalization within 42 days: RR 0.42 (0.35 to 0.51); Hospitalization for lower respiratory event within 42 days: RR 0.46 (0.35 to 0.61)

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
	conditions during 2014-2015 season who received LAIV4 and their match unvaccinated controls and matched controls vaccinated with IIV (2013-2014 also examined, but used LAIV3 so excluded from this analysis) Out of scope: None	geographic location). Note there are also matched controls who received any IIV (matched on age, calendar date , healthcare utilization in past 12 mon Counts No prespecified AE Power calculation Followup: 6 months			Any hospitalization within 6 months: RR 0.53 (0.47 to 0.59); Hospitalization for lower respiratory event within 6 months: RR 0.59 (0.50 to 0.70) LAIV within-cohort analysis, 2014-2015 season (risk versus comparison period) (RR 95% CI): Any hospitalization: RR 1.00 (0.79 to 1.26); Hospitalization for lower respiratory event: RR 1.12 (0.79 to 1.60) LAIV vs no vaccine 2014-2015 season (RR, 95% CI): Hypersensitivity: 2.00 (0.26-12.07); Seizures (counts in table): 1.65 (0.95-2.80); Vasculitis: 3.00 (0.20-9.94) LAIV vs IIV, 2014-2015 season (RR, 95% CI): Hypersensitivity: 0.66 (0.02, 2.60); Seizures (22/6745 vs 52/6738): 0.42 (0.25-0.69); Vasculitis: NE Risk factors: Study in children with asthma and high-risk conditions, no increased risk of hospitalizations
Mallory, 2018a[164] AstraZeneca, 2015[241] NCT02269475 Article RCT N=1301 Industry funded Japan	Age: 10.9 (2.9) years % female: 49% Ethnicity: Ethnicity NR Children aged 7-18-years Out of scope: None	Influenza LAIV FluMist Quadrivalent 0.2 ml in one dose; those aged 7-8 yrs without prior vaccination for seasonal flu received a second dose Intranasal adjuvant free preservative free No co-intervention Placebo Placebo of 0.1 mL per nostril (0.2 mL total) Counts Prespecified AE Power NR Followup: 1 months	Runny/Stuffy Nose Cough Sore Throat Headache Lethargy Fever Decreased Appetite Generalized Muscle Aches Nasopharyngitis Appendicitis Peritonsillar abscess Pneumonia Osteochondrosis Convulsion Renal and urinary disorders Hydronephrosis	Seizure: 17.X Convulsion I: 1/868, 17.X Convulsion C: 0/433	Severe AEs: Treatment-emergent AEs: QLAIV 0/868 (0%) vs Control 0/433 (0%) Serious AEs (from clincialtrials.gov), Intervention (QLAIV) vs Control (Placebo) Total 3/868 (0.35%) vs 3/433 (0.69%) Appendicitis 1/868 (0.12%)vs 0/433 (0.00%) Peritonsillar abscess 1/868 (0.12%) vs 0/433 (0.00%) Pneumonia 0/868 (0.00%) vs 1/433 (0.23%) Musculoskeletal and connective tissue disorders Osteochondrosis 0/868 (0.00%) vs 1/433 (0.23%) Hydronephrosis 0/868 (0.00%) vs 1/433 (0.23%) Risk factors: NR

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
Mallory, 2020[163] MedImmune, 2017[308] NCT03143101 Article RCT N=200 Industry funded USA	Age: 35.3 months (6.7) % female: 47% Ethnicity: 0.5% American Indian or Alaska Native, 0.5% Asian, 15.5% Black or African American, 1.5% Native Hawaiian or other Pacific Islander, 78.0% White, 0.5% Other, 3.5% Multiple categories checked; 17% Hispanic or Latino Children aaged 24 to <48 months at the time of screening; were healthy by medical history and physical examination or had a stable underlying chronic medical condition for which hospitalization was not required in the previous year. Out of scope: None	Influenza LAIV FluMist Quadrivalent LAIV4 2015–2016 (LAIV4A/Bolivia [Vaccine lot number: JC2196; Manufacturer: MedImmune, LLC] (Did not include 2017-2018 intervention as no comparator) Single 0.2 mL dose of vaccine (0.1 mL per nostril) on Day 1 and a second dose on Day 28 of the study Intranasal adjuvant NR preservative NR No co-intervention Other : Trivalent live attenuated influenza vaccine Trivalent LAIV (LAIV3) 2015–2016 (LAIV3A/Bolivia [Vaccine lot number: JC2195; Manufacturer: MedImmune, LLC]) (a formulation developed as a comparator for this study) No brand name Single 0.2 mL dose of vaccine (0.1 mL per nostril) on Day 1 and a second	Tympanic membrane perforation Eye oedema Ocular hyperaemia Strabismus Abdominal discomfort Abdominal pain Abdominal pain upper Constipation Dental caries Diarrhoea Haematochezia Mouth haemorrhage Nausea Oral discomfort Oral pain Toothache Vomiting Chills Developmental delay Pyrexia Allergy to arthropod bite Seasonal allergy Cellulitis Conjunctivitis Croup infectious Ear infection Escherichia urinary tract infection Folliculitis Gastroenteritis viral Hand-foot-and-mouth disease Herpes simplex Localised infection Otitis media acute Pharyngitis Pharyngitis streptococcal	Death: NA NA I: 0/66, NA NA C: 0/67	No serious AEs. No severe AEs in the 2015-2016 intervention or comparator group. Risk factors: No

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
		dose on Day 28 of the study Intranasal adjuvant NRpreservative NR Counts No prespecified AE Power other outcome Followup: 2 months			
Stockwell, 2017[207] Columbia University, 2013[248] NCT01764269 Article Cohort study N=540 Not industry funded USA	Age: Intervention (LAIV) 24% 24-35 mos, 38% 36-47 mos, 38% 48-59 mos; Control (IIV) 43% 24-35 mos, 27% 36-47 mos, 30% 48-59 mos % female: Intervention 56%; Control 45% Ethnicity: Intervention 90% Latino, 8% Black non-Latino, <1% White non-Latino, 2% Other; Control 82% Latino, 15% Black non-Latino, <1% White non-Latino, 3% Other Children aged 24 to 59 months receiving first influenza vaccine (LAIV or IIV) dose of that	Influenza LAIV FluMist Quadrivalent Not reported Route NR adjuvant NR preservative NR No co-intervention IIV IIV (either trivalent or quadrivalent) Not reported Not reported route NR adjuvant NRpreservative NR Counts No prespecified AE Power calculation Followup: 1 months	Fever Febrile seizures Upper respiratory infection/allergy Pharyngitis/asthma Gastroenteritis Viral illness Laceration Pneumonia Vomiting Blepharitis Thumb issue Diaper dermatitis	Febrile seizures: 17.X NA I: 0/226, 17.X NA C: 0/314	Temperature ≥ 100.4○F on d0–d2 LAIV4 7/183 (3.8%) vs IIV 15/264 (5.7%), adjusted RR 0.60 (95% CI 0.25–1.46) LAIV4 6/142 (4.2%) vs IIV4 6/85 (7.1%), adjusted RR 0.58 (95% CI 0.19–1.72) LAIV4 6/85 (7.1%) vs IIV3 4/67 (6.0%), adjusted RR 1.02 (95% CI 0.30–3.46) Sub-group/modifier analysis in multivariate model: Fever reported on all days (d0–d2): aRR, 0.65 [95% CI 0.27–1.59] Those who received influenza vaccine alone: aRR, 0.60 [95% CI, 0.15–2.40] When excluded those who were given an antipyretic: aRR, 0.64 [95% CI, 0.22–1.88] When analysis was limited to ≥3-year-olds: aRR, 0.61 [95% CI, 0.23–1.64 When previous influenza vaccination removed from model: aRR, 0.58 [95% CI, 0.24–1.42] When race/ ethnicity added to model: aRR 0.72 [95% CI 0.29–1.75] Presence of a high- risk medical condition added to model: aRR 0.56 [95% CI 0.23–1.36] Risk factors: Yes: nothing statistically significant

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
	season at the time of enrollment Out of scope: None				
Abdelnour, 2014[51] Novartis, 2008[321] NCT00806195 Article RCT N=7744 Industry funded US, Guatemala, Peru, Taiwan, Costa Rica, and Panama	Age: MenACWY-CRM + routine vaccinations = 65.1 (7.2) days; Routine vaccinations only = 64.8 (6.9) days % female: MenACWY-CRM + routine vaccinations = 49%; Routine vaccinations = 47% Ethnicity: MenACWY-CRM + routine vaccinations: 11% Asian, 6% Black, 31% Caucasian, 42% Hispanic, 9% Other. Routine vaccinations only: 11% Asian, 6% Black, 32% Caucasian, 42% Hispanic, 9% Other	Men quadrivalent Menveo [MenACWY-CRM] 0.5 mL dose with 10 mcg of MenA and 5 mcg each of MenC, MenW, MenY, each in 4 doses given at 2, 4, 6, 12 months of age Intramuscular adjuvant free preservative free Co-intervention Minimum core set of routine infant vaccinations including diphtheria, tetanus, pertussis (DTaP), inactivated polio vaccine (IPV), and H. influenzae type b (Hib) vac- cine at 2, 4 and 6 months of age, 7-valent pneumococcal	Local tenderness Erythema Induration Change in eating habit Sleepiness Persistent crying Irritability Vomiting Diarrhea Fever Anaemia Iron Deficiency Anaemia Leukocytosis Mesenteric Lymphadenopathy Thrombocytopenia Lymphadenitis Lymphadenopathy Cardiac Arrest Cyanosis Supraventricular Tachycardia Ventricular Tachycardia Eye disorders Retinal Haemorrhage Abdominal Pain Constipation Diarrhoea Enteritis Enterocolitis Gastritis	Asthma: 22.X severity not specified I: 6/5760, 22.X severity not specified C: 1968/2 Cardiovascular events: 2.X Supraventricular tachycardia I: 1/5760, 2.X Supraventricular tachycardia C: 1/1968 Death: NA none of which were considered to be related to MenACWY-CRM I: 7/5772, NA Due to nosocomial pneumonia occurred in an infant randomized to routine vaccines alone. In this case, the subject had a late-identified congenital cardiac anomaly and death occurred after the subject was withdrawn from the study, 75 days after final vacci C: 1/1968 Encephalitis: 11.X NR I: 1/5760, NA NA C: 0/1968 Encephalomyelitis: 11.X 1 ADEM, Possibly related to MenACWY-CRM (per article) I: 1/5760, NA NA C: 0/1968 Febrile seizures: 17.X NR I: 9/5760, 17.X NR C: 6/1968 Immune Thrombocytopenia Purpura: 1.X NR I: 0/5760, 1.X NR C: 1/1968 Intussusception: 7.X NR I: 4/5760, 7.X NR C: 3/1968	Serious AEs (Intervention Groups 1 and 3 vs Controls Groups 2 and 4): Day 1 to study end (18 months): 354/5757 (6%) vs 114/1967 (6%); Day 1 to 12 months of age: 275/5760 (5%) vs 88/1968 (4%); Day 1 to <Month 7: 158/5760 (3%) vs 42/1968 (2%); >Month 7 to <Month 12: 131/5429 (2%) vs 131/5429 (2%); >Month 13 to study end: 78/5128 (2%) vs 31/1738 (2%) Similar percentage of subjects experienced ≥1 severe solicited systemic reaction from 15 min to Day 7 after vaccination in Group 3 (16%) and Group 4 (13%) Severe solicited AEs (Intervention Group 3 vs Controls Group 4): Local tenderness dose any dose: 90/1348 (7%) vs 44/461 (10%); Erythema any dose: 3/1346 (<1%) vs 2/460 (<1%); Induration any dose: 0/1346 (0%) vs 1/460 (<1%); Change in eating habit: 46/1343 (3%) vs 12/461 (3%) Sleepiness: 55/1348 (4%) vs 12/460 (3%) Persistent crying: 16/1094 (1%) vs 6/353 (2%) Irritability: 79/1346 (6%) vs 27/460 (6%) Vomiting: 10/1346 (1%) vs 0/460 (0%) Diarrhea: 28/1346 (2%) vs 7/460 (2%)

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
	Healthy 2-month-old infants (aged 55–89 days), born at ≥37 weeks gestation, with a birth weight ≥2.5 kg Out of scope: None	conjugate vaccine at 2, 4, 6 and Base treatment Routine vaccines alone Counts No prespecified AE Power calculation Followup: 16 months	Gastrooesophageal Reflux Disease Ileus Inguinal Hernia Inguinal Hernia, Obstructive Stomatitis Vomiting Brain Death Hernia Pyrexia Jaundice Acute Tonsilitis Adenovirus Infection Arthritis Bacterial Ascariasis Bacteraemia Bacterial Diarrhoea Bacterial Tracheitis Bronchiolitis Bronchitis Bronchopneumonia Cellulitis Cellulitis Staphylococcal Cellulitis Streptococcal Chest Wall Abscess Croup Infectious Diarrhoea Infectious Dysentery Enterovirus Infection Escherichia Urinary Tract Infection Exanthema Subitam Furuncle Gastroenteritis Gastroenteritis Rotavirus Gastroenteritis Salmonella Gastroenteritis Viral Genital Abscess Groin Abscess Haemophilus Bacteraemia Hand-Foot-And-Mouth Disease Herpangina Incision Site Cellulitis Infected Cyst Influenza	Kawasaki Disease: 10.X 2 possibly related to MenACWY-CRM I: 4/5760, 10.X NR C: 1/1968 Meningitis: 11.X Meningitis I: 1/5760, 11.X Meningitis C: 0/1968 Reproduction issues: 21.X Scrotal mass I: 1/5760, 21.X Scrotal mass C: 0/1968	Fever (not captured for any dose, only by dose): dose 1 0/1297 (0%) vs 1/446 (<1%); dose 2 0/1251 (0%) vs 1/416 (<1%); dose 3 0/1101 (0%) vs 0/368 (0%); dose 4 4/1092 (<1%) vs 1/353 (<1%) Analgesic and antipyretic medicines used: 1110/1347 (82%) vs 368/460 (80%) Serious AEs from clinicaltrials.gov (excludes those already in table, also excludes congenital/familial/genetic disorders): [MenACWY-CRM197 + Routine Vaccines (All) vs Routine Vaccines (All)] Affected / at Risk (%)Affected / at Risk (%) Blood and lymphatic system disorders Anaemia 2/5760 (0.03%) 0/1968 (0.00%) Idiopathic Thrombocytopenic Purpura (in AE table) Iron Deficiency Anaemia1/5760 (0.02%) 0/1968 (0.00%) Leukocytosis 2/5760 (0.03%) 0/1968 (0.00%) Mesenteric Lymphadenopathy 1/5760 (0.02%) 0/1968 (0.00%) Thrombocytopenia 1/5760 (0.02%) 0/1968 (0.00%) Lymphadenitis 4/5760 (0.07%) 0/1968 (0.00%) Lymphadenopathy 1/5760 (0.02%) 0/1968 (0.00%) Cardiac disorders Cardiac Arrest 1/5760 (0.02%) 0/1968 (0.00%) Cyanosis 2/5760 (0.03%) 0/1968 (0.00%) Supraventricular Tachycardia (in AE table) Ventricular Tachycardia 1/5760 (0.02%) 0/1968 (0.00%) Congenital, familial and genetic disorders (removed as all birth or congenital defects) Eye disorders Retinal Haemorrhage 1/5760 (0.02%) 0/1968 (0.00%) Gastrointestinal disorders Abdominal Pain 2/5760 (0.03%) 0/1968 (0.00%)

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
			Klebsiella Bacteraemia Lobar Pneumonia Lower Respiratory Tract Infection Lymph Node Abscess Meningitis Enteroviral Metapneumovirus Infection Otitis Media Otitis Media Acute Periorbital Cellulitis Peritonsillar Abscess Pharyngitis Pneumonia Pharyngotonsillitis Pneumococcal bacteraemia Pneumonia Adenoviral Pneumonia Bacterial Pneumonia Influenzal Pneumonia Primary Atypical Pneumonia Respiratory Syncytial Viral Pneumonia Viral Pyelonephritis Pyelonephritis Acute Respiratory Syncytial Virus Bronchiolitis Respiratory Synctial Virus Infection Rotavirus Infection Sepsis Septic Shock Sinusitis Staphylococcal Abscess Tonsilitis Upper Respiratory Tract Infection Urachal Abscess Urinary Tract Infection Urinary Tract Infection Enterococcal Urosepsis Varicella Viral Diarrhoea Viral Infection Wound Infection		Constipation 0/5760 (0.00%) 1/1968 (0.05%) Diarrhoea 5/5760 (0.09%) 3/1968 (0.15%) Enteritis 1/5760 (0.02%) 0/1968 (0.00%) Enterocolitis 3/5760 (0.05%) 1/1968 (0.05%) Gastritis 2/5760 (0.03%) 0/1968 (0.00%) Gastrooesophageal Reflux Disease 3/5760 (0.05%) 0/1968 (0.00%) Ileus 1/5760 (0.02%) 1/1968 (0.05%) Inguinal Hernia 2/5760 (0.03%) 0/1968 (0.00%) Inguinal Hernia, Obstructive 0/5760 (0.00%) 1/1968 (0.05%) Stomatitis 1/5760 (0.02%) 0/1968 (0.00%) Vomiting 3/5760 (0.05%) 0/1968 (0.00%) General disorders Brain Death 1/5760 (0.02%) 0/1968 (0.00%) Hernia 0/5760 (0.00%) 1/1968 (0.05%) Pyrexia 7/5760 (0.12%) 3/1968 (0.15%) Hepatobiliary disorders Jaundice1/5760 (0.02%) 0/1968 (0.00%) Infections and infestations Acute Tonsilitis 1/5760 (0.02%) 1/1968 (0.05%) Adenovirus Infection 1/5760 (0.02%) 0/1968 (0.00%) Arthritis Bacterial 0/5760 (0.00%) 1/1968 (0.05%) Ascariasis 1/5760 (0.02%) 0/1968 (0.00%) Bacteraemia1/5760 (0.02%) 0/1968 (0.00%) Bacterial Diarrhoea 1/5760 (0.02%) 0/1968 (0.00%) Bacterial Tracheitis 1/5760 (0.02%) 0/1968 (0.00%) Bronchiolitis 64/5760 (1.11%) 15/1968 (0.76%) Bronchitis 1/5760 (0.02%) 3/1968 (0.15%) Bronchopneumonia19/5760 (0.33%) 5/1968 (0.25%) Cellulitis 5/5760 (0.09%) 4/1968 (0.20%) Cellulitis Staphylococcal 1/5760 (0.02%) 0/1968 (0.00%)

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
			Meningitis Viral Staphylococcal Infection Accidental Poisoning Contusion Craniocerebral Injury Electrical Burn Fall Foreign Body Head Injury Humerus Fracture Injury Post Procedural Complication Skull Fracture Subdural Haemorrhage Thermal Burn Tibia Fracture Upper Limb Fracture Subdural Hematoma Electrocardiogram Qt Prolonged Dehydration Failure To Thrive Feeding Disorder Hypoglycaemia Metabolic Acidosis Convulsion Acute Disseminated Encephalomyelitis Epilepsy Febrile Convulsion Hydrocephalus Presyncope Syncope Tremor Breath Holding Drug Abuse Mental Status Changes Renal Failure Acute Renal Mass Vesicoureteric Reflux Balanitis Scrotal mass Adenoidal Hypertrophy Apnoea Asthma Atelectasis		Cellulitis Streptococcal 1/5760 (0.02%) 0/1968 (0.00%) Chest Wall Abscess 1/5760 (0.02%) 0/1968 (0.00%) Croup Infectious 10/5760 (0.17%) 5/1968 (0.25%) Diarrhoea Infectious 1/5760 (0.02%) 0/1968 (0.00%) Dysentery 1/5760 (0.02%) 0/1968 (0.00%) Enterovirus Infection 1/5760 (0.02%) 0/1968 (0.00%) Escherichia Urinary Tract Infection1/5760 (0.02%) 2/1968 (0.10%) Exanthema Subitam 0/5760 (0.00%) 3/1968 (0.15%) Furuncle 0/5760 (0.00%) 1/1968 (0.05%) Gastroenteritis 20/5760 (0.35%) 7/1968 (0.36%) Gastroenteritis Rotavirus2/5760 (0.03%) 0/1968 (0.00%) Gastroenteritis Salmonella 1/5760 (0.02%) 0/1968 (0.00%) Gastroenteritis Viral 7/5760 (0.12%) 3/1968 (0.15%) Genital Abscess 2/5760 (0.03%) 0/1968 (0.00%) Groin Abscess *2/5760 (0.03%) 0/1968 (0.00%) Haemophilus Bacteraemia 1/5760 (0.02%) 0/1968 (0.00%) Hand-Foot-And-Mouth Disease 10/5760 (0.17%) 0/1968 (0.00%) Herpangina 4/5760 (0.07%) 2/1968 (0.10%) Incision Site Cellulitis1/5760 (0.02%) 0/1968 (0.00%) Infected Cyst 1/5760 (0.02%) 0/1968 (0.00%) Influenza 4/5760 (0.07%) 0/1968 (0.00%) Klebsiella Bacteraemia 1/5760 (0.02%) 0/1968 (0.00%) Lobar Pneumonia 1/5760 (0.02%) 1/1968 (0.05%) Lower Respiratory Tract Infection 1/5760 (0.02%) 0/1968 (0.00%) Lymph Node Abscess 0/5760 (0.00%) 1/1968 (0.05%)

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
			Bronchial Hyperreactivity Bronchomalacia Bronchospasm Cough Epistaxis Hypoxia Pneumonia Aspiration Pneumonitis Pulmonary Oedema Respiratory Distress Respiratory Failure Status Asthmaticus Wheezing Dermal Cys Dermatitis Atopic Erythema Multiforme Urticaria Hernia Repair Inguinal Hernia Repair Angiopathy Kawasaki's Disease Vasculitis Anaemia Conjunctivitis Constipation Diarrhoea Teething Vomiting Injection Site Erythema Injection Site Induration Injection Site Pain Irritability Pyrexia Bronchiolitis Bronchitis Croup Infectious Gastroenteritis Influenza Nasopharyngitits Otitis Media Otitis Media Acute Pharyngitits Sinusitis Upper Respiratory Tract Infection Viral Infection Crying		Meningitis (in AE table) Meningitis Enteroviral 1/5760 (0.02%) 0/1968 (0.00%) Metapneumovirus Infection 1/5760 (0.02%) 0/1968 (0.00%) Otitis Media 2/5760 (0.03%) 3/1968 (0.15%) Otitis Media Acute1/5760 (0.02%) 3/1968 (0.15%) Periorbital Cellulitis 3/5760 (0.05%) 0/1968 (0.00%) Peritonsillar Abscess1/5760 (0.02%) 0/1968 (0.00%) Pharyngitis2/5760 (0.03%) 0/1968 (0.00%) Pneumonia 31/5760 (0.54%) 10/1968 (0.51%) Pharyngotonsillitis0/5760 (0.00%) 1/1968 (0.05%) Pneumococcal bacteraemia0/5760 (0.00%) 1/1968 (0.05%) Pneumonia Adenoviral1/5760 (0.02%) 0/1968 (0.00%) Pneumonia Bacterial 1/5760 (0.02%) 0/1968 (0.00%) Pneumonia Influenzal 1/5760 (0.02%) 0/1968 (0.00%) Pneumonia Primary Atypical 0/5760 (0.00%) 1/1968 (0.05%) Pneumonia Respiratory Syncytial Viral 1/5760 (0.02%) 0/1968 (0.00%) Pneumonia Viral 3/5760 (0.05%) 1/1968 (0.05%) Pyelonephritis 1/5760 (0.02%) 2/1968 (0.10%) Pyelonephritis Acute 4/5760 (0.07%) 0/1968 (0.00%) Respiratory Syncytial Virus Bronchiolitis 20/5760 (0.35%) 7/1968 (0.36%) Respiratory Synctial Virus Infection 4/5760 (0.07%) 2/1968 (0.10%) Rotavirus Infection 1/5760 (0.02%) 0/1968 (0.00%) Sepsis 1/5760 (0.02%) 0/1968 (0.00%) Septic Shock 3/5760 (0.05%) 0/1968 (0.00%) Sinusitis 0/5760 (0.00%) 1/1968 (0.05%)

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
			Somnolence Eating Disorder Cough Dermatitis Diaper Eczema Rash Seizure-like activity and fever Pulmonary edema and pneumonitis Congenital cardiac condition, Brain stem dysfunction, Head injury due to a fall, Septic shock or acute bronchopneumonia. Nosocomial pneumonia		Staphylococcal Abscess 1/5760 (0.02%) 2/1968 (0.10%) Tonsilitis 0/5760 (0.00%) 1/1968 (0.05%) Upper Respiratory Tract Infection 4/5760 (0.07%) 1/1968 (0.05%) Urachal Abscess 1/5760 (0.02%) 0/1968 (0.00%) Urinary Tract Infection 28/5760 (0.49%) 10/1968 (0.51%) Urinary Tract Infection Enterococcal 1/5760 (0.02%) 0/1968 (0.00%) Urosepsis 1/5760 (0.02%) 0/1968 (0.00%) Varicella 1/5760 (0.02%) 0/1968 (0.00%) Viral Diarrhoea 1/5760 (0.02%) 0/1968 (0.00%) Viral Infection 4/5760 (0.07%) 0/1968 (0.00%) Wound Infection 1/5760 (0.02%) 0/1968 (0.00%) Meningitis Viral 2/5760 (0.03%) 0/1968 (0.00%) Staphylococcal Infection 1/5760 (0.02%) 0/1968 (0.00%) Injury, poisoning and procedural complications Accidental Poisoning 1/5760 (0.02%) 0/1968 (0.00%) Contusion 1/5760 (0.02%) 0/1968 (0.00%) Craniocerebral Injury 5/5760 (0.09%) 2/1968 (0.10%) Electrical Burn 1/5760 (0.02%) 0/1968 (0.00%) Fall 1/5760 (0.02%) 0/1968 (0.00%) Foreign Body 1/5760 (0.02%) 0/1968 (0.00%) Head Injury 1/5760 (0.02%) 2/1968 (0.10%) Humerus Fracture 1/5760 (0.02%) 0/1968 (0.00%) Injury 1/5760 (0.02%) 0/1968 (0.00%) Post Procedural Complication 0/5760 (0.00%) 1/1968 (0.05%) Skull Fracture 1/5760 (0.02%) 1/1968 (0.05%) Subdural Haemorrhage 1/5760 (0.02%) 0/1968 (0.00%)

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
					Thermal Burn 1/5760 (0.02%) 0/1968 (0.00%) Tibia Fracture 1/5760 (0.02%) 0/1968 (0.00%) Upper Limb Fracture 1/5760 (0.02%) 0/1968 (0.00%) Subdural Hematoma 1/5760 (0.02%) 0/1968 (0.00%) Investigations Electrocardiogram Qt Prolonged 1/5760 (0.02%) 0/1968 (0.00%) Metabolism and nutrition disorders Dehydration 18/5760 (0.31%) 9/1968 (0.46%) Failure To Thrive 1/5760 (0.02%) 0/1968 (0.00%) Feeding Disorder 1/5760 (0.02%) 0/1968 (0.00%) Hypoglycaemia 2/5760 (0.03%) 0/1968 (0.00%) Metabolic Acidosis 2/5760 (0.03%) 0/1968 (0.00%) Nervous system disorders Acute Disseminated Encephalomyelitis (in AE table) Convulsion5/5760 (0.09%) 3/1968 (0.15%) Encephalitis (in AE table) Epilepsy 2/5760 (0.03%) 0/1968 (0.00%) Febrile Convulsion (in AE table) Hydrocephalus 1/5760 (0.02%) 0/1968 (0.00%) Presyncope 1/5760 (0.02%) 0/1968 (0.00%) Syncope 1/5760 (0.02%) 0/1968 (0.00%) Tremor 1/5760 (0.02%) 0/1968 (0.00%) Psychiatric disorders Breath Holding 1/5760 (0.02%) 0/1968 (0.00%) Drug Abuse 1/5760 (0.02%) 0/1968 (0.00%) Mental Status Changes 1/5760 (0.02%) 0/1968 (0.00%) Renal and urinary disorders Renal Failure Acute 1/5760 (0.02%) 0/1968 (0.00%)

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
					Renal Mass 0/5760 (0.00%) 2/1968 (0.10%) Vesicoureteric Reflux 1/5760 (0.02%) 0/1968 (0.00%) Reproductive system and breast disorders Balanitis 1/5760 (0.02%) 0/1968 (0.00%) Scrotal mass 1/5760 (0.02%) 0/1968 (0.00%) Respiratory, thoracic and mediastinal disorders Adenoidal Hypertrophy 1/5760 (0.02%) 0/1968 (0.00%) Apnoea 0/5760 (0.00%) 1/1968 (0.05%) Asthma (in AE table) Atelectasis 2/5760 (0.03%) 0/1968 (0.00%) Bronchial Hyperreactivity 6/5760 (0.10%) 6/1968 (0.30%) Bronchomalacia 1/5760 (0.02%) 0/1968 (0.00%) Bronchospasm2/5760 (0.03%) 1/1968 (0.05%) Cough 1/5760 (0.02%) 0/1968 (0.00%) Epistaxis 1/5760 (0.02%) 0/1968 (0.00%) Hypoxia 3/5760 (0.05%) 0/1968 (0.00%) Pneumonia Aspiration 0/5760 (0.00%) 1/1968 (0.05%) Pneumonitis 0/5760 (0.00%) 1/1968 (0.05%) Pulmonary Oedema1/5760 (0.02%) 0/1968 (0.00%) Respiratory Distress 12/5760 (0.21%) 3/1968 (0.15%) Respiratory Failure 1/5760 (0.02%) 0/1968 (0.00%) Status Asthmaticus 1/5760 (0.02%) 3/1968 (0.15%) Wheezing 1/5760 (0.02%) 0/1968 (0.00%) Skin and subcutaneous tissue disorders Dermal Cys 1/5760 (0.02%) 0/1968 (0.00%) Dermatitis Atopic0/5760 (0.00%) 1/1968 (0.05%) Erythema Multiforme 1/5760 (0.02%) 0/1968 (0.00%) Urticaria1/5760 (0.02%) 0/1968 (0.00%) Surgical and medical procedures

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
					Hernia Repair 1/5760 (0.02%) 0/1968 (0.00%) Inguinal Hernia Repair 0/5760 (0.00%) 1/1968 (0.05%) Vascular disorders Angiopathy * 1 1/5760 (0.02%) 0/1968 (0.00%) Kawasaki's Disease (in AE table) Vasculitis * 1 1/5760 (0.02%) 0/1968 (0.00%) Risk factors: NR
Baccarini, 2020[57] Sanofi Pasteur, 2017[370] NCT03077438 Article RCT N=1000 Industry funded USA (including Puerto Rico)	Age: 6.0 years (2.34) % female: 48% Ethnicity: 82% White, 13% Black or African American, 0.1% American Indian or Alaska Native, 0.4% Asian, 0.4% Native Hawaiian or Other Pacific Islander, 4.2% More than one race, 0.3% Unknown or Not Reported Healthy meningococcal vaccine-naïve children 2–9 years of age Out of scope: None	Men quadrivalent MenQuadFi [MenACWY-TT] Single 0.5 mL dose Intramuscular adjuvant NR preservative NR No co-intervention Meningococcal conjugate MenACWY-CRM Menveo Single 0.5 mL dose Intramuscular adjuvant NRpreservative NR Counts Prespecified AE Power other outcome Followup: 1 months	Osteomyelitis Partial Seizures Tethered Cord Syndrome Adenoidal Hypertrophy Asthma Status Asthmaticus Tonsillar Hypertrophy Wheezing Circulatory Collapse Injection Site Erythema Injection Site Pain Injection Site Swelling Malaise Pyrexia Pharyngitis Pharyngitis Streptococcal Upper Respiratory Tract Infection Myalgia Headache Cough Solicited injection site pain (prespecified) Solicited injection site erythema (prespecified) Solicited injection site swelling (prespecified) Systemic reactions fever Systemic reactions headache	Asthma: 22.X NA I: 1/498, 22.X NA C: 1/498 Cardiovascular events: 26.X Circulatory collapse, not related to vaccination I: 1/498, 26.X NA C: 0/494 Death: NA NA I: 0/498, NA NA C: 0/494 Febrile seizures: 17.X NA I: 0/498, 17.X NA C: 0/494 Guillain-Barré syndrome: 10.X NA I: 0/498, 10.X NA C: 0/494 Immune Thrombocytopenia Purpura: 1.X NA I: 0/498, 1.X NA C: 0/494 Kawasaki Disease: 10.X NA I: 0/498, 10.X NA C: 0/494 Seizure: 17.X NA I: 0/498, 17.X Temporal partial seizure, not related to vaccine C: 1/494	Group 1: MenACYW Conjugate VaccineGroup 2: MENVEO® Vaccine Affected / at Risk (%)Affected / at Risk (%) Total 7/498 (1.41%) 3/494 (0.61%) Infections and infestations Osteomyelitis 1/498 (0.20%) 0/494 (0.00%) Nervous system disorders Partial Seizures 0/498 (0.00%) 1/494 (0.20%) (in AE table) Tethered Cord Syndrome 1/498 (0.20%) 0/494 (0.00%) Respiratory, thoracic and mediastinal disorders Adenoidal Hypertrophy 1/498 (0.20%) 1/494 (0.20%) Asthma 1/498 (0.20%) 1/494 (0.20%) (in AE table) Status Asthmaticus 1/498 (0.20%) 0/494 (0.00%) Tonsillar Hypertrophy 1/498 (0.20%) 1/494 (0.20%) Wheezing 1/498 (0.20%) 0/494 (0.00%) Vascular disorders Circulatory Collapse 1/498 (0.20%) 0/494 (0.00%) (in AE table) No SAEs were related to vaccination. Risk factors: No

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
			Systemic reactions malaise Systemic reactions myalgia Kawasaki disease Guillain-Barré syndrome Generalized seizures, including febrile seizures Idiopathic thrombocytopenic purpura		
Black, 2010[68] Article RCT N=619 Industry funded USA	Age: 5.7 years (range 2-10 years) % female: Intervention 47%, Control 51% Ethnicity: 18% Asian, 6% Black, 32% Caucasian, 24% Hispanic, 20% Other Healthy children 2–10 years of age Out of scope: None	Men quadrivalent Menveo [MenACWY-CRM] Single dose Intramuscular adjuvant NR preservative NR No co-intervention Meningococcal polysaccaride Menomune Single dose route NR adjuvant NR preservative NR Counts Prespecified AE Power other outcome Followup: 12 months	Pain Erythema Induration Irritability Sleepiness Anorexia Vomiting Diarrhoea Arthralgia Headache Fever Analgesic/antipyretic use Malaise Chills Myalgia Nausea Serious AEs (SAEs) Medically significant events (e.g. hospitalizations, emergency-room visits, new onset of chronic diseases)	NA	No SAEs judged to be possibly or probably related to vaccine administration were reported. Severe AEs, local (all) Pain 1% vs 0%, p=0.028 Erythema >100 mm 1% vs 0%, p=0.0028 Induration >100 mm 1% vs 0%, p=0.0001 Severe AEs, subjects aged 2-5 years Irritability 0% vs 0% Sleepiness 1% vs 1% Anorexia 0% vs 0% Vomiting 1% vs 0% Diarrhoea 0% vs 0% Arthralgia 1% vs 0% Headache 0% vs 0% Fever, axillary temp. ≥40 ◦ C 0% vs 0% Severe AEs, subjects aged 6-10 years Headache 2% vs 1% Malaise 2% vs 1% Chills 1% vs 1% Myalgia 2% vs 1% Nausea 0% vs 1% Arthralgia 1% vs 0% Fever, oral temp. ≥40 ◦ C 0% vs 0% Risk factors: Stratified adverse effects by age (but different AEs)

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
Chang, 2020a[78] Sanofi Pasteur a Sanofi Company, 2014[365]; Hedrick, 2018[283] NCT02199691 Article RCT N=1715 Industry funded USA	Age: 11.4 (1.32) % female: 48% Ethnicity: 89% White, 5% African American, 5% Mixed Origin, 1% Native Hawaiian or other Pacific Islander, 1% American Indian or Alaska Native, 1% Asian Participants were meningococcal vaccine-naïve 10-17 year olds capable of attending all events Out of scope: None	Men quadrivalent MenQuadFi [MenACWY-TT] 0.5 mL in one dose Intramuscular adjuvant free preservative free No co-intervention Meningococcal conjugate MenACWY-CRM Menveo 0.5 mL in 1 dose Intramuscular adjuvant freepreservative free Counts No prespecified AE Power other outcome Followup: 6 months	Hypothyroidism Faecaloma Mucosal Inflammation Appendicitis Staphylococcal Scalded Skin Syndrome Type 1 Diabetes Mellitus Convulsion Abnormal Behaviour Major Depression Suicidal Ideation Asthma Erythema Multiforme Injection Site Erythema Injection Site Pain Injection Site Swelling Malaise Pharyngitis Upper Respiratory Tract Infection Myalgia Headache	Asthma: 22.X NA I: 0/503, 22.X NA C: 0/501 Death: NA NA I: 0/503, NA NA C: 0/501 Diabetes: 14.X NR I: 1/503, 14.X NA C: 0/501 Seizure: 17.X NR I: 1/503, 17.3 NR C: 1/501	Serious AEs (from clinicaltrials.gov) Intervention (MenQuadFi) Control (Menveo) Affected / at Risk (%)Affected / at Risk (%) Total 4/503 (0.80%) 4/501 (0.80%) Endocrine disorders Hypothyroidism 0/503 (0.00%) 0/501 (0.00%) Gastrointestinal disorders Faecaloma 1/503 (0.20%) 0/501 (0.00%) General disorders Mucosal Inflammation 1/503 (0.20%) 0/501 (0.00%) Infections and infestations Appendicitis 0/503 (0.00%) 1/501 (0.20%) Staphylococcal Scalded Skin Syndrome 0/503 (0.00%) 0/501 (0.00%) Metabolism and nutrition disorders Type 1 Diabetes Mellitus (in AE table) Nervous system disorders Convulsion (in AE table) Psychiatric disorders Abnormal Behavior 0/503 (0.00%) 1/501 (0.20%) Major Depression 0/503 (0.00%) 1/501 (0.20%) Suicidal Ideation 0/503 (0.00%) 0/501 (0.00%) Respiratory, thoracic and mediastinal disorders Asthma (in AE table) Skin and subcutaneous tissue disorders Erythema Multiforme0/503 (0.00%) 1/501 (0.20%) Risk factors: NR

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
Chang, 2020b[79] Sanofi Pasteur a Sanofi Company, 2014[365] NCT02199691 Article RCT N=1715 Industry funded USA	Age: 11.4 (1.32) % female: 48% Ethnicity: 89% White, 5% African American, 5% Mixed Origin, 1% Native Hawaiian or other Pacific Islander, 1% American Indian or Alaska Native, 1% Asian Participants were meningococcal vaccine-naïve 10-17 year olds capable of attending all events Out of scope: None	Men quadrivalent MenQuadFi [MenACWY-TT] 0.5 mL in one dose Intramuscular adjuvant free preservative free Co-intervention Tdap (Adacel) and HPV (Gardasil) Base treatment Tdap and HPV Adacel and Gardasil Counts No prespecified AE Power other outcome Followup: 6 months	Hypothyroidism Faecaloma Mucosal inflammation Appendicitis Staphylococcal scalded skin syndrome Type 1 diabetes mellitus Convulsion Abnormal behaviour Major depression Suicidal ideation Asthma Erythema multiforme Injection site erythema Injection site pain Injection site swelling Malaise Pharyngitis Upper respiratory tract infection Myalgia Headache	Asthma: 22.X NR I: 1/392, 22.X NA C: 0/296 Death: NA NA I: 0/392, NA NA C: 0/296 Diabetes: 14.X Type 1 diabetes mellitus I: 0/392, 14.X Type 1 diabetes mellitus C: 0/296 Seizure: 17.X NR I: 1/392, 17.X NA C: 0/296	Serious AEs (from clinicaltrials.gov) Intervention (MenQuadFi+Tdap+HPV)Control (Tdap+HPV) Affected / at Risk (%)Affected / at Risk (%) Total 4/392 (1.02%) 4/296 (1.35%) Endocrine disorders Hypothyroidism 1/392 (0.26%) 0/296 (0.00%) Gastrointestinal disorders Faecaloma 0/392 (0.00%) 0/296 (0.00%) General disorders Mucosal Inflammation 0/392 (0.00%) 0/296 (0.00%) Infections and infestations Appendicitis 0/392 (0.00%) 2/296 (0.68%) Staphylococcal Scalded Skin 0/392 (0.00%) 1/296 (0.34%) Metabolism and nutrition disorders Type 1 Diabetes Mellitus (in AE table) Nervous system disorders Convulsion (in AE table) Psychiatric disorders Abnormal Behaviour 0/392 (0.00%) 0/296 (0.00%) Major Depression 0/392 (0.00%) 0/296 (0.00%) Suicidal Ideation 1/392 (0.26%) 1/296 (0.34%) Respiratory, thoracic and mediastinal disorders Asthma (in AE table) Skin and subcutaneous tissue disorders Erythema Multiforme 0/392 (0.00%) 0/296 (0.00%) Risk factors: NR

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
Gasparini, 2014[112] Novartis, 2011[323] NCT01424644 Article RCT N=801 Industry funded Italy, USA	Age: 11.9 (1.6) % female: 40 Ethnicity: 79% White, 9% Black, 1% Asian, 1% Native American/Alaskan or Native Hawaiian/Pacific Islander, 10% Other Healthy adolescents 10-18 years old Out of scope: None	Men quadrivalent Menveo [MenACWY-CRM] 0.5 mL as one dose Intramuscular adjuvant NR preservative NR Co-intervention Tdap (Boostrix) as one dose, HPV4 (Gardasil) as three doses Placebo,Base treatment Placebo+Tdap+HPV4 Placebo, Boostrix, Gardasil 0.5 mL dose each of Placebo and Boostrix; 3 doses of Gardasil Intramuscular adjuvant NRpreservative NR Counts No prespecified AE Power other outcome Followup: 7 months	Hypothyroidism Abdominal adhesions Small intestinal obstruction Peritonsillar abscess Accidental overdose Type 1 Diabetes mellitus Affective disorder Aggression Haematuria Nausea Chills Injection site erythema Injection site induration Injection site pain Malaise Pharyngitis Arthralgia Myalgia Headache Syncope Pyrexia Acne Atopic dermatitis	Death: NA NA I: 0/396, NA NA C: 0/397 Diabetes: 14.X Type 1 Diabetes mellitus I: 1/396, 14.X NA C: 0/397	Serious AEs (from clinicaltrials.gov): Intervention (MenACWY-CRM+Tdap+HPV) vsControl (Placebo+Tdap+HPV) Affected / at Risk (%)Affected / at Risk (%) Total 4/396 (1.01%) 3/397 (0.76%) Hypothyroidism 1/396 (0.25%) 0/397 (0.00%) Abdominal adhesions 1/396 (0.25%) 0/397 (0.00%) Small intestinal obstruction 1/396 (0.25%) 0/397 (0.00%) Peritonsillar abscess0/396 (0.00%) 1/397 (0.25%) Accidental overdose 0/396 (0.00%) 1/397 (0.25%) Type 1 Diabetes mellitus (in AE table) Affective disorder 0/396 (0.00%) 1/397 (0.25%) Aggression 1/396 (0.25%) 0/397 (0.00%) Haematuria 1/396 (0.25%) 0/397 (0.00%) Risk factors: NR

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
Hansen, 2018[127] Sanofi Pasteur a Sanofi Company, 2011[363]; Sanofi Pasteur a Sanofi Company, 2005[357] NCT00728260; NCT01689155 Article Other design N=1421 Industry funded USA	Age: For 2-10 year-old study: 9% <4 years, 13% 4-6 years, 17% 7-9 years, 61% 10 years. For 9-23 months study, mean age at first dose 15.9 months % female: For 2-10 year-old study: 50%; For 9-23 months study: 53% Ethnicity: For 2-10 year-old study: 16% Asian, 19% Black, 22% Hispanic, 4% Multiracial, <1% Native American, 1% Pacific Islander, 24% White, 15% Unknown; For 9-23 months study: 11% Asian, 40% Black, 13% Hispanic, 2% Multiracial, 1% Native American, 1% Pacific Islander, 22% White, 10% Unknown Children receiving MenACWY-D vaccine at Kaiser Permanente Northern California	Men quadrivalent Menactra [MenACWY-D] Route NR adjuvant NR preservative NR Co-intervention Concomitant routine vaccines Base treatment Control is comparison interval (31-60 days in 2-10 year-olds and 31-75 days in 9-23 month-olds); presumably may have received concomitant vaccines Analytic study No prespecified AE Insufficient power Followup: 42 months	Congenital Anomaly of ureter Sickle Cell Anemia Digestive congenital anomalies Congenital atresia Cerebral palsy Hereditary spherocytosis Abdominal Pain Small bowel obstruction Febrile Illness Aspergillosis Pyogenic arthritis Respiratory infection, upper Cellulitis and abscess Pneumonia Trauma Feeding problem Other non-traumatic joint disorders Malignant neoplasm Psychiatric Hydronephrosis Asthma Abdominal pain Acute bronchitis Allergic reactions Asthma Bronchospasm Cellulitis/abscess Constipation Convulsions Cough Diarrhea Dyspepsia Epistaxis Fatigue Febrile illness Headache Ingrown nail Nausea with vomiting Noninfectious gastroenteritis Otalgia Otitis externa Otitis media	NA	Results of self-controlled case series after MenACWY-D (Incidence rate ratio, IRR, 95% CI): 2–10-year-olds, ED: No significant findings 2–10-year-olds, Inpatient: Cellulitis/abscess: IRR NE (1.42, NE) in both 2–10- year-olds combined and 10-year-olds (Medical record review revealed that the cases of cellulitis/abscess involved non-vaccination sites [i.e., the knee and foot]; neither case was consid- ered related to MenACWY-D.) 2–10-year-olds, Outpatient: No significant findings 9–23-month-olds, ED: No significant findings 9–23-month-olds, Inpatient: No significant findings 9–23-month-olds, Outpatient: No significant findings Relative risk of observational safety outcomes days 0–30 after MenACWY-D (compared to control window Days 31–60 or 31–75) 2-10 years, ED Abdominal pain RR 0.74 (0.14, 3.57) *Asthma RR 0.98 (0.03, 38.35) Bronchospasm RR 0.00 (0.00, 18.67) Cellulitis and abscess RR NE (0.05, NE) Constipation RR 0.00 (0.00, 18.68) *Convulsions RR 0.00 (0.00, 18.68) Diarrhea RR NE (0.05, NE) Febrile illness RR 0.66 (0.08, 4.41) Nausea with vomiting RR 2.95 (0.31, 77.79) Non-traumatic joint disorders RR 0.00 (0.00, 18.67) Noninfectious gastroenteritis RR NE (0.05, NE) Otitis externa RR 0.00 (0.00, 18.68) Pneumonia RR 0.00 (0.00, 18.68) Sickle cell anemia RR 0.33 (0.01, 3.07) Trauma RR 1.23 (0.31, 5.14) Upper respiratory infection RR 0.00 (0.00, 18.68)

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
	Out of scope: None		Pain in soft tissues of limb Painful respiration Palpitations Pharyngitis Pneumonia Psychiatric disorders Rash Upper respiratory infection Sickle cell anemia Trauma Urinary tract infection Urticaria Viral infection Vomiting Warts Abdominal pain Aspergillosis Asthma Cellulitis/abscess Cerebral palsy Congenital anomaly of ureter Digestive congenital anomalies Febrile illness Hereditary spherocytosis Malignant neoplasm Pneumonia Psychiatric Sickle cell anemia Trauma Death		Urinary tract infection RR NE (0.05, NE) 2-10 years, hospital Cellulitis and abscess RR NE (0.28, NE) Febrile illness RR NE (0.05, NE) Hereditary spherocytosis RR 0.00 (0.00, 18.68) Malignant neoplasm RR 0.98 (0.03, 38.35) Other non-traumatic joint disorders RR NE (0.05, NE) Pneumonia RR 0.00 (0.00, 18.68) Pyogenic arthritis RR NE (0.05, NE) Sickle cell anemia RR 1.97 (0.15, 58.05) Trauma RR NE (0.05, NE) Upper respiratory infection RR NE (0.05, NE) 2-10 years, clinic Chiari malformation type 1 RR NE (0.05, NE) Migraine RR NE (0.28, NE) 9-23 months, ED *Asthma RR 1.48 (0.04, 57.69) Cough RR 1.48 (0.04, 57.64) *Febrile seizure RR NE (0.08, NE) Otitis media RR NE (0.08, NE) Trauma RR NE (0.43, NE) Upper respiratory infection RR NE (0.08, NE) Viral syndrome RR NE (0.08, NE) Vomiting RR NE (0.08, NE) No deaths observed during the three-year accrual and subsequent six-month surveillance period for either study. Risk factors: Yes, by age. The only significantly elevated outcome among 2–10-year-olds was cellulitis/abscess (2 cases occurred during the risk interval versus 0 during comparison interval; IRR not evaluable [NE], 95% CI: 1.42, NE). After medical record review, the 2 cases were considered unrelated to vaccination. Among 9–23-month-olds, no outcomes were significantly elevated after vaccination and there were no hospitalizations. There were no deaths observed during the three-year accrual and subsequent six-month surveillance period for either study.

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
Novartis Vaccines and Diagnostics s.r.l, 2014[105] Novartis Vaccines and Diagnostics S.r.l., 2014[333]; Novartis Vaccines, 2006[325] EudraCT 2014-003514-91; NCT00329849 Trial record RCT N=1500 Industry funded Argentina	Age: Treatment: 5.8 (2.5), Control: 5.7 (2.5) % female: 51% Ethnicity: Ethnicity NR Healthy children 2 - 10 years of age Out of scope: None	Men quadrivalent Menveo [MenACWY-CRM] 0.5 mL in 1 dose Intramuscular adjuvant NR preservative NR No co-intervention Meningococcal polysaccaride Meningococcal polysaccharide vaccines Menomune 0.5 mL in 1 dose Other : Subcutaneous use adjuvant NRpreservative NR Counts No prespecified AE Power NR Followup: 6 months	Appendicitis Lobar Pneumonia Pneumonia Injury Febrile Convulsion Tonic Convulsion Asthmatic Crisis Injection site pain Injection site erythema Injection site induration Pyrexia Malaise Headache	Asthma: 22.X not deemed causally related to vaccination I: 1/950, 22.X NA C: 0/550 Death: NA NA I: 0/950, NA NA C: 0/550 Febrile seizures: 17.X NR I: 1/950, 17.X NA C: 0/550 Seizure: 17.X Tonic convulsion I: 1/950, 17.X Tonic convulsion C: 0/550	Serious AEs (from clincaltrials.gov) Intervention (MenACWY-CRM) vs Control (MenACWY-PS) Affected / at Risk (%)# EventsAffected / at Risk (%)# Events Total 9/950 (0.95%) 1/550 (0.18%) Infections and infestations Appendicitis 2/950 (0.21%) 0/550 (0.00%) Lobar Pneumonia 0/950 (0.00%) 1/550 (0.18%) Pneumonia 3/950 (0.32%) 0/550 (0.00%) Injury, poisoning and procedural complications Injury 1/950 (0.11%) 0/550 (0.00%) Nervous system disorders Febrile Convulsion (in AE table) Tonic Convulsion 1/950 (0.11%) 0/550 (0.00%) Respiratory, thoracic and mediastinal disorders Asthmatic Crisis (in AE table) Risk factors: NR
Tregnaghi, 2014[219] Novartis Vaccines, 2007[326] NCT00474526 Article RCT N=3037 Industry funded Colombia, Argentia, USA	Age: Intervention group (MenACWY-CRM in 4-dose series+routine vaccines) 65.0 days (9.4); Control (routine vaccines through infant series, toddler doses of MenACWY-CRM) 65.1 days (9.1) % female: Intervention 52%, Control 50%	Men quadrivalent Menveo [MenACWY-CRM] 2.0 mL in 4 doses, with 0.5 mL doses at 2, 4, 6, and 16 months Intramuscular adjuvant free preservative free Co-intervention Routine vaccines Base treatment Routine vaccines alone. Counts No prespecified AE	Iron deficiency anaemia Lymphadenitis Cyanosis Pulmonary valve stenosis Atrial septal defect Fallot's tetralogy Hypospadias Optic nerve hypoplasia Pyloric stenosis Haematotympanum Blepharitis Diarrhoea Diarrhoea haemorrhagic Gastritis Gastrooesophageal reflux disease Haematochezia Inguinal hernia Intestinal obstruction	NA	Severe AEs after the first infant series vaccination at 2 months: Intervention (MenACWY-CRM+routine vaccines) vs Control (routine vaccines only, toddler doses of MenACWY-CRM) Tenderness (crying when injured limb moved): 92/1423 (6%) vs 74/709 (10%) Erythema >50 mm: 1/1423 (1%) vs 4/709 (1%) Induration >50 mm: 2/1423 (<1%) vs 0/709 (0%) Fever >= 40C: 1/1422 (<1%) vs 0/709 (0%) Risk factors: NR

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
	Ethnicity: Ethnicity NR Healthy infants aged 55-89 days old with birth weight 2.5 kg or more and gestational age 37 weeks or more Out of scope: None	Power other outcome Followup: 18 months	Intussusception Nausea Peritonitis Stomatitis Vomiting Oedema Pyrexia Drug hypersensitivity Food allergy Hypogammaglobulinaemia Abscess limb Abscess neck Abscess oral Acarodermatitis Acute sinusitis Arthritis bacterial Bacteraemia Bacterial diarrhoea Botulism Bronchiolitis Bronchitis Bronchitis viral Bronchopneumonia Cellulitis Croup infectious Dengue fever Enteritis infectious Exanthema subitum Febrile infection Gastroenteritis Gastroenteritis viral Impetigo Infectious mononucleosis Influenza Lower respiratory tract infection Lung infection Osteomyelitis Otitis media Otitis media acute Periorbital cellulitis Pertussis Pharyngitis Pneumonia Pneumonia bacterial Pneumonia primary atypical		

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
			Pneumonia respiratory syncytial viral Pneumonia viral Respiratory syncytial virus bronchiolitis Respiratory syncytial virus infection Respiratory tract infection Respiratory tract infection viral Sepsis Sinusitis Staphylococcal abscess Staphylococcal infection Staphylococcal skin infection Subcutaneous abscess Upper respiratory tract infection Urinary tract infection Varicella Viral diarrhoea Viral infection Viral pharyngitis Vulval abscess Accidental drug intake by child Accidental exposure Burns second degree Foreign body Head injury Limb traumatic amputation Rib fracture Road traffic accident Skull fracture Thermal burn Traumatic brain injury Upper limb fracture Cow's milk intolerance Dehydration Diabetes mellitus Diabetic ketoacidosis Hypoglycaemia Hyponatraemia Synostosis Acute myeloid leukaemia Brain neoplasm		

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
			Complex partial seizures Convulsion Febrile convulsion Grand mal convulsion Psychomotor skills impaired Subarachnoid haemorrhage Tonic convulsion Nephrotic syndrome Apnoea Asthma Bronchial hyperreactivity Bronchospasm Choking Foreign body aspiration Hypoxia Laryngospasm Pulmonary hypertension Respiratory disorder Sleep apnoea syndrome Status asthmaticus Tachypnoea Wheezing Rash Urticaria Intestinal operation Kawasaki's disease Conjunctivitis Diarrhoea Flatulence Gastrooesophageal reflux disease Teething Vomiting Injection site erythema Injection site induration Injection site pain Irritability Malaise Pyrexia Bronchiolitis Bronchitis Croup infectious Gastroenteritis Nasopharyngitis Otitis media		

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
			Otitis media acute Respiratory tract infection Upper respiratory tract infection Viral infection Crying Somnolence Eating disorders Bronchospasm Cough Nasal congestion Dermatitis atopic Dermatitis diaper Eczema Rash		
Lee, 2016[156] Novartis Vaccines, 2014[332] NCT01973218 Article RCT N=264 Industry funded South Korea	Age: 13.5 (1.8) % female: 43 Ethnicity: 100% Asian Healthy 11-17-year-olds Out of scope: None	MenB Bexsero [MenB-4C] 1.0 ml in 2 doses at day 1 and 31 (each 0.5 mL dose contained contained 50 Intramuscular adjuvant free preservative free No co-intervention Placebo,Meningococcal conjugate Saline placebo (dose 1) + MenACWY (dose 2) Menveo 0.5 ml in 1 dose (each dose contained contained 5 Intramuscular adjuvant freepreservative free Counts No prespecified AE Power calculation	Gastroenteritis Parovarian cyst Nausea (prespecified) Injection site erythema (prespecified) Injection site induration (prespecified) Injection site pain (prespecified) Injection site swelling (prespecified) Malaise Pyrexia/Fever (prespecified) Nasopharyngitis Arthralgia (prespecified) Myalgia (prespecified) Headache (prespecified) Eating Disorders Pain (bodyache) Decreased appetite (prespecified) Rash Arthralgia Chest pain Dizziness Abdominal pain Acne Acute tonsillitis Allergic conjunctivitis Bronchitis	Reproduction issues: 21.X Parvovarian cyst I: 1/174, 21.X Parvovarian cyst C: 0/99 Seizure: 17.X Medically attended convulsion I: 0/174, 17.2 Medically attended convulsion C: 1/88	Any medically attended AE: Intervention: 45/174 (26%); Control 23% Serious AEs (from clinicaltrials.gov) Total serious AEs: Intervention 2/174 (1.15%); Control 0/88 (0.00%) Gastroenteritis: Intervention 1/174 (0.57%); Control 0/88 (0.00%) Parovarian cyst: Intervention 1/174 (0.57%); Control 0/88 (0.00%) (in AE table) Risk factors: NR

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
		Followup: 2 months	Chest pain Circumcision Convulsion Cough Dental caries Diarrhoea Eczema Foot fracture Furuncle Gastroenteritis rotavirus Histiocytic necrotising lymphadenitis Hordeolum Influenza Ligament sprain Lymphangitis Nausea Neck pain Oropharyngeal pain Pain in extremity Pharyngitis Pneumonia Rhinitis Rhinitis allergic Rhinorrhoea Scarlet fever Scoliosis Skin abrasion Stomatitis Syncope Tooth extraction Upper respiratory tract infection Vocal cord thickening Vomiting		

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
Richmond, 2012[186] Pfizer, 2009[344] NCT00808028 Article RCT N=539 Industry funded Australia, Spain, Poland	Age: Intervention (120 µg): 14.3 (2.1), placebo: 13.8 (2.0) % female: Intervention 57%; Placebo 50% Ethnicity: Intervention 96% White; Placebo 99% White Healthy male and female adolescents (aged 11–18 years) Out of scope: None	MenB Trumenba [MenB-FHbp] 360 µg in three doses, 0.5 mL per dose (each dose with equal amounts of the lipidated recombinant lipoprotein 2086 proteins (subfamily A, A05 variant and subfamily B, B01 variant) expressed in Escherichia coli, 120 µg of protein was suspended in 0·5 mL of solution per dose formulated with 250 µg aluminium phosphate as a stabiliser, 150 mmol/L NaCl, 0·0012–0·0058% polysorbate 80, and 10 mmol/L histidine, at pH 6·0) Intramuscular Aluminum preservative free No co-intervention Placebo Sterile saline solution - 3 doses Counts No prespecified AE Power other outcome Followup: 48 months	Abdominal injury Abdominal pain Abnormal behaviour Acarodermatitis Acne Acute tonsillitis Alcohol poisoning Allergy to animal Allergy to chemicals Alopecia Anaphylactic reaction Ankle fracture Appendicitis Arthralgia Arthralgia Arthropathy Arthropod bite Asthma exercise induced Asthma Back injury Back pain Blood iron decreased Bronchitis Burning sensation mucosal Cardiac disorders Cellulitis Cerebellar tumour Chemical burn of skin Chest injury Chest pain Chills CNS germinoma Concussion Conjunctivitis Contusion Costochondritis Cough Decreased appetite Dental caries Depression Dermatitis allergic Dermatitis atopic Dermatitis contact Dermatitis Diarrhoea Diarrhoea Drug eruption	Anaphylaxis: 10.3 Anaphylactic reaction I: 0/198, 10.3 Anaphylactic reaction C: 0/121 Asthma: 22.X NA I: 0/198, 22.X NA C: 0/121 Cardiovascular events: 26.X Hypertension I: 0/198, 26.X Hypertension C: 0/121 Reproduction issues: 21.X Ovarian cyst I: 1/198, 21.X Ovarian cyst C: 0/121	Severe AEs (from article) (Intervention vs Control): Pain at injection site, severe: Dose 1: 2/197 (1.0%) vs 0/119 (0%), Dose 2: 2/194 (1.1%) vs 0/118 (0%), Dose 3: 2/189 (1.1%) cs 0/115 (0%) Induration, severe: Dose 1: 1/197 (0.5%) vs 0/119 (0%), Dose 2: 1/194 (0.5%) vs 0/118 (0%), Dose 3: 2/189 (1.1%) vs 0/115 (0%) Erythema, severe; Dose 1: 0/197 (0%) vs 0/119 (0%), Dose 2: 0/194 (0%) vs 0/118 (0%), Dose 3: 3/189 (1.6%) vs 0/115 (0%) Fatigue, severe: Dose 1: 7/197 (3.6%) vs 0/119 (0%), Dose 2: 1/194 (0.5%) vs 0/118 (0%), Dose 3: 5/189 (2.6%) vs 0/115 (0%) Headache, severe: Dose 1: 3/197 (1.5%) vs 0/119 (0%), Dose 2: 0/194 (0%) vs 0/118 (0%), Dose 3: 1/189 (0.5%) vs 0/115 (0%) Diarrhea, severe: Dose 1: 0/197 (0%) vs 0/119 (0%), Dose 2: 0/194 (0%) vs 0/118 (0%), Dose 3: 0/189 (0%) vs 0/115 (0%) Nausea, severe: Dose 1: 0/197 (0%) vs 0/119 (0%), Dose 2: 0/194 (0%) vs 0/118 (0%), Dose 3: 0/189 (0%) vs 0/115 (0%), Chills, severe: Dose 1: 0/197 (0%) vs 0/119 (0%), Dose 2: 0/194 (0%) vs 0/118 (0%), Dose 3: 0/189 (0%) vs 0/115 (0%) Myalgia, severe: Dose 1: 1/197 (0.5%) vs 0/119 (0%), Dose 2: 0/194 (0%) vs 0/118 (0%), Dose 3: 1/189 (0.5%) vs 0/115 (0%) Arthralgia, severe: Dose 1: 0/197 (0%) vs 0/119 (0%), Dose 2: 0/194 (0%) vs 0/118 (0%), Dose 3: 0/189 (0%) vs 1/115 (0.9%) Serious AEs (from clinicaltrials.gov, stratified by stage 1 at 6 months at stage 2 at 48 months) Control-Stage 1 vs Intervention-Stage 1 vs Control-Stage 1 Follow-up vs Intervention Stage 1 Follow-up vs Control-Stage 2 vs Intervention-Stage 2 Affected / at Risk (%)Affected / at Risk (%)Affected / at Risk (%)Affected / at Risk (%)Affected

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
			Dysmenorrhoea Dyspepsia Ear infection Ear pain Eczema impetiginous Electrocardiogram QT prolonged Epistaxis Erythema Eye disorders Eye inflammation Eyelid cyst Factor V Leiden mutation Fatigue Fibroma Food poisoning Foot fracture Forearm fracture Foreign body Gastritis viral Gastroenteritis viral Gastroenteritis Gingivitis Glossodynia H1N1 influenza Hand fracture Hangnail Head injury Headache Headache Herpes simplex Hypertension Hypothermia Immune system disorders Impetigo Induration Influenza like illness Influenza Ingrowing nail Inguinal hernia Injection site dermatitis Injection site erythema Injection site haematoma Injection site pain Injection site pallor Injection site paraesthesia Injection site pruritus		Total 3/121 (2.48%) 3/198 (1.52%) 0/121 (0.00%) 1/198 (0.51%) 1/80 (1.25%) 6/170 (3.53%) Lymphadenitis1/121 (0.83%) 0/198 (0.00%) 0/121 (0.00%) 0/198 (0.00%) 0/80 (0.00%) 0/170 (0.00%) Anaphylactic reaction 0/121 (0.00%) 0/198 (0.00%) 0/121 (0.00%) 0/198 (0.00%) 0/80 (0.00%) 0/170 (0.00%) (in AE table) Eczema impetiginous 0/121 (0.00%) 0/198 (0.00%) 0/121 (0.00%) 0/198 (0.00%) 0/80 (0.00%) 1/170 (0.59%) Perirectal abscess 0/121 (0.00%) 0/198 (0.00%) 0/121 (0.00%) 0/198 (0.00%) 01/80 (1.25%) 0/170 (0.00%) Pilonidal cyst 0/121 (0.00%) 0/198 (0.00%) 0/121 (0.00%) 0/198 (0.00%) 0/80 (0.00%) 0/170 (0.00%) Tonsillitis 0/121 (0.00%) 0/198 (0.00%) 0/121 (0.00%) 0/198 (0.00%) 0/80 (0.00%) 1/170 (0.59%) Tonsillitis streptococcal 0/121 (0.00%) 0/198 (0.00%) 0/121 (0.00%) 0/198 (0.00%) 0/80 (0.00%) 0/170 (0.00%) Gastroenteritis 0/121 (0.00%) 0/198 (0.00%) 0/121 (0.00%) 0/198 (0.00%) 0/80 (0.00%) 0/170 (0.00%) Sinusitis 0/121 (0.00%) 0/198 (0.00%) 0/121 (0.00%)1/198 (0.51%) 00/80 (0.00%) 0/170 (0.00%) Appendicitis 0/121 (0.00%) 0/198 (0.00%) 0/121 (0.00%) 0/198 (0.00%) 0/80 (0.00%) 0/170 (0.00%) Mononucleosis syndrome 0/121 (0.00%) 0/198 (0.00%)0/121 (0.00%) 0/198 (0.00%) 0/80 (0.00%) 0/170 (0.00%) Pneumonia 0/121 (0.00%) 0/198 (0.00%) 0/121 (0.00%) 0/198 (0.00%) 0/80 (0.00%) 0/170 (0.00%) Alcohol poisoning 0/121 (0.00%) 0/198 (0.00%) 0/121 (0.00%) 0/198 (0.00%) 0/80 (0.00%) 1/170 (0.59%) Head injury 0/121 (0.00%) 0/198 (0.00%) 0/121 (0.00%) 0/198 (0.00%) 0/80 (0.00%) 1/170 (0.59%)

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
			Injection site swelling Investigations Irritable bowel syndrome Jaw fracture Joint sprain Laryngitis Ligament injury Ligament sprain Limb injury Lower respiratory tract infection Lymphadenitis Lymphadenopathy Migraine Mononucleosis syndrome Mouth ulceration Mumps Muscle contracture Myalgia Myalgia Nasopharyngitis Nausea Neck pain Nervous system disorders Oropharyngeal pain Otitis media Ovarian cyst Pain at the injection site Pain in extremity Palpitations Penile discharge Perirectal abscess Pertussis Pharyngitis Photophobia Photosensitivity reaction Pilonidal cyst Pneumonia Post concussion syndrome Post procedural haematoma Presyncope Procedural pain Psychiatric disorders Pulpitis dental Pyelonephritis Pyrexia		Ligament sprain 0/121 (0.00%) 0/198 (0.00%) 0/121 (0.00%) 0/198 (0.00%) 0/80 (0.00%) 0/170 (0.00%) Road traffic accident 0/121 (0.00%) 0/198 (0.00%) 0/121 (0.00%) 0/198 (0.00%) 0/80 (0.00%) 1/170 (0.59%) Hand fracture 0/121 (0.00%) 0/198 (0.00%) 0/121 (0.00%) 0/198 (0.00%) 0/80 (0.00%) 0/170 (0.00%) Abdominal injury 0/121 (0.00%) 0/198 (0.00%) 0/121 (0.00%) 0/198 (0.00%) 0/80 (0.00%) 0/170 (0.00%) Chest injury 0/121 (0.00%) 0/198 (0.00%) 0/121 (0.00%) 0/198 (0.00%) 0/80 (0.00%) 0/170 (0.00%)) Concussion 0/121 (0.00%) 1/198 (0.51%) 0/121 (0.00%) 0/198 (0.00%) 0/80 (0.00%) 0/170 (0.00%) Forearm fracture 1/121 (0.83%) 0/198 (0.00%) 0/121 (0.00%) 0/198 (0.00%) 0/80 (0.00%) 0/170 (0.00%) Jaw fracture 0/121 (0.00%) 1/198 (0.51%) 0/121 (0.00%) 0/198 (0.00%) 0/80 (0.00%) 0/170 (0.00%) Limb injury 0/121 (0.00%) 1/198 (0.51%) 0/121 (0.00%) 0/198 (0.00%) 0/80 (0.00%) 0/170 (0.00%) CNS germinoma 0/121 (0.00%) 0/198 (0.00%) 0/121 (0.00%) 0/198 (0.00%) 0/80 (0.00%) 1/170 (0.59%) Cerebellar tumour 0/121 (0.00%) 0/198 (0.00%) 0/121 (0.00%) 0/198 (0.00%) 0/80 (0.00%) 0/170 (0.00%) Headache 0/121 (0.00%) 0/198 (0.00%) 0/121 (0.00%) 0/198 (0.00%) 0/80 (0.00%) 0/170 (0.00%) Depression 0/121 (0.00%) 0/198 (0.00%) 0/121 (0.00%) 0/198 (0.00%) 0/80 (0.00%) 1/170 (0.59%) Ovarian cyst 0/121 (0.00%) 1/198 (0.51%) 0/121 (0.00%) 0/198 (0.00%) 0/80 (0.00%) 0/170 (0.00%) (in AE table) Asthma 0/121 (0.00%) 0/198 (0.00%) 0/121 (0.00%) 0/198 (0.00%) 0/80 (0.00%) 0/170 (0.00%) (in AE table)

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
			Radius fracture Rash Respiratory tract infection viral Respiratory tract infection Rheumatoid arthritis Rhinitis allergic Rhinitis Rhinorrhoea Road traffic accident Scar Seasonal allergy Sinusitis Skeletal injury Skin laceration Soft tissue injury Subcutaneous abscess Syncope Tendonitis Thermal burn Tonsillitis streptococcal Tonsillitis Tooth impacted Toothache Torticollis Tremor Upper limb fracture Upper respiratory tract infection Urinary tract infection Urticaria Vaccination site pallor Vertigo Vessel puncture site haematoma Viral infection Viral upper respiratory tract infection Vomiting Vomiting Whiplash injury Wrist fracture		Cough 1/121 (0.83%) 0/198 (0.00%) 0/121 (0.00%) 0/198 (0.00%) 00/80 (0.00%) 0/170 (0.00%) Rhinitis allergic 0/121 (0.00%) 0/198 (0.00%) 0/121 (0.00%) 1/198 (0.51%) 0/80 (0.00%) 0/170 (0.00%) Hypertension 0/121 (0.00%) 0/198 (0.00%) 0/121 (0.00%) 0/198 (0.00%) 0/80 (0.00%) 0/170 (0.00%) (in AE table) Risk factors: Tested 3 doses, concluded vaccine is well tolerated

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
Santolaya, 2012[193] Novartis Vaccines, 2008[327]; Erratum, 2015[240] NCT00661713 Article RCT N=1631 Industry funded Chile	Age: Two doses 1 month apart: 13.9 (1.9); Two doses 2 months apart: 13.7 (1.9); Placebo 13.8 (2.0) % female: Two doses 1 month apart: 57%; Two doses 2 months apart: 56%; Placebo 52% Ethnicity: 99% Hispanic Healthy adolescents of either sex, aged 11–17 years, with no previous history of meningococcal serogroup B vaccination or meningococcal disease, were eligible. In post-menarchal participants a negative pregnancy test was required at study start and before any future injection together with use of contraception throughout. Exclusion criteria were allergy to any vaccine component, household contact with a confirmed case of	MenB Bexsero [MenB-4C] Each 0·5 mL dose contained 50 µg each of neisserial adhesin A, factor H binding protein, and neisseria heparin binding antigen fusion proteins, and 25 µg of outer membrane vesicles from N meningitidis strain NZ98/254, with 1·5 mg Al(OH)3 in 10 mM histidine buffer containing 110–120 mM saline. 0.5 ml per dose. In arms of interest, groups received two doses either 1 or 2 months apart, or three doses Intramuscular Aluminum preservative free No co-intervention Placebo 1·5 mg Al(OH) in the histidine and saline buffer Analytic study No prespecified AE Power other outcome Followup: 6 months	Appendicitis Dysentery Meningitis bacterlal Pneumonia viral Shigellain fection Joint injury Ligament rupture Road traffic accident Toxicity to varlous agents Juvenile idiopathic arthritis Adenoma benign Bengin ovarian tumour Convulsion Epilepsy Syncope Premature labour Major depression Panic attack Suicide attempt Glomerulonephritis minimal lesion Testicular torsion Asthmatic crisis Urticaria Adenoidectomy Tonsillectomy Nausea (prespecified) Injection site erythema (prespecified) Injection site induration (prespecified) Injection site pain (prespecified) Injection site swelling (prespecified) Malaise (prespecified) Pyrexia Bronchitis Gastroenteritis Nasopharyngitis Pharyngitis Tonsillitis Ligament sprain Arthralgia (prespecified) Myalgia (prespecified) Headache (prespecified)	NA	Reaction rates: Intervention (2 doses) post-dose 1: 352/380 (93%) vs Placebo 118/128 (92%) Intervention (2 doses) post-dose 2: 306/341 (90%) vs Placebo 104/124 (84%) Risk factors: NR

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
	meningococcal disease within 60 days, any immunisation within 30 days with the exception of influenza vaccination, which was permitted more than 14 days before or after a study injection, receipt of antibiotics within 6 days or blood products or any investigational product within 90 days of enrollment Out of scope: None				
Senders, 2016[196] Article RCT N=2499 Industry funded USA	Age: Intervention: 13.7 (1.9); Control: 13.6 (1.9) % female: Intervention: 33%; Control 34% Ethnicity: Intervention: 83% White, 12% Black, 5% Other; Control: 83% White, 11% Black, 6% Other Healthy subjects 11 to under 28-years-old Out of scope: None	MenB Trumenba [MenB-FHbp] 1.5 ml in 3 doses (0.5 mL per dose) Intramuscular adjuvant NR preservative NR Co-intervention HPV4 (Gardasil), 3 doses Base treatment HPV vaccine + saline placebo solution Gardasil 3 doses (volume not reported) Intramuscular adjuvant NRpreservative NR Counts	Death Anaphylaxis Respiratory tract infections Fainting (syncope) Redness Swelling Pain Fever Vomiting Diarrhea Headache Fatigue Chills Muscle Pain Use of antipyretic medications	Anaphylaxis: 10.3 Anaphylaxis I: 0/992, 10.3 Anaphylaxis C: 0/501 Death: NA NR I: 0/992, NA NR C: 0/501	Syncope: Intervention 1/922 (same day as dose 3) vs Control 0/501 Antipyretic medication use was higher among groups that received bivalent rLP2086 + HPV-4 (37.8%) or bivalent rLP2086 (39.8%) than HPV-4 (26.2%). Overall, the incidence and severity of local reactions and systemic events associated with bivalent rLP2086 was similar when administered with HPV-4. No serious AEs were considered vaccine related or led to study discontinuation. Risk factors: Local reactions and systemic events did not increase with concomitant administration of vaccines

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
		Prespecified AE Power other outcome Followup: 2 months			
Vesikari, 2016[230] Pfizer, 2011[346] NCT01323270 Article RCT N=749 Industry funded Finland, Germany, and Poland	Age: Intervention: 13.8 (2.54); Control 13.9 (2.60) % female: 49% Ethnicity: 99% White Healthy adolescents at least 11 to <19 years of age at enrollment who had received the full series of DTaP/IPV vaccines per the country-specific recommendations applicable at the time of vaccination. Out of scope: None	MenB Trumenba [MenB-FHbp] 60 µg each of a purified subfamily A and a purified subfamily B rLP2086 protein, a 2.8 molar ratio of polysorbate 80 to protein, and 0.25 mg of Al3+ as aluminum phosphate (AlPO4) in 10 mM histidine-buffered saline at pH 6.0 180 µg in 3 doses (each 0.5 mL dose containing 60 µg each of a purified subfamily A and a purified subfamily B rLP2086 protein, a 2.8 molar ratio of polysorbate 80 to protein, and 0.25 mg of Al3+ as aluminum phosphate (AlPO4) in 10 mM	Idiopathic thrombocytopenic purpura Vertigo positional Appendicitis Abdominal abscess Appendicitis perforated Arthritis infective Cellulitis Gastroenteritis Peritonsillar abscess Sinusitis Tonsillitis Urinary tract infection Hip fracture Injury Joint dislocation Road traffic accident Headache Hydrocephalus Syncope Depression Drug abuse Ovarian cyst ruptured Dyspnoea Conjunctivitis Diarrhoea Nausea Pyrexia Injection site pain Injection site swelling Nasopharyngitis	Death: NA Motor vehicle crash I: 1/374, NA NA C: 0/378 Immune Thrombocytopenia Purpura: 1.X NR I: 1/374, 1.X NR C: 0/378 Reproduction issues: 21.X Ovarian cyst ruptured I: 0/374, 21.X Ovarian cyst ruptured C: 1/378	Severe AEs: (Intervention vs control) Headache, severe: 1.1% vs 2.1% Fatigue, severe: 4.0% vs 2.9% Serious AEs (from clinicaltrials.gov) Intervention (rLP2086 + Repevax) vsControl (Saline+Repevax) Affected / at Risk (%)Affected / at Risk (%) Total 12/374 (3.21%) 9/378 (2.38%) Blood and lymphatic system disorders Idiopathic thrombocytopenic purpura (in AE table) Congenital, familial and genetic disorders (removed as pre-existing birth defect Ear and labyrinth disorders Vertigo positional 1/374 (0.27%) 0/378 (0.00%) Infections and infestations Appendicitis 1/374 (0.27%) 2/378 (0.53%) Abdominal abscess 1/374 (0.27%) 0/378 (0.00%) Appendicitis perforated 1/374 (0.27%) 0/378 (0.00%) Arthritis infective 1/374 (0.27%) 0/378 (0.00%) Cellulitis 1/374 (0.27%) 0/378 (0.00%) Gastroenteritis 1/374 (0.27%) 0/378 (0.00%) Peritonsillar abscess 0/374 (0.00%) 1/378 (0.26%) Sinusitis 1/374 (0.27%) 0/378 (0.00%) Tonsillitis 1/374 (0.27%) 0/378 (0.00%)

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
		histidine-buffered saline at pH 6.0) Intramuscular Aluminum preservative free Co-intervention DTaP/IPV Placebo,Base treatment DTaP/IPV and saline placebo Repexa 1.5 mL in 3 doses (each 0.5 mL dose containing diphtheria toxoid (not less than 2 IU [2 limits of flocculation (Lf)]), tetanus toxoid (not less than 20 IU [5 Lf]), pertussis antigens (pertussis toxoid [2.5 µg], filamentous hemagglutinin [5 µg], pertacti Intramuscular Aluminumpreservative free Counts No prespecified AE Power other outcome Followup: 6 months	Pharyngitis Upper respiratory tract infection Bronchitis Gastroenteritis Sinusitis Otitis media Acute tonsillitis Tonsillitis Rhinitis Contusion Back pain Headache Cough Local reactions (redness, swelling, and pain) (prespecified)		Urinary tract infection 0/374 (0.00%) 1/378 (0.26%) Injury, poisoning and procedural complications Hip fracture 0/374 (0.00%) 1/378 (0.26%) Injury 0/374 (0.00%) 1/378 (0.26%) Joint dislocation 0/374 (0.00%) 1/378 (0.26%) Road traffic accident 1/374 (0.27%) 0/378 (0.00%) Nervous system disorders Headache 1/374 (0.27%) 0/378 (0.00%) Hydrocephalus 1/374 (0.27%) 0/378 (0.00%) Syncope 0/374 (0.00%) 1/378 (0.26%) Psychiatric disorders Depression 1/374 (0.27%) 1/378 (0.26%) Drug abuse 0/374 (0.00%) 1/378 (0.26%) Reproductive system and breast disorders Ovarian cyst ruptured (in AE table) Respiratory, thoracic and mediastinal disorders Dyspnoea 0/374 (0.00%) 1/378 (0.26%) Risk factors: NR

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
Geier, 2020[113] Article Cohort study N=65211 Not industry funded USA	Age: Vaccinated: 14.26 months ± 1.5 (age at vaccination); Unvaccinated: 14.49 months (range 12–17) (age at examination) % female: 47% Ethnicity: NR Children persons who received at least one dose of MMR vaccine between 12 and 17 months (vaccinated) and children not receiving a measles-containing vaccine (unvaccinated) Out of scope: None	MMR M-M-R II 1 dose Route NR adjuvant NR preservative NR Co-intervention unclear No intervention Analytic study Prespecified AE Power NR Followup: 108 months	Seizure episode Seizure disorder	NA	Unadjusted model (Vaccinated within 6-11 days versus unvaccinated): Seizure episode: HR 5.73 (2.71 to 12.1), p<0.0001 Seizure disorder (among those diagnosed with an initial seizure episode): HR 17.7 (2.27 to 138), p=0.0061 Adjusted model (Vaccinated with 6-11 days versus unvaccinated): Seizure episode: HR 5.94 (2.81 to 12.58), p<0.0001 Seizure disorder (among those diagnosed with an initial seizure episode): HR 17.4 (2.23 to 136), p=0.0064 Person-time model (Vaccinated within 6-11 days versus unvaccinated): Seizure episode: Rate Ratio (95% CI) 4.64 (3.07 to 6.77), Rate Difference (per 100,000 person-days) (95% CI) 24.2 (18.9 to 29.6), p-value < 0.0001 Rate (per 100,000 person-days) 30.9 vs 6.654 Seizure disorder (among those diagnosed with an initial seizure episode): Rate Ratio (95% CI) 5.51 (2.58 to 10.5), Rate Difference (per 100,000 person-days) (95% CI) 8.7 (5.8 to 11.6), p-value < 0.0001 Rate (per 100,000 person-days) 10.66 vs 1.933 Self-controlled case series (6-11 days post-vaccination vs 49-60 days post-vaccination): Seizure episode: Rate Ratio (95% CI) 3.80 (2.06 to 7.17), Rate Difference (per 100,000 person-days) (95% CI) 22.8 (13.6 to 31.9), p-value < 0.0001 Seizure Disorder (among those diagnosed with an initial seizure episode): Rate Ratio (95% CI) 4.15 (1.37 to 13.9), Rate Difference (per 100,000 person-days) (95% CI) 8.1 (2.8 to 13.4), p-value < 0.01 Person-time model (Vaccinated any time post-MMR vs Unvaccinated any time from 12 months of age): Seizure episode: Rate Ratio (95% CI) 1.11 (1.05 to 1.17), Rate Difference (per

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
					1,000 person-years) (95% CI) 0.94 (0.42 to 1.47), p-value < 0.001 Seizure Disorder (among those diagnosed with an initial seizure episode): Rate Ratio (95% CI) 0.98 (0.88 to 1.09), Rate Difference (per 1,000 person-years) (95% CI) 0.06 (-0.35 to 0.23), p-value 0.70 Cox proportional hazards survival plot reveals that during the 4 day follow-up period post-MMR vaccination (from 6 to 11 days post-MMR vaccination) there were a greater number of initial seizure episode diagnoses than in the unvaccinated cohort. The overall incidence of an initial seizure episode diagnosis during the 152 follow-up days (between 12 months through 16 months of age) in the unvaccinated cohort remained relatively constant. Cox proportional hazards survival plot evaluating the incidence rate of seizure disorder diagnoses following an initial seizure episode diagnosis shows that during the 4 day follow-up period post-MMR vaccination (from 6 to 11 days post-MMR for initial seizure diagnosis) there were a greater number of initial onsets of seizure disorder diagnoses than in the unvaccinated cohort. The overall incidence rate of initial seizure disorder diagnoses was lower in the first 25 days of follow-up in the unvaccinated cohort than in the subsequent period between 25 days to 152 days. During the latter period, the incidence rate of initial seizure disorder diagnoses remained relatively constant. Risk factors: No

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
Hviid, 2019[138] Article Cohort study N=160569 Not industry funded Denmark	Age: N/A % female: 49 Ethnicity: Ethnicity NR All children born in Denmark of Danish-born mothers from 1999-2010 Out of scope: None	MMR M-M-R II 2 doses Route NR adjuvant NR preservative NR Co-intervention Routine vaccines Base treatment Routine vaccines Analytic study Prespecified AE Power calculation Followup: 48 months	Autism	Autism: 17.X NR I: 289/150831, 17.X NR C: 32/9738	Autism HR 0.94 (0.63-1.42), vaccinated: 289/150831, unvaccinated: 32/9738 (2008-2010 birth cohort - MMR-II time period) Risk factors: No increased risk for autism consistently observed in subgroups of children defined according to sibling history of autism, autism risk factors (based on a disease risk score) or other childhood vaccinations
Jain, 2015[141] Article Cohort study N=95727 Not industry funded USA	Age: NR % female: 49% Ethnicity: Ethnicity NR Children health-insured from birth to >5, with an older sibling enrolled for >6 months Out of scope: None	MMR M-M-R II 1-2 doses Route NR adjuvant NR preservative NR Co-intervention unclear No intervention No MMR vaccine Analytic study Prespecified AE Power NR Followup: 60 months	Autism	Autism: 17.X Among 2 year-olds after dose 1 of siblings with and without ASD I: 60/79216, 17.X Among 2 year-olds after dose 1 of siblings with and without ASD C: 19/15769	Risk factors: Older Sibling Without ASD (n = 93798) adjusted RR of autism by MMR vaccination status Age 2y 1 dose 53/77822 vs unvaccinated 13/15249, aRR 0.91 (0.68-1.20), p=.50 Age 3y 1 dose 239/79666 vs unvaccinated 45/12853, aRR 0.97 (0.77-1.21), p=0.76 Age 4y 1 dose 395/79691 vs unvaccinated 65/11957, aRR 1.03 (0.81-1.31), p=0.82 Age 5y 2 dose 244/45568 vs unvaccinated 56/7735, aRR 1.09 (0.76-1.54), p=0.65 Age 5y 1 dose 339/40 495 vs unvaccinated 56/7735, aRR 1.10 (0.79-1.53), p=0.59 Older Sibling With ASD (n = 1929) adjusted RR of autism by MMR vaccination status Age 2y 1 dose 7/1394 vs unvaccinated 6/520, aRR 0.76 (0.48-1.22), p=0.25 Age 3y 1 dose 38/1458 vs unvaccinated 17/438, aRR 0.81 (0.53-1.25), p=0.34 Age 4y 1 dose 64/1491 vs unvaccinated 25/387, aRR 0.86 (0.56-1.34), p=0.51 Age 5y 2 dose 244/45568 vs unvaccinated 56/7735, aRR 0.56 (0.30-1.04), p=0.07 Age 5y 1 dose 339/40 495 vs unvaccinated 56/7735, aRR 0.92 (0.56-1.50), p=0.74

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
Timmermann, 2015[215] Article Cohort study N=640 Not industry funded Denmark (Faroe Islands)	Age: 4.95 years (no SD) % female: 47% Ethnicity: NR Children born in the Faroe Islands from 1997-2000 Out of scope: None	MMR M-M-R II 1 dose at age 15 months and 1 at 12 years (did not abstract after 5 years as US schedule is toddler dose and dose at 4-6 years) Route NR adjuvant NR preservative NR No co-intervention No intervention Counts Prespecified AE Power NR Followup: 45 months	Asthma Current wheezing without a cold Hypersensitivity/allergy Eczema	Asthma: 22.X NR I: 70/524, 22.X NR C: 8/22	Outcomes at age 5 for vaccinated versus unvaccinated, p-value Asthma 70/524 (13.4%) vs 8/22 (36.4%), p=0.003 Current wheezing without a cold 27/528 (5.1%) vs 3/21 (14.3%), p=0.07 Hypersensitivity/allergy 65/523 (12.4%) vs 9/21 (42.9%), p<0.001 Eczema 46/526 (8.4%) vs 2/21 (9.5%), p=0.90 OR (95% CI) at age 5 for vaccinated versus unvaccinated, adjusted for variables associated with MMR (birth weight, family history) Asthma OR 0.33 (0.12, 0.90) Hypersensitivity/allergy OR 0.32 (0.11, 0.88) OR (95% CI) at age 5 for vaccinated versus unvaccinated, adjusted for additional confounders Asthma OR 0.32 (0.10, 1.05) Hypersensitivity/allergy OR 0.36 (0.11, 1.21) OR (95% CI) at age 5 for vaccinated versus unvaccinated, adjusted for DTaP/IPV/Hib and OPV Asthma OR 0.40 (0.14, 1.16) Hypersensitivity/allergy OR 0.30 (0.10, 0.89) OR (95% CI) at age 5 for vaccinated versus unvaccinated, sensitivity analyses (adjusted for additional confounders and excluding children without vaccine information) Asthma OR 0.55 (0.16, 1.82) Hypersensitivity/allergy OR 0.36 (0.11, 1.19) Risk factors: No, but adjusted for confounders

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
Uno, 2015[224] Article Case-Control N=413 Not industry funded Japan	Age: Cases, mean age 22.6 years (SD 2.2); Controls, mean age 22.6 years (SD 2.2) (at time of study; all cases and controls were 6-36 months at time of vaccination) % female: NR Ethnicity: NR Eligible case subjects: (1) were diagnosed with ASD, and (2) had been born between April 1, 1986 and April 30, 1992, the possible time period for MMR vaccination. Control subjects were recruited as volunteers from general schools in the same area where patients reside, who were born from April 1986 to April 1992 (students who had previously been recognized as having developmental problems and were already receiving care were excluded).	MMR Brand NR NR NR Route NR adjuvant NR preservative NR Co-intervention unclear No intervention Analytic study Prespecified AE Power calculation Followup: 264 months	Autism Spectrum Disorder (ASD)	NA	OR of MMR vaccination causing ASD (unadjusted) 36 months: 1.04 (0.65–1.68). 18 months: 0.81 (95% CI: 0.31–2.09) 24 months: 0.93 (0.55–1.57) at 24 months. Conditional multiple logistic model: 18 months: 0.875 (0.345–2.222) 24 months: 0.724 (0.421–1.243) 36 months: 1.040 (0.648–1.668) Risk factors: By age.

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
	Out of scope: Some				
McClure, 2019[167] Article Other design N=829 Not industry funded USA	Age: 13 months +/- 2 months at vaccination % female: Preterm 46%; Term 49% Ethnicity: NR children who received their first dose of measles-containing vaccine at age 12 through 23 months from January 1, 2003 through September 30, 2015 at seven integrated health care organizations (sites) located throughout the United States that participate in the Centers for Disease Control and Prevention (CDC)	MMR,MMR-V Brand NR MMR or MMR-V vaccine. Risk period is 7-10 days following vaccination. NR Route NR adjuvant NR preservative NR Co-intervention unclear No intervention Control period is 15-42 days Analytic study Prespecified AE Power NR Followup: 2 months	Seizure	NA	MMR vaccine (IRR for seizures in risk window 7-10 days versus control window 15-42 days): Pre-term IRR 3.2 (95% CI 1.9–5.3) Term IRR 2.7 (95% CI 2.2–3.2) IRR for pre-term vs term IRR 1.2 (95% CI 0.70–2.0), p=0.51 MMR-V vaccine (IRR for seizures in risk window 7-10 days versus control window 15-42 days): Pre-term IRR 7.9 (95% CI 3.0–20) Term IRR 5.7 (95% CI 4.1–7.8) IRR for pre-term vs term IRR 1.4 (95% CI 0.51–3.8), p=0.52 Risk factors: Yes, for pre-term vs term

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
	sponsored Vaccine Safety Datalink (VSD). Out of scope: None				
Deichmann, 2015[89] Merck Sharp, 2007[312] NCT00432042 Article RCT N=955 Industry funded Germany, Italy	Age: Mean age (SD), in months: ProQuad+hexavalent: 13.6 (1.9); hexavalent only: 13.5 (1.7) % female: 47% Ethnicity: Ethnicity NR Healthy children 12-23 months old Out of scope: None	MMR-V ProQuad 1 dose Subcutaneous adjuvant NR preservative free Co-intervention Infanrix hexa Base treatment DTaP-HBs-IPV//Hib Infanrix hexa 0.5 mL in 1 dose Intramuscular adjuvant NRpreservative NR Counts No prespecified AE Power other outcome Followup: 2 months	Bronchitis Bronchopneumonia Conjunctivitis bacterial Gastroenteritis Gastroenteritis rotavirus Influenza Otitis media Upper respiratory tract infection Urinary tract infection Viral upper respiratory tract infection Electric shock Febrile convulsion Diarrhoea Vomiting Injection site erythema Injection site pain Injection site swelling Pyrexia Bronchitis Nasopharyngitis Rhinitis Cough Skin and subcutaneous tissue disorders Rash morbilliform Death Measles (prespecified) Mumps (prespecified) Rubella (prespecified)	Death: NA NA I: 0/474, NA NA C: 0/239 Febrile seizures: 17.2 One moderate and one severe event occurred 2 days and 33 days after vaccination, respectively. Both participants had concomitant infections. I: 2/474, 17.X NA C: 0/239	Serious AEs (from clinicaltrials.gov): Intervention (ProQuad® + Infanrix® Hexa) vs Control (Infanrix® Hexa) Affected / at Risk (%)# EventsAffected / at Risk (%)# EventsAffected / at Risk (%)# Events Total 7/474 (1.48%) 4/239 (1.67%) Infections and infestations Bronchitis 0/474 (0.00%) 01/239 (0.42%) 1 Bronchopneumonia 1/474 (0.21%) 10/239 (0.00%) 0 Conjunctivitis bacterial 0/474 (0.00%) 00/239 (0.00%) 0 Gastroenteritis 1/474 (0.21%) 10/239 (0.00%) 0 Gastroenteritis rotavirus 1/474 (0.21%) 11/239 (0.42%) 1 Influenza 0/474 (0.00%) 01/239 (0.42%) 1 Otitis media 1/474 (0.21%) 10/239 (0.00%) 0 Upper respiratory tract infection 1/234 (0.43%) 10/239 (0.00%) 0 Urinary tract infection 1/474 (0.21%) 10/239 (0.00%) 0 Viral upper respiratory tract infection 1/474 (0.21%) 10/239 (0.00%) 0 Injury, poisoning and procedural complications Electric shock 0/474 (0.00%) 01/239 (0.42%) 1

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
			Varicella (prespecified) Hepatitis B Haemophilusinfluenzaetype b Diphtheria Tetanus Poliomyelitis type 1 Poliomyelitis type 2 Poliomyelitis type 3		Nervous system disorders Febrile convulsion (in AE table) Risk factors: NR
Klein, 2010[148] Article Cohort study N=459461 Not industry funded USA	Age: 45% 12 months; 22% 13-14 months; 20% 15-16 months; 9% 17-19 months; 4% 20-23 months % female: N/A Ethnicity: N/A Children aged 12 to 23 months who were members of the 7 participating VSD sites and received their first dose of MMRV (Merck & Co, Inc, West Point, PA) were eligible for study inclusion. Out of scope: None	MMR-V ProQuad NR Route NR adjuvant NR preservative NR Co-intervention Presumably received routine vaccines as well (not specified) MMR,Varicella Received MMR and varicella vaccines separately (and presumably routine vaccines) NR NR route NR adjuvant NRpreservative NR Analytic study Prespecified AE Power NR Followup: 2 months	Seizures	NA	During days 7 to 10, unadjusted rates for seizures were 84.6 seizures per 1000 person-years after MMRV vaccination, 42.2 seizures per 1000 person-years after MMR + VAR. Risk of febrile seizures following MMR-V [excess risk per 10,000 doses; 95% CI] 7–10 days, not chart confirmed: RR 1.98 (1.43–2.73) [4.6; 2.8–5.9] 7–10 days, chart confirmed: RR 2.04 (1.44–2.90) [4.3; 2.6–5.6] 0–42 days, not chart confirmed: RR 1.42 (1.11–1.81) [6.7; 1.7–12.9] 0–42 days, chart confirmed: RR 1.46 (1.11–1.92) [6.2; 2.0–9.5] 0–30 days, not chart confirmed: RR 1.40 (1.06–1.85) [5.1; 0.8–10.8] 0–30 days, chart confirmed: RR 1.44 (1.05–1.97) [4.7; 0.7–7.6)] Risk factors: No

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
Klein, 2015[149] Rowhani-Rhabar, 2013[353] Article Cohort study N=708187 Not industry funded USA	Age: N/A % female: N/A Ethnicity: Ethnicity NR Children aged 12-23 months who were members of 8 Vaccine Safety Datalink sites from January 2020 through June 2012 Out of scope: None	MMR-V ProQuad Route NR adjuvant NR preservative NR Co-intervention unclear MMR,Varicella Measles-mumps-rubella (MMR) and varicella (and presumably routine vaccines) route NR adjuvant NRpreservative NR Analytic study Prespecified AE Power calculation Followup: 2 months	Acute disseminated encephalomyelitis Anaphylaxis Arthritis/arthralgia Ataxia Immune thrombocytopenia purpura Kawasaki disease Encephalitis/meningitis/ encephalopathy Fever Seizure	NA	Primary analysis, unadjusted risk difference per 100,000 doses (95% CI), then adjusted RR comparing MMRV to MMR + V (outcome risk during outcome-specific risk intervals): ADEM 3-21 days: 0.00 (NE to 3.69), RR Not estimable ADEM 1-42 days: -0.17 (–0.98 to 3.06), RR Not estimable Anaphylaxis 0 days: 0.82 (–0.85 to 5.29), RR Not estimable Arthritis/arthralgia 1-42 days: 0.32 (–0.91 to 4.26), RR 12.12 (0.03 to 4443.16) Ataxia 14-28 days: 9.45 (–2.50 to 24.13), RR 1.31 (0.78 to 2.17) Ataxia 1-42 days: 12.75 (–6.98 to 35.11), RR 0.98 (0.71 to 1.35) ITP I 14-28 days: -0.28 (–3.10 to 5.15), RR 0.79 (0.1 to 6.2) ITP 1 1-42 days: 0.16 (–3.66 to 6.64), RR 0.9 (0.18 to 4.77) ITP II 14-28 days: -1.03 (–4.65 to 5.17), RR 1.26 (0.26 to 5.37) ITP II 1-42 days: -3.75 (–8.75 to 3.77), RR 0.9 (0.28 to 2.69) Kawasaki disease 1-28 days: -2.93 (–4.70 to 0.48), RR 0 (0 to 53.38) Kawasaki disease 1-56 days: 0.48 (–3.32 to 6.95), RR 0.69 (0.17 to 2.98) Meningitis/encephalitis 3-21 days: 0.82 (–0.86 to 5.29), RR Not estimable (0.01 to NE) Meningitis/encephalitis 1-42 days: 0.12 (–1.75 to 4.63), RR 2.98 (0.04 to 627.05) Fever 7-10 days: 20 (–110.84 to 170.28), RR 1.16 (0.96 to 1.39) Seizure 7-10 days: 48.63 (10.38 to 107.63), RR 1.99 (1.08 to 3.53) Secondary analysis, OR (95% CI) comparing MMRV to itself (case-centered analysis comparing risk interval shortly after vaccination versus comparator interval 56-180 days after vaccination): ADEM 3-21 days: Not estimable ADEM 1-42 days: Not estimable Anaphylaxis 0 days: 15.34 (2.16 to 108.86) (based on only 2 cases, neither of

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
					which was confirmed as acute anaphylaxis after chart review; both diagnoses were related to a history of allergic reactions) Arthritis/arthralgia 1-42 days: 0.05 (0 to 22.13) Ataxia 14-28 days: 0.61 (0.37 to 1.02) Ataxia 1-42 days: 0.7 (0.51 to 0.95) ITP I 14-28 days: 11.28 (1.87 to 68.2) ITP 1 1-42 days: 3.75 (0.65 to 21.73) ITP II 14-28 days: 2.86 (0.83 to 9.86) ITP II 1-42 days: 0.95 (0.28 to 3.17) Kawasaki disease 1-28 days: NE Kawasaki disease 1-56 days: 0.31 (0.06 to 1.69) Meningitis/encephalitis 3-21 days: 4.88 (0.47 to 50.42) Meningitis/encephalitis 1-42 days: 2.13 (0.21 to 22.02) Fever 7-10 days: 5.7 (4.05 to 8.01) Seizure 7-10 days: 17.26 (8.09 to 36.83) Secondary analysis, OR (95% CI) comparing MMRV versus MMR+V (case-centered analysis comparing risk interval shortly after vaccination versus comparator interval 56-180 days after vaccination): ADEM 3-21 days: Not estimable ADEM 1-42 days: Not estimable Anaphylaxis 0 days: 10.07 (0.81 to124.64) Arthritis/arthralgia 1-42 days: 0.22 (0 to 124.03) Ataxia 14-28 days: 0.78 (0.45 to 1.37) Ataxia 1-42 days: 0.87 (0.62 to 1.22) ITP I 14-28 days: 1.12 (0.16 to 8.07) ITP 1 1-42 days: 0.63 (0.1 to 4.18) ITP II 14-28 days: 0.67 (0.17 to 2.66) ITP II 1-42 days: 0.34 (0.09 to 1.23) Kawasaki disease 1-28 days: Not estimable Kawasaki disease 1-56 days: 0.25 (0.04 to 1.49) Meningitis/encephalitis 3-21 days: 3.08 (0.2 to 48.38) Meningitis/encephalitis 1-42 days: 1.88 (0.14 to 24.89) Fever 7-10 days: 1.48 (1.04 to 2.11)

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
					Seizure 7-10 days: 3.9 (1.75 to 8.71) Risk factors: NR
Amdekar, 2013[55] Article RCT N=709 Industry funded India	Age: Median age 7 weeks % female: 48% Ethnicity: 100% Asian Healthy infants 6 weeks of age (rand 42-72 days) who had not undergone previous vaccination with any pneumococcal, diphtheria, tetanus, pertussis, or His conjugate vaccine Out of scope: None	Pneumococcal PCV13 Prevnar 13 2.2µg per 0.5ml dose in 4 doses for PCV13, other concomitant vaccine are routine vacccines(DTwP-Hib-HBV) in 4 doses and measles vaccine in 1 dose. Intramuscular Aluminum preservative free Co-intervention Routine vaccines (DTwP-Hib-HBV, OPV, Measles) Base treatment,PCV PCV7 and routine vaccines (DTwP-Hib-HBV, OPV, Measles) Prevnar 2.2µg per 0.5ml dose in 4 doses for PCV7, other concomitant vaccine are	Anemia Hepatosplenomegaly Acutelymphocytic leukemia Septic shock and status epilepticus Lower respiratory tract infection Febrile convulsion Cardiac failure congestive and heart disease congenital Injection site tenderness Injection site swelling Injection site redness Decreased appetite Irritability Increased sleep Decreased sleep Fever Death	Cardiovascular events: 2.X NR I: 0/354, 2.X one case was a cardiac arrest that eventually resulted to death while the second was a heart failure due to congenital heart disease C: 2/355 Death: NA NA I: 0/354, NA s judged to be not related to vaccination by the investigator - Death from cardiac arrest attributed to myocarditis following hospitalization for RSV brochiolitis C: 1/355 Febrile seizures: 17.3 Severe enough to be withdrawn from study after the infant series I: 1/219, 17.X NA C: 0/214 Meningitis: 11.3 Though no bacteria was cultured, severe enough to cause seizure in the child I: 1/354, 11,X NA C: 0/355 Seizure: 17.X system disorder 1 seizure was due to meningitis and the second case was a status epilepticus due to septic shock I: 2/354, 17.X 1 seizure was due to hypocalcemia. Both were severe enough to cause withdrawal from the study C: 2/355	Severe AEs: Severe swelling dose 1: PCV13 0/329 (0%) vs PCV7 0/336 (0%) Severe swelling dose 2: PCV13 0/273 (0%) vs PCV7 0/271 (0%) Severe swelling dose 3: PCV13 0/191 (0%) vs PCV7 0/193 (0%) Severe swelling toddler dose: PCV13 0/167 (0%) vs PCV7 0/169 (0%) Severe redness dose 1: PCV13 0/329 (0%) vs PCV7 0/336 (0%) Severe redness dose 2: PCV13 0/273 (0%) vs PCV7 0/271 (0%) Severe redness dose 3: PCV13 0/191 (0%) vs PCV7 0/193 (0%) Severe redness toddler dose: PCV13 0/167 (0%) vs PCV7 0/169 (0%) Significant tenderness dose 1: PCV13 144/341 (42%) vs PCV7 139/343 (40%) Significant tenderness 2: PCV13 74/278 (27%) vs PCV7 78/279 (28%) Significant tenderness 3: PCV13 48/199 (24%) vs PCV7 46/196 (24%) Significant tenderness toddler dose: PCV1327/171 (16%) vs PCV7 29/170 (17%) Serious AEs: Infant series: PCV13 2.3% vs PCV7 1.7% Toddler dose: PCV13 2.0% vs PCV7 0.5% Risk factors: Stratified by age, concluded that PCV13 has an acceptable safety

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
		routine vacccines(DTwP-Hib-HBV) in 4 doses and measles vaccine in 1 dose. Intramuscular Aluminumpreserv ative free Counts No prespecified AE Power other outcome Followup: 1 months			profile in both infants and toddlers, comparable with that of PCV7
Baker, 2019[58] Article Pre-post N=6177795 Not industry funded US	Age: <2 years of age % female: N/A Ethnicity: Ethnicity NR Children under 2 years of age from six Sentinel/PRISM Data partners Out of scope: None	Pneumococcal PCV13 Prevnar 13 Route NR adjuvant NR preservative NR Co-intervention Presumably routine vaccines No intervention Self-controlled risk interval analysis Analytic study Prespecified AE Power NR Followup: 3 months	Kawasaki's disease	NA	Self-controlled risk interval analysis with pre-specified control window: HCUP age-adjusted analysis: RR 1.07 (95% CI 0.75-1.60) Unadjusted analysis: RR 0.98 (95% CI 0.64-1.49) Include possible Kawasaki disease adjusted analysis: RR 1.09 (95% CI 0.75-1.60) Include possible Kawasaki disease unadjusted analysis: RR 1.00 (95% CI 0.68-1.46) Self-controlled risk interval analysis with control window of 29-56 days: HCUP age-adjusted analysis: RR 0.89 (95% CI 0.59-1.34) Unadjusted analysis: RR 0.82 (0.54-1.24) Include possible Kawasaki disease adjusted analysis: RR 0.89 (95% CI 0.61-1.29) Include possible Kawasaki disease unadjusted analysis: RR 0.82 (95% CI 0.56-1.19) Cohort analysis: Risk window 1-28 days compared to unexposed time: RR 0.84 (95% CI 0.65-1.08) Risk window 1-42 days compared to unexposed time: RR 0.97 (95% CI 0.79-1.19) Risk factors: NR

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
Baker, 2020[59] Article Other design N=173 Not industry funded USA	Age: 18.5% 6-11 months, 65.3% 12-15 months, 16.2% 16-23 months % female: NR Ethnicity: NR Children 6 through 23 months of age who were members of one of four participating Sentinel Data Partners, Aetna, HealthCore, Humana, or OptumInsight Life Sciences, for all or a portion of the period of interest, July 1, 2013 to June 30, 2015 (sample size is those who had PCV13 during the study period and febrile seizures) Out of scope: None	Pneumococcal PCV13 Prevnar 13 NR Route NR adjuvant NR preservative NR Co-intervention Presumably routine vaccines Base treatment : Presumably routine vaccines Risk interval (0-1 days) versus control interval (14-20 days) Analytic study Power NR Followup: 1 months	Febrile seizures	NA	PCV 13 and febrile seizures (0-1 days versus 14-20 days) Unadjusted IRR (95% CI): 1.72 (1.25, 2.36) IRR, adjusted for age and calendar time (95% CI): 1.87 (1.36, 2.57) Primary analysis: IRR, adjusted for age, calendar time, and concomitant IIV or PCV13 vaccine (95% CI): 1.80 (1.29, 2.52) Sensitivity Analysis: Risk of febrile seizures using a broad definition (includes febrile seizures and seizures) following IIV and/or PCV13 vaccines Unadjusted IRR (95% CI): 1.47 (1.11, 1.94) IRR, adjusted for age and calendar time (95% CI): 1.57 (1.19, 2.07) Primary analysis: IRR, adjusted for age, calendar time, and concomitant IIV or PCV13 vaccine (95% CI): 1.55 (1.16, 2.07) Exploratory analysis: Risk of febrile seizures following PCV13 without IIV and concomitant IIV and PCV13 Unadjusted IRR (95% CI): PCV13 without IIV 1.46 (0.98, 2.16); PCV13+IIV 2.41 (1.40, 4.15) IRR, adjusted for age and calendar time (95% CI): PCV13 without IIV1.54 (1.04, 2.28); PCV13+IIV 2.80 (1.63, 4.83) Risk factors: Concomitant administration of IIV (trivalent; not included in current report)

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
Cutland, 2018[86] Pfizer, 2013[348] NCT01939158 Article RCT N=802 Industry funded Australia, Canada, Czech Republic, Panama, South Africa, Turkey	Age: Intervention (PCV13+MenACWY-TT): 12.8 months (0.9), Control (MenACWY-TT alone): 12.8 months (0.9) % female: Intervention: 49%), Control 46% Ethnicity: Intervention: 67% White, 15% African Heritage/African American, 14% Other,; Control 66% White, 16% African Heritage/African American, 14% Other Healthy 12–14-month-olds at the time of first vaccination, with documented receipt of the full primary series of PCV13 and diphtheria, tetanus and pertussis-containing vaccines according to local recommendations at least 5 months prior to enrollment Out of scope: None	Pneumococcal PCV13 Prevnar 13 0.5-mL dose once Intramuscular Aluminum preservative free Co-intervention MenACWY-TT Base treatment MenACWY-TT alone Nimenrix 0.5 mL in 1 dose Intramuscular adjuvant freepreservative free Counts No prespecified AE Power other outcome Followup: 9 months	Injection site redness irritability/fussiness Diarrhoea Vomiting Pyrexia Rash Bruise Leukopenia Neutropenia Pneumonia Asphyxiation Aspiration of food Eczema Asthma	Death: NA Cause of death was asphyxiation (121 days post-vaccination), and considered unrelated to the study vaccines by the investigator. I: 1/193, NA NA C: 0/195	Intervention (PCV13+MenACWY-TT at month 0) vs Control (MenACWY-TT at month 0): Serious AEs (one or more): 11/201 (5.5) vs 10/203 (5.1%) New-onset chronic illness: 1/201 (0.5%) vs 4/203 (2.0%) Risk factors: NR

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
Dagan, 2013[87] Pfizer, 2007[340] NCT00508742 Article RCT N=1866 Industry funded Israel	Age: 2.2 months (0.3) % female: 51 Ethnicity: Ethnicity: 66% Jewish, 34% Bedouin Healthy 2 month-old infants in Israel Out of scope: None	Pneumococcal PCV13 Prevnar 13 2.0 mL in 4 doses at ages 2, 4, 6, and 12 months Intramuscular Aluminum preservative free Co-intervention Other routine vaccines Base treatment,PCV Prevnar (PCV7) and other routine vaccines Prevnar 2.0 mL in 4 doses at ages 2, 4, 6, and 12 months Intramuscular Aluminumpreservative free Counts No prespecified AE Power other outcome Followup: 24 months	Abdominal pain Abscess Accidental poisoning Acute tonsillitis Adenoiditis Anaemia Anal abscess Animal bite Antibiotic prophylaxis Apathy Aphthous stomatitis Apparent life threatening event Arthritis bacterial Asthma Bacteraemia Breath holding Bronchial hyperreactivity Bronchiolitis Bronchitis Bronchitis viral Brucellosis Bullous impetigo Burns second degree Cardiac disorders Cardiac failure congestive Cellulitis Cellulitis orbital Cephalhaematoma Cerebral infarction Cheilitis Chills Choking Conjunctivitis Constipation Contusion Convulsion Corneal perforation Corynebacterium infection Cough Croup infectious Cyanosis Dehydration Dermatitis Dermatitis atopic Developmental delay Diarrhoea	Asthma: 22.X Post-toddler dose only shown here I: 7/882, 22.X Post-toddler dose only shown here C: 5/875 Autoimmune disease: 10.X Henoch-Schonlein purpura between infant and toddler doses (zero in all other follow-up periods) I: 1/929, 10.X Henoch-Schonlein purpura C: 0/931 Cardiovascular events: 2.X Cardiac failure congestive within one month of infant series I: 1/930, 2.X Cardiac failure congestive within one month of infant series C: 0/933 Death: NA 1 sudden death of unknown cause; no reported SAEs considered vaccine-related I: 1/884, NA NA C: 0/877 Intussusception: 7.X Within one month of infant series shown here I: 1/930, 7.X Within one month of infant series shown here C: 1/933 Meningitis: 11.X Aseptic meningitis within one month of infant series shown here (zero in other follow-up periods) I: 1/930, 11.X Aseptic meningitis within one month of infant series shown here (zero in other follow-up periods) C: 1/931 Reproduction issues: 21.X Testicular torsion post-toddler dose (zero in other follow-up periods) I: 1/882, 21.X Testicular torsion post-toddler dose (zero in other follow-up periods) C: 0/875 Seizure: 17.X Convulsions within one month of infant series shown here I: 2/930, 17.X Convulsions within one month of infant series shown here C: 2/933 Stroke: 17.X Cerebral infarction within one month of infant series shown here, but zero in other follow-up periods too I: 0/930, 17.X Cerebral infarction within one month of infant series shown here, but zero	Overall there were no significant differences between PCV13 and PCV7 groups in the incidence of AEs and none of the reported SAEs was considered related to the study vaccines. Serious AEs (from clinicaltrials. gov) PCV 13 Infant Series vs PCV 7 Infant Series vs PCV13 post-Infant Series vs PCV7 post-Infant Series vs PCV13 post-Toddler Dose vs PCV7 post-Toddler Dose Affected / at Risk (%)Affected / at Risk (%)Affected / at Risk (%)Affected / at Risk (%)Affected / at Risk (%)Affected / at Risk (%)Affected / at Risk (%)Affected / at Risk (%) Total 64/930 (6.88%) 57/933 (6.11%) 48/929 (5.17%) 64/931 (6.87%) 15/882 (1.70%) 23/875 (2.63%) 91/882 (10.32%) 73/875 (8.34%) Blood and lymphatic system disorders Leukocytosis 1/930 (0.11%) 0/933 (0.00%) 1/929 (0.11%) 0/931 (0.00%) 0/882 (0.00%) 0/875 (0.00%) 1/882 (0.11%) 1/875 (0.11%) Lymphadenitis 0/930 (0.00%) 0/933 (0.00%) 0/929 (0.00%) 1/931 (0.11%) 0/882 (0.00%) 0/875 (0.00%) 2/882 (0.23%) 1/875 (0.11%) Neutropenia 0/930 (0.00%) 0/933 (0.00%) 1/929 (0.11%) 0/931 (0.00%) 0/882 (0.00%) 0/875 (0.00%) 0/882 (0.00%) 0/875 (0.00%) Anaemia 0/930 (0.00%) 0/933 (0.00%) 0/929 (0.00%) 0/931 (0.00%) 0/882 (0.00%) 0/875 (0.00%) 1/882 (0.11%) 0/875 (0.00%) Cardiac disorders Cardiac failure congestive 1/930 (0.11%) 0/933 (0.00%) 0/929 (0.00%) 0/931 (0.00%) 0/882 (0.00%) 0/875 (0.00%) 0/882 (0.00%) 0/875 (0.00%) Cyanosis (infant series in AE table) 0/929 (0.00%) 0/931 (0.00%) 1/882 (0.11%) 0/875 (0.00%) 0/882 (0.00%) 0/875 (0.00%) Congenital, familial and genetic disorders

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
			Diet refusal Dysentery Dyspnoea Dysuria Ear infection Endophthalmitis Erysipelas Escherichia urinary tract infection Exanthema subitum Exposure to toxic agent External ear cellulitis Eye disorders Eye movement disorder Eye swelling Fall Febrile convulsion Feeding disorder Femur fracture Fontanelle bulging Food allergy Foreign body Fracture Gait disturbance Gastroenteritis Gastroenteritis rotavirus Gingivitis Grunting H1N1 influenza Haematemesis Haematochezia Haemoptysis Hand fracture Hand-foot-and-mouth disease Head injury Henoch-Schonlein purpura Hepatomegaly Herpangina Hordeolum Hypertension Hypotonia Hypoxia Impetigo Infantile spasms Infected bites Infection	in other follow-up periods too C: 1/933	Ventricular septal defect 1/930 (0.11%) 0/933 (0.00%) 0/929 (0.00%) 0/931 (0.00%) 0/882 (0.00%) 0/875 (0.00%) 0/882 (0.00%) 0/875 (0.00%) Eye disorders Eye movement disorder 0/930 (0.00%) 1/933 (0.11%) 0/929 (0.00%) 0/931 (0.00%) 0/882 (0.00%) 0/875 (0.00%) 0/882 (0.00%) 0/875 (0.00%) Conjunctivitis 0/930 (0.00%) 0/933 (0.00%) 0/929 (0.00%) 1/931 (0.11%) 0/882 (0.00%) 0/875 (0.00%) 0/882 (0.00%) 0/875 (0.00%) Corneal perforation 0/930 (0.00%) 0/933 (0.00%) 0/929 (0.00%) 0/931 (0.00%) 0/882 (0.00%) 0/875 (0.00%) 0/882 (0.00%) 1/875 (0.11%) Gastrointestinal disorders Diarrhoea 3/930 (0.32%) 1/933 (0.11%) 2/929 (0.22%) 2/931 (0.21%) 0/882 (0.00%) 1/875 (0.11%) 2/882 (0.23%) 3/875 (0.34%) Haematemesis 0/930 (0.00%) 1/933 (0.11%) 0/929 (0.00%) 1/931 (0.11%) 0/882 (0.00%) 0/875 (0.00%) 0/882 (0.00%) 0/875 (0.00%) Intussusception (infant series in AE table)0/929 (0.00%) 3/931 (0.32%) 0/882 (0.00%) 0/875 (0.00%) 0/882 (0.00%) 2/875 (0.23%) Oral disorder 0/930 (0.00%) 1/933 (0.11%) 0/929 (0.00%) 0/931 (0.00%) 0/882 (0.00%) 0/875 (0.00%) 0/882 (0.00%) 0/875 (0.00%) Vomiting 2/930 (0.22%) 5/933 (0.54%) 2/929 (0.22%) 0/931 (0.00%) 0/882 (0.00%) 4/875 (0.46%) 14/882 (1.59%) 7/875 (0.80%) Aphthous stomatitis 0/930 (0.00%) 0/933 (0.00%) 0/929 (0.00%) 1/931 (0.11%) 0/882 (0.00%) 0/875 (0.00%) 4/882 (0.45%) 1/875 (0.11%) Stomatitis 0/930 (0.00%) 0/933 (0.00%) 1/929 (0.11%) 0/931 (0.00%) 0/882 (0.00%) 0/875 (0.00%) 0/882 (0.00%) 0/875 (0.00%)

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
			Infectious mononucleosis Inflammation Influenza Influenza virus test positive Ingrowing nail Injection site erythema Injection site swelling Intervertebral discitis Intussusception Investigations Irritability Kidney enlargement Laboratory test Laceration Lactose intolerance Leukocytosis Leukocyturia Leukopenia Limb injury Lip swelling Localised infection Lower respiratory tract infection Lung infiltration Lymphadenitis Lymphadenopathy Medulloblastoma Meningitis Meningitis aseptic Meningitis viral Meningococcal infection Metabolic acidosis Milk allergy Monarthritis Mouth injury Myoclonic epilepsy Nasopharyngitis Near drowning Nervous system disorder Nervous system disorders Neutropenia Oedema peripheral Oral candidiasis Oral disorder Oral infection Osteomyelitis Otitis media		Abdominal pain 0/930 (0.00%) 0/933 (0.00%) 0/929 (0.00%) 0/931 (0.00%) 0/882 (0.00%) 0/875 (0.00%) 1/882 (0.11%) 0/875 (0.00%) General disorders Irritability 0/930 (0.00%) 1/933 (0.11%) 0/929 (0.00%) 1/931 (0.11%) 0/882 (0.00%) 0/875 (0.00%) 0/882 (0.00%) 0/875 (0.00%) Pyrexia 8/930 (0.86%) 4/933 (0.43%) 6/929 (0.65%) 4/931 (0.43%) 0/882 (0.00%) 4/875 (0.46%) 11/882 (1.25%) 10/875 (1.14%) Sudden death 1/930 (0.11%) 0/933 (0.00%) 0/929 (0.00%) 0/931 (0.00%) 0/882 (0.00%) 0/875 (0.00%) 0/882 (0.00%) 0/875 (0.00%) Gait disturbance 0/930 (0.00%) 0/933 (0.00%) 0/929 (0.00%) 0/931 (0.00%) 0/882 (0.00%) 1/875 (0.11%) 3/882 (0.34%) 0/875 (0.00%) Hepatobiliary disorders Hepatomegaly 0/930 (0.00%) 0/933 (0.00%) 0/929 (0.00%) 0/931 (0.00%) 0/882 (0.00%) 1/875 (0.11%) 0/882 (0.00%) 0/875 (0.00%) Immune system disorders Milk allergy 1/930 (0.11%) 0/933 (0.00%) 0/929 (0.00%) 0/931 (0.00%) 0/882 (0.00%) 0/875 (0.00%) 0/882 (0.00%) 0/875 (0.00%) Infections and infestations Anal abscess 0/930 (0.00%) 1/933 (0.11%) 0/929 (0.00%) 0/931 (0.00%) 0/882 (0.00%) 1/875 (0.11%) 0/882 (0.00%) 0/875 (0.00%) Bacteraemia 0/930 (0.00%) 1/933 (0.11%) 0/929 (0.00%) 0/931 (0.00%) 0/882 (0.00%) 0/875 (0.00%) 0/882 (0.00%) 0/875 (0.00%) Bronchiolitis 10/930 (1.08%) 8/933 (0.86%) 3/929 (0.32%) 4/931 (0.43%) 0/882 (0.00%) 0/875 (0.00%) 1/882 (0.11%) 1/875 (0.11%) Bronchitis 1/930 (0.11%) 0/933 (0.00%) 0/929 (0.00%) 0/931 (0.00%) 0/882

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
			Otitis media acute Otorrhoea Overfeeding of infant Pain in extremity Parainfluenzae virus infection Paronychia Parotitis Partial seizures Periorbital cellulitis Pertussis Petechiae Pharyngeal erythema Pharyngitis Pneumococcal bacteraemia Pneumonia Pneumonia influenzal Pneumonia respiratory syncytial viral Pneumonia viral Pneumonitis Post procedural haemorrhage Postoperative fever Postoperative wound infection Pruritus Psychiatric disorders Pulmonary tuberculosis Pyrexia Radius fracture Rash Rash macular Rash maculo-papular Rectal haemorrhage Respiratory distress Respiratory syncytial virus bronchiolitis Respiratory tract infection Restlessness Rhinitis Rhinorrhoea Road traffic accident Rotavirus infection Scarlet fever Seborrhoeic dermatitis		(0.00%) 1/875 (0.11%) 0/882 (0.00%) 0/875 (0.00%) Bronchitis viral 1/930 (0.11%) 0/933 (0.00%) 0/929 (0.00%) 0/931 (0.00%) 0/882 (0.00%) 0/875 (0.00%) 0/882 (0.00%) 0/875 (0.00%) Croup infectious 1/930 (0.11%) 0/933 (0.00%) 0/929 (0.00%) 0/931 (0.00%) 0/882 (0.00%) 0/875 (0.00%) 0/882 (0.00%) 0/875 (0.00%) Dysentery 1/930 (0.11%) 0/933 (0.00%) 1/929 (0.11%) 0/931 (0.00%) 1/882 (0.11%) 0/875 (0.00%) 4/882 (0.45%) 3/875 (0.34%) Gastroenteritis 11/930 (1.18%) 8/933 (0.86%) 12/929 (1.29%) 13/931 (1.40%) 3/882 (0.34%) 4/875 (0.46%) 13/882 (1.47%) 14/875 (1.60%) Lower respiratory tract infection 1/930 (0.11%) 4/933 (0.43%) 5/929 (0.54%) 4/931 (0.43%) 0/882 (0.00%) 1/875 (0.11%) 3/882 (0.34%) 1/875 (0.11%) Meningitis aseptic (in AE table) Meningitis viral 1/930 (0.11%) 0/933 (0.00%) 0/929 (0.00%) 0/931 (0.00%) 0/882 (0.00%) 0/875 (0.00%) 0/882 (0.00%) 0/875 (0.00%) Meningococcal infection 0/930 (0.00%) 1/933 (0.11%) 0/929 (0.00%) 0/931 (0.00%) 0/882 (0.00%) 0/875 (0.00%) 0/882 (0.00%) 0/875 (0.00%) Otitis media 3/930 (0.32%) 5/933 (0.54%) 9/929 (0.97%) 10/931 (1.07%) 1/882 (0.11%) 3/875 (0.34%) 13/882 (1.47%) 11/875 (1.26%) Otitis media acute 2/930 (0.22%) 2/933 (0.21%) 0/929 (0.00%) 0/931 (0.00%) 0/882 (0.00%) 0/875 (0.00%) 1/882 (0.11%) 3/875 (0.34%) Pertussis 0/930 (0.00%) 1/933 (0.11%) 0/929 (0.00%) 0/931 (0.00%) 0/882 (0.00%) 0/875 (0.00%) 0/882 (0.00%) 0/875 (0.00%) Pharyngitis 0/930 (0.00%) 1/933 (0.11%) 0/929 (0.00%) 1/931 (0.11%) 0/882 (0.00%) 0/875 (0.00%) 1/882 (0.11%) 0/875 (0.00%)

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
			Sinusitis Skin infection Skull fracture Skull fractured base Sleep apnoea syndrome Somnolence Status epilepticus Stomatitis Streptococcal bacteraemia Stridor Subcutaneous abscess Sudden death Swollen tongue Testicular torsion Thermal burn Tonsillitis Tooth abscess Tooth fracture Tooth injury Tracheitis Trigger finger Tympanic membrane hyperaemia Upper respiratory tract infection Urinary tract infection Urine analysis abnormal Varicella Ventricular septal defect Vesicoureteric reflux Viral infection Vomiting Vulvovaginal candidiasis Weight gain poor Wheezing White blood cells urine positive Wound infection		Pneumonia 2/930 (0.22%) 1/933 (0.11%) 5/929 (0.54%) 7/931 (0.75%) 0/882 (0.00%) 1/875 (0.11%) 9/882 (1.02%) 5/875 (0.57%) Postoperative wound infection 1/930 (0.11%) 0/933 (0.00%) 0/929 (0.00%) 0/931 (0.00%) 0/882 (0.00%) 0/875 (0.00%) 0/882 (0.00%) 0/875 (0.00%) Respiratory syncytial virus bronchiolitis 3/930 (0.32%) 0/933 (0.00%) 0/929 (0.00%) 3/931 (0.32%) 0/882 (0.00%) 0/875 (0.00%) 1/882 (0.11%) 2/875 (0.23%) Respiratory tract infection 0/930 (0.00%) 1/933 (0.11%) 1/929 (0.11%) 0/931 (0.00%) 0/882 (0.00%) 1/875 (0.11%) 0/882 (0.00%) 1/875 (0.11%) Rotavirus infection 1/930 (0.11%) 0/933 (0.00%) 0/929 (0.00%) 0/931 (0.00%) 0/882 (0.00%) 0/875 (0.00%) 0/882 (0.00%) 0/875 (0.00%) Streptococcal bacteraemia 1/930 (0.11%) 0/933 (0.00%) 0/929 (0.00%) 0/931 (0.00%) 0/882 (0.00%) 0/875 (0.00%) 0/882 (0.00%) 0/875 (0.00%) Upper respiratory tract infection 4/930 (0.43%) 4/933 (0.43%) 1/929 (0.11%) 2/931 (0.21%) 0/882 (0.00%) 2/875 (0.23%) 2/882 (0.23%) 3/875 (0.34%) Urinary tract infection 0/930 (0.00%) 3/933 (0.32%) 1/929 (0.11%) 0/931 (0.00%) 0/882 (0.00%) 0/875 (0.00%) 2/882 (0.23%) 1/875 (0.11%) Viral infection 1/930 (0.11%) 0/933 (0.00%) 0/929 (0.00%) 0/931 (0.00%) 0/882 (0.00%) 1/875 (0.11%) 0/882 (0.00%) 0/875 (0.00%) Escherichia urinary tract infection 0/930 (0.00%) 0/933 (0.00%) 0/929 (0.00%) 1/931 (0.11%) 0/882 (0.00%) 0/875 (0.00%) 0/882 (0.00%) 0/875 (0.00%) Exanthema subitum 0/930 (0.00%) 0/933 (0.00%) 1/929 (0.11%) 0/931 (0.00%) 0/882 (0.00%) 0/875 (0.00%) 0/882 (0.00%) 0/875 (0.00%) Gastroenteritis rotavirus 0/930 (0.00%) 0/933 (0.00%) 1/929 (0.11%) 0/931

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
					(0.00%) 0/882 (0.00%) 0/875 (0.00%) 2/882 (0.23%) 0/875 (0.00%) Osteomyelitis 0/930 (0.00%) 0/933 (0.00%) 1/929 (0.11%) 1/931 (0.11%) 0/882 (0.00%) 0/875 (0.00%) 0/882 (0.00%) 0/875 (0.00%) Parainfluenzae virus infection 0/930 (0.00%) 0/933 (0.00%) 0/929 (0.00%) 1/931 (0.11%) 0/882 (0.00%) 0/875 (0.00%) 0/882 (0.00%) 1/875 (0.11%) Periorbital cellulitis 0/930 (0.00%) 0/933 (0.00%) 0/929 (0.00%) 2/931 (0.21%) 1/882 (0.11%) 0/875 (0.00%) 1/882 (0.11%) 0/875 (0.00%) Pneumococcal bacteraemia 0/930 (0.00%) 0/933 (0.00%) 0/929 (0.00%) 1/931 (0.11%) 0/882 (0.00%) 0/875 (0.00%) 0/882 (0.00%) 0/875 (0.00%) Pneumonia influenzal 0/930 (0.00%) 0/933 (0.00%) 0/929 (0.00%) 1/931 (0.11%) 0/882 (0.00%) 0/875 (0.00%) 0/882 (0.00%) 0/875 (0.00%) Pneumonia viral 0/930 (0.00%) 0/933 (0.00%) 0/929 (0.00%) 1/931 (0.11%) 0/882 (0.00%) 0/875 (0.00%) 0/882 (0.00%) 0/875 (0.00%) Acute tonsillitis 0/930 (0.00%) 0/933 (0.00%) 0/929 (0.00%) 0/931 (0.00%) 1/882 (0.11%) 0/875 (0.00%) 1/882 (0.11%) 0/875 (0.00%) Herpangina 0/930 (0.00%) 0/933 (0.00%) 0/929 (0.00%) 0/931 (0.00%) 1/882 (0.11%) 0/875 (0.00%) 0/882 (0.00%) 0/875 (0.00%) Tonsillitis 0/930 (0.00%) 0/933 (0.00%) 0/929 (0.00%) 0/931 (0.00%) 1/882 (0.11%) 0/875 (0.00%) 0/882 (0.00%) 0/875 (0.00%) Arthritis bacterial 0/930 (0.00%) 0/933 (0.00%) 0/929 (0.00%) 0/931 (0.00%) 0/882 (0.00%) 0/875 (0.00%) 0/882 (0.00%) 1/875 (0.11%) Cellulitis 0/930 (0.00%) 0/933 (0.00%) 0/929 (0.00%) 0/931 (0.00%) 0/882 (0.00%) 0/875 (0.00%) 1/882 (0.11%) 1/875 (0.11%)

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
					Corynebacterium infection 0/930 (0.00%) 0/933 (0.00%) 0/929 (0.00%) 0/931 (0.00%) 0/882 (0.00%) 0/875 (0.00%) 0/882 (0.00%) 1/875 (0.11%) Endophthalmitis 0/930 (0.00%) 0/933 (0.00%) 0/929 (0.00%) 0/931 (0.00%) 0/882 (0.00%) 0/875 (0.00%) 0/882 (0.00%) 1/875 (0.11%) H1N1 influenza 0/930 (0.00%) 0/933 (0.00%) 0/929 (0.00%) 0/931 (0.00%) 0/882 (0.00%) 0/875 (0.00%) 0/882 (0.00%) 1/875 (0.11%) Influenza 0/930 (0.00%) 0/933 (0.00%) 0/929 (0.00%) 0/931 (0.00%) 0/882 (0.00%) 0/875 (0.00%) 0/882 (0.00%) 1/875 (0.11%) Intervertebral discitis 0/930 (0.00%) 0/933 (0.00%) 0/929 (0.00%) 0/931 (0.00%) 0/882 (0.00%) 0/875 (0.00%) 1/882 (0.11%) 0/875 (0.00%) Localised infection 0/930 (0.00%) 0/933 (0.00%) 0/929 (0.00%) 0/931 (0.00%) 0/882 (0.00%) 0/875 (0.00%) 1/882 (0.11%) 0/875 (0.00%) Pneumonia respiratory syncytial viral 0/930 (0.00%) 0/933 (0.00%) 0/929 (0.00%) 0/931 (0.00%) 0/882 (0.00%) 0/875 (0.00%) 1/882 (0.11%) 0/875 (0.00%) Pulmonary tuberculosis 0/930 (0.00%) 0/933 (0.00%) 0/929 (0.00%) 0/931 (0.00%) 0/882 (0.00%) 0/875 (0.00%) 1/882 (0.11%) 0/875 (0.00%) Sinusitis 0/930 (0.00%) 0/933 (0.00%) 0/929 (0.00%) 0/931 (0.00%) 0/882 (0.00%) 0/875 (0.00%) 1/882 (0.11%) 0/875 (0.00%) Subcutaneous abscess 0/930 (0.00%) 0/933 (0.00%) 0/929 (0.00%) 0/931 (0.00%) 0/882 (0.00%) 0/875 (0.00%) 1/882 (0.11%) 0/875 (0.00%) Tooth abscess 0/930 (0.00%) 0/933 (0.00%) 0/929 (0.00%) 0/931 (0.00%) 0/882 (0.00%) 0/875 (0.00%) 1/882 (0.11%) 0/875 (0.00%) Wound infection 0/930 (0.00%) 0/933 (0.00%) 0/929 (0.00%) 0/931 (0.00%)

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
					0/882 (0.00%) 0/875 (0.00%) 1/882 (0.11%) 0/875 (0.00%) Injury, poisoning and procedural complications Fall 0/930 (0.00%) 1/933 (0.11%) 0/929 (0.00%) 0/931 (0.00%) 0/882 (0.00%) 0/875 (0.00%) 0/882 (0.00%) 0/875 (0.00%) Head injury 3/930 (0.32%) 2/933 (0.21%) 1/929 (0.11%) 4/931 (0.43%) 0/882 (0.00%) 2/875 (0.23%) 4/882 (0.45%) 0/875 (0.00%) Post procedural haemorrhage 0/930 (0.00%) 1/933 (0.11%) 0/929 (0.00%) 0/931 (0.00%) 0/882 (0.00%) 0/875 (0.00%) 1/882 (0.11%) 0/875 (0.00%) Skull fracture 0/930 (0.00%) 1/933 (0.11%) 1/929 (0.11%) 1/931 (0.11%) 0/882 (0.00%) 0/875 (0.00%) 0/882 (0.00%) 0/875 (0.00%) Burns second degree 0/930 (0.00%) 0/933 (0.00%) 0/929 (0.00%) 1/931 (0.11%) 0/882 (0.00%) 0/875 (0.00%) 1/882 (0.11%) 0/875 (0.00%) Exposure to toxic agent 0/930 (0.00%) 0/933 (0.00%) 0/929 (0.00%) 1/931 (0.11%) 0/882 (0.00%) 0/875 (0.00%) 3/882 (0.34%) 0/875 (0.00%) Foreign body 0/930 (0.00%) 0/933 (0.00%) 1/929 (0.11%) 1/931 (0.11%) 0/882 (0.00%) 0/875 (0.00%) 0/882 (0.00%) 0/875 (0.00%) Near drowning 0/930 (0.00%) 0/933 (0.00%) 0/929 (0.00%) 1/931 (0.11%) 0/882 (0.00%) 0/875 (0.00%) 0/882 (0.00%) 0/875 (0.00%) Skull fractured base 0/930 (0.00%) 0/933 (0.00%) 0/929 (0.00%) 1/931 (0.11%) 0/882 (0.00%) 0/875 (0.00%) 0/882 (0.00%) 0/875 (0.00%) Thermal burn 0/930 (0.00%) 0/933 (0.00%) 0/929 (0.00%) 2/931 (0.21%) 1/882 (0.11%) 1/875 (0.11%) 1/882 (0.11%) 2/875 (0.23%) Laceration 0/930 (0.00%) 0/933 (0.00%) 0/929 (0.00%) 0/931 (0.00%) 1/882

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
					(0.11%) 0/875 (0.00%) 0/882 (0.00%) 0/875 (0.00%) Accidental poisoning 0/930 (0.00%) 0/933 (0.00%) 0/929 (0.00%) 0/931 (0.00%) 0/882 (0.00%) 0/875 (0.00%) 0/882 (0.00%) 1/875 (0.11%) Contusion 0/930 (0.00%) 0/933 (0.00%) 0/929 (0.00%) 0/931 (0.00%) 0/882 (0.00%) 0/875 (0.00%) 0/882 (0.00%) 1/875 (0.11%) Femur fracture 0/930 (0.00%) 0/933 (0.00%) 0/929 (0.00%) 0/931 (0.00%) 0/882 (0.00%) 0/875 (0.00%) 1/882 (0.11%) 1/875 (0.11%) Hand fracture 0/930 (0.00%) 0/933 (0.00%) 0/929 (0.00%) 0/931 (0.00%) 0/882 (0.00%) 0/875 (0.00%) 1/882 (0.11%) 0/875 (0.00%) Mouth injury 0/930 (0.00%) 0/933 (0.00%) 0/929 (0.00%) 0/931 (0.00%) 0/882 (0.00%) 0/875 (0.00%) 0/882 (0.00%) 1/875 (0.11%) Postoperative fever 0/930 (0.00%) 0/933 (0.00%) 0/929 (0.00%) 0/931 (0.00%) 0/882 (0.00%) 0/875 (0.00%) 0/882 (0.00%) 1/875 (0.11%) Radius fracture 0/930 (0.00%) 0/933 (0.00%) 0/929 (0.00%) 0/931 (0.00%) 0/882 (0.00%) 0/875 (0.00%) 1/882 (0.11%) 0/875 (0.00%) Road traffic accident 0/930 (0.00%) 0/933 (0.00%) 0/929 (0.00%) 0/931 (0.00%) 0/882 (0.00%) 0/875 (0.00%) 1/882 (0.11%) 0/875 (0.00%) Investigations Urine analysis abnormal 1/930 (0.11%) 0/933 (0.00%) 0/929 (0.00%) 0/931 (0.00%) 0/882 (0.00%) 0/875 (0.00%) 0/882 (0.00%) 0/875 (0.00%) Influenza virus test positive 0/930 (0.00%) 0/933 (0.00%) 0/929 (0.00%) 1/931 (0.11%) 0/882 (0.00%) 0/875 (0.00%) 0/882 (0.00%) 0/875 (0.00%) Metabolism and nutrition disorders Dehydration 1/930 (0.11%) 1/933 (0.11%) 1/929 (0.11%) 0/931 (0.00%)

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
					0/882 (0.00%) 2/875 (0.23%) 8/882 (0.91%) 6/875 (0.69%) Diet refusal 1/930 (0.11%) 0/933 (0.00%) 0/929 (0.00%) 0/931 (0.00%) 0/882 (0.00%) 0/875 (0.00%) 0/882 (0.00%) 0/875 (0.00%) Lactose intolerance 2/930 (0.22%) 0/933 (0.00%) 0/929 (0.00%) 0/931 (0.00%) 0/882 (0.00%) 0/875 (0.00%) 0/882 (0.00%) 0/875 (0.00%) Metabolic acidosis 0/930 (0.00%) 1/933 (0.11%) 0/929 (0.00%) 0/931 (0.00%) 0/882 (0.00%) 0/875 (0.00%) 0/882 (0.00%) 0/875 (0.00%) Weight gain poor 0/930 (0.00%) 1/933 (0.11%) 0/929 (0.00%) 0/931 (0.00%) 0/882 (0.00%) 0/875 (0.00%) 0/882 (0.00%) 0/875 (0.00%) Feeding disorder 0/930 (0.00%) 0/933 (0.00%) 1/929 (0.11%) 0/931 (0.00%) 0/882 (0.00%) 0/875 (0.00%) 0/882 (0.00%) 0/875 (0.00%) Musculoskeletal and connective tissue disorders Trigger finger 0/930 (0.00%) 0/933 (0.00%) 0/929 (0.00%) 0/931 (0.00%) 1/882 (0.11%) 0/875 (0.00%) 0/882 (0.00%) 0/875 (0.00%) Monarthritis 0/930 (0.00%) 0/933 (0.00%) 0/929 (0.00%) 0/931 (0.00%) 0/882 (0.00%) 0/875 (0.00%) 0/882 (0.00%) 1/875 (0.11%) Pain in extremity 0/930 (0.00%) 0/933 (0.00%) 0/929 (0.00%) 0/931 (0.00%) 0/882 (0.00%) 0/875 (0.00%) 0/882 (0.00%) 1/875 (0.11%) Neoplasms benign, malignant and unspecified (incl cysts and polyps) Medulloblastoma 0/930 (0.00%) 1/933 (0.11%) 0/929 (0.00%) 0/931 (0.00%) 0/882 (0.00%) 0/875 (0.00%) 0/882 (0.00%) 0/875 (0.00%) Nervous system disorders Cerebral infarction (in AE table) Convulsion (infant series in AE table)1/929 (0.11%) 1/931 (0.11%) 0/882

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
					(0.00%) 0/875 (0.00%) 0/882 (0.00%) 0/875 (0.00%) Febrile convulsion 1/930 (0.11%) 2/933 (0.21%) 3/929 (0.32%) 5/931 (0.54%) 1/882 (0.11%) 1/875 (0.11%) 7/882 (0.79%) 8/875 (0.91%) Fontanelle bulging 2/930 (0.22%) 3/933 (0.32%) 0/929 (0.00%) 0/931 (0.00%) 0/882 (0.00%) 0/875 (0.00%) 0/882 (0.00%) 0/875 (0.00%) Hypotonia 0/930 (0.00%) 1/933 (0.11%) 0/929 (0.00%) 0/931 (0.00%) 0/882 (0.00%) 0/875 (0.00%) 0/882 (0.00%) 0/875 (0.00%) Partial seizures 0/930 (0.00%) 1/933 (0.11%) 0/929 (0.00%) 0/931 (0.00%) 0/882 (0.00%) 0/875 (0.00%) 0/882 (0.00%) 0/875 (0.00%) Infantile spasms 0/930 (0.00%) 0/933 (0.00%) 1/929 (0.11%) 0/931 (0.00%) 0/882 (0.00%) 0/875 (0.00%) 0/882 (0.00%) 0/875 (0.00%) Status epilepticus 0/930 (0.00%) 0/933 (0.00%) 0/929 (0.00%) 1/931 (0.11%) 0/882 (0.00%) 0/875 (0.00%) 0/882 (0.00%) 1/875 (0.11%) Myoclonic epilepsy 0/930 (0.00%) 0/933 (0.00%) 0/929 (0.00%) 0/931 (0.00%) 0/882 (0.00%) 0/875 (0.00%) 0/882 (0.00%) 1/875 (0.11%) Pregnancy, puerperium and perinatal conditions Cephalhaematoma 0/930 (0.00%) 1/933 (0.11%) 0/929 (0.00%) 0/931 (0.00%) 0/882 (0.00%) 0/875 (0.00%) 0/882 (0.00%) 0/875 (0.00%) Psychiatric disorders Breath holding 1/930 (0.11%) 1/933 (0.11%) 1/929 (0.11%) 0/931 (0.00%) 0/882 (0.00%) 0/875 (0.00%) 1/882 (0.11%) 0/875 (0.00%) Restlessness 1/930 (0.11%) 1/933 (0.11%) 0/929 (0.00%) 0/931 (0.00%) 0/882 (0.00%) 0/875 (0.00%) 0/882 (0.00%) 0/875 (0.00%) Apathy 0/930 (0.00%) 0/933 (0.00%) 0/929 (0.00%) 0/931 (0.00%) 0/882

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
					(0.00%) 0/875 (0.00%) 0/882 (0.00%) 1/875 (0.11%) Renal and urinary disorders Leukocyturia 1/930 (0.11%) 0/933 (0.00%) 0/929 (0.00%) 0/931 (0.00%) 0/882 (0.00%) 0/875 (0.00%) 0/882 (0.00%) 0/875 (0.00%) Kidney enlargement 0/930 (0.00%) 0/933 (0.00%) 0/929 (0.00%) 0/931 (0.00%) 0/882 (0.00%) 1/875 (0.11%) 0/882 (0.00%) 0/875 (0.00%) Dysuria 0/930 (0.00%) 0/933 (0.00%) 0/929 (0.00%) 0/931 (0.00%) 0/882 (0.00%) 0/875 (0.00%) 1/882 (0.11%) 0/875 (0.00%) Reproductive system and breast disorders Testicular torsion (in AE table) Respiratory, thoracic and mediastinal disorders Apparent life threatening event 1/930 (0.11%) 0/933 (0.00%) 0/929 (0.00%) 0/931 (0.00%) 0/882 (0.00%) 0/875 (0.00%) 0/882 (0.00%) 0/875 (0.00%) Asthma 2/930 (0.22%) 0/933 (0.00%) 3/929 (0.32%) 1/931 (0.11%) 1/882 (0.11%) 2/875 (0.23%) (toddler dose in AE table) Bronchial hyperreactivity 0/930 (0.00%) 1/933 (0.11%) 0/929 (0.00%) 0/931 (0.00%) 0/882 (0.00%) 0/875 (0.00%) 0/882 (0.00%) 0/875 (0.00%) Choking 3/930 (0.32%) 0/933 (0.00%) 0/929 (0.00%) 0/931 (0.00%) 0/882 (0.00%) 0/875 (0.00%) 0/882 (0.00%) 0/875 (0.00%) Cough 0/930 (0.00%) 2/933 (0.21%) 0/929 (0.00%) 1/931 (0.11%) 2/882 (0.23%) 0/875 (0.00%) 0/882 (0.00%) 2/875 (0.23%) Grunting 1/930 (0.11%) 0/933 (0.00%) 0/929 (0.00%) 0/931 (0.00%) 0/882 (0.00%) 0/875 (0.00%) 1/882 (0.11%) 0/875 (0.00%) Hypoxia 0/930 (0.00%) 1/933 (0.11%) 0/929 (0.00%) 0/931 (0.00%) 0/882 (0.00%) 0/875 (0.00%) 0/882 (0.00%) 1/875 (0.11%)

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
					Lung infiltration 1/930 (0.11%) 0/933 (0.00%) 0/929 (0.00%) 0/931 (0.00%) 0/882 (0.00%) 0/875 (0.00%) 0/882 (0.00%) 3/875 (0.34%) Respiratory distress 2/930 (0.22%) 1/933 (0.11%) 1/929 (0.11%) 2/931 (0.21%) 1/882 (0.11%) 2/875 (0.23%) 2/882 (0.23%) 2/875 (0.23%) Sleep apnoea syndrome 0/930 (0.00%) 1/933 (0.11%) 0/929 (0.00%) 1/931 (0.11%) 0/882 (0.00%) 1/875 (0.11%) 2/882 (0.23%) 1/875 (0.11%) Stridor 1/930 (0.11%) 0/933 (0.00%) 1/929 (0.11%) 0/931 (0.00%) 1/882 (0.11%) 0/875 (0.00%) 0/882 (0.00%) 2/875 (0.23%) Wheezing 2/930 (0.22%) 0/933 (0.00%) 2/929 (0.22%) 2/931 (0.21%) 0/882 (0.00%) 0/875 (0.00%) 0/882 (0.00%) 2/875 (0.23%) Haemoptysis 0/930 (0.00%) 0/933 (0.00%) 0/929 (0.00%) 0/931 (0.00%) 0/882 (0.00%) 0/875 (0.00%) 1/882 (0.11%) 0/875 (0.00%) Pneumonitis 0/930 (0.00%) 0/933 (0.00%) 0/929 (0.00%) 0/931 (0.00%) 0/882 (0.00%) 0/875 (0.00%) 1/882 (0.11%) 0/875 (0.00%) Rash macular 0/930 (0.00%) 0/933 (0.00%) 0/929 (0.00%) 1/931 (0.11%) 0/882 (0.00%) 0/875 (0.00%) 0/882 (0.00%) 0/875 (0.00%) Skin and subcutaneous tissue disorders Rash 0/930 (0.00%) 1/933 (0.11%) 0/929 (0.00%) 0/931 (0.00%) 0/882 (0.00%) 0/875 (0.00%) 1/882 (0.11%) 0/875 (0.00%) Rash maculo-papular 1/930 (0.11%) 0/933 (0.00%) 0/929 (0.00%) 0/931 (0.00%) 0/882 (0.00%) 0/875 (0.00%) 0/882 (0.00%) 0/875 (0.00%) Henoch-Schonlein purpura (in AE table) Petechiae 0/930 (0.00%) 0/933 (0.00%) 0/929 (0.00%) 0/931 (0.00%) 0/882 (0.00%) 0/875 (0.00%) 2/882 (0.23%) 0/875 (0.00%)

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
					Pruritus 0/930 (0.00%) 0/933 (0.00%) 0/929 (0.00%) 0/931 (0.00%) 0/882 (0.00%) 0/875 (0.00%) 0/882 (0.00%) 1/875 (0.11%) Social circumstances Overfeeding of infant 0/930 (0.00%) 2/933 (0.21%) 0/929 (0.00%) 0/931 (0.00%) 0/882 (0.00%) 0/875 (0.00%) 0/882 (0.00%) 0/875 (0.00%) Vascular disorders Hypertension 0/930 (0.00%) 0/933 (0.00%) 0/929 (0.00%) 0/931 (0.00%) 0/882 (0.00%) 1/875 (0.11%) 0/882 (0.00%) 0/875 (0.00%) Risk factors: NR
Kim, 2013[146] Wyeth, 2008[350] NCT00689351 Article RCT N=180 Industry funded Korea	Age: 2.1 months (range 1.5-3.4) % female: 47% Ethnicity: 100% Asian Healthy infants Out of scope: None	Pneumococcal PCV13 Prevnar 13 Four doses of PCV13 at 2, 4, 6, 12 months Route NR adjuvant NR preservative NR Co-intervention Routine vaccines (DTaP at same visit, IPV and Hib within 7-21 days) Base treatment : Routine vaccines (DTaP at same visit, IPV and Hib within 7-21 days),Other : PCV7 Routine vaccines as above plus PCV7 Four doses of PCV7 at 2, 4, 6, 12 months route NR adjuvant NRpreservative NR Counts		Asthma: 22.X Not categorized as SAE; followed dose 4 I: 1/84, 22.X NA C: 0/88 Cardiovascular events: 2.X NA I: 0/88, 2.X Supraventricular tachycardia, not categorized as SAE; followed dose 1 C: 1/89 Death: NA NA I: 0/84, NA NA C: 0/88 Intussusception: 7.X Not categorized as SAE; followed dose 1 I: 1/88, 7.X C: 0/89 Kawasaki Disease: 10.X No causal association with study vaccines; followed dose 1 I: 1/88, 10.X NA C: 0/89 Reproduction issues: 21.X N/A I: 0/88, 21.X Perineal fistula, not categorized as SAE; followed dose 1 C: 0/89 Seizure: 17.X NA I: 0/88, 17.X No causal association with study vaccines; followed dose 1 C: 1/89	Serious adverse events (from clinicaltrials.gov) Infant Series 13vPnCInfant Series 7vPnCAfter the Infant Series 13vPnCAfter the Infant Series 7vPnCToddler Dose 13vPnCToddler Dose 7vPnC Affected / at Risk (%)Affected / at Risk (%)Affected / at Risk (%)Affected / at Risk (%)Affected / at Risk (%)Affected / at Risk (%) Total 8/88 (9.09%) 9/89 (10.11%) 9/88 (10.23%) 12/89 (13.48%) 3/84 (3.57%) 3/88 (3.41%) Diarrhoea 0/88 (0.00%) 1/89 (1.12%) 0/88 (0.00%) 0/89 (0.00%) 0/84 (0.00%) 0/88 (0.00%) Inguinal hernia 0/88 (0.00%) 0/89 (0.00%) 1/88 (1.14%) 0/89 (0.00%) 0/84 (0.00%) 0/88 (0.00%) Soft tissue inflammation 0/88 (0.00%) 0/89 (0.00%) 0/88 (0.00%) 0/89 (0.00%) 0/84 (0.00%) 1/88 (1.14%) Hepatitis 0/88 (0.00%) 0/89 (0.00%) 0/88 (0.00%) 1/89 (1.12%) 0/84 (0.00%) 0/88 (0.00%) Bronchiolitis 2/88 (2.27%) 4/89 (4.49%) 1/88 (1.14%) 1/89 (1.12%) 0/84 (0.00%) 0/88 (0.00%) Pneumonia 3/88 (3.41%) 1/89 (1.12%) 1/88 (1.14%) 1/89 (1.12%) 1/84 (1.19%) 1/88 (1.14%)

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
		Power other outcome Followup: 11 months			Urinary tract infection 0/88 (0.00%) 2/89 (2.25%) 0/88 (0.00%) 1/89 (1.12%) 0/84 (0.00%) 0/88 (0.00%) Bronchitis 1/88 (1.14%) 0/89 (0.00%) 1/88 (1.14%) 1/89 (1.12%) 1/84 (1.19%) 1/88 (1.14%) Bronchopneumonia 0/88 (0.00%) 1/89 (1.12%) 0/88 (0.00%) 1/89 (1.12%) 0/84 (0.00%) 0/88 (0.00%) Gastroenteritis 1/88 (1.14%) 0/89 (0.00%) 3/88 (3.41%) 2/89 (2.25%) 1/84 (1.19%) 0/88 (0.00%) Kawasaki's disease (in AE table) Otitis media acute 0/88 (0.00%) 0/89 (0.00%) 1/88 (1.14%) 3/89 (3.37%) 0/84 (0.00%) 0/88 (0.00%) Herpangina 0/88 (0.00%) 0/89 (0.00%) 1/88 (1.14%) 1/89 (1.12%) 0/84 (0.00%) 0/88 (0.00%) Adenovirus infection 0/88 (0.00%) 0/89 (0.00%) 0/88 (0.00%) 1/89 (1.12%) 0/84 (0.00%) 0/88 (0.00%) Bacterial infection 0/88 (0.00%) 0/89 (0.00%) 0/88 (0.00%) 1/89 (1.12%) 0/84 (0.00%) 0/88 (0.00%) Exanthema subitum 0/88 (0.00%) 0/89 (0.00%) 1/88 (1.14%) 0/89 (0.00%) 0/84 (0.00%) 0/88 (0.00%) Gastroenteritis rotavirus 0/88 (0.00%) 0/89 (0.00%) 0/88 (0.00%) 1/89 (1.12%) 0/84 (0.00%) 0/88 (0.00%) Hand-foot-and-mouth disease 0/88 (0.00%) 0/89 (0.00%) 1/88 (1.14%) 0/89 (0.00%) 0/84 (0.00%) 0/88 (0.00%) Influenza 0/88 (0.00%) 0/89 (0.00%) 0/88 (0.00%) 1/89 (1.12%) 0/84 (0.00%) 0/88 (0.00%) Rhinitis 0/88 (0.00%) 0/89 (0.00%) 0/88 (0.00%) 1/89 (1.12%) 0/84 (0.00%) 0/88 (0.00%) Tonsillitis 0/88 (0.00%) 0/89 (0.00%) 0/88 (0.00%) 1/89 (1.12%) 0/84 (0.00%) 0/88 (0.00%) Pharyngitis 0/88 (0.00%) 0/89 (0.00%) 0/88 (0.00%) 0/89 (0.00%) 0/84 (0.00%) 1/88 (1.14%)

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
					Dehydration 1/88 (1.14%) 0/89 (0.00%) 0/88 (0.00%) 0/89 (0.00%) 0/84 (0.00%) 0/88 (0.00%) Convulsion (in AE table) Nephrolithiasis 0/88 (0.00%) 0/89 (0.00%) 0/88 (0.00%) 1/89 (1.12%) 0/84 (0.00%) 0/88 (0.00%) Other severe adverse events (from clinicaltrials.gov; did not include non-key or non-severe adverse events here): Infant Series 13vPnCInfant Series 7vPnCAfter the Infant Series 13vPnCAfter the Infant Series 7vPnCToddler Dose 13vPnCToddler Dose 7vPnC Affected / at Risk (%)Affected / at Risk (%)Affected / at Risk (%)Affected / at Risk (%)Affected / at Risk (%)Affected / at Risk (%) Total 78/88 (88.64%) 75/89 (84.27%) 18/88 (20.45%) 19/89 (21.35%) 28/84 (33.33%) 36/88 (40.91%) Supraventricular tachycardia (in AE table) Intussusception (in AE table) Fever > 40 degrees C (Infant Series Dose 1 and Toddler Dose; Fever > 40 degrees C)0/67 (0.00%) 0/70 (0.00%) 0/0 0/0 0/49 (0.00%) 0/49 (0.00%) Fever > 40 degrees C (Infant Series Dose 2; Fever > 40 degrees C)0/55 (0.00%) 0/58 (0.00%) 0/0 0/0 0/0 0/0 Fever > 40 degrees C (Infant Series Dose 3; Fever > 40 degrees C)0/58 (0.00%) 0/51 (0.00%) 0/0 0/0 0/0 0/0 Asthma (in AE table) Tenderness (significant) (Infant Series Dose 1 and Toddler Dose; Tenderness [significant]=present and interfered with limb movement)6/68 (8.82%) 2/72 (2.78%) 0/0 0/0 3/51 (5.88%) 1/50 (2.00%) Tenderness (significant) (Infant Series Dose 2; Tenderness [significant]=present and interfered with limb movement) 0/55 (0.00%) 3/60 (5.00%) 0/0 0/0 0/0 0/0 Tenderness (significant) (Infant Series Dose 3; Tenderness [significant]=present and interfered with limb movement) 0/58 (0.00%) 1/54 (1.85%) 0/0 0/0 0/0 0/0

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
					Swelling (severe) (Infant Series Dose 1 and Toddler Dose; Swelling [severe] >7.0 cm)0/67 (0.00%) 0/70 (0.00%) 0/0 0/0 1/49 (2.04%) 0/50 (0.00%) Swelling (severe) (Infant Series Dose 2; Swelling [severe] >7.0 cm)0/55 (0.00%) 0/59 (0.00%) 0/0 0/0 0/0 0/0 Swelling (severe) (Infant Series Dose 3; Swelling [severe] >7.0 cm)0/58 (0.00%) 0/53 (0.00%) 0/0 0/0 0/0 0/0 Redness (severe) (Infant Series Dose 1 and Toddler Dose; Redness [severe] >7.0 cm) 0/67 (0.00%) 0/70 (0.00%) 0/0 0/0 0/49 (0.00%) 0/50 (0.00%) Redness (severe) (Infant Series Dose 2; Redness [severe] >7.0 cm)0/55 (0.00%) 0/59 (0.00%) 0/0 0/0 0/0 0/0 Redness (severe)(Infant Series Dose 3; Redness [severe] >7.0 cm)0/58 (0.00%) 0/53 (0.00%) 0/0 0/0 0/0 0/0 Risk factors: No
Stockwell, 2014[206] Columbia University, 2011[247] NCT01467934 Article Cohort study N=530 Not industry funded USA	Age: 54% were 6-11 mos, 46% were 12-23 mos % female: 50% Ethnicity: 86% Latino, 11% Black (non-Latino), 1% White (non-Latino) 1% Other (non-Latino) Healthy children aged 6-23 months Out of scope: None	Pneumococcal PCV13 Prevnar 13 0.5 mL for one dose Intramuscular adjuvant NR preservative NR Co-intervention With TIV Base treatment,Other : h trivalent inactivated influenza vaccine TIV 0.5 mL for one dose Intramuscular adjuvant NRpreservative NR Counts Prespecified AE Power calculation	Fever After Vaccination Febrile seizure	Febrile seizures: 17.X NA I: 0/212, 17.X NA C: 0/208	Temperature ≥38°C on Days 0-1 TIV and PCV13 64/170 (37.6%), TIV 12/159 (7.5%), adjusted RR 2.69 (95% CI 1.30-5.60) Temperature ≥39°C on Days 0-1 TIV and PCV13 19/170 (11.2%), TIV 4/159 (2.5%), adjusted RR 7.50 3.92 (95% CI 1.09-14.14) Risk factors: Yes, when children whose families reported antipyretic use on days 0 to 1 (n = 50) were excluded or when analyses were limited to first enrollments (n = 484), findings were similar.

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
		Followup: 1 months			
Togashi, 2015[217] Pfizer, 2010[345] NCT01200368 Article RCT N=551 Industry funded Japan	Age: 4.1 months (no SD) % female: 49% Ethnicity: 100% Japanese Healthy infants aged 3-6 months Out of scope: None	Pneumococcal PCV13 Prevnar 13 2.0 mL in 0.5 mL doses at day 0, 4-8 weeks later, 4-8 weeks later, and 12-15 months of age Intramuscular Aluminum preservative free Co-intervention DTaP "Kaketsuken" given subcutaneously Base treatment,Other PCV7 (control vaccine) and DTaP (base treatment that intervention get) Prevnar and DTaP "Kaketsuken" given subcutaneously 2.0 mL in 0.5 mL doses at day 0, 4-8 weeks later, 4-8	Dacryostenosis congenital Deafness bilateral Bronchiolitis Bronchitis Gastroenteritis Gastroenteritis norovirus Gastroenteritis viral Laryngitis Pneumonia Pneumonia respiratory syncytial viral Respiratory syncytial virus bronchiolitis Urinary tract infection Bronchopneumonia Exanthema subitum Gastroenteritis rotavirus Herpangina Mycoplasma infection Otitis media Parotitis Pharyngitis Rotavirus infection Respiratory syncytial virus infection Thermal burn Muscular weakness Febrile convulsion Neuritis cranial Asthma Kawasaki's disease	Asthma: 22.X Occurred only during infant series follow-up I: 1/183, 22.X NA C: 0/183 Death: NA NA I: 0/183, NA NA C: 0/183 Febrile seizures: 17.X Number reported here occurred only during infant series follow-up period; none after infant series or after toddler dose I: 6/183, 17.X Number reported here occurred only during infant series follow-up period; another 1 occurred after infant series and 3 after toddler dose C: 5/183 Kawasaki Disease: 10.X Occurred only during infant series follow-up I: 1/183, 10.X Occurred only during infant series follow-up C: 1/183	Severe AEs, Intervention (PCV13+DTaP) vs Control (PCV7+DTaP) Significant tenderness dose 1: 0.0% vs 0.0% Significant tenderness dose 2: 0.6% vs 0.0% Significant tenderness dose 3: 0.0% vs 0.0% Significant tenderness toddler dose: 0.7% vs 0.0% Significant swelling dose 1: 0.0% vs 0.6% Significant swelling dose 2: 0.0% vs 0.0% Significant swelling dose 3: 0.0% vs 0.0% Significant swelling toddler dose: 0.0% vs 0.0% Significant redness dose 1: 0.0% vs 0.6% Significant redness dose 2: 0.0% vs 0.0% Significant redness dose 3: 0.0% vs 0.0% Significant redness toddler dose: 0.0% vs 0.0% Significant fever (>40C) dose 1: 0.0% vs 0.0% Significant fever (>40C) dose 2: 0.0% vs 0.0% Significant fever (>40C) dose 3: 0.0% vs 0.7% Significant fever (>40C) toddler dose: 1.4% vs 2.2% Serious AEs (from clinicaltrials.gov): Intervention Infant Series (PCV13+DTaP) Control Infant Series (PCV7+DTaP)

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
		weeks later, and 12-15 months of age Intramuscular Aluminumpreserv ative free Counts No prespecified AE Power other outcome Followup: 15 months	Iron deficiency anaemia Lymphadenopathy Dacryostenosis congenital Ear haemorrhage Blepharitis Conjunctivitis Conjunctivitis allergic Dacryostenosis acquired Eye discharge Keratitis Eye pruritus Eyelid oedema Acetonaemic vomiting Anal fissure Cheilitis Constipation Diarrhoea Dyspepsia Haematochezia Melaena Vomiting Stomatitis Haemorrhoidal haemorrhage Application site erythema Injection site dermatitis Injection site erythema Injection site induration Injection site swelling Pyrexia Vaccination site induration Vaccination site erythema Vaccination site swelling Redness (prespecified) Swelling (prespecified) Tenderness (prespecified) Fever (prespecified) Decreased appetite (prespecified) Irritability (prespecified) Increased sleep (prespecified) Decreased sleep (prespecified) Hives (urticaria) (prespecified)		Intervention Infant Series Follow-up (PCV13+DTaP) Control Infant Series Follow-up (PCV7+DTaP) Intervention Toddler Dose (PCV13+DTaP) Control Toddler Dose (PCV7+DTaP) Affected / at Risk (%)Affected / at Risk (%)Affected / at Risk (%)Affected / at Risk (%)Affected / at Risk (%)Affected Total 5/183 (2.73%) 8/183 (4.37%) 13/183 (7.10%) 15/183 (8.20%) 0/162 (0.00%) 4/162 (2.47%) Congenital, familial and genetic disorders Dacryostenosis congenital 0/183 (0.00%) 0/183 (0.00%) 0/183 (0.00%) 0/183 (0.00%) 0/162 (0.00%) 0/162 (0.00%) Ear and labyrinth disorders Deafness bilateral 0/183 (0.00%) 0/183 (0.00%) 0/183 (0.00%) 1/183 (0.55%) 0/162 (0.00%) 0/162 (0.00%) Infections and infestations Bronchiolitis 1/183 (0.55%) 0/183 (0.00%) 0/183 (0.00%) 0/183 (0.00%) 0/162 (0.00%) 0/162 (0.00%) Bronchitis 1/183 (0.55%) 1/183 (0.55%) 1/183 (0.55%) 2/183 (1.09%) 0/162 (0.00%) 0/162 (0.00%) Gastroenteritis 1/183 (0.55%) 1/183 (0.55%) 0/183 (0.00%) 3/183 (1.64%) 0/162 (0.00%) 0/162 (0.00%) Gastroenteritis norovirus 0/183 (0.00%) 1/183 (0.55%) 0/183 (0.00%) 0/183 (0.00%) 0/162 (0.00%) 0/162 (0.00%) Gastroenteritis viral 0/183 (0.00%) 1/183 (0.55%) 0/183 (0.00%) 0/183 (0.00%) 0/162 (0.00%) 0/162 (0.00%) Laryngitis 0/183 (0.00%) 1/183 (0.55%) 0/183 (0.00%) 0/183 (0.00%) 0/162 (0.00%) 0/162 (0.00%) Pneumonia 1/183 (0.55%) 0/183 (0.00%) 0/183 (0.00%) 0/183 (0.00%) 0/162 (0.00%) 1/162 (0.62%) Pneumonia respiratory syncytial viral 0/183 (0.00%) 0/183 (0.00%) 0/183 (0.00%) 0/183 (0.00%) 0/162 (0.00%) 0/162 (0.00%) Respiratory syncytial virus bronchiolitis 1/183 (0.55%) 0/183 (0.00%) 1/183

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
			Use of antipyretic medication to treat symptoms (prespecified) Food allergy Milk allergy Acute sinusitis Adenoviral conjunctivitis Adenovirus infection Anal abscess Anal fungal infection Bacterial infection Bronchiolitis Bronchitis Candidiasis Conjunctivitis bacterial Conjunctivitis infective Conjunctivitis viral Croup infectious Enteritis infectious Echo virus infection Erythema infectiosum Exanthema subitum Folliculitis Gastroenteritis Gastroenteritis norovirus Gastroenteritis viral Gastroenteritis rotavirus Genital candidiasis Genital infection fungal Gianotti-Crosti syndrome Hand-foot-and-mouth disease Herpangina Herpes simplex Hordeolum Impetigo Influenza Laryngitis Molluscum contagiosum Nasopharyngitis Omphalitis Oral candidiasis Oral fungal infection Oral herpes Otitis externa Otitis media Otitis media acute		(0.55%) 0/183 (0.00%) 0/162 (0.00%) 0/162 (0.00%) Urinary tract infection 1/183 (0.55%) 1/183 (0.55%) 0/183 (0.00%) 0/183 (0.00%) 0/162 (0.00%) 0/162 (0.00%) Bronchopneumonia 0/183 (0.00%) 0/183 (0.00%) 0/183 (0.00%) 1/183 (0.55%) 0/162 (0.00%) 0/162 (0.00%) Exanthema subitum 0/183 (0.00%) 0/183 (0.00%) 1/183 (0.55%) 1/183 (0.55%) 0/162 (0.00%) 0/162 (0.00%) Gastroenteritis rotavirus 0/183 (0.00%) 0/183 (0.00%) 0/183 (0.00%) 2/183 (1.09%) 0/162 (0.00%) 0/162 (0.00%) Herpangina 0/183 (0.00%) 0/183 (0.00%) 0/183 (0.00%) 0/183 (0.00%) 0/162 (0.00%) 0/162 (0.00%) Mycoplasma infection 0/183 (0.00%) 0/183 (0.00%) 0/183 (0.00%) 1/183 (0.55%) 0/162 (0.00%) 0/162 (0.00%) Otitis media 0/183 (0.00%) 0/183 (0.00%) 0/183 (0.00%) 1/183 (0.55%) 0/162 (0.00%) 0/162 (0.00%) Parotitis 0/183 (0.00%) 0/183 (0.00%) 0/183 (0.55%) 0/183 (0.00%) 0/162 (0.00%) 0/162 (0.00%) Pharyngitis 0/183 (0.00%) 0/183 (0.00%) 1/183 (0.55%) 0/183 (0.00%) 0/162 (0.00%) 0/162 (0.00%) Rotavirus infection 0/183 (0.00%) 0/183 (0.00%) 1/183 (0.55%) 0/183 (0.00%) 0/162 (0.00%) 0/162 (0.00%) Respiratory syncytial virus infection * 1 0/183 (0.00%) 0/183 (0.00%) 0/183 (0.00%) 0/183 (0.00%) 0/162 (0.00%) 0/162 (0.00%) Injury, poisoning and procedural complications Thermal burn 0/183 (0.00%) 0/183 (0.00%) 0/183 (0.00%) 0/183 (0.00%) 0/162 (0.00%) 0/162 (0.00%) Musculoskeletal and connective tissue disorders Muscular weakness 0/183 (0.00%) 0/183 (0.00%) 1/183 (0.55%) 0/183 (0.00%) 0/162 (0.00%) 0/162 (0.00%) Nervous system disorders

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
			Paronychia Perirectal abscess Pharyngitis Pharyngotonsillitis Pneumococcal bacteraemia Pneumonia Pneumonia respiratory syncytial viral Rash pustular Respiratory syncytial virus bronchiolitis Respiratory syncytial virus bronchitis Respiratory syncytial virus infection Respiratory tract infection Rhinitis Rotavirus infection Sinusitis Skin candida Skin infection Streptococcal infection Tonsillitis Upper respiratory tract infection Urinary tract infection Varicella Viral infection Viral rash Gastroenteritis bacterial Arthropod bite Arthropod sting Chillblains Contusion Ear injury Excoriation Eye injury Fall Frostbite Head injury Joint dislocation Laceration Mouth injury Scratch Thermal burn Body height below normal		Febrile convulsion 0/183 (0.00%) 1/183 (0.55%) (infant series follow-up reported in AE table) 0/162 (0.00%) 3/162 (1.85%) Neuritis cranial 0/183 (0.00%) 1/183 (0.55%) 0/183 (0.00%) 0/183 (0.00%) 0/162 (0.00%) 0/162 (0.00%) Respiratory, thoracic and mediastinal disorders Asthma (in AE table) Vascular disorders Kawasaki's disease (in AE table) Risk factors: Yes, stratified by infant series vs toddler dose and study itself has modifier of concomitant administration with DTaP. "Systemic events were reported more frequently after the toddler dose. ... Use of antipyretic medication to treat symptoms was reported most frequently after the toddler dose."

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
			Lactose intolerance Arthralgia Haemangioma of skin Neuritis cranial Vesicoureteric reflux Balanoposthitis Breast swelling Genital labial adhesions Posthitis Adenoidal hypertrophy Asthma Epistaxis Fibrinous bronchitis Infantile asthma Nasal obstruction Pulmonary artery stenosis Rhinitis allergic Rhinorrhoea Asteatosis Dermatitis Dermatitis atopic Dermatitis contact Dermatitis diaper Dry skin Eczema Eczema asteatotic Eczema infantile Erythema Haemorrhage subcutaneous Heat rash Hyperkeratosis palmaris and plantaris Onychomadesis Papule Pityriasis rosea Rash Rash generalised Rash maculo-papular Scar Seborrhoeic dermatitis Urticaria Vascular disorders Haematoma Kawasaki's disease		

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
Tseng, 2013[221] Article Pre-post N=599229 Not industry funded USA	Age: N/A % female: N/A Ethnicity: Ethnicity NR Children aged 1 months to 2 years of age at any of the eight managed care organizations participating in the Vaccine Safety Datalink Project who were vaccinated with PCV13 Out of scope: None	Pneumococcal PCV13 Prevnar 13 1 to 4 doses Route NR adjuvant NR preservative NR Co-intervention Routine vaccines Base treatment,PCV Routine vaccines and PCV7 Prevnar Varies, 1 to 4 doses route NR adjuvant NRpreservative NR Analytic study Prespecified AE Power calculation Followup: 21 months	Febrile seizures Encephalopathy Urticaria and angioneurotic edema Asthma Anaphylaxis Rhrombocytopenia Kawasaki disease	NA	Relative risk of AE following PCV13 compared to historical comparison group (PCV7) Febrile seizures Age 1 < 4 months: 1.29 Febrile seizures Age 4 < 6 months: 0.91 Febrile seizures Age 6 < 12 months: 1.04 Febrile seizures Age 12–24 months: 0.99 Febrile seizures Dose 1: 1.11 Febrile seizures Dose 2: 0.87 Febrile seizures Dose 3: 1.13 Febrile seizures Dose 4: 1.06 Encephalopathy: 3.05 *Not confirmed following medical record review. Encephalopathy (using 5 years of PCV7 background data): 3.13 Urticaria, angioneurotic edema Age 1 < 4 months: 0.34 Urticaria, angioneurotic edema Age 4 < 6 months: 1.73 Urticaria, angioneurotic edema Age 6 < 12 months: 0.86 Urticaria, angioneurotic edema Age 12–24 months: 1.29 Urticaria, angioneurotic edema Dose 1: 0.34 Urticaria, angioneurotic edema Dose 2: 1.89 Urticaria, angioneurotic edema Dose 3: 0.96 Urticaria, angioneurotic edema Dose 4: 1.35 Asthma Age 1 < 4 months: 0.69 Asthma Age 4 < 6 months: 0.72 Asthma Age 6 < 12 months: 0.67 Asthma Age 12–24 months: 0.95 Asthma Dose 1: 0.85 Asthma Dose 2: 0.73 Asthma Dose 3: 0.45 Asthma Dose 4: 0.60 Anaphylaxis: – Anaphylaxis (using 5 years of PCV7 background data): – Thrombocytopenia (two platelet counts of ≤50,000 within 7 days of each other): 0.43

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
					Thrombocytopenia (two platelet counts of ≤100,000 within 7 days of each other): 0.42 Kawasaki disease: 4.24 *On further investigation of Kawasaki disease with medical record review, relative risk was 1.94 (95% CI 0.79, 4.86) based on confirmed complete and incomplete cases plus possible KD cases Risk factors: Yes, age-stratified analyses found no differences by age that would be detectable by the pre-registered metric
Yung, 2019[238] Article Other design N=288 Not industry funded Singapore	Age: 11.32 months (vaccinated Kawasaki disease cases) % female: 43% Ethnicity: 79% Chinese, 12% Malay, 3% Indian, 6% Other All hospitalized cases of KD in our surveillance database from 1st January 2010 to 31st December 2014 with age of onset <2 years and children who were citizens or permanent residents of Singapore Out of scope: None	Pneumococcal PCV13 Prevnar 13 1, 2, 3, or 4 doses Route NR adjuvant NR preservative NR Co-intervention Routine vaccines No intervention Risk interval (0-28 days) vs control interval (any time outside of 0-28 days) Analytic study Prespecified AE Power NR Followup: 22 months	Kawasaki disease	NA	Age-adjusted RI for all Kawasaki disease following PCV13 (risk interval 1-28 days compared to all other times) Dose 1: 1.40 (95%CI, 0.72 to 2.71) Dose 2: 1.23 (95% CI, 0.62 to 2.44) Dose 3: 0.34 (95% CI, 0.08 to 1.40) Stratified analysis of complete Kawasaki disease following PCV13 (risk interval 1-28 days compared to all other times) Dose 1: age-adjusted RI 2.59 (95% CI, 1.16 to 5.81) Dose 2: age-adjusted RI 1.31 (95% CI, 0.52 to 3.28). No Complete KD cases occurred during the risk interval after dose 3 or dose 4 of PCV13. Stratified analysis of incomplete Kawasaki disease following PCV13 (risk interval 1-28 days compared to all other times) Dose 1: age-adjusted RI 0.65 (95% CI, 0.20 to 2.12). RI of Incomplete KD during the risk interval for subsequent PCV13 doses was also not statistically significantly higher than the control interval Risk factors: No

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
Briggs-Steinberg, 2019[73] Article Pre-post N=390 Not industry funded USA	Age: 59 days (range 42-103) % female: Intervention 46%, Historic controls 40% Ethnicity: Intervention: 37% White, 23% Black, 24% Hispanic, 16% Other/Unknown; Historic controls 33% White, 31% Black, 24% Hispanic, 12% Other/Unknow Premature infants in NICU aged 42-105 days who received RV5 during hospitalization and their matched historic controls Out of scope: None	RV RotaTeq Route NR adjuvant NR preservative NR No co-intervention Base treatment Historical controls matched by gestational age, birth weight Counts Prespecified AE Power NR Followup: 1 months	Apnea Bradycardia Nonbilious emesis Increased proportion of stools defined as “loose” Sepsis Feeding intolerance Elevation in mode of ventilation Presence of feeding intolerance	Cardiovascular events: 2.1 Bradycardia with stimulation at 7 days I: 38/201, 2.1 Bradycardia with stimulation at 7 days C: 20/198	Pre-/post-RV5 comparison: Total number of bradycardia events within 7 days: Pre-RV5 1523 vs post-RV5 1236, p=0.03 (no differences at 1, 3, 7 days) Bradycardia with stimulation within 7 days: Pre-RV5 882 vs post-RV5 699, p=0.02 (no difference at 1, 3 days) Total number of stools within 7 days: Pre-RV5 437 vs post-RV5 470, p=0.04 Nonbilious emesis within 7 days: Pre-RV5 11 vs post-RV5 26, p=0.02 (no difference at 1 and 3 days) RV5 (N=201) to Historical controls (N=189) Increase in apnea within 3 days: 35 vs 19, p=0.04 Apnea with stimulation within 3 days: 35 vs 13, p=0.02 Bradycardia with stimulation within 3 days: 39 vs 18, p=.008 Increase in apnea within 7 days: 39 vs 12, p=0.0002 Bradycardia with stimulation within 7 days: 38 vs 20, p=.02 Loose stools within 1 day: 21 vs 4, p=0.0009 Loose stools within 7 days: 50 vs 15, p=0.00002 No differences in total number of events, stool frequency, emesis, number of infants with abdominal x-ray studies, sepsis evaluations, elevation in mode of ventilation, presence of feeding intolerance. In sub-group analysis of different methods of respiratory support and infants on caffeine, no difference in apnea and bradycardia events Risk factors: Sample is a subgroup of NICU hospitalized infants

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
Burke, 2020[74] Article Cohort study N=1858827 Not industry funded USA	Age: NR % female: NR Ethnicity: NR Children born after January 1, 2006 in the Truven Health MarketScan Commercial Claims and Encounters database. Out of scope: None	RV Rotarix,RotaTeq 3 doses of RV5 or 2 doses of RV1 was considered fully vaccinated Oral adjuvant NR preservative NR Co-intervention Routine vaccines Base treatment : Routine vaccines Analytic study Power NR Followup: 24 months	Intussusception	NA	Risk of intussusception: Fully vaccinated vs non-vaccinated aHR 0.79 (95% CI 0.57, 1.09) Partially vaccinated vs non-vaccinated aHR 0.89 (95% CI 0.66, 1.19) Results similar in sensitivity analyses that restricted intussusception to first diagnostic position, or only children who received at least 1 DTaP by 6 months of age, or both. Risk factors: No
Carlin, 2013[75] Article Case-Control N=320 Not industry funded Australia	Age: N/A % female: N/A Ethnicity: Ethnicity NR Infants with cases of intussusception between 1 and 12 months, and their matched controls (on date of birth, sex, state or territory) Out of scope: None	RV Rotarix,RotaTeq RV1: 2-dose schedule at 2 and 4 months; RV5: 3-dose schedule at 2, 4, and 6 months Oral adjuvant NR preservative NR No co-intervention No intervention SCCS: Comparison unexposed period; Matched controls Analytic study Prespecified AE Power calculation Followup: 1 months	Intussusception Rotavirus-attributable gastroenteritis	NA	Self-controlled case series analysis (RI=relative incidence, 95% CI): RV1 (Rotarix) associated with intussusception at first dose, 1-7d: 1–7 days, 6.76 (2.40–19.01); 8–21 days, 3.45 (1.33–8.94) RV1 (Rotarix) associated with intussusception at second dose, 1-7d: 1–7 days, 2.84 (1.10-7.34); 8–21 days, 2.11 (0.97-4.62) RV5 (Rotateq) associated with intussusception at first dose: 1–7 days, 9.89 (3.70–26.42); 8–21 days, 6.32 (2.78–14.37) RV5 (Rotateq) associated with intussusception at second dose: 1–7 days, 2.81 (1.16–6.80), 8-21 days, 1.77 (0.81-3.88) RV5 (Rotateq) associated with intussusception at third dose: 1–7 days, 0.75 (0.18-3.11), 8-21 days, 0.56 (0.17-1.82) Case-control study (OR, 95% CI) RV1 (Rotarix) associated with intussusception at first dose, 1-7d: 1–7 days, 15.61 (3.36–72.57); 8–21 days, 6.48 (1.74–24.16) RV1 (Rotarix) associated with intussusception at second dose, 1-7d: 1–

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
					7 days, 2.44 (0.80–7.47); 8–21 days, 1.35 (0.50–3.63) RV5 (Rotateq) associated with intussusception at first dose: 1–7 days, 4.65 (1.80–12.00); 8–21 days, 4.65 (1.80–12.00) RV5 (Rotateq) associated with intussusception at second dose: 1–7 days, 2.53 (0.89–7.20), 8-21 days, 1.38 (0.53–3.62) RV5 (Rotateq) associated with intussusception at third dose: 1–7 days, 1.06 (0.23–4.84), 8-21 days, 0.80 (0.18–3.64) Risk factors: NR
Contopoulos-Ioannidis, 2015[83] Article Pre-post N=13849663 Not industry funded USA	Age: N/A % female: 37 Ethnicity: 34% White, 7% Black, 50% Hispanic, 5% Asian, 4% Other Live born infants in California hospitals from 1985-2010 (cases were infants < 1 year of age hospitalized with intussusception) Out of scope: Unclear	RV Rotarix,RotaTeq Route NR adjuvant NR preservative NR Co-intervention Routine vaccines Base treatment 2000-2005 cohort (routine vaccines during period with no recommendation for any live enteric virus vaccine) Other Prespecified AE Power unclear Followup: 11 months	Intussusception	NA	Upward trend in yearly incidence rates of intussusception hospitalizations was documented during 2006-2010, after introduction of RotaTeq and Rotarix in the US (+2 excess cases per 100,000 births/year; P = 0.023). Primary cohort (hospitalized infants with discharge diagnosis code for intussusception): excess of 3.2 excess cases/100,000 births/year (0.0 to +6.5, P = 0.052) from 2006-2010 compared to 2000-2005. Restricted cohort (hospitalized infants with discharge diagnosis code for intussusception and intussusception related surgical repair and/or radiologic reduction procedure codes): excess of 3.2 cases/100,000 births/ per year (−1.5 to +7.9, P = 0.178) from 2006-2010 compared to 2000-2005. IR in 2006–2010 was 10% higher than in 2000–2005 (IRR: 1.10; 95% CI: 1.01–1.19). The IRR in 2006–2010 vs 2000–2005 for the 6–14 weeks age subgroup was 1.90 (95% CI: 1.33–2.74). Risk factors: In the age subgroup analysis, a statistically significant difference between period 3 and period 2 was seen for the 6–14 weeks age subgroup, with mean IR in period 3 almost 2-fold higher compared with the IR in period 2 [IRR:

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					1.90; 95% confidence intervals (CIs): 1.33–2.74; P < 0.00]. A statistically significant difference between the last 2 periods was also detected for the 33–52 weeks age subgroup; however, when the narrower 33–40 weeks age subgroup was considered, no difference was seen.
Dhingra, 2014[92] Clinical Trials Registry-India, July 31, 2013[245] CTRI/2012/07/002820 Article RCT N=100 Industry funded India	Age: Intervention: 45.7 days (2.9), Control 46.7 days (4.5) % female: Intervention: 55%, Control 65% Ethnicity: Ethnicity NR Healthy infants Out of scope: None	RV RotaTeq 6.0 mL in three doses of 2.0 mL each at day 0, day 28, day 56 Oral adjuvant NR preservative NR Co-intervention Routine vaccines ((combined Diphtheria, Tetanus, Whole-cell Bordetella pertussis, Hepatitis B and Haemophilus influenzae type b [DTPwHB- Hib] pentavalent vaccine (Pentavac SD) and Trivalent Oral Polio Vaccine) Placebo,Base treatment Placebo 6.0 mL in three doses of 2.0 mL each at day 0, day 28, day 56 as well as routine	Diarrhoea Irritability Lethargy Crying Fever Loss of appetite Vomiting Bronchiolitis Rickets Candidiasis Cough Nasopharyngitis Nasal congestion Acute gastroenteritis Dehydration Megaloblastic anaemia Injection site reactions (redness, swelling, tenderness)	NA	Grade 3 diarrhea: Intervention 0/20, Control 1/20 Serious AEs: Intervention 0/20, Control 1/20 (4 month-old female developed acute gastroenteritis, dehydration, and megaloblastic anemia 20 days after 3rd placebo dose) Risk factors: NR

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		vaccines (combined Diphtheria, Tetanus, Whole-cell Bordetella pertussis, Hepatitis B and Haemophilus influenzae type b [DTPwHB- Hib] pentavalent vaccine (Pentavac SD) 2.0 mL in 1 dose for Cohort 1, 6.0 mL in 3 doses for Cohort 2 Counts No prespecified AE Power NR Followup: 1 months			
Escolano, 2015[102] Article Other design N=502 Not industry funded Worldwide	Age: Median age at intussucpetion in weeks (range): 17 (4-78) % female: 44% Ethnicity: Ethnicity NR Self-reporting patients Out of scope: None	RV RotaTeq 3 doses Route NR adjuvant NR preservative NR Co-intervention Presumably routine vaccines) Base treatment Control is the comparison period (15-30 days post-vaccine), presumably may receive routine vaccines Analytic study Prespecified AE Power NR Followup: 1 months	Intussusception (prespecified)	NA	Relative incidence (RI, 95% CI) of intussusception in risk windows following RV compared to observation window (15-30 days): Dose 1, 0-2 days: 1.02 (0.44–2.38) Dose 1, 3-7 days: 3.45 (1.84–6.55) Dose 1, 8-14 days: 0.91 (0.51–1.62) Dose 2, 0-2 days: 1.47 (0.68–3.21) Dose 2, 3-7 days: 1.63 (0.86–3.13) Dose 2, 8-14 days: 1.07 (0.63–1.80) Dose 3, 0-2 days: 1.68 (0.73–3.88) Dose 3, 3-7 days: 1.73 (0.86–3.51) Dose 3, 8-14 days: 1.14 (0.62–2.08) Risk factors: NR

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
Fernandes, 2016[106] Article Pre-post N=331 Not industry funded Brazil	Age: Cases: Median age 26 weeks % female: Cases: 40% Ethnicity: Ethnicity NR Cases of infant intussusception, 2001 to 2008 Out of scope: None	RV Rotarix Route NR adjuvant NR preservative NR Co-intervention Presumably routine vaccines Base treatment Controls are from pre-RV1 introduction (and presumably received routine vaccines) Other No prespecified AE Power NR Followup: 12 months	Intussusception (prespecified) Vomiting Bloody stool Abdominal distention Hematochezia Blood detected on rectal exam Pallor Fever Abdominal mass Lethargy Rectal mass	NA	Number of intussusception events post-RV1 introduction (2007 n = 26 and 2008 n = 19) was somewhat lower than the average annual number of intussusception cases (n = 32 cases per year, range 24---42 cases per year) during 2001---2005 pre-RV1 introduction Risk factors: NR
Fotso Kamdem, 2019[108] Article Case-Control N=572 Industry funded France	Age: N/A % female: Cases 42% Ethnicity: Ethnicity NR Children under 1 year admitted to the hospital and diagnosed with intussusception (cases) and controls not admitted to the hospital not diagnosed with intussusception matched on sex, age (±1 week), admission period (one month before or after the admission of the case)	RV Rotarix,RotaTeq 2-3 doses depending on vaccine Oral adjuvant NR preservative NR No co-intervention No intervention Controls are those without intussusception (comparison of interest is no rotavirus vaccine) Analytic study Prespecified AE Insufficient power Followup: 10 months	Intussusception (prespecified)	NA	Risk factors for intussusception in infants: Exposure to first dose of rotavirus vaccine 7 days prior: OR not calculated, p=0.99 Exposure to one dose of rotavirus vaccine 14 days prior: 1.33 (0.14–12.82), p=0.80 Risk factors: NR

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
	Out of scope: None				
Glanz, 2020[115] Article Cohort study N=386937 Not industry funded USA	Age: N/A % female: 49% Ethnicity: 17% Asian, 6% Black, 27% Hispanic, 42% Non-Hispanic White, 2% Other, 6% Unknown Children born between January 1, 2006, and December 31, 2014 with continuous health plan enrollment from 6 weeks to 2 years in 7 integrated health care organizations that participate in the Vaccine Safety Datalink (VSD) Out of scope: None	RV Rotarix,RotaTeq Route NR adjuvant NR preservative NR Co-intervention Routine vaccines Base treatment Routine vaccines Counts Prespecified AE Power calculation Followup: 65 months	Diabetes (prespecified)	Diabetes: 14.X In fully exposed cohort and partially exposed cohorts together I: 402/320881, 14.X In unexposed cohort C: 16/8843	Diabetes in fully exposed vs unexposed, adjusted hazard ratio (HR) and (95% CI) Primary complete case-analysis: 372/307851 vs 16/8843, aHR 1.03 (0.62-1.72) Rotateq only: 279/176078 vs 16/8843, aHR 0.98 (0.59-1.64) Rotarix only: 90/127515 vs 16/8843, aHR 2.03 (0.66-6.28) 8 mos to 4 yrs age only: 204/307851 vs 9/8843, aHR 0.84 (0.42-1.67) 5-10 yrs of age only: 166/307647 vs 7/8834, aHR 1.27 (0.59-2.74) Expanded cohort across range of vaccine exposures: 416/339340 vs 40/22301, aHR 0.94 (0.67-1.30) Diabetes in partially exposed vs unexposed, adjusted hazard ratio (HR) and (95% CI) Primary complete case-analysis: 30/13030 vs 16/8843, aHR 1.50 (0.81-2.77) Rotateq only: 29/12054 vs 16/8843, aHR 1.48 (0.79-2.74) Rotarix only: 1/976 vs 16/8843, aHR 2.81 (0.30-26.75) 8 mos to 4 yrs age only: 14/13030 vs 9/8843, aHR 1.19 (0.51-2.79) 5-10 yrs of age only: 16/13016 vs 7/8834, aHR 1.92 (0.78-4.72)

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
					Expanded cohort across range of vaccine exposures: 62/28413 vs 40/22301, aHR 1.92 (0.78-4.72) Risk factors: Yes, by age and vaccine type. None statistically significant.
Groome, 2019[122] Article Other design N=346 Not industry funded South Africa	Age: Cases median age 26 weeks (range 20-30) % female: 48% Ethnicity: 82% Black South African children under age 3 years hospitalized with intussuception Out of scope: None	RV Rotarix 2 doses Route NR adjuvant NR preservative NR Co-intervention Presumably routine vaccines Base treatment Control is unexposed period (28-275 post-vaccine), and presumably routine vaccines Analytic study Prespecified AE Power NR Followup: 10 months	Intussusception	NA	Self-controlled case series, risk incidence (RI, 95% CI) of intussusception in risk period following RV1 (1-21 days) vs unexposed per (28-275 days) Dose 1, 1–7 days: RI 0 Dose 1, 8-21 days: RI 4.01 (0.87–10.56) Dose 1, 2-21 days: RI 3.14 (0.66–8.49) Dose 2, 1–7 days: RI 1.71 (0.83–3.01) Dose 2, 8-21 days: RI 0.96 (0.52-1.60) Dose 2, 2-21 days: RI 1.19 (.74–1.85) Case-control analysis of odds (OR, 95% CI) of intussusception following RV1 Dose 1, 1–7 days: OR 0 Dose 1, 8-21 days: OR 2.00 (.18–22.06) Dose 1, 2-21 days: OR 2.00 (.18–22.06) Dose 2, 1–7 days: OR 2.22 (.50–9.78 Dose 2, 8-21 days: OR 1.51 (0.40-5.63) Dose 2, 2-21 days: OR 1.92 (.68–5.40) Risk factors: NR

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
Hattori, 2018[130] Article Pre-post N= Not industry funded Japan	Age: N/A % female: N/A Ethnicity: Ethnicity NR Patients care for in hospitals in Aichi Prefecture Out of scope: None	RV Rotarix,RotaTeq Route NR adjuvant NR preservative NR No co-intervention No intervention Counts No prespecified AE Power NR Followup: 12 months	Encephalitis/encephalopathy Sudden death Urinary tract stone GI bleeding	NA	Before introduction of RV vaccine 2008/09: Encephalitis/encephalopathy 2, Sudden death 1, Urinary stone 0, GI bleeding 0 Vaccine coverage N/A Before introduction of RV vaccine 2009/10: Encephalitis/encephalopathy 4, Sudden death 1, Urinary stone 0, GI bleeding 0, Vaccine coverage N/A Before introduction of RV vaccine 2010/11: Encephalitis/encephalopathy 7, Sudden death 2, Urinary stone 0, GI bleeding 0, Vaccine coverage N/A RV vaccine transition period 2011/12: Encephalitis/encephalopathy 7, Sudden death 1, Urinary stone 1, GI bleeding 1, Vaccine coverage 34.9% RV vaccine transition period 2012/13: Encephalitis/encephalopathy 4, Sudden death 3, Urinary stone 2, GI bleeding 2, Vaccine coverage 60.4% After introduction of RV vaccine 2013/14: Encephalitis/encephalopathy 2, Sudden death 0, Urinary stone 0, GI bleeding 0, Vaccine coverage 67.2 % After introduction of RV vaccine 2014/15: Encephalitis/encephalopathy 3, Sudden death 0, Urinary stone 0, GI bleeding 0, Vaccine coverage 75.4% Risk factors: NR
Hawken, 2017[131] Article Pre-post N=100000 Not industry funded Canada	Age: N/A % female: N/A Ethnicity: Ethnicity NR All infants admitted to a Canadian hospital between 2002 and 2013, with cases being defined as those with a diagnosis of intussusception Out of scope: None	RV Rotarix Route NR adjuvant NR preservative NR Co-intervention Routine vaccines Base treatment Routine vaccines Counts Prespecified AE Power calculation Followup: 12 months	Intussusception	NA	Found no evidence of an increase incidence of intussusception following implementation of universal rotavirus immunization programs in Canada. Intussusception rates were 23.4 per 100,000 infants (95% CI 21.5-25.4) before program introduction and 22.4 per 100,000 infants (95% CI 18.3-27.4) after program introduction for a relative incidence of intussusception after vs. before program introduction of 0.96 (95% CI 0.78, 1.18, p 0.69). Risk factors: Sensitivity analyses limiting the age of intussusception incidence to infants 2 to 8 months, and then further limiting it to infants 2 to 6 months and 2 to 4 months did not change the conclusions

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					of the comparisons by year or comparing pre- and post- program introduction. 2-8 months: Before 35.1 (32.0,38.7); After 31.9 (24.8, 41.0), p 0.47 2-6 months: Before 34.3 (30.5, 38.7); After 31.6 (23.1, 43.1), p 0.61 2-4 months: Before 31.5 (26.4, 37.5); After 27.6 (17.1, 44.5), p 0.60
Hoffman, 2018[133] Article Other design N=390659 Industry funded USA	Age: 2 months % female: 48 Ethnicity: Ethnicity NR Infants receiving at least one dose of RV1 as part of routine health care within the Optum Research Database (ORD) and HealthCore Integrated Research Databased (HIRD) from August 2008 to June 2013 along with concurrent IPV versus IPV alone. Out of scope: None	RV Rotarix At least 1 dose Route NR adjuvant NR preservative NR Co-intervention IPV Base treatment Self-controlled time series Counts Prespecified AE Power calculation Followup: 4 months	Intussusception Hospitalization due to acute lower respiratory tract infection Kawasaki disease Convulsion All-cause mortality	NA	No significant temporal clusters of acute LRTI cases were observed among RV1 recipients. Risk factors: Convulsions: Any dose: IRR 2.67 (95% CI 0.93-7.69) 1 dose: IRR 2.40 (95% CI 0.73-7.86) 2 doses: IRR 4.00 (95% CI 0.36-44.12)

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
Huang, 2020[135] Article Other design N=4143 Not industry funded Taiwan	Age: 6-34 weeks % female: NR Ethnicity: NR Infants less than 365 days of age who were enrolled in the National Health Insurance (NHI) data-bases from 1 January 2007 through 31 December 2014. Out of scope: None	RV Rotarix,RotaTeq NR Route NR adjuvant NR preservative NR Co-intervention Routine vaccines, including PCV13 for some infants No intervention Control window (outside of -14 to +21 days for intususscception, and outside of +28 days for Kawasaki Disease) Analytic study Prespecified AE Power NR Followup: 10 months	Intussusception Kawasaki disease	NA	Intussusception (N=2046 cases) (IRR for 1-21 days versus control outside of -14 to +21 days) Dose 1, RV5: IRR 1.06 (9 cases; 95% confidence interval [CI] 0.41–2.74) Dose 1, RV1: IRR 4.58 (53 cases; 95% CI 3.08–6.80) Secondary analysis: Dose 1, RV1 at 1-7 days: IRR 12.59 (38 cases; 95% CI 8.07–19.66) Dose 1, RV1 at 8–21 days IRR 1.78 (15 cases; 95% CI 1.00–3.16) Kawasaki Disease (N=2079 cases) (IRR for 1-28 days versus control after 28 days) Dose 1, RV5: IRR 0.54 (18 cases; 95% CI 0.30–0.99). Results of other primary analyses were null. Secondary analysis: RV5, dose 2, at 15–21 days: IRR 2.33 (16 cases; 95% CI 1.35–4.00) RV1, dose 1, at 22–28 days: IRR 1.98 (19 cases; 95% CI 1.16–3.40) Risk factors: No
Iwata, 2013[139] Merck Sharp, 2008[313] NCT00718237 Article RCT N=762 Industry funded Japan, USA	Age: Intervention (RV5) 7.6 (1.7); Control 7.5 (1.6) % female: Intervention 54%; Control 52% Ethnicity: Ethnicity NR Healthy Japanese infants 6 to 12 weeks of age at enrollment Out of scope: None	RV RotaTeq 6 mL in 3 doses at 28 to 70 day intervals Oral adjuvant NR preservative NR Co-intervention Concomitant routine vaccines Placebo,Base treatment Placebo (same buffered solution) and concomitant routine vaccines Counts No prespecified AE Power NR Followup: 2 months	Lymphadenitis Congenital absence of bile ducts Pyrexia Bronchitis Bronchitis viral Gastroenteritis Influenza Meningitis coxsackie viral Pneumonia Respiratory syncytial virus bronchiolitis Urinary tract infection Infantile spasms Psychomotor retardation Asphyxia Upper respiratory tract inflammation Dermatitis atopic Conjunctivitis Constipation Diarrhoea Infantile spitting up	Death: NA Occurred 36 days after dose 2 due to RSV bronchiolitis (not thought to be vaccine-related) I: 1/380, NA NA C: 0/381 Intussusception: 7.X NA I: 0/380, 7.X NA C: 0/381 Meningitis: 11.X Meningitis coxsackie viral I: 1/380, 11.X NA C: 0/381	Serious AEs (from clinicaltrials.gov): Intervention (RotaTeq) vs Control (Placebo) Affected / at Risk (%)Affected / at Risk (%) Total 7/380 (1.84%) 9/381 (2.36%) Lymphadenitis 0/380 (0.00%) 1/381 (0.26%) Congenital absence of bile ducts0/380 (0.00%) 1/381 (0.26%) Pyrexia 1/380 (0.26%) 1/381 (0.26%) Bronchitis 1/380 (0.26%) 0/381 (0.00%) Bronchitis viral 1/380 (0.26%) 0/381 (0.00%) Gastroenteritis 0/380 (0.00%) 1/381 (0.26%) Influenza 0/380 (0.00%) 1/381 (0.26%) Meningitis coxsackie viral (in AE table) Pneumonia 1/380 (0.26%) 0/381 (0.00%) Respiratory syncytial virus bronchiolitis 2/380 (0.53%) 0/381 (0.00%) Urinary tract infection 0/380 (0.00%) 1/381 (0.26%)

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			Vomiting (prespecified) Pyrexia Bronchitis Gastroenteritis Nasopharyngitis Respiratory syncytial virus infection Rhinitis Upper respiratory tract infection Asthma Cough Rhinorrhoea Upper respiratory tract inflammation Dermatitis diaper Eczema Eczema infantile Rash Irritability (prespecified) Fever (prespecified)		Infantile spasms 0/380 (0.00%) 1/381 (0.26%) Psychomotor retardation 0/380 (0.00%) 1/381 (0.26%) Respiratory, thoracic and mediastinal disorders Asphyxia 1/380 (0.26%) 0/381 (0.00%) Upper respiratory tract inflammation 0/380 (0.00%) 1/381 (0.26%) Dermatitis atopic 0/380 (0.00%) 1/381 (0.26%) Risk factors: Yes, premature infants had comparable incidence of clinical AEs (no data provided)
Layton, 2018[155] Article Cohort study N=1031431 Not industry funded USA	Age: 11.2 weeks (5.0) % female: 48% Ethnicity: Ethnicity NR Infants born to mothers with commercial insurance Out of scope: None	RV Rotarix,RotaTeq 2 or 3 doses depending on brand Route NR adjuvant NR preservative NR Co-intervention DTaP and other routine vaccines (varied) Base treatment DTaP and other routine vaccines (varied) route NR adjuvant NRpreservative NR Analytic study Prespecified AE Power NR Followup: 1 months	Intussusception Kawasaki Disease Seizure Meningitis Encephalitis Diarrhea Blood in Stool Appendicitis Febrile Convulsions Thrombocytopenia Otitis Media All-cause ED visit All-cause hospitalization	NA	RV + DTaP vs DtaP alone Format - AE: Adjusted Hazard ratio and 95% CI for 1st dose; Adjusted Hazard ratio and CI for 2nd dose; Adjusted Hazard ratio and CI for 3rd dose; Adjusted Hazard ratio Pooled Intussusception: 0.84 (0.35, 2.03); 2.32 (0.90, 5.96); 0.83 0.36, 1.93(; 1.13 (0.68, 1.88) Kawasaki Disease: NA for dose 1; 0.54 (0.14, 2.07); 0.55 (0.12, 2.48); 0.54 (0.20, 1.48) Seizure: 0.83 (0.65, 1.07); 1.14 (0.84, 1.56); 0.68 (0.51, 0.90); 0.85 (0.72, 0.99) Meningitis: 1.26 (0.69, 2.33); 5.13 (1.13, 23.26); 1.35 (0.28, 6.53); 1.52 (0.89, 2.59) Encephalitis: 0.47 (0.19, 1.16); 0.63 (0.23, 1.72); 0.50 (0.12, 2.15); 0.52 (0.29, 0.97) Diarrhea: 0.94 (0.87, 1.00)l 0.96 (0.90, 1.03); 0.93 (0.87, 1.00); 0.94 (0921, 0.98) Blood in Stool : 1.07 (0.95, 1.20); NA for dose 2; 0.93 (0.79, 1.09); 1.00 (0.79, 1.25) Appendicitis: NA for dose 1; 0.40 (0.05, 3.01); NA for dose 3; NA for pooled

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					Febrile Convulsions: 1.22 (0.62, 2.38); 1.36 (0.75, 2.49); 0.67 (0.43, 1.02); 0.91 (0.67, 1.24) Thrombocytopenia: 0.66 (0.40, 1.10); 1.44 (0.66, 3.15); 0.97 (0.48, 1.96); 0.87 (0.60, 1.25) Otitis Media: 1.02 (0.99, 1.06); 1.11 (1.08, 1.15); 1.00 (0.98, 1.03); 1.04 (1.02, 1.06) All-cause ED visit: 0.90 (0.86, 0.93); 0.89 (0.86, 0.93); 0.92 (0.88, 0.95); 0.91 (0.89, 0.92) All-cause hospitalization: 0.79 (0.73, 0.85); 0.83 (0.75, 0.92); 0.91 (0.81, 1.02); 0.83 (0.78, 0.87) Sub-group analyses for otitis media Format - AE: Adjusted Hazard ratio and 95% CI for 1st dose; Adjusted Hazard ratio and CI for 2nd dose; Adjusted Hazard ratio and CI for 3rd dose Male: 0.99 (0.95, 1.04); 1.11 (1.07, 1.16); 1.01 (0.98, 1.04) Female: 1.07 (1.01, 1.13); 1.11 (1.06, 1.17); 1.00 (0.96, 1.03) Risk factors: In post hoc subgroup analyses, the observed otitis media association with RV dose 2, and specifically with RV1, was consistent across levels of sex, US region, and time period
Li, 2014[161] Li, 2013[300]; Li, 2016[299]; GlaxoSmithKline, 2010[265] NCT01171963 Article RCT N=3333 Industry funded China	Age: 9.6 (2.62) % female: 0 Ethnicity: 100% Asian Male infants Out of scope: None	RV Rotarix 2 doses Oral adjuvant NR preservative NR No co-intervention Placebo Same constituents and appearance as the active vaccine but without the vaccine viral strain Counts No prespecified AE Power other outcome	Deficiency anaemia Lymphadenitis Anaemia Myocarditis Enteritis Diarrhoea Gastrointestinal disorder Inguinal hernia, obstructive Intestinal obstruction Intussusception Dyspepsia Food poisoning Gastrooesophageal reflux disease Inguinal hernia Multi-organ failure Death Drowning	Asthma: 22.X NR I: 3/1666, 22.X NR C: 1/1667 Cardiovascular events: 2.X myocarditis I: 1/1666, 2.X NA C: 0/1667 Death: NA deemed unrelated to vaccination I: 6/1666, NA deemed unrelated to vaccination C: 7/1667 Febrile seizures: 17.2 NR I: 0/1666, 17.2 NR C: 2/1667 Intussusception: 7.X 142 d after 2nd dose I: 1/1666, 7.X 65 d after 2nd dose C: 1/1667 Meningitis: 11.X NR I: 1/1666, 11.X NR C: 0/1667 Stroke: 17.X Haemorrhage intracranial I: 1/1666, 17.X	Serious AEs (from clinicaltrials.gov): (all deemed unrelated to vaccine by authors, except for 1 diarrhea in placebo group) Rotarix Group vs Placebo Group Affected / at Risk (%)Affected / at Risk (%) Total sAEs 183/1666 (10.98%) 246/1667 (14.76%) Blood and lymphatic system disorders Deficiency anaemia 0/1666 (0.00%) 1/1667 (0.06%) Lymphadenitis 0/1666 (0.00%) 1/1667 (0.06%) Anaemia 2/1666 (0.12%) 3/1667 (0.18%) Cardiac disorders Myocarditis (in AE table) Congenital, familial and genetic disorders (removed)

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
		Followup: 24 months	Hernia Hepatic function abnormal Bronchitis Bronchopneumonia Pneumonia Pharyngitis Hand-foot-and-mouth disease Tracheitis Acute tonsillitis Candidiasis Gastroenteritis Laryngitis Diarrhoea infectious Cytomegalovirus infection Gastroenteritis bacterial Herpangina Pneumonia klebsiella Varicella Bacterial diarrhoea Central nervous system infection Infectious mononucleosis Lobar pneumonia Meningitis Otitis media Pneumonia staphylococcal Shigella infection Tracheobronchitis Upper respiratory tract infection Bronchiolitis Brain contusion Brain herniation Skull fracture Liver function test abnormal Hypokalaemia Acidosis Hyponatraemia Malnutrition Dehydration Acute lymphocytic leukaemia Histiocytosis haematophagic Convulsion	Subarachnoid haemorrhage C: 1/1667	Enteritis 44/1666 (2.64%) 73/1667 (4.38%) Diarrhoea 4/1666 (0.24%) 11/1667 (0.66%) Gastrointestinal disorder 1/1666 (0.06%) 3/1667 (0.18%) Inguinal hernia, obstructive 1/1666 (0.06%) 1/1667 (0.06%) Intestinal obstruction 0/1666 (0.00%) 2/1667 (0.12%) Intussusception (in AE table) Dyspepsia 0/1666 (0.00%) 1/1667 (0.06%) Food poisoning 0/1666 (0.00%) 1/1667 (0.06%) Gastrooesophageal reflux disease 0/1666 (0.00%) 1/1667 (0.06%) Inguinal hernia 0/1666 (0.00%) 1/1667 (0.06%) General disorders Multi-organ failure 1/1666 (0.06%) 2/1667 (0.12%) Death 0/1666 (0.00%) 1/1667 (0.06%) (note that deaths in AE table are from article and count multiple causes of death captured here as well) Drowning 1/1666 (0.06%) 0/1667 (0.00%) Hernia 0/1666 (0.00%) 1/1667 (0.06%) Hepatobiliary disorders Hepatic function abnormal *1/1666 (0.06%) 0/1667 (0.00%) Infections and infestations Bronchitis 74/1666 (4.44%) 98/1667 (5.88%) Bronchopneumonia 58/1666 (3.48%) 61/1667 (3.66%) Pneumonia 14/1666 (0.84%) 14/1667 (0.84%) Pharyngitis 2/1666 (0.12%) 8/1667 (0.48%) Hand-foot-and-mouth disease 5/1666 (0.30%) 4/1667 (0.24%) Tracheitis 4/1666 (0.24%) 4/1667 (0.24%) Acute tonsillitis 5/1666 (0.30%) 2/1667 (0.12%) Candidiasis 3/1666 (0.18%) 1/1667 (0.06%)

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
			Febrile convulsion Cerebral haematoma Epilepsy Extrapyramidal disorder Haemorrhage intracranial Hydrocephalus Subarachnoid haemorrhage Hydronephrosis Ureteric stenosis Asphyxia Respiratory failure Asthma Dermatitis diaper Urticaria Cough/runny nose Diarrhea Irritability/Fussiness Loss of appetite Fever Vomiting Drowsiness Gastrointestinal (nausea, vomiting, diarrhea and/or abdominal pain Pain Redness Swelling Drowsiness Upper respiratory tract infection Nasopharyngitis		Gastroenteritis 2/1666 (0.12%) 2/1667 (0.12%) Laryngitis 2/1666 (0.12%) 2/1667 (0.12%) Diarrhoea infectious 1/1666 (0.06%) 2/1667 (0.12%) Cytomegalovirus infection 2/1666 (0.12%) 0/1667 (0.00%) Gastroenteritis bacterial 0/1666 (0.00%) 2/1667 (0.12%) Herpangina 1/1666 (0.06%) 1/1667 (0.06%) Pneumonia klebsiella 2/1666 (0.12%) 0/1667 (0.00%) Varicella 2/1666 (0.12%) 0/1667 (0.00%) Bacterial diarrhoea 0/1666 (0.00%) 1/1667 (0.06%) Central nervous system infection 1/1666 (0.06%) 0/1667 (0.00%) Infectious mononucleosis 1/1666 (0.06%) 0/1667 (0.00%) Lobar pneumonia 0/1666 (0.00%) 1/1667 (0.06%) Meningitis (in AE table) Otitis media 1/1666 (0.06%) 0/1667 (0.00%) Pneumonia staphylococcal 1/1666 (0.06%) 0/1667 (0.00%) Shigella infection 0/1666 (0.00%) 1/1667 (0.06%) Tracheobronchitis 1/1666 (0.06%) 0/1667 (0.00%) Upper respiratory tract infection 16/1666 (0.96%) 26/1667 (1.56%) Bronchiolitis 1/1666 (0.06%) 1/1667 (0.06%) Injury, poisoning and procedural complications Brain contusion 0/1666 (0.00%) 1/1667 (0.06%) Brain herniation 0/1666 (0.00%) 1/1667 (0.06%) Skull fracture 0/1666 (0.00%) 1/1667 (0.06%) Investigations Liver function test abnormal 0/1666 (0.00%) 1/1667 (0.06%) Metabolism and nutrition disorders

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
					Hypokalaemia 1/1666 (0.06%) 3/1667 (0.18%) Acidosis 0/1666 (0.00%) 2/1667 (0.12%) Hyponatraemia 1/1666 (0.06%) 0/1667 (0.00%) Malnutrition 0/1666 (0.00%) 1/1667 (0.06%) Dehydration 1/1666 (0.06%) 3/1667 (0.18%) Neoplasms benign, malignant and unspecified (incl cysts and polyps) Acute lymphocytic leukaemia 0/1666 (0.00%) 1/1667 (0.06%) Histiocytosis haematophagic 0/1666 (0.00%) 1/1667 (0.06%) Nervous system disorders Convulsion 1/1666 (0.06%) 1/1667 (0.06%) Febrile convulsion (in AE table) Cerebral haematoma 0/1666 (0.00%) 1/1667 (0.06%) Epilepsy 1/1666 (0.06%) 0/1667 (0.00%) Extrapyramidal disorder 0/1666 (0.00%) 1/1667 (0.06%) Haemorrhage intracranial 1/1666 (0.06%) 0/1667 (0.00%) Hydrocephalus 0/1666 (0.00%) 1/1667 (0.06%) Subarachnoid haemorrhage 0/1666 (0.00%) 1/1667 (0.06%) Renal and urinary disorders Hydronephrosis 1/1666 (0.06%) 0/1667 (0.00%) Ureteric stenosis 1/1666 (0.06%) 0/1667 (0.00%) Respiratory, thoracic and mediastinal disorders Asphyxia 2/1666 (0.12%) 0/1667 (0.00%) Respiratory failure 0/1666 (0.00%) 1/1667 (0.06%) Asthma (in AE table) Skin and subcutaneous tissue disorders Dermatitis diaper 1/1666 (0.06%) 1/1667 (0.06%) Urticaria 1/1666 (0.06%) 0/1667 (0.00%)

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
					From related study (same trial) focusing on concomitant routine childhood vaccines: Severe AEs Grade 3 or higher: Format RIX4414 (N=1513) % (95% CI); Placebo (N=1514) % (95% CI) Total vaccinated cohort (excluding co-administered) (Intervention N=1513; Control N=1514) Any Grade 3: 11.2 (9.7; 12.9); 10.1 (8.6; 11.7) Cough/runny nose: 1.3 (0.8; 2.0); 0.5 (0.2; 1.0) Diarrhea: 3.6 (2.8; 4.7); 4.0 (3.0; 5.1) Irritability/Fussiness: 2.8 (2.1; 3.8); 2.6 (1.8; 3.5) Loss of appetite: 0.2 (0.0; 0.6); 0.5 (0.2; 1.0) Fever: 0.1 (0.0; 0.4); 0.1 (0.0; 0.5) Vomiting: 5.3 (4.2; 6.5); 5.0 (3.9; 6.2) Drowsiness: NR Gastrointestinal (nausea, vomiting, diarrhea and/or abdominal pain): NR Co-administered cohort (Intervention N=153; Control N=153) Any Grade 3: 5.2 (2.3; 10.0); 4.6 (1.9; 9.2) Cough/runny nose: NR Diarrhea: NR Irritability/Fussiness: 3.3 (1.1; 7.5); 2.6 (0.7; 6.6) Loss of appetite: 0.7 (0.0; 3.6); 1.3 (0.2; 4.6) Fever: 0.0 (0.0; 2.4); 0.7 (0.0; 3.6) Vomiting: NR Drowsiness: 2.0 (0.4; 5.6); 0.7 (0.0; 3.6) Gastrointestinal (nausea, vomiting, diarrhea and/or abdominal pain): 1.3 (0.2; 4.6); 1.3 (0.2; 4.6) Risk factors: NR

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
McGeoch, 2020[168] Article Pre-post N=3026 Not industry funded England	Age: Median age 37 weeks (25–59) % female: 36% Ethnicity: NR All children aged 0–36 months admitted to hospitals in England with intussusception using the Hospital Episode Statistics dataset Out of scope: None	RV Rotarix Two doses Route NR adjuvant NR Co-intervention Routine vaccines Base treatment : Routine vaccines Routine vaccines alone Analytic study Prespecified AE Power NR Followup: 34 months	Intussusception	NA	Post-vaccine versus pre-vaccine period (RR, 95% CI): For the 0–12 months age group: RR 0.86, 0.78–0.94; when accounting for the pre-existing baseline trend in sensitivity analysis RR 0.80, 0.67–0.96 For 8-16 weeks: RR 1.46, 1.12–1.91 For 8–12 weeks: RR 1.83, 1.17–2.88 , corresponding to individuals receiving the first vaccine dose, For 13–16 weeks: RR 1.29, 0.93–1.80, corresponding to those receiving the second dose. For 17–24 weeks: RR 0.77, 0.63–0.94 For 25–32 weeks: RR 0.71, 0.59–0.86 For 41–52 weeks: RR 0.80, 0.66–0.98 For 33–40 weeks: RR 0.94, 0.76–1.15 For 13–24 months: RR 0.96, 0.81–1.13 For 25–36 months: RR 0.96, 0.75–1.23 For 0-36 months: RR 0.86, 0.80–0.93; when accounting for the pre-existing baseline trend in sensitivity analysis RR 1.09, 0.98–1.20 % children with intussusception in the 41–52 weeks age group who had a recorded OPCS 4.7 procedure code for a surgical intervention to address intussusception was lower in the post-vaccine period (17.5%) than in the pre-vaccine period (26.8%). No other differences between the two time periods in the percentage of intussusception cases with a recorded surgical intervention, either among the 0–36 months age group as a whole or among other age subgroups. No identifiable differences in the proportion of children developing any of several important complications of intussusception between the two time periods. Risk factors: Yes analysis stratified by age

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
Mo, 2017[169] Merck Sharp, 2015[309] NCT02062385 Article RCT N=4040 Industry funded China	Age: Intervention: 60 days (10), Control: 59 days (10) % female: Intervention: 49%, Control: 47% Ethnicity: Ethnicity Nr Healthy infants aged 6–12 weeks at the time of the first dose were eligible to be enrolled. Out of scope: None	RV RotaTeq 3 doses four weeks apart Oral adjuvant free preservative free Co-intervention Most infants were on staggered (but some concomitant) routine vaccines per Chinese schedule: OPV at age ~2.5, 3.5, and 4.5 months, and DTaP at age ~3.5, 4.5, and 5.5 months Placebo,Base treatment Saline placebo plus routine vaccines (OPV at age ~2.5, 3.5, and 4.5 months, and DTaP at age ~3.5, 4.5, and 5.5 months) OPV at age ~2.5, 3.5, and 4.5 months, and DTaP at age ~3.5, 4.5, and 5.5 months) Intramuscular,Oral adjuvant NRpreservative NR Counts No prespecified AE Power other outcome Followup: 1 months	Agranulocytosis Anaemia Granulocytopenia Cardiomyopathy Eye disorders Cataract Diarrhoea Dyspepsia Enteritis Functional gastrointestinal disorder Gastrointestinal disorder Incarcerated inguinal hernia Intestinal obstruction Intussusception Developmental delay Hepatic function abnormal Transient hypogammaglobulinaemia of infancy Acute tonsillitis Bronchiolitis Bronchitis Bronchopneumonia Candida infection Conjunctivitis Cytomegalovirus infection Diarrhoea infectious Exanthema subitum Gastroenteritis Gastroenteritis adenovirus Gastroenteritis bacterial Gastroenteritis rotavirus Gastroenteritis shigella Gingivitis Hand-foot-and-mouth disease Herpangina Herpes virus infection Infection Omphalitis Oral candidiasis Oral herpes Oral infection Otitis media Pharyngitis	Asthma: 22.X NR I: 17/2015, 22.X NR C: 9/2019 Cardiovascular events: 2.X Cardiomyopathy I: 1/2015, 2.X Cardiomyopathy C: 1/2019 Death: NA NA I: 0/2015, NA NA C: 0/2019 Febrile seizures: 17.X NR I: 0/2015, 17.X NR C: 3/2019 Intussusception: 7.3 day 32 postdate 1; day 53 postdate 3; not considered related to vaccine I: 2/2015, 7.X NA C: 0/2019 Seizure: 17.X Epilepsy I: 1/2015, 17.X C: 0/2019	Serious AEs (from clinicaltrials.gov): Intervention vsPlacebo Affected / at Risk (%)# EventsAffected / at Risk (%)# Events Total serious AEs 339/2015 (16.82%) 338/2019 (16.74%) Blood and lymphatic system disorders Agranulocytosis 1/2015 (0.05%) 10/2019 (0.00%) 0 Anaemia 1/2015 (0.05%) 11/2019 (0.05%) 1 Granulocytopenia 1/2015 (0.05%) 10/2019 (0.00%) 0 Cardiac disorders Cardiomyopathy (in AE table) Congenital, familial and genetic disorders (excluded as all birth defects/congenital issues) Eye disorders Cataract 1/2015 (0.05%) 10/2019 (0.00%) 0 Gastrointestinal disorders Diarrhoea 1/2015 (0.05%) 19/2019 (0.45%) 9 Dyspepsia 0/2015 (0.00%) 01/2019 (0.05%) 1 Enteritis 47/2015 (2.33%) 5241/2019 (2.03%) 42 Functional gastrointestinal disorder 2/2015 (0.10%) 22/2019 (0.10%) 2 Gastrointestinal disorder 0/2015 (0.00%) 01/2019 (0.05%) 1 Incarcerated inguinal hernia 0/2015 (0.00%) 01/2019 (0.05%) 1 Intestinal obstruction 1/2015 (0.05%) 16/2019 (0.30%) 6 Intussusception (in AE table) General disorders Developmental delay 1/2015 (0.05%) 10/2019 (0.00%) 0 Hepatobiliary disorders Hepatic function abnormal 0/2015 (0.00%) 01/2019 (0.05%) 1 Immune system disorders Transient hypogammaglobulinaemia of infancy 2/2015 (0.10%) 21/2019 (0.05%) 1

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
			Pharyngitis bacterial Pneumonia Sepsis Sinusitis Tonsillitis Tonsillitis bacterial Toxoplasmosis Upper respiratory tract infection Burns second degree Eye contusion Hypomagnesaemia Malnutrition Rickets Central nervous system lesion Epilepsy Febrile convulsion Asthma Dermatitis allergic Dermatitis diaper Urticaria Diarrhoea (prespecified) Pyrexia Nasopharyngitis Upper respiratory tract infection Cough Fever Vomiting (prespecified) Intussusception		Infections and infestations Acute tonsillitis 9/2015 (0.45%) 95/2019 (0.25%) 5 Bronchiolitis 2/2015 (0.10%) 21/2019 (0.05%) 1 Bronchitis 84/2015 (4.17%) 89101/2019 (5.00%) 108 Bronchopneumonia † 129/2015 (6.40%) 144141/2019 (6.98%) 158 Candida infection 0/2015 (0.00%) 03/2019 (0.15%) 3 Conjunctivitis 1/2015 (0.05%) 10/2019 (0.00%) 0 Cytomegalovirus infection 1/2015 (0.05%) 10/2019 (0.00%) 0 Diarrhoea infectious 20/2015 (0.99%) 2021/2019 (1.04%) 22 Exanthema subitum 1/2015 (0.05%) 11/2019 (0.05%) 1 Gastroenteritis 3/2015 (0.15%) 33/2019 (0.15%) 3 Gastroenteritis adenovirus 0/2015 (0.00%) 01/2019 (0.05%) 1 Gastroenteritis bacterial 1/2015 (0.05%) 11/2019 (0.05%) 1 Gastroenteritis rotavirus 7/2015 (0.35%) 724/2019 (1.19%) 24 Gastroenteritis shigella 0/2015 (0.00%) 01/2019 (0.05%) 1 Gingivitis 0/2015 (0.00%) 01/2019 (0.05%) 1 Hand-foot-and-mouth disease 19/2015 (0.94%) 1910/2019 (0.50%) 10 Herpangina 13/2015 (0.65%) 132/2019 (0.10%) 2 Herpes virus infection 0/2015 (0.00%) 01/2019 (0.05%) 1 Infection 1/2015 (0.05%) 10/2019 (0.00%) 0 Omphalitis 1/2015 (0.05%) 10/2019 (0.00%) 0 Oral candidiasis 0/2015 (0.00%) 01/2019 (0.05%) 1 Oral herpes 2/2015 (0.10%) 23/2019 (0.15%) 3 Oral infection 0/2015 (0.00%) 01/2019 (0.05%) 1

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
					Otitis media0/2015 (0.00%) 01/2019 (0.05%) 1 Pharyngitis 21/2015 (1.04%) 2123/2019 (1.14%) 23 Pharyngitis bacterial 2/2015 (0.10%) 25/2019 (0.25%) 5 Pneumonia 30/2015 (1.49%) 3414/2019 (0.69%) 14 Sepsis 1/2015 (0.05%) 11/2019 (0.05%) 1 Sinusitis 0/2015 (0.00%) 01/2019 (0.05%) 1 Tonsillitis 1/2015 (0.05%) 10/2019 (0.00%) 0 Tonsillitis bacterial 3/2015 (0.15%) 33/2019 (0.15%) 3 Toxoplasmosis 0/2015 (0.00%) 01/2019 (0.05%) 1 Upper respiratory tract infection 16/2015 (0.79%) 1618/2019 (0.89%) 19 Injury, poisoning and procedural complications Burns second degree 0/2015 (0.00%) 01/2019 (0.05%) 1 Eye contusion 0/2015 (0.00%) 01/2019 (0.05%) 1 Metabolism and nutrition disorders Hypomagnesaemia 1/2015 (0.05%) 10/2019 (0.00%) 0 Malnutrition 0/2015 (0.00%) 01/2019 (0.05%) 1 Musculoskeletal and connective tissue disorders Rickets 1/2015 (0.05%) 10/2019 (0.00%) 0 Nervous system disorders Central nervous system lesion 1/2015 (0.05%) 10/2019 (0.00%) 0 Epilepsy 1/2015 (0.05%) 10/2019 (0.00%) 0 (in AE table) Febrile convulsion (in AE table) Respiratory, thoracic and mediastinal disorders Asthma (in AE table) Skin and subcutaneous tissue disorders Dermatitis allergic 0/2015 (0.00%) 01/2019 (0.05%) 1

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
					Dermatitis diaper 0/2015 (0.00%) 01/2019 (0.05%) 1 Urticaria 2/2015 (0.10%) 20/2019 (0.00%) 0 Risk factors: NR
Oberle, 2020[175] Article Case-Control N=388 Not industry funded Germany	Age: Cases: 218 days (44-363) among intervention group, Controls: 219 days (44-363) % female: Cases: 29%, Controls: 32% Ethnicity: Cases: 91% Caucasian, Controls: 93% Caucasian Children with place of birth and residence in Germany who had been treated for intussusception from 2010 to 2014 and who had been less than 1 year old at the time of intussusception were recruited and matched to controls from the	RV Rotarix,RotaTeq 2 or 3 doses depending on vaccine Oral adjuvant NR preservative NR Co-intervention routine vaccines, not necessarily at same time Base treatment Controls were matched based on date of birth +/- 30 days, gender, federal state, and place of residence; they may or may not have received rotavirus vaccine and presumably received routine vaccines Analytic study Prespecified AE Power NR Followup: 10 months	Intussusception (prespecified)	NA	N 116 cases, 292 matched controls Rotavirus vaccines did not affect overall risk for intussusception in the first year of life (48.3% and 43.8%; OR 1.09, 95% CI 0.66-1.81). Significantly increased adjusted OR for intussusception (5.74, 95%, CI 1.51-21.79) in individuals immunized with rotavirus vaccine dose 1 prior to symptom onset compared to non-exposed individuals. Age at the start of rotavirus immunization series did not modify the risk of intussusception. Odds were not increased postdose 2 or 3. Risk factors: Age at the start of rotavirus immunization series did not modify the risk of intussusception.

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
	general German pediatric population Out of scope: None				
Rogers, 2019[189] Article Cohort study N=1474535 Not industry funded USA	Age: Vaccinated: 3.5 years at diagnosis; Partially vaccinated: 3.0 years at diagnosis; Unvaccinated: 3.8 years at diagnosis % female: 49% Ethnicity: Ethnicity NR Infants < 1 year of age at start of insurance coverage and with continuous health insurance coverage for a minimum of 365 days. Out of scope: None	RV Rotarix,RotaTeq 3 doses of RotaTeq or 2 doses of Rotarix for complete series Route NR adjuvant NR preservative NR No co-intervention No intervention Analytic study Prespecified AE Power NR Followup: 36 months	Type 1 diabetes mellitus (prespecified)	NA	Risk of diabetes by completely vaccinated versus unvaccinated, Incidence Rate Ratio (95% CI), Incidence Rate Difference (95% CI) All: 0.59 (0.48, 0.73), −8 (−12, −5) Girls: 0.59 (0.43, 0.80), −9 (−14, −4) Boys: 0.60 (0.44, 0.81), −8 (−13, −3) Year of birth 2006–2011: 0.67 (0.53, 0.84), −7 (−11, −3) Year of birth 2012–2016: 0.46 (0.26, 0.86), −10 (−18, −1) Risk of diabetes by partially vaccinated versus unvaccinated, Incidence Rate Ratio (95% CI), Incidence Rate Difference (95% CI) All: 0.99 (0.75, 1.30), 0 (−6, 5) Girls: 0.81 (0.52, 1.23), −4 (−1, 3) Boys: 1.17 (0.81, 1.70), 4 (−4, 11) Year of birth 2006–2011: 1.04 (0.76, 1.41), 0 (−5, 7) Year of birth 2012–2016: 0.80 (0.38, 1.69), −3 (−14, 7) 3.4% decrease in the rates of diabetes (95% CI: 1.6%, 5.1%; p < 0.001) annually in children ages 0–4 from 2006-2017. Using all children combined, there was a 7.2% annual increase in the incidence prior to 2006 (95% CI: 3.4%, 11.2%) and a 6.9% decrease afterward (95% CI: 2.8%, 19.9%). The pre-to-post change in slope was significant (p = 0.007).

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
					Hospitalizations during 60 days after rotavirus vaccine: IRR 0.69 (95% CI: 0.65, 0.73); p < 0.001 (31% reduction in hospitalizations) Hospitalizations for enteritis due to rotavirus during 60 days after rotavirus vaccine: IRR 0.061 (95% CI: 0.028, 0.118); p < 0.001 (93.9% reduction in hospitalizations for enteritis) Hazard ratio for associated between diabetes and completed rotavirus vaccine: Completed rotavirus series: unadjusted HR 0.64 (95% CI 0.52, 0.79), p<0.001; adjusted HR 0.67 (95% CI 0.54, 0.83), p<0.001 Use of insulin: unadjusted HR 0.73 (95% CI 0.56, 0.95), p=0.017; adjusted HR 0.71 (95% CI 0.54, 0.94), p=0.015 Hospitalization for type 1 diabetes: unadjusted HR 0.68 (95% CI 0.51, 0.92), p=0.013; adjusted HR 0.70 (95% CI 0.50, 0.97), p=0.031 Two or more type 1 diabetes codes and the use of insulin: unadjusted HR 0.73 (95% CI 0.56, 0.95), p=0.019; adjusted HR 0.70 (95% CI 0.53, 0.93), p=0.014 Risk factors: Girls were more vulnerable than boys, and winter>summer>autumn>spring for diabetes likelihood. Year of birth and gender did not have a statistically significant effect on the impact of vaccination on diabetes risk (inferred from tables)

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
Salas, 2019[190] Article Pre-post N=7712 Industry funded Spain	Age: N/A % female: N/A Ethnicity: Ethnicity NR Patients under 5 years old hospitalized for seizures during the pre-intervention period compared to vaccination period Out of scope: None	RV Rotarix,RotaTeq Route NR adjuvant NR preservative NR No co-intervention No intervention No rotavirus vaccine available (time period) Analytic study Prespecified AE Power NR Followup: 57 months	Seizures (prespecified) Convulsions (prespecified) Myoclonus (prespecified) Epilepsy (prespecified)	NA	Rotavirus vaccination coverage: 0%: All kinds of seizures OR 1; Convulsions OR 1 1-14%: All kinds of seizures OR 0.89 (0.81, 0.98); Convulsions OR 0.84 (0.75, 0.93) 15-29%: All kinds of seizures OR 0.83 (0.74, 0.93); Convulsions OR 0.74 (0.65, 0.85) >=30%: All kinds of seizures OR 0.70 (0.64, 0.78); Convulsions OR 0.57 (0.51, 0.64) Regression models indicate a negative association between RV vaccination and hospitalizations for all kind of seizures.Using ordinary least square methods, we obtained an estimated value of b1 = 4.782 (P-value = 5.9 10 5), which strongly supports the relation existing between ‘‘all kind of seizures” hospitalization rates and vaccination coverage. An analogous analysis was performed for monthly hospitalization rates for convulsions, with an estimated value of b1 = 4.648 (P-value = 5.2 10 6). Risk factors: NR
Stowe, 2016[208] Article Other design N=95 Not industry funded England	Age: 15% 6w–9w/6d, 20% 10w–13w/6d, 28% 14w–17w/6d, 19% 18w–21w/6d, 18% 22w–26w/1d % female: 31% Ethnicity: N/A Infants aged 42–183 days old at the start of their admission with an ICD-10 code for intussusception in the primary diagnosis field	RV Rotarix May have received 1 or 2 doses Route NR adjuvant NR preservative NR Co-intervention Presumably routine vaccines Base treatment Presumably routine vaccines Analytic study Prespecified AE Power calculation Followup: 4 months	Intussusception	NA	Historical cases for age effect in place: Dose 1: 1–7 days, 13.81 (6.44–28.32) Dose 1: 8-21 days, 1.59 (0.34–3.75) Dose 1: 1-21 days, 4.53 (2.34–8.58) Dose 2: 1–7 days, 2.20 (0.50–5.02) Dose 2: 8-21 days, 2.77 (1.36–5.32) Dose 2: 1-21 days, 2.60 (1.43–4.81) Historical cases for age effect not in place: Dose 1: 1–7 days, 8.50 (3.27–28.75) Dose 1: 8-21 days, 1.18 (0.28–3.99) Dose 1: 1-21 days, 3.13 (1.34–7.57) Dose 2: 1–7 days, 1.74 (0.37–5.16) Dose 2: 8-21 days, 2.74 (1.22–5.89) Dose 2: 1-21 days, 2.41 (1.15–5.59) Risk factors: NR

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
	and born from 11/03/2013 Out of scope: None				
Tate, 2016[213] Article Pre-post N=15231 Not industry funded USA	Age: N/A % female: N/A Ethnicity: Ethnicity NR Children <12 months of age with intussusception hospitalizations from 2000 through 2013 Out of scope: None	RV Rotarix,RotaTeq Route NR adjuvant NR preservative NR Co-intervention Presumably routine vaccines Base treatment Presumably routine vaccines Analytic study Prespecified AE Power NR Followup: 11 months	Intussusception	NA	Before rotavirus vaccine introduction in 2006,: Rates of intussusception relatively constant over time, ranging from 33.9 per 100 000 children <12 months of age in 2004 to 37.2 per 100 000 children <12 months of age in 2003 and 2005 Post-introduction of rotavirus vaccines: Rates of intussusception significantly elevated in 2007 (40.7 per 100 000 children <12 months of age; RR: 1.13, 95% CI: 1.07–1.20) and in 2010 (40.3 per 100 000 children <12 months of age; RR: 1.12, 95% CI: 1.06-1.20) but were not different from baseline in other postvaccine introduction years Children 6 to 14 weeks of age: Rates of intussusception hospitalization were elevated by 43% in 2007 (21.4 per 100 000; RR: 1.43, 95% CI: 1.16–1.76), 50% in 2008 (22.5 per 100 000; RR: 1.50, 95% CI: 1.22–1.83), 25% in 2009 (18.7 per 100 000; RR: 1.25, 95% CI: 1.00–1.56), 42% in 2010 (21.3 per 100 000; RR: 1.42, 95% CI: 1.15–1.75), and 42% in 2012 (21.4 per 100 000; RR: 1.42 (95% CI: 1.15–1.76) but no different from the prevaccine baseline in the remaining 2 postvaccine years (2011 and 2013). Children 8 to 11 weeks of age: Rate of intussusception hospitalization significantly elevated in all years by 46%

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
					to 101% (range: 16.7–22.9 per 100 000 children 8–11 weeks of age) compared with the prevaccine baseline (11.4 per 100 000; range: 8.3–14.1 per 100 000) except in 2011 (15.0 per 100 000) and 2013 (14.7 per 100 000) when the rate was not significantly different from baseline. Children 15 to 24 weeks of age: Rate of intussusception hospitalization significantly elevated in 2010 (55.0 per 100 000 children 15 to 24 weeks of age; RR: 1.18, 95% CI: 1.05–1.34) compared with the pre-vaccine average of 46.4 per 100 000 but not significantly elevated in any other post-vaccine introduction year. Children 25 to 34 weeks of age: Rate of intussusception hospitalization significantly lower in 2008 (45.5 per 100 000 children 25 to 34 weeks of age; RR: 0.82, 95% CI: 0.72–0.93) compared with the pre-vaccine average of 55.6 per 100 000 and not significantly different from baseline rates in the remaining post-vaccine introduction years. Rate of surgery remained constant over the entire study period from 2000 through 2013 (range: 16.7–21.8 per 100 000) with ~50% of children requiring surgery. Risk factors: No consistent change in intussusception hospitalization rates was observed among all children <12 months of age and among children 15 to 24 weeks and 25 to 34 weeks of age. The intussusception hospitalization rate for children aged 8 to 11 weeks was significantly elevated by 46% to 101% (range: 16.7–22.9 per 100 000) in all postvaccine years except 2011 and 2013 compared with the prevaccine baseline (11.7 per 100 000).

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
Tate, 2018[212] Article Other design N=717 Not industry funded Ethiopia, Ghana, Kenya, Malawi, Tanzania, Zambia, Zimbabwe	Age: 28 days to 12 months of age % female: N/A Ethnicity: Ethnicity NR Infants with intussusception in sub-Saharan African countries Out of scope: None	RV Rotarix 2 doses Route NR adjuvant NR preservative NR Co-intervention Routine vaccines Base treatment Control is non-risk observation window; routine vaccines given Analytic study Prespecified AE Power calculation Followup: 8 months	Intussusception (prespecified)	NA	Relative incidence (RI, 95% CI) of intussusception in risk periods after RV1 (compared to observation window): Dose 1, days 1-7: 0.25 (<0.001–1.16) Dose 1, days 8-21: 1.01 (0.26–2.24) Dose 1, days 1-21: 0.85 (0.35–1.73) Dose 2, days 1-7: 0.76 (0.16–1.87) Dose 2, days 8-21: 0.74 (0.39–1.20) Dose 2, days 1-21: 0.81 (0.49–1.22) Risk factors: NR
Uhlig, 2014[223] Article Pre-post N=81800000 Author COI Germany	Age: 0-5 years % female: N/A Ethnicity: NR Children living in Germany from 2006-2012 Out of scope: None	RV Rotarix,RotaTeq Route NR adjuvant NR preservative NR Co-intervention Presumably routine vaccines No intervention Analytic study Power NR Followup: 70 months	Intussusception Kawasaki disease	NA	Analyzed hospitalizations for Kawasaki disease and intussusception during the years 2006 to 2011 in high vaccination coverage areas and low vaccination coverage areas for the age groups 0 and 1-year-old, 2-year- old and 3- to 5-year-old children retrieved from the nationwide DRG hospitalization data set. Changes per 100,000 children of that age group for diagnosis and age group were not significant. Risk factors: No

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
Vaarala, 2017[225] Article Cohort study N=121650 Not industry funded Finland	Age: N/A % female: N/A Ethnicity: NR Children in a cohort born in 2009–2010 Out of scope: None	RV RotaTeq Doses at 2, 3, 5 months Route NR adjuvant NR preservative NR Co-intervention Presumably routine vaccines No intervention Counts Prespecified AE Power NR Followup: 72 months	Celiac disease Type 1 diabetes	Autoimmune disease: 10.X Celiac disease I: 201/94437, 10.X Celiac disease C: 92/27213 Diabetes: 14.X Type 1 diabetes I: 243/94437, 14.X Type 1 diabetes C: 102/27213	Adjusted RR for type 1 diabetes 0.91 (0.69–1.20) Adjusted RR for celiac disease 0.87 (0.65–1.17) Risk factors: No
Vesikari, 2007[229] GlaxoSmithKline, 2004[258] NCT00140686 Article RCT N=3994 Industry funded Czech Republic, Finland, France, Germany, Italy, Spain	Age: Age at dose 1: 11.5 weeks (1.77); Age at dose 2 19.7 weeks (2.69) % female: 47% Ethnicity: <1% African, 98% White, <1% Arabic and north African, <1% East and southeast Asia, <1% South Asian, <1% American Hispanic, 0% Japanese, 1% Other Healthy infants aged 6–14 weeks who weighed more than 2000 g at birth Out of scope: None	RV Rotarix Rotarix (RIX4414) vaccine contained 106·5 median cell culture infectious dose of the vaccine strain per vaccine dose Schedule of 0, 1, or 2 months at the same time as the first two doses of their primary childhood vaccination series Route NR adjuvant NR preservative NR Co-intervention Routine vaccines Base treatment : Routine vaccines Routine vaccines alone plus placebo Counts Unclear Power other outcome	Serious adverse events (as a group) Intussusception	Intussusception: 7.X I: 2/2646, 7.X C: 1/1348	Serious adverse events: Intervention 290/2646 (11%) vs control 176/1348 (13%). Intussusception: 2/2646 vs 1/1348 Risk factors: NR

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
		Followup: 24 months			
Yih, 2014[236] Yih, 2013[388] Article Other design N=1380654 Not industry funded USA	Age: N/A % female: N/A Ethnicity: Ethnicity NR Children aged 5-36.9 weeks who were members of an Aetna, HealthCore, or Humana health plan between January 2004 and September 2011 Out of scope: None	RV Rotarix,RotaTeq Route NR adjuvant NR preservative NR Co-intervention Presumably routine vaccines Base treatment Self-controlled with comparison interval day 22 to day 42; presumably received routine vaccines as well route NR adjuvant NRpreservative NR Counts Prespecified AE Insufficient power Followup: 8 months	Intussusception (prespecified)	NA	RV5 (Rotateq) risk of confirmed intussusception: relative risk (95% CI), attributable risk/ 100,000 doses (95% CI) Dose 1 prespecified SCRI 1-7 days: 9.1 (2.2 to 38.6), 1.1 (0.3 to 2.7) Dose 1 prespecified SCRI 1-21 days: 4.2 (1.1 to 16.0), 1.5 (0.2 to 3.2) Dose 1 prespecified cohort analysis 1-21 days: 2.6 (1.2 to 5.8), 1.2 (0.2 to 3.2) Dose 1 post hoc SCRI 1-7 days: 7.0 (1.7 to 29.2), 1.1 (0.3 to 2.6) Dose 1 post hoc SCRI 1-21 days: 3.4 (0.9 to 13.0), 1.4 (−0.01 to 3.1) Dose 1 post hoc cohort analysis 1-21 days: 2.9 (1.4 to 6.0), 1.3 (0.3 to 3.3) Dose 2 prespecified SCRI 1-7 days: 1.8 (0.4 to 7.2), 0.4 (−0.3 to 1.9) Dose 2 prespecified SCRI 1-21 days: 1.0 (0.3 to 3.1), -0.1 (-1.8 to 1.8) Dose 2 prespecified cohort analysis 1-21 days: 0.9 (0.4 to 2.2), −0.2 (−1.1 to 1.8) Dose 2 post hoc SCRI 1-7 days: 1.8 (0.4 to 7.2), 0.4 (−0.3 to 1.9) Dose 2 post hoc SCRI 1-21 days: 1.0 (0.3 to 3.1), -0.1 (-1.8 to 1.8) Dose 2 post hoc cohort analysis 1-21 days: 0.8 (0.3 to 2.0), −0.3 (−1.2 to 1.6) Dose 3 prespecified SCRI 1-7 days: 2.2 (0.5 to 9.7), 0.6 (−0.4 to 2.6) Dose 3 prespecified SCRI 1-21 days: 1.0 (0.2 to 3.9), −0.05 (−2.3 to 2.1)

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
					Dose 3 prespecified cohort analysis 1-21 days: 0.9 (0.3 to 2.2), −0.3 (−1.5 to 2.3) Dose 3 post hoc SCRI 1-7 days: 2.3 (0.5 to 10.2), 0.7 (−0.3 to 2.7) Dose 3 post hoc SCRI 1-21 days: 1.0 (0.2 to 4.0), 0.01 (−2.1 to 2.2) Dose 3 post hoc cohort analysis 1-21 days: 0.9 (0.4 to 2.2), −0.2 (−1.4 to 2.4) All doses prespecified SCRI 1-7 days: 3.3 (1.5 to 7.4), 0.8 (0.2 to 1.6) All doses prespecified SCRI 1-21 days: 1.6 (0.8 to 3.3), 0.6 (-0.4 to 1.7) All doses prespecified cohort analysis 1-21 days: 1.3 (0.8 to 2.1), 0.4 (−0.4 to 1.4) All doses post hoc SCRI 1-7 days: 3.0 (1.4 to 6.8), 0.7 (0.2 to 1.6) All doses post hoc SCRI 1-21 days: 1.5 (0.7 to 3.1), 0.6 (-0.4 to 1.6) All doses post hoc cohort analysis 1-21 days: 1.3 (0.8 to 2.1), 0.4 (−0.4 to 1.4) RV1 (Rotarix) risk of confirmed intussusception: relative risk (95% CI), attributable risk/ 100,000 doses (95% CI) Dose 1 prespecified SCRI 1-7 days: Not estimable (NE), 2.4 Dose 1 prespecified SCRI 1-21 days: NE, 2.4 Dose 1 prespecified cohort analysis 1-21 days: 2.9 (0.4 to 21.8), 1.6 (−0.6 to 10.4) Dose 1 post hoc SCRI 1-7 days: NE, 2.4 Dose 1 post hoc SCRI 1-21 days: NE, 2.4 Dose 1 post hoc cohort analysis 1-21 days: 3.2 (0.4 to 22.9), 1.6 (−0.5 to 10.4) Dose 2 prespecified SCRI 1-7 days: 3.5 (0.5 to 25.1), 4.3 (−1.8 to 17.8) Dose 2 prespecified SCRI 1-21 days: 1.7 (0.3 to 10.1), 3.7 (−10.0 to 19.4) Dose 2 prespecified cohort analysis 1-21 days: 5.1 (1.6 to 16.4), 7.3 (0.8 to 22.5 Dose 2 post hoc SCRI 1-7 days: 3.6 (0.5 to 25.3), 4.4 (−1.7 to 17.8) Dose 2 post hoc SCRI 1-21 days: 1.7 (0.3 to 10.2), 3.7 (−9.8 to 19.5) Dose 2 post hoc cohort analysis 1-21 days: 4.6 (1.5 to 14.7), 7.1 (0.6 to 22.3) All doses prespecified SCRI 1-7 days: 5.7 (0.9 to 34.2), 3.1 (0.01 to 9.3)

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
					All doses prespecified SCRI 1-21 days: 2.3 (0.4 to 12.8), 2.8 (−2.9 to 9.9) All doses prespecified cohort analysis 1-21 days: 3.8 (1.4 to 10.4), 3.7 (0.3 to 10.5) All doses post hoc SCRI 1-7 days: 5.5 (0.9 to 33.0), 3.1 (−0.02 to 9.3) All doses post hoc SCRI 1-21 days: 2.3 (0.4 to 12.6), 2.8 (−3.0 to 9.9) All doses post hoc cohort analysis 1-21days: 3.7 (1.4 to 10.1), 3.6 (0.3 to 10.5) Cluster analysis: In the analyses of dose 1 and of all doses of RV5, the temporal scan statistic showed a significant cluster of onset of intussusception 3 to 7 days after vaccination (P = 0.008 for dose 1; P = 0.004 for all doses). There was only a single case of intussusception after dose 1 of RV1; therefore, there were insufficient data for the analysis of clusters of onset after dose 1. For all doses of RV1, there was a significant cluster on day 4 after vaccination (P<0.001) Risk factors: NR
Yung, 2015[237] Article Other design N=20 Not industry funded Singapore	Age: Mean age at admission, in days: Vaccinated: 224; Unvaccinated: 230 % female: 35 Ethnicity: Intervention: 70% Chinese, 15% Malay, 10% Indian, 5% Other; Control: 53% Chinese, 20% Malay, 18% Indian, 9% Other Infants under 1 year of age hospitalized for intussusception from 2005-2012	RV Rotarix 2 doses Oral adjuvant NR preservative NR Co-intervention Presumably routine vaccines Base treatment Control period (time before vaccination and >21 days post-vaccination; presumably routine vaccines as well Analytic study Prespecified AE Power calculation Followup: 11 months	Intussusception	NA	Age-adjusted risk incidence (RI, 95% CI) of intussusception during risk periods following RV compared to observation periods: Dose 1 (1-7 days): 8.36 (2.42-28.96) Dose 2 (1-7 days): 3.09 (0.41-23.37) Dose 2 (8-21 days): 1.54 (0.20-11.69) Above results age-adjusted for days; similar results for age-adjusted for months and age-adjusted by quadratic function. Risk factors: NR

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
	Out of scope: None				

Table D.3. KQ2 evidence table safety of vaccines in samples of children and adults

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
Baxter, 2016[63] Article Case-Control N=1929 Not industry funded USA	Age: NA Different for each vaccine sub population and not reported % female: NA Ethnicity: Ethnicity NR Cases of first-ever SSNHL at Kaiser Permanente Northern California from 2007 through 2013 who had 1 year of membership prior to the diagnosis, and their controls matched on age, sex, and receipt of same vaccines as the case in the 9 months prior to the onset date of the index case Out of scope: Unclear	DTap,Hep A,Hep B,MMR,Men quadrivalent,Pneumococcal PSV23,Polio inactivated,Td,Tdap,Varicella,HepA-HepB IPOL,M-M-RII,Pneumovax,Twinrix,Varivax Route NR adjuvant NR preservative NR Co-intervention unclear Case-centered design compares vaccination patterns during an exposure interval prior to the outcome in cases versus the entire study population, matched by age, sex, vaccines received Analytic study Prespecified AE Power NR Followup: 9 months	Sudden-onset sensorineural hearing loss	NA	Risk of vaccination in the 1 week prior to onset of sudden-onset sensorineural hearing loss, OR of vaccination in risk vs control interval (95% Confidence Interval), p-value: Measles, mumps, rubella (MMR): 0 (0.00-33.29), p=0.873 Injectable polio: 0 (0.00-92.95), p=0.928 Hepatitis A/B (Twinrix): 2.388 (0.37-9.14), p=0.285 MCV4: 0 (0.00-21.06), p=0.822 Tdap: 0.842 (0.39-1.62), p=0.665 Zostavax: 0.454 (0.08-1.53, p=0.258 DTaP: 0 (0.00-36.61), p=0.874 Varicella: 0 (0.00-155.27), p=0.957 Pneumovax: 0.813 (0.20-2.26), p=0.784 Hepatitis A: 0 (0.00-3.42), p=0.400 Hepatitis B: 0.667 (0.03-3.51), p=0.783 Td: 0 (0.00-2.67), p=0.317 Risk factors: NR

Baxter, 2016[62] Lewis, 2016[244]; Baker, 2015[243] Article Case-Control N=114 Not industry funded USA	Age: NA Different for each vaccine sub population and not reported % female: NA Ethnicity: Ethnicity NR Members of integrated healthcare systems that report to the Vaccine Safety Datalink Out of scope: Unclear	DTap,Hib,Hep A,Hep B,MMR,Men quadrivalent,Pneu mococcal PCV13,Pneumococ cal PSV23,Polio inactivated,RV,Td,T dap,Varicella,DTaP -HepB-IPV,DTaP-IPV-Hib,DTaP-IPV,MMR-V,HepA-HepB Kinrix,Menactra [MenACWY-D],Menveo [MenACWY-CRM],Pediarix,Prev nar 13,Pneumovax,Pen tacel,ProQuad,Rota rix,RotaTeq,Twinrix Route NR adjuvant NR preservative NR Co-intervention unclear No intervention Case-centered design compares vaccination patterns during an exposure interval prior to the outcome in cases versus the entire study population, matched by age, sex, site Analytic study Prespecified AE Power NR Followup: 9 months	Transverse myelitis Acute disseminated encephalomyelitis Optic neuritis	NA	RR of transverse myelitis in 5 to 28-Day Risk interval Following Vaccines, Compared to Remainder of the 9 Months After Vaccination: MMR: aOR 0 (.0 - 129.8) DTaP/IPV/HBV (Pediarix): aOR 0 (.0–64.8) MCV4 (Menactra, Sanofi): aOR 5.2 (.2–70.9) Tdap: aOR 0.7 (.0–3.8) RV5 (Rotateq): aOR 0 (.0–73.5) PCV13: aOR 0 (.0–64.6) Varicella: aOR 0 (.0–10.7) PPSV23: aOR 0 (.0–9.4) Any MCV4: aOR 5.2 (.2-70.9) HAV: aOR 0 (.0–12.6) HBV: aOR 0 (.0–30.0) Hib: aOR 0 (.0–66.2) Td: aOR 0 (.0–34.1) RR of acute disseminated encephalomyelitis in the 5- to 28-Day Risk Interval Following Vaccines, compared to Remained of 9 Months After Vaccination: MMR: aOR 5 (.6–29.9) IPV: aOR 0 (.0–270.1) MCV4 (Menactra, Sanofi): aOR 0 (.0–18.0) Tdap: aOR 15.8 (1.2–471.6) DTaP/IP/Hib (Pentacel): aOR 0 (.0–40.7) DTaP/IPV (Kinrix): aOR 4.1 (.1–44.0) PCV13: aOR 3.6 (.1–95.4) DTaP: aOR 0 (.0–270.4) Varicella: aOR 4.3 (.5–25.4) MPSV4: aOR NE (0.1-NE) PPSV23: aOR 0 (.0–14.5) MMR-Varicella: aOR 0 (.0–292.0) Any MCV4: aOR0 (.0-17.5) HAV: aOR 1.9 (.1–13.0) HBV: aOR 0 (.0–128.7) Hib: aOR 0 (.0–25.3) Td: aOR 0 (.0–962.7) Results same for 5-42 days interval, except Tdap no longer significant RR and RD of optic neuritis in the 2-42 day risk interval after vaccines vs the remainder of the 9 months after vaccination

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
					Vaccine: adjusted OR (95% CI), RD per 1 million doses (95% CI) MMR: aOR 0 (.0-136.1), −0.45 (−.70 to 4.15) Hep A/B Combination: aOR NE (>.2), 14.21 (−5.63 to 53.67) MCV4: aOR 2.7 (.3–15.6), 3.04 (−2.39 to 11.86) Tdap: aOR 2.7 (.3-15.6), 1.81 (−1.08 to 5.54) VZV: aOR 2.1 (.1–23.2), 0.88 (−1.50 to 5.72) PPSV23: aOR 3.4 (.4-23.3), 3.50 (−1.90 to 12.79) Hep A: aOR 0 (.0-7.5), −0.76 (−1.09 to 1.35) Hep B: aOR 0 (.0-6.5), −2.67 (−4.22 to 3.47) Td: aOR 0 (.0-95.9), −1.29 (−1.79 to 9.82) Analysis repeated for 5-28 day intervals, and no significant aOR Risk factors: NR

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
Donahue, 2019[95] Article RCT N=838991 Not industry funded USA	Age: 9-26 years % female: N/A Ethnicity: N/A The study population consisted of persons 9 to 26 years old during the study period (October 4, 2015 through October 7, 2017) at six integrated health care organizations in the VSD contributed data for this surveillance: Kaiser Permanente Northern California, Southern California, Colorado, Oregon, and Washington and Marshfield Clinic (Marshfield, Wisconsin) Out of scope: None	HPV Gardasil 9 Route NR adjuvant NR preservative NR Co-intervention unclear No intervention Two comparators: general group who kay have received HPV4; second group who had not gotten HPV4 Analytic study Prespecified AE Power NR Followup: 6 months	Anaphylaxis Appendicitis Guillain- Barré syndrome (GBS) Pancreatitis Seizures Stroke Venous thromboembolism (VTE) Chronic inflammatory demyelinating polyneuropathy (CIDP) Injection site reactions Allergic reactions (evaluated separately in the outpatient, ED, and inpatient settings) Syncope Nonspecific reactions (eg, adverse effect of viral vaccines)	NA	No signals were detected for anaphylaxis*, CIDP, GBS*, pancreatitis, seizure*, stroke*, or VTE* Appendicitis, allergic reactions: statistical signal was classified as a false-positive signal No follow-up investigations were conducted for syncope, injection site reaction, or nonspecific reactions because they were expected based on clinical trials of 9vHPV, clinical experience with 4vHPV and because the diagnoses were unlikely to indicate a serious adverse event. Risk factors: NR

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
Garland, 2015[111] Merck Sharp, 2010[314] NCT01047345 Article RCT N=924 Industry funded Australia, Canada, Colombia, Denmark, Hong Kong, Mexico, Sweden, USA	Age: Intervention (9vHPV): 19.0 (3.7); Control (placebo): 18.9 (3.7) % female: 100 Ethnicity: Intervention: 78% White, 15% Multi-racial, 6% Asian, <1% Black, <1% American Indian or Alaska native, 21% Hispanic; Control 76% White, 19% Multi-racial, 5% Asian, <1% Black, 0% American Indian or Alaska native, 22% Hispanic Females 12–26 years old who were previously vaccinated with 3 doses of qHPV vaccine Out of scope: None	HPV Gardasil 9 1.5 mL in 3 doses at day 1, month 2, and month 6 Intramuscular Aluminum preservative free No co-intervention Placebo Placebo (saline) 0.5 mL intramuscularly at day 1, month 2, and month 6 Counts Prespecified AE Power other outcome Followup: 7 months	Abdominal pain Diarrhoea Appendicitis Tonsillitis Lumbar vertebral fracture Thoracic vertebral fracture Migraine Syncope Abortion induced Nausea Injection site erythema Injection site pain Injection site pruritus Injection site swelling Pyrexia Nasopharyngitis Dizziness Headache Oropharyngeal pain	Birth defects: 3.X Out of 2 pregnancies I: 0/608, 3.X Out of 1 pregnancy C: 0/305 Death NA NA I: 0/608, NA NA C: 0/305 Reproduction issues: 18.X Induced abortion I: 0/608, 18.X Induced abortion C: 1/305	Injection site AEs: Intervention 554/608 (91.1%) vs Control 134/305 (43.9%) Vaccine-related systemic AEs: Intervention 186/608 (30.6%) vs Control 79/305 (25.9%) Severe AEs: Pain Severe: Intervention 24/608 (3.9%) vs vs Control 1/305 (0.3%) Swelling Severe (>5.0 cm): Intervention 46/608 (7.6%) vs Control 1/305 (0.3%) Erythema Severe (>5 cm): Intervention 20/608 (3.3%) vs Control 1/305 (0.3%) Pruritus Severe: Intervention 2/608 (0.3%) vs Control 0/305 (0%) Hematoma Severe: Intervention 0/608 (0%) vs Control 0/305 (0%) Serious AEs (from clinicaltrials.gov): Intervention (9vHPV Vaccine) vsPlacebo Affected / at Risk (%)# EventsAffected / at Risk (%)# Events Total 3/608 (0.49%) 3/305 (0.98%) Gastrointestinal disorders Abdominal pain 0/608 (0.00%) 00/305 (0.00%) 0 Diarrhoea 0/608 (0.00%) 00/305 (0.00%) 0 Infections and infestations Appendicitis 1/608 (0.16%) 10/305 (0.00%) 0 Tonsillitis1/608 (0.16%) 10/305 (0.00%) 0 Injury, poisoning and procedural complications Lumbar vertebral fracture 0/608 (0.00%) 01/305 (0.33%) 1 Thoracic vertebral fracture 0/608 (0.00%) 01/305 (0.33%) 1 Nervous system disorders Migraine 0/608 (0.00%) 01/305 (0.33%) 1 Syncope 1/608 (0.16%) 10/305 (0.00%) 0 Surgical and medical procedures Abortion induced 0/608 (0.00%) 01/305 (0.33%) 1 (in AE table) Risk factors: NR

Huh, 2017 [136] Garland, 2018[256]; Ruiz-Sternberg, 2018[354]; Guevara, 2019[281]; Luxembourg, 2015[302]; Petersen, 2017[337]; Joura, 2015[290]; Guevara, 2017[280]; Giuliano, 2019[257]; Merck Sharp, 2007[311]; Mayrand, 2015[303] NCT00543543 Article RCT N=14840 Industry funded Austria, Brazil, Canada, Chile, Colombia, Denmark, Germany, Hong Kong, Japan, South Korea, Mexico, New Zealand, Norway, Peru, Sweden, Taiwan, Thailand, USA	Age: 9vHPV: 21.9 (2.5); qHPV: 21.8 (2.5) % female: 100% Ethnicity: 55% White, 15% Asian, 3% Black, 27% Other Women 16-26 years old who were generally healthy, had no history of abnormal cervical cytology, no more than four lifetime sexual partners and no previous abnormal cervical biopsy results Out of scope: None	HPV Gardasil 9 3 doses total on day 1, month 2, month 6 (each dose contained 30 µg of HPV6, 40 µg of HPV11, 60 µg of HPV 16, 40 µg of HPV 18, 20 µg of HPV 31, 20 µg of HPV 33, 20 µg of HPV 45, 20 µg of HPV 52, and 20 µg of HPV 58 virus-like particles, and 500 µg of amorphous aluminum hydroxyphosphate sulphate (AAHS)) Intramuscular Aluminum preservative free No co-intervention HPV qHPV vaccine Gardasil 3 doses total on day 1, month 2, month 6 (each dose contained 20 µg of HPV 6, 40 µg of HPV 11, 40 µg of HPV 16, and 20 µg of HPV 18 virus-like particles, and 225 µg of AAHS) Intramuscular Aluminumpreservative free Counts No prespecified AE Power other outcome Followup: 54 months	Anaemia Aortic valve incompetence Postural orthostatic tachycardia syndrome Atrial fibrillation Cleft lip and palate Diverticulitis Meckel's Vertigo positional Abdominal pain Abdominal pain lower Anal fistula Coeliac disease Colitis ulcerative Crohn's disease Diarrhoea Enterocolitis Gastritis Haemorrhoids Inguinal hernia Irritable bowel syndrome Omental infarction Pancreatitis acute General disorders Accidental death Non-cardiac chest pain Pyrexia Sudden death Cholangitis Cholecystitis Cholelithiasis Cholestasis of pregnancy Allergy to vaccine Anaphylactic reaction Hypersensitivity Sarcoidosis Abscess jaw Appendicitis Bronchitis Cellulitis Cholecystitis infective Chronic tonsillitis Conjunctivitis Dengue fever Enteritis infectious Gastroenteritis Gastroenteritis viral Haemorrhagic fever Infectious mononucleosis Influenza	Anaphylaxis: 10.4 Anaphylaxis (caused by a non-study medication) I: 1/7071, 10.4 Anaphylaxis C: 0/7078 Asthma: 22.X Asthmatic crisis I: 1/7071, 22.X Asthmatic crisis, C: 0/7078 Autoimmune disease: 7.X Crohn's disease I: 1/7071, 7.X Ulcerative colitis C: 1/7078 Birth defects: 3.X NA I: 0/7071, 3.X Cleft lip and palate C: 2/7078 Cardiovascular events: 2.X Cardiac disorders (from appendix) I: 2/7071 2.XCardiac disorders (from appendix), C: 0/7078 Death NA Investigator considered the deaths to be unrelated to study vaccination. I: 6/7071, NA Investigator considered the deaths to be unrelated to study vaccination. C: 5/7078 Diabetes: 14.X Gestational diabetes I: 0/7071, 14.X Gestational diabetes C: 1/7078 Multiple Sclerosis: 17.X NR I: 2/7071, 17.X NR C: 1/7078 Preterm labor: 18.X Premature labor I: 1/7071, 18.X Premature labor C: 1/7078 Reproduction issues: 18.X Reproductive system and breast disorders (from appendix) I: 9/7071, 18.X Reproductive system and breast disorders (from appendix) C: 8/7078 Spontaneous abortion: 18.X NR I: 36/7071, 18.X NR C: 36/7078 Stroke: 17.X Cerebral haemorrhage I: 0/7071, 17.X Cerebral haemorrhage C: 1/7078	Intervention (HPV9) vs Control (HPV4) Affected / at Risk (%) # Events Affected / at Risk (%) # Events Total 233/7071 (3.30%) 184/7078 (2.60%) Anaemia 1/7071 (0.01%) 11/7078 (0.01%) 1 Aortic valve incompetence 1/7071 (0.01%) 10/7078 (0.00%) 0 Postural orthostatic tachycardia syndrome (in AE table) Atrial fibrillation 0/7071 (0.00%) 00/7078 (0.00%) 0 Diverticulitis Meckel's 0/7071 (0.00%) 01/7078 (0.01%) 1 Vertigo positional 1/7071 (0.01%) 10/7078 (0.00%) 0 Abdominal pain 0/7071 (0.00%) 02/7078 (0.03%) 2 Abdominal pain lower 0/7071 (0.00%) 01/7078 (0.01%) 1 Anal fistula 1/7071 (0.01%) 10/7078 (0.00%) 0 Coeliac disease 1/7071 (0.01%) 10/7078 (0.00%) 0 Diarrhoea 1/7071 (0.01%) 10/7078 (0.00%) 0 Enterocolitis 0/7071 (0.00%) 01/7078 (0.01%) Gastritis 1/7071 (0.01%) 11/7078 (0.01%) 1 Haemorrhoids 1/7071 (0.01%) 10/7078 (0.00%) Inguinal hernia 1/7071 (0.01%) 11/7078 (0.01%) Irritable bowel syndrome 1/7071 (0.01%) 10/7078 (0.00%) Omental infarction 0/7071 (0.00%) 01/7078 (0.01%) 1 Pancreatitis acute 0/7071 (0.00%) 01/7078 (0.01%) 1 Accidental death 0/7071 (0.00%) 01/7078 (0.01%) 1 Non-cardiac chest pain 0/7071 (0.00%) 01/7078 (0.01%) 1 Pyrexia 1/7071 (0.01%) 10/7078 (0.00%) 0 Sudden death 1/7071 (0.01%) 100/7078 (0.00%) 0

			Pelvic inflammatory disease Pharyngitis Post abortion infection Pyelonephritis Pyelonephritis acute Septic shock Tonsillitis Tonsillitis streptococcal Urinary tract infection Urosepsis Viral pharyngitis Wound infection Pneumonia Postoperative wound infection Bladder injury Burns second degree Craniocerebral injury Femur fracture Foreign body in eye Fracture displacement Hand fracture Head injury Humerus fracture Joint dislocation Ligament rupture Lower limb fracture Multiple injuries Neck injury Poisoning Post procedural haemorrhage Pubis fracture Road traffic accident Spinal compression fracture Spinal cord injury Spinal cord injury cervical Ulna fracture Hyperglycaemia Fibromyalgia Myalgia Osteoarthritis Acute lymphocytic leukaemia Acute promyelocytic leukaemia Adenocarcinoma gastric		Cholangitis 1/7071 (0.01%) 10/7078 (0.00%) 0 Cholecystitis 1/7071 (0.01%) 11/7078 (0.01%) 1 Cholelithiasis 1/7071 (0.01%) 12/7078 (0.03%) 2 Cholestasis of pregnancy 0/7071 (0.00%) 00/7078 (0.00%) 0 Allergy to vaccine 1/7071 (0.01%) 10/7078 (0.00%) 0 Anaphylactic reaction 1/7071 (0.01%) 10/7078 (0.00%) Hypersensitivity 1/7071 (0.01%) 10/7078 (0.00%) 0 Sarcoidosis 1/7071 (0.01%) 10/7078 (0.00%) 0 Abscess jaw 1/7071 (0.01%) 10/7078 (0.00%) 0 Appendicitis 9/7071 (0.13%) 916/7078 (0.23%) 16 Bronchitis 0/7071 (0.00%) 02/7078 (0.03%) 2 Cellulitis 0/7071 (0.00%) 01/7078 (0.01%) 1 Cholecystitis infective 1/7071 (0.01%) 10/7078 (0.00%) 0 Chronic tonsillitis 1/7071 (0.01%) 10/7078 (0.00%) 0 Conjunctivitis 0/7071 (0.00%) 01/7078 (0.01%) 1 Dengue fever 1/7071 (0.01%) 10/7078 (0.00%) 0 Enteritis infectious 2/7071 (0.03%) 20/7078 (0.00%) 0 Gastroenteritis 1/7071 (0.01%) 12/7078 (0.03%) 2 Gastroenteritis viral 1/7071 (0.01%) 10/7078 (0.00%) 0 Haemorrhagic fever 1/7071 (0.01%) 10/7078 (0.00%) 0 Infectious mononucleosis 1/7071 (0.01%) 10/7078 (0.00%) 00 Influenza 1/7071 (0.01%) 11/7078 (0.01%) 1 Pelvic inflammatory disease 0/7071 (0.00%) 01/7078 (0.01%) 1 Pharyngitis 1/7071 (0.01%) 10/7078 (0.00%) 0 Post abortion infection 0/7071 (0.00%) 01/7078 (0.01%) 1

			Adenocarcinoma of the cervix Brain neoplasm Ependymoma Leukaemic infiltration brain Malignant melanoma Malignant melanoma in situ Malignant palate neoplasm Nasal cavity cancer Ovarian neoplasm Pituitary tumour benign Respiratory papilloma Thyroid cancer Breast cancer Glioma Benign intracranial hypertension Cerebral haemorrhage Diabetic coma Epilepsy Facial paresis Headache Hydrocephalus Hypersomnia Hypoaesthesia Intracranial venous sinus thrombosis Migraine Multiple sclerosis Neuritis Orthostatic intolerance Presyncope Sciatica Sensory disturbance Spondylitic myelopathy Syncope Tension headache Trigeminal nerve disorder Pregnancy, puerperium and perinatal conditions Abortion spontaneous Abortion spontaneous complete Abortion spontaneous incomplete Blighted ovum		Pyelonephritis 2/7071 (0.03%) 21/7078 (0.01%) 1 Pyelonephritis acute 1/7071 (0.01%) 12/7078 (0.03%) 2 Septic shock 1/7071 (0.01%) 10/7078 (0.00%) 0 Tonsillitis 1/7071 (0.01%) 10/7078 (0.00%) 0 Tonsillitis streptococcal 1/7071 (0.01%) 10/7078 (0.00%) 0 Urinary tract infection 2/7071 (0.03%) 22/7078 (0.03%) 2 Urosepsis 1/7071 (0.01%) 10/7078 (0.00%) 0 Viral pharyngitis 0/7071 (0.00%) 01/7078 (0.01%) 1 Wound infection 1/7071 (0.01%) 10/7078 (0.00%) 0 Pneumonia 0/7071 (0.00%) 00/7078 (0.00%) 0 Postoperative wound infection 0/7071 (0.00%) 00/7078 (0.00%) 0 Bladder injury 1/7071 (0.01%) 10/7078 (0.00%) 0 Burns second degree 1/7071 (0.01%) 10/7078 (0.00%) 0 Craniocerebral injury 1/7071 (0.01%) 10/7078 (0.00%) 0 Femur fracture 1/7071 (0.01%) 10/7078 (0.00%) 0 Foreign body in eye 0/7071 (0.00%) 01/7078 (0.01%) 1 Fracture displacement 0/7071 (0.00%) 01/7078 (0.01%) 1 Hand fracture 0/7071 (0.00%) 01/7078 (0.01%) 1 Head injury 0/7071 (0.00%) 01/7078 (0.01%) 1 Humerus fracture 1/7071 (0.01%) 20/7078 (0.00%) 0 Joint dislocation 0/7071 (0.00%) 02/7078 (0.03%) 2 Ligament rupture 1/7071 (0.01%) 10/7078 (0.00%) 0 Lower limb fracture 1/7071 (0.01%) 10/7078 (0.00%) 0 Multiple injuries 2/7071 (0.03%) 20/7078 (0.00%) 0 Neck injury 0/7071 (0.00%) 01/7078 (0.01%) 1

			Cephalo-pelvic disproportion Cervix dystocia Ectopic pregnancy False labour Foetal death Foetal distress syndrome Foetal malposition Foetal malpresentation Gestational diabetes Labour complication Oligohydramnios Pre-eclampsia Premature labour Premature rupture of membranes Prolonged labour Uterine contractions during pregnancy Psychiatric disorders Anorexia and bulimia syndrome Anorexia nervosa Bipolar disorder Completed suicide Depression Major depression Calculus ureteric Calculus urinary Cystitis haemorrhagic Nephrolithiasis Renal failure Renal failure acute Renal colic Bartholinitis Cervical dysplasia Cervix haemorrhage uterine Dysmenorrhoea Endometriosis Fallopian tube cyst Ovarian cyst Pelvic pain Asthmatic crisis Dyspnoea Nasal polyps Pneumonia aspiration Pneumothorax Respiratory failure Vocal cord polyp		Poisoning 0/7071 (0.00%) 01/7078 (0.01%) 1 Post procedural haemorrhage 0/7071 (0.00%) 01/7078 (0.01%) 2 Pubis fracture 1/7071 (0.01%) 10/7078 (0.00%) 0 Road traffic accident 1/7071 (0.01%) 10/7078 (0.00%) 0 Spinal compression fracture 1/7071 (0.01%) 10/7078 (0.00%) 0 Spinal cord injury 0/7071 (0.00%) 01/7078 (0.01%) 1 Spinal cord injury cervical 0/7071 (0.00%) 01/7078 (0.01%) 1 Ulna fracture † 2 0/7071 (0.00%) 00/7078 (0.00%) 0 Hyperglycaemia 1/7071 (0.01%) 10/7078 (0.00%) 0 Fibromyalgia 0/7071 (0.00%) 01/7078 (0.01%) 2 Myalgia 1/7071 (0.01%) 10/7078 (0.00%) 0 Osteoarthritis 1/7071 (0.01%) 10/7078 (0.00%) 0 Neoplasms benign, malignant and unspecified (incl cysts and polyps) Acute lymphocytic leukaemia 1/7071 (0.01%) 10/7078 (0.00%) 0 Acute promyelocytic leukaemia 1/7071 (0.01%) 10/7078 (0.00%) 0 Adenocarcinoma gastric 0/7071 (0.00%) 01/7078 (0.01%) 1 Adenocarcinoma of the cervix 1/7071 (0.01%) 10/7078 (0.00%) 0 Brain neoplasm 1/7071 (0.01%) 10/7078 (0.00%) 0 Ependymoma 1/7071 (0.01%) 10/7078 (0.00%) 0 Leukaemic infiltration brain 1/7071 (0.01%) 10/7078 (0.00%) 0 Malignant melanoma 2/7071 (0.03%) 20/7078 (0.00%) 0 Malignant melanoma in situ 01/7071 (0.01%) 10/7078 (0.00%) 0 Malignant palate neoplasm 00/7071 (0.00%) 01/7078 (0.01%) 1 Nasal cavity cancer 1/7071 (0.01%) 10/7078 (0.00%) 0 Ovarian neoplasm 1/7071 (0.01%) 10/7078 (0.00%) 0

			Urticaria Abortion induced Vascular disorders Axillary vein thrombosis Deep vein thrombosis Hypovolaemic shock Nausea Injection site erythema Injection site pain Injection site pruritus Injection site swelling Pyrexia Infections and infestations Influenza Nasopharyngitis Dizziness Headache		Pituitary tumour benign 0/7071 (0.00%) 01/7078 (0.01%) 1 Respiratory papilloma 0/7071 (0.00%) 01/7078 (0.01%) 1 Thyroid cancer 0/7071 (0.00%) 01/7078 (0.01%) 1 Breast cancer 0/7071 (0.00%) 00/7078 (0.00%) 0 Glioma 0/7071 (0.00%) 00/7078 (0.00%) 0 Benign intracranial hypertension 0/7071 (0.00%) 01/7078 (0.01%) 1 Cerebral haemorrhage 0/7071 (0.00%) 01/7078 (0.01%) 1 Diabetic coma 1/7071 (0.01%) 10/7078 (0.00%) 0 Epilepsy 1/7071 (0.01%) 11/7078 (0.01%) 1 Facial paresis 0/7071 (0.00%) 01/7078 (0.01%) 1 Headache 0/7071 (0.00%) 01/7078 (0.01%) 1 Hydrocephalus 0/7071 (0.00%) 01/7078 (0.01%) 1 Hypersomnia 1/7071 (0.01%) 10/7078 (0.00%) 0 Hypoaesthesia 0/7071 (0.00%) 01/7078 (0.01%) 1 Intracranial venous sinus thrombosis 1/7071 (0.01%) 10/7078 (0.00%) 0 Migraine 1/7071 (0.01%) 10/7078 (0.00%) 0 Neuritis 0/7071 (0.00%) 01/7078 (0.01%) 1 Orthostatic intolerance 0/7071 (0.00%) 01/7078 (0.01%) 1 Presyncope 1/7071 (0.01%) 10/7078 (0.00%) 0 Sciatica 1/7071 (0.01%) 10/7078 (0.00%) 0 Sensory disturbance 1/7071 (0.01%) 10/7078 (0.00%) 0 Spondylitic myelopathy 0/7071 (0.00%) 01/7078 (0.01%) 1 Syncope 2/7071 (0.03%) 20/7078 (0.00%) 0 Tension headache 1/7071 (0.01%) 11/7078 (0.01%) 1 Trigeminal nerve disorder 0/7071 (0.00%) 00/7078 (0.00%) 0

					Pregnancy, puerperium and perinatal conditions Abortion spontaneous 36/7071 (0.51%) 3826/7078 (0.37%) 28 Abortion spontaneous complete 0/7071 (0.00%) 02/7078 (0.03%) 2 Abortion spontaneous incomplete 1/7071 (0.01%) 10/7078 (0.00%) 0 Blighted ovum 1/7071 (0.01%) 11/7078 (0.01%) 1 Cephalo-pelvic disproportion 4/7071 (0.06%) 46/7078 (0.08%) 6 Cervix dystocia 1/7071 (0.01%) 11/7078 (0.01%) 1 Ectopic pregnancy (in AE table) False labour 1/7071 (0.01%) 10/7078 (0.00%) 0 Foetal death 1/7071 (0.01%) 10/7078 (0.00%) 0 Foetal distress syndrome 4/7071 (0.06%) 41/7078 (0.01%) 1 Foetal malposition 0/7071 (0.00%) 01/7078 (0.01%) 1 Foetal malpresentation 0/7071 (0.00%) 01/7078 (0.01%) 1 Gestational diabetes (in AE table) Labour complication 1/7071 (0.01%) 10/7078 (0.00%) 0 Oligohydramnios 0/7071 (0.00%) 01/7078 (0.01%) 1 Pre-eclampsia 1/7071 (0.01%) 11/7078 (0.01%) 1 Premature labour (in AE table) Premature rupture of membranes 4/7071 (0.06%) 42/7078 (0.03%) 2 Prolonged labour 2/7071 (0.03%) 21/7078 (0.01%) 1 Uterine contractions during pregnancy 1/7071 (0.01%) 10/7078 (0.00%) 0 Anorexia and bulimia syndrome 1/7071 (0.01%) 10/7078 (0.00%) 0 Anorexia nervosa 0/7071 (0.00%) 01/7078 (0.01%) 1 Bipolar disorder 3/7071 (0.04%) 31/7078 (0.01%) 1 Completed suicide 1/7071 (0.01%) 10/7078 (0.00%) 0 Depression 0/7071 (0.00%) 01/7078 (0.01%) 1

					Major depression 1/7071 (0.01%) 10/7078 (0.00%) 0 Renal and urinary disorders Calculus ureteric 1/7071 (0.01%) 10/7078 (0.00%) 0 Calculus urinary 1/7071 (0.01%) 10/7078 (0.00%) 0 Cystitis haemorrhagic 0/310 (0.00%) 00/7071 (0.00%) 01/7078 (0.01%) 1 Nephrolithiasis 1/7071 (0.01%) 10/7078 (0.00%) 0 Renal failure 2/7071 (0.03%) 20/7078 (0.00%) 0 Renal failure acute 00/7071 (0.00%) 01/7078 (0.01%) 1 Renal colic 0/7071 (0.00%) 00/7078 (0.00%) 0 Reproductive system and breast disorders (in AE table) Respiratory, thoracic and mediastinal disorders Asthmatic crisis (in AE table) Dyspnoea 0/7071 (0.00%) 01/7078 (0.01%) 1 Nasal polyps 0/7071 (0.00%) 01/7078 (0.01%) 1 Pneumonia aspiration 1/7071 (0.01%) 10/7078 (0.00%) 0 Pneumothorax 1/7071 (0.01%) 10/7078 (0.00%) 0 Respiratory failure 1/7071 (0.01%) 10/7078 (0.00%) 0 Vocal cord polyp 1/7071 (0.01%) 10/7078 (0.00%) 0 Skin and subcutaneous tissue disorders Urticaria 0/7071 (0.00%) 00/7078 (0.00%) 0 Abortion induced 73/7071 (1.03%) 7653/7078 (0.75%) 53 Axillary vein thrombosis 0/7071 (0.00%) 01/7078 (0.01%) 1 Deep vein thrombosis 1/7071 (0.01%) 10/7078 (0.00%) 0 Hypovolaemic shock 2/7071 (0.03%) 20/7078 (0.00%) 0 Risk factors: Stratified by country/ethnicity and gender in (pooled) analyses: participants in Asian countries no safety concerns), Latin

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
					American girls, boys, and young women no safety concerns
Van Damme, 2016[226] Merck Sharp, 2014[316] NCT02114385 Article RCT N=500 Industry funded Belgium, Germany, and the Netherlands	Age: 21 (2.85) % female: 0% Ethnicity: Ethnicity NR Males aged >=16 to <27 years who were in good physical health and had a history of no more than five lifetime female and no male sexual partners Out of scope: None	HPV Gardasil 9 1.5 ML in 3 doses at day 1, month 2, and month 6 Intramuscular adjuvant NR preservative NR No co-intervention HPV HPV4 Gardasil 1.5 ML in 3 doses 1.5 ML in 3 doses at day 1, month 2, and month 6 Intramuscular adjuvant NRpreservative NR Counts No prespecified AE Power other outcome Followup: 7 months	Cytomegalovirus infection Concussion Foot fracture Joint dislocation Ligament injury Ligament rupture Injection-site erythema Injection-site pain Injection-site swelling Nasopharyngitis Headache Lymphadenopathy Pyrexia Fatigue Nausea Diarrhea Myalgia Dizziness Oropharyngeal pain	Death NA NA I: 0/248, NA NA C: 0/248	Severe AEs: Severe injection-site pain: Intervention 0/248 (0%) vs Control 0/248 (0%) Severe injection-site swelling (>5 cm): Intervention 1.2% vs Control 1.6% Serious AEs (from clinicaltrials.gov): Intervention (HPV9) vs Control (HPV4) Total 0/248 (0.00%) 6/248 (2.42%) Cytomegalovirus infection 0/248 (0.00%) 01/248 (0.40%) 1 Concussion 0/248 (0.00%) 01/248 (0.40%) 1 Foot fracture 0/248 (0.00%) 01/248 (0.40%) 1 Joint dislocation 0/248 (0.00%) 01/248 (0.40%) 1 Ligament injury 0/248 (0.00%) 01/248 (0.40%) 1 Ligament rupture 0/248 (0.00%) 01/248 (0.40%) 1 Risk factors: NR

Baxter, 2017[61] MedImmune LLC, 2014[307] NCT01985997 Article Cohort study N=181028 Industry funded USA	Age: 88% were 2-17 years old % female: 53% Ethnicity: Ethnicity NR All Q/LAIV recipients aged 2–49 years at the time of vaccination during influenza season 2013–2014 who had been members in the KPNC health care plan for at least 12 months prior to vaccination and at least 6 months after immunization, as wel as frequency matched controls who received IIV or no flu vaccine Out of scope: None	Influenza LAIV FluMist Quadrivalent Intranasal adjuvant NR preservative NR No co-intervention No intervention No influenza vaccine (note there is also a TIV group, results are included in the text field) Analytic study Prespecified AE Power calculation Followup: 6 months	Hypersensitivity Seizures/convulsions Lower respiratory tract infection Wheezing Guillain-Barré syndrome Bell's palsy Encephalitis Neuritis Vasculitis Any hospitalization Respiratory hospitalization (Respiratory hospitalizations included pneumonia, influenza, empyema, chronic obstructive pulmonary disease, chronic bronchitis, emphysema, asthma, bronchiectasis, or other diseases of the respiratory system)	Encephalitis: 11.X Within 1-42 days I: 0/62040, 11.X Within 1-42 days (and none in TIV cohort) C: 0/61803 Guillain-Barré syndrome: 10.X Within 1-42 days I: 0/62040, 10.X Within 1-42 days (and none in TIV cohort) C: 0/61803	Within-Q/LAIV cohort analysis adjusted HR (95% CI): Days 0–3 risk interval vs Days 7–9 reference period: Hypersensitivity 0.81 (0.39–1.66) Seizures/convulsions NE Days 1–14 risk interval vs Days 15–29 reference period Lower respiratory tract infection 0.84 (0.55–1.28) Wheezing 0.75 (0.45–1.24) Guillain-Barré syndrome NE Bell's palsy NE Encephalitis NE Neuritis 1.13 (0.36–3.60) Vasculitis NE Any hospitalization 0.76 (0.35–1.65) Respiratory hospitalization NE Days 1–42 risk interval vs Days 43–84 reference period: Lower respiratory tract infection 0.77 (0.58–1.02) Wheezing 0.82 (0.59–1.14) Guillain-Barré syndrome NE Bell's palsy NE Encephalitis NE Neuritis 0.44 (0.17–1.17) Vasculitis NE Any hospitalization 0.60 (0.31–1.16) Respiratory hospitalization NE Between cohort analysis adjusted HR (95% CI): Hypersensitivity 0–3 days: Q/LAIV vs unvaccinated 0.52 (0.27–1.03); Q/LAIV vs IIV 1.32 (0.58–2.97) Seizures/convulsions 0-3 days: Q/LAIV vs unvaccinated NE; Q/LAIV vs IIV NE Lower respiratory tract infection 1-42 days: Q/LAIV vs unvaccinated 0.61 (0.50–0.75); Q/LAIV vs IIV 1.00 (0.80–1.25) Wheezing 1-42 days: Q/LAIV vs unvaccinated 0.66 (0.52–0.84); Q/LAIV vs IIV 1.20 (0.92–1.57) Guillain-Barré syndrome 1-42 days: Q/LAIV vs unvaccinated NE; Q/LAIV vs IIV NE Bell's palsy 1-42 days: Q/LAIV vs unvaccinated NE; Q/LAIV vs IIV NE

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
					Encephalitis 1-42 days: Q/LAIV vs unvaccinated NE; Q/LAIV vs IIV NE Neuritis 1-42 days: Q/LAIV vs unvaccinated 1.05 (0.53–2.06); Q/LAIV vs IIV 1.29 (0.60–2.79) Vasculitis 1-42 days: Q/LAIV vs unvaccinated NE; Q/LAIV vs IIV NE Any hospitalization 1-42 days: Q/LAIV vs unvaccinated 0.35 (0.24–0.50); Q/LAIV vs IIV 0.76 (0.50–1.15) Respiratory hospitalization 1-42 days: Q/LAIV vs unvaccinated 0.28 (0.08–1.01); Q/LAIV vs IIV 0.85 (0.17–4.23) Risk factors: Compared to other age groups, children aged 2-4 years had significantly lower risk of wheezing (aHR 0.67; CI 0.48, 0.92), lower respiratory tract infection (aHR 0.69; CI 0.51, 0.93), and hospitalization (aHR 0.39; CI 0.18, 0.87) when comparing LAIV to IIV. This effect was not observed for the within cohort analysis, nor when comparing LAIV to no vaccine, neither of which were significant (though both with aHR less than 1). Children aged 5-9 years who received LAIV had lower risk of lower respiratory tract infection (aHR 0.55; CI 0.39, 0.79) and hospitalization (aHR 0.12; CI 0.03, 0.54) compared to IIV and lower risk of hospitalization (aHR 0.14; CI 0.03, 0.63) when compared to no vaccine. Adolescents aged 9-17 years had lower risk of wheezing (aHR 0.51; CI 0.27, 0.96) and lower respiratory tract infection (0.57; CI 0.35, 0.93) when comparing LAIV to IIV. Among adults aged 18-49 years, LAIV was associated with significant decrease in risk of hospitalization (aHR 0.33, CI 0.13–0.87 when comparing to no vaccine and aHR 0.13, CI 0.06–0.30 when comparing to IIV), except for the within cohort analysis.

Anez, 2020[56] Hedrick, 2019[284]; Sanofi Pasteur a Sanofi Company, 2016[366] NCT02752906 Article RCT N=810 Industry funded USA	Age: 20.0 (5.77) % female: 50% Ethnicity: 84% White, 2% Asian, 11% Black, <1% American Indian or Alaska Native, <1% Native Hawaiian or other Pacific Islander, 3.1% Mixed origin Healthy adolescents and adults aged ≥15 y who had documented evidence of receiving one dose of an MCV4 vaccine (MCV4-DT or MCV4-CRM) at age 10 y or older, 4–10 y previously Out of scope: None	Men quadrivalent MenQuadFi [MenACWY-TT] 10 µg of meningococcal capsular polysaccharides from each serogroup (A, C, Y, and W) conjugated to approximately 55 µg of tetanus toxoid protein carrier. 10 µg in 1 0.5ml dose Intramuscular adjuvant free preservative NR No co-intervention Meningococcal conjugate MCV4 Menactra 4 µg in 1 0.5 ml dose Intramuscular adjuvant freepreservative NR Counts No prespecified AE Power other outcome Followup: 6 months	Intestinal perforation Chest pain Cholelithiasis Allergy to arthropod sting Appendicitis Clavicle fracture Major depression Suicidal ideation Pulmonary embolism Injection site pain Malaise Myalgia Headache	Death NA NA I: 0/402, NA NA C: 0/407	Severe AEs: Grade 3 solicited reaction within 7 days: 20/398 (5.05%. 3.1, 7.7) vs 22/402 (5.5%, 3.5, 8.2) Grade 3 solicited injection site reaction within 7 days: 4/298 (1.0%, 0.3-2.6) vs 8/402 (2.0%, 0.9-3.9) Grade 3 solicited systemic reaction within 7 days: 20/398 (5.0%, 3.1-7.7) vs 20/402 (5.0%, 3.1-7.6) Grade 3 immediate unsolicited non-serious AE within 30 days: 0 (0.0%, 0.0-0.9) vs 0 (0.0%, 0.0-0.9) Grade 3 immediate unsolicited non-serious AR within 30 days: 0 (0.0%, 0.0-0.9) vs 0 (0.0%, 0.0-0.9) Grade 3 unsolicited non-serious AE within 30 days: 15 (3.7%, 2.1-6.1) vs 18 (4.4%, 2.6-6.9) Grade 3 unsolicited non-serious AR within 30 days: 0 (0.0%, 0.0-0.9) vs 2 (0.5%, 0.1-1.8) Grade 3 unsolicited non-serious injection site AR within 30 days: 0 (0.0%, 0.0-0.9) vs 1 (0.2% 0.0-1.4) Grade 3 unsolicited non-serious systemic AE within 30 days: 15 (3.7%, 2.1-6.1) vs 17 (4.2% (2.5-6.6) Grade 3 unsolicited non-serious systemic AR within 30 days: 0 (0.0%, 0.0-0.9) vs 1 (0.2%, 0.0-1.4) Serious AEs (from clinicaltrials.gov): Total 5/402 (1.24%) 4/407 (0.98%) Intestinal Perforation 0/402 (0.00%) 1/407 (0.25%) Chest Pain 0/402 (0.00%) 1/407 (0.25%) Cholelithiasis 1/402 (0.25%) 0/407 (0.00%) Allergy To Arthropod Sting 1/402 (0.25%) 0/407 (0.00%) Appendicitis 1/402 (0.25%) 0/407 (0.00%) Clavicle Fracture 1/402 (0.25%) 0/407 (0.00%) Major Depression 0/402 (0.00%) 1/407 (0.25%) Suicidal Ideation 0/402 (0.00%) 1/407 (0.25%)

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
					Pulmonary Embolism 1/402 (0.25%) 0/407 (0.00%) Risk factors: NR

Dhingra, 2020[93] Sanofi Pasteur, 2017[355]; Peterson, 2019[338]; Peterson, 2019[339]; Simon, 2019[375] NCT02842853 Article RCT N=3344 Industry funded USA	Age: 27.0 (15.6) % female: 57% Ethnicity: 22% Hispanic or Latino; <1% American Indian or Alaska Native, 2% Asian, <1% Native Hawaiian or Other Pacific Islander, 19% Black or African American, 74% White, 3% More than one race, <1% Unknown or Not Reported Children and adults aged 10 to 55 years in 90 centers in the United States (US) from 15 July 2016 to 16 August 2016. Out of scope: None	Men quadrivalent MenQuadFi [MenACWY-TT] 0.5 mL in one dose Intramuscular adjuvant NR preservative NR No co-intervention Meningococcal conjugate MenACWY-D Menactra 0.5 mL in one dose Intramuscular adjuvant NRpreservative NR Counts No prespecified AE Power NR Followup: 6 months	Anaphylaxis Coronary artery disease Gastrointestinal ulcer perforation Pancreatitis acute Chest pain Cholelithiasis Abdominal abscess Appendicitis Appendicitis perforated Gastroenteritis norovirus Pneumonia pseudomonal Pyelonephritis Craniocerebral injury Foot fracture Diabetes mellitus inadequate control Type 2 diabetes mellitus Back pain Uterine leiomyoma Alcoholic seizure Migraine Multiple sclerosis Paraesthesia Presyncope Status epilepticus Abortion spontaneous Abortion spontaneous incomplete Conversion disorder Depression Disruptive mood dysregulation disorder Somatic symptom disorder Suicidal ideation Nephrolithiasis Asthma Chronic obstructive pulmonary disease Throat tightness Henoch-schonlein purpura Injection site erythema Injection site pain Malaise Myalgia Headache	Anaphylaxis: 10.X I: 0/2676, 10.X C: 0/635 Asthma: 22.X Not vaccine-related I: 1/2676, 22.X NA, C: 0/635 Autoimmune disease: 10.X Henoch-Schonlein purpura I: 0/2676, 10.X Henoch-Schonlein purpura, not vaccine-related C: 1/635 Cardiovascular events: 2.X Coronary artery disease, not vaccine-related I: 1/2676 2.XCoronary artery disease, C: 0/635 Death NA NA I: 0/2676, NA NA C: 0/635 Diabetes: 14.X Type 2 diabetes mellitus, not vaccine-related I: 1/2676, 14.X Type 2 diabetes mellitus C: 0/635 Multiple Sclerosis: 17.X Not vaccine-related I: 1/2676, 17.X NA C: 0/635 Seizure: 17.4 Status epilepticus, not vaccine-related I: 1/2676, 17.X Status epilepticus C: 0/635 Spontaneous abortion: 18.X Not vaccine-related I: 1/2676, 18.X NA C: 0/635	All-Cause Mortality: MenQuadFi Lot 1 vs MenQuadFi Lot 2 vs MenQuadFi Lot 3 vs Menactra Affected / at Risk (%)Affected / at Risk (%)Affected / at Risk (%)Affected / at Risk (%) Total 0/895 (0.00%) 0/883 (0.00%) 0/898 (0.00%) 0/635 (0.00%) (in AE table with first 3 groups merged) Serious AEs (from clinical trials.gov): MenQuadFi Lot 1MenQuadFi Lot 2MenQuadFi Lot 3Menactra Affected / at Risk (%)Affected / at Risk (%)Affected / at Risk (%)Affected / at Risk (%) Total 9/895 (1.01%) 13/883 (1.47%) 6/898 (0.67%) 5/635 (0.79%) Cardiac disorders Coronary artery disease 0/895 (0.00%) 1/883 (0.11%) 0/898 (0.00%) 0/635 (0.00%) (in AE table with first 3 groups merged) Gastrointestinal disorders Gastrointestinal ulcer perforation 0/895 (0.00%) 0/883 (0.00%) 1/898 (0.11%) 0/635 (0.00%) Pancreatitis acute 1/895 (0.11%) 0/883 (0.00%) 0/898 (0.00%) 0/635 (0.00%) General disorders Chest pain 1/895 (0.11%) 1/883 (0.11%) 0/898 (0.00%) 0/635 (0.00%) Hepatobiliary disorders Cholelithiasis 0/895 (0.00%) 0/883 (0.00%) 1/898 (0.11%) 0/635 (0.00%) Infections and infestations Abdominal abscess 0/895 (0.00%) 0/883 (0.00%) 1/898 (0.11%) 0/635 (0.00%) Appendicitis 1/895 (0.11%) 2/883 (0.23%) 0/898 (0.00%) 0/635 (0.00%) Appendicitis perforated 0/895 (0.00%) 1/883 (0.11%) 0/898 (0.00%) 0/635 (0.00%) Gastroenteritis norovirus 0/895 (0.00%) 0/883 (0.00%) 0/898 (0.00%) 1/635 (0.16%) Pneumonia pseudomonal 1/895 (0.11%) 0/883 (0.00%) 0/898 (0.00%) 0/635 (0.00%)

					Pyelonephritis 1/895 (0.11%) 0/883 (0.00%) 0/898 (0.00%) 0/635 (0.00%) Injury, poisoning and procedural complications Craniocerebral injury 0/895 (0.00%) 1/883 (0.11%) 0/898 (0.00%) 0/635 (0.00%) Foot fracture 1/895 (0.11%) 0/883 (0.00%) 0/898 (0.00%) 0/635 (0.00%) Metabolism and nutrition disorders Diabetes mellitus inadequate control 0/895 (0.00%) 0/883 (0.00%) 0/898 (0.00%) 1/635 (0.16%) Type 2 diabetes mellitus 1/895 (0.11%) 0/883 (0.00%) 0/898 (0.00%) 0/635 (0.00%) (in AE table with first 3 groups merged) Musculoskeletal and connective tissue disorders Back pain 0/895 (0.00%) 1/883 (0.11%) 0/898 (0.00%) 0/635 (0.00%) Neoplasms benign, malignant and unspecified (incl cysts and polyps) Uterine leiomyoma 1/895 (0.11%) 0/883 (0.00%) 0/898 (0.00%) 0/635 (0.00%) Nervous system disorders Alcoholic seizure 0/895 (0.00%) 1/883 (0.11%) 0/898 (0.00%) 0/635 (0.00%) Migraine 0/895 (0.00%) 0/883 (0.00%) 1/898 (0.11%) 0/635 (0.00%) Multiple sclerosis 0/895 (0.00%) 1/883 (0.11%) 0/898 (0.00%) 0/635 (0.00%) (in AE table with first 3 groups merged) Paraesthesia 1/895 (0.11%) 0/883 (0.00%) 0/898 (0.00%) 0/635 (0.00%) Presyncope 0/895 (0.00%) 0/883 (0.00%) 1/898 (0.11%) 0/635 (0.00%) Status epilepticus 0/895 (0.00%) 1/883 (0.11%) 0/898 (0.00%) 0/635 (0.00%) (in AE table with first 3 groups merged) Pregnancy, puerperium and perinatal conditions Abortion spontaneous 0/895 (0.00%) 1/883 (0.11%) 0/898 (0.00%) 0/635 (0.00%) (in AE table with first 3 groups merged) Abortion spontaneous incomplete 0/895 (0.00%) 1/883 (0.11%) 0/898 (0.00%) 0/635 (0.00%)

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
					Psychiatric disorders Conversion disorder 0/895 (0.00%) 0/883 (0.00%) 1/898 (0.11%) 0/635 (0.00%) Depression 0/895 (0.00%) 1/883 (0.11%) 0/898 (0.00%) 0/635 (0.00%) Disruptive mood dysregulation disorder 0/895 (0.00%) 0/883 (0.00%) 0/898 (0.00%) 1/635 (0.16%) Somatic symptom disorder 0/895 (0.00%) 1/883 (0.11%) 0/898 (0.00%) 0/635 (0.00%) Suicidal ideation 0/895 (0.00%) 0/883 (0.00%) 1/898 (0.11%) 0/635 (0.00%) Renal and urinary disorders Nephrolithiasis 0/895 (0.00%) 0/883 (0.00%) 0/898 (0.00%) 1/635 (0.16%) Respiratory, thoracic and mediastinal disorders Asthma 1/895 (0.11%) 0/883 (0.00%) 0/898 (0.00%) 0/635 (0.00%) (in AE table with first 3 groups merged) Chronic obstructive pulmonary disease 1/895 (0.11%) 0/883 (0.00%) 0/898 (0.00%) 0/635 (0.00%) Throat tightness 0/895 (0.00%) 0/883 (0.00%) 0/898 (0.00%) 1/635 (0.16%) Skin and subcutaneous tissue disorders Henoch-Schonlein purpura 0/895 (0.00%) 0/883 (0.00%) 0/898 (0.00%) 1/635 (0.16%) (in AE table with first 3 groups merged) Risk factors: NR

Hansen, 2017[128] Sanofi Pasteur a Sanofi Company, 2005[358] NCT00254995 Article Other design N=62626 Industry funded USA	Age: Younger than 11: 0.3%, 11-16: 68.3% ; 17-18: 25.7%; 19-29:2.8%; 30-55: 2.6%; older than 55: 0,2% % female: 50% Ethnicity: Caucasian: 40%; Hispanic: 18%; Asian: 12%; Black: 10%; Native American: 0.4%; mixed: 3% 11–55-year-old patients who received the vaccine as part of routine clinical care in KPNC Out of scope: None	Men quadrivalent Menactra [MenACWY-D] Route NR adjuvant NR preservative NR No co-intervention No intervention Self-controlled case series or matched controls Analytic study No prespecified AE Power NR Followup: 6 months	Bell's palsy (prespecified) Seizure (prespecified) Neuritis (prespecified) Guillain-Barré syndrome (prespecified) Encephalopathy (prespecified) Encephalitis (prespecified) Epilepsy (prespecified) Transverse myelitis (prespecified) Hypersensitivity reactions (including urticaria, angioedema, and anaphylaxis) (prespecified) New-onset autoimmune disease (including idiopathic thrombocytopenic purpura, diabetes, arthritis, hemolytic anemia, and collagen-vascular disease) (prespecified) Mortality (prespecified) Idiopathic thrombocytopenic purpura (precedes) Splenomegaly Arrhythmia Congenital anomaly Congenital heart disease Sickle cell disease Pectus excavatum Abdominal pain Constipation Diarrhea Gastrooesophageal reflux Pancreatitis Tooth disorder (dental) Cyst Febrile illness Cholelithiasis Fatty liver Transplant rejection Abscess/cellulitis Appendicitis Gastroenteritis	NA	Summary of Significantly Elevated Findings IRR (95% CI): ED Short-term risk interval All ages combined Abdominal pain: 1.91 (1.05, 2.56) p=0.03 ED Short-term risk interval 11–16 years old Abdominal pain: 2.83 (1.29, 6.72) p=<0.01 ED Long-term matched 11–16 years old Diabetes, type 1 (prior onset): NE (1.22, NE) p=0.03 ED Long-term matched 11–16 years old Difficulty breathing/shortness of breath: 4.50 (1.07, 30.57) p=0.04 Hospital Long-term matched All ages combined Elective procedure: 2.15 (1.20, 3.98) p<0.01 Hospital Long-term matched 11–16 years old Elective procedure: 3.13 (1.45, 7.38) p<0.01 ED Short-term risk interval All ages combined Febrile illness: 11.80 (2.04, 254.6) p<0.01 ED Short-term risk interval 11–16 years old Febrile illness: 6.88 (1.06, 156.3) p=0.04 ED Long-term matched All ages combined Febrile illness: 1.93 (1.18, 3.20) p<0.01 ED Long-term matched 11–16 years old Febrile illness: 1.93 (1.04, 3.70) p=0.04 ED Long-term matched All ages combined Genital pain: NE (1.20, NE), p=0.03 Clinic Long-term matched 11–16 years old Hives/urticaria: 1.70 (1.09, 2.70) p=0.02 ED Long-term matched All ages combined Hyperglycemia: NE (1.52, NE) p=0.02 ED Long-term matched All ages combined Mononucleosis: NE (1.20, NE) p=0.03 ED Long-term matched 17–18 years old Mononucleosis: NE (1.13, NE) p=0.04 ED Long-term matched 11–16 years old Otitis externa: NE (1.22, NE) p=0.03 ED Short-term risk interval All ages combined Suicidal ideation/attempt: NE (1.52, NE) p=0.02

			Pneumonia Urinary tract infection Aseptic meningitis Encephalitis due to epstein-barr virus Viral syndrome Pelvic inflammatory disease Pharyngitis Labyrinthitis Osteomyelitis Respiratory syncytial virus infection Tonsillitis Toxic shock syndrome Pneumocystosis Injury, poisoning and procedural complications Complications of transplanted organ Foreign body Poisoning/ingestion Trauma Dehydration Diabetes, type 1 (new onset) Diabetes, type 1 (prior onset) Femoral epiphysiolysis Kyphosis Systemic lupus erythematosus (new dx, symptoms precede) Systemic lupus erythematosus (prior onset) Scoliosis Temporomandibular joint disorder Cancer, cervix Cancer, melanoma Cancer, ovarian Cancer, pancreatic Benign lesion nos Cancer, r/o cancer Hodgkin's disease Lymphocytic leukemia (chronic, precedes) Idiopathic polycystic splenomegaly		ED Short-term risk interval 11–16 years old Suicidal ideation/attempt: NE 1.20, NE) p=0.03 Hospital Long-term matched All ages combined Tympanic perforation: NE (1.20, NE) p=0.03 ED Long-term matched All ages combined Vomiting: 1.83 (1.08, 3.16) p=0.02 ED Long-term matched 11–16 years old Vomiting: 2.09 (1.03, 4.46) p=0.04 Summary of significantly decreased findings (all Long-term matched) IRR (95% CI): ED 30–55 years old Abdominal pain: 0.11 (0.00, 0.67) p=0.01 ED All ages combined Abscess/cellulitis: 0.47 (0.28, 0.78) p<0.01 ED 11–16 years old Abscess/cellulitis: 0.41 (0.16, 0.97) p=0.04 ED All ages combined Allergic reaction: 0.18 (0.03, 0.72) p=0.01 ED 11–16 years old Allergic reaction: 0.00 (0.00, 0.82) p=0.03 ED All ages combined Allergy, drug: 0.00 (0.00, 0.81) p=0.03 Hospital All ages combined Benign lesion: 0.51 (0.31, 0.85) p<0.01 Hospital 11–16 years old Benign lesion: 0.43 (0.21, 0.83) p=0.01 Hospital All ages combined Congenital anomaly: 0.57 (0.32 0.99) p=0.05 Hospital 11–16 years old Congenital anomaly: 0.41 (0.19, 0.81) p<0.01 Hospital All ages combined Cyst: 0.41 (0.17, 0.93) p=0.03 Hospital 11–16 years old Cyst: (0.33 (0.09, 1.00) p=0.05 ED All ages combined Fatigue: 0.14 (0.01, 0.91) p=0.04 ED All ages combined Insect bite: 0.22 (0.03, 0.92) p=0.04 ED All ages combined Musculoskeletal pain: 0.68 (0.48, 0.99) p=0.05 ED All ages combined Pelvic pain: 0.13 (0.02, 0.50) p<0.01 ED 17-18 years old Pelvic pain: 0.00 (0.00, 0.42) p<0.01

			Nervous system disorders Encephalitis Cranial nerve palsy Chronic inflammatory demyelinating polyneuritis (prior onset) Epilepsy (hx of seizure disorder, possible seizure) Epilepsy (seizure event, w/hx of seizure disorder) Horner's syndrome Hydrocephalus Migraine Syncope/loc Delirium tremens Psychiatric Suicidal ideation/attempt Acute renal failure Renal calculus End-stage renal disease Reproductive system and breast disorders Pregnancy Pregnancy - stillborn delivery post prolapsed cord Testicular torsion Asthma/rad Asphyxiation Chronic obstructive pulmonary disease Pneumothorax Pulmonary embolism Sleep apnea Elective procedure Inguinal hernia/repair Hypertension		Hospital All ages combined Poisoning/ingestion: 0.23 (0.05, 0.74) p=0.01 ED All ages combined Postoperative complication: 0.08 (0.00, 0.47) p<0.01 Hospital All ages combined Postoperative complication: 0.12 (0.01, 0.77) p=0.02 ED 17-18 years old Postoperative complication: 0.13 (0.01, 0.85) p=0.03 Hospital All ages combined Pregnancy - delivery:).00 (0.00, 0.64) p=0.01 ED All ages combined Psychiatric: 0.63 (0.48, 0.83) p<0.01 Hospital All ages combined Psychiatric: 0.57 (0.41, 0.87) p<0.01 Hospital 11-16 years old Psychiatric: 0.62 (0.42, 0.91) p=0.02 ED 17-18 years old Psychiatric: 0.32 (0.19, 0.52) p<0.01 Hospital 17-18 years old Psychiatric: 0.50 (0.28, 0.87) p=0.01 ED All ages combined Testicular pain: 0.10 (0.00, 0.59) p<0.01 ED 11-16 years old Testicular pain: 0.12 (0.01, 0.78) p=0.02 Hospital All ages combined Tonsillitis: 0.30 (0.17, 0.52) p<0.01 Hospital 11–16 years old Tonsillitis: 0.33 (0.16, 0.65) p<0.01 ED 17–18 years old Tonsillitis: 0.18 (0.03, 0.76) p=0.02 Hospital 17–18 years old Tonsillitis: 0.26 (0.09, 0.66) p<0.01 ED All ages combined Trauma: 0.73 (0.67, 0.81) p<0.01 ED 11–16 years old Trauma: 0.83 (0.74, 0.94) p<0.01 ED 17–18 years old Trauma: 0.69 (0.56, 0.83) p<0.01 ED 19–29 years old Trauma: 0.32 (0.18, 0.55) p<0.01 Hospital 19–29 years old Trauma: 0.00 (0.00, 0.60) 0.01 ED 30–55 years old Trauma: 0.27 (0.15, 0.50) p<0.01 Hospital 30–55 years old Trauma: 0.00 (0.00, 0.82) p=0.03 Hospital All ages combined Vision disorder: 0.22 (0.03, 0.92) p=0.04

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
					ED All ages combined Well care/reassurance/FU: 0.29 (0.15, 0.53) p<0.01 ED 11–16 years old Well care/reassurance/FU: 0.29 (0.11, 0.68) p<0.01 ED 17–18 years old Well care/reassurance/FU: 0.27 (0.09, 0.71) p<0.01 Risk factors: NR
Lee, 2014[157] Novartis Vaccines, 2010[328] NCT01274897 Article RCT N=450 Industry funded South Korea	Age: Treatment 19.6 (9.2); Control 19.3 (8.9) % female: 48% Ethnicity: 100% Asian Healthy people 11-55-years-old Out of scope: None	Men quadrivalent Menveo [MenACWY-CRM] 0.5 ml in 1 dose (10 mg of MenA oligosaccharide and 5 mg each of oligosaccharides from MenC, MenW, and MenY conjugated to CRM197) Intramuscular adjuvant free preservative free No co-intervention Placebo Saline placebo Counts No prespecified AE Power other outcome Followup: 1 months	Nausea Chills Injection site erythema Injection site induration Injection site pain Malaise Myalgia Headache Arthralgia Rash Fever	Death NA NA I: 0/297, NA NA C: 0/153	Serious AEs: No serious AEs in either intervention or control group. Severe AEs: Format - AE name: Treatment event N/treatment N (%), Control event N/control N (%) Pain, Severe: 0/297 (0%); 0/153 (0%) Erythema (mm) > 100mm: 8/297 (3%); 0/153 (0%) Induration (mm) > 100mm: 4/297 (1%); 0/153 (0%) Chills Severe: 0/297 (0%); 0/153 (0%) Nausea Severe: 1/297 (<1%); 0/153 (0%) Myalgia Severe: 0/297 (0%); 0/153 (0%) Arthralgia Severe: 0/297 (0%); 0/153 (0%) Headache Severe: 1/297 (<1%); 0/153 (0% Rash Severe: 0/297 (0%); 0/153 (0%) Fever (above 38 degrees C): 3/297 (3%); 1/153 (1%) Risk factors: NR

Tseng, 2017[220] Article Case-Control N=1127 Industry funded USA	Age: 15.0 (3.4) % female: 52% Ethnicity: 49% Hispanic, 30% Caucasian, 9% African American, 6% Asian, <1% Native American, 1% Pacific Islander, 1% Multiple, 1.1% other, 3% Unknown Vaccinated members of Kaiser Permanente Southern California aged 11 to 21 years Out of scope: None	Men quadrivalent Menveo [MenACWY-CRM] 1 dose Route NR adjuvant NR preservative NR No co-intervention No intervention Control was comparison period (compared to risk period after vaccination) Counts Prespecified AE Power NR Followup: 12 months	Bell's palsy Multiple sclerosis Guillain-Barre syndrome Acute disseminated encephalomyelitis Cerebellar ataxia Transverse myelitis Brachial neuritis Myasthenia gravis Systemic lupus erythematosus Rheumatoid arthritis Henoch-Schonlein purpura Juvenile diabetes mellitus Graves' disease Acute glomerulonephritis Nephrotic syndrome Meningococcal disease Seizure Seizure (chart reviewed) Iridocyclitis (uveitis) Iridocyclitis (uveitis) (chart reviewed) Hashimoto disease Hashimoto disease (chart reviewed) Anaphylaxis Anaphylaxis (chart reviewed) Idiopathic thrombocytopenic purpura Autoimmune hemolytic anemia Aseptic meningitis Asthma Allergic urticaria Suicide attempt	NA	Self-controlled case-series (N in risk window, N in comparison window, adjusted Relative Incidence, 95% CI) Committee reviewed AEs: Bell's palsy: 8 vs 10, 2.9 (1.1-7.5) Multiple sclerosis: 0 vs 2, NE Transverse myelitis: 0 vs 1, NE Rheumatoid arthritis: 0, vs 3, NE Henoch-Schonlein purpura: 0 vs 1, NE Juvenile diabetes mellitus: 3 vs 8, 1.2 (0.3-4.7) Graves' disease: 1 vs 6 1.1 (0.1-10.0) Acute glomerulonephritis: 1 vs 0, NE Nephrotic syndrome: 0 vs 1, NE Non committee reviewed AEs: Seizure: 9 vs 72, 2.9(1.5-5.9) Seizure (chart reviewed): 0 vs 25, NE Iridocyclitis (unveitis): 5 vs 13, 3.1 (1.1-8.7) Iridocyclitis (unveitis, chart reviewed): 4 vs 10 (3.4, 1.02-1.12) Hashimoto disease: 13 vs 8, 5.5 (2.3-13.3) Hashimoto disease (chart reviewed): 2 vs 3, 5.1 (0.5-55.0) Anaphylaxis: 2 vs 10, 5.5(1.1-26.2) Anaphylaxis (chart reviewed: 0 vs 4, NE ITP: 1 vs 1, NE Autoimmune hemolytic anemia: 0 vs 1, NE Aseptic meningitis: 0 vs 4, NE Asthma: 206 vs 635, 1.1(0.9-1.3) Allergic urticaria: 2 vs 27, 1.8 (0.4-7.4) Suicide attempt: 9 vs 64, 1.1(0.5-2.2) Total: 260 vs 867 Stratified analyses demonstrated an increased risk for Bell's palsy in subjects receiving concomitant vaccines (RI = 5.0, 95% CI = 1.4–17.8), and no increased risk for those without concomitant vaccine (RI = 1.1, 95% CI = 0.2–5.5). Occurred primarily 5-10 weeks post-vaccination. Risk factors: Stratified analyses demonstrated an increased risk for Bell's palsy in subjects receiving concomitant vaccines (RI = 5.0, 95% CI = 1.4–17.8), and no increased risk for those without concomitant vaccine (RI = 1.1, 95% CI = 0.2–5.5).

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
Naleway, 2018[173] Article Cohort study N=46 Not industry funded USA	Age: Age at diagnosis of primary ovarian insufficiency: 2% 11-14 years; 11% 15-18 years; 9% 19-22 years; 15% 23-26 years; 28% 27-30 years; 35% 31-34 years % female: 100 Ethnicity: 61% White, 11% Multiracial or people of color; 28% Unknown Female patients 11 to 34 years of age with at least 30 days of health plan enrollment at KPNW from August 1, 2006, to December 31, 2014 Out of scope: None	Men quadrivalent,Tdap Brand NR NR NR Route NR adjuvant NR preservative NR Co-intervention Presumably may have received routine vaccines together No intervention Analytic study Prespecified AE Power calculation Followup: 276 months	Primary ovarian insufficiency	NA	Risk of primary ovarian failure Tdap: Unadjusted HR 0.78 (0.34–1.84); Age-adjusted HR 0.88 (0.37–2.10) MenACWY: Unadjusted HR 0.70 (0.24–2.03); Age-adjusted HR 0.94 (0.27–3.23) Risk factors: No

Ostergaard, 2016[178] Pfizer, 2012[347] NCT01352793 Article RCT N=5712 Industry funded Australia, Chile, Czech Republic, Denmark, Estonia, Finland, Germany, Lithuania, Poland, Spain, Sweden, USA	Age: Intervention: 17 (5), Control: 17 (5) % female: Intervention: 52%, Control: 52% Ethnicity: Intervention: 88% White, 9% Black, 2% Asian, 1% Other, Control: 89% White, 9% Black, 2% Asian, 1% Other Healthy males or females ≥10 to <26 years of age at enrollment available for the entire study period. Sexually active subjects of childbearing potential had to agree to use a highly effective method of contraception throughout the study. Key exclusion criteria were receipt of a previous MnB or HAV vaccine, contraindication for HAV vaccination, scheduled to receive ≥1 dose of human papillomavirus vaccine between visit 1 and 28 days after vaccination 2, experienced a	MenB Trumenba [MenB-FHbp] Only comparing dose 2 (to placebo) 0.5 mL Intramuscular adjuvant NR preservative NR No co-intervention Placebo Saline placebo at dose 2 Counts No prespecified AE Power other outcome Followup: 1 months	Neutropenia Autoimmune thyroiditis Hyperprolactinaemia Hypothalamo-pituitary disorder Abdominal pain Constipation Duodenal perforation Duodenal ulcer perforation Enteritis Biliary dyskinesia Allergy to arthropod sting Anaphylactic reaction Drug hypersensitivity Appendicitis Gastroenteritis Peritonsillar abscess Meningitis viral Abdominal abscess Acute tonsillitis Breast abscess Carbuncle Cellulitis Cystitis Gastrointestinal viral infection Meningitis enterococcal Meningitis enteroviral Pertussis Pilonidal cyst Pneumonia Postoperative wound infection Rectal abscess Salpingitis Tick-borne viral encephalitis Pyelonephritis Concussion Intentional overdose Cartilage injury Clavicle fracture Contusion Craniocerebral injury Fibula fracture Forearm fracture Gun shot wound Head injury Heat stroke	NA	Note: Doses 1 and 3 of MenB were compared to HAV. Analyses below are restricted to comparisons within 30 days of Men B dose 2 (which was against saline placebo): Any AEs: MenB 31.5% vs Placebo 19.0% One or more serious AEs within 30 days of vaccine dose 2: MenB 6/3529 (0.2%) vs Placebo 8/1806 (0.4%), p=0.087 One or more medically attended AEs within 30 days of vaccine dose 2: MenB 194/3529 (5.5) vs Placebo 110/1806 (6.1%), p=0.383 Newly diagnosed chronic medical condition within 30 days of vaccine dose 2: MenB 6/3529 (0.2%) vs Placebo 6/1806 (0.3%), p=0.238 One or more reactogenicity events (severe) within 7 days of dose 2: MenB 3/3529 (0.9%) vs Placebo 0/1806 (0.0%), p0.556 One or more AEs within 30 days of dose 2: MenB 719/3529 (20.4%) vs Placebo 223/1806 (12.4%), p<0.001 One or more AEs within 30 days of dose 2, excluding reactogenicity events: MenB 362/3529 (10.3%) vs Placebo 183/1806 (10.1%), p 0.924 Risk factors: NR

	previous anaphylactic reaction to any vaccine or vaccine-related component, a history of microbiologically -proven disease caused by N. meningitidis or N. gonorrhea, or current pregnancy or breastfeeding Out of scope: None		Jaw fracture Lower limb fracture Overdose Snake bite Spinal compression fracture Traumatic intracranial haemorrhage Diabetes mellitus inadequate control Type 1 diabetes mellitus Intervertebral disc protrusion Osteochondrosis Pain in extremity Central Nervous System germinoma Migraine Multiple sclerosis Convulsion Demyelination Headache Meningism Neuralgia Radicular syndrome Tension headache Abortion spontaneous Abortion missed Ectopic pregnancy Suicidal ideation Depression Major depression Substance abuse Attention deficit or hyperactivity disorder Psychotic disorder Schizoaffective disorder Renal tubular necrosis Menorrhagia Testicular torsion Asthma Hyperventilation Status asthmaticus Ingrowing nail Nausea Vomiting Abdominal pain Diarrhoea Injection site pain Pyrexia		

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
			Injection site erythema Vaccination site pain Fatigue Injection site swelling Upper respiratory tract infection Nasopharyngitis Pharyngitis Gastroenteritis Bronchitis Sinusitis Urinary tract infection Pharyngitis streptococcal Tonsillitis Viral pharyngitis Ligament sprain Contusion Fall Pain in extremity Back pain Arthralgia Headache Oropharyngeal pain Cough		
Rivera, 2018[187] GlaxoSmithKline, 2014[269] NCT01767376 Article RCT N=691 Industry funded Dominican Republic, Germany, Republic of Korea	Age: Intervention (Tdap+MenACWTT) 18.1 (4.2), Control (MenACWY) 18.2 (4.5) % female: 55% Ethnicity: 48% Asian, 26% White, 26% Other Healthy 11–25-year-olds Out of scope: None	Tdap Boostrix 1 dose Intramuscular adjuvant NR preservative NR Co-intervention MenACWY-TT (Nimenrix) Base treatment MenACWY-TT Nimenrix 0.5 mL in 1 dose Intramuscular adjuvant NRpreservative NR Counts No prespecified AE Power other outcome Followup: 1 months	Gastroenteritis Orthostatic intolerance Depression Gastrointestinal disorder (prespecified) Fatigue (prespecified) Pain (prespecified) Pyrexia (prespecified) Swelling (prespecified) Nasopharyngitis Headache (prespecified) Erythema (prespecified) New onset of chronic illness (prespecified)	Cardiovascular events: NA Orthostatic intolerance I: 0/231 2.XOrthostatic intolerance, C: 0/228 Death NA NA I: 0/231, NA NA C: 0/228	Severe AE (comparing first dose only, which is Tdap+MenACWY-TT versus MenACWY-TT) Grade 3 reaction: Intervention 1.3% (0.3; 3.7) vs Control 0.4% (0.0; 2.4) Grade 3 reaction related: Intervention 0.0% (0.0; 1.6) vs Control 0.0% (0.0; 1.6) Serious AEs (from clinicaltrials.gov) Intervention (Nimenrix+ Boostrix) vs Control (Nimenrix) Affected / at Risk (%)# Events Affected / at Risk (%) # Event Total 0/231 (0.00%) 0/228 (0.00%) Gastroenteritis 0/231 (0.00%) 0/228 (0.00%) Orthostatic intolerance(in AE table) Depression 0/231 (0.00%) 0/228 (0.00%) Risk factors: NR

Table D.4. KQ3 evidence table safety of vaccines in pregnant women

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
Glover, 2020[116] Article Cohort study N=13758 Not industry funded Australia	Age: Median age was 31 years % female: 100% Ethnicity: 1.5% Aboriginal and Torres Strait Islander Pregnant women receiving seasonal IIV or Tdap vaccines at 219 sentinel AusVaxSafety immunization provider sites usingthe SmartVax software from 1 August 2015 to 31 December 2018 were included in this study Out of scope: None	IIV,Tdap Adacel,Afluria Quandrivalent,Boostrix,Fluarix Quadrivalent,Fluzone Quadrivalent One dose at 28 to 32 weeks' gestation Route NR adjuvant NR preservative NR Co-intervention IIV (quadrivalent) IIV IIV only FluQuadRi, Fluarix Tetra One dose at any time during pregnancy route NR adjuvant NRpreservative NR Counts Prespecified AE Power NR Followup: 1 months	Fever Injection site (IS) pain Redness/swelling Tiredness Irritability Sleep pattern change Rash Headache Vomiting Diarrhoea Seizure Rigors Non-responsiveness/loss of consciousness	NA	Pregnant Women: IIV+Tdap vs IIV alone (intervention is Tdap) Any adverse event: 7.4% vs 4.9% (RR 1.52, 95% CI 1.23 to 1.89) Solicited local adverse events: Pain 2.5% vs 1.3% (RR 1.91 , 95% CI 1.27–2.87) Swelling and/or redness 1.9% vs 0.7% (RR 2.71, 95% CI 1.63–4.53) Solicited systemic adverse events: Medical advice via telephone 0.4% vs 0.2% (RR 2.53, 95% CI 0.89–7.2) Medical attendance 0.5% vs 0.3% (RR 1.82, 95% CI 0.73–4.51) IIV+Tdap vs Tdap alone (intervention is IIV) Any adverse event: 7.4% vs 6.4% (RR 1.16, 95% CI 0.96–1.40) Solicited local adverse events: Pain 2.5% vs 2.6% (RR 0.95, 95% CI 0.68–1.33) Swelling and/or redness 1.9% vs 1.9% (RR 0.96, 95% CI 0.65–1.42) Solicited systemic adverse events: Medical advice via telephone 0.4% vs 0.3% (RR 1.38, 95% CI 0.60–3.20) Medical attendance 0.5% vs 0.3% (RR 1.79, 95% CI 0.79–4.04) Newborns: Risk factors: No (there were sub-group analyses, but none used a comparator)
Acosta, 2016[52] Article Case-Control N=557 Not industry funded Spain	Age: N/A % female: N/A Ethnicity: Ethnicity NR Pregnant women Out of scope: None	Tdap Brand NR Route NR adjuvant NR preservative NR No co-intervention No intervention No Tdap Counts Prespecified AE Power NR Followup: 6 months	No severe adverse maternal side effects were recorded	NA	Pregnant Women: No differences were observed in terms of duration of pregnancy (279 days vs. 278 days; p>0.05). No severe adverse maternal side effects were recorded Newborns: No differences in weight at birth (3290 vs. 3220; p>0.05), admission at NICU (1,58% vs. 1,87%; p>0.05) nor in Apgar test score<7 at 5 minutes (0.27% vs. 0%; p>0.05). Risk factors: NR

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
Becerra-Culqui, 2018[64] Article Cohort study N=109536 Not industry funded USA	Age: N/A % female: 100% Ethnicity: 26% Caucasian, 6% African-American, 48% Hispanic,16% Asian-American & Pacific Islander, 3% others Pregnant women who did not have in vitro fertilization and gave birth to live singleton infants at 22 to 45 weeks' gestation Out of scope: None	Tdap Adacel Route NR adjuvant NR preservative NR No co-intervention No intervention No vaccine Counts Prespecified AE Power NR Followup: 82 months	Autism spectrum disorder	Pregnant Women NA Newborns Autism: 17.X NR I: 569/39077, 17.X NR C: 772/42916	Pregnant Women: No maternal AEs measured. Newborns: The ASD incidence rate was 3.78 per 1000 person-years in the Tdap vaccinated and 4.05 per 1000 person-years in the unvaccinated group Unadjusted HR: 0.98 (95% CI: 0.88–1.09) Adjusted HR: 0.85 (95% CI: 0.77–0.95) Risk factors: NR

Becerra-Culqui, 2020[65] Article Cohort study N=85607 Not industry funded USA	Age: Vaccinated: 18.8% <=25 years, 30.3% 26-30 years, 27.7% 31-34 years, 23.2 >=35 years; Unvaccinated: 20.4% <=25 years, 29.5% 26-30 years, 27.0% 31-34 years, 23.1 >=35 years % female: 100% Ethnicity: Vaccinated: 24.7% Non-Hispanic White, 6.6 % Non-Hispanic Black, 50.4% Hispanic, 15.7% Non-Hispanic Asian/Pacific Islander, 2.7% Other/multiple/unknown; Unvaccinated: 24.2% Non-Hispanic White, 8.9% Non-Hispanic Black, 50.8% Hispanic, 13.6% Non-Hispanic Asian/Pacific Islander, 2.5% Other/multiple/unknown Pregnant women without assisted conceptions (i.e., in vitro fertilization) who had a documented birth of a live singleton infant	Tdap Other : Not specified (administrative records) N/R Route NR adjuvant NR preservative NR No co-intervention No intervention Counts Prespecified AE Power NR Followup: 60 months	Attention-deficit/hyperactivity disorder (ADHD)	NA	Pregnant Women: Number of cases: Tdap vaccinated 351/41781 (0.8%), unvaccinated 531/43826 (1.2%) ADHD incidence rate: 3.41 per 1,000 person-years in the vaccinated group and 3.93 per 1,000 person- years in the unvaccinated group Unadjusted hazard ratio: 1.01 (95% CI 0.88, 1.16) IPTW-adjusted HR: 1.00 (95% CI 0.88, 1.14) Results were consistent across study birth years and among nulliparous women Newborns: Risk factors: No

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
	no later than 45 weeks' gestation Out of scope: None				

Berenson, 2016[67] Article Cohort study N=1759 Not industry funded USA	Age: 27 (6) % female: 100% Ethnicity: 31.2% White, 18.0% Black, 45.9% Hispanic Women with singleton pregnancies delivered at 27 or more weeks gestation Out of scope: None	Tdap Brand NR Route NR adjuvant NR preservative NR Co-intervention Varied but could include other routine or non-routine vaccines (influenza, Hep A, Hep B, meningococcal, pneumococcal vaccines) Base treatment Other routine vaccines (influenza, Hep A, Hep B, meningococcal, pneumococcal) Analytic study Prespecified AE Power NR Followup: 11 months	Chorioamnionitis Postpartum endometritis Preterm premature rupture of membranes Preterm delivery Induced labor Mode of delivery Low birth weight Very low birth weight Small for gestational age Apgar <8 at 5 minutes NICU admission Presence of birth defect (spina bifida, transposition of great arteries, tetralogy of Fallot, atrioventricular septal defect, cleft palate, cleft lip, rectal and large intestinal atresia/ stenosis, reduction deformity of upper limbs, gastroschisis, or diaphragmatic hernia)	Pregnant Women Preterm labor: 18.X Preterm delivery I: 58/1109, 18.X Preterm delivery C: 59/650 Stillbirth: 18.4 NA I: 0/1109, 18.4 NR C: 1/650 Newborns Birth defects: 3.X See text for description of defects I: 15/1109, 3.X See Other Results for description of defects C: 18/650	Pregnant Women: Tdap (N=1109) vs No Tdap (N=650) n(%) vs n(%), aOR (95% CI), p-value Chorioamnionitis: 39 (3.5) vs 14 (2.2), aOR 1.53 (0.80–2.90), p=0.19 Postpartum endometritis: 9 (0.8) vs 5 (0.8), aOR 1.67 (0.51–5.50), p=0.41 Preterm premature rupture of membranes: 36 (3.2) vs 19 (2.9), aOR 1.05 (0.57–1.95), p=0.87 Preterm delivery: 58 (5.2) vs 59 (9.1), aOR 0.68 (0.45–1.03) 0.07 (in AE table) Any above maternal outcome: 152 (13.7) vs 89 (13.7), aOR 1.09 (0.81–1.48) 0.56 Induced labor: 656 (59.2) vs 338 (52.0), aOR 0.82 (0.66–1.51) 0.06 Mode of delivery Vaginal: 759 (68.4) vs 405 (62.3) Cesarean: 350 (31.6) vs 245 (37.7), aOR 0.78 (0.63–0.98) 0.03 Newborns: Tdap (N=1109) vs No Tdap (N=650) n(%) vs n(%), aOR (95% CI), p-value Low birth weight: 61 (5.5) vs 59 (9.1), aOR 0.76 (0.51–1.14), p=0.19 Very low birth weight: 2 (0.2) vs 12 (1.8), aOR 0.24 (0.05–1.20), p=0.08 Small for gestational age (<10th percentile): 46 (4.2) vs 31 (4.8), aOR 0.89 (0.55–1.46) p=0.65 Apgar score at 5 min of life <8: 14 (1.3) vs 10 (1.5), aOR 0.87 (0.22–3.52), p=0.85 Birth defect: 18 (1.6) vs 15 (2.3), aOR 0.80 (0.38–1.67) p=0.55 (in AE table) NICU admission: 103 (9.3) vs 86 (13.2), aOR 0.78 (0.56–1.08), p=0.14 Any infant outcome: 159 (14.3) vs 123 (18.9), aOR 0.80 (0.61–1.06), p=0.12 Birth defects included: spina bifida, transposition of great arteries, tetralogy of Fallot, atrioventricular septal defect, cleft palate, cleft lip, rectal and large intestinal atresia/stenosis, reduction deformity of upper limbs, gastroschisis, and/or diaphragmatic hernia. No difference in any individual defect between Tdap and no Tdap Risk factors: NR
DeSilva, 2017[91]	Age: Exposed: 1% <18, 13%	Tdap Brand NR Route NR	Chorioamnionitis	Pregnant Women NA Newborns	Pregnant Women: Chorioamnionitis:

DeSilva, 2016[250] Article Cohort study N=197564 Not industry funded USA	18-24, 63% 25-34, 24% >=35; Unexposed: 1% <18, 13% 18-24, 61% 25-34, 24% >=35 % female: 100% Ethnicity: Exposed: 35% White, 33% Hispanic, 17% Asian, 6% Black, 9% Other; Unexposed: 40% White, 29% Hispanic, 16% Asian, 7% Black, 8% Other Pregnant women with a live birth (mother-infant cohort) Out of scope: None	adjuvant NR preservative NR No co-intervention No intervention No Tdap Counts Prespecified AE Power NR Followup: 11 months	Transient tachypnea of the newborn (TTN) Neonatal sepsis Neonatal pneumonia Respiratory distress syndrome (RDS) Newborn convulsions	Seizure: 17.X Newborn convulsions I: 68/45008, 17.X Newborn convulsions C: 261/152556	Any Tdap: 2883/45008 (6.4%); No Tdap 7970/152556 (5.2%), aRR 1.23 (1.17, 1.28) Among only Tdap at 27-36 weeks: 1430/22,772 (6.3%); No Tdap 7109/133,882 (5.3%), aRR 1.20 (1.14, 1.28) Among only infants born <34 weeks: 28/426 (6.6%), No Tdap 221/2711 (8.2%), aRR 0.87 (0.59, 1.30) Newborns: Transient tachypnea newborn: Any Tdap: 973/45008 (2.2%); No Tdap 3524/152556 (2.3%), aRR 1.03 (0.96, 1.11) Tdap at 27-36 weeks: 520/22,772 (2.3%); No Tdap 3061/133,882 (2.3%), aRR 1.08 (0.98, 1.19) Among only infants born <34 weeks: 51/426 (12.0%); No Tdap 291/2711 (10.7%), aRR 1.07 (0.79, 1.45) Neonatal sepsis: Any Tdap: 231/45008 (0.5%); No Tdap 939/152556 (0.6%), aRR 1.06 (0.91, 1.23) Tdap at 27-36 weeks: 103/22,772 (0.4%); No Tdap 785/133,882 (0.6%), aRR 0.90 (0.73, 1.11) Among only infants born <34 weeks: 48/426 (11.3%); No Tdap 318/2711 (11.7%), aRR 1.11 (0.81, 1.51) Pneumonia: Any Tdap: 73/45008 (0.2%); No Tdap 371/152556 (0.2%), aRR 0.94 (0.72, 1.22) Tdap at 27-36 weeks: 34/22,772 (0.2%); No Tdap 329/133,882 (0.3%), aRR 0.82 (0.57, 1.17) Among only infants born <34 weeks: 9/426 (2.1%); No Tdap 121/2711 (4.5%), aRR 0.60 (0.30, 1.19) RDS: Any Tdap: 49/45008 (0.1%); No Tdap 215/152556 (0.1%), aRR 0.91 (0.66, 1.26) Tdap at 27-36 weeks: 21/22,772 (0.1%); No Tdap 168/133,882 (0.1%), aRR 0.79 (0.50, 1.26) Among only infants born <34 weeks: 5/426 (1.2%); No Tdap 46/2711 (1.7%), aRR 0.84 (0.33, 2.14) Convulsions:

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
					Any: Captured in table, aRR 1.16 (0.87, 1.53) Tdap at 27-36 weeks: 28/22,772 (0.1%); No Tdap 229/133,882 (0.2%), aRR 0.88 (0.58, 1.31) Among only infants born <34 weeks: 5/426 (1.2%); No Tdap 40/2711 (1.5%), aRR 0.98 (0.38, 2.50) Risk factors: NR

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
Griffin, 2018[121] Colindres, 2020[246] Article Cohort study N=68550 Unrestricted industry grant New Zealand	Age: 29.3 (6.0) % female: 100 Ethnicity: 51% White, 35% Pacific Islander, 14% Asian, <1% Missing All pregnancies resulting in a delivery of a live born baby or stillbirth of at least 20 weeks gestation, and who were eligible to receive NZ MoH-funded Tdap (Boostrix, GSK) vaccination from 28 to 38 weeks gestation in 2013 Out of scope: None	Tdap Boostrix Route NR adjuvant NR preservative NR No co-intervention No intervention No Tdap Counts Prespecified AE Power calculation Followup: 13 months	Chronic hypertension with superimposed pre-eclampsia Gestational hypertension Pre-eclampsia Pre-eclampsia with severe features Eclampsia Fetal growth restriction Preterm labour Post-partum haemorrhage Maternal death Stillbirth Deep vein thrombosis Gestational diabetes mellitus Pre-labour rupture of membranes Placental abruption Antenatal bleeding Preterm delivery Fetal distress Uterine rupture Maternal fever during labour Maternal fever after labour Maternal cardiomyopathy Lactation disorders (agalactia or hypogalactia) Anaemia during pregnancy and purpura Aaternal neurologic disorders	Pregnant Women Cardiovascular events: 26.1 Gestational hypertension I: 262/8178, 26.1 Gestational hypertension C: 1484/60372 Death: NA NAI: 0/8178, NA NA C: 1/60372 Diabetes: 14.X Gestational diabetes mellitus. I: 326/8178, 14.X Gestational diabetes mellitus. C: 2426/60372 Eclampsia: 18.X 26 of these events were classified as pre-eclampsia with severe features. I: 159/8178, 18.X 271 of these events were classified as pre-eclampsia with severe features. C: 1278/60372 Preterm labor: 18.X NR I: 10/8178, 18.X NR C: 292/60372	Pregnant Women: Participants in the Tdap vaccinated (N=8168) and Tdap unvaccinated (N=60372) experienced the following AEs (significant aHR noted): IUGR: 401/8178 (5%), 2916/60372 (5%) Postpartum hemorrhage: 715/8178 (9%), 4611/60372 (8%) Chorioamnionitis: 26/8178 (0.3%), 198/60372 (0.3%) Pre-labor rupture of membranes: 672/8178 (8%), 4496/60372 (8%) Placental abruption: 35/8178 (0.4%), 257/60372 (0.4%) Antenatal bleeding: 105/8178 (1%), 1224/60372 (2%) (significantly decreased aHR 0.61, 95% CI 0.49, 0.78) Preterm delivery: 297/8178 (4%), 2829/60372 (5%) (significantly decreased aHR 0.72, 95% CI 0.63, 0.83) Fetal distress: 1218/8178 (15%), 6830/60372 (10%) Maternal fever during labor: 79/8178 (1%), 542/60372 (1%) Maternal fever after labor: 33/8178 (0.4%), 263/60372 (0.4%) Lactation disorders 54/8178 (1%), 146/60372 (0.2%) (significantly elevated aHR 1.63, 95% CI 1.15, 2.33) Anemia during pregnancy and purpura: 271/8178 (3%), 2171/60372 (4%) Maternal neurologic disorders: 79/8178 (1%), 540/60372 (1%) Captured in AE table (significant aHR here only) Pre-term labor: aHR 0.32 95% CI 0.17, 0.62 Pre-eclampsia with severe features: aHR fo 0.67 95% CI 0.39-0.94 Newborns: Risk factors: NR

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
Hall, 2020[123] Article Cohort study N=145883 Not industry funded USA	Age: Tdap: 40% 17-24, 32% 25-29, 20% 30-34, 8% >=35; No Tdap: 50% 17-24, 28% 25-29, 15% 30-34, 7% >=35 % female: 100% Ethnicity: Tdap: 47% White non-Hispanic, 24% Black non-Hispanic, 14% Hispanic, 15% Other/unknown; No Tdap: 48% White non-Hispanic, 27% Black non-Hispanic, 14% Hispanic, 12% Other/unknown Military women on active duty status for duration of pregnancy Out of scope: None	Tdap Brand NR Route NR adjuvant NR preservative NR No co-intervention No intervention Counts Prespecified AE Power NR Followup: 22 months	Preeclampsia Preterm labor Spontaneous abortion Low birth weight (LBW; birth weight under 2500 g) Preterm birth (birth before 37 weeks' gestation) Growth problems in utero Growth problems in infancy Major birth defects	Pregnant Women Eclampsia: 18.2 Preeclampsia I: 548/10340, 18.2 Preeclampsia C: 5949/106482 Preterm labor: 18.X NR I: 531/10463, 18.X NR C: 8160/105974 Spontaneous abortion: 18.4 Only among those vaccinated 0-13 weeks gestation I: 233/1252, 18.4 Among unexposed C: 22931/130289 Newborns Birth defects: 3.3 Major structural birth defect I: 33/970, 3.3 Major structural birth defect C: 3091/103033	Pregnant Women: Newborns: Growth problems in infancy: Unexposed 3840 (3.7%), 0-13 weeks Tdap 33 (3.4%), 27-36 weeks Tdap 526 (5.6%) Low birth weight: Unexposed 5111 (4.9%), 0-13 weeks Tdap 33 (3.4%), 27-36 weeks Tdap 318 (3.4%) Any major structural birth defect: Captured in table and stratified below Cardiovascular birth defect: Unexposed 990 (1.0%), 0-13 weeks Tdap 11 (1.1%) Genitourinary birth defect: Unexposed 1261 (1.2%), 0-13 weeks Tdap 15 (1.5%) Risk factors: Sub-group by trimester of receipt Preeclampsia: 0-13 weeks: Unexposed 5949 (5.6%), Exposed 54 (5.3%) vs 27-36 weeks: Unexposed 5963 (5.6%), Exposed 494 (5.3%) Preterm labor: 0-13 weeks: Unexposed 8099 (7.7%), Exposed 68 (6.7%) vs 27-36 weeks: Unexposed 8160 (7.7%), Exposed 463 (4.9%) Preterm birth: Unexposed 8421 (8.1%), 0-13 weeks Tdap 60 (6.1%), 27-36 weeks Tdap 569 (6.1%) Growth problems in utero: Unexposed 3316 (3.2%), 0-13 weeks Tdap 25 (2.5%), 27-36 weeks Tdap 408 (4.4%)

Halperin, 2018[125] Scott Halperin, 2007[371] NCT00553228 Article RCT N=273 Industry funded Canada	Age: Tdap: 30.9 (5.3); Td: 31.4 (4.8) % female: 100 Ethnicity: Tdap: 79% White, 7% Asian, 6% Black, 1% Hispanic, 7% Other; Td: 87% White, 4% Asian, 4% Black, 1% Hispanic, 5% Other Healthy pregnant women 18–45 years old assessed at >=30 weeks gestation to be at low risk for complications Out of scope: None	Tdap Adacel 0.5 mL in 1 dose Intramuscular adjuvant free preservative free No co-intervention Td Td vaccine No brand name (presumed to be Tenivac as states manufactured by Sanofi) 0.5 mL in 1 dose Intramuscular adjuvant freepreservative free Counts No prespecified AE Power other outcome Followup: 21 months	Congestive heart failure Crohn's disease/colitis Gastroenteritis Urinary tract infection Perineal infection Adjustment disorder Nephrolithiasis Decreased lactation Pulmonary embolism Hypertension Gestational hypertension Hemolysis, elevated liver enzymes, low platelet count (HELLP) syndrome Postpartum hemorrhage Preeclampsia Premature delivery Retained placenta Meconium aspiration Neonatal asphyxia/hypoxia/respiratory distress Pulmonary stenosis Septal defect Hypospadias Syndactyly Gastroesophageal reflux disease Intussusception Fever/other general Hyperbilirubinemia/jaundice RSV/bronchiolitis Meningitis Otitis media Respiratory tract/pneumonia Herpes simplex virus Urinary tract infection Periorbital cellulitis Respiratory rate increase Lethargy, decreased response, facial palsy, attention/sleep disturbance Failure to thrive/poor weight gain Injection-site erythema and swelling (prespecified)	Pregnant Women Autoimmune disease: 7.X Crohn's disease/colitis I: 1/135, 7.X Crohn's disease/colitis C: 1/138 Cardiovascular events: 2.X Congestive heart failure I: 0/135, 2.X Congestive heart failure C: 1/138 Death: NA NAI: 0/135, NA NA C: 0/138 Eclampsia: 18.X NR I: 1/135, 18.X Possibly vaccine-related C: 2/138 Preterm labor: 18.X Premature delivery not labor I: 2/135, 18.X Premature delivery not labor C: 1/138 Reproduction issues: 21.X Postpartum hemorrhage I: 1/135, 21.X Postpartum hemorrhage C: 1/138 Newborns Birth defects: 3.X Septal defect I: 0/134, 3.X Septal defect C: 2/138 Intussusception: 7.X NA I: 0/134, 7.X NR C: 1/138 Meningitis: 11.X NR I: 1/134, 11.X NR C: 1/138	Pregnant Women: Serious AEs: Congestive heart failure Tdap 0, Td 1 (in AE table) Crohn's disease/colitis Tdap 1, Td 1 (in AE table) Gastroenteritis Tdap 2, Td 0 Urinary tract infection Tdap 1, Td 1 Perineal infection Tdap 0, Td 1 Adjustment disorder Tdap 0, Td 1 Nephrolithiasis Tdap 0, Td 1 Decreased lactation Tdap 1, Td 1 Pulmonary embolism Tdap 1, Td 0 Hypertension Tdap 0, Td 1 Gestational hypertension Tdap 2, Td 0 Hemolysis, elevated liver enzymes, low platelet count (HELLP) syndrome Tdap 0, Td 1 Postpartum hemorrhage Tdap 1, Td 1 (in AE table) Preeclampsia Tdap 1, Td 2 (in AE table) Premature delivery Tdap 2, Td 1 (in AE table) Retained placenta Tdap 0, Td 1 Newborns: Meconium aspiration Tdap 2, Td 0 Neonatal asphyxia/hypoxia/respiratory distress Tdap 0, Td 3 Pulmonary stenosis Tdap 1, Td 0 Septal defect Tdap 0, Td 2 (in AE table) Hypospadias Tdap 1, Td 1 Syndactyly Tdap 0, Td 1 Gastroesophageal reflux disease Tdap 1, Td 0 Intussusception Tdap 0, Td 1 (in AE table) Fever/other general Tdap 0, Td 6 Hyperbilirubinemia/jaundice Tdap 7, Td 0 RSV/bronchiolitis Tdap 1, Td 5 Meningitis Tdap 1, Td 1 (in AE table) Otitis media Tdap 1, Td 1 Respiratory tract/pneumonia Tdap 1, Td 2 Herpes simplex virus Tdap 1, Td 0 Urinary tract infection Tdap 2, Td 0 Periorbital cellulitis Tdap 0, Td 1 Respiratory rate increase Tdap 0, Td 1 Lethargy, decreased response, facial palsy, attention/sleep disturbance Tdap 2, Td 6 Failure to thrive/poor weight gain Tdap 1, Td 1

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
					Risk factors: NR
Kharbanda, 2016[144] Kharbanda, 2014[293] Article Cohort study N=163138 Author COI USA	Age: Tdap: <20 years 3.4%, 20–34 years 73.7%, ≥35 years 22.9%; Unvaccinated: <20 years 4.1%, 20–34 years 73.2%, ≥35 years 22.7% % female: 100% Ethnicity: Ethnicity NR Insured pregnant women with live births across seven health systems Out of scope: None	Tdap Brand NR Route NR adjuvant NR preservative NR No co-intervention No intervention Unvaccinated women Counts Prespecified AE Power NR Followup: 2 months	Allergic reaction Malaise Fever Seizures Altered mental status Local and other reactions Neurologic events Autonomic disorders Cranial nerve disorders Central nervous system degeneration/demyelinating Peripheral neuropathy Gullain-Barre syndrome Meningoencephalities Movement disorders Paralytic syndromes Spinocerebellar disease Proteinuria Venous thromboembolism Gestational diabetes Cardiac events Thrombocytopenia Percaritis Myocarditis Cardiomyopathy Heart failure	Pregnant Women Cardiovascular events: 2.X Cardiac events I: 90/53885, 2.X Cardiac events C: 198/109253 Diabetes: 14.X Gestational diabetes I: 1101/53885, 14.X Gestational diabetes C: 2263/109253 Encephalitis: 11.X Meningoencephalitis I: 3/53885, 11.X Meningoencephalitis C: 9/109253 Guillain-Barré syndrome: 10.X NA I: 53885, 10.X NR C: 3/109253 Seizure: 17.X NR I: 1/53885, 17.X NR C: 1/109253 Newborns NA	Pregnant Women: All Tdap Overall neurologic event: vaccinated: 51/53885; unvaccinated: 104/109253 *Includes autonomic disorders (2 vs 7), cranial nerve disorders (19 vs 38), CNS degeneration/demyelinating (0 vs 3), peripheral neuropathy (18 vs 27), Guillain-Barre (0 vs 3; noted above), meningoecephalitidies (3 vs 9; noted in table under encephalitis), movement disorders (13 vs 32), paralytic syndromes (1 vs 0), spinocerebellar diseases (0 vs 6) Venous thromboembolism: vaccinated: 22/53885; unvaccinated: 69/109253 Cardiac events included pericarditis, myocarditis, cardiomyopathy, heart failure Newborns: Risk factors: By timing of dose: In the subset of women receiving Tdap at ≥20 weeks gestation, as compared to their unvaccinated matches, there was no increased risk for incident gestational diabetes, thrombocytopenia, venous thromboembolism or cardiac events (myocarditis, pericarditis, cardiomyopathy, or heart failure)

Layton, 2017[154] Article Cohort study N=1079034 Not industry funded USA	Age: 29.2 (5.4) % female: 100% Ethnicity: Ethnicity NR Females with live or stillbirth deliveries Out of scope: None	Tdap Brand NR Route NR adjuvant NR preservative NR No co-intervention No intervention No Tdap vaccination Counts Prespecified AE Power NR Followup: 9 months	Anaphylaxis Fever Cellulitis Pain in limb Encephalopathy Guillain-Barre Syndrome Preeclampsia/Eclampsia Premature rupture of membranes Chorioamnionitis Cesarean section Placental abruption Post-partum hemorrhage Neonatal intensive care unit admission Neonatal respiratory distress Neonatal pulmonary hypertension Neonatal jaundice Neonatal encephalopathy Neonatal seizures Neonatal sepsis	Pregnant Women Eclampsia: 18.X Preeclampsia/Eclampsia I: 6344/148795, 18.X Preeclampsia/Eclampsia C: 40930/930227 Newborns Encephalitis: 11.X Encephalopathy I: 165/113094, 11.X Encephalopathy C: 577/577000 Seizure: 17.X NR I: 336/112971, 17.X NR C: 1607/573928	Pregnant Women: Additional result, by Tdap (Optimal and Early Dosing) and No Tdap (aRR and aHR adjusted using IPTW [inverse probability of treatment weighting]) Premature rupture of membranes: Tdap 8942/148,803 [Optimal 7524/123,750 (6.08%), Early 1418/25,053 (5.66%)], No Tdap 43,485/931,156 (4.67%) Premature rupture of membranes: optimal aHR 1.03 (1.00, 1.06), early aHR 1.08 (1.02, 1.15) Chorioamnionitis: Tdap 5513/148,782 [Optimal 4529/123,743 (3.66%), Early 984/25,038 (3.93%)], No Tdap 25,149/931,444 (2.70%) Chorioamnionitis: optimal aHR 1.11 (1.07, 1.15), early aHR 1.19 (1.11, 1.28) Cesarean section: Tdap 45,789/148,811 [Optimal 37,900/123,775 (30.62%), Early 7889/25,036 (31.51%)], No Tdap 305,882/930,298 (32.88%) Cesarean section: optimal aHR 0.95 (0.94, 0.96), early aHR 0.97 (0.95, 0.99) Placental abruption: Tdap 1071/148,034 [Optimal 874/123,098 (0.71%), Early 197/24,936 (0.79%)], No Tdap 7601/926,951 (0.82%) Placental abruption: optimal aHR 0.86 (0.80, 0.93), early aHR 0.88 (0.73, 1.08) Post-partum hemorrhage: Tdap 4643/148,426 [Optimal 3814/123,831 (3.08%), Early 829/25,045 (3.31%)], No Tdap 21,120/930,396 (2.27%) Post-partum hemorrhage: optimal aRR 1.23 (1.18, 1.28), early aRR 1.34 (1.25, 1.44) For preeclamspia/eclampsia (abstracted in AE table), the breakdown by optimal and early was: Preeclampsia/Eclampsia: Optimal 5248/123,773 (4.24%). Early 1096/25,022 (4.38%) Preeclamspia/eclampsia: optimal aRR 0.96 (0.94, 0.99), early aRR 1.05 (0.99, 1.12) Newborns: Additional result, by arm - count of event in arm/N in arm (%); note that N in each arm was extrapolated from count and %

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
					NICU admission: Tdap 2154/112,822 [Optimal 6996/96496 (7.25%), Early 1458/16,326 (8.93%)], No Tdap 42,904/580,568 (7.39%) Respiratory distress: Tdap 6,864/112,944 [Optimal 5739/96,616 (5.94%), Early 1125/16,328 (6.89%)], No Tdap 37,241/580,982 (6.41%) Pulmonary hypertension: Tdap 255/113748 [Optimal 205/97,619 (0.21%), Early 50/16,129 (0.31%)], No Tdap 1408/586,667 (0.24%) Neonatal jaundice: Tdap 17,165/112,834 [Optimal 14,603/96,516 (15.13%), Early 2562/16,318 (15.70%)], No Tdap 90,215/580,534 (15.54%) Neonatal sepsis: Tdap 2168/112,761 [Optimal 1774/96,413 (1.84%), Early 394/16,348 (2.41%)], No Tdap 13,187/580,925 (2.27%) For encephalopathy, the breakdown in Tdap by timing was: Optimal 135/96,428 (0.14%), Early 30/16,667 (0.18%) For seizures the breakdown in Tdap by timing was: Optimal 261/96,667 (0.27%), Early 75/16,304 (0.46%) Risk factors: Optimally-timed immunization was associated with small increased relative risks of: chorioamnionitis [RR = 1.11, (95% CI: 1.07–1.15), overall risk = 2.8%], and postpartum hemorrhage [RR = 1.23 (95% DI: 1.18–1.28), overall risk = 2.4%]; however, these relative increases corresponded to low absolute risk increases. Tdap was not associated with increased risk of any adverse newborn outcome. Overall, prenatal Tdap immunization was not associated with newborn adverse events, but potential associations with chorioamnionitis consistent with one previ- ous study and postpartum hemorrhage require further investigation.

Morgan, 2015[170] Article Cohort study N=7378 Not industry funded USA	Age: Intervention: 28.2 (6.4), Control: 27.8 (6.7) % female: 100% Ethnicity: Intervention: 11% Black, 2% White, 84% Hispanic, 3% Other; Control: 27% Black, 4% White, 66% Hispanic, 3% Other, I Pregnant women Out of scope: None	Tdap Brand NR Route NR adjuvant NR preservative NR No co-intervention No intervention No Tdap vaccine Counts Unclear Power NR Followup: 2 months	Stillbirth rate Major malformations Chorioamnionitis 5-minute Apgar scores Cord blood pH values Ventilation requirement sepsis Intraventricular hemorrhage Neonatal death Preterm birth Small for gestational age (SGA) Length of neonatal hospitalization	Pregnant Women Preterm labor: 18.2 36 weeks or less (see breakdown below) I: 526/7152, 18.2 36 weeks or less (see breakdown below) C: 35/226 Stillbirth: 18.4 NR I: 25/7152, 18.4 NR C: 1/226 Newborns Birth defects: 3.3 Major malformation I: 84/7152, 3.3 Major malformation C: 226/3 Death: NA NR I: 2/7152, NA NA C: 0/226 Stroke: 17.3 Intraventricular hemorrhage, grade 3–4 I: 1/7152, 17.3 NAC: 0/226	Pregnant Women: Chorioamnionitis: Tdap 421/7152 (6%), No Tdap 9/226 (4%) [Single Tdap dose 76/4159 (2%); Two or more Tdap doses 20/1229 (2%)] Sitllbirths: Count in AE table [Single Tdap dose 15/4159 (0.4%); Two or more Tdap doses 3/1229 (0.2%)] Breakdown of preterm labor: Gestational age 34 weeks or less: Tdap 99/7152 (1%), No Tdap 8/226 (4%) [Single Tdap dose 50/4159 (1%); Two or more Tdap doses 14/1229 (1%)] Gestational age 36 weeks or less: Tdap 427/7152 (6%), No Tdap 27/226 (12%) [Single Tdap dose 233/4159 (6%); Two or more Tdap doses 66/1229 (5%)] Newborns: Major malformation: Counts in AE table [Single Tdap dose 50/4159 (1%); Two or more Tdap doses 11/1229 (0.9%)] Intraventricular hemorrhage: Counts in AE table [Single Tdap dose 1/4159 (0%); Two or more Tdap doses 0/1229 (0%)] Neonatal death: Counts in AE table [Single Tdap dose 2/4159 (0%); Two or more Tdap doses 0/1229 (0%)] Birth weight Less than 3rd percentile: Tdap 206/7152 (3%), No Tdap 15/226 (7%) [Single Tdap dose 109/4159 (3%); Two or more Tdap doses 26/1229 (2%)] Less than 5th percentile: Tdap 364/7152 (5%), No Tdap 23/226 (15%) [Single Tdap dose 187/4159 (5%); Two or more Tdap doses 44/1229 (4%)] Less than 10th percentile: Tdap 714/7152 (10%), No Tdap 33/226 (15%) [Single Tdap dose 374/4159 (9%); Two or more Tdap doses 93/1229 (8%)] Greater than 90th percentile: Tdap 809/7152 (11%), No Tdap 23/226 (10%) [Single Tdap dose 529/4159 (13%); Two or more Tdap doses 152/1229 (12%)] Newborn nursery admission: Tdap 6620/7152 (93%), No Tdap 201/226 (89%) [Single Tdap dose 3840/4159 (93%); Two or more Tdap doses 1145/1229 (95%)]

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
					Sepsis: Tdap 3/7152 (0%), No Tdap 0/226 (0%) [Single Tdap dose 0/4159 (0%); Two or more Tdap doses 1/1229 (0.1%)] Ventilation during first 24h: Tdap 27/7152 (0%), No Tdap 1/226 (0%) [Single Tdap dose 12/4159 (0.3%); Two or more Tdap doses 3/1229 (0.2%)] Cord blood pH 7.0 or less: Tdap 50/7152 (0.7%), No Tdap 0/226 (0%) [Single Tdap dose 30/4159 (0.8%); Two or more Tdap doses 9/1229 (0.8%)] 5-minute Apgar score <4: Tdap 12/7152 (0.2%), No Tdap 1/226 (0.4%) [Single Tdap dose 3/4159 (0.1%); Two or more Tdap doses 1/1229 (0.1%)] Length of neonatal hospitalization: Tdap 3.9 +/- 3.0, No Tdap 4.7 +/- 6.2 [Single Tdap dose 3.8 +/- 3.0; Two or more Tdap doses 3.7 +/- 2.5] Risk factors: No difference in neonatal outcomes was noted between women who were administered at least two Tdap vaccines in the past 5 years and those who received only a single dose

Munoz, 2014[172] Munoz, 2017[319]; National Institute of Allergy Infectious Diseases, 2009[320] NCT00707148 Article RCT N=48 Not industry funded USA	Age: Treatment: 28.1 (6.7) ; Control: 27.8 (6.7) % female: 100 Ethnicity: Treatment: 15% Asian, 36% African American, 39% White, 3% Multiracial, 6% Other/unknown; 70% Hipsanic, 30% Nonhispanic; Control: 7% Asian, 47% African American, 47% White, 0% Multiracial, 0% Other/unknown; 80% Hipsanic, 20% Nonhispanic Healthy pregnant women aged 18-45 years Out of scope: None	Tdap Adacel 0.5 ml in 1 dose Intramuscular adjuvant free preservative free No co-intervention Placebo Saline placebo injection Counts Unclear Power NR Followup: 27 months	Atrial septum and ventricular septum defect Cardiomyopathy with biventricular hypertrophy Hypertension 48 d postvaccination Preterm contractions 33 d postvaccination Wound hematoma after cesarean delivery Gastroenteritis requiring hospitalization Respiratory distress at birth Vomiting requiring hospitalization 44 d after placebo injection Bronchiolitis requiring hospitalization Respiratory distress/tachypneac Anemiac Hypoglycemia Poor feeding due to gastroesophageal reflux Pregnancy-induced hypertension 30 d postvaccination Pancreatitis 3 mo after delivery Acute appendicitis 19 d after delivery Choking with feeds requiring prolonged hospitalization Febrile seizuresa Dehydration due to oral herpes simplex virus requiring hospitalization Bronchiolitis Preterm labor requiring hospitalization 18 d after placebo injection Pelvic fracture (motor vehicle crash) Fetal distress resulting in cesarean delivery Bilateral pneumothoraces Injection site pain Injection site erythema/redness	Pregnant Women Cardiovascular events: 26.3 Hypertension 48d post-vaccine (moderate), Pregnancy-induced hypertension (severe) I: 2/33, 26.X Hypertension, pregnancy-induced hypertension C: 0/15 Preterm labor: 18.X Preterm labor requiring hospitalization I: 0/33, 18.2 Preterm labor requiring hospitalization C: 1/15 Stillbirth: 18.4 NA I: 0/33, 18.4 NA C: 0/15 Newborns Birth defects: 3.X Atrial septum and ventricular septum defect I: 0/33, 3.1 Atrial septum and ventricular septum defect C: 1/15 Cardiovascular events: 2.X Cardiomyopathhy with biventricular hypertrophy I: 0/33, 2.1 Cardiomyopathhy with biventricular hypertrophy C: 1/15 Febrile seizures: 17.3 Febrile seizures; two distinct events of severe severity, no information on timing I: 1/33, 17.X Presumed to be 0 C: 1/15	Pregnant Women: Serious AEs in pregnant women (non-attributable to Tdap per authors): Treatment 7/33, Control 2/15 Severe AEs (not captured in table above): Pancreatitis: Treatment 1/33 (3 months post-delivery vs Control (presumed) 0/15 Acute appendicitis: Treatment 1/33 (19 d post-delivery) vs Control (presumed) 0/15 Fetal distress: Treatment 1/33 (life-threatening, required C-section) vs control 2/33 (life-threatening) [included under pregnant women for treatment and infants for control] Newborns: Serious AEs in infants (non attributable to Tdap per authors): Treatment 7/33, Control 6/15 Severe AEs (not captured in table above): Choking with feeds requiring prolonged hospitalization: Treatment 1/33 vs Controls 0/15 (presumed) Dehydration due to oral herpes simplex virus requiring hospitalization: Treatment 1/33 vs Controls 0/15 (presumed) Bronchiolitis: Treatment 1/33 vs Controls 0/15 (presumed) Bilateral pneumothoraces: Treatment 0/33 (presumed) vs Control 1/15 (life-threatening) [note that fetal distress abstracted under pregnant women] Risk factors: NR

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
			Injection site induration/swelling Any injection site symptom Fever Headache Malaise Myalgia Any systematic symptom Pertussis illness		
Perez, 2017[179] Hospital Universitario Dr. Jose E. Gonzalez, 2011[286] NCT01445743 Article RCT N=171 Funding unclear Mexico	Age: Experimental arm 23.8 (4.8), Control arm 23.7 (5.0) % female: 100% Ethnicity: Ethnicity NR Pregnant women who sought prenatal care from 2011-2014 at 12 outpatient health centers Out of scope: None	Tdap Adacel 1 dose of 0.5 mL containing 2.5 ug of detoxified pertussis toxin (PT), filamentous haemagglutinin 5 ug, 3 ug Pertactina; 5 ug Fimbriae type 2 and 3, (in addition to Tetanus Toxoid (5 Lf) and diphtheria toxoid (2Lf) Intramuscular adjuvant free preservative free No co-intervention Placebo Placebo (not specified) Counts Prespecified AE Power other outcome Followup: 9 months	Headache Local erythema Local heat Mild local pain Nausea and/or vomiting Fatigue	NA	Pregnant Women: No significant difference in adverse events between the two groups (only mild-moderate AEs reported including headache, local erythema, local health, mild local pain, nausea and/or vomiting, fatigue). Newborns: Risk factors: NR

Perrett, 2019[181] Perrett, 2019[335]; Perrett, 2019[336]; EUCTR(GSK), 2015 [254]; GlaxoSmithKline, 2019[279] GlaxoSmithKline, 2018[278] GlaxoSmithKline, 2017[276] NCT02377349, NCT02422264 (follow up), NCT02853929 (follow up) Article RCT N=690 Industry funded Australia, Canada, Czech Republic, Finland, Italy, Spain	Age: Intervention: 32.7 (4.4), Control: 32.5 (4.3) % female: 100% Ethnicity: Intervention: 93% White, 3% Asian, 4% Other, Control: 94% White, 1% Asian, 5% Other Pregnant women Out of scope: None	Tdap Boostrix 1 dose of usual Boostrix vaccine (2 IU diphtheria toxoid, 20 IU tetanus toxoid, 8mg pertus-sis toxoid (PT), 8mg filamentous hemagglutinin (FHA), 2.5 mg pertactin (PRN) and 500mgAl) Intramuscular adjuvant free preservative free No co-intervention Placebo Placebo (saline) Counts No prespecified AE Power other outcome Followup: 10 months	Anaemia neonatal Isoimmune haemolytic disease Atrioventricular block complete Supraventricular tachycardia Atrial septal defect Cardiac septal defect Congenital cardiovascular anomaly Congenital hydronephrosis Cryptorchism Hypospadias Microtia Polydactyly Pyloric stenosis Syndactyly Transposition of the great vessels Trisomy 21 Ventricular septal defect Gastrooesophageal reflux disease Vomiting Pyrexia Hyperbilirubinaemia Hyperbilirubinaemia neonatal Jaundice Infections and infestat Amniotic cavity infection Beta haemolytic streptococcal infection Bronchiolitis Endometritis decidual Enterovirus infection Gastroenteritis Influenza Mastitis Nasopharyngitis Neonatal infection Perineal infection Pneumonia Respiratory syncytial virus bronchiolitis Sepsis Sepsis neonatal Superinfection bacterial	Pregnant Women Cardiovascular events: 26.X Deep vein thrombosis I: 1/341, 26.X Deep vein thrombosis C: 0/346 Death: NA NAI: 0/341, NA NA C: 0/346 Diabetes: 14.X Gestational diabetes I: 0/341, 14.X Gestational diabetes C: 0/346 Eclampsia: 18.2 Pre-eclampsia only I: 1/341, 18.2 Pre-eclampsia only C: 5/346 Preterm labor: 18.X Note was reported as 11 in clinical trials.gov I: 13/341, 18.X NR C: 11/346 Reproduction issues: 22.X Vaginal or uterine hemorrhage I: 9/346, 22.X Vaginal or uterine hemorrhage C: 10/346 Stillbirth: 18.4 NR I: 1/341, 18.4 NR C: 1/346 Newborns Birth defects: 3.X From latest f/u; ASD most common (includes severe and non-severe) I: 24/341, 3.X From latest f/u; ASD most common (includes severe and non-severe) C: 28/346 Cardiovascular events: 2.X Arrhythmia (atrioventricular block complete) I: 1/341, 2.X Arrhythmia (supra ventricular tachycardia) C: 1/346 Death: NA NA I: 0/341, NA NA C: 0/346 Encephalitis: 17.X Neonatal hypoxic-ischemic encephalopathy I: 0/341, 17.X Neonatal hypoxic-ischemic encephalopathy C: 0/346	Pregnant Women: Serious AEs from NCT02377349 clinical trials.gov (not captured in above AE table) dTpa Group-Mother vs Control Group-Mother: Total 51/341 (14.96%) vs 52/346 (15.03%) Anaemia neonatal 0/341 (0.00%) vs 0/346 (0.00%) Isoimmune haemolytic disease 0/341 (0.00%) vs 0/346 (0.00%) Atrioventricular block complete 0/341 (0.00%) 0/346 (0.00%) Supraventricular tachycardia 0/341 (0.00%) 0/346 (0.00%) Gastrooesophageal reflux disease 0/341 (0.00%) vs 0/346 (0.00%) Vomiting 0/341 (0.00%) vs 0/346 (0.00%) Pyrexia 0/341 (0.00%) vs 0/346 (0.00%) Hyperbilirubinaemia 0/341 (0.00%) vs 0/346 (0.00%) Jaundice 0/341 (0.00%) vs 0/346 (0.00%) Amniotic cavity infection 0/341 (0.00%) vs 2/346 (0.58%) Beta haemolytic streptococcal infection 1/341 (0.29%) vs 0/346 (0.00%) Bronchiolitis 0/341 (0.00%) vs 0/346 (0.00%) Endometritis decidual 2/341 (0.59%) vs 0/346 (0.00%) Enterovirus infection 0/341 (0.00%) vs 0/346 (0.00%) Gastroenteritis 2/341 (0.59%) vs 1/346 (0.29%) Influenza 0/341 (0.00%) vs 0/346 (0.00%) Mastitis 0/341 (0.00%) vs 1/346 (0.29%) Nasopharyngitis 0/341 (0.00%) vs 0/346 (0.00%) Perineal infection 0/341 (0.00%) vs 1/346 (0.29%) Pneumonia 0/341 (0.00%) vs 0/346 (0.00%) Respiratory syncytial virus bronchiolitis 0/341 (0.00%) vs 0/346 (0.00%) Sepsis 0/341 (0.00%) vs 0/346 (0.00%) Superinfection bacterial 0/341 (0.00%) vs 0/346 (0.00%) Tracheitis 0/341 (0.00%) vs 0/346 (0.00%) Upper respiratory tract infection 0/341 (0.00%) vs 0/346 (0.00%)

			Tracheitis Upper respiratory tract infection Urinary tract infection Fall Procedural haemorrhage Investigat Cardiac murmur Dehydration Hypernatraemia Hypocalcaemia Hypoglycaemia Hypoglycaemia neonatal Neonatal hypocalcaemia Hypotonia Somnolence neonatal Cephalhaematoma Foetal distress syndrome Foetal growth restriction Gestational hypertension Hellp syndrome Jaundice neonatal Large for dates baby Placenta praevia haemorrhage Polyhydramnios Postpartum haemorrhage Pre-eclampsia Premature baby Premature delivery Premature labour Premature rupture of membranes Preterm premature rupture of membranes Retained placenta or membranes Small for dates baby Threatened labour Uterine contractions during pregnancy Renal and urinary disor Acute kidney injury Hydronephrosis Vesicoureteric reflux Female genital tract fistula Metrorrhagia Uterine atony Uterine haemorrhage		Urinary tract infection 1/341 (0.29%) vs 0/346 (0.00%) Fall 1/341 (0.29%) vs 0/346 (0.00%) Procedural haemorrhage 0/341 (0.00%) vs 1/346 (0.29%) Cardiac murmur 0/341 (0.00%) vs 0/346 (0.00%) Dehydration 0/341 (0.00%) vs 0/346 (0.00%) Hypernatraemia 0/341 (0.00%) vs 0/346 (0.00%) Hypocalcaemia 0/341 (0.00%) vs 0/346 (0.00%) Hypoglycaemia 0/341 (0.00%) vs 0/346 (0.00%) Hypotonia 0/341 (0.00%) vs 0/346 (0.00%) Cephalhaematoma 0/341 (0.00%) vs 0/346 (0.00%) Foetal distress syndrome 0/341 (0.00%) vs 2/346 (0.58%) Foetal growth restriction 3/341 (0.88%) vs 0/346 (0.00%) Gestational hypertension 4/341 (1.17%) vs 4/346 (1.16%) (in AE table) Hellp syndrome 0/341 (0.00%) vs 2/346 (0.58%) Jaundice neonatal 0/341 (0.00%) vs 0/346 (0.00%) Large for dates baby 0/341 (0.00%) vs 0/346 (0.00%) Placenta praevia haemorrhage 0/341 (0.00%) vs 1/346 (0.29%) Polyhydramnios 1/341 (0.29%) vs 0/346 (0.00%) Postpartum haemorrhage 5/341 (1.47%) vs 7/346 (2.02%) Premature baby 0/341 (0.00%) vs 0/346 (0.00%) Premature delivery 4/341 (1.17%) vs 4/346 (1.16%) Premature rupture of membranes 13/341 (3.81%) vs 17/346 (4.91%) Preterm premature rupture of membranes 4/341 (1.17%) vs 5/346 (1.45%) Retained placenta or membranes 0/341 (0.00%) vs 1/346 (0.29%) Small for dates baby 0/341 (0.00%) vs 0/346 (0.00%)

			Vaginal haemorrhage Apnoea Asphyxia Dyspnoea Meconium aspiration syndrome Neonatal asphyxia Neonatal respiratory depression Pneumothorax Pulmonary embolism Respiratory distress Transient tachypnoea of the newborn Rash neonatal Deep vein thrombosis Anaemia Anaemia of pregnancy Cardiac disor Bradycardia Supraventricular extrasystoles Deafness Ear pain Hypothyroidism Thyroid dysfunction in pregnancy Conjunctival haemorrhage Dacryostenosis acquired Eczema eyelids Gastrointestinal disor Abdominal discomfort Abdominal pain Abdominal pain lower Abdominal pain upper Constipation Diarrhoea Dyspepsia Flatulence Gastritis Gastrointestinal disorder Gastrooesophageal reflux disease Haemorrhoids Inguinal hernia Stomatitis Toothache Umbilical hernia Vomiting		Threatened labour 2/341 (0.59%) vs 0/346 (0.00%) Uterine contractions during pregnancy 1/341 (0.29%) vs 0/346 (0.00%) Acute kidney injury 0/341 (0.00%) vs 0/346 (0.00%) Hydronephrosis 0/341 (0.00%) vs 1/346 (0.29%) Vesicoureteric reflux 0/341 (0.00%) vs 0/346 (0.00%) Female genital tract fistula 1/341 (0.29%) vs 0/346 (0.00%) Metrorrhagia 0/341 (0.00%) vs 1/346 (0.29%) Uterine atony 1/341 (0.29%) vs 0/346 (0.00%) Uterine haemorrhage 2/341 (0.59%) vs 1/346 (0.29%) Vaginal haemorrhage 2/341 (0.59%) vs 1/346 (0.29%) Note for reproductive disorders that most common is uterine or vaginal hemorrhage. They cannot be combined as both could occur in one individual. In article, rate of vaginal or uterine hemorrhage is 9/341 (2.6%, CI 1.2–5.0) vs 10/346 (2.9%; CI 1.4–5.3), which is used here. Dyspnoea 0/341 (0.00%) vs 0/346 (0.00%) Pneumothorax 0/341 (0.00%) vs 0/346 (0.00%) Pulmonary embolism 0/341 (0.00%) vs 1/346 (0.29%) Respiratory distress 0/341 (0.00%) vs 0/346 (0.00%) Deep vein thrombosis 1/341 (0.29%) vs0/346 (0.00%) (in AE table) Newborns: SGA: Tdap 2/341, No Tdap 2/341 Failure to thrive or growth deficiencies Tdap 0/341, No Tdap 0/341 Serious AEs (from infants at birth through month 2, NCT02377349, clinical trials.gov): Tdap vs Control Total 52/341 (15.25%) vs 45/346 (13.01%) Blood and lymphatic system disorders Anaemia neonatal 0/341 (0.00%) 1/346 (0.29%)

			General disor Asthenia Axillary pain Chills Discomfort Fatigue Granuloma Hypothermia Impaired healing Influenza like illness Injection site bruising Injection site erythema Injection site haematoma Injection site induration Injection site mass Injection site pain Injection site pruritus Injection site rash Injection site reaction Injection site swelling Injection site urticaria Malaise Nodule Peripheral swelling Pyrexia Swelling Vaccination site pain Vessel puncture site bruise Hepatobiliary disor Cholestasis of pregnancy Hyperbilirubinaemia Jaundice Milk allergy Seasonal allergy Amniotic cavity infection Bronchiolitis Bronchitis Conjunctivitis Cystitis Endometritis Fungal infection Fungal skin infection Gastroenteritis Gastroenteritis viral Genital herpes Genital infection Genital infection fungal Groin abscess Herpes simplex		Isoimmune haemolytic disease 1/341 (0.29%) vs 0/346 (0.00%) Atrioventricular block complete 0/341 (0.00%) vs 1/346 (0.29%) Supraventricular tachycardia 1/341 (0.29%) vs 0/346 (0.00%) Gastrooesophageal reflux disease 1/341 (0.29%) vs 0/346 (0.00%) Vomiting 2/341 (0.59%) vs 0/346 (0.00%) Pyrexia 1/341 (0.29%) vs1/346 (0.29%) Hyperbilirubinaemia 3/341 (0.88%) vs 1/346 (0.29%) Hyperbilirubinaemia neonatal 0/341 (0.00%) vs 1/346 (0.29%) Jaundice vs 8/341 (2.35%) vs 6/346 (1.73%) Beta haemolytic streptococcal infection 0/341 (0.00%) vs 0/346 (0.00%) Bronchiolitis 3/341 (0.88%) vs 2/346 (0.58%) Enterovirus infection 0/341 (0.00%) vs 1/346 (0.29%) Gastroenteritis 0/341 (0.00%) vs 0/346 (0.00%) Influenza 1/341 (0.29%) vs 0/346 (0.00%) Nasopharyngitis 0/341 (0.00%) vs 1/346 (0.29%) Neonatal infection 2/341 (0.59%) vs 1/346 (0.29%) Pneumonia 1/341 (0.29%) vs 0/346 (0.00%) Respiratory syncytial virus bronchiolitis 2/341 (0.59%) vs 0/346 (0.00%) Sepsis 1/341 (0.29%) vs 1/346 (0.29%) Sepsis neonatal 0/341 (0.00%) vs 2/346 (0.58%) Superinfection bacterial 1/341 (0.29%) vs 0/346 (0.00%) Tracheitis 0/341 (0.00%) vs 1/346 (0.29%) Upper respiratory tract infection 1/341 (0.29%) vs 0/346 (0.00%) Urinary tract infection 2/341 (0.59%) vs 1/346 (0.29%) Fall 0/341 (0.00%) vs 0/346 (0.00%) Procedural haemorrhage 0/341 (0.00%) vs 0/346 (0.00%) Cardiac murmur 0/341 (0.00%) vs 1/346 (0.29%) Dehydration 2/341 (0.59%) vs /346 (0.29%)

			Hordeolum Influenza Mastitis Mastitis postpartum Nasopharyngitis Nipple infection Oral candidiasis Oral herpes Otitis media acute Periodontitis Pharyngitis Pneumonia Postoperative abscess Postoperative wound infection Pyelonephritis Respiratory tract infection Respiratory tract infection viral Rhinitis Sinusitis Tinea pedis Upper respiratory tract infection Urinary tract infection Vaginal infection Vulvovaginal candidiasis Vulvovaginal mycotic infection Clavicle fracture Dislocation of vertebra Foreign body Incision site pain Joint injury Laceration Ligament sprain Post procedural haematoma Post procedural inflammation Procedural haemorrhage Procedural headache Procedural pain Suture related complication Suture rupture Wound dehiscence Investigat Blood pressure increased Heart rate decreased		Hypernatraemia 1/341 (0.29%) vs 0/346 (0.00%) Hypocalcaemia 2/341 (0.59%) vs 0/346 (0.00%) Hypoglycaemia 2/341 (0.59%) vs 2/346 (0.58%) Hypoglycaemia neonatal 0/341 (0.00%) vs1/346 (0.29%) Neonatal hypocalcaemia 0/341 (0.00%) vs 1/346 (0.29%) Hypotonia 1/341 (0.29%) vs 0/346 (0.00%) Somnolence neonatal 1/341 (0.29%) vs 0/346 (0.00%) Acute kidney injury 0/341 (0.00%) vs 1/346 (0.29%) Hydronephrosis 0/341 (0.00%) vs 0/346 (0.00%) Vesicoureteric reflux 0/341 (0.00%) vs 1/346 (0.29%) Apnoea 1/341 (0.29%) vs 0/346 (0.00%) Asphyxia 0/341 (0.00%) vs 1/346 (0.29%) Dyspnoea 0/341 (0.00%) vs 1/346 (0.29%) Meconium aspiration syndrome 0/341 (0.00%) vs 1/346 (0.29%) Neonatal asphyxia 1/341 (0.29%) vs 0/346 (0.00%) Neonatal respiratory depression 0/341 (0.00%) vs 1/346 (0.29%) Pneumothorax 0/341 (0.00%) vs 1/346 (0.29%) Pulmonary embolism 0/341 (0.00%) vs0/346 (0.00%) Respiratory distress 5/341 (1.47%) vs 4/346 (1.16%) Transient tachypnoea of the newborn 0/341 (0.00%) vs 1/346 (0.29%) Rash neonatal 0/341 (0.00%) vs1/346 (0.29%) Deep vein thrombosis 0/341 (0.00%) vs 0/346 (0.00%) Serious AEs (from infants 6 weeks through 6 month vaccines, NCT02422264, clinical trials.gov): Tdap vs Control Total 7/296 (2.36%) vs 7/305 (5.57%) Intestinal hemorrhage 1/296 (0.34%) vs 0/305 (0.00%) Vomiting 0/296 (0.00%) vs 1/305 (0.33%)

			Cow's milk intolerance Fluid retention Iron deficiency Arthralgia Back pain Flank pain Ligament pain Limb discomfort Muscle haemorrhage Musculoskeletal stiffness Myalgia Neck pain Pain in extremity Anogenital warts Melanocytic naevus Aphonia Dizziness Extrapyramidal disorder Headache Migraine Migraine with aura Paraesthesia Paralysis Restless legs syndrome Sciatica Somnolence Syncope Afterbirth pain Cephalhaematoma Cervical dilatation Labour pain Oligohydramnios Small for dates baby Traumatic delivery Uterine contractions during pregnancy Uterine hypotonus Uterine irritability Psychiatric disor Affect lability Depression Insomnia Irritability Dysuria Pyelocaliectasis Renal colic Urethral prolapse Breast engorgement Breast inflammation Breast mass		Milk allergy 1/296 (0.34%) vs 0/305 (0.00%) Bacterial infection 0/296 (0.00%) vs 1/305 (0.33%) Bronchiolitis 1/296 (0.34%) vs 4/305 (1.31%) Bronchitis 0/296 (0.00%) vs 1/305 (0.33%) Candida infection 0/296 (0.00%) vs 1/305 (0.33%) Conjunctivitis 0/296 (0.00%) vs 1/305 (0.33%) Pyelonephritis 0/296 (0.00%) vs 1/305 (0.33%) Respiratory syncytial virus bronchiolitis 0/296 (0.00%) vs 1/305 (0.33%) Superinfection bacterial 0/296 (0.00%) vs 1/305 (0.33%) Upper respiratory tract infection 0/296 (0.00%) vs 1/305 (0.33%) Urinary tract infection 1/296 (0.34%) vs 1/305 (0.33%) Viral infection 0/296 (0.00%) vs 1/305 (0.33%) Fall 0/296 (0.00%) vs 1/305 (0.33%) Femur fracture 0/296 (0.00%) vs 1/305 (0.33%) Skull fracture 1/296 (0.34%) vs 0/305 (0.00%) Skull fractured base 1/296 (0.34%) vs 0/305 (0.00%) Wound haemorrhage 0/296 (0.00%) vs 1/305 (0.33%) Altered state of consciousness 1/296 (0.34%) vs 0/305 (0.00%) Risk factors: NR

			Breast pain Cervical discharge Menorrhagia Metrorrhagia Nipple disorder Nipple inflammation Nipple pain Ovarian cyst torsion Pelvic pain Perineal pain Pruritus genital Suppressed lactation Uterine pain Uterine prolapse Vaginal discharge Varicose veins vulval Vulvovaginal pain Cough Epistaxis Grunting Nasal congestion Nasal obstruction Oropharyngeal pain Respiratory distress Rhinitis allergic Rhinorrhoea Sinus congestion Throat irritation Transient tachypnoea of the newborn Upper-airway cough syndrome Alopecia areata Dermatitis Dermatitis contact Erythema Hyperhidrosis Ingrowing nail Night sweats Pruritus Pruritus generalised Rash Urticaria Hot flush Hypertension Hypotension Phlebitis Raynaud's phenomenon Thrombosis Varicose vein		

Petousis-Harris, 2019[182] Article Cohort study N=69389 Unrestricted industry grant New Zealand	Age: Maternal age 28.6 (6.1) % female: 49 Ethnicity: 26% Maori, 11% Pacific, 14% Asian, 49% European/Other Live-born infants in NZ weighing at least 400 g at delivery and born to women who were eligible for the NZ Ministry of Health (MoH)-funded, national-level vaccination program in 2013 Out of scope: None	Tdap Brand NR Route NR adjuvant NR preservative NR Co-intervention Some received influenza vaccine as well Base treatment No maternal Tdap, some received influenza vaccine as well Counts Prespecified AE Power NR Followup: 12 months	Stillbirth Perinatal death Neonatal death Infant death Preterm birth Congenital anomalies (major and minor) Infection Sudden infant death syndrome Fetus and newborn affected by maternal conditions Fetus and newborn affected by maternal complications of pregnancy Fetus and newborn affected by abnormality of membranes Fetus and newborn affected by complications of labor and delivery Small for gestational age (SGA) Other fetal malnutrition Low birth weight (LBW) Moderate to late preterm High birth weight Large for gestational age infants Scalp injury due to birth trauma Birth trauma to face Other specified birth trauma Intrauterine hypoxia Asphyxia Respiratory distress syndrome Transient tachypnea of newborn Respiratory distress Congenital pneumonia Meconium aspiration syndrome Interstitial emphysema and related conditions Apnea	Pregnant Women Preterm labor: 18.1 Moderate to late preterm (32 to <37 weeks): I: 398/8299, 18.1 Moderate to late preterm (32 to <37 weeks): C: 3412/61090 Newborns Birth defects: 3.X Ankyloglossia I: 221/8299, 3.X Ankyloglossia C: 1063/61090 Cardiovascular events: 2.X Tachycardia or bradycardia I: 55/8299, 2.X Tachycardia or bradycardia C: 515/61090 Encephalitis: 17.X Hypoxic ischemic encephalopathy I: 12/8299, 17.X Hypoxic ischemic encephalopathy C: 101/61090 Seizure: 17.X NR I: 18/8299, 17.X NR C: 136/61090	Pregnant Women: Tdap exposed (N=8299) vs Tdap Unexposed (N=61090), adjusted OR (95% CI): Moderate to late preterm 32 to <37 weeks: counts in AE table, aOR 0.831 (0.729,0.947) Newborns: Tdap exposed (N=8299) vs Tdap Unexposed (N=61090), adjusted OR (95% CI): Low birth weight (1500 to <2500 g): 186 (2.2%) vs 1800 (2.9%), 0.784 (0.653,0.941) Small for gestational age: 117 (1.4%) vs 1204 (2.0%), 0.721 (0.574,0.905) Large for gestational age: 31 (0.4%) vs 335 (0.5%), 0.567 (0.359,0.894) Respiratory distress syndrome: 131 (1.5%) vs 1392 (2.3%), 0.652 (0.524,0.811) Transient tachypnea of newborn: 247 (3.0%) vs 2034 (3.3%), 0.839 (0.721,0.975) Tachycardia or bradycardia: counts in AE table, 0.691 (0.501,0.954) Hemolytic diseases: 39 (0.5%) vs 416 (0.7%), 0.663 (0.444,0.990) Other neonatal jaundice: 308 (3.7%) 2722 (4.5%), 0.827 (0.733,0.932) Anemia: 20 (0.2%) vs 256 (0.4%), 0.461 (0.270,0.786) Syndrome of infant of mother with gestational diabetes: 50 (0.6%) vs 538 (0.9%), 0.683 (0.487,0.960) Hypoglycemia: 236 (2.8%) vs 2178 (3.6%), 0.795 (0.681,0.929) Infant Apgar score at 5 min after birth: mean 9.537 (SD 0.879) vs mean 9.531 (SD 0.870), adjusted means difference 0.000 (−0.022,0.023) Asphyxia: 49 (0.6%) vs 318 (0.5%), 1.374 (0.968,1.951) Sepsis or infection: Bacterial sepsis: 37 (0.4%) vs 339 (0.6%), 0.872 (0.599,1.270) Candidiasis: 17 (0.2%) vs 178 (0.3%), 0.656 (0.381,1.131) Omphalitis: 29 (0.3%) vs 181 (0.3%), 1.399 (0.875,2.236)

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
			Tachycardia or bradycardia Benign and innocent cardiac murmurs in newborn Bacterial sepsis of newborn, specified or unspecified Candidiasis Omphalitis Neonatal conjunctivitis and dacryocystitis Neonatal skin infection Neonatal hemorrhage Haemolytic diseases Other neonatal jaundice Thrombocytopenia Anemia Syndrome of infant of mother with gestational diabetes Syndrome of infant of a diabetic mother Hypoglycemia Dehydration of newborn Electrolyte anomalies Hypothermia Other disturbances of temperature regulation of newborn Neonatal erythema toxicum Congenital hydrocele Other conditions of integument Seizure Hypoxic ischemic encephalopathy Vomiting Difficulty feeding Congenital hypotonia Jittery baby Ankyloglossia Talipes equinovarus, metatarsus varus, other congenital deformities of feet		Hypoxic ischemic encephalopathy: counts in AE table, 0.786 (0.390,1.585) Mean birthweight: mean 3467 (SD 532) vs mean 3429 (SD 592), adjusted means difference 35.585 (21.392,49.778) Ankyloglossia: counts in AE table with birth defects, 1.241 (1.044,1.474) Talipes equinovarus, metatarsus varus, or other congenital deformities of feet: 33 (0.4%) vs 276 (0.5%), 0.963 (0.612,1.516) Neonatal erythema toxicum: 47 (0.6%) vs 219 (0.4%), 1.661 (1.163,2.372) Seizures, counts in AE table 1.059 (0.602,1.862) There were insufficient observations to allow examination of the effect of Tdap on extreme preterm and very preterm birth, and stillbirth, infant death, or microcephaly (0 infants with microcephaly in exposed group, 3 in unexposed). Risk factors: NR

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
Sancovski, 2019[191] GlaxoSmithKline, 2017[275] NCT02757950 Article Cohort study N=2447 Industry funded Brazil	Age: Tdap: 26.49 (6.15), No Tdap 26.28 (6.24) % female: 100% Ethnicity: Ethnicity NR Pregnant women Out of scope: None	Tdap Boostrix 1 dose Route NR adjuvant NR preservative NR No co-intervention No intervention Unvaccinated women Counts Prespecified AE Power calculation Followup: 3 months	Premature rupture of membranes, Preterm premature rupture of membranes, Premature uterine contraction Neonatal death Maternal death Still birth Congenital anomalies Neonatal hypoxic ischaemic encephalopathy Gestational diabetes Pregnancy-related hypertension Pregnancy hemorrhage or Vaginal hemorrhage Preterm birth Small for gestational age Pre-eclampsia Eclampsia Hemolysis, elevated liver enzymes, and low platelet count (HELLP) Syndrome	Pregnant Women Cardiovascular events: 26.1 Pregnancy-related hypertension I: 11/1199, 26.1 Pregnancy-related hypertension C: 31/1259 Death: NA NAI: 0/1199, NA NA C: 0/1259 Diabetes: 14.X Gestational diabetes I: 10/1199, 14.X Gestational diabetes C: 22/1259 Eclampsia: 18.3 Pre-eclampsia (10) and eclampsia (2) I: 12/1199, 18.3 Pre-eclampsia (30) and eclampsia (0) C: 30/1259 Preterm labor: 18.X Preterm birth I: 64/1199, 18.X Preterm birth C: 121/1259 Reproduction issues: 21.X Vaginal hemorrhage I: 4/1199, 21.X Vaginal hemorrhage C: 19/1259 Stillbirth: 18.4 NR I: 1/1199, 18.4 NR C: 6/1259 Newborns Birth defects: 3.X Congenital anomalies, none thought to be due to Tdap I: 5/1199, 3.X Congenital anomalies, none thought to be due to Tdap C: 22/1259 Death: NA NA I: 0/1199, NA NA C: 8/1259 Encephalitis: 11.X Neonatal hypoxic ischemic encephalopathy I: 0/1199, 11.X Neonatal hypoxic ischemic encephalopathy C: 0/1259	Pregnant Women: HELLP syndrome: Tdap 0/1199, No Tdap 1/1259 Premature rupture of membranes Tdap 190/1199, No Tdap 261/1259 Preterm premature rupture of membranes: Tdap 17/1199, No Tdap 36/1259 Newborns: SGA: Tdap 69/1199, No Tdap 62/1259 Risk factors: NR

Shakib, 2013[198] Article Cohort study N=690 Not industry funded USA	Age: 27 % female: 100% Ethnicity: Ethnicity NR Pregnant women Out of scope: None	Tdap Brand NR Route NR adjuvant NR preservative NR No co-intervention No intervention No Tdap Counts Prespecified AE Power NR Followup: 22 months	Stillbirth Spontaneous abortion Ventricular sept defect Secundum atrial sept def Congenital hydrocele Upper limb vessel anomal Skin anomaly nec Common truncus Skin anomaly nec Cong heart anomaly nec Abn fetal hrt unspec Congenital chordee Bladder disorder nec Congenital hydrocele Cong skin pigment anomal Hypospadias Congenital hydrocele Lower limb anomaly nec Ventricular sept defect Secundum atrial sept def Anomal skull/face bones Cong skin pigment anomal Secundum atrial sept def Cong esoph fistula/ atres Reduction deform, brain Secundum atrial sept def Intestinal anomaly nec Longitud defic phalanges V293 obs susp genetic metabol Obst def renal pel/uret Cardiovascular (Complex chronic condition) Neuromuscular (Complex chronic condition) Respiratory (Complex chronic condition) Cardiovascular (Complex chronic condition) Renal (Complex chronic condition) Gastrointestinal (Complex chronic condition) Metabolic (Complex chronic condition) Genetic (Complex chronic condition)	Pregnant Women Preterm labor: 18.X <37 weeks I: 8/134, 18.X <37 weeks C: 38/505 Spontaneous abortion: 18.X NR I: 4/138, 18.X NR C: 49/552 Stillbirth: 18.4 NR I: 0/138, 18.4 NR C: 5/552 Newborns Birth defects: 3.X Congenital anomalies I: 5/134, 3.X Congenital anomalies C: 22/505 Cardiovascular events: 2.X Cardiovascular complex chronic conditions I: 2/134, 2.X Cardiovascular complex chronic conditions C: 14/505	Pregnant Women: Newborns: Gestational age (mean): Tdap: 39 weeks, No Tdap 39 weeks Birth weight (mean): Tdap 3384g, No Tdap 3305g Complex chronic condition diagnosis in first 12 months of life: Tdap 3/83, No Tdap 32/307 Risk factors: NR

Study Details	Participant Characteristics	Intervention Comparator Analysis	Assessed Adverse Events	Rates and Severity of Key Adverse Events	Other Results
			Malignancy (Complex chronic condition)		