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CADTH RAPID RESPONSE REPORT:
SUMMARY WITH CRITICAL APPRAISAL

Skin Preparation for Injections: A Review of Clinical Effectiveness, Cost-Effectiveness and Guidelines

Service Line:	Rapid Response Service
Version:	2.0 Corrected Version (see page 16 for the correction notice)
Publication Date:	March 2020
Report Length:	16 Pages

CADTH

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Cite As: Skin preparation for injections: a review of clinical effectiveness, cost-effectiveness, and guidelines. Ottawa: CADTH; 2020 Mar. (CADTH Rapid Response Report: Summary with Critical Appraisal).

ISSN: 1922-8147 (online)

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Funding: CADTH receives funding from Canada's federal, provincial, and territorial governments, with the exception of Quebec.

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Abbreviations

RCT	Randomized controlled trial
SD	Standard deviation
WHO	World Health Organization

Context and Policy Issues

Infection control is a priority for all health care professionals and includes a variety of practices commonly used for patients and the general public. One branch of infection control is skin preparation, also known as alcohol swabbing. This a common technique often involving the application of a disinfectant to the skin prior to a surgical or non-surgical procedures.[1] An example of skin preparation is when health professionals wipe (or swab) an alcohol or other disinfectant solution before they administer an injectable or when withdrawing blood from an individual. Although skin preparation has been widely used and implemented across health organizations, there has been recent debate whether skin preparation before vaccine (or other injectables) administration reduces infection rates for patients.[2]

According to the World Health Organization (WHO)[1], injections are unsafe when administered with unsterile or improper technique and it is important to avoid contamination when administering injectables like vaccinations or medication (e.g., insulin). The WHO suggests that the standard practice for skin preparation with regards to vaccination or other injectables is swabbing the injection site with a saturated 60% to 70% alcohol swab for 30 seconds and allowing the area to dry for 30 seconds.[1] A variety of alcohol swabs are available on market including isopropyl or ethanol-based swabs. Alcohol swabs can be costly for health organizations to prioritize in budgets due to a high volume of vaccinations taking place. For instance, vaccination programs can be costly given the number of publicly funded vaccines recommended for Canadian children and adults as these programs not only encompass the administration of vaccines but also staff training, and infection control procedures surrounding vaccine administration, including skin preparation.[3]

Various health organizations including the WHO,[1] United Kingdom's Department of Health,[4] and Australia's Department of Health[5] have stated that if the skin is visibly clean, disinfecting the skin (or alcohol swabbing) is not necessary and does not reduce infection. To the contrary, the Public Health Agency of Canada[6] advises the practice of cleaning the skin with a suitable antiseptic solution prior to vaccination or injection. Hence, there is ongoing debate whether the continued use of alcohol swabbing is clinically necessary and effective for routine injections or vaccinations.

The purpose of this report is to summarize the evidence regarding the clinical effectiveness and cost-effectiveness of skin preparation prior to injections. Evidence-based guidelines regarding preparing the skin for injection will also be sought.

Research Questions

1. What is the clinical effectiveness of skin preparation prior to injections in patients eligible for injections?
2. What is the cost-effectiveness of skin preparation prior to injections in patients eligible for injections?
3. What are the evidence-based guidelines for preparing the skin for injection?

Key Findings

One relevant randomized controlled trial was identified regarding the effectiveness of skin preparation prior to vaccinations in children. The study found that there was no statistically significant difference in local skin reactions and infection rates when comparing alcohol skin cleansing to no cleansing prior to vaccinations. The duration of pain was statically significantly higher in the alcohol swab group compared to the control group. There were no identified cases of cellulitis, pus leaking and infectious abscess. However, the study was insufficiently powered to detect a difference in the primary outcome of skin infection. Due to the limitations of the study it is difficult to draw sound conclusions of whether alcohol swabbing reduces infection rates compared to no swabbing.

No cost-effectiveness studies or evidence-based guidelines were identified regarding skin preparation prior to injection.

Methods

Literature Search Methods

A limited literature search was conducted by an information specialist on key resources including PubMed, CINAHL via EBSCO, the Cochrane Library, the University of York Centre for Reviews and Dissemination (CRD) databases, the websites of Canadian and major international health technology agencies, as well as a focused Internet search. The search strategy was comprised of both controlled vocabulary, such as the National Library of Medicine's MeSH (Medical Subject Headings), and keywords. The main search concepts were skin preparation and injections. No filters were applied to limit the retrieval by study type. Where possible, retrieval was limited to the human population. The search was also limited to English language documents published between January 1, 2009 and October 22, 2019.

Selection Criteria and Methods

One reviewer screened citations and selected studies. In the first level of screening, titles and abstracts were reviewed and potentially relevant articles were retrieved and assessed for inclusion. The final selection of full-text articles was based on the inclusion criteria presented in Table 1.

Table 1: Selection Criteria

Population	Q1-Q3: Patients of all ages eligible for injection
Intervention	Q1-Q3: Skin preparation before injection of a medicinal substance (e.g., vaccination, insulin injection, therapeutic) Excludes: single-use cosmetic injections
Comparator	Q1-Q2: Any alternative method to prepare the skin; no preparation of skin Q3: Not applicable
Outcomes	Q1: Clinical effectiveness (e.g., skin infection, skin reaction, abscesses, sepsis, pain, anxiety during the procedure) Q2: Cost-effectiveness (e.g., cost per patient adverse events avoided, cost per benefit gained) Q3: Evidence-based guidelines
Study Designs	Health technology assessments, systematic reviews, meta-analyses, randomized-controlled trials, non-randomized studies, economic evaluations and evidence-based guidelines

Exclusion Criteria

Articles were excluded if they did not meet the selection criteria outline in Table 1, they were duplicate publications or were published prior to 2009. Guidelines with unclear methodology were also excluded.

Critical Appraisal of Individual Studies

The included study was critically appraised by one reviewer using the Downs and Black checklist.[7] Summary scores were not calculated for the included studies; rather, a review of the strengths and limitations of each included study were described narratively.

Summary of Evidence

Quantity of Research Available

A total of 321 articles were identified in the literature search. Following screening of titles and abstracts, 312 citations were excluded and nine potentially relevant articles from the electronic search were retrieved for full review. Additionally, eight potentially relevant publications were retrieved from the grey literature search for full text review. Of these potentially relevant articles, one study[8] met the inclusion criteria and was included in this report while the remaining 16 publications were excluded for various reasons. Appendix 1 presents the PRISMA flowchart of the study selection. References of potential interest that are not included in the main report can be found in Appendix 5.

Summary of Study Characteristics

The characteristics of the identified study (Table 2) are presented in Appendix 2.

Study Design

The identified study was a single center, partially blinded randomized controlled trial (RCT) conducted in a private outpatient pediatric clinic.[8] Patients, parents, and pediatricians performing the vaccine injections were blinded in the study. Moreover, the clinic-based research assistant was unblinded for the purpose of treatment allocation and obtained

consent, confirmed the vaccines being administered, and performed the alcohol swabbing at the allocation site on participants.

Country of Origin

The RCT was conducted by authors in Toronto, Canada.[8]

Patient Population

Healthy patients 18 years or younger and qualified for vaccination with the Ontario Immunization Schedule at the pediatric clinic were included in the RCT. Patients were excluded if the parent was not fluent in English, previously participated in a similar study, the child had a documented allergy to isopropyl alcohol, were taking antibiotics, had a vaccine contradiction or was unavailable for the duration of post-vaccination follow-up. Patients included in the study did not differ between the two groups with respect to age, sex and number of vaccine injections administered. During the study, patients received between one to four standard childhood vaccinations such as polio, mumps, measles and rubella.[8]

Interventions and Comparators

The RCT examined the use of alcohol swabbing at the injection site (i.e., alcohol swab group) versus alcohol swabbing adjacent to the vaccine injection site (i.e., control group) using a commercial 70% isopropyl swab packet. The alcohol swab was applied using a spiral motion starting from the center outwards covering a 2-inch circular area in diameter for 30 seconds followed by a 30 second drying period before administering the injection.[8]

Outcomes

The RCT was underpowered to measure the primary outcome, skin infection. As a result, the secondary surrogate outcome was the incidence of local skin reaction encompassing delayed pain, redness, swelling, warmth to touch, cellulitis, infectious abscess and pus leaking. The sample size calculation was performed to detect differences between groups specifically in delayed pain. Outcomes were reported 15 days post-vaccination by the parents of the included patients with written and oral instructions provided on how to measure the outcomes; no other details on the outcome measures were provided. Cellulitis and infectious abscesses were diagnosed by a pediatrician using the Brighton level diagnostic criteria.[8]

Summary of Critical Appraisal

The reporting of the RCT was considered well done overall, with a clear description of the objective, patient eligibility criteria, inventions and controls. The outcomes were described; however, most of the outcomes were reported by the parents of the patients (except cellulitis and infectious abscesses which were diagnosed by a pediatrician) rather than an objective assessment of the outcome by a health professional. This subjective approach to reporting outcomes may bias the outcomes; though the authors noted that this would not introduce differential reporting between groups. As patients and the parents were blinded to the treatment group, they would unlikely be influenced differently between groups in their outcome reporting (i.e., the assessment of outcomes is equally flawed across groups). The study reported that approximately 20% of diaries were not returned by parents which may impact the validity and interpretation of results. Furthermore, the authors undertook a post-hoc analysis for both groups regarding the duration of local skin reaction and this analysis was considered justifiable as this outcome was unspecified before the data was seen.[8]

Additionally, the study was described as being partially blinded with the all participants, parents and pediatricians (administering the injections) being blinded, though the clinic-based research assistant who performed the skin preparation for both intervention and control groups was not blinded. The choice of unblinding the clinic-based research assistant who performed skin preparation was considered justifiable as it may not have been possible to blind the individual performing this task. As this was the only unblinded person in this study, the risk of bias was. Nevertheless, the same clinic-based research assistant who performed the skin preparation also interviewed the parents post-vaccination for the results. This may bias the study results as the clinic-based research assistant's knowledge of treatment group allocation for each patient may have affected the reporting of results. Additionally, the randomization and allocation were clearly defined in the study protocol and both groups were followed up for the same amount of time. This reduces selection bias and the influence of confounding variables in the study and strengthens the internal validity (the extent to which the study supports a claim about cause and effect) of the study.[8]

A power calculation was performed, but the study did not recruit enough participants to meet this threshold and to appropriately measure to main outcome. Rather, the researchers powered it for the secondary outcome (i.e., incidence of delayed pain). Although the authors indicated that it was not feasible to recruit a sufficient number of patients for the primary outcome, this may limit the interpretation of results and conclusion of the study.

Additional details regarding the strengths and limitations of the study are provided in Appendix 3, **Table 3**.

Summary of Findings

A detailed summary of findings is provided in Appendix 4Appendix 3, Table 4.

Clinical Effectiveness of Alcohol Swabbing Prior to Injectables

The incidences of any local skin reaction, including delayed pain, redness, swelling, warmth to touch, pus leaking, cellulitis and infectious abscesses, were reported for both the alcohol swab and control group and categorized by different skin reactions. The overall incidence of local skin reaction was not statistically significantly different between the alcohol swab and control groups.[8]

Pain

The study reported the incidence of delayed pain was not statistically significantly different in the alcohol swab group compared to the control group. Post-hoc analysis indicated the duration of pain was longer among the alcohol swab group and statically significant compared to the control group. The authors did not comment on the clinical significance of the difference in this outcome between groups.[8]

Redness

The incidence of redness was not statistically significantly different between the alcohol swab and control group in the study. Similarly, post-hoc analysis revealed the duration of redness were similar between groups.[8]

Swelling

Both the incidence of swelling and post-hoc analysis of the duration of swelling were not statistically significantly different between the alcohol swab and control group in the study.[8]

Warmth to touch

The incidence of warmth to touch and the post-hoc analysis for the duration of warmth to touch were not statically significantly different between the alcohol swab group and control group in the study.[8]

Pus leaking

No cases were identified in the study.[8]

Cellulitis

No cases were identified in the study.[8]

Infectious abscess

No cases were identified in the study.[8]

Cost-Effectiveness of Alcohol Swabbing Prior to Injectables

No relevant evidence regarding the cost-effectiveness of alcohol swabbing prior to injections were identified; therefore, no summary can be provided.

Guidelines for Preparing the Skin for Injection

No relevant guidelines for preparing the skin for injection were identified; therefore, no summary can be provided.

Limitations

No relevant health technology assessments, systematic reviews and non-randomized studies were identified regarding the effectiveness of skin preparation prior to injections. Additionally, no cost-effectiveness studies or evidence-based guidelines were identified.

There were several gaps in the literature associated with the included randomized-controlled trial. A primary limitation of this review is the paucity of available comparative evidence. In order to draw conclusions about the effectiveness of alcohol swabbing prior to injections, it is important to have additional randomized controlled trials with vaccinations and other injectables. Moreover, no cost-effectiveness studies or evidence-based guidelines for skin preparation prior to injections were identified.[8]

The study was underpowered to report on the primary outcome of the study (skin infection) while the recruitment rate was slightly lower than the target of 50% of eligible patients (44% for alcohol swab group and 50% for control group recruited) and 21% of parents did not provide diary or phone interview data during the follow-up period. This may limit the ability to draw strong conclusions due to some deficiencies in sample size and data availability. There were some limitations regarding the generalizability of the identified study. Although the study was conducted in Canada, it was a single center (pediatric clinic) trial and may not be generalizable to other injection or administration sites throughout Canada. Moreover, the study only included healthy patients which may not be generalizable to the overall population, as all children are likely to receive at least one type of childhood vaccination whether they are considered healthy or sick. However, the researchers may have eliminated confounders for infection risk by limiting the study to only healthy participants. While the study only focused on skin preparation prior to vaccinations and did not include

other injectables (or withdrawing blood), there may be no difference in terms infection rates between other injectables and vaccinations.[8]

Finally, future studies could improve their measured outcomes as the identified study[8] outcomes were reported by parents of the participants rather than a more objective measurement approach (e.g., clinician measuring incidence of skin reaction with criteria). Hence, more research is needed to form a definitive conclusion as to whether skin preparation is necessary prior to injections or vaccinations.

Conclusions and Implications for Decision or Policy Making

One randomized controlled trial was included in this report comparing skin preparation to no skin preparation prior to injection. No relevant cost-effectiveness studies or evidence-based guidelines were identified regarding preparing the skin for injection.

Evidence from the randomized-controlled trial suggested that alcohol swabbing does not reduce local skin reactions prior to vaccination. The study had reasonable attempts at blinding where possible and described the main outcomes, recruitment process and overall results. There were no statistically significant differences between the alcohol swab group and control group for delayed pain, redness, swelling and warmth to touch while there were no reported cases of cellulitis and infectious abscesses. Post-hoc analysis showed that the duration of pain was statistically significantly higher in the alcohol swab group compared to the control group although the clinical significance of this outcome not discussed by the authors. The study was underpowered to detect differences in the primary outcome of skin infection and instead focused on the differences of local skin reaction between groups. Therefore, the study did not answer the primary outcome and a larger sample size is needed to detect whether alcohol swabbing does reduce the risk of infection. While the authors report that this is one of the first studies to report on the effectiveness of alcohol swabbing prior to vaccinations, it is difficult to draw definitive conclusions from a single trial.[8]

While there is continued support regarding the importance of infection control and sanitization across the health care field, it may not be necessary to continue skin preparation for routine vaccinations or injectables. However, further research including larger studies, is necessary to reduce uncertainty and conclude whether skin cleaning prior to vaccination reduces local skin reactions. Moreover, future studies examining other types injectables, not only routine vaccinations, will provide better insight if skin preparation, is necessary for all injectables.

References

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2. Gittens G, Bunnell T. Skin disinfection and its efficacy before administering injections. *Nurs Stand.* 2009;23(39):42-44.
3. Government of Canada. Vaccination coverage and registries. Ottawa (ON): Government of Canada; 2019 Oct: https://www.canada.ca/en/public-health/services/immunization-coverage-registries.html. Accessed 2019 Nov 19.
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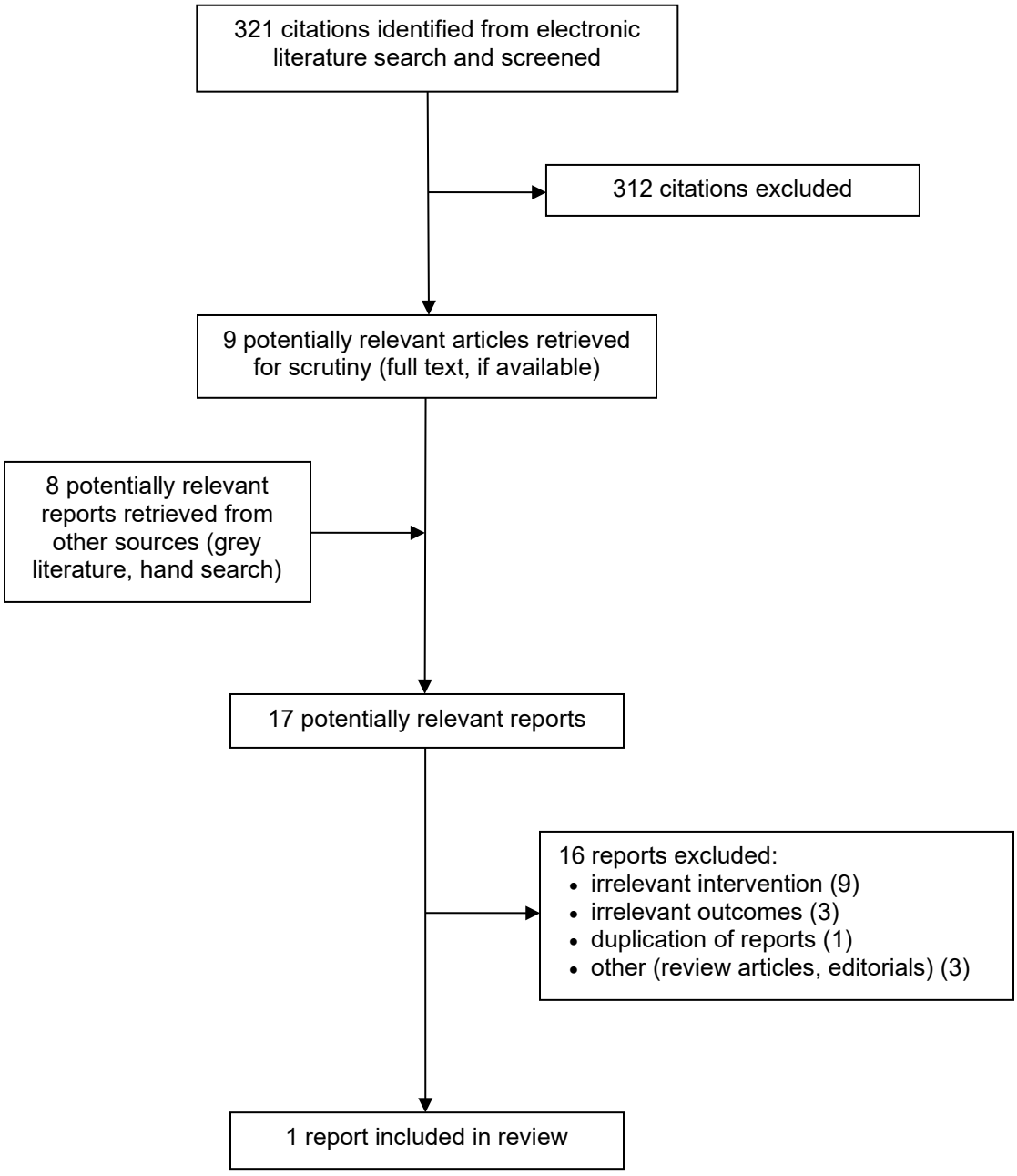
8. Wong H, Moss C, Moss SM, et al. Effect of alcohol skin cleansing on vaccination-associated infections and local skin reactions: a randomized controlled trial. *Hum Vaccin Immunother.* 2019;15(4):995-1002.

Appendix 1: Selection of Included Studies



Appendix 2: Characteristics of Included Publications

Table 2: Characteristics of Included Primary Clinical Study

First Author, Publication Year, Country	Study Design	Population Characteristics	Intervention and Comparator(s)	Clinical Outcomes, Length of Follow-Up
Wong 2019, Canada **Funding**: Provided by Dean's award to Dr. Taddio and miscellaneous funds by Dr. Taddio	RCT, semi-blinded, single center Two pediatricians administered all vaccine injections **Setting:** Pediatric primary care clinic in Toronto, Canada **Objective**: "to determine the impact of alcohol application at the site of injection before vaccination injections on the incidence of local skin reactions, including infection." (pg. 3)	**Inclusion criteria**: Healthy children aged zero to 18 years who qualified for vaccination in accordance with the Ontario Immunization Schedule were eligible. Participants received one to four vaccinations **Exclusion criteria**: Children were excluded if a parent was not fluent in English or was unavailable for the 15 days post vaccination follow-up period, previously participated in the study, documented allergy to isopropyl alcohol, taking antibiotics or had a contraindication to vaccination. **Number of patients:** 420 patients were screened and 170 recruited **Mean age**: 5.6 years (alcohol swab) and 5.9 years (control) **Sex**: 53% male (alcohol swab) and 60% male (control)	**Intervention**: Alcohol swab at injection site (70% isopropyl alcohol) group N=85 **Control group**: Swabbing adjacent to injection site N=85 **Procedure**: Staff administered a commercial 70% isopropyl alcohol swab packet and swabbed the allocated site, either the injection site (alcohol swab group) or adjacent to the site (control group) using a spiral motion for 30 seconds, followed by a drying time of at least 30 seconds.	• Primary outcome: skin infection • Secondary (surrogate) outcome: Local skin reactions (delayed pain, redness, swelling, warmth, and spontaneous drainage of pus at injection site, cellulitis, infectious abscesses) Length of follow-up: 14 days

RCT = randomized controlled trial

Appendix 3: Critical Appraisal of Included Publications

Table 3: Strengths and Limitations of Clinical Studies using Downs and Black[7]

Strengths	Limitations
Wong, 2019[8]	
• The aim of the study, outcomes, eligibility criteria, intervention, and comparators were all well described • The main findings of the study are clearly described, and actual probability values were clearly reported • The study provided estimates of the random variability in the data for the main outcomes • Study patients were randomized and allocation procedures were clearly described • Patients, parents and staff were blinded in the study • The patients that participated in the study were likely representative of the entire population from which they were recruited • The staff, places, and facilities where the patients were treated, were likely representative of the treatment and entire population • Statistical testing was conducted to assess the appropriateness of outcomes • Post-hoc analysis was justified and appropriate by the authors. The researchers acknowledged that the duration of local skin reactions was not included in the initial protocol of the study (i.e., only looking at incidence of skin reaction across groups rather than the duration) • Patients from each group were recruited from the same population and recorded for the same follow-up time • Losses of patients to follow-up were reported in the study • Potential conflicts of interest and risk of bias from funding was declared	• Minimal information was provided about the study population and overall differences between groups are uncertain • Local skin reaction outcomes were assessed and reported by parents of children receiving vaccinations in both groups • A power calculation was performed, but the study did not recruit enough participants to meet this threshold and to appropriately measure to main outcome. Rather, the researchers powered for the secondary outcome, incidence of delayed pain • Complete follow up data were not available for 21% of patients

Appendix 4: Main Study Findings and Authors' Conclusions

Table 4: Summary of Findings of Included Primary Clinical Study

Main Study Findings	Authors' Conclusion
Wong, 2019 [8]	
138/170 (81%) parent participants returned their diaries Follow-up telephone surveys were available for 99% (168/170) on Day 1, 99% (168/170) on Day 5, and 94% (160/170) on Day 14 postvaccination **Incidence of reactions day 0-14 post-vaccination:** *Any local skin reaction:* 58% (49/85) alcohol swab vs. 54% (45/83) control group *P* = 0.59 *Delayed Pain:* 45% (38/85) alcohol swab vs. 40% (33/83) control group *P* = 0.47 *Redness:* 26% (22/85) alcohol swab vs. 21% (17/83) control group *P* = 0.38 *Swelling:* 20% (17/85) alcohol swab vs. 13% (11/83) control group *P* = 0.23 *Warmth to touch:* 19% (16/85) alcohol swab vs. 27% (22/83) control group *P* = 0.25 *Cellulitis, pus leaking or infectious abscess:* No reported cases for both groups **Post-hoc analysis:** *Mean duration (days) of pain (standard deviation):* 0.6 (1.2) alcohol swab vs. 0.3 (0.7) control group *P* < 0.001 *Mean duration (days) of redness (standard deviation):* 0.4 (1.2) alcohol swab vs. 0.4 (1.4) control group *P* = 0.91 *Mean duration (days) of swelling (standard deviation):* 1.0 (1.6) alcohol swab vs. 0.8 (1.4) control group *P* = 0.38 *Mean duration (days) warmth to touch (standard deviation):* 0.3 (0.7) alcohol swab vs. 0.3 (0.8) control group *P* = 0.79 *Mean duration (days) or cellulitis, pus leaking and infectious abscess:* No reported cases in both groups	*"This is the first RCT to specifically examine the effect of alcohol swab skin cleansing on the incidence of local skin reactions and infection in children undergoing vaccine injections. We found no evidence of a difference in the rate of local skin reactions and no cases of cellulitis or infectious abscess when alcohol swabs were and were not used" (pp997)* *"This study demonstrated no evidence of a difference in the incidence of delayed pain post-vaccination when skin cleansing at the injection site was and was not done. There were no cases of cellulitis or infectious abscess" (pp999)*

Appendix 5: Additional References of Potential Interest

CADTH Related Reports

Ke Xin Li, McCormack S. Chlorhexidine Gluconate for skin preparation during minor procedures: clinical effectiveness and guidelines (*CADTH Rapid Response Report: Summary of Abstracts*). Ottawa (ON): CADTH; 2019 Jun. https://cadth.ca/chlorhexidine-gluconate-skin-preparation-during-minor-procedures-clinical-effectiveness-and-0 Accessed 2019 Nov 19.

Hafizi D, McCormack S. Alcohol for skin preparation during minor procedures: clinical effectiveness (*CADTH Rapid Response Report: Summary of Abstracts)*. Ottawa (ON): CADTH; 2019 Jun. https://www.cadth.ca/sites/default/files/pdf/htis/2019/RB1347%20Alcohol%20Skin%20Preparation%20Final.pdf Accessed 2019 Nov 19.

Use of Chlorhexidine Gluconate with alcohol for the prevention of peripheral intravenous device infections: a review of clinical and cost effectiveness, and guidelines (*CADTH Rapid Response Report: Summary of Abstracts)*. Ottawa (ON): CADTH; 2014 Apr. https://www.cadth.ca/sites/default/files/pdf/htis/nov-2014/RC0540%20CHXG%20with%20alcohol%20Final.pdf Accessed 2019 Nov 19.

Clinical Trials – Ongoing

Taddio A. NCT03131843: Effectiveness of alcohol swabs for preventing infections during vaccination. (*ClinicalTrials.gov*). Toronto (ON): University of Toronto; 2017 May: https://clinicaltrials.gov/ct2/show/NCT03131843 Accessed 2019 Nov 19.

Guidelines

Clinical Practice Guidelines – Unclear Methodology

Bartley N. Guidelines on the administration of intramuscular and sub-cutaneous injections. Crumlin, Ireland: Our Lady's Children's Hospital; 2017 Feb. https://www.olchc.ie/Healthcare-Professionals/Nursing-Practice-Guidelines/Intramuscular-and-Sub-Cutaneous-Injections-.pdf Accessed 2019 Nov 19.

World Health Organization. WHO best practices for injections and related procedures toolkit. Geneva, Switzerland: WHO; 2010: http://www.rho.org/files/rb3/WHO_Best_Practices_Injections_Toolkit_WHO_2010.pdf Accessed 2019 Nov 19
See section: 2.1.4 – Skin preparation and disinfection (p7)

Government of Canada. Vaccine administration practices. Canadian immunization guide: part 1 - key immunization information. Ottawa (ON): Government of Canada; 2017 Nov: https://www.canada.ca/en/public-health/services/publications/healthy-living/canadian-immunization-guide-part-1-key-immunization-information/page-8-vaccine-administration-practices.html Accessed 2019 Nov 19.

Review Articles

O'Neill J, Grinager H, Smith SD, Sibley S, Harrison AR, Lee MS. Isopropyl alcohol skin antisepsis does not reduce incidence of infection following insulin injection. *Am J Infect Control*. 2013 Aug;41(8):755-756
PubMed: PM23419612

Gittens G, Bunnell T. Skin disinfection and its efficacy before administering injections. *Nurs Stand*. 2009 Jun 3-9;23(39):42-44.
PubMed: PM19552279

Correction

The Context and Policy Issues section of the original report, published on November 19, 2019, inaccurately referenced the Public Health Agency of Canada as being one of the bodies that have deemed it unnecessary to disinfect the skin prior to vaccination if a patient's skin is visibly clean.

A correction has been made on page 3, paragraph 3, to accurately reflect the position of the Public Health Agency of Canada; the *Canadian Immunization Guide* advises the practice of cleaning the skin with a suitable antiseptic solution before a vaccination or injection.