National Clinical Guideline Centre

Final

Fractures (non-complex): assessment and management

Fractures: diagnosis, management and follow-up of fractures

NICE Guideline NG38

Methods, evidence and recommendations

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1 Foreword

Trauma is important for two main reasons: minor trauma affects a large number of people, major trauma affects a smaller number of people but more severely.

Major trauma describes serious and often multiple injuries that may require lifesaving interventions. Trauma has a bimodal age distribution with the first peak in the under-20s and then the second peak in the over-65 age group. It is the biggest killer of people aged below 45 years in the UK and in those people that survive a traumatic injury; a large number will have permanent disabilities. The estimated costs of major trauma are between £0.3 and £0.4 billion a year in immediate treatment. The cost of any subsequent hospital treatments, rehabilitation, home care support or informal carer costs are unknown. The National Audit Office estimated that the annual lost economic output as a result of major trauma is between £3.3 billion and £3.7 billion.

In the UK over the last 25 years there has been substantial improvement in outcomes for patients.

This has been due to a variety of reasons, which include better education as well as improvements in pre-hospital, emergency department and hospital management.

More recently, the development of integrated Trauma networks has aimed to organise regional trauma care that provides co-ordinated multidisciplinary care that is provided at a time and place that benefits the patient most. The benefits of the networks are demonstrated by progressive improvements in patient outcomes reported by The Trauma Audit and Research Network (TARN).

There are still improvements to be made and the Department of Health asked NICE to develop the following four clinical guidelines and one service delivery guideline related to the management of people with traumatic injuries:

- **Spinal injury assessment**: assessment and imaging and early management for spinal injury (spinal column or spinal cord injury)
- Remit: To produce guidance on the assessment and imaging of patients at high risk of spinal injury.
- **Complex fractures**: assessment and management of complex fractures
- Remit: Complex fractures: assessment and management of complex fractures (including pelvic fractures and open fractures of limbs)
- **Fractures**: diagnosis, management and follow-up of fractures
- Remit: Fractures - Diagnosis, management and follow-up of fractures (excluding head and hip, pelvis, open and spinal)
- **Major trauma**: assessment and management of airway, breathing and ventilation, circulation, haemorrhage and temperature control.
- Remit: Assessment and management of major trauma including resuscitation following major blood loss associated with trauma
- **Service delivery of trauma services**

These guidelines are related topics with overlap in populations and key clinical areas for review. The guidelines have been developed together to avoid overlap and ensure consistency. However, each guideline ‘stands alone’ and addresses a specific area of care. See section 3.3 for more information on how the suite of guidelines was developed.

In summary, these guidelines represent the best current evidence available to support the trauma practitioner to optimally manage trauma patients, and that by encouraging increasing uniformity of care both mortality and morbidity will fall further.

2 Introduction

Two of the five guidelines in the NICE trauma suite relate to fractures. These are titled non-complex and complex fractures. In broad terms, non-complex fractures are those likely to be treated at the receiving hospital, whereas complex fractures require transfer or the consideration of transfer of the injured person to a specialist.

The annual incidence of fractures in Britain is estimated at 3.6% and the lifetime prevalence of fracture is near 40%.[47] The majority of the 1.8 million fractures occurring every year in England are non-complex. These include a very wide range of injuries. The injured person may be any age from infancy to elderly. There are many anatomical sites at which a fracture may occur. The mechanisms of injury are many and varied. The range of treatment options is wide and varied. Because of these factors, non-complex fractures present an enormous challenge to healthcare systems.

Many non-complex fractures have a benign natural history and minimal clinical intervention is required. The nature of healthcare systems can be to overcomplicate matters; individuals offering treatment within their own field of expertise. Thus, surgeons may tend to operate and physiotherapists to provide therapy. A pathway expending unnecessary time and effort can evolve. Some non-complex fractures can present as an apparently minor and easily missed injury, yet still have a potential for a poor long-term outcome; scaphoid fracture is an example. Therefore, there is a need to explore a framework where important injuries are not missed whilst avoiding over-treating the majority of patients who have a benign injury.

It is clear that a single guideline cannot address individually all potential situations. However, since non-complex fractures present a huge burden and workload to the NHS it is a sound objective to provide a guideline to act as a rational basis for patient management embracing and accepting a wide range of circumstances. To this end, the guideline is based around a group of indicative topics chosen in the scoping stage of development.

Instead of tracing the pathway of a single injury, the guideline topics were chosen to inform various stages on a notional pathway of patient care. These topics were chosen on the basis of their prevalence, their relevance to a particular step in the patient pathway of care or perceived variation in current practice. It was inherent in the development of the guideline that, whilst recommendations are necessarily only made in relation to the individual topics of the scope, these recommendations should be considered as representative of the management of non-complex fractures in general.

3 Development of the guideline

3.1 What is a NICE clinical guideline?

NICE clinical guidelines are recommendations for the care of individuals in specific clinical conditions or circumstances within the NHS – from prevention and self-care through primary and secondary care to more specialised services. We base our clinical guidelines on the best available research evidence, with the aim of improving the quality of healthcare. We use predetermined and systematic methods to identify and evaluate the evidence relating to specific review questions.

NICE clinical guidelines can:

- provide recommendations for the treatment and care of people by health professionals
- be used to develop standards to assess the clinical practice of individual health professionals
- be used in the education and training of health professionals
- help patients to make informed decisions
- improve communication between patient and health professional.

While guidelines assist the practice of healthcare professionals, they do not replace their knowledge and skills.

We produce our guidelines using the following steps:

- Guideline topic is referred to NICE from the Department of Health.
- Stakeholders register an interest in the guideline and are consulted throughout the development process.
- The scope is prepared by the National Clinical Guideline Centre (NCGC).
- The NCGC establishes a Guideline Development Group.
- A draft guideline is produced after the group assesses the available evidence and makes recommendations.
- There is a consultation on the draft guideline.
- The final guideline is produced.

The NCGC and NICE produce a number of versions of this guideline:

- the ‘full guideline’ contains all the recommendations, plus details of the methods used and the underpinning evidence
- the ‘NICE guideline’ lists the recommendations
- ‘information for the public’ is written using suitable language for people without specialist medical knowledge
- NICE Pathways brings together all connected NICE guidance.

This version is the full version. The other versions can be downloaded from NICE at www.nice.org.uk.

3.2 Remit

NICE received the remit for this guideline from the Department of Health. They commissioned the NCGC to produce the guideline.

The remit for this guideline is: Diagnosis, management and follow-up of fractures (excluding head and hip, pelvis, open and spinal).

3.3 Who developed the trauma guidelines?

As noted in section 1, the four clinical guidelines and service delivery guidance consist of related topics with overlap in populations and key clinical areas for review. The guidelines have been developed together to avoid overlap and ensure consistency. This required careful planning to ensure the guideline development groups had the support they needed. Senior clinical expertise was recruited in addition to the standard guideline development group.

Project Executive Team

The overlap in the content of the four clinical guidelines and the service delivery guidance required an approach that ensured coherence and avoided duplication across the guidelines. To address this, clinical experts from across the guidelines were recruited to form an umbrella group, the Project Executive Team (PET). The PET met quarterly throughout the development of the guidelines. At the PET meetings, the members provided expert advice to the technical team and GDGs on the crossover of reviews across guidelines. (See the list of project executive team members). Also see the list of Guideline Development Group members and the acknowledgements.

Guideline Development Group expert members

Expert members were healthcare professionals who worked across the four clinical guidelines and the service delivery guidance, and attended the GDGs that were relevant to their expertise. The expert members provided an additional level of coherence across the guidelines, helping to identify potential duplication in the areas of their expertise (see the list of the Guideline Development Group expert members).

Guideline Development Group (GDG)

Each guideline 'stands alone' and addresses a specific area of care. A dedicated, multidisciplinary Guideline Development Group (GDG), comprising health professionals, researchers and lay members developed this guidance. See the list of Guideline Development Group members and the acknowledgements.

The GDG was convened by the NCGC and chaired by Mr Bob Handley and Mr Iain McFadyen in accordance with guidance from NICE.

The GDG met for two days every 6 weeks during the development of the guideline. At the start of the guideline development process all GDG members declared interests including consultancies, fee-paid work, share-holdings, fellowships and support from the healthcare industry. At all subsequent GDG meetings, members declared new and arising conflicts of interest.

Members were either required to withdraw completely, or for part of the discussion, if their declared interest made it appropriate. The details of declared interests and the actions taken are shown in Appendix B.

Staff from the NCGC provided methodological support and guidance for the development process. The technical team working on the guideline included a project manager, systematic reviewers, health economists and information scientists. The team undertook systematic searches of the literature, appraised the evidence, conducted meta-analysis and cost-effectiveness analysis where appropriate, and drafted the guideline in collaboration with the GDG.

3.3.1 What this guideline covers

Groups that will be covered

Adults, young people and children who present with a suspected non-complex facture.

Key clinical issues that will be covered

- Assessment tools for initial triage
- Acute-stage imaging assessment
- Initial management and treatment plan
- Ongoing management
- Follow-up clinics
- Skills to be present within the multidisciplinary team
- Documentation of clinical assessments and management for people with fractures
- Information and support needs of patients and their families and carers when appropriate.

For further details please refer to the scope in Appendix A and the review questions in Section 4.1.

3.3.2 What this guideline does not cover

Groups that will not be covered

Any person with a complex fracture including: skull fracture; hip fracture; spinal injury and open fracture.

Clinical issues that will not be covered

- Prevention of fractures
- Management and follow-up of dislocations
- Management and follow-up of pathological conditions (such as osteoporosis and arthritis) predisposing to fractures
- Any management and follow-up of fractures once a patient has been referred to a specialist centre.

3.3.3 Relationships between the guideline and other NICE guidance

Related NICE Interventional procedures guidance:

Low intensity pulse ultrasound to promote fracture healing. NICE interventional procedures 374 (2010).

Related NICE medical technologies guidance:

- EXOGEN ultrasound bone healing system for long bone fractures with non-union or delayed healing. NICE medical technologies guidance 12 (2013).

Related NICE Clinical guidelines:

- Patient experience in adult NHS services. NICE clinical guideline 138 (2012).
- Hip fracture. NICE clinical guideline 124 (2011).
- Falls. NICE clinical guideline 161 (2013).

Related NICE guidance currently in development:

- Spinal injury assessment. NICE clinical guideline. Publication expected February 2016.
- Complex fractures. NICE clinical guideline. Publication expected February 2016.
- Major trauma. NICE clinical guideline. Publication expected February 2016.
- Major trauma services. NICE clinical guideline. Publication expected February 2016.

4 Methods

This chapter sets out in detail the methods used to review the evidence and to generate the recommendations that are presented in subsequent chapters. This guidance was developed in accordance with the methods outlined in the NICE guidelines manual 2012[131].

Sections 4.1 to 4.3 describe the process to review clinical evidence (summarised in Figure 1) and section 4.4 the process to review the cost-effectiveness evidence.

Figure 1: Step-by-step process of review of evidence in the guideline

4.1 Developing the review questions and outcomes

Review questions were developed in a PICO framework (patient, intervention, comparison and outcome) for intervention reviews. Review questions were developed with a framework of population, prognostic factor and outcomes for prognostic reviews, and with a framework of population, index tests, reference standard and target condition for reviews of diagnostic test accuracy. This was to guide the literature searching process, critical appraisal and synthesis of evidence, and to facilitate the development of recommendations by the guideline development group (GDG). They were drafted by the NCGC technical team and refined and validated by the GDG. The questions were based on the key clinical areas identified in the scope (Appendix A).

A total of 27 review questions were identified.

Full literature searches, critical appraisals and evidence reviews were completed for all the specified review questions.

Table 1: Review questions

Chapter	Review questions	Outcomes
Initial pharmacological pain management	What is the most effective initial acute pharmacological management to alleviate pain in patients with a suspected long bone fracture (tibia and fibula, humerus, radius and ulna, or unspecified) in acute care settings?	Critical: • Pain (1 hour) • Pain (4–6 hours) • Health-related quality of life • Missed diagnosis of compartment syndrome • Delayed bone healing • Local infection • Nerve and vascular damage • Respiratory depression (<6 hours) • Local anaesthetic toxicity • Nausea and vomiting (<6 hours) • Admission solely for recovery from pharmacological agent Important: • Need for rescue analgesia
Initial pharmacological pain management	What is the most clinically and cost-effective nerve block for the initial management in patients with a suspected femoral fracture in acute care settings (pre-hospital and ED)?	Critical: • Pain (1 hour) • Pain (4-6 hours) • Health-related quality of life • Missed/Delayed diagnosis of compartment syndrome • Femoral injury • Delayed bone healing • Haematoma • Local infection • Nerve and vascular damage • Respiratory depression (<6 hours) • Nausea and vomiting (<6 hours) • Admission solely for recovery from pharmacological agent including cardiac depression, arrhythmia Important: • Need for rescue analgesia
Acute stage assessment and diagnostic imaging	a) Are validated clinical prediction rules clinically and cost effective at predicting suspected knee fractures?	Critical: • Pain/discomfort • Return to health-care • Provider • Returning to normal activity • Health-related quality of life • Missed diagnosis (false negative rate) and misdiagnosis (false positive rate) • Unnecessary radiation

Chapter	Review questions	Outcomes
		Important: • Patient satisfaction
Acute stage assessment and diagnostic imaging	b) Are validated clinical prediction rules accurate at predicting suspected knee fractures?	Diagnostic accuracy: • Sensitivity • Specificity
Acute stage assessment and diagnostic imaging	a) Are validated clinical prediction rules clinically and cost effective at predicting suspected ankle fractures?	Critical: • Pain/discomfort • Return to healthcare provider • Returning to normal activity • Health-related quality of life • Missed diagnosis (false negative rate) and misdiagnosis (false positive rate) • unnecessary radiation Important: • Patient satisfaction.
Acute stage assessment and diagnostic imaging	b) Are validated clinical prediction rules accurate at predicting suspected ankle fractures?	Diagnostic accuracy: • Sensitivity • Specificity
Acute stage assessment and diagnostic imaging	a) What is the most clinically and cost-effective imaging strategy for patients with clinically suspected scaphoid fracture?	Critical: • Time in plaster cast • Number of outpatient visits • health-related quality of life • Pain/discomfort • Return to normal activities • Psychological wellbeing • missed injury • non-union/malunion • avascular necrosis • post-traumatic arthritis • additional radiation exposure Important: • Grip strength • Range of motion
Acute stage assessment and diagnostic imaging	b) What is the diagnostic accuracy of imaging strategies for a suspected scaphoid fracture?	• Sensitivity • Specificity
Acute stage assessment and diagnostic imaging	Is the use of CT scanning in addition to initial plain film X-ray clinically- and cost-effective for planning surgical treatment of unstable/displaced ankle fractures?	Critical: • Health-related quality of life • Pain/discomfort • Return to normal activities • Psychological wellbeing • unnecessary imaging • need for revision surgery

Chapter	Review questions	Outcomes
		• functional outcomes Important: • Radiological outcomes – satisfactory fracture reduction
Acute stage assessment and diagnostic imaging	Is the use of definitive hot reporting of X-Rays clinically and cost-effective for use in patients with suspected fractures?	Critical: • Health-related quality of life • Pain/discomfort • Return to normal activities • Psychological wellbeing • Missed fractures • Change in management plan • Patient recalled
Management and treatment plan in the emergency department	Is the reduction through manipulation of a dorsally displaced distal radius fracture without neurovascular compromise influenced by timing and/or the use of an image intensifier?	Critical: • Health-related quality of life • Need for re-manipulation • Need for surgical fixation • Patient-reported function PRWE, DASH Important: • Pain/discomfort • Return to normal activities
Management and treatment plan in the emergency department	a) What type of anaesthetic is the most clinically and cost effective for closed reduction of dorsally displaced distal radius fractures in people without neurovascular compromise in the emergency department? b) What are the rates of serious adverse events for selected anaesthetic techniques used in the emergency department?	Critical: • Health-related quality of life • Pain • Need for re-manipulation • Need for surgical fixation • Patient-reported function PRWE, DASH • Death • Laryngospasm/Respiratory depression • Nausea/vomiting • Cardiac arrhythmias • Nerve damage • Infection • Hallucinations/emergent phenomena Important: • Return to normal activities
Management and treatment plan in the emergency department	What is the most clinically and cost-effective management strategy for children with torus fractures of the forearm?	Critical: • pain/discomfort • Patient experience • Return to normal activities • Health-related quality of life • Skin problems

Chapter	Review questions	Outcomes
		• Re-fracture Important: • Number of outpatient visits • Cast changes Population size and directness: • No limitations on sample size • Studies with indirect populations will not be considered.
Management and treatment plan in the emergency department	Who are the most clinically and cost-effective referral pathway decision-makers for patients with non-complex fractures?	Critical • Patients recalled for change of management • Number of different types of attendances • Unnecessary attendance at a clinic • Time to definitive management plan • Number of referrals to a specialist clinic • Indicator of patient satisfaction (including quality of life) • Other measure of efficiency of management plan process
Management and treatment plan in the emergency department	What is the clinical and cost effectiveness of referral to virtual fracture clinics compared to face to face fracture clinics for patients with non-complex fractures?	Accuracy of achieving appropriate management plan (assume that OT formulated management plan is gold standard): Proxy outcomes are: • Number of recalled patients requiring change of management • Number of different types of attendances (i.e. to show number of times management plan not formulated). • Unnecessary attendance at a clinic (i.e. Discharge after one attendance without any further physical management undertaken.) • Time to definitive management plan (i.e. in person attendance at a fracture clinic vs no attendance needed?) • Number of referrals to a specialist clinic? • Indicator of patient satisfaction (inc.QoL) Population size and directness: • No limitations on sample size • Studies with indirect populations will not be considered.

Chapter	Review questions	Outcomes
Management and treatment plan in the emergency department	What is the clinical and cost effectiveness of different referral destinations for patients with non-complex fractures?	Accuracy of achieving appropriate management plan (assume that OT formulated management plan is gold standard): Proxy outcomes are: • Number of recalled patients requiring change of management • Number of different types of attendances (i.e. to show number of times management plan not formulated). • Unnecessary attendance at a clinic (i.e. Discharge after one attendance without any further physical management undertaken.) • Time to definitive management plan (i.e. in person attendance at a fracture clinic vs no attendance needed?) • Number of referrals to a specialist clinic? • Indicator of patient satisfaction (inc.QoL) Population size and directness: • No limitations on sample size • Studies with indirect populations will not be considered.
On-going management	What is the most clinically- and cost-effective mobilisation strategy in patients with stable ankle fractures?	Critical: • Health-related quality of life • Patient-reported outcomes (OMAS, AAOFAS, DRI) • Return to normal activities • Displacement • Need for operative treatment • Non-union/malunion • DVT/PE at 3 months Important: • Number of hospital/out-patient attendances • Length of hospital stay, length till return to normal residence/ step down
On-going management	What is the most clinically- and cost-effective timing of surgical treatment of an ankle fracture?	Critical: • Pain/discomfort • Return to normal activities • Psychological wellbeing • Inpatient length of stay • Health-related quality of life • Skin breakdown

Chapter	Review questions	Outcomes
		• Wound infection • VTE Important: • Physiotherapy appointments
On-going management	What is the maximum safe delay in surgical management of fractures of the distal radius before outcome is compromised?	Critical: • Health-related quality of life • Need for re-operation • PROMS • Wound infection • Anaesthetic complications • Growth plate arrest Important: • Pain/discomfort • Return to normal activities • Psychological wellbeing Population size and directness: • No limitations on sample size • Studies with indirect populations will not be considered
On-going management	What is the most clinically and cost effective definitive treatment for dorsally displaced low-energy fractures of the distal radius?	Critical: • Health-related quality of life • Pain/discomfort • Return to normal activities • Psychological wellbeing • Hand and wrist function • Pin-site infection • Post traumatic osteoarthritis • Complex regional pain syndrome Important: • Need for revision surgery • Need for further surgery (for example, removal of metalwork) • Number of attendances/bed days • Radiological anatomical measures
On-going management	What is the most cost effective definitive treatment for displaced low-energy fractures of the proximal humerus?	Critical: • Mortality at 1 and 12 months • Health-related quality of life • Functional score (DASH/Constant/Oxford) • Infection • Avascular necrosis • Need for further/operative treatment • Nerve damage

Chapter	Review questions	Outcomes
		Important: • Return to normal activities
On-going management	What is the most clinically and cost-effective treatment for paediatric femoral shaft fractures?	Critical: • Health-related quality of life • Number of follow-up/revision surgeries? • PODCI-POSNA score • Mortality • Neurovascular damage • Deformity/limb length discrepancy • Non-union/malunion • Vascular compromise • Avascular necrosis (femoral head) Important: • Pain/discomfort • Return to normal activities • Duration hospital stay • Psychological wellbeing
On-going management	What is the most clinically and cost-effective weight-bearing strategy in patients with operatively treated fractures of the distal femur?	Critical: • Mortality • Health-related quality of life • Return to pre-injury mobility status/normal activity • Displacement of fracture (angular deformity) • Re-operation (non-union and mal-union) • DVT/PE within 3 months • Chest infections • UTIs Important: • Hospital bed days •
On-going management	What is the most clinically- and cost- effective mobilisation strategy in post-operative patients following internal fixation of ankle fracture?	Critical: • Health-related quality of life • Patient-reported outcomes (OMAS, AAOFAS, DRI) • return to normal activities • Displacement • Need for re-operation • Non-union/malunion • DVT/PE at 3 months • Wound infection

Chapter	Review questions	Outcomes
		Important: • Number of hospital/out-patient attendances • Length of hospital stay, length till return to normal residence/ step down
Documentation, information and support	In patients with non-complex fractures does documentation recording safeguarding, comorbidities, falls risk and fracture classification alongside standard diagnosis documentation improve outcomes compared with standard diagnosis documentation alone?	Critical: • Mortality (short- and long-term) • Health-related quality of life (short- and long-term) • Future fractures • Additional treatments/unplanned surgery Important: • Return to normal activities •
Documentation, information and support	What information and support do people with fractures and their families and carers require?	No outcomes as qualitative review

4.2 Searching for evidence

4.2.1 Clinical literature search

The aim of the literature search was to systematically identify all published clinical evidence relevant to the review questions. Searches were undertaken according to the parameters stipulated within the NICE Guidelines Manual [2012].[131] Databases were searched using medical subject headings and free-text terms. Foreign language studies were not reviewed and, where possible, searches were restricted to articles published in the English language. All searches were conducted in MEDLINE, Embase, and the Cochrane Library, and were updated for the final time on either 8th or 9th April 2015. No papers added to the databases after this date were considered.

Search strategies were quality assured by cross-checking reference lists of highly relevant papers, analysing search strategies in other systematic reviews, and asking GDG members to highlight any additional studies. The questions, the study types applied, the databases searched and the years covered can be found in Appendix F.

The titles and abstracts of records retrieved by the searches were sifted for relevance, with potentially significant publications obtained in full text. These were then assessed against the inclusion criteria.

4.2.2 Health economic literature search

Systematic searches were undertaken to identify relevant health economic evidence within the published literature. The NHS Economic Evaluation Database (NHS EED), the Health Economic Evaluations Database (HEED) and Health Technology Assessment (HTA) database were searched using broad population terms and no date restrictions. A search was also run in MEDLINE and Embase using a specific economic filter with population terms. Where possible, searches were restricted to articles published in the English language. Economics search strategies are included in

Appendix F. All searches were updated for the final time on either 8th or 9th April 2015 except in HEED which ceased production in 2014. No papers added to the databases after this date were considered.

4.3 Evidence gathering and analysis

The tasks of the research fellow are listed below and described in further detail in sections 4.3.1 to 4.3.7. The research fellow:

- Identified potentially relevant studies for each review question from the relevant search results by reviewing titles and abstracts, and deciding which should be ordered as full papers. Full papers were then obtained.
- Reviewed full papers against pre-specified inclusion / exclusion criteria to identify studies that addressed the review question in the appropriate population, and reported on outcomes of interest (see Appendix C for review protocols).
- Critically appraised relevant studies using the appropriate study design checklists as specified in The Guidelines Manual [National Institute for Health and Clinical Excellence (2012)[131]]. Available from: https://www.nice.org.uk/article/PMG6/chapter/1Introduction
- Critically appraised relevant studies with a prognostic or qualitative study design NCGC checklist.
- Extracted key information about interventional study methods and results using Evibase, NCGC purpose-built software. Evibase produces summary evidence tables, with critical appraisal ratings. Key information about non-interventional study methods and results were manually extracted onto standard evidence tables and critically appraised separately (see Appendix G for the evidence tables).
- Generated summaries of the evidence by outcome. Outcome data is combined, analysed and reported according to study design:
  - Randomised data is meta analysed where appropriate and reported in GRADE profiles
  - Observational data presented as a range of values in GRADE profiles
  - Diagnostic data is meta-analysed if appropriate or presented as a range of values in adapted GRADE profiles
  - Prognostic data is meta-analysed where appropriate and reported in GRADE profiles.
  - Qualitative data is summarised across studies where appropriate and reported in themes.
- A sample of a minimum of 20% of the abstract lists of the first three review questions by new reviewers were double sifted by a senior research fellow. As no papers were missed by any reviewers, no further double sifting was carried out. All of the evidence reviews were quality assured by a senior research fellow. This included checking:
  - papers were included or excluded appropriately
  - a sample of the data extractions,
  - correct methods were used to synthesis data
  - a sample of the risk of bias assessments.

4.3.1 Inclusion and exclusion criteria

The inclusion and exclusion of studies was based on the criteria defined in the review protocols (see Appendix C). Excluded studies by review question (with the reasons for their exclusion) are listed in Appendix K. The GDG was consulted about any uncertainty regarding inclusion or exclusion.

The key population inclusion criterion was:

- People of all ages experiencing a fracture as a result of a traumatic physical event.

The key population exclusion criterion was:

- People with an open, pelvic or pilon fracture.

Conference abstracts were not automatically excluded from any review, but no relevant conference abstracts were identified for this guideline. Literature reviews, posters, letters, editorials, comment articles, unpublished studies and studies not in English were excluded.

4.3.2 Type of studies

Randomised trials, non-randomised trials, and observational studies (including diagnostic or prognostic studies) were included in the evidence reviews as appropriate.

For most intervention reviews in this guideline, parallel randomised controlled trials (RCTs) were included because they are considered the most robust type of study design that could produce an unbiased estimate of the intervention effects. Crossover RCTs were not appropriate for any questions.

If non-randomised studies were appropriate for inclusion in intervention reviews (that is, non-drug trials with no randomised evidence) the GDG identified a-priori in the protocol the variables which must either be equivalent at baseline or that the analysis had to adjust for any baseline differences. If the study did not fulfil either criterion it was excluded. Please refer to Appendix C for full details on the study design of studies selected for each review question. Where data from observational studies were included meta-analysis was conducted provided the studies had comparable populations, interventions and comparators. Because observational studies had to consider all key confounding variables, it was assumed that there were no important differences between studies in terms of the extent that confounding had occurred, and meta-analysis was therefore regarded as acceptable in this context.

For diagnostic reviews, diagnostic RCTs, cross-sectional and retrospective studies were included. For prognostic reviews, prospective and retrospective cohort studies were included. Case–control studies were not included.

4.3.3 Contacting authors

If a study had inadequate information to permit a full evaluation of risk of bias, or had insufficient details on the outcomes, then the GDG had the option to request more information from the study's authors.

This only occurred once in the guideline. For the proximal humerus review, further data was requested and received from Professor A. Rangan, who is involved in the ProFHER trial.[150]

4.3.4 Methods of combining evidence

4.3.4.1 Data synthesis for intervention reviews

Where possible, meta-analyses were conducted to combine the data from the studies for each of the outcomes in the review question using RevMan5 software.[4]

All analyses were stratified for skeletal maturity or age (under 18 years and 18 years or over), which meant that different studies with predominant groups (whether skeletal maturity or age) in different strata were not combined and analysed together. For some questions additional stratification was used, and this is documented in the individual question protocols (see Appendix C). If additional strata were used this led to sub-strata (for example, 2 stratification criteria would lead to 4 sub-strata categories, or 3 stratification criteria would lead to 8 sub-strata categories) which would be analysed separately.

Age was defined as the stratification group in the protocols. However, it was decided during after reviews were started that skeletal maturity was seen as a more clinically relevant strata. Skeletal maturity leads to different recovery trajectories and informs different forms of management. It can occur at various ages and can vary between bones. However, often papers did not specify the skeletal maturity of the sample. Consequently, analyses were split by skeletal maturity where possible, and by an age a proxy where this wasn't reported.**Analysis of different types of data**

Dichotomous outcomes

Fixed-effects (Mantel-Haenszel) techniques (using an inverse variance method for pooling) were used to calculate risk ratios (relative risk) for the binary outcomes, which included:

- Mortality
- Missed diagnosis/misdiagnosis
- Development of SCI
- Patient-assessed symptoms
- Adverse events

The absolute risk difference was also calculated using GRADEpro software[1], using the median event rate in the control arm of the pooled results.

For binary variables where there were zero events in either arm, Peto odds ratios, rather than risk ratios, were calculated. Peto odds ratios are more appropriate for data with a low number of events.

Where there was sufficient information provided, Hazard Ratios were calculated in preference for outcomes such as mortality.

Continuous outcomes

The continuous outcomes were analysed using an inverse variance method for pooling weighted mean differences. These outcomes included:

- Heath-related quality of life (HRQL)
- Length of stay (hospital/spinal cord injury centre)
- Symptom scales (normally VAS)
- Spinal cord neurological function (for example, ASIA/Frankel)
- Function and activities of daily living

Where the studies within a single meta-analysis had different scales of measurement, standardised mean differences were used, where each different measure in each study was 'normalised' to the standard deviation value pooled between the intervention and comparator groups in that same study.

The means and standard deviations of continuous outcomes are required for meta-analysis. However, in cases where standard deviations were not reported, the standard error was calculated if the p values or 95% confidence intervals (CIs) were reported, and meta-analysis was undertaken with the mean and standard error using the generic inverse variance method in Cochrane Review Manager (RevMan5) software. Where p values were reported as 'less than', a conservative approach was undertaken. For example, if a p value was reported as "p ≤0.001", the calculations for standard deviations were based on a p value of 0.001. If these statistical measures were not available then the methods described in section 16.1.3 of the Cochrane Handbook (version 5.1.0, updated March 2011)[2] were applied.

Generic inverse variance

If a study reported only the summary statistic and 95% CIs the generic-inverse variance method was used to enter data into RevMan5.[4] If the control event rate was reported this was used to generate the absolute risk difference in GRADEpro.[1] If multivariate analysis was used to derive the summary statistic but no adjusted control event rate was reported no absolute risk difference was calculated.

Heterogeneity

Statistical heterogeneity was assessed for each meta-analysis estimate by considering the chi-squared test for significance at $p<0.1$, or an I-squared inconsistency statistic of >50%, as indicating significant heterogeneity. Where significant heterogeneity was present, a priori subgrouping of studies was carried out for either:

- age category of child (under 28 days; 29–364 days; 1-15 years; and 16-17 years) if the under 18 year strata was being analysed, or
- age category of adult (under 65 years, 65 years and over) if the over 18 years strata was being analysed.

Post-hoc, skeletal maturity was considered to be more clinically relevant as the cut-off between children and adults.

If the subgroup analysis reduced heterogeneity within all of the derived subgroups, then each of the derived subgroups were adopted as separate outcomes. For example, instead of the single outcome of 'missed diagnosis', this would be separated into two outcomes 'missed diagnosis in people aged under 65 years' and 'missed diagnosis in people aged 65 years and over'. Assessments of potential differences in effect between subgroups were based on the chi-squared tests for heterogeneity statistics between subgroups. Any subgroup differences were interpreted with caution as separating the groups breaks the study randomisation and as such are subject to uncontrolled confounding.

For some questions additional subgrouping was applied, and this is documented in the individual question protocols (see Appendix C). These additional subgrouping strategies were applied independently, so sub-units of subgroups were not created, unlike the situation with strata. Other subgrouping strategies were only used if the age category subgroup was unable to explain heterogeneity, and then these further subgrouping strategies were applied in order of priority. Again, once a subgrouping strategy was found to explain heterogeneity from all derived subgroups, further subgrouping strategies were not used.

If all pre-defined strategies of subgrouping were unable to explain statistical heterogeneity within each derived subgroup, then a random effects (DerSimonian and Laird) model was employed to the entire group of studies in the meta-analysis. A random-effects model assumes a distribution of populations, rather than a single population. This leads to a widening of the CIs around the overall estimate, thus providing a more realistic interpretation of the true distribution of effects across more than 1 population. If, however, the GDG considered the heterogeneity was so large that meta-analysis was inappropriate, then the results were described narratively.

Complex analysis /further analysis

Network meta-analysis was considered for the comparison of interventional treatments, but was not pursued because of insufficient data available for the outcomes.

No studies used a cross-over design as this was not appropriate for any of the questions asked.

4.3.4.2 Data synthesis for diagnostic test accuracy reviews

Two separate review protocols were produced to reflect the two different diagnostic study designs:

Diagnostic RCTs

Diagnostic RCTs (sometimes referred to as test and treat trials) are a randomised comparison of two diagnostic tests, with study outcomes being clinically important consequences of diagnostic accuracy (patient outcomes similar to those in intervention trials, such as mortality). Patients are randomised to receive test A or test B, followed by identical therapeutic interventions based on the results of the test (that is, someone with a positive result would receive the same treatment regardless of whether they were diagnosed by test A or test B). Downstream patient outcomes are then compared between the two groups. As treatment is the same in both arms of the trial, any differences in patient outcomes will reflect the accuracy of the tests in correctly establishing who does and does not have the condition. Diagnostic RCTs were searched for first in preference to diagnostic accuracy studies (see below). Data were synthesised using the same methods for intervention reviews (see dichotomous or continuous outcomes above)

Diagnostic accuracy studies

For diagnostic test accuracy studies, a positive result on the index test was found in two different ways, according to whether the index test was measured on a continuous scale or was bivariate.

For continuous index test measures, a positive result on the index test was found if the patient had values of the chosen measured quantity above or below a threshold value, and different thresholds could be used. The threshold of a diagnostic test is defined as the value at which the test can best differentiate between those with and without the target condition and, in practice, it varies amongst studies. Diagnostic test accuracy measures used in the analysis were sensitivity and specificity, and, if different diagnostic thresholds were used within a single study, area under the receiver operating characteristics (ROC) curve

For bivariate index test measures a positive result on the index test was found if a particular clinical sign was detected. For example, a positive test would be recorded if a fracture was observed. Diagnostic test accuracy measures used in the analysis were sensitivity and specificity.

Coupled forest plots of sensitivity and specificity with their 95% CIs across studies (at various thresholds) were produced for each test, using RevMan5.[4] In order to do this, 2x2 tables (the number of true positives, false positives, true negatives and false negatives) were directly taken from the study if given, or else were derived from raw data or calculated from the set of test accuracy statistics.

Diagnostic meta-analysis was conducted where appropriate; that is, when 5 or more studies were available per threshold. Test accuracy for the studies was pooled using the bivariate method modelled in Winbugs®.[113] The bivariate method uses logistic regression on the true positives, true negatives, false positives and false negatives reported in the studies. Overall sensitivity and specificity and confidence regions were plotted (using methods outlined by Novielli et al. 2010[137,137]). For scores with less than five studies, median sensitivity and the paired specificity were reported where possible. If an even number of studies were reported the lowest value of the two middle pairs was reported.

Heterogeneity or inconsistency amongst studies was visually inspected in the forest plots.

4.3.4.3 Data synthesis for risk prediction rules

Evidence reviews on risk prediction rules/tools results were presented separately for discrimination and calibration. The discrimination data was analysed according to the principles outlined under the section on data synthesis for diagnostic accuracy studies. Calibration data, such as, R^2 , if reported were presented separately to the discrimination data. The results were presented for each study

separately along with the quality rating for the study. Inconsistency and imprecision were not assessed.

4.3.4.4 Data synthesis for qualitative reviews

For each included paper sub-themes were identified and linked to a generic theme. An example of a sub-theme identified by patients and carers is 'keeping an open channel of communication about reasons for any delays in the emergency room' and this is linked to a broader generic theme of 'information'. In some cases, sub-themes would relate to more than one generic theme. A summary evidence table of generic themes and underpinning sub-themes was then produced alongside the quality of the evidence.

4.3.5 Appraising the quality of evidence by outcomes

4.3.5.1 Interventional studies

The evidence for outcomes from the included RCT and observational studies were evaluated and presented using an adaptation of the 'Grading of Recommendations Assessment, Development and Evaluation (GRADE) toolbox' developed by the international GRADE working group (http://www.gradeworkinggroup.org/). The software (GRADEpro[1]) developed by the GRADE working group was used to assess the quality of each outcome, taking into account individual study quality and the meta-analysis results.

Each outcome was first examined for each of the quality elements listed and defined in Table 2.

Table 2: Description of quality elements in GRADE for intervention studies

Quality element	Description
Risk of bias	Limitations in the study design and implementation may bias the estimates of the treatment effect. Major limitations in studies decrease the confidence in the estimate of the effect. Examples of such limitations are selection bias (often due to poor allocation concealment), performance and detection bias (often due to a lack of blinding of the patient, health care professional and assessor) and attrition bias (due to missing data causing systematic bias in the analysis).
Indirectness	Indirectness refers to differences in study population, intervention, comparator and outcomes between the available evidence and the review question.
Inconsistency	Inconsistency refers to an unexplained heterogeneity of effect estimates between studies in the same meta-analysis.
Imprecision	Results are imprecise when studies include relatively few patients and few events (or highly variable measures) and thus have wide CIs around the estimate of the effect relative to clinically important thresholds. 95% CIs denote the possible range of locations of the true population effect at a 95% probability, and so wide CIs may denote a result that is consistent with conflicting interpretations (for example a result may be consistent with both clinical benefit AND clinical harm) and thus be imprecise.
Publication bias	Publication bias is a systematic underestimate or an overestimate of the underlying beneficial or harmful effect due to the selective publication of studies. A closely related phenomenon is where some papers fail to report an outcome that is inconclusive, thus leading to an over-estimate of the effectiveness of that outcome.
Other issues	Sometimes randomisation may not adequately lead to group equivalence of confounders, and if so this may lead to bias, which should be taken into account. Potential conflicts of interest, often caused by excessive pharmaceutical company involvement in the publication of a study, should also be noted.

Details of how the four main quality elements (risk of bias, indirectness, inconsistency and imprecision) were appraised for each outcome are given below. Publication or other bias was only taken into consideration in the quality assessment if it was apparent.

Risk of bias

The main domains of bias for RCTs are listed in Table 3. Each outcome had its risk of bias assessed within each paper first. For each paper, if there were no risks of bias in any domain, the risk of bias was given a rating of 0. If there was risk of bias in just one domain, the risk of bias was given a 'serious' rating of -1, but if there was risk of bias in two or more domains the risk of bias was given a 'very serious' rating of -2. A weighted average score was then calculated across all studies contributing to the outcome, by taking into account the weighting of studies according to study precision. For example if the most precise studies tended to each have a score of -1 for that outcome, the overall score for that outcome would tend towards -1.

Table 3: Principle domains of bias in RCTs

Limitation	Explanation
Selection bias – sequence generation and allocation concealment	If those enrolling patients are aware of the group to which the next enrolled patient will be allocated, either because of a non-random sequence that is predictable, or because a truly random sequence was not concealed from the researcher, this may translate into systematic selection bias. This may occur if the researcher chooses not to recruit a participant into that specific group because of 1) knowledge of that participant's likely prognostic characteristics and 2) a desire for one group to do better than the other.
Performance and detection bias - Lack of patient and health care professional blinding	Patients, caregivers, those adjudicating and/or recording outcomes, and data analysts should not be aware of the arm to which patients are allocated. Knowledge of group can influence 1) the experience of the placebo effect, 2) performance in outcome measures, 3) the level of care and attention received, and 4) the methods of measurement or analysis, all of which can contribute to systematic bias.
Attrition bias	Attrition bias results from loss of data beyond a certain level (a differential of 10% between groups) which is not accounted for. Loss of data can occur when participants are compulsorily withdrawn from a group by the researchers (for example, when a per-protocol approach is used) or when participants do not attend assessment sessions. If the missing data are likely to be different from the data of those remaining in the groups, and there is a differential rate of such missing data from groups, systematic attrition bias may result.
Selective outcome reporting	Reporting of some outcomes and not others on the basis of the results can also lead to bias, as this may distort the overall impression of efficacy.
Other limitations	For example: • Stopping early for benefit observed in randomised trials, in particular in the absence of adequate stopping rules • Use of unvalidated patient-reported outcomes • lack of washout periods to avoid carry-over effects in cross-over trials • Recruitment bias in cluster randomised trials

Indirectness

Indirectness refers to the extent to which the populations, intervention, comparisons and outcome measures are dissimilar to those defined in the inclusion criteria for the reviews. Indirectness is important when these differences are expected to contribute to a difference in effect size, or may affect the balance of harms and benefits considered for an intervention. As for risk of bias, each outcome had its indirectness assessed within each paper first. For each paper, if there were no

sources of indirectness, indirectness was given a rating of 0. If there was indirectness in just one source (for example in terms of population), indirectness was given a 'serious' rating of -1, but if there was indirectness in two or more sources (for example, in terms of population and treatment) the indirectness was given a 'very serious' rating of -2. A weighted average score was then calculated across all studies contributing to the outcome, by taking into account study precision. For example if the most precise studies tended to have an indirectness score of -1 each for that outcome, the overall score for that outcome would probably tend towards -1.

Inconsistency

Inconsistency refers to an unexplained heterogeneity of results for an outcome across different studies. When estimates of the treatment effect across studies differ widely, this suggests true differences in underlying treatment effect, which may be due to differences in populations, settings or doses. When heterogeneity existed within an outcome (Chi square $p<0.1$ or I^2 inconsistency statistic of more than 50%), but no plausible explanation could be found, the quality of evidence for that outcome was downgraded. Inconsistency for that outcome was given a 'serious' score of -1 if the I^2 was 50-74, and a 'very serious' score of -2 if the I^2 was 75 or more.

If inconsistency could be explained based on pre-specified subgroup analysis (that is, each subgroup had an I^2 less than 50), the GDG took this into account and considered whether to make separate recommendations on new outcomes based on the subgroups defined by the assumed explanatory factors. In such a situation the quality of evidence was not downgraded for those emergent outcomes.

Since the inconsistency score was based on the meta-analysis results, the score represented the whole outcome and so weighted averaging across studies was not necessary.

Imprecision

The criteria applied for imprecision were based on the CIs for the pooled estimate of effect, and the minimal important differences (MID) for the outcome. The MIDs are the threshold for appreciable benefits and harms, separated by a zone either side of the line of no effect where there is assumed to be no clinically important effect. If either of the 95% CIs of the overall estimate of effect crossed **one** of the MID lines, imprecision was regarded as serious and a 'serious' score of -1 was given. This was because the overall result, as represented by the span of the CIs, was consistent with two interpretations as defined by the MID (for example, no clinically important effect and either clinical benefit or harm). If **both** MID lines were crossed by either or both of the CIs then imprecision was regarded as very serious and a 'very serious' score of -2 was given. This was because the overall result was consistent with three interpretations defined by the MID (no clinically important effect and clinical benefit and clinical harm). This is illustrated in Figure 2. As for inconsistency, since the imprecision score was based on the meta-analysis results, the score represented the whole outcome and so weighted averaging across studies was not necessary.

The position of the MID lines is ideally determined by values as reported in the literature. 'Anchor-based' methods aim to establish clinically meaningful changes in a continuous outcome variable by relating or 'anchoring' them to patient-centred measures of clinical effectiveness that could be regarded as gold standards with a high level of face validity. For example, the minimum amount of change in an outcome necessary to make a patient decide that they felt their quality of life had 'significantly improved' might define the MID for that outcome. MIDs in the literature may also be based on expert clinician or consensus opinion concerning the minimum amount of change in a variable deemed to affect quality of life or health. For binary variables, any MIDs reported in the literature will inevitably be based on expert consensus, as such MIDs relate to all-or-nothing population effects rather than measurable effects on an individual, as so are not amenable to patient-centred 'anchor' methods.

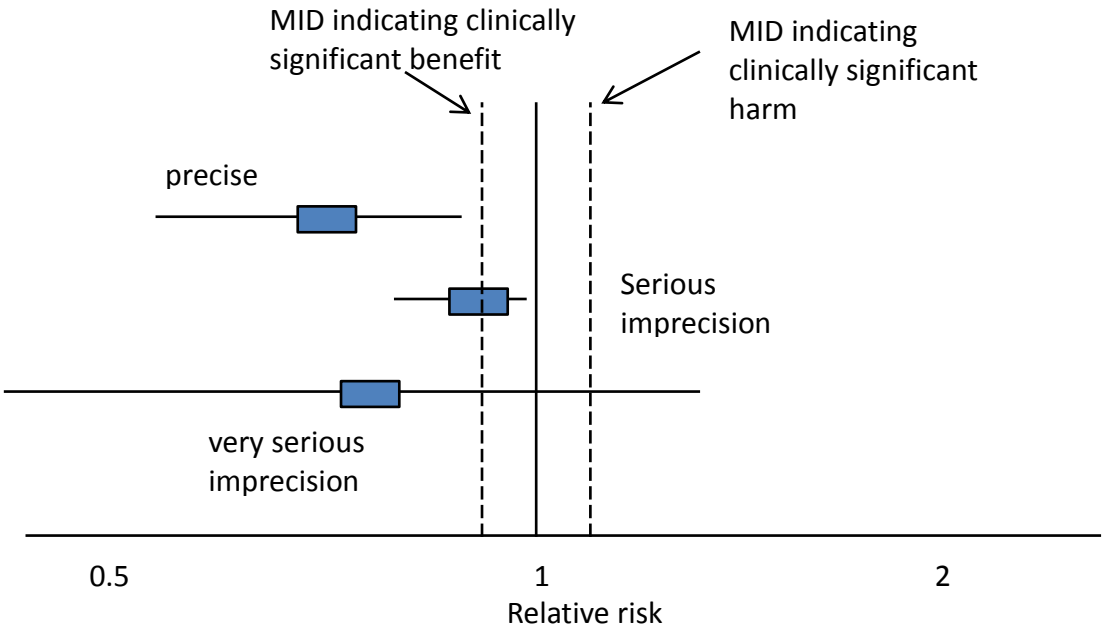
In the absence of literature values, the alternative approach to deciding on MID levels is the 'default' method, as follows:

- For categorical outcomes the MIDs are taken as risk ratios (RRs) of 0.75 and 1.25. For 'positive' outcomes, such as 'patient satisfaction', the RR of 0.75 is taken as the line denoting the boundary between no clinically important effect and a clinically significant harm, whilst the RR of 1.25 is taken as the line denoting the boundary between no clinically important effect and a clinically significant benefit. For 'negative' outcomes such as 'bleeding', the opposite occurs, so the RR of 0.75 is taken as the line denoting the boundary between no clinically important effect and a clinically significant benefit, whilst the RR of 1.25 is taken as the line denoting the boundary between no clinically important effect and a clinically significant harm.
- For continuous outcome variables the MID is taken as half the median baseline standard deviation of that variable, across all studies in the meta-analysis. Hence the MID denoting the minimum clinically significant benefit will be a positive for a positive" outcome (for example, a quality of life measure where a higher score denotes better health), and negative for a 'negative' outcome (for example, a VAS pain score). Clinically significant harms will be the converse of these. If baseline values are unavailable, then half the median comparator group standard deviation of that variable will be taken as the MID.
- If standardised mean differences have been used, then the MID will be set at the absolute value of + 0.5. This follows because standardised mean differences are mean differences normalised to the pooled standard deviation of the two groups, and are thus effectively expressed in units of 'numbers of standard deviation'. The 0.5 MID value in this context therefore indicates half a standard deviation, the same definition of MID as used for non-standardised mean differences.

The default MID value was subject to amendment after discussion with the GDG. If the GDG decided that the MID level should be altered, after consideration of absolute as well as relative effects, this was allowed, provided that any such decision was not influenced by any bias towards making stronger or weaker recommendations for specific outcomes.

For this guideline, no appropriate MIDs for continuous or dichotomous outcomes were found in the literature, and so the default method was used.

Figure 2: Illustration of precise and imprecise outcomes based on the CI of dichotomous outcomes in a forest plot. Note that all three results would be pooled estimates, and would not, in practice, be placed on the same forest plot



Overall grading of the quality of clinical evidence

Once an outcome had been appraised for the main quality elements, as above, an overall quality grade was calculated for that outcome. The scores from each of the main quality elements (0, −1 or −2) were summed to give a score that could be anything from 0 (the best possible) to −8 (the worst possible). However, scores were capped at −3. This final score was then applied to the starting grade that had originally been applied to the outcome by default, based on study design. For example, all RCTs started as High and the overall quality became Moderate, Low or Very low if the overall score was −1, −2 or −3 points respectively. The significance of these overall ratings is explained in Table 3. The reasons or criteria used for downgrading were specified in the footnotes of the GRADE tables.

On the other hand, observational interventional studies started at Low, and so a score of -1 would be enough to take the grade to the lowest level of very low. Observational studies could, however, be upgraded if there was: a large magnitude of effect, a dose-response gradient, and if all plausible confounding would reduce a demonstrated effect.

Table 4: Overall quality of outcome evidence in GRADE

Level	Description
High	Further research is very unlikely to change our confidence in the estimate of effect
Moderate	Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate
Low	Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate
Very low	Any estimate of effect is very uncertain

4.3.5.2 Prognostic studies

The quality of evidence for prognostic studies was evaluated according to the criteria given in Table 5. If data were meta-analysed the quality for pooled studies was presented. If the data was not pooled then a quality rating was presented for each study.

Table 5: Description of quality elements for prospective studies

Quality element	Description of cases where the quality measure would be downgraded
Study design	If case control rather than prospective cohort
Patient recruitment	If potential for selection bias
Validity of risk factor measure(s)	If non-validated and no reasonable face validity
Validity of outcome measure	If non-validated and no reasonable face validity
Blinding	if assessors of outcome not blinded to risk factor measurement (or vice versa)
Adequate follow up (or retrospective) duration	If follow up/retrospective period inadequate to allow events to occur, or retrospective period so short that causality is in doubt because the outcome may have preceded the risk factor
Confounder consideration	If there is a lack of consideration of all reasonable confounders in a multivariable analysis
Attrition	If attrition is too high and there is no attempt to adjust for this.
Directness	If the population, risk factors or outcome differ from that in the review question.

Because prognostic reviews were not usually based on multiple outcomes per study, quality rating was assigned by study. However if there was more than one outcome involved in a study, then the quality rating of the evidence statements for each outcome was adjusted accordingly. For example, if one outcome was based on an invalidated measurement method, but another outcome in the same study wasn't, the latter outcome would be graded one grade higher than the other.

Quality rating started at High for prospective studies, and each major limitation (see Table 5) brought the rating down by one increment to a minimum grade of Low, as explained for interventional studies.

4.3.5.3 Diagnostic studies

Quality of evidence for diagnostic data was evaluated by study using the Quality Assessment of Diagnostic Accuracy Studies version 2 (QUADAS-2) checklists. Risk of bias and applicability in primary diagnostic accuracy studies in QUADAS-2 consists of 4 domains (see Figure 3):

- Patient selection
- Index test
- Reference standard
- Flow and timing

Figure 3: Summary of QUADAS-2 with list of signalling, risk of bias and applicability questions.

Domain	Patient selection	Index test	Reference standard	Flow and timing
Description	Describe methods of patient selection. Describe included patients (prior testing, presentation, intended use of index	Describe the index test and how it was conducted and interpreted	Describe the reference standard and how it was conducted and interpreted	Describe any patients who did not receive the index test(s) and/or reference standard or who were excluded from

	test and setting)			the 2x2 table (refer to flow diagram). Describe the time interval and any interventions between index test(s) and reference standard
Signalling questions (yes/no/unclear)	Was a consecutive or random sample of patients enrolled?	Were the index test results interpreted without knowledge of the results of the reference standard?	Is the reference standard likely to correctly classify the target condition?	Was there an appropriate interval between index test(s) and reference standard?
	Was a case-control design avoided?	If a threshold was used, was it pre-specified?	Were the reference standard results interpreted without knowledge of the results of the index test?	Did all patients receive a reference standard?
	Did the study avoid inappropriate exclusions?			Did all patients receive the same reference standard?
				Were all patients included in the analysis?
Risk of bias; (high/low/unclear)	Could the selection of patients have introduced bias?	Could the conduct or interpretation of the index test have introduced bias?	Could the reference standard, its conduct or its interpretation have introduced bias?	Could the patient flow have introduced bias?
Concerns regarding applicability (high/low/unclear)	Are there concerns that the included patients do not match the review question?	Are there concerns that the index test, its conduct, or interpretation differ from the review question?	Are there concerns that the target condition as defined by the reference standard does not match the review question?	

4.3.5.4 Qualitative reviews

Table 6 below summarises the factors which were assessed to inform the quality rating for each sub-theme. Quality was rated as trustworthy or not trustworthy based on these criteria.

Table 6: Summary of factors assessed in qualitative reviews

Quality element	Factors
Limitations of evidence	• Were qualitative studies/surveys an appropriate approach? • Were the studies approved by an ethics committee? • Were the studies clear in what they seek to do? • Is the context clearly described? • Is the role of the researcher clearly described? • How rigorous was the research design/methods? • Is the data collection rigorous? • Is the data analysis rigorous? • Are the data rich (for qualitative study and open ended survey questions)?

	• Are the findings relevant to the aims of the study? • Are the findings and conclusions convincing?
Coherence of findings	• Do the subthemes identified complement, reinforce or contradict each other?
Applicability of evidence	• Are the findings of the study applicable to the evidence review? For example population and setting

4.3.6 Assessing clinical importance

The GDG assessed the evidence by outcome in order to determine if there was, or potentially was, a clinically important benefit, a clinically important harm or no clinically important difference between interventions. To facilitate this, binary outcomes were converted into absolute risk differences (ARDs) using GRADEpro software[1]: the median control group risk across studies was used to calculate the ARD and its 95% CI from the pooled risk ratio.

The assessment of clinical benefit, harm, or no benefit or harm was based on the point estimate of absolute effect for intervention studies which was standardised across the reviews. The GDG considered for most of the outcomes in the intervention reviews that if at least 100 participants per 1000 (10%) achieved (if positive) the outcome of interest in the intervention group compared with the comparison group then this intervention would be considered beneficial. The same point estimate but in the opposite direction would apply if the outcome was negative. For the critical outcomes of mortality any reduction represented a clinical benefit. For adverse events 50 events or more represented clinical harm. For continuous outcomes if the mean difference was greater than the minimally important difference then this presented a clinical benefit or harm. For outcomes such as mortality any reduction or increase was considered to be clinically important.

This assessment was carried out by the GDG for each critical outcome, and an evidence summary table was produced to compile the GDG's assessments of clinical importance per outcome, alongside the evidence quality and the uncertainty in the effect estimate (imprecision).

4.3.7 Clinical evidence statements

Clinical evidence statements are summary statements that are presented after the GRADE profiles, summarising the key features of the clinical effectiveness evidence presented. The wording of the evidence statements reflects the certainty/uncertainty in the estimate of effect. The evidence statements were presented by outcome and encompassed the following key features of the evidence:

- The number of studies and the number of participants for a particular outcome
- An indication of the direction of clinical importance (if one treatment is beneficial or harmful compared to the other or whether there is no difference between the two tested treatments).
- A description of the overall quality of evidence (GRADE overall quality).

4.4 Evidence of cost-effectiveness

Evidence on cost-effectiveness related to the key clinical issues being addressed in the guideline was sought. The health economist:

- Undertook a systematic review of the economic literature
- Undertook new cost-effectiveness analysis in priority areas

4.4.1 Literature review

The Health Economist:

- Identified potentially relevant studies for each review question from the economic search results by reviewing titles and abstracts – full papers were then obtained.
- Reviewed full papers against pre-specified inclusion / exclusion criteria to identify relevant studies (see below for details).
- Critically appraised relevant studies using the economic evaluations checklist as specified in The Guidelines Manual 2012[132]
- Extracted key information about the study's methods and results into evidence tables (See Appendix H. Studies considered eligible but were excluded can be found in Appendix L)
- Generated summaries of the evidence in NICE economic evidence profiles (included in the relevant chapter write-ups) – see below for details.

4.4.1.1 Inclusion and exclusion

Full economic evaluations (studies comparing costs and health consequences of alternative courses of action: cost–utility, cost-effectiveness, cost-benefit and cost-consequence analyses) and comparative costing studies that addressed the review question in the relevant population were considered potentially applicable as economic evidence.

Studies that only reported cost per hospital (not per patient) or only reported average cost effectiveness without disaggregated costs and effects were excluded. Abstracts, posters, reviews, letters and editorials, foreign language publications and unpublished studies were excluded. Studies judged to have an applicability rating of 'not applicable' were excluded (this included studies that took the perspective of a non-OECD country).

Remaining studies were prioritised for inclusion based on their relative applicability to the development of this guideline and the study limitations. For example, if a high quality, directly applicable UK analysis was available other less relevant studies may not have been included. Where exclusions occurred on this basis, this is noted in the relevant section.

For more details about the assessment of applicability and methodological quality see the economic evaluation checklist (The Guidelines Manual 2012, Appendix H[132] and the health economics research protocol in Appendix C.

When no relevant economic analysis was found from the economic literature review, relevant UK NHS unit costs related to the compared interventions were presented to the GDG to inform the possible economic implication of the recommendation being made.

4.4.1.2 NICE economic evidence profiles

The NICE economic evidence profile has been used to summarise cost and cost-effectiveness estimates. The economic evidence profile shows, for each economic study, an assessment of applicability and methodological quality, with footnotes indicating the reasons for the assessment. These assessments were made by the health economist using the economic evaluation checklist from The Guidelines Manual 2012, Appendix H [132]. It also shows incremental costs, incremental outcomes (for example, QALYs) and the incremental cost-effectiveness ratio from the primary analysis, as well as information about the assessment of uncertainty in the analysis. See Table 7 for more details.

If a non-UK study was included in the profile, the results were converted into pounds sterling using the appropriate purchasing power parity http://stats.oecd.org/Index.aspx?datasetcode=SNA_TABLE4

Table 7: Content of NICE economic profile

Item	Description
Study	First author name, reference, date of study publication and country perspective.

Item	Description
Limitations	An assessment of methodological quality of the study[a]: • Minor limitations – the study meets all quality criteria, or the study fails to meet one or more quality criteria, but this is unlikely to change the conclusions about cost effectiveness. • Potentially serious limitations – the study fails to meet one or more quality criteria, and this could change the conclusion about cost effectiveness • Very serious limitations – the study fails to meet one or more quality criteria and this is very likely to change the conclusions about cost effectiveness. Studies with very serious limitations would usually be excluded from the economic profile table.
Applicability	An assessment of applicability of the study to the clinical guideline, the current NHS situation and NICE decision-making[a]: • Directly applicable – the applicability criteria are met, or one or more criteria are not met but this is not likely to change the conclusions about cost effectiveness. • Partially applicable – one or more of the applicability criteria are not met, and this might possibly change the conclusions about cost effectiveness. • Not applicable – one or more of the applicability criteria are not met, and this is likely to change the conclusions about cost effectiveness.
Other comments	Particular issues that should be considered when interpreting the study.
Incremental cost	The mean cost associated with one strategy minus the mean cost of a comparator strategy.
Incremental effects	The mean QALYs (or other selected measure of health outcome) associated with one strategy minus the mean QALYs of a comparator strategy.
ICER	Incremental cost-effectiveness ratio: the incremental cost divided by the respective QALYs gained.
Uncertainty	A summary of the extent of uncertainty about the ICER reflecting the results of deterministic or probabilistic sensitivity analyses, or stochastic analyses of trial data, as appropriate.

(a) Limitations and applicability were assessed using the economic evaluation checklist from The Guidelines Manual 2012, Appendix H[132].

Where economic studies compare multiple strategies, results are presented in the economic evidence profiles for the pair-wise comparison specified in the review question, irrespective of whether or not that comparison was 'appropriate' within the analysis being reviewed. A comparison is 'appropriate' where an intervention is compared with the next most expensive non-dominated option – a clinical strategy is said to 'dominate' the alternatives when it is both more effective and less costly. Footnotes indicate if a comparison was 'inappropriate' in the analysis.

4.4.2 Undertaking new health economic analysis

As well as reviewing the published economic literature for each review question, as described above, new economic analysis was undertaken by the Health Economist in priority areas. Priority areas for new health economic analysis were agreed by the GDG after formation of the review questions and consideration of the available health economic evidence.

Additional data for the analysis was identified as required through additional literature searches undertaken by the Health Economist, and discussion with the GDG. Model structure, inputs and assumptions were explained to and agreed by the GDG members during meetings, and they commented on subsequent revisions.

See Appendix M for details of the health economic analysis/analyses undertaken for the guideline.

4.4.3 Cost-effectiveness criteria

NICE's report 'Social value judgements: principles for the development of NICE guidance' sets out the principles that GDGs should consider when judging whether an intervention offers good value for money.[130]

In general, an intervention was considered to be cost effective if either of the following criteria applied (given that the estimate was considered plausible):

a. The intervention dominated other relevant strategies (that is, it was both less costly in terms of resource use and more clinically effective compared with all the other relevant alternative strategies), or
b. The intervention cost less than £20,000 per quality-adjusted life-year (QALY) gained compared with the next best strategy.

If the GDG recommended an intervention that was estimated to cost more than £20,000 per QALY gained, or did not recommend one that was estimated to cost less than £20,000 per QALY gained, the reasons for this decision are discussed explicitly in the 'from evidence to recommendations' section of the relevant chapter with reference to issues regarding the plausibility of the estimate or to the factors set out in the 'Social value judgements: principles for the development of NICE guidance'.[130]

In the absence of economic evidence

When no relevant published studies were found, and a new analysis was not prioritised, the GDG made a qualitative judgement about cost effectiveness by considering expected differences in resource use between options and relevant UK NHS unit costs, alongside the results of the clinical review of effectiveness evidence.

The UK NHS costs reported in the guideline are those that were presented to the GDG and were correct at the time recommendations were drafted. They may have changed subsequently before the time of publication.

4.5 Developing recommendations

Over the course of the guideline development process, the GDG was presented with:

- Evidence tables of the clinical and economic evidence reviewed from the literature. All evidence tables are in Appendix G.
- Summary of clinical and economic evidence and quality as presented in chapters 6-13.
- Forest plots and summary ROC curves (Appendix J)
- A description of the methods and results of the cost-effectiveness analysis undertaken for the guideline (Appendix M)

Recommendations were drafted on the basis of the GDG interpretation of the available evidence, taking into account the balance of benefits, harms and costs. When clinical and economic evidence was of poor quality, conflicting or absent, the GDG drafted recommendations based on their expert opinion. The considerations for making consensus based recommendations include the balance between potential harms and benefits, economic or implications compared with the benefits, current practices, recommendations made in other relevant guidelines, patient preferences and equality issues. The consensus recommendations were done through discussions in the GDG. The GDG also considered whether the uncertainty was sufficient to justify delaying making a recommendation to await further research, taking into account the potential harm of failing to make a clear recommendation (See section 5.1.2).

The main considerations specific to each recommendation are outlined in the Evidence to Recommendation Section preceding the recommendation section.

4.5.1 Research recommendations

When areas were identified for which good evidence was lacking, the GDG considered making recommendations for future research. Decisions about inclusion were based on factors such as:

- the importance to patients, including patient safety, or the population
- national priorities
- potential impact on the NHS and future NICE guidance
- ethical and technical feasibility

4.5.2 Validation process

The guidance is subject to an eight week public consultation and feedback as part of the quality assurance and peer review the document. All comments received from registered stakeholders are responded to in turn and posted on the NICE website when the pre-publication check of the full guideline occurs.

4.5.3 Updating the guideline

Following publication, and in accordance with the NICE guidelines manual 2014[132], NICE will consider whether the evidence base has progressed sufficiently to alter the guideline recommendations and warrant an update.

4.5.4 Disclaimer

Health care providers need to use clinical judgement, knowledge and expertise when deciding whether it is appropriate to apply guidelines. The recommendations cited here are a guide and may not be appropriate for use in all situations. The decision to adopt any of the recommendations cited here must be made by the practitioners in light of individual patient circumstances, the wishes of the patient, clinical expertise and resources.

The National Clinical Guideline Centre disclaims any responsibility for damages arising out of the use or non-use of these guidelines and the literature used in support of these guidelines.

4.5.5 Funding

The National Clinical Guideline Centre was commissioned by the National Institute for Health and Care Excellence to undertake the work on this guideline.

5 Guideline summary

5.1.1 Full list of recommendations

1. For the initial management of pain in children (under 16s) with suspected long bone fractures of the legs (femur, tibia, fibula) or arms (humerus, radius, ulna), offer:
   - oral ibuprofen, or oral paracetamol, or both for mild to moderate pain
   - intranasal or intravenous opioids for moderate to severe pain (use intravenous opioids if intravenous access has been established).
2. For the initial management of pain in adults (16s or over) with suspected long bone fractures of the legs (tibia, fibula) or arms (humerus, radius, ulna), offer:
   - oral paracetamol for mild pain
   - oral paracetamol and codeine for moderate pain
   - intravenous paracetamol supplemented with intravenous morphine titrated to effect for severe pain.
3. Use intravenous opioids with caution in frail or older adults.
4. Do not offer non-steroidal anti-inflammatory drugs (NSAIDs) to frail or older adults with fractures.
5. Consider NSAIDs to supplement the pain relief in recommendation 2 except for frail or older adults.
6. Consider a femoral nerve block or fascia iliaca block in the emergency department for children (under 16s) with suspected displaced femoral fractures.
7. Use the Ottawa knee rules to determine whether an X-ray is needed in people over 2 years with suspected knee fractures.
8. Use the Ottawa ankle and foot rules to determine whether an X-ray is needed in people over 5 years with suspected ankle fractures.
9. Consider MRI for first-line imaging in people with suspected scaphoid fractures following a thorough clinical examination.
10. A radiologist, radiographer or other trained reporter should deliver the definitive written report of emergency department X-rays of suspected fractures before the patient is discharged from the emergency department.
11. Consider intravenous regional anaesthesia (Bier's block) when reducing dorsally displaced distal radius fractures in adults (16 or over) in the emergency department. This should be performed by healthcare professionals trained in the technique, not necessarily anaesthetists.
12. Do not use gas and air (nitrous oxide and oxygen) on its own when reducing dorsally displaced distal radius fractures in the emergency department.
13. Do not use a rigid cast for torus fractures of the distal radius.
14. Discharge children with torus fractures after first assessment and advise parents and carers that further review is not usually needed.
15. In the non-surgical management of unimalleolar ankle fractures:

- advise immediate unrestricted weight-bearing as tolerated
- arrange for orthopaedic follow-up within 2 weeks if there is uncertainty about stability
- advise all patients to return for review if symptoms are not improving 6 weeks after injury.

16. If treating an ankle fracture with surgery, consider operating on the day of injury or the next day.
17. When needed for distal radius fractures, perform surgery:
    - within 72 hours of injury for intra-articular fractures
    - within 7 days of injury for extra-articular fractures.
18. When needed for re-displacement of distal radius fractures, perform surgery within 72 hours of the decision to operate.
19. Consider manipulation and a plaster cast in adults (skeletally mature) with dorsally displaced distal radius fractures.
20. When surgical fixation is needed for dorsally displaced distal radius fractures in adults (skeletally mature):
    - offer K-wire fixation if:
    - no fracture of the articular surface of the radial carpal joint is detected, or
    - displacement of the radial carpal joint can be reduced by closed manipulation
    - consider open reduction and internal fixation if closed reduction of the radial carpal joint surface is not possible.
21. In children (skeletally immature) with dorsally displaced distal radius fractures (including fractures involving a growth plate) who have undergone manipulation, consider:
    - a below-elbow plaster cast, or
    - K-wire fixation if the fracture is completely displaced (off-ended).
22. For adults (skeletally mature) with displaced low energy proximal humerus fractures:
    - offer non-surgical management for definitive treatment of uncomplicated injuries
    - consider surgery for injuries complicated by an open wound, tenting of the skin, vascular injury, fracture dislocation or a split of the humeral head.
23. Admit all children (skeletally immature) with femoral shaft fractures and consider 1 of the following according to age and weight:
    - prematurity and birth injuries: simple padded splint
    - 0 to 6 months: Pavlik's harness or Gallows traction
    - 3 to 18 months (but not in children over 15 kg): Gallows traction
    - 1 to 6 years: straight leg skin traction (becomes impractical in children over 25 kg) with possible conversion to hip spica cast to enable early discharge

- 4 to 12 years (but not in children over 50 kg): elastic intramedullary nail
- 11 years to skeletal maturity (weight more than 50 kg): elastic intramedullary nails supplemented by end-caps, lateral-entry antegrade rigid intramedullary nail, or submuscular plating.

24. Consider advising immediate unrestricted weight-bearing as tolerated for people who have had surgery for distal femoral fractures.

25. Consider developing and using standard documentation to prompt the assessment of the following from first presentation in people with fractures:
    - safeguarding
    - comorbidities
    - falls risk
    - nature of fracture, including classification where possible.

26. Follow a structured process when handing over care within the emergency department (including shift changes) and to other departments. Ensure that the handover is documented.

27. Ensure that all patient documentation, including images and reports, goes with patients when they are transferred to other departments or centres.

28. Produce a written summary, which gives the diagnosis, management plan and expected outcome, and:
    - is aimed at and sent to the patient's GP within 24 hours of admission
    - includes a summary written in plain English that is understandable by patients, family members and carers
    - is readily available in the patient's records.

29. If possible, ask the patient if they want someone (family member, carer or friend) with them.

30. Allocate a dedicated member of staff to contact the next of kin and provide support for unaccompanied children and vulnerable adults.

31. For a child or vulnerable adult with a fracture, enable their family members or carers to remain within eyesight if appropriate.

32. Work with family members and carers of children and vulnerable adults to provide information and support. Take into account the age, developmental stage and cognitive function of the child or vulnerable adult.

33. Include siblings of an injured child when offering support to family members and carers.

34. Address issues of non-accidental injury before discharge in all children with femoral fractures. This is particularly important for children who are not walking or talking. For more information, see the NICE guideline on when to suspect child maltreatment.

35. Reassure people while they are having procedures for fractures under local and regional anaesthesia.

36. When communicating with patients, family members and carers:
    - manage expectations and avoid misinformation
    - answer questions and provide information honestly, within the limits of your knowledge

- do not speculate and avoid being overly optimistic or pessimistic when discussing information on further investigations, diagnosis or prognosis
- ask if there are any other questions.

37. Document all key communications with patients, family members and carers about the management plan.

38. Explain to patients, family members and carers, what is happening and why it is happening. Provide:
    - information on known injuries
    - details of immediate investigations and treatment, and if possible include time schedules.

39. Offer people with fractures the opportunity to see images of their injury taken before and after treatment.

40. Provide people with fractures with both verbal and written information on the following when the management plan is agreed or changed:
    - expected outcomes of treatment, including time to returning to usual activities and the likelihood of any permanent effects on quality of life (such as pain, loss of function or psychological effects)
    - activities they can do to help themselves
    - home care options, if needed
    - rehabilitation, including whom to contact and how (this should include information on the importance of active patient participation for achieving goals and the expectations of rehabilitation)
    - mobilisation and weight-bearing, including upper limb load-bearing for arm fractures.

41. Ensure that all health and social care practitioners have access to information previously given to people with fractures to enable consistent information to be provided.

42. For patients who are being transferred from an emergency department to another centre, provide verbal and written information that includes:
    - the reason for the transfer
    - the location of the receiving centre and the patient's destination within the receiving centre
    - the name and contact details of the person responsible for the patient's care at the receiving centre
    - the name and contact details of the person who was responsible for the patient's care at the initial hospital.

5.1.2 Additional recommendations

The evidence for the following recommendations was reviewed in other guidelines from this suite of 5 guidelines.

Pain assessment

- See the NICE guideline on patient experience in adult NHS services for advice on assessing pain in adults.
- Assess pain regularly in people with fractures using a pain assessment scale suitable for the person's age, developmental stage and cognitive function.
- Continue to assess pain in hospital using the same pain assessment scale that was used in the pre-hospital setting.

Splinting long bone fractures of the leg in the pre-hospital setting

- In the pre-hospital setting, consider the following for people with suspected long bone fractures of the legs:
  - A traction splint or adjacent leg as a splint if the suspected fracture is above the knee
  - A vacuum splint for all other suspected long bone fractures.

Training and skills

- Ensure that each healthcare professional within the trauma service has the training and skills to deliver, safely and effectively, the interventions they are required to give, in line with the NICE guidelines on non-complex fractures, complex fractures, major trauma and spinal injury assessment.
- Enable each healthcare professional who delivers care to people with fractures to have up-to-date training in the interventions they are required to give.

5.2 Key research recommendations

1. **Is CT scanning in addition to initial plain film X-ray clinically effective and cost effective for planning surgical treatment of unstable/displaced ankle fractures compared with plain film X-ray alone?**

2. **What is the clinical and cost effectiveness of virtual new patient fracture clinics compared with next-day consultant-led face-to-face clinics in people presenting with non-complex fractures in the emergency department and thought to need an orthopaedic opinion?**

3. **For patients with displaced fractures of the distal radius, is manipulation with real-time image guidance more clinically and cost effective than manipulation without real-time image guidance?**

4. **What is the most clinically effective and cost-effective strategy for weight-bearing in people who have had surgery for internal fixation of an ankle fracture?**

5. **What is the clinical effectiveness and cost effectiveness of no treatment for torus fractures of the distal radius in children compared with soft splints, removable splints or bandages?**

6 Initial pain management

6.1 Initial pharmacological pain management

6.1.1 Introduction

Patients commonly present to the accident and emergency departments with suspected fractures and require early and effective analgesia. In-hospital management of pain is generally considered suboptimal and over 50% of patients are dissatisfied with their initial pain management. Clinicians can administer a range of pharmacological agents, through a series of routes, depending on mechanism of injury, clinical experience and patient-reported pain scores, and the appropriate analgesic varies widely between patients. For example, intravenous (IV) morphine has been the mainstay of treatment in patients with moderate to severe isolated limb trauma, while non-opioid oral medications are considered for less severe injuries. However, the efficacy of each drug to reduce pain should be debated, as many drugs are associated with undesirable side-effects, including nausea and respiratory depression.

6.1.2 Review question: What is the most effective initial acute pharmacological management to alleviate pain in patients with a suspected long bone fracture (tibia and fibula, humerus, radius and ulna, or unspecified) in acute care settings?

For full details see review protocol in Appendix C.

Table 8: PICO characteristics of review question

Population	Children, young people and adults with a suspected long bone fracture following traumatic incident.

Intervention(s)	Oral:
	• Opioids
	  ○ codeine
	  ○ tramadol
	  ○ morphine
	• Paracetamol
	• Nonsteroidal anti-inflammatory drugs (NSAIDs)
	
	Rectal:
	• NSAIDs
	
	Inhaled:
	• Nitrous oxide (Entonox)
	
	Intranasal:
	• Opioids
	  ○ Diamorphine and fentanyl
	
	IV:
	• Paracetamol
	• NSAIDs
	• Opioids (such as morphine)

Comparison(s)	A comparison of the above (include any combination, either between or within classes)

Outcomes	Critical: • Pain (1 hour) • Pain (4–6 hours) • Health-related quality of life • Missed diagnosis of compartment syndrome • Delayed bone healing • Local infection • Nerve and vascular damage • Respiratory depression (<6 hours) • Local anaesthetic toxicity • Nausea and vomiting (<6 hours) • Admission solely for recovery from pharmacological agent Important: • Need for rescue analgesia
Study design	RCTs or systematic reviews of RCTs

6.1.3 Clinical evidence

We searched for systematic reviews and randomised trials comparing the effectiveness of pharmacological interventions for the management of pain in non-complex fractures (see protocol above). The protocol pre-specified that non-randomised studies would not be considered for review. Fifteen trials across sixteen comparisons were found and summarised in Table 9. Clinical evidence summaries for all comparisons are also presented (see Table 10 to Table 25). See also the study selection flow chart in Appendix D, study evidence tables in Appendix G, forest plots in Appendix j, GRADE tables in Appendix I and excluded studies list in Appendix K.

Table 9: Summary of studies included in the review

Study	Intervention and comparison	Population	Outcomes	Comments
Borland 2007[28]	Intranasal opioids (fentanyl) versus IV opioids (morphine)	Children aged 7–15 years presenting with clinically deformed closed long-bone fractures, identified at triage	Pain at 1 hour; Adverse event – Nausea; Need for rescue analgesia	
Charney 2008 [37]	Oral opioids (codeine) versus oral opioids (codeine – oxycodone)	Children with suspected forearm fractures	Adverse event – Nausea	
Clark 2007[39]	Oral paracetamol versus Oral NSAIDs (ibuprofen) versus oral opioids (Codeine)	Children aged 6–17 years with pain from musculoskeletal injury (to extremities neck, and back) occurring in the previous 2 days	Pain at 1 hour	
Craig 2012 [43]	IV opioid (Morphine) versus oxycodone Paracetamol	Isolated limb trauma, moderate to severe pain, with initial verbal pain score of 7 or more, Age>15 and <66 years	Pain at 1 hour; Need for further analgesia	
Friday 2009 [58]	Oral NSAIDs (ibuprofen) versus oral paracetamol –	Isolated extremity injury and a pain score of at least 5 out of 10 on initial triage in	Pain at 1 hours; Adverse event – Nausea	Only 55% of patients had fracture.

Study	Intervention and comparison	Population	Outcomes	Comments
	opioid (codeine) combination	children aged 5–17 years		
Furyk 2009 [59]	Intranasal opioid (fentanyl) versus oxycodone opioid (morphine)	Patients with pain from a clinically suspected limb fracture and pain considered sufficient to manage with narcotic analgesia	Pain at 1 hour; Adverse event – Nausea; Need for rescue analgesia	
Jalili 2012[87]	Oral opioid (sublingual buprenorphine and IV opioid (morphine)	Acute extremity fracture with scores of higher than 3 out of 10 on a numeric pain scale	Pain at 1 hour; Adverse events – Nausea	
Kariman 2011[99]	Inhaled – Entonox versus IV opioid (fentanyl)	Patients aged 15–18 years presenting with isolated extremity injury	Pain at 1 hour	
Koller [105]	Oral opioid (codeine – oxycodone) versus oral NSAID (ibuprofen) versus oral opioids (codeine – oxycodone) plus oral NSAIDs (ibuprofen)	Children aged 6–18 years presenting at the emergency department (ED) with a suspected orthopaedic injury	Adverse Effects – Nausea; Need for rescue analgesia	
Mahar 2007 [114]	Oral opioid (morphine) versus IV opioid (morphine)	Children with a visual analogue pain rating greater than 50/100	Pain at 1 hour; Adverse event – nausea	
Marco 2005 [119]	Oral opioid (codeine-oxycodone) versus oral opioid (codeine – hydrocodone)	Adults and adolescents with an acute fracture (less than 3 days) and in severe pain with a >5 (out 10) pain score	Pain at 1 hour; Adverse event – Nausea; Need for rescue analgesia	
Neri 2013[133]	Oral NSAIDs (ketorolac) versus oral opioids (tramadol)	Presence of suspected fracture of dislocation; Pain score greater than 6 out of 10 in children aged 4-17 years	Adverse event; nausea; Need for rescue analgesia	
Poonai 2014 [146]	Oral opioid versus oral NSAID	Children aged 5 -17 years with a non-operative radiographic ally detected fracture.	Pain at 4 hours; Adverse event – nausea; need for rescue analgesia.	
Rainer 2000[148]	IV NSAIDs (ketorolac) versus IV opioids (tramadol)	Patients aged above 16 years with an isolated painful limb injury	Adverse event – nausea	Patients entered trial with suspected fracture. Only two-thirds confirmed (reported separately).
Shepard 2009 [169]	Oral – NSAIDs. ibuprofen versus oral – paracetamol.	Presentation to the emergency room for fracture management within 24 hours of injury, an acute, non-pathological	Adverse event-nausea; Adverse event – delayed union; Need for	

Study	Intervention and comparison	Population	Outcomes	Comments
		fracture of distal humerus, radius, or ulna, or any tibia or fibula and the patient able to be discharged from the ED	further analgesia	

Table 10: Clinical evidence summary: Intranasal opioid versus IV opioid (children)

Outcome	Number of studies (participants)	Imprecision	GRADE rating	Absolute difference	Control event rate (per 1000)	Control group value for continuous outcomes
Pain (final Score) (follow-up mean 30 minutes; range of scores 0–100; Better indicated by lower)	1 (n=67)	Very serious	LOW	MD 4.0 higher (15.99 lower to 7.99 higher)	–	35
Pain (final Score) (follow-up mean 30 minutes; range of scores 0–10; Better indicated by lower)	1 (n=72)	Serious	LOW	MD 0.52 lower (0.57 lower to 1.61 higher)	–	4.03
Nausea/vomiting	2 (n=137)	Very serious	VERY LOW	1 more per 1000 (from 12 fewer to 90 more)	14	–
Need for further analgesia	2 (n=139)	Very serious	LOW	10 more per 1000 (from 11 fewer to 166 more	14	–

Table 11: Clinical evidence summary: Oral codeine (codeine) versus oral codeine (oxycodone) (children)

Outcome	Number of studies (participants)	Imprecision	GRADE rating	Absolute difference	Control event rate (per 1000)	Control group value for continuous outcomes
Pain (final Score) (follow-up mean 180 minutes; range of scores 1–4; Better indicated by lower)	1 (n=107)	Serious impression	VERY LOW	MD 0.4 lower (0.69 to 0.11 lower)	–	1.75
Nausea/vomiting	1 (n=107)	Very serious	VERY LOW	2 more per 1000 (from 17 fewer to 290 more)	18	–

Table 12: Clinical evidence summary: Oral NSAIDs versus oral codeine (children)

Outcome	Number of studies (participants)	Imprecision	GRADE rating	Absolute difference	Control event rate (per 1000)	Control group value for continuous outcomes
Pain score at 60 minutes	1 (n=108)	No serious imprecision	HIGH	MD 22 lower (28.58 to 15.42 lower)	–	-7
Nausea/vomiting	1 (n=44)	–	–	Cannot be pooled	0	–
Need for further analgesia	1 (n=44)	Very serious imprecision	VERY LOW	50 more 1000 (0 more to 160 more)	0	–

Table 13: Clinical evidence summary: Oral NSAIDs versus oral paracetamol (children)

Outcome	Number of studies (participants)	Imprecision	GRADE rating	Absolute difference	Control event rate (per 1000)	Control group value for continuous outcomes
Pain (Change Score) (follow-up mean 60 minutes; range of scores 0–100; Better indicated by lower)	1 (n=109)	Serious	MODERATE	MD 15 lower (23.2 to 6.8 lower)	–	-14
Nausea/vomiting	1 (n=72)	Serious	VERY LOW	70 more per 1000 (from 0 more to 170 more)	0	–
Delayed union	1 (n=72)	–	–	Cannot be pooled	0	–
Need for further analgesia (2 hours)	1 (n=72)	Serious	VERY LOW	69 more per 1000 (from 36 fewer to 420 more)	70	–
Need for further analgesia (48 hours)	1 (n=72)	Serious	VERY LOW	23 more per 1000 (from 37 fewer to 420 more)	47	–

Table 14: Clinical evidence summary: Oral codeine versus oral paracetamol (children)

Outcome	Number of studies (participants)	Imprecision	GRADE rating	Absolute difference	Control event rate (per 1000)	Control group value for continuous outcomes
Pain (Change Score) (follow-up mean 60 minutes; range of scores 0–100; Better indicated by lower)	1 (n=101)	Serious	MODERATE	MD 7 higher (1.9 to 12.1 higher)	–	-14

Table 15: Clinical evidence summary: Oral opioid versus IV opioid (children)

Outcome	Number of studies (participants)	Imprecision	GRADE rating	Absolute difference	Control event rate (per 1000)	Control group value for continuous outcomes
Pain (final Score) (follow-up mean 30 minutes; range of scores 0–100; Better indicated by lower)	1 (n=87)	Serious	LOW	MD 10.9 lower (20.58 to 1.22 lower)	–	44.7
Pain (final Score) (follow-up mean 60 minutes; range of scores 0–10; Better indicated by lower)	1 (n=87)	Serious	LOW	MD 14.4 lower (24.2 to 4.6 lower)	–	39.8
Nausea/vomiting	1 (n=87)	Very serious	VERY LOW	35 more per 1000 (from 34 fewer to 391 more)	50	–

Table 16: Clinical evidence summary: Oral NSAIDs versus oral tramadol (children)

Outcome	Number of studies (participants)	Imprecision	GRADE rating	Absolute difference	Control event rate (per 1000)	Control group value for continuous outcomes
Nausea/vomiting	1 (n=125)	Very serious	VERY LOW	26 fewer per 1000 (from 30 fewer to 11 more)	46	–
Need for further analgesia	1 (n=125)	Serious	LOW	90 fewer per 1000 (from 116 fewer to 28 more)	123	–

Table 17: Clinical evidence summary: Oral NSAIDs versus oral paracetamol – codeine combination (children)

Outcome	Number of studies (participants)	Imprecision	GRADE rating	Absolute difference	Control event rate (per 1000)	Control group value for continuous outcomes
Pain (final Score) (follow-up mean 20 minutes; range of scores 0–10; Better indicated by lower)	1 (n=66)	Serious	VERY LOW	MD 0.6 higher (1.42 lower to 0.22 higher)	–	-0.8
Pain (final Score) (follow-up mean 60 minutes; range of scores 0–10; Better indicated by lower)	1 (n=66)	Serious	VERY LOW	MD 0.2 higher (0.82 lower to 1.22 higher)	–	-2.3
Nausea/vomiting	1 (n=66)	Very serious	VERY LOW	27 fewer per 1000 (from 31 fewer to 139 more)	31	–

Table 18: Clinical evidence summary: Oral NSAIDs plus codeine combination versus oral NSAIDs (children)

Outcome	Number of studies (participants)	Imprecision	GRADE rating	Absolute difference	Control event rate (per 1000)	Control group value for continuous outcomes
Nausea/vomiting	1 (n=43)	Very serious	VERY LOW	50 more per 1000 (from 0 more 170 more)	0	–
Need for further analgesia	1 (n=43)	Very serious	VERY LOW	39 fewer 1000 (from 45 fewer to 209 more)	50	–

Table 19: Clinical evidence summary: Oral NSAIDs plus codeine combination versus oral codeine (children)

Outcome	Number of studies (participants)	Imprecision	GRADE rating	Absolute difference	Control event rate (per 1000)	Control group value for continuous outcomes
Nausea/vomiting	1 (n=43)	Very serious	VERY LOW	50 more per 1000 (from 0 more 170 more)	0	–
Need for further analgesia	1 (n=43)	–	–	Cannot be pooled	0	–

Table 20: Clinical evidence summary: Oral NSAIDs versus oral morphine (children)

Outcome	Number of studies (participants)	Imprecision	GRADE rating	Absolute difference	Control event rate (per 1000)	Control group value for continuous outcomes
Pain at 4 hours	1 (134)	None	MODERATE	MD 0.2 lower (0.57 lower to 0.17 higher)	-	1.5
Nausea	1 (134)	Serious	MODERATE	123 fewer per 1000 (from 23 fewer to 146 more)	152	–
Need for further analgesia	1 (134)	Serious	MODERATE	103 more per 1000 (from 24 fewer to 359 more)	147	–

Table 21: Clinical evidence summary: Oral opioid versus IV opioid (adult)

Outcome	Number of studies (participants)	Imprecision	GRADE rating	Absolute difference	Control event rate (per 1000)	Control group value for continuous outcomes
Pain (final Score) (follow-up mean 30 minutes; range of scores 0–10; Better indicated by lower)	1 (n=99)	No serious imprecision	MODERATE	MD 0 higher (0.69 lower to 0.69 higher)	–	5.0
Pain (final Score) (follow-up mean 60 minutes; range of scores 0–10; Better indicated by lower)	1 (n=89)	No serious imprecision	MODERATE	MD 0 higher (0.29 lower to 0.29 higher)	–	2.2
Nausea/vomiting at 30 minutes	1 (n=99)	Very serious	VERY LOW	23 more per 1000 (from 68 fewer to 275 more	120	–
Nausea/Vomiting at 60 minutes	1 (n=89)	Very serious	VERY LOW	19 fewer per 1000 (from 22 fewer to 114 more)	220	–

Table 22: Clinical evidence summary: Oral codeine versus oral codeine (adult)

Outcome	Number of studies (participants)	Imprecision	GRADE rating	Absolute difference	Control event rate (per 1000)	Control group value for continuous outcomes
Pain (Change Score)	1 (n=62)	Serious	LOW	MD 1.2 lower (2.32 to	–	-2.5

(follow-up mean 30 minutes; range of scores 0–100; Better indicated by lower)				0.08)		
Pain (Change Score) (follow-up mean 60 minutes; range of scores 0–10; Better indicated by lower)	1 (n=47)	Serious	LOW	MD 1.4 lower (2.81 lower to 0.01 higher)	–	-3.0
Nausea/vomiting at 30 minutes	1 (n=34)	Very serious	VERY LOW	49 fewer per 1000 (from 104 fewer to 514 more)	111	–
Need for further analgesia	1 (n=67)	Very serious	VERY LOW	105 fewer per 1000 (from 182 fewer to 136 more)	219	–

Table 23: Clinical evidence summary: IV opioids versus IV paracetamol (adult)

Outcome	Number of studies (participants)	Imprecision	GRADE rating	Absolute difference	Control event rate (per 1000)	Control group value for continuous outcomes
Pain (final score) (follow-up mean 30 minutes; range of scores 0–100; Better indicated by lower)	1 (n=55)	Serious	LOW	MD 8.5 lower (22.42 lower to 5.42 higher)	–	63.5
Pain (Change Score) (follow-up mean 60 minutes; range of scores 0–100; Better indicated by lower)	1 (n=55)	Serious	LOW	MD 8.9 lower (22.15 lower to 4.35 higher)	–	52.9
Need for further analgesia	1 (n=55)	Very serious	VERY LOW	12 more per 1000 (from 163 fewer to 406 more)	286	–

Table 24: Clinical evidence summary: Entonox versus IV opioid (adult)

Outcome	Number of studies (participants)	Imprecision	GRADE rating	Absolute difference	Control event rate (per 1000)	Control group value for continuous outcomes
Pain (final score) (follow-up mean 60 minutes; range of scores 0–10; Better indicated by lower)	1 (n=100)	No serious imprecision	MODERATE	MD 0.1 higher (0.59 lower to 0.79 higher)	–	7.8

Table 25: Clinical evidence summary: IV NSAIDs versus IV opioid (adult)

Outcome	Number of studies (participants)	Imprecision	GRADE rating	Absolute difference	Control event rate (per 1000)	Control group value for continuous outcomes
Nausea/vomiting	1 (n=148)	No serious imprecision	LOW	320 fewer per 1000 (from 265 to 347 fewer)	370	–

6.1.4 Economic evidence

Published literature

No relevant economic evaluations were identified.

See also the economic article selection flow chart in Appendix E.

Unit costs

Table 26: Equipment needed for the different methods of access

Intervention	Resources needed	Cost	Cost per patient	Source
Intranasal	Blunt filter drawing up needle 18 g x 38 mm	£44.70 Box of 100	£0.45	NHS Supply chain[3]
	Nasal atomisation device	£269.52 Box of 100	£2.70	NHS supply chain
			Total = £3.14	
Inhaled	Entonox cylinder rental	£62.05 per annum	Likely to be small	GDG contact
	Entonox delivery circuit mask	£59.81 Box of 10	£5.98	NHS supply chain
	Entonox delivery circuit mouthpiece	£79.09 Box of 20	£3.95	NHS supply chain
	Entonox mouthpiece filter	£74.23 Box of 50	£1.48	NHS supply chain
	Demand valve	£280 [a]	£0.06	
			Total = £11.48	
Rectal	gloves	£32.87 Box of 50	£0.66	NHS supply chain
			Total: likely to be lower than inhaled	
IV	Pre-injection 70% isopropyl alcohol wipe 60 mm x 30 mm (10,000 sachets)	£105.88 10,000 sachets	£0.01	NHS SC
	cannulas (22–14G)	£42 box of 50	£0.84	The Air Ambulance Service (through GDG contact)
	Tegaderm Film	£28.82 box of 100	£0.29	The Air Ambulance Service (through GDG contact)
	10 ml syringe green 21 gauge x 1.5-inch needle	£26.30 Box of 100	£0.53	NHS Supply chain
	10 ml sodium chloride	£3.36 pack of 10	£0.34	Drug tariff[135]
			Total = £2	

(a) Assumed can be used on 5000 people

Table 27: Drug costs

Drug	Dose	Cost	Cost of an average dose	Method of access suitable for	Source
Pain relief					
Entonox	Assumed 6 litres per minute for 15 minutes		£0.36	Inhaled	Entonox supplier
Codeine	60 mg, 28-tab pack	£2.99	£0.21 120mg	Oral	BNF[95]
	60 mg/ml, 1-ml ampoule	£2.37		IV	BNF
Tramadol	50 mg, 100-cap pack	£4.23	£0.08 100mg	Oral (capsules)	BNF
	100 mg/ml, 10 ml	£3.50		Oral (drops)	BNF
	50 mg/ml, 2-ml ampoule	£0.98		IV	BNF
Morphine	10 mg/5 ml, 100-ml pack	£1.89		Oral	BNF
	1 mg/ml, 50-ml vial	£5.25	£1.05 10mg	Intranasal, IV	BNF
Diamorphine	10 mg, 100-tab pack	£24.09		Oral	BNF
	10-mg ampoule	£2.51		Intranasal, IV	BNF
Paracetamol	500 mg, 100-tab pack	£2.75	£0.06 1000mg	Oral	BNF
	10 mg/ml, 100-ml vial	£1.20		IV	BNF
Ibuprofen (NSAID)	200 mg, 84-tab pack	£3.12	£0.15 800mg	Oral	BNF
Ketorolac (NSAID)	30 mg/ml, 1-ml ampoule	£1.09	£1.09 30mg	IV	BNF
Fentanyl	50 micrograms/ml, 2-ml ampoule	£0.30	£0.60 200mcg	Intranasal, IV	BNF
Antiemetic (administered with morphine or diamorphine to prevent nausea)					
Cyclizine lactate	50 mg/ml, 1-ml ampoule	£0.65			BNF
Metoclopramide	5 mg/ml, 2-ml ampoule (=10 mg)	£0.30			BNF

(a) The doses used to cost up an average dose are taken from the doses in the clinical review. These are conservative doses, meaning if more than one study used the same drug, then the highest dose was used here for costing.

6.1.5 Evidence statements

Clinical

Intranasal opioid versus IV opioid (children)

Low quality evidence from 2 RCTs comprising 139 participants demonstrated no clinical difference between intranasal and IV opioid treatment with regards to pain relief at 1 hour, with very serious imprecision.

Very low quality evidence from 2 RCTs with 137 participants demonstrated no clinical difference between intranasal and IV opioid treatment for incidence of nausea, with very serious imprecision.

Low quality evidence from 2 RCTs comprising 139 participants demonstrated no clinical difference between intranasal and IV opioid treatment regarding further need for analgesia, with very serious imprecision.

Oral opioid (codeine) versus oral opioid (codeine - oxycodone) (children)

Very low quality evidence from a single RCT comprising 107 participants demonstrated no clinical difference between oxycodone and hydrocodone for incidence of nausea, with very serious imprecision.

Oral NSAIDs versus oral opioid (codeine) (children)

High quality evidence from a single RCT comprising 108 participants demonstrated a clinical benefit of oral NSAIDs over oral opioid (codeine) in the pain management of children with suspected fracture, with no serious imprecision.

Evidence for incidence of nausea and need for further analgesia demonstrated no difference between groups. The data could not be pooled as there were no events in either arm.

Oral NSAIDs versus oral paracetamol (children)

Moderate quality evidence from a single RCT comprising 109 participants demonstrated a clinical benefit of oral NSAIDs and oral paracetamol in children with suspected fractures, with serious imprecision.

Very low quality evidence from a single RCT comprising 72 participants demonstrated no clinical difference between the interventions for the incidence of nausea, with very serious imprecision.

Evidence for incidence of delayed union demonstrated no difference between groups. The data could not be pooled as there were no events in either arm.

Very low quality evidence from a single RCT comprising 72 participants demonstrated no clinical difference between the interventions regarding the need for further analgesia at 2 hours and 48 hours, with very serious imprecision.

Oral codeine versus oral paracetamol (children)

Moderate quality evidence from a single RCT comprising 101 participants demonstrated no clinical difference between oral codeine and oral paracetamol, with serious imprecision.

Oral opioid versus IV opioid (children)

Low quality evidence from an RCT comprising 87 participants demonstrated a clinical benefit of oral opioid over IV opioid for pain management in children with suspected fractures at 30 and 60 minutes, with serious imprecision.

Very low quality evidence from the same study of 53 participants demonstrated no clinical difference between the interventions for nausea, with very serious imprecision.

Oral NSAIDs versus oral tramadol (children)

Very low quality evidence from a single RCT comprising 125 participants demonstrated no clinical difference between the interventions regarding the incidence of nausea, with very serious imprecision.

Low quality evidence from a single RCT of 125 patients demonstrated clinical benefits of oral NSAIDs over oral tramadol in the reduction of further need for analgesia, with no serious imprecision.

Oral NSAIDs versus oral paracetamol-codeine combination (children)

Very low quality evidence from a single RCT comprising 66 participants demonstrated no clinical difference between the interventions for the management of pain at 20 and 60 minutes, with a serious risk of imprecision. The population was also determined to be indirect as only 55% suffered fractures.

Very low quality evidence from the same study of 66 participants demonstrated no clinical difference between the interventions for nausea, with very serious imprecision. The population was also determined to be indirect as only 55% suffered fractures.

Oral NSAIDs and codeine combination versus Oral NSAIDs (children)

Very low quality evidence from a single RCT of 43 patients demonstrated no clinical difference between the interventions for incidence of nausea, with very serious risk of imprecision.

Very low quality evidence from a single RCT of 43 patients demonstrated no clinical difference between the interventions for the need for further analgesia, with very serious risk of imprecision.

Oral NSAIDs and codeine combination versus oral codeine (children)

Very low quality evidence from a single RCT of 43 patients demonstrated no clinical difference between the interventions for incidence of nausea, with very serious risk of imprecision.

Very low quality evidence from a single RCT of 43 patients demonstrated no clinical difference between the interventions for the need for further analgesia, with very serious risk of imprecision.

Oral NSAIDs versus oral morphine (children)

Moderate quality evidence from a single RCT of 134 patients demonstrated no clinical difference between the interventions for change in pain score, with no serious imprecision.

Moderate evidence from a single RCT of 134 patients demonstrated a clinical benefit with oral NSAIDs between the interventions for incidence nausea, with serious imprecision.

Moderate quality evidence from a single RCT of 134 patients demonstrated a clinical harm of oral NSAIDs over oral morphine in the reduction of further need for analgesia, with serious imprecision.

Oral opioid versus IV opioid (adults)

Moderate quality evidence from a single RCT comprising 99 participants demonstrated no clinical difference between oral opioids and IV opioids for the management of pain at 30 and 60 minutes, with no serious imprecision.

Very low quality evidence from a single RCT of 99 patients demonstrated no clinical difference between the interventions for the incidence of nausea at 30 and 60 minutes, with very serious imprecision.

Oral codeine versus oral codeine (adults)

Low quality evidence from a single RCT demonstrated no clinical difference between oxycodone and hydrocodone with regards pain relief at 30 (62 patients) and 60 (47 patients) minutes, with serious imprecision.

Very low quality evidence the same RCT with 34 patients demonstrated no clinical difference between the interventions for the incidence of nausea, with very serious imprecision.

Very low quality evidence from a single RCT of 67 patients demonstrated a clinical benefit of oral codeine (oxycodone) versus oral codeine (hydrocodone) regarding the need for further analgesia, with very serious imprecision.

IV opioids versus IV paracetamol (adults)

Low quality evidence of a single study with 55 patients demonstrated no clinical difference between IV opioids and IV paracetamol for pain relief in adults at 30 and 60 minutes with serious imprecision.

Very low quality evidence from a single RCT of 99 patients demonstrated no clinical difference between the interventions for the requirement of further analgesia, with very serious imprecision.

Entonox versus IV opioid (adults)

Moderate quality evidence from a single RCT comprising 100 participants demonstrated no clinical difference between Entonox and IV opioids for the management of pain, with no serious imprecision.

IV NSAIDs versus IV opioid (adults)

Moderate quality evidence from a single RCT (148 participants) demonstrated a clinical benefit for IV NSAIDs over IV opioids for the incidence of nausea in adults with a suspected limb fracture, with no serious imprecision.

Economic

No relevant economic evaluations were identified.

6.1.6 Recommendations and link to evidence

Recommendations	**Children** **1. For the initial management of pain in children (under 16s) with suspected long bone fractures of the legs (femur, tibia, fibula) or arms (humerus, radius, ulna), offer:** • **oral ibuprofen, or oral paracetamol, or both for mild to moderate pain** • **intranasal or intravenous opioids for moderate to severe pain (use intravenous opioids if intravenous access has been established).**
Relative values of different outcomes	Critical outcomes were: short (up to 1 hour) and longer term (3-4 hours) pain scores, as they offer the best outcome to measure pain relief; health-related quality of life; and adverse events, as some could be severe (including nausea, delayed bone healing, local infection, nerve and vascular damage). The need for further analgesia was considered important as it could imply an additional cost but this outcome was also likely to be captured by the pain score.
Trade-off between clinical benefits and harm	The GDG considered the evidence and noted that clinical experience and assessment (type of injury, mechanism, patient reported pain) would be an important factor in deciding appropriate pain management. The evidence considered two primary pathways in children: **Oral administration** Six studies compared oral NSAIDS (ibuprofen and ketorolac), paracetamol and oral opioids (codeine and tramadol) or a combination of these in children. Most studies

	reported no clinical difference between these classes for pain and other clinical measures such as adverse effects and need for rescue analgesia. However, a single RCT in children with acute musculoskeletal injuries to the neck, back and extremities provided evidence for a clinical benefit of NSAIDs (ibuprofen) compared with both codeine and paracetamol in a 3-arm trial. A separate study also reported a clinical benefit of NSAIDs (ketorolac) compared with tramadol with regard to the need for further analgesia. The GDG considered this evidence and felt Ibuprofen had a better balance of benefits and harms compared with both paracetamol and codeine. These interventions are commonly used for analgesia and would not represent a significant change from practice. The GDG also noted that current public perception of ibuprofen was that it was ineffective, and that an evidence-based guideline supporting its use would, therefore, create added value. **Non-oral administration** The GDG noted that based on fracture type and clinical assessment of pain, more aggressive pain management may be indicated. Two studies in children compared opioids (morphine and fentanyl) and their route of administration (IV and intranasal). The GDG noted that with regard to analgesia and adverse effects there was no clinical difference between the interventions. As the IV route was considered to be the most invasive, the GDG felt that the intranasal administration should be used in the first-line. However, the recommendations should still include provision for the IV route as this reflected the majority of current clinical practice.
Economic considerations	No relevant economic evidence was identified for this question. There are two components of the costs of pharmacological pain management interventions: the cost incurred by the method of administration and the cost of the drugs themselves. The greatest cost component is the method of administration. Using the inhaled pain management interventions has the highest administrative cost of £11.48 per person due to the disposable mouthpiece, mask, filter and the rental cost of the gas cylinder. The rectal method has a minimal cost, while IV has costs of around £2 and intranasal a cost of £3.14. For oral interventions, there was a clinical benefit of NSAIDs compared with paracetamol and codeine in the paediatric population. Codeine is the most expensive of the three and so this was agreed not to be cost effective. Ibuprofen is £0.15 per dose and paracetamol is £0.06 per dose so there is a very small increase of £0.09 per patient for ibuprofen but due to the increased clinical benefit, the GDG believed that this was the most cost effective oral intervention. In circumstances where stronger pain relief is required, the GDG considered evidence that compared morphine and fentanyl as well as the method of administration. The GDG agreed that there was no clinical difference between the two pharmacological interventions in terms of analgesia and adverse events; however, they thought the less invasive intranasal method should be recommended for children when non-oral methods are considered, unless IV access has already been established. The GDG believed the costs of the two methods to be similar due to the additional costs incurred by monitoring patients after IV injection and those incurred for disposal of needles, which have not been included in the unit cost presented.
Quality of evidence	Quality of evidence ranged from moderate to very low for most comparisons. This

	was primarily due to imprecision and risk of bias in the studies. The studies demonstrated a range of biases including allocation concealment, lack of blinding and attrition bias. The population was generally quite specific and the GDG felt it accurately reflected a non-complex fracture population. One study was downgraded as being indirect as only 55% of the population displayed a fracture (musculoskeletal injury).
Other considerations	The GDG felt that pain should be managed following initial assessment of pain severity which would dictate subsequent management. In the absence of evidence for all comparisons of pharmacological analgesics the GDG used consensus to form recommendations. The GDG also considered the Royal College of Emergency Medicine guidelines on pain management.[182] It was also noted that the Medicines and Healthcare products Regulatory Agency (MHRA) have restricted use in codeine to those over the age of 12 years of age. Furthermore, it is contraindicated in a number of other groups between the ages of 12 and 18 years.

Recommendations	**Adults** **2. For the initial management of pain in adults (16 or over) with suspected long bone fractures of the legs (tibia, fibula) or arms (humerus, radius, ulna), offer:** **• oral paracetamol for mild pain** **• oral paracetamol and codeine for moderate pain** **• intravenous paracetamol supplemented with intravenous morphine titrated to effect for severe pain.** **3. Use intravenous opioids with caution in frail or older adults.** **4. Do not offer non-steroidal anti-inflammatory drugs (NSAIDs) to frail or older adults with fractures.** **5. Consider NSAIDs to supplement the pain relief in recommendation 2 except for frail or older adults.**
Relative values of different outcomes	Pain Scores were considered critical as they offer the best outcome to measure pain relief. We decided to report both short term (up to 1 hour) and longer term (3-4 hours) outcomes providing an immediate and longer term effect for analgesia. Health-related quality of life was also considered critical as it could reflect more global effects of the interventions. The GDG felt it was critical to assess adverse events as some could be severe (including nausea, delayed bone healing, local infection, nerve and vascular damage). The need for further analgesia was considered important as it could imply an additional cost but was felt likely to be captured by the pain score.
Trade-off between clinical benefits and harm	The evidence considered two primary pathways in adults: **Oral administration**

One study considered oral administration in adults; this was a within class comparison showing that oxycodone led to a lower need for further analgesia than hydrocodone, but did not demonstrate any other differences.

Non-oral administration

Four studies compared non-oral non-opiate analgesics (including paracetamol and NSAIDs) against IV opiates. There were no clinical differences noted, apart from less nausea in the IV NSAIDs group.

Given the paucity of the evidence for both oral and non-oral administration, the GDG used consensus to form recommendations. The GDG also considered the Royal College of Emergency Medicine guidelines on pain management.[183] The recommendations in this guideline are similar to those except that more caution is applied to the use of NSAIDs for the initial management of pain in patients with suspected long bone fractures. The GDG discussions used to form the recommendations are summarised below.

The GDG considered paracetamol to be the safest analgesic for oral pain relief of mild pain as it had the safest risk profile, so agreed that oral paracetamol should be used to manage mild pain and could be supplemented with codeine, which also has a well reported safety profile, to manage moderate pain. The GDG discussed the increased risk profile of IV morphine, and felt that this meant it should not be given for mild or moderate pain.

For the management of severe pain, the GDG discussed the use of paracetamol and morphine. The GDG indicated that IV paracetamol has a longer time to take effect compared with IV morphine, which suggests IV morphine is more suitable for severely injured patients. However, the GDG discussed the increased risk profile associated with IV morphine, particularly in frail or older adults, who are at increased risk of side effects following administration. The GDG decided to recommend IV paracetamol as the first-line agent but recognised the requirement for rapid co-administration of morphine to obtain maximum and rapid efficacious pain control in patients with severe pain. Moreover, the GDG emphasised that particular care should be taken during administration of IV morphine to frail or older adults.

NSAIDs

The group also discussed the benefits and harms of NSAID administration in adults. In particular, two aspects were discussed: 1) the use of NSAIDS in frail or older adults where they may pose a risk of life-threatening gastrointestinal bleeding and significant adverse effects on renal function; and 2) the potential negative effect of NSAIDs on bone healing.

NSAIDS in frail or older adults

There was a lack of agreement on whether NSAIDs could be used safely in this population with two different opinions in the GDG:

1. Some of the GDG thought that it is possible to safely administer NSAIDs to some frail or older adults, and that they have an opiate-sparing effect. Therefore, they believed that clinicians should have the option of deciding whether NSAIDs could be appropriately used. However, they also believed that the recommendation could include a warning about the contraindications to NSAIDs.
2. Others thought that while certain groups of older patients could benefit from the safe administration of NSAIDs, identifying these patients was difficult. Overall, they believed that the risks outweighed the benefits because of the seriousness of the potential adverse events. Therefore, they felt it would be safer to not recommend the use of NSAIDs in frail or older patients. Moreover, this is in

	accordance with the guidance in the NICE hip fracture guideline (CG124), which covers a group of patients similar to the patients discussed here. The final decision went to a vote with the second option informing the final recommendation. **NSAIDs and bone healing** The GDG also discussed the use of NSAIDs in younger patients. The GDG noted that NSAIDS have a recognised opiate-sparing effect and supported their use in providing multi-modal analgesia as they have a well revised safety profile. However, members of the group discussed the risk of NSAIDs for maintenance analgesia in terms of the potential negative effects of NSAIDs on bone healing, especially when administered for maintenance analgesia. The group noted that this risk is unproven but that that since NSAIDs are commonly used and freely available in the community the simplest way to avoid their unintended longer term use in people with fractures is not to start them. A decision was taken by vote to consider NSAIDs only for supplemental analgesia in pain management.
Economic considerations	No relevant economic evidence was identified for this question. There are two components of the costs of pharmacological pain management interventions: the cost incurred by the method of administration and the cost of the drugs themselves. The greatest cost component is the method of administration. Using the inhaled pain management interventions has the highest administrative cost of £11.42 per person due to the disposable mouthpiece, mask, filter and the rental cost of the gas cylinder. The rectal method has a minimal cost, while IV has costs of around £2 and intranasal a cost of £3.14. For oral interventions, there was only evidence comparing oxycodone and hydrocodone in the adult population. The GDG considered all the interventions based on their opinion and the available evidence and believed that paracetamol should be offered for mild pain as it is the cheapest (£0.06) and believed to be effective for this level of pain. The GDG believed that this could be supplemented with codeine for mild to moderate pain which is slightly more expensive (£0.21). When considering IV interventions, the GDG considered the evidence comparing morphine and ketorolac and found there to be no clinical difference other than an increase in nausea for morphine use. The GDG were concerned that opiates have an increased risk of adverse events, although this was not found in the evidence. However, they were also concerned about the adverse effect of NSAIDs on bone healing and in frail or older patients, the risk of gastrointestinal bleeding and renal problems. The cost of the two drugs is approximately the same per dose. Morphine is £1.05 per dose and ketorolac is £1.09 per dose, based on the doses used in the included clinical papers. Due to the concern with adverse events, for people with severe pain, the GDG decided to recommend IV paracetamol, due to its safety profile, but supplemented with IV morphine where necessary. The GDG decided to not recommend NSAIDs in frail or older people but to consider it in all other adults. The clinical evidence for Entonox did not show any benefit over other interventions and due to the greater expense and difficulty of administering it, the GDG thought that this was not cost effective.
Quality of evidence	Quality of evidence ranged from moderate to very low for most comparisons. This was primarily due to imprecision and risk of bias in the studies. The population was generally quite specific and the GDG felt it accurately reflected a non-complex fracture population. One study was downgraded as being indirect as

	only 55% of the population displayed a fracture (musculoskeletal injury).
Other considerations	The GDG felt that pain should be managed following initial assessment of pain severity which would dictate subsequent management. The GDG also considered the evidence in adults for Entonox, but felt that this was more difficult to administer clinically and may not have the same efficacy as other interventions. The GDG recognised that the initial management of pain in a person with a suspected or obvious fracture would include splinting, elevation, traction, realignment, reduction, protection from pressure and rest. It was believed that these are the prime factors which provide pain relief for a person with suspected or obvious fracture. Frail or older patients may have medial comorbidities, including impaired renal function and susceptibility to peptic ulcer disease, which may not be identified in an emergency unit assessment focused on management of a fracture and associated acute injuries. Frailty is most simply considered as a loss of physiological reserve. Older people commonly have reduced organ function that is not apparent on initial history, examination and investigation. Frailty is common among older people, but may also arise in the context of complex comorbidities, such as cardiovascular disease and diabetes. Frail or older people presenting with major limb fractures may suffer periods of hypotension as a result of the injury, associated blood loss and subsequent surgery. It is recognised that the use of NSAIDs further increases the risk that renal function will be compromised, potentially precipitating an acute kidney injury. There may be less risk of this in the context of minor fractures, but in this situation, there remains a significant risk of peptic ulceration that will often outweigh any minor additional analgesic benefit.

6.2 Paediatric nerve blocks femoral fractures

6.2.1 Introduction

Femoral fractures in children cause great pain and distress, but this co-exists with an urgent need to examine and reduce the fracture. Effective and rapid pain management is therefore essential. There is currently uncertainty about the most clinically and cost-effective method to achieve such pain control. Nerve blocks are a relatively new modality that are thought to have a relatively quick onset of action and a high level of pain relief, and this review aims to compare nerve blocks with standard analgesia.

6.2.2 Review question: What is the most clinically and cost-effective nerve block for the initial management in patients with a suspected femoral fracture in acute care settings (pre-hospital and ED)?

For full details see review protocol in Appendix C.

Table 28: PICO characteristics of review question

Population	Children and young people with a suspected femoral fracture following traumatic incident.
Intervention(s)	Femoral nerve block (FNB)[a] Fascia iliaca compartment block[a]
Comparison(s)	Standard analgesia (oral, intranasal or parenteral: intramuscular or intravenous [IV])
Outcomes	Critical: • Pain (1 hour) • Pain (4-6 hours) • Health-related quality of life Adverse effects: • Missed/Delayed diagnosis of compartment syndrome • Femoral injury • Delayed bone healing • Haematoma • Local infection • Nerve and vascular damage • Respiratory depression (<6 hours) • Nausea and vomiting (<6 hours) • Admission solely for recovery from pharmacological agent including cardiac depression, arrhythmia Important: • Need for rescue analgesia
Study design	RCTs or systematic reviews of RCTs

(a) With or without standard analgesia

6.2.3 Clinical evidence

A single RCT was included in the review.[191] A Cochrane review[25] was also identified but it only reported data from the same RCT. The RCT is summarised in Table 29 below.

Evidence from these studies is summarised in the clinical evidence summary below (Table 30). See also the study selection flow chart in Appendix D, study evidence tables in Appendix G, forest plots in Appendix j, GRADE tables in Appendix I and excluded studies list in Appendix K.

Table 29: Summary of studies included in the review

Study	Intervention and comparison	Population	Outcomes	Comments
Wathen 2007[191]	Fascia iliaca compartment block versus IV morphine	Patients presenting with an acute femur fracture	Pain; respiratory depression; nausea and vomiting; nerve and vascular damage	Some patients in the fascia iliaca group received morphine prior to enrolment.

Table 30: Clinical evidence summary: Fascia iliaca compartment block versus IV morphine

Outcome	Number of studies (participants)	Imprecision	GRADE rating	Absolute difference	Control event rate (per 1000)	Control group value for continuous outcomes
Pain (Change Score) (follow-up mean 5 minutes; range of scores 4-13; Better indicated by lower)	1 (n=55)	Serious	VERY LOW	MD 0.7 higher (0.28 lower to 1.12 higher)	-	0.95
Pain (Change Score) (follow-up mean 30 minutes; range of scores 4-13; Better indicated by lower)	1 (n=55)	Serious	VERY LOW	MD 1.39 higher (0.58 lower to 2.2 higher)	-	1.95
Respiratory depression	1 (n=55)	Very serious	VERY LOW	168 fewer per 1000 (from 203 fewer to 91 more)	207	
Nerve and vascular Damage	1 (n=55)	Very serious	VERY LOW	59 fewer per 1000 (from 68 fewer to 91 more)	69	
Nausea/vomiting	1 (n=55)	Serious	VERY LOW	118 fewer per 1000 (from 135 fewer to 1 more)	138	-

6.2.4 Economic evidence

Published literature

No relevant economic evaluations were identified.

See also the economic article selection flow chart in Appendix E.

Unit costs

Table 31: UK costs for ropivacaine

Drug	Weight of child	Dosage[(a)]	Cost (or per unit)
Ropivacaine	10 kg	37.5 mg	£2.50
	30 kg	75 mg	£2.50
	50 kg	125 mg	£5
	70 kg	150 mg	£5

Source: NHS Drug Tariff [135]
(a) Based on dosages from the included study.

Table 32: Equipment costs

Intervention	Resources needed	Cost	Cost per patient	Source
Regional nerve block	10-ml syringe	£26.30 Box of 100	£0.53	NHS supply chain [3]
	Ultrasound (US) unit	£1,179	£0.24[a]	NHS supply chain
Intra nasal	Blunt filter drawing up needle 18 g x 38 mm	£44.70 Box of 100	£0.45	NHS supply chain
	Nasal atomisation device	£269.52 Box of 100	£2.70	NHS supply chain
			Total = £3.14	
Inhaled	Entonox cylinder rental	£62.05 per annum	Likely to be small	GDG contact
	Entonox delivery circuit mask	£59.81 Box of 10	£5.98	NHS supply chain
	Entonox delivery circuit mouthpiece	£79.09 Box of 20	£3.95	NHS supply chain
	Entonox mouthpiece filter	£74.23 Box of 50	£1.48	NHS supply chain
			Total = £11.42	
Rectal	Gloves	£32.87 Box of 50	£0.66	NHS supply chain
			Total: likely to be lower than inhaled	
IV	Pre-injection 70% isopropyl alcohol wipe 60 mm x 30 mm (10,000 sachets)	£105.88 10,000 sachets	£0.01	NHS supply chain
	cannulas (22–14G)	£42	£0.84	The Air Ambulance

Intervention	Resources needed	Cost	Cost per patient	Source
		box of 50		Service (through GDG contact)
	Tegaderm Film	£28.82 box of 100	£0.29	The Air Ambulance Service (through GDG contact)
	10-ml syringe green 21 gauge x 1.5-inch needle	£26.30 Box of 100	£0.53	NHS Supply chain
	10-ml sodium chloride	£3.36 pack of 10	£0.34	Drug tariff
			Total = £2	

(a) Assuming 5000 uses per machine.

6.2.5 Evidence statements

Clinical

Fascia iliaca compartment block versus IV morphine

Very low quality evidence from a single RCT comprising 55 participants demonstrated a clinical benefit of fascia iliaca compartment block compared with IV morphine in children with suspected femoral fractures for reduction of pain at 5 minutes, with serious imprecision.

Very low quality evidence from a single RCT comprising 55 participants demonstrated a clinical benefit of fascia iliaca compartment block compared with IV morphine in children with suspected femoral fractures for reduction of pain at 30 minutes, with serious imprecision.

Very low quality evidence from a single RCT comprising 55 participants demonstrated a clinical benefit of fascia iliaca compartment block compared with IV morphine in children with suspected femoral fractures for incidence of respiratory depression, with very serious imprecision.

Very low quality evidence from a single RCT comprising 55participants demonstrated no clinical difference between the interventions for the incidence of nerve and vascular damage, with very serious imprecision.

Very Low quality evidence from a single RCT comprising 55 participants demonstrated no clinical difference between the interventions for the incidence of nausea, with very serious imprecision.

Economic

No relevant economic evaluations were identified.

6.2.6 Recommendations and link to evidence

Recommendations	**6. Consider a femoral nerve block or fascia iliaca block in the emergency department for children (under 16s) with suspected displaced femoral fractures.**
Relative values of different outcomes	Critical outcomes were pain, health-related quality of life and adverse effects (missed/delayed diagnosis of compartment syndrome, femoral injury, delayed bone healing, haematoma, local infection, nerve and vascular damage, respiratory depression (<6 hours), nausea and vomiting (<6 hours) and admission solely for recovery from pharmacological agent including cardiac depression, arrhythmia).

	An important outcome was the need for rescue analgesia.
Trade-off between clinical benefits and harms	**Fascia iliaca compartment block versus IV morphine** The single RCT showed that there was a clinically important benefit for fascia iliaca compartment block (compared with IV morphine) for pain, respiratory depression, and nausea and vomiting. There were no reported relative harms for fascia iliaca compartment block, so overall the nerve block was the optimal treatment.
Economic considerations	No economic evidence was identified for this question. There is a small increase in the cost of the drugs for a FNB in comparison to standard analgesia, with ropivacaine costing between £2.50 and £5 depending on the weight of the child and the more expensive standard analgesia, such as IV morphine and IV ketorolac costing £1.05 and £1.09, respectively for a standard dose. Another cost implication is the time required to give the different interventions. The GDG considered the additional time required to give a nerve block and the cost increase that this would have. They also considered the benefits in helping the application of a splint, improved X-rays and the ease and improved quality of traction that can be performed. These can all increase the time along the treatment pathway and so the GDG came to the consensus that using a FNB would overall save time, which could outweigh the increased cost of the drug. They also thought that the reduction in pain and discomfort for the patient meant that a FNB was likely to be cost effective. They also believed that FNBs are already used as current practice in some hospitals and so the potential cost increase would not have a large impact compared to current practice.
Quality of evidence	The overall quality of the single RCT was very low, with very serious risk of bias. Nearly all patients received opiate analgesic medication before entering the trial (morphine or fentanyl) thus limiting the ability to directly compare the fascia iliaca block with morphine. Moreover, the patient or physician could not be blinded in the RCT. The evidence was also imprecise making it difficult to interpret the true effect of the intervention.
Other considerations	The GDG felt that, whilst the results of the single RCT indicated a benefit for nerve blocks, the quantity and quality of evidence was insufficient to allow a strong recommendation. Hence the GDG added to the information by drawing on personal experience. The GDG discussed anecdotal reports of nerve block's risk of nerve damage or damage to adjacent vessels, but indicated that the procedure is relatively safe when performed by a trained physician. The GDG discussed how the technical challenge associated with the administration of the procedure was believed to be the primary reason it is not commonly used, but indicated that it could be easily conducted with limited training. However, the GDG also emphasised how the injury is relatively uncommon, and so clinicians may not be confident with the nerve block procedure. A US machine is used in some centres to facilitate accurate needle placement and the GDG discussed how some physicians may not be trained in use of the machine, and that this may also limit its use. The potential for greater child distress with a nerve block was also discussed. However, the GDG indicated that the procedure is relatively quick, taking about 5 minutes to complete, depending on experience. The GDG also discussed the benefit of early fascia iliaca administration to help in the acquisition of X-rays and application of the splint. In particular, the GDG noted that

	the early splinting is important as it may reduce bleeding. The GDG noted that patients would normally have opiate management prior to or on admission to the emergency department, and so use of a nerve block would not completely remove the risk of opiate adverse effects. However, the lack of repeated doses would likely reduce their severity. Moreover, the GDG suggested that the withholding of opiates would allow a more accurate assessment of additional injuries. It was pointed out that distal neurological function should be recorded prior to administration of the block, partly to elucidate if any later deficits were as a result of the injury or the procedure. This review question was restricted to children as the adult recommendations for pain relief of femoral fractures are being made through cross-referral to the hip fracture guidelines.

7 Acute stage assessment and diagnostic imaging

7.1 Selecting patient for imaging – clinical prediction rules for knee fractures

7.1.1 Introduction

Injuries to the knee often suggest the possibility of a fracture in the distal femur, patella or proximal tibia and/or fibula. Radiographic imaging is therefore often used, but because only a small proportion of people with knee trauma usually have a fracture, providing X-rays to all people presenting with knee trauma leads to an unnecessary radiation risk and increased time in the emergency department (ED) for many, as well as increasing costs. Although clinicians will tend to carry out a clinical assessment before ordering an X-ray, structured clinical assessment tools that may more accurately predict the likelihood of a knee fracture have been developed. Their use is designed to allow clinicians to rule out fracture in a significant proportion of people, thus permitting more directed use of X-rays. Such tools should be highly sensitive, as missing a fracture could have adverse consequences. Specificity is less of a concern, as an unnecessary X-ray is likely to have lower adverse effects, though of course, sufficient specificity to significantly reduce unnecessary X-ray use is important.

7.1.2 Review questions

a) Are validated clinical prediction rules clinically and cost effective at predicting suspected knee fractures?

b) Are validated clinical prediction rules accurate at predicting suspected knee fractures?

Table 33: PICO characteristics of review question a

Population	Children, young people and adults with a suspected knee fracture following a traumatic incident.
Intervention	Validated clinical prediction tool, for example, Ottawa knee rules.
Comparison	Clinical examination
Outcomes	Critical: • Pain/discomfort • Return to health-care • Provider • Returning to normal activity • Health-related quality of life • Missed diagnosis (false negative rate) and misdiagnosis (false positive rate) • Unnecessary radiation Important: • Patient satisfaction
Study design	RCTs

Table 34: PICO characteristics of review question b

Population	Children, young people and adults with a suspected knee fracture following a traumatic

	incident.
Index test	Validated clinical prediction tool, for example, Ottawa or Pittsburgh knee rules
Reference test	X-ray or other appropriate scanning; later surgical or clinical findings
Outcomes	Diagnostic accuracy: • Sensitivity • Specificity
Study design	Diagnostic Studies

7.1.3 Clinical evidence

Diagnostic RCT review

No RCTs were found for this review question. A further search was then undertaken to find diagnostic studies, and this review summarises the diagnostic accuracy of such tools.

Diagnostic accuracy review

Adult studies

Thirteen adult studies were found that evaluated the diagnostic accuracy of validated methods to predict knee fractures.

- Eleven of these studies[15,38,88,93,102,106,151,163,175,177,185] assessed the diagnostic accuracy of the Ottawa Knee Assessment and were meta-analysed (see Table 36 and Figure 4).
- Five of these studies[38,106,163,164,171] assessed the diagnostic accuracy of the Pittsburgh and were meta-analysed (see Table 38 and Figure 6)
- One of these studies [151] assessed the diagnostic accuracy of the Bauer tool. This single result is described in Table 39.
- Three of these studies[38,106,164] examined both the Ottawa and Pittsburgh against the same gold standard within the same study, and these paired results are shown in Figure 7. There were insufficient data points (<5) to allow a paired diagnostic meta-analysis. One study[151] examined both the Ottawa and Bauer tool against the same gold standard within the same study, and this paired result is shown in Figure 8.

Child studies

Two studies [33,104] in children were also found, evaluating the diagnostic accuracy of the Ottawa. These could not be meta-analysed as there were <5 studies, but the results have been presented in Table 37 and Figure 5.

General issues

The major flaw in 8 out of 15 studies (see Table 35) was that not all participants in each study had the gold standard test of X-ray. This was because many studies were purely observational and so patients tended not to receive X-rays unless they would have received them in the normal clinical course of events. Hence for many studies later clinical findings were used as a 'back-up' gold standard for those patients not given X-rays. The validity of this as a measure of fracture is unclear, but probably acceptable.

Another issue was that some studies used different personnel to collect and to interpret the tool data. Often the study researchers would interpret the data which had been collected by clinicians. This in itself is unlikely to be a major problem as the interpretation of the Ottawa and Pittsburgh responses, once the data are collected, is largely independent of expertise because the decision

algorithms are very simple. However if the interpretation of the data were done after the X-rays were carried out, then a blinding issue would emerge. Normally the index testers didn't need to be blinded to X-ray results as the X-rays would always, as per the purpose of the rule, follow the tool assessment; however if the tool results were interpreted later this might not be the case.

Most studies did not document the time between index and reference tests but because this would not be more than a few days, given the study designs, this would not affect concordance and so this was not regarded as a problem. For example, even if X-rays were done one week after the index test, this will not have affected the detection of the true diagnosis.

Some studies attempted to test variations of existing tests (for example, using one or some of the criteria only), often deciding post-hoc on the optimum format, which will have increased the play of chance in contributing to higher levels of accuracy. Since these were, by definition, non-validated, they violated the protocol and were excluded.

Table 35: Summary of studies included in the review

Study	Population	Index test(s)	Reference test	Comments
Atkinson 2004[15]	Adults from UK with non-penetrating knee injuries N=72	Ottawa	X-rays or clinical follow up	Blinding unclear
Bulloch 2003[33]	1–16 year olds in Canada with acute knee injuries N=750	Ottawa	X-rays or 14 day structured telephone interview	Any fracture regarded as clinically important, regardless of size
Cheung 2013A[38]	28–79 year olds from Holland N=180	Ottawa Pittsburgh	X-rays	Rigorous study
Jalili 2010[88]	37(14) year olds from Iran with knee injuries N=283	Ottawa	X-rays	Any fracture included. Some risk that the Ottawa could have been altered after the assessor viewed X-rays immediately afterwards
Jenny 2005[93]	>15 year olds from France with acute knee injuries N=138	Ottawa	X-rays	Unclear blinding
Ketelslegers 2002[102]	18–89 year olds from Belgium with acute knee injuries N=261	Ottawa	X-rays or later telephone interview/clinical examination within 60 days	Unclear blinding
Khine 2001[104]	2–18 year olds from USA with traumatic knee pain N=234	Ottawa	X-rays	Blinding unclear
Konan 2013[106]	12–68 year olds in UK with acute knee injuries N=106	Ottawa Pittsburgh	X-ray or later MRI	Poorly reported. Retrospective and interpretation of index test performed in real-time – hence those estimating Ottawa score

Study	Population	Index test(s)	Reference test	Comments
				may have been aware of X-ray results.
Richman 1997[151]	34 (16) year olds from USA with acute knee injuries N=351	Ottawa Bauer	X-rays or later telephone interview/clinical examination at 3 weeks	Clinically important fractures only. Unclear blinding
Seaberg 1994[163]	People with knee injuries in USA N=133	Pittsburgh	X-rays	Unclear blinding
Seaberg 1998[164]	6–96 year olds in USA with acute knee injuries N=750 (Ottawa) N=745 (Pittsburgh)	Ottawa Pittsburgh	X-rays	All fractures on X-ray regarded as clinically important. Physician diagnosis visible to person collecting index test data (though this may not have included X-ray results). Included children but majority were adults
Simon 2006[171]	8–83 year olds from USA with acute knee injuries N=152	Pittsburgh	X-rays	Rigorous study
Stiell 1996B[175]	18–92 year olds in Canada with acute knee injuries N=1096	Ottawa	X-rays or 14 day structured telephone interview	Clinically important fractures on X-ray only – this may have elevated sensitivity of Ottawa. Interpretation of Ottawa may have occurred after X-ray, and no mention of X-ray findings being blinded
Stiell 1997A[177]	18–101 year olds from Canada with acute knee injuries N=987	Ottawa	X-rays or later telephone interview/clinical examination at 10 days	Poorly reported analysis. Clinically important fractures only. Unclear blinding
Tigges 1999[185]	Unknown age from USA (adults) with acute knee injuries N=378	Ottawa	X-rays or 45 day structured telephone interview	Blinding unclear as index and reference examiners given access to clinical diagnosis.

Table 36: Diagnostic accuracy profile for Ottowa in predicting knee fracture (gold standard=X-ray) in studies with sufficient data for meta-analysis

N studies	N patients	Risk of bias	Inconsistency	Indirectness	Imprecision	Pooled Sensitivity (95% CI)	Pooled Specificity (95% CI)	Study quality
Ottowa for predicting knee fracture (with X-ray as the gold standard) in ADULTS								
11	4602	Serious[a]	Serious[b]	None	Serious[c]	0.953 (0.915 to 0.977)*	0.373 (0.283 to 0.472)[d]	VERY LOW

(a) Risk of bias mainly due to lack of information on a lack of blinding.
(b) Some lack of overlap of CIs on forest plot for specificity
(c) Precision of sensitivity good, but a high range in specificity
(d) This is a conservative estimate. The WinBugs software112 used to calculate the pooled sensitivity and specificity (and parameters for calculation of the 95% CIs) does not function when zeroes are present in the raw diagnostic data set. Hence where there were zero false negatives, or zero false positives, the zero had to be converted to the value of 1. This had the effect of creating less favourable sensitivity and specificity estimates than otherwise.

Table 37: Diagnostic accuracy profile for Ottawa in predicting knee fracture (gold standard = X-ray) in studies with insufficient data for meta-analysis

N studies	N patients	Risk of bias	Inconsistency	Indirectness	Imprecision	Sensitivity (95% CI)	Specificity (95% CI)	Quality
Ottawa for predicting knee fracture (with X-ray as the gold standard) in CHILDREN								
2	984	Serious[a]	None	None	Serious[b]	1 (0.95 to 1) 0.92(0.64 to 1) Median: 0.92 (0.64 to 1)	0.43 (0.39 to 0.47) 0.49 (0.42 to 0.56) Median: 0.43 (0.39 to 0.47)	LOW

(a) Risk of bias mainly due to lack of information on a lack of blinding.
(b) Precision of sensitivity not good in one study

Table 38: Diagnostic accuracy profile for Pittsburgh in predicting knee fracture (gold standard = X-ray) in studies with sufficient data for meta-analysis

N studies	N patients	Risk of bias	Inconsistency	Indirectness	Imprecision	Pooled Sensitivity (95% CI)	Pooled Specificity (95% CI)	Quality
Pittsburgh for predicting knee fracture (with X-ray as the gold standard) in ADULTS								
5	1317	Serious[a]	Serious[b]	None	Serious[c]	0.857(0.573 to 0.978)*	0.675(0.456 to 0.848)[d]	VERY LOW

(a) Risk of bias mainly due to lack of information on blinding.
(b) Some lack of overlap of CIs on forest plot

(c) Precision of specificity and sensitivity very poor

(d) This is a conservative estimate. The WinBugs software112 used to calculate the pooled sensitivity and specificity (and parameters for calculation of the 95% CIs) does not function when zeroes are present in the raw diagnostic data set. Hence where there were zero false negatives, or zero false positives, the zero had to be converted to the value of 1. This had the effect of creating less favourable sensitivity and specificity estimates than otherwise

Table 39: Diagnostic accuracy profile for Bauer in predicting knee fracture (gold standard = X-ray) in studies with insufficient data for meta-analysis

N studies	N patients	Risk of bias	Inconsistency	Indirectness	Imprecision	Sensitivity (95% CI)	Specificity (95% CI)	Quality
Bauer for predicting knee fracture (with X-ray as the gold standard) in ADULTS								
1	351	Very serious[a]	None	None	Serious[b]	0.85(0.65 to 0.96)	0.49 (0.43 to 0.55)	VERY LOW

(a) Risk of bias mainly due to lack of information on blinding and unclear time between index and reference tests.

(b) Precision of specificity and sensitivity poor

7.1.4 Diagnostic accuracy findings

Figure 4: Diagnostic meta-analysis for Ottawa in predicting knee fracture (gold standard = X-ray)

The solid black circle represents the pooled value of sensitivity and specificity. The dotted curve drawn around this point represents the 95% CIs around this point. The open ovals represent the results of individual studies, and their area is proportional to the study size. This is a conservative estimate. The WinBugs software[113] used to calculate the pooled sensitivity and specificity (and parameters for calculation of the 95% CIs) does not function when zeroes are present in the raw diagnostic data set. Hence where there were zero false negatives, or zero false positives, the zero had to be converted to the value of 1. This had the effect of creating less favourable sensitivity and specificity estimates than otherwise.

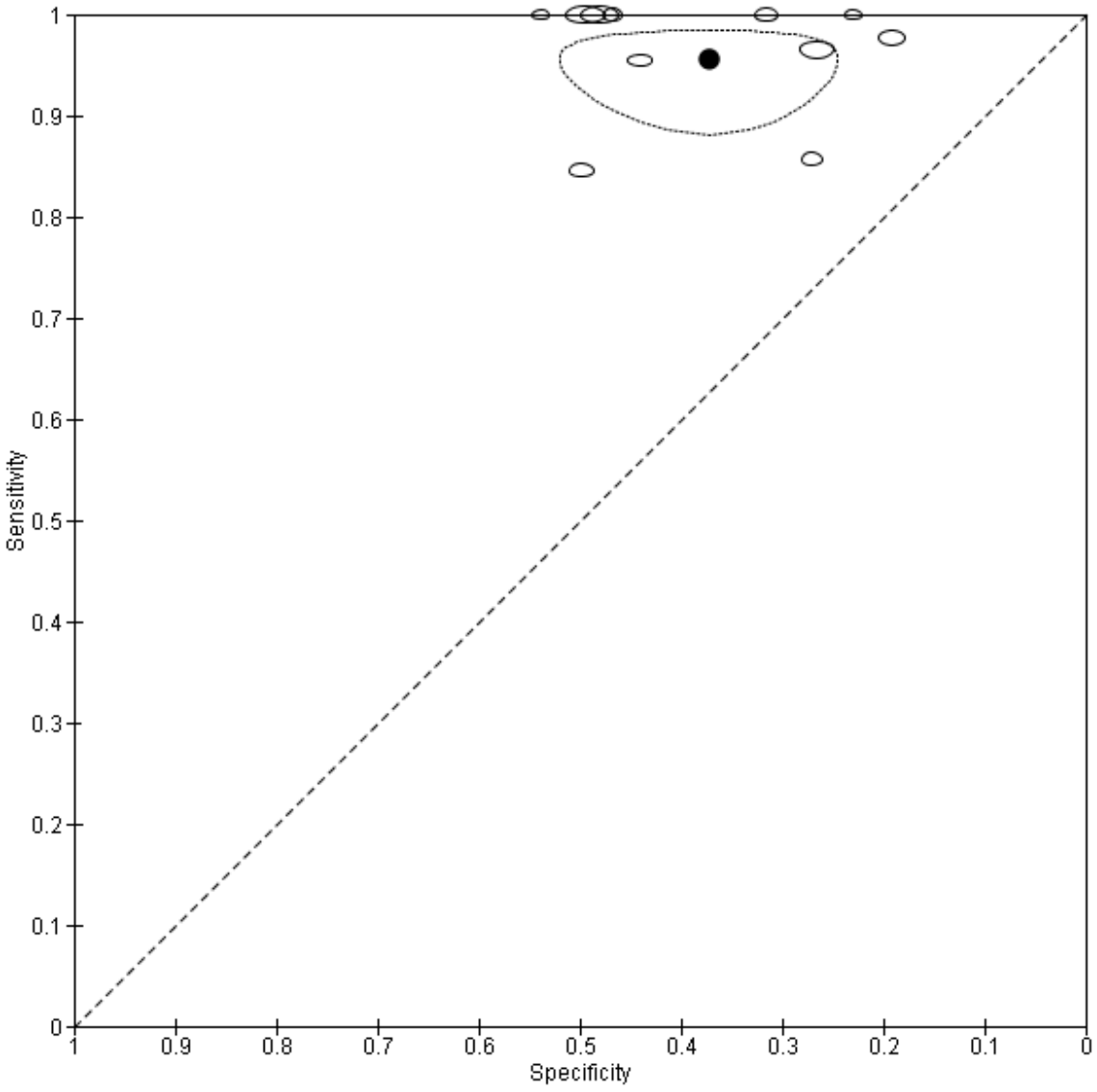


Figure 5: Non-pooled diagnostic data analysis for Ottawa in predicting knee fracture (gold standard = X-ray) in children

The solid black circle represents the pooled value of sensitivity and specificity. The open ovals represent the results of individual studies, and their area is proportional to the study size. This is a conservative estimate.

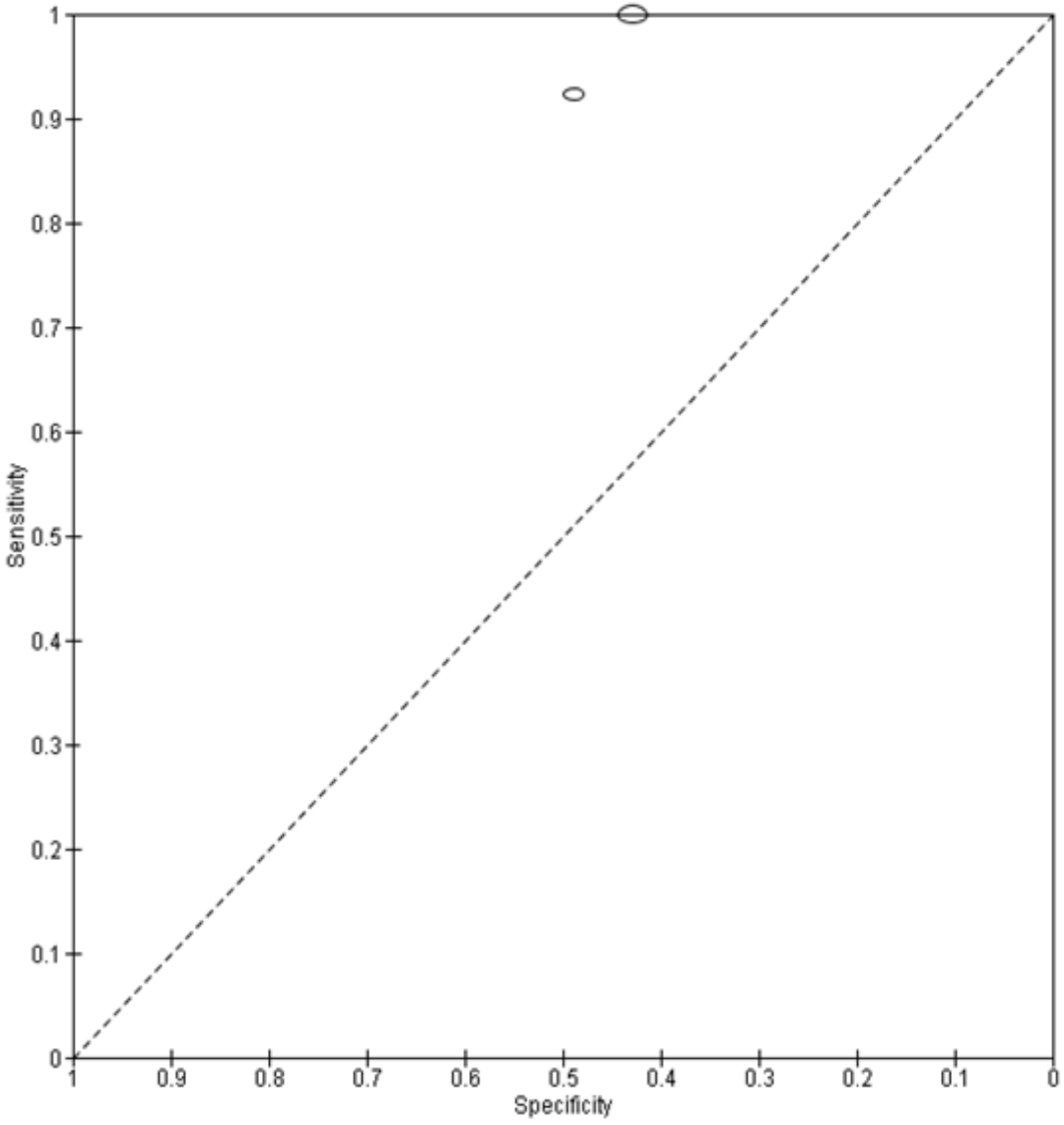


Figure 6: Diagnostic meta-analysis for Pittsburgh in predicting knee fracture (gold standard=CT)

The solid black circle represents the pooled value of sensitivity and specificity. The dotted curve drawn around this point represents the 95% CIs around this point. The open ovals represent the results of individual studies, and their area is proportional to the study size. This is a conservative estimate. The WinBugs software[113] used to calculate the pooled sensitivity and specificity (and parameters for calculation of the 95% CIs) does not function when zeroes are present in the raw diagnostic data set. Hence where there were zero false negatives, or zero false positives, the zero had to be converted to the value of 1. This had the effect of creating less favourable sensitivity and specificity estimates than otherwise.

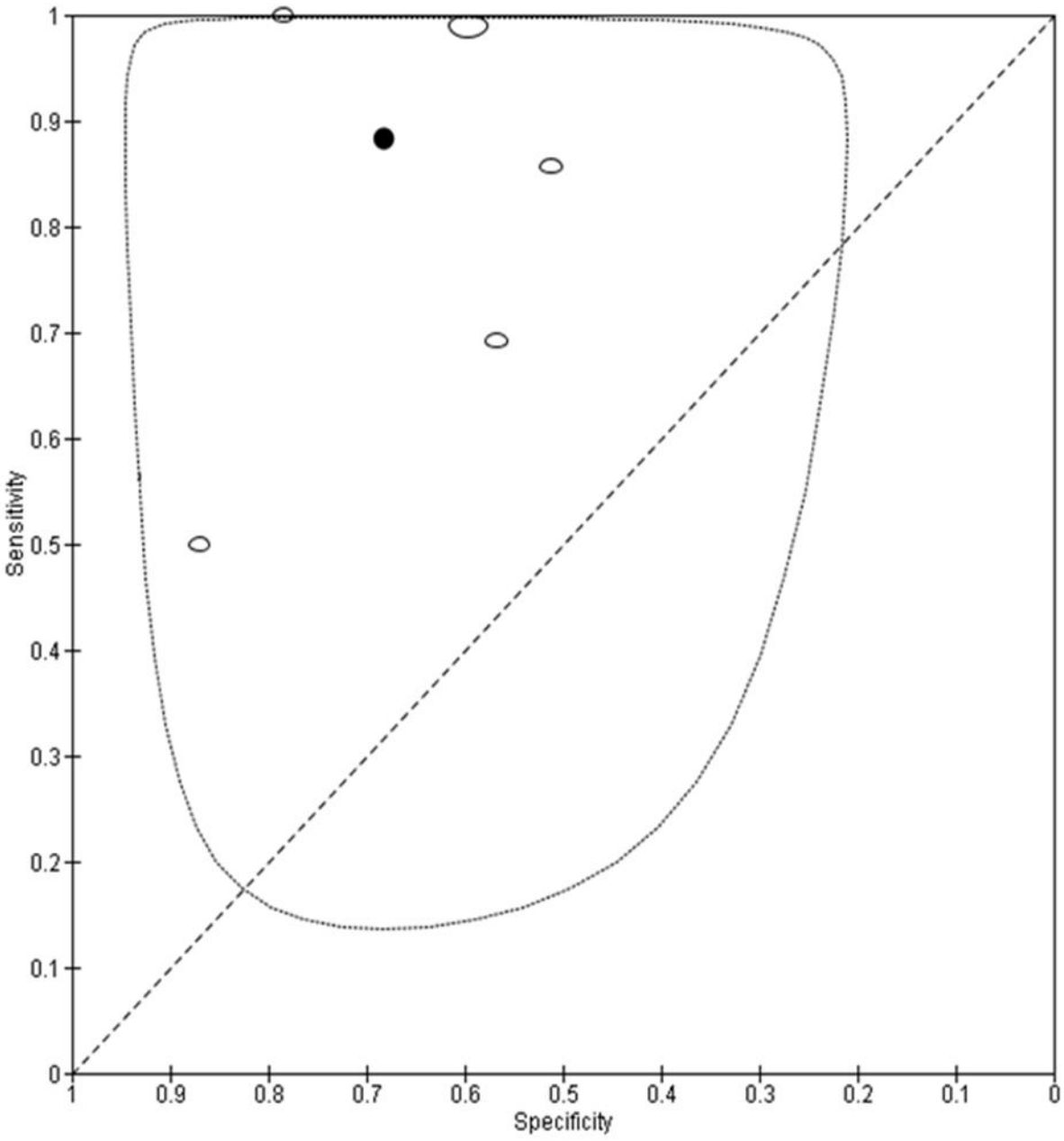


Figure 7: Superimposed plot of diagnostic accuracy of Ottawa and Pittsburgh

Studies comparing both against a common gold standard and with data sufficient for meta-analysis were included. The open circles and diamonds respectively represent the Ottawa and Pittsburgh results of individual studies, and their area is proportional to the study size. Ottawa and Pittsburgh results from the same study are linked by dotted lines. This contains data already viewed in previous figures, but has been repeated here to show the within-study differences between tools.

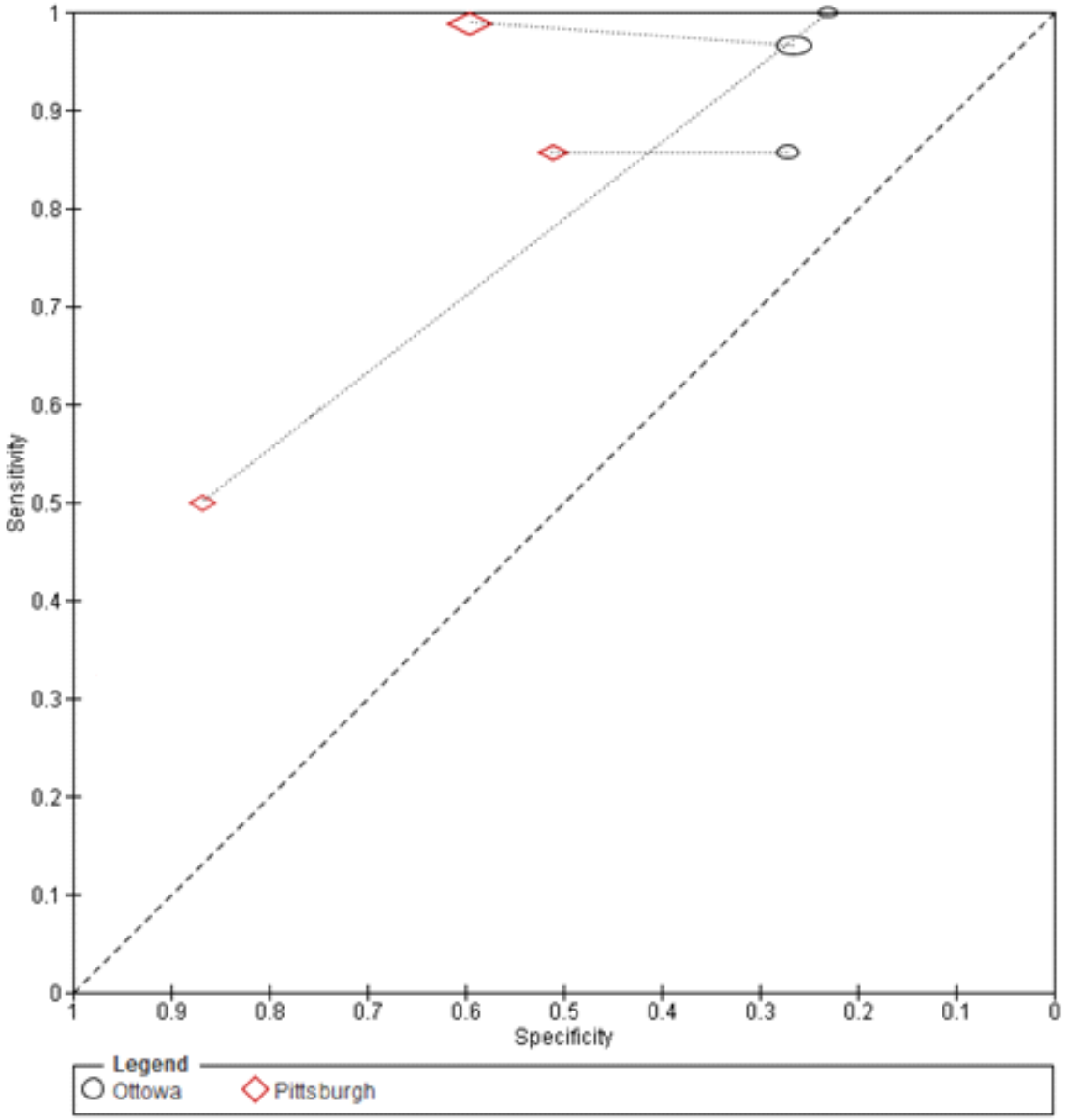
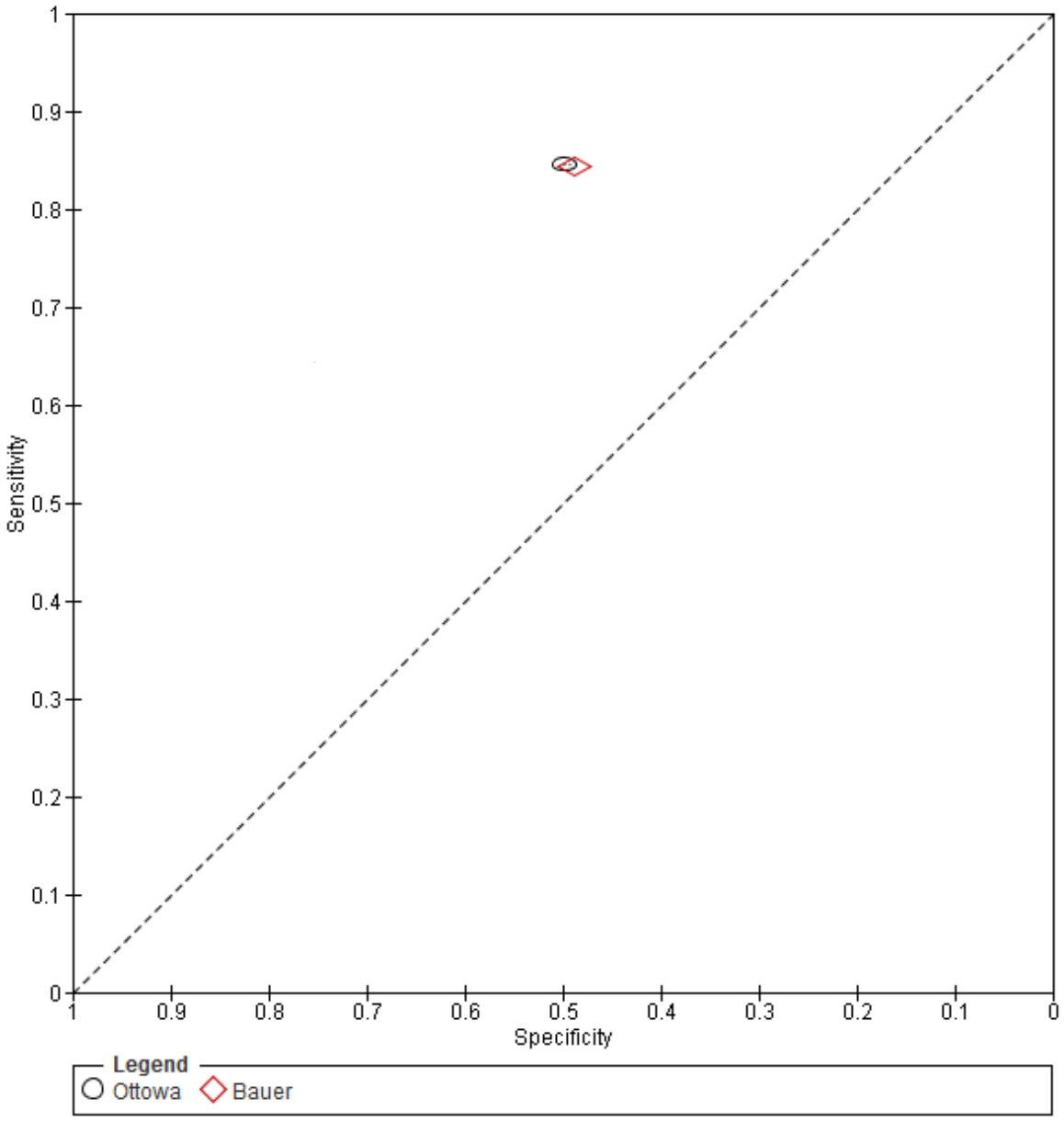


Figure 8: Superimposed plot of diagnostic accuracy of Ottawa and Bauer

A study comparing both against a common gold standard and with data sufficient for meta-analysis was included. The open circles and diamonds respectively represent the Ottawa and Pittsburgh results of the individual study, and their area is proportional to the study size. This contains data already viewed in a previous figure, but has been repeated here to show the within-study difference between tools.



7.1.5 Economic evidence

Published literature

Two comparative cost studies were identified with the relevant comparison and have been included in this review.[136,184] These are summarised in the economic evidence profile table (on the next page) and the economic evidence tables in Appendix H.

See also the economic article selection flow chart in Appendix E.

Table 40: Economic evidence profile: Ottawa knee rule versus no rule

Study	Applicability	Limitations	Other comments	Incremental cost	Incremental effects	Cost effectiveness	Uncertainty
Nichol 1999[136] (Canada)	Partially applicable[a]	Potentially serious limitations[b]	Decision tree of the diagnostic accuracy and costs of the Ottawa knee rules compared with usual practice.	US Medicare perspective: Saves £22 per person. Canadian perspective: Saves £20 person.[(c)]	n/a	n/a	The results were affected by changes to the sensitivity and specificity of the Ottawa knee rule. The thresholds for which the Ottawa knee rules are cost saving (holding all other variables constant) are: **Sensitivity** Base case: 99.5% USA Medicare threshold: ≥98.5 % Canada threshold: ≥96.9% **Specificity**: Base case: 46% USA Medicare threshold: ≥0% Canada threshold: ≥24%
Tigges 2001[184] (US)	Partially applicable[(d)]	Potentially serious limitations[(e)]	Decision tree of the diagnostic accuracy and costs of the Ottawa knee rules compared with usual practice.	Saves £2 per person.[c]	n/a	n/a	The Ottawa rule was the least costly strategy when the sensitivity of the Ottawa rule was at least 0.94. A best-case and worst-case analysis was also performed to combine the effect of uncertainty in all parameters. **Best case:** £24 saving per person for Ottawa rule. **Worst case:** £17 saving per person for 'no rule'. An additional analysis was performed where the worst-case scenario was adjusted by using the baseline sensitivity of the Ottawa rule. This resulted in a saving of £1 per person for the 'no rule' strategy.

(a) Appropriate interventions are compared but the study is from a USA/Canadian perspective. A societal cost perspective is used. This study is a comparative cost analysis and so does not include any health effects. Costs were from 1996.

(b) Costs included radiography, ED examination and societal costs. Downstream costs of treatment were not taken into account.

(c) Converted using 1999 purchasing power parities.[142]

(d) Appropriate interventions are compared but the study is from a USA perspective. A societal cost perspective is used. This study is a comparative cost analysis and so does not include any health effects.

(e) Costs included radiography, physician visit and societal costs. Downstream costs of treatment are not taken into account.

The difference in the size of the cost savings between the two studies could be due to the difference in the values used for the specificity of the Ottawa ankle rules. The Nichol 1999 study[136] uses a higher specificity than the Tigges 2001[184] study (46% compared with 21%). The pooled results from the clinical review show a sensitivity and specificity lower than that used in Nichol 1999 [136] and also below the thresholds at which the Ottawa knee rule is still cost saving. The values are greater than the thresholds from Tigges 2001 [184] and so the results would still favour the Ottawa ankle rules if this study used our pooled estimates.

Another key difference between these two studies is that the prevalence of fracture used in the Tigges 2001[184] study was 11%, whereas for the Nichol 1999[136] study, the prevalence used was 6.3%.

7.1.6 Evidence statements

Clinical

Very low quality evidence from 11 diagnostic studies comprising 4602 adults showed the pooled sensitivity (95% CI) and specificity (95% CI) of Ottawa knee fracture prediction tool were 0.953 (0.915 to 0.977) and 0.373 (0.283 to 0.472), respectively.

Low quality non-pooled evidence from two diagnostic studies comprising 984 children showed that the Ottawa knee fracture prediction tool has a median sensitivity (95% CI) of 0.92 (0.64 to 1), and a median specificity (95% CI) of 0.43 (0.39 to 0.47).

Very low quality evidence from 5 diagnostic studies comprising 1317 adults showed that the pooled sensitivity (95% CI) and specificity (95% CI) of the Pittsburgh knee fracture prediction tool were 0.857 (0.573 to 0.978) and 0.675(0.456 to 0.848), respectively.

Low quality evidence from one diagnostic study comprising 351 adults showed that the Bauer knee fracture prediction tool had a sensitivity of 0.85 (95% CI, 0.65 to 0.96), and a specificity of 0.49 (95% CI, 0.43 to 0.55).

Economic

Two comparative cost studies showed that the Ottawa knee rule was cost saving compared with usual procedures without the rule for predicting suspected knee fractures (saving of between £2 and £22 per person). These studies were assessed as partially applicable with potentially serious limitations.

7.1.7 Recommendations and link to evidence

Recommendations	7. **Use the Ottawa knee rules to determine whether an X-ray is needed in people over 2 years with suspected knee fractures.**
Relative values of different outcomes	While diagnostic cohort studies can tell us about the relative accuracy of a diagnostic test compared with a reference standard, they do not tell us whether adopting a particular diagnostic strategy improves patient outcomes. Evidence on patient outcomes is only available from diagnostic RCTs which compare two diagnostic interventions with identical subsequent treatment as indicated by the diagnostic test. No such RCTs were identified and so diagnostic accuracy studies were used for this review. The outcomes for this diagnostic review question are therefore, sensitivity and specificity of the knee fracture prediction tests relative to the reference test of X-rays (which is assumed to give the 'true' diagnosis). Sensitivity is a very important outcome, because poor sensitivity may result in people with a fracture being undiagnosed and therefore initially untreated. In contrast, low specificity, leading to incorrect positive diagnoses, will lead to unnecessary X-rays. Though carrying a risk of unnecessary radiation exposure and higher costs, such additional X-rays secondary to misdiagnoses are unlikely to be as much of a risk to the patient as missed diagnoses. Hence, though still important, specificity is regarded as of lower importance than sensitivity.
Trade-off between clinical benefits and harms	The Ottawa was moderately sensitive in adults and children from the age of two years (0.95). This was superior to that seen with the Pittsburgh and Bauer tests, though these tests were only tested in adults. Despite this superiority to the other tests, the Ottawa would tend to miss 5% of fractures, which could mean delayed imaging and treatment for these cases. However, the evidence

	largely related to the detection of any fracture, whereas in reality only clinically important fractures are of relevance. Hence the GDG noted that the Ottawa is probably even better at picking up clinically significant knee fractures than the sensitivity data (which is based on any fracture) suggest (that is, >0.95 sensitivity is likely). All prediction tools had relatively poor specificity, but the specificity would be enough to permit a substantial reduction in unnecessary X-ray use compared to the situation in which clinical suspicion alone were used as the criterion for X-rays.
Economic considerations	Two cost comparison studies were identified comparing the Ottawa knee prediction rule to clinical assessment alone.[136,184] The studies show that using the Ottawa knee prediction rule leads to cost savings, however, no downstream costs, such as treatment, have been included in the studies, thus, it is difficult to infer cost effectiveness as the benefit of correctly identifying the fractures would stem from the treatment. However, there are resource implications and potentially future health implications from either using a blanket X-ray strategy or clinical judgement as application of the prediction rules can reduce the number of X-rays that patients go on to receive. This will, however, depend upon the sensitivity and specificity of the rules, as a rule with a low sensitivity will lead to many false negatives that then have a delayed diagnosis or remain untreated, impacting later quality of life. Specificity is also important because a low specificity leads to many false positives that may then undergo unnecessary treatment. The sensitivity estimates identified from the clinical review were generally quite high, with the pooled estimate for the Ottawa knee rule being 0.95. The pooled specificity was not as good at 0.37. The Tigges study had a higher sensitivity than our clinical review estimate but a lower specificity (sensitivity=0.98, and specificity=0.19). The Nichol study also had a higher sensitivity but had a higher specificity as well (sensitivity=1, and specificity=0.48). The prevalence of a knee fracture in the trauma population is also important as this will influence the positive and negative predictive values of the prediction rule (Tigges study=11%, in Nichol=6.3%). A smaller prevalence increases the importance of the specificity because most people do not have a fracture, so a lower specificity can reduce the cost savings from the studies due to an increase in false positives indicated for X-ray. The other prediction rules (Pittsburgh and Bauer) had lower sensitivity but higher specificity estimates. The GDG felt that because of its high sensitivity, the Ottawa knee rule is more likely to pick up the clinically significant fractures which would benefit from treatment. Missing those that have a fracture was considered more important than the unnecessary additional resource use and potential radiation risk to the false positives when using this tool compared with a tool with a lower sensitivity but higher specificity, such as the Pittsburgh or Bauer.
Quality of evidence	**Clinical evidence** Fifteen diagnostic accuracy studies were found. The main limitations concerned a lack of blinding, and in 8/15 studies the gold standard included later clinical assessment. However, the GDG felt that later clinical assessment would probably be as good as X-ray for the purposes of a gold standard. **Economic evidence**

	Both studies were rated as partially applicable with potentially serious limitations as they only compare costs and do not include health effects, as well as being from the USA and Canada.
Other considerations	The GDG recognised that the use of the clinical decision rules did not constitute or replace the need for full examination of the knee/ankle joints and documentation of all relevant findings

7.2 Selecting patients for imaging – prediction rules for ankle fractures

7.2.1 Introduction

Injuries to the ankle often suggest the possibility of a fracture in the distal tibia or fibula, and possibly fractures in the tarsal bones. Radiographic imaging is, therefore, often used, but because only a small proportion of people with ankle trauma usually have a fracture, providing X-rays to all people presenting with ankle trauma leads to an unnecessary radiation risk and increased time in the emergency department (ED) for many, as well as increasing costs. Although clinicians will tend to carry out a clinical assessment before ordering an X-ray, structured clinical assessment tools that may more accurately predict the likelihood of an ankle fracture have been developed. Their use is designed to allow clinicians to rule out fracture in a significant proportion of people, thus permitting the more directed use of X-rays. Such tools should be highly sensitive, as missing a fracture could have adverse consequences. Specificity is less of a concern, as an unnecessary X-ray is likely to have lower adverse effects, though of course, sufficient specificity to significantly reduce unnecessary X-ray use is important.

7.2.2 Review questions

a) Are validated clinical prediction rules clinically and cost effective at predicting suspected ankle fractures?

b) Are validated clinical prediction rules accurate at predicting suspected ankle fractures?

Table 41: PICO characteristics of review question a

Population	Children, young people and adults with a suspected ankle fracture following a traumatic incident.
Intervention(s)	Validated clinical prediction tool, for example, Ottawa ankle rule
Comparison(s)	Clinical examination
Outcomes	Critical: • Pain/discomfort • Return to healthcare provider • Returning to normal activity • Health-related quality of life • Missed diagnosis (false negative rate) and misdiagnosis (false positive rate) • unnecessary radiation Important: • Patient satisfaction.
Study design	RCTs or systematic reviews of RCTs

Table 42: PICO characteristics of review question b

Population	Children, young people and adults with a suspected ankle fracture following a traumatic incident
Index test	Validated clinical prediction tool e.g. Ottawa ankle rules
Reference test	X ray
Outcomes	Sensitivity specificity
Study design	RCTs or systematic reviews of RCTs

7.2.3 Clinical evidence

We searched for randomised trials comparing the clinical efficacy and cost-effectiveness of two methods for predicting the need for ankle X-ray in people with an ankle fracture: a validated clinical tool or clinical assessment.

One study was included in the review.[52] The aim of this study was to assess whether the Ottawa ankle prediction rule was effective at improving clinical outcomes and cost-effectiveness by ensuring that only the most appropriate patients were given ankle X-rays.

Evidence from this study is summarised in the clinical evidence summary below (Table 44). See also the study selection flow chart in Appendix D, study evidence tables in Appendix G, forest plots in Appendix j, GRADE tables in Appendix I and excluded studies list in Appendix K.

As a randomised trial had been found it was not necessary to drop down to diagnostic accuracy studies.

Table 43: Summary of studies included in the review

Study	Intervention/ comparison	Population	Outcomes	Comments
Fan 2006[52]	Ottawa ankle prediction tool versus clinical assessment	Adults with ankle or foot-twisting injuries in urgent care departments in Canada	• Exposure to radiation • Patient satisfaction • Length of stay in urgent care department	Randomised by patient. The intervention was actually two-level. Ottawa was given first and if negative a further clinical assessment was given prior to any decision on whether to give/not give X-ray. Hence this is indirect evidence.

Table 44: Clinical evidence summary: Ottawa versus clinical assessment

Outcome	Number of studies (participants)	Imprecision	GRADE rating	Absolute difference	Control event rate (per 1000)	Control event rate for continuous outcomes
Number with X-rays	1 (n=123)	None	MODERATE	53 more per 1000 (from 44 fewer to 159 more)	885	-
Length of stay in emergency department	1 (n=123)	Serious	LOW	6.7 lower (from 20.65 lower to 7.25 higher)	-	79.7

Narrative summary

Fan 2006[52] measured patient satisfaction using the Sun satisfaction scale. Results were reported as median interquartile range (IQR) and so were not included in a meta-analysis. People assessed with the Ottawa scale had a median (IQR) of 4 (3.75–5) (n=55), and people assessed with clinical examination had a median (IQR) of 4 (3–5) (n=53). Risk of bias was very high, due to high attrition and lack of patient blinding.

7.2.4 Economic evidence

Published literature

No relevant economic evaluations were identified.

See also the economic article selection flow chart in Appendix E.

7.2.5 Evidence statements

Clinical

Moderate quality evidence from one RCT comprising 123 participants showed that there was no difference in clinical effectiveness between the Ottawa and clinical assessment in terms of the proportion requiring X-rays, with no serious imprecision.

Low quality evidence from one RCT comprising 123 participants showed that there was no difference in clinical effectiveness between the Ottawa and clinical assessment in terms of the length of stay in emergency department, with serious imprecision.

Economic

No relevant economic evaluations were identified.

7.2.6 Recommendations and link to evidence

Recommendations	**8. Use the Ottawa ankle and foot rules to determine whether an X-ray is needed in people over 5 years with suspected ankle fractures.**
Relative values of different outcomes	While diagnostic cohort studies can tell us about the relative accuracy of a diagnostic test compared with a reference standard, they do not tell us whether adopting a particular diagnostic strategy improves patient outcomes. Evidence on patient outcomes is only available from diagnostic randomised controlled trials which compare two diagnostic interventions with identical subsequent treatment as indicated by the diagnostic test. One such RCT was identified and was used for this review. Critical outcomes were: health-related quality of life; patient-reported outcomes; rates of missed diagnosis and misdiagnosis, as these will underpin overall outcome; and the adverse event of excessive radiation due to its potential for serious sequelae. Patient satisfaction was regarded as an important outcome as this may be a proxy for quality of life.
Trade-off between clinical benefits and harms	No net benefits or harms of the Ottawa in relation to clinical assessment were identified. Length of stay in ED was reduced by about 7 minutes in the Ottawa group, but this was not regarded as clinically important by the GDG. The Ottawa group had numerically more X-rays, nullifying its purpose as a means to reduce X-ray use, but the difference between groups could be explained by chance.
Economic considerations	No relevant economic evaluations were included. There are both resource implications and potentially future health implications from using different prediction methods for injuries that require an X-ray. These two implications come as a result of imperfect sensitivity and specificity of the prediction rules. A rule with imperfect sensitivity will lead to false negative diagnoses that either causes delays to treatment or deprives the patient of treatment altogether. This is likely to impact quality of life. An imperfect specificity is also important

	because this will lead to false positives that may then undergo unnecessary treatment resulting in excess cost as well as increased exposure to harmful radiation. Another important factor is the prevalence. This affects how much of an impact the sensitivity and specificity of the prediction tools has on the overall population. A low prevalence means that a large proportion of the population will be unnecessarily imaged if a prediction tool with low specificity is used. On the other hand, a high prevalence means that a large proportion of the population will have a false negative diagnosis with if a prediction tool with a low sensitivity is used. The GDG felt that it was more important to identify clinically significant fractures and so prioritised the sensitivity of the rule over the specificity. They agreed that the sensitivity of the Ottawa Ankle Rule was high and so is likely to pick up the clinically important fractures. Although the evidence showed that using the Ottawa ankle rule increased the number of people who received an X-ray, the GDG thought that this was likely to have been due to random variation. It was agreed that the costs implications were likely to be minimal if not in favour of the Ottawa ankle rule and that the clinical benefit of this prediction tool would make them cost-effective.
Quality of evidence	Only one RCT was found. There were no risks of bias. However, evidence was downgraded as a result of indirectness, because the Ottawa group also used additional clinical assessment. Imprecision of the results contributed to a further downgrading of evidence. Evidence was graded low to very low.
Other considerations	In the absence of convincing RCT evidence, the GDG used consensus to decide on the efficacy of the Ottawa ankle rule. The GDG highlighted the high sensitivity (close to 100% sensitive) of the Ottawa ankle and foot rules, which has been widely reported in adults[17] and also children from the age of 5 years.[49] Sensitivity was not an outcome in this review question (because it was a diagnostic RCT question) but a high sensitivity would mean that most people with a fracture would not be missed by this tool, and thus, negative sequelae relating to delayed diagnosis and treatment would not tend to arise. Specificity was known to be moderate, but it was agreed that because the tool would only be used on people for whom there was already a clinical suspicion based on mechanism and clinical findings, the tool could only increase the specificity relative to what might be observed without the tool. Hence significant number of patients can be ruled out (by having a negative test) and thus, be discharged from the ED without the need for X-ray. The GDG agreed that these benefits outweighed any potential harms in adults. The GDG were also aware of a multicentre before and after controlled trial testing the Ottawa Ankle Rules.[176] This demonstrated a significant reduction in ankle radiology without an increased rate of missed ankle fractures. The GDG therefore felt that the Ottawa ankle rule is an efficient screening test to allow selection of those requiring ankle X-rays. Use of the tool also allows clinical examinations to be performed in a reproducible way, which ensures consistency in how examinations for all suspected ankle fractures are performed across varying skill levels and healthcare providers. The GDG recognised that the use of the clinical decision rules did not constitute or replace the need for full examination of the ankle joints and documentation of all relevant findings. The GDG discussed that there are no validated tools for assessing ankle fractures in children aged under 5 years. The pattern of injury is different in skeletally immature patients and the risk of growth plate injury rather than ligament injury must be considered. The need to limit the radiation dose in children while recognising growth plate injury emphasizes the need for clinical assessment of this group by an experienced clinician.

7.3 Imaging of scaphoid

7.3.1 Introduction

Fractures to the scaphoid are frequently difficult to see on plain film X-ray immediately following injury. In some patients, scaphoid fractures may only be visible 10–14 days post-injury. However, a missed scaphoid fracture can have a significant negative impact on patients' long-term hand function and quality of life. As a consequence, clinicians frequently treat patients with a suspected scaphoid fracture cautiously and may refer patients for an additional form of imaging or may immobilise patients for two weeks until the fracture is visible on X-ray. This review investigated the most clinically and cost effective imaging strategy for diagnosing scaphoid fractures. This review addressed both whether an alternative imaging strategy should be used as the primary imaging modality for patients with a suspected scaphoid fracture following clinical examination, as well as what imaging modality should be used if patients receive an X-ray on admission and findings are indeterminate.

7.3.2 Review questions:

a) What is the most clinically and cost-effective imaging strategy for patients with clinically suspected scaphoid fracture?

b) What is the diagnostic accuracy of imaging strategies for a suspected scaphoid fracture?

This review sought to identify the optimum imaging strategy for patients with a suspected scaphoid fracture. We included studies that evaluated imaging strategies in patients with a suspected scaphoid fracture following clinical examination alone, as well as studies that evaluated imaging strategies amongst patients who had a suspected scaphoid fracture following clinical examination but had indeterminate X-ray findings.

Initially, we developed a diagnostic RCT review protocol, to examine the clinical and cost-effectiveness of the different imaging strategies. The PICO characteristics for this review question are displayed in Table 45. A second review protocol to examine the diagnostic accuracy of each of the imaging strategies, summarised in Table 46, was developed for use in the event that no RCT data were retrieved. For full details of both protocols see review protocol in Appendix C.

Table 45: PICO characteristics of diagnostic RCT review question a

Population	Children, young people and adults with a suspected scaphoid fracture following a traumatic incident.
Intervention(s)	• CT • MRI • X-ray
Comparison(s)	Compared with each other
Outcomes	Critical: • Time in plaster cast • Number of outpatient visits • Health-related quality of life • Pain/discomfort • Return to normal activities • Psychological wellbeing • Missed injury

	• Non-union/malunion • Avascular necrosis • Post-traumatic arthritis • Additional radiation exposure Important: • Grip strength • Range of motion
Study design	RCTs or systematic reviews of RCTs

Table 46: PICO characteristics of the diagnostic accuracy review question b

Population	Children, young people and adults with a suspected scaphoid fracture following a traumatic incident
Index tests	• Early CT/multidetector CT (MDCT) • Further X-ray (10–14 days post-injury)
Reference standard	Early MRI
Outcomes	Diagnostic accuracy (sensitivity, specificity, positive predictive value, negative predictive value) of tests to identify the presence of a scaphoid fracture.
Study design	Cohorts or case control studies

7.3.3 Clinical evidence

Diagnostic RCT review

Two studies were included in the diagnostic RCT review[31,144]. These studies, summarised in Table 47 below compared the clinical effectiveness of immediate MRI imaging compared with re-assessment in the clinic 2-weeks post-admission for patients with a suspected scaphoid fracture but indeterminate X-ray findings. In both studies, patients in the control group who returned for re-assessment were most likely to receive X-ray; however, a minority of patients received alternative imaging strategies (for example, bone scintigraphy, MRI) at the discretion of the caring physician. The GDG agreed to consider the evidence in these studies; however both were downgraded due to risk of bias.

Evidence from these studies is summarised in the GRADE clinical evidence profile (Table 48). See also the study selection flow chart in Appendix D, study evidence tables in Appendix G, forest plots in Appendix j, GRADE tables in Appendix I and excluded studies list in Appendix K.

No RCTs examining the relative efficacy of immediate CT to delayed X-ray, or immediate CT to immediate MRI, were identified. As a consequence, evidence was sought to assess the diagnostic accuracy of the imaging modalities.

Table 47: Summary of studies included in the diagnostic RCT review

Study	Intervention/comparison	Population	Outcomes	Comments
Brooks 2005[31]	MRI between 2–5 days following admission versus re-assessment >2 weeks following admission	Adults (>18 years) with suspected scaphoid fracture but indeterminate initial X-ray findings	Unnecessary immobilisation; healthcare use; self-reported pain.	Conducted in emergency departments (EDs) in five major hospitals in Australia (2000-2002). The majority of

Study	Intervention/comparison	Population	Outcomes	Comments
				patients in the control group received X-ray at follow-up, with a minority of patients receiving bone scintigraphy or MRI. Patients in the control group were all immobilised prior to scan.
Patel 2013[144]	MRI <2 days following admission versus re-assessment >2 weeks following admission	Young people and adults (16-80 years) with suspected scaphoid fracture but indeterminate initial X-ray findings	Number of fracture clinic appointments; self-reported pain; additional radiation exposure	Conducted in one medium general hospital in the UK (2003–2006). The majority of patients in the control group received X-ray at follow-up, with a minority of patients receiving bone scintigraphy or MRI. Patients in the control group were all immobilised prior to follow-up.

Table 48: Clinical evidence profile: Early MRI versus delayed X-ray for patients with a suspected scaphoid fracture but indeterminate X-ray findings

Outcomes	Number of studies (n)	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with Delayed X-ray	Risk difference with Early MRI (95% CI)
Time spent in plaster cast time spent unnecessarily immobilised	1 (n=27)	LOW	Not estimable	The median time spent immobilised unnecessarily in the control group was 7 days	The median time spent immobilised unnecessarily following early MRI was 0 days
Mean fracture clinic appointments	1 (n=84)	LOW		The mean fracture clinic appointments in the control groups was 2.3 appointments	The mean fracture clinic appointments in the intervention groups was 1.2 lower (1.49 to 0.91 lower)
Outpatient appointments Measured as ED visits, general practitioner consultation, specialist physiotherapy, and diagnostic services (radiographs, skeletal scintigraphy and MRI) at 3 months	1 (n=27)	LOW	Not estimable	The median number of health care appointments in the control group was 5 appointments	The median number of health care appointments in the MRI group was 3 appointments
Self-reported pain (14 days) Author-developed scale. Scale from: 0 to 10.	1 (n=84)	VERY LOW		The mean self-reported pain (14 days) in the control groups was 3.5	The mean self-reported pain (14 days) in the intervention groups was 0.6 lower (1.92 lower to 0.72 higher)
Self-reported pain (42 days) Author-developed scale. Scale from: 0 to 10.	1 (n=84)	VERY LOW		The mean self-reported pain (42 days) in the control groups was 2.7	The mean self-reported pain (42 days) in the intervention groups was 0.9 lower (2.34 lower to 0.54 higher)
Pain (1 month) Patient-rated wrist evaluation	1 (n=27)	LOW	Not estimable	-	-

Outcomes	Number of studies (n)	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with Delayed X-ray	Risk difference with Early MRI (95% CI)
Pain (2-months) Patient-rated wrist evaluation	1 (n=27)	LOW	Not estimable	-	-
Pain (3-months) Patient-rated wrist evaluation	1 (n=27)	LOW	Not estimable	-	-
Additional radiation exposure Mean number of X-rays after initial assessment	1 (n=84)	LOW		The mean number of X-rays after initial assessment in the control groups was 1.7 X-rays	The mean number of X-rays after initial assessment in the intervention groups was 1.20 lower (1.2 to 0.91 lower)

Diagnostic Accuracy review

A review of the literature indicated that there is no universally agreed reference standard for assessing the presence of an occult scaphoid fracture. Authors of a recent review on this topic[115] suggest that X-ray findings 6-weeks post-injury is the most frequently used reference standard, however, there are known limitations with this method (notably, evidence has demonstrated that later x-ray does not identify all true cases of scaphoid fracture). Due to these limitations, the GDG agreed that MRI should be used as the reference standard for this review.

Two studies were included in the diagnostic accuracy review; one of these[83]compared early MDCT to MRI amongst patients with suspected scaphoid fracture but indeterminate X-ray findings. One study[96] compared X-ray and CT with MRI amongst patients with post-traumatic radial wrist tenderness. Population and evidence from this study is summarised in the clinical evidence profiles below (Table 50 and Table 51). See also the study selection flow chart in Appendix D, study evidence tables in Appendix G, forest plots in Appendix J, GRADE tables in Appendix I and excluded studies list in Appendix K.

Table 49: Summary of studies included in the diagnostic accuracy review

Study	Population	Index test(s)	Reference test	Comments
Ilica 2011[83]	Adults with a clinically suspected scaphoid fracture and negative initial conventional radiographs	MDCT	MRI	Up to 1 week between the tests.
Jorgsholm 2013[96]	Adults with posttraumatic radial wrist tenderness	X-ray CT	MRI	X-ray performed on admission, MRI performed up to 14 days from injury. CT only undertaken in those patients with positive X-ray and/or MRI findings.

Table 50: Clinical evidence profile: Studies evaluating imaging strategies in relation to the reference test of MRI for scaphoid fractures in patients with posttraumatic radial wrist tenderness

Number of studies	Population (n) (in study order)	Risk of bias	Inconsistency	Indirectness	Imprecision	Sensitivity (95% CI) (in study order)	Specificity (95% CI)	Positive predictive	Negative predictive	Quality
Diagnostic accuracy of X-ray in relation to the reference test of MRI – scaphoid fractures										
1	Adults with a posttraumatic radial wrist tenderness (n=296, 300 wrists)	Serious limitations[a]	Not applicable	None	Not applicable	0.70	0.98	-	-	MODERATE
Diagnostic accuracy of CT in relation to the reference test of MRI – scaphoid fractures										
1	Adults with a posttraumatic radial wrist tenderness (n=296, 300 wrists)	Very serious limitations[b]	Not applicable	None	Not applicable	0.95	Not assessed	-	-	LOW

(a) Unclear if clinicians interpreting the MRI scan were blinded to the results of the X-ray scan

(b) Risk of selection bias (only patients with positive X-ray and/or MRI findings received CT); unclear if clinicians interpreting the CT scan were blinded to the selection of patients/the results of the X-ray and/or MRI; unclear timeframe between tests.

Table 51: Clinical evidence profile: Studies evaluating MDCT in relation to the reference test of MRI for scaphoid fractures in patients with suspected scaphoid fracture but indeterminate X-ray findings

Number of studies	Population (n) (in study order)	Risk of bias	Inconsistency	Indirectness	Imprecision	Sensitivity (95% CI) [in study order]	Specificity (95% CI)	Positive predictive	Negative predictive	Quality
Diagnostic accuracy of MDCT in relation to the reference test of MRI – scaphoid fractures										
1	Adults with a clinically suspected scaphoid fracture and negative initial conventional radiographs (n=54, 55 wrists)	Very serious limitations[a]	Not applicable	No serious limitations	Not applicable	0.88	1.00	1.00	0.91	LOW

(a) Risk of selection bias (unclear recruitment, fracture rate higher than average [36%], 7 patients excluded as they did not return for an MRI); unclear if clinicians interpreting the MRI scan were blinded to the results of the MDCT scan; MRI conducted up to one week following MDCT.

7.3.4 Economic evidence

Published literature

One cost consequence analysis was identified with the relevant comparison and has been included in this review.[144] This is summarised in the economic evidence profile below (Table 52) and the economic evidence tables in Appendix H.

Six economic evaluations relating to this review question were identified but were excluded due to limited applicability or methodological limitations.[31,48,61,70,92,128] These are summarised in Appendix L, with reasons for exclusion given.

See also the economic article selection flow chart in Appendix E.

New cost effectiveness analysis

This area was prioritised for new economic analysis.

One original cost utility analysis was undertaken comparing immediate CT, immediate MRI, CT after indeterminate X-ray, MRI after indeterminate X-ray, and follow up at the fracture clinic after an indeterminate X-ray.

This is summarised in the economic evidence profile below (Table 53). For further detail see appendix M.

Table 52: Economic evidence profile: Early MRI versus further X-ray

Study	Applicability	Limitations	Other comments	Incremental cost[c]	Incremental effects	Cost effectiveness	Uncertainty
Patel 2013[144] (UK)	Partially applicable[a]	Potentially serious limitations[b]	Within-trial analysis (RCT) of resource use as well as patient-reported pain and satisfaction scores.	MRI saves £28.74 per person	**Pain[d]:** Day 0: 0.3 (p=0.85) Day 14: 0.9 (p=0.27) Day 42: 0.9 (p=0.35) **Satisfaction[e]:** Day 0: 0 (p=0.65) Day 14: -0.6 (p=0.46) Day 42: -0.9 (p=0.22) **Hindrance[f]:** 1.4 (p = 0.03) **Perceived effect on activities[g]:** **Work effect** Day 14: 0.4 (p=0.27) Day 42: -0.6 (p=0.35) **Carer effect** Day 14: 0.2 (p=0.27) Day 42: 0.4 (p=0.35) **Sport effect** Day 14: 0.5 (p=0.27) Day 42: -0.4 (p=0.35)	n/a	No analysis of uncertainty.

(a) Relevant comparators in a UK NHS setting, although costs are from a specific hospital rather than the national average. No quality of life outcomes are reported.
(b) The trial is unblinded which could lead to bias. Not all relevant outcomes are reported, for example, malunion, non-union, missed fractures and functional outcomes
(c) 2005/2006 costs from West Middlesex University Hospital
(d) Patient reported on a 0–10 scale: No pain = 0, Worst pain ever = 10
(e) Patient reported on a 0–10 scale: Disgusted = 0; Blissfully happy = 10
(f) Defined as the overall difficulty with daily life. Patient reported on a scale of 0–10, where 0=no effect and 10=total hindrance
(g) Patient reported on a 0–4 scale. No effect=0; inability to participate=4

Table 53: Economic evidence profile: Original analysis of imaging strategies for suspected scaphoid fractures

Study	Applicability	Limitations	Other comments	Total cost per person	Total QALYs per person	Cost effectiveness	Uncertainty
Original NCGC analysis	Directly applicable[a]	Potentially serious limitations[b]	A probabilistic decision tree model using diagnostic accuracy data from the clinical review. Mapping was done to estimate an EQ5D score from a PRWE score for people with scaphoid fractures at one year post injury. The duration for which this utility was applied was extended to a lifetime if the fracture was not identified. Identified fractures returned to full health after the first year.	**Immediate CT:** £151 **Immediate MRI:** £214 **CT after indeterminate X-ray:** £292 **MRI after indeterminate X-ray:** £343 **Follow up X-rays:** £416	**Immediate CT:** 22.545 **Immediate MRI:** 22.561 **CT after indeterminate X-ray:** 22.549 **MRI after indeterminate X-ray:** 22.561 **Follow up X-rays:** 22.560	**Immediate MRI versus immediate CT:** £3,854 per QALY Immediate MRI dominates all other strategies.	Various one way sensitivity analyses were undertaken to assess uncertainty. The following changed the conclusion to immediate CT: Increasing the sensitivity of CT to 100%. The HRQoL detriment following a missed fracture is only sustained for one additional year.

(a) All comparators in a UK NHS setting.

(b) Long term QoL was based on assumptions. Short term quality of life was based on mapping from the PRWE score. Assumptions were made about sensitivity of follow up x-ray. Radiation risk not included.

(c) Average cost per person including imaging costs, clinic attendance costs and subsequent treatment costs.

7.3.5 Evidence statements

Clinical

Early MRI versus delayed X-ray for occlusive scaphoid fractures

Low quality evidence from 1 study comprising 27 participants demonstrated a clinical benefit of early MRI compared with delayed X-ray for time spent immobilised unnecessarily in plaster cast, with no serious imprecision.

Low quality evidence from 1 study comprising 84 participants demonstrated a clinical benefit of early MRI compared with delayed X-ray for the mean number of fracture clinic appointments attended by patients, with no serious imprecision.

Low quality evidence from 1 study comprising 27 participants demonstrated a clinical benefit of early MRI compared with delayed X-ray for the mean number of outpatient appointments attended by patients, with no serious imprecision.

Very low quality evidence from 1 study comprising 84 participants demonstrated no clinical difference between early MRI and delayed X-ray for self-reported pain at 14 days, with serious imprecision.

Very low quality evidence from 1 study comprising 84 participants demonstrated a clinical benefit of early MRI compared with delayed X-ray for self-reported pain at 42 days, with serious imprecision.

Low quality evidence from 1 study comprising 27 participants demonstrated no clinical difference between early MRI and delayed X-ray for self-reported pain at 1, 2 or 3 months, with no serious imprecision.

Low quality evidence from 1 study comprising 84 participants demonstrated clinical benefit of MRI compared with delayed X-ray for the mean number of X-rays received following the initial assessment, with no serious imprecision..

Early CT versus delayed X-ray for occlusive scaphoid fractures

There was no evidence comparing early CT with delayed X-ray for the identification of occlusive scaphoid fractures.

Early CT versus early MRI for occlusive scaphoid fractures

There was no evidence comparing early CT with early MRI for the identification of occlusive scaphoid fractures.

Diagnostic accuracy

Moderate quality evidence from 1 study comprising 296 participants demonstrated immediate X-ray to have a sensitivity of 0.7 and a specificity of 0.98, when measured against the gold standard of MRI.

Low quality evidence from 1 study comprising 296 participants demonstrated CT to have a sensitivity of 0.95 in detecting scaphoid fractures, when measured against the gold standard of MRI.

No evidence was found comparing the diagnostic accuracy of a further X-ray (10-14 days post-injury) or an early CT with the gold standard reference test of an early MRI.

Low quality evidence from 1 study comprising 54 participants demonstrated early MDCT to have a sensitivity of 0.88 and a specificity of 1.0, when measured against the gold standard of MRI.

Economic

One cost-consequence analysis found that delayed X-rays were more costly than MRI (£29 more per patient) following an initial assessment and X-ray for diagnosing people with a suspected scaphoid fracture, and had a small improvement in pain scores and a small perceived improvement for usual activities in the long term. This study was assessed as partially applicable with potentially serious limitations.

One original cost-utility analysis found that immediate MRI was cost effective compared to immediate CT (£3,854 per QALY) for diagnosing people with a suspected scaphoid fracture. It also found that immediate MRI was dominant compared to indeterminate X-ray followed by MRI, indeterminate X-ray followed by CT, and indeterminate X-ray followed by fracture clinic follow up. This study was assessed as directly applicable with potentially serious limitations.

7.3.6 Recommendations and link to evidence

Recommendations	9. Consider MRI for first-line imaging in people with suspected scaphoid fractures following a thorough clinical examination.
Relative values of different outcomes	While diagnostic cohort studies can tell us about the relative accuracy of a diagnostic test compared to a reference standard, they do not tell us whether adopting a particular diagnostic strategy improves patient outcomes. Evidence on patient outcomes is only available from diagnostic randomised controlled trials which compare two diagnostic interventions with identical subsequent treatment as indicated by the diagnostic test. One diagnostic RCT was included, but because this evidence did not cover all the tests in the protocol, diagnostic accuracy studies were also included. Critical outcomes were time spent in plaster cast, number of outpatient visits, health-related quality of life, pain/discomfort, return to normal activities, psychological wellbeing, and adverse effects (missed injury, non-union/malunion, avascular necrosis, post-traumatic arthritis, additional radiation exposure). Important outcomes were grip strength and range of motion. For the diagnostic accuracy review, the GDG identified sensitivity as the most important outcome, due to the significant clinical implications of a missed scaphoid fracture. The GDG were aware that there is no established reference standard for diagnosing scaphoid fractures. The GDG chose to use MRI as the reference standard in this review as they had a strong belief that MRI has 100% sensitivity for detecting scaphoid fractures. The GDG noted that MRI may be associated with reduced specificity, due to the risk that MRI may detect less severe scaphoid injuries that would not result in clinical harm for patients if untreated. However, as sensitivity was identified as the most critical outcome for decision-making in this review, the GDG chose to use MRI as the reference standard and considered this limitation when making their recommendation.
Trade-off between clinical benefits and harms	The diagnostic RCT evidence demonstrated a benefit of MRI over later imaging for the time spent in plaster cast, number of fracture clinic appointments, the number of outpatient appointments, and the number of X-rays after initial assessment. The diagnostic accuracy evidence demonstrated that X-ray missed 30% of true scaphoid fractures (when MRI was used as the reference standard) in patients with

	post-traumatic radial wrist tenderness. The diagnostic accuracy evidence also demonstrated that CT imaging missed 5% of true scaphoid fractures in patients with post-traumatic radial wrist tenderness and 12% of scaphoid fractures in patients with a clinically suspected scaphoid fracture but indeterminate X-ray findings (when MRI was used as the reference standard). On this basis, neither X-rays nor CT can be regarded as adequate proxies for MRI, which, as the reference standard, is assumed to be the most accurate method.
Economic considerations	This question was prioritised for economic modelling and a probabilistic decision tree was developed to conduct a cost-utility analysis. This model showed that the MRI and CT strategies in patients with an indeterminate X-ray were cheaper than having follow-up X-rays. This was due to removing unnecessary return visits and immobilisation costs for patients without a fracture, and this was great enough to outweigh the more expensive imaging cost for MRI and CT. Immediate MRI and immediate CT without the initial X-ray were cheaper still as these strategies remove the cost of the follow-up attendance. The reason many people have follow up visits, as the clinical review showed, is because an X-ray is not sensitive enough to identify all fractures. As a result, patients with a negative X-ray will be treated in plaster as a precaution and attend the fracture clinic at a later date for further assessment. For many people this is unnecessary as they will only require symptomatic treatment. When considering both costs and QALYs in the full probabilistic economic analysis, the immediate MRI strategy dominated all but the immediate CT strategy. This is because the immediate MRI strategy is the most clinically effective by identifying all fractures as well as being cheaper than all but the immediate CT strategy. The ICER for immediate MRI compared to immediate CT was £3,854 per QALY and so immediate MRI was shown to be cost effective compared to all other strategies. The immediate MRI strategy had the highest net benefit in the full economic analysis as it identified all fractures and so there was an improvement in quality of life compared to those with missed fractures in other strategies. Although immediate CT is less expensive than the immediate MRI strategy, it is only 95% sensitive and so 5% of the fractures would have been missed, causing a reduction in quality of life due to delayed, or no treatment. This resulted in an overall lower net benefit than the immediate MRI strategy. In the model, the specificity of MRI was considered to be 100% as it was the reference standard. However, based on the GDG experience that MRI results in a number of false positive diagnoses they believe it is likely to be less than 100%. This decreases the positive predictive value of MRI and therefore would underestimate the sensitivity of other imaging modalities when used as the reference standard. If CT were to be 100% sensitive then immediate CT becomes the optimal strategy for the initial imaging of a suspected scaphoid fracture because it is cheaper than MRI and has the same clinical outcome if it is equally sensitive. However CT would still miss some potentially important ligamentous injuries. The immediate MRI and CT strategies require a scanner to be available at the hospital where the patient presents. This is not currently the case for all hospitals. Implementation of this would add further costs but may be justified for MRI as it can provide benefit to a wider population e.g. patients attending with knee ligament injuries. The wider population would make the implementation costs per person smaller.

	MRI scanners in current practice have a high occupancy, which means access to MRI is not always possible, especially early access. Providing MRI scanners at hospitals that do not currently have them will improve access, reduce the delays to diagnosis and reduce the need for additional attendances for a broad group of patients. The reduction in delays to diagnosis could improve quality of life for some people and the reduced attendances could save some of the cost invested in the additional equipment. Extremity scanners are now becoming available at a lower purchase cost and with lower running costs. This may be a cost effective way of providing definitive imaging for scaphoid fractures and other injuries without increasing the burden on the larger MRI and CT scanners, which may be needed for more serious injuries, such as spinal injuries. The GDG also believed that the number of extremity injuries, scaphoid or other, that are currently imaged using a full sized MRI scanner could be large enough to optimise the use of an extremity scanner to image these injuries in ED. This could potentially allow a full sized scanner to be decommissioned by diverting this subgroup of patients to an extremity scanner, without reducing the capacity required for patients who require imaging using a full sized scanner. This could therefore result in a service that has lower operating costs than current service provisions. Another implication for immediate imaging using MRI or CT is the provision of trained clinicians to provide immediate reports of images before the patient is discharged from ED. The GDG believed this to be achievable as there are currently courses available for radiographers to be trained to report MRI or CT images of injuries such as scaphoid fractures, who can then support radiologists with the workload. Although this would incur an initial increased cost of providing training, the cost per report will become minimal over time. The radiologists on the GDG were concerned about the availability of trained reporting staff at night. The GDG believed there to be very few suspected scaphoid fracture attendances at night and they could therefore be reported by outsourcing or by asking the person to return the next day when staff are available. The GDG considered the radiation risk from CT scans and believed that the wrist has very low susceptibility to radiation absorption and so the risk of radiation induced cancer would be small. However, MRI has no radiation risk at all. The GDG considered all of the above discussion and decided that immediate MRI was the most clinically and cost effective strategy based on the available evidence and the model results.
Quality of evidence	**Clinical evidence** In the clinical review, two studies of low and very low quality were included in the diagnostic RCT review, and two studies of moderate and low quality were included in the diagnostic accuracy review. No evidence was found for the identification of suspected scaphoid fractures in children **Economic evidence** One cost consequence analysis from a UK NHS perspective was included based on an included RCT. It has been assessed as partially applicable with potentially serious limitations. An original cost-utility analysis assessed all comparators from a UK NHS perspective was developed. This has been assessed as directly applicable with potentially serious limitations. Limitations of the model include; Long term QoL was based on assumptions; short term quality of life was based on mapping from the PRWE score; assumptions were made about sensitivity of follow up x-ray; radiation risk not

	included. These were not felt to change the conclusions of the model and the GDG felt the model was robust for the purposes of decision making.
Other considerations	The GDG identified MRI as the gold standard method for imaging of the scaphoid, and the results from the RCT partially support this assumption. However access to MRI is commonly restricted in the NHS, and so the diagnostic accuracy question attempted to evaluate if potentially more feasible or available methods such as X-ray or CT were sufficiently accurate (in relation to the gold standard) to serve as acceptable alternatives. However, neither X-ray nor CT appeared to have sufficient sensitivity to prohibit unacceptable levels of missed fractures and so MRI was regarded as the only acceptable method. The GDG therefore chose to recommend that immediate MRI be used as the first line investigation in all patients with a clinically suspected scaphoid fracture. This is because they had a strong belief that MRI will identify all true cases of scaphoid fracture, and that any missed diagnoses from the less sensitive X-ray and CT would result in significant clinical harm. The GDG also noted that MRI is able to diagnose soft tissue injuries and would therefore reduce the need for further imaging and reduce repeat hospital appointments. Furthermore, CT is associated with a radiation risk, which is not the case with MRI. The GDG felt that MRIs should not be given purely because of suspicion based on mechanism. It was felt that thorough prior clinical examination should be used to ensure that MRI is not given to those people who are unlikely to have a scaphoid injury. The GDG recognised that the use of imaging did not constitute or replace the need for full examination of the wrist and documentation of all relevant findings The GDG felt it was important that clinicians use extra discretion when using MRI to diagnose a suspected scaphoid fracture in some children, if patients are thought to require an anaesthetic for imaging. In these cases, the GDG felt that clinicians may wish to consider using X-ray imaging as the first line investigation. The GDG noted that this recommendation may require a significant change in service for some emergency departments, due to restricted access to MRI in some services. Nevertheless, an extremity MRI scanner could be used instead, which would reduce the reliance on the main hospital MRI machine, might be more appropriate for children, and may also be used for the diagnosis of other extremity injuries. The GDG noted that given restricted access to MRI in some services and at some times of the day, some services may have difficulty in implementing this recommendation for all people with suspected scaphoid fractures immediately. However, the GDG felt that as the evidence indicates that MRI is the most clinically and cost-effective first imaging strategy for suspected scaphoid fractures, hospitals should work towards increasing access to MRI for this population. The GDG further noted that greater access to MRI would have benefits for other patient populations also. The GDG discussed how access to MRI may be more difficult overnight, due to the need to have access to have a trained healthcare professional to provide a definitive report on the MRI scan, who may not always be available out of normal working hours. The GDG believed that only a very small proportion of people with scaphoid injuries present to emergency departments overnight, and so the GDG felt that these patients could be recalled to hospital the following day for an MRI without undermining the cost-effectiveness of MRI as the first line imaging strategy. The GDG noted that this recommendation does not prevent clinicians from requesting alternative or additional imaging where necessary in the care of a patient; for example when MRI is contraindicated or additional imaging is required to plan surgery. However, the GDG wished to emphasise that alternative imaging strategies

	should not include multiple plain radiograph series.

7.4 Hot reporting

7.4.1 Introduction

On the day of injury, fracture diagnosis and initial decisions about patient care are most frequently made by clinicians in the emergency department (ED). ED clinicians will base their decision on their clinical examination of the patient, imaging of the fracture, and may be further supplemented by a 'red dot' system, where a radiographer or radiologist will mark patient X-rays with a red dot where they see a fracture. However, a definitive diagnosis by a radiographer or radiologist is frequently only available after patients have been discharged from the ED. This may result in missed diagnosis of fractures, and potential for subsequent recall of patients to the hospital. This review investigated whether hot reporting, where a definitive report by a radiographer or radiologist is available to ED clinicians before the patient is discharged, may be a more clinically and cost effective method of diagnosing patients with suspected fractures.

7.4.2 Review question: Is the use of definitive hot reporting of X-Rays clinically and cost-effective for use in patients with suspected fractures?

For full details see review protocol in Appendix C.

Table 54: PICO characteristics of review question

Population	Children, young people and adults with a suspected fracture, having experienced a traumatic incident
Intervention(s)	Definitive report by radiographer/radiologist during hospital attendance
Comparison(s)	No radiology report during hospital attendance No radiology report
Outcomes	Critical: • Health-related quality of life • Pain/discomfort • Return to normal activities • Psychological wellbeing • Missed fractures • Change in management plan • Patient recalled
Study design	RCTs or systematic reviews of RCTs; cohorts if no RCTs retrieved. If cohorts are used, these must consider all the key confounders chosen by the GDG.

7.4.3 Clinical evidence

Two papers, which reported on the same randomised trial, were included in the review[71,72]. These are summarised in Table 55 below. Evidence from the study is summarised in the clinical evidence summary below (Table 56). See also the study selection flow chart in Appendix D, study evidence tables in Appendix G, forest plots in Appendix J, GRADE tables in Appendix I and excluded studies list in Appendix K.

We searched for randomised trials that compared hot reporting with either delayed or no radiology report amongst individuals who had experienced a fracture following a traumatic incident. The review protocol further specified that the study population be stratified by age (children [0-17 years]; adults [18 years and over]). The studies included in the review deviated from the review protocol as

they used a study population that (i) did not stratify participants by age; (ii) did not specify whether trauma was the cause of injury in all cases; and (iii) used the broader inclusion criteria of musculoskeletal injuries. Following discussion with the GDG, these deviations were perceived to be acceptable as to not exclude the study from review.

Table 55: Summary of studies included in the review

Study	Intervention/comparison	Population	Outcomes	Comments
Hardy 2013[72]	Hot reporting versus delayed report (cold reporting)	Children and adults with musculoskeletal injuries	Patient recalled, missed fractures	–
Hardy 2013a[72]	Hot reporting versus delayed report (cold reporting)	Children and adults with musculoskeletal injuries	Change in health-related quality of life baseline – 8 weeks post intervention (EQ-5D)	–

Table 56: Clinical evidence summary: hot reporting versus cold reporting

Outcome	Number of studies (participants)	Imprecision	GRADE rating	Absolute difference	Control event rate (per 1000)	Control event rate for continuous outcomes Mean change (SD)
Health-related quality of life (Change score; EQ-5D)	1 (n=763)	None	HIGH	MD 0.01 lower (0.05 lower to 0.04 higher)	–	0.345 (0.33)
Patient recalled	1 (n=1502)	None	HIGH	8 fewer per 1000 (from 4 fewer to 9 fewer)	9 patients per 1000	–
Missed fractures	1 (n=1502)	None	HIGH	13 fewer per 1000 (from 7 fewer to 15 fewer)	16 per 1000	–

7.4.4 Economic evidence

Published literature

One cost utility analysis was identified with the relevant comparison and has been included in this review.[72] This is summarised in the economic evidence profile below (Table 57) and the economic evidence tables in Appendix H.

See also the economic article selection flow chart in Appendix E.

Table 57: Economic evidence profile: Hot reporting versus cold reporting

Study	Applicability	Limitations	Other comments	Incremental cost	Incremental effects	Cost effectiveness	Uncertainty
Hardy 2013[72] (UK)	Directly applicable[(a)]	Potentially serious limitations[(b)]	Within-trial analysis (RCT) with EQ-5D scores collected and unit costs applied. The RCT has been included also in the review of clinical evidence (Section 7.4.2)	Saves £23 per person.[(c)]	EQ-5D score: -0.005[(d)] Missed fractures: 11 fewer Patients recalled to ED: 7 fewer	Cold reporting is dominated as it has no clinical benefit.	No analysis.

(a) UK NHS and PSS perspective.
(b) The costs of implementing the hot reporting service are not formally included in the analysis.
(c) Costs included: Hospital in-patient days, outpatient clinic referral, and ED clinic referral. All costs are from NHS Reference Costs 2009–2010.
(d) The GDG concluded this difference was not clinically significant. Although hot reporting was associated with a decrease of 0.005 in EQ-5D score, this outcome was in conflict with the other two outcomes reported in the RCT as hot reporting was associated with fewer patients recalled and missed fractures.

Hardy et al.[72] estimated that a typical NHS hospital trust with 20,000 ED musculoskeletal radiography referrals a year would save £468,000. Although service implementation costs were not monitored, the study reported that they estimated that a minimum of 5–6 whole-time equivalent reporting radiographers would be needed to implement the service. Assuming an advanced practitioner salary at midpoint Agenda for Change Band 7 (point 30 - £35,184) and 20% on-costs (£7,037), the annual staff cost for this service was estimated to be £253,326.

7.4.5 Evidence statements

Clinical

High quality evidence from one randomised study comprising 763 participants demonstrated no clinical difference between hot reporting and cold reporting of X-rays for change in health-related quality of life, with no serious imprecision.

High quality evidence from one randomised study comprising 1502 participants demonstrated a clinical benefit of hot reporting of X-rays compared with cold reporting for the number of patients recalled to hospital, with no serious imprecision.

High quality evidence from one randomised study comprising 1502 participants demonstrated a clinical benefit of hot reporting of X-rays compared with cold reporting for the number of missed fractures, with no serious imprecision.

Economic

One cost utility analysis showed that a hot reporting service would be cost saving compared with cold reporting (hot reporting saves £23 per person). This study was assessed as directly applicable with potentially serious limitations.

7.4.6 Recommendations and link to evidence

Recommendations	**10. A radiologist, radiographer or other trained reporter should deliver the definitive written report of emergency department X-rays of suspected fractures before the patient is discharged from the emergency department.**
Relative values of different outcomes	Critical outcomes were health-related quality of life, pain/discomfort, return to normal activities, psychological wellbeing, and adverse effects (missed fractures, change in management plan, and numbers of patients recalled). No additional, important, outcomes were identified.
Trade-off between clinical benefits and harms	The evidence indicated no clinical benefit of hot reporting (rapid availability of radiology reports) for patients' health-related quality of life. However, hot reporting resulted in a smaller number of patients recalled to the hospital emergency department for review and fewer missed fractures. The GDG noted that only a small number of fractures were missed when hot reporting was not used; these included one fracture to the vertebrae (T5 wedge), two distal radius fractures, two fractures to the tibial plateau knee, one fracture to the distal humerus (supracondylar), and one fracture to the base of the small meta-carpal. The GDG believed that these fractures may not necessarily lead to significant harm if not identified in first attendance; however, they GDG suggested that missing some fracture types (for example, some fractures of the vertebrae) may have a significant long-term effect on patients' wellbeing and quality of life, and therefore even a small difference in missed injuries could be critical.

	The GDG felt that the clinical and cost effectiveness of hot reporting would only be achieved if a definitive report were provided. This is because a definitive report is able to inform decisions around management while the patient is in attendance, and therefore reduces the need for subsequent patient recall due to a change in the management plan after the patient has left ED. The GDG therefore considered 'red dot' reporting (where a red dot is placed on X-ray images where a fracture has been identified, but no detail about the number, location or severity of the fracture is provided) to not be as useful because this would not necessarily be able to inform management decisions. In order to benefit from the reduced number of patients recalled to hospital with hot reporting, the GDG chose to emphasise in the recommendation that a definitive report of patients' X-ray findings be available before patients are discharged from the ED. The GDG felt that it was important that the implementation of hot reporting should not extend waiting times for patients in the ED, and that provision should be made to deliver hot reporting within current targets of a 4-hour discharge from the ED. The included study only evaluated the clinical and cost effectiveness of hot reporting delivered between 8am and 2am, but the GDG chose to recommend that hot reporting be in operation over a 24-hour period. This is because the GDG believed that all patients should receive the same service, regardless of what time they were admitted.
Economic considerations	One economic evaluation[72] based on the RCT included in the clinical review estimated that , on the basis of the service being delivered by 6 reporting radiographers, that a radiographer led, immediate reporting service is cost saving compared to a one day delayed service. However, the cost of service delivery was not monitored as part of the study and it was indicated that the set up cost for the service would be a minimum of £253,326 in terms of 2013 costs. The study reported an increase in EQ5D of 0.005 for delayed reporting but the GDG did not believe this was clinically important. The included economic study showed that the interpretive errors incurred costs of £4520 and £1200 in the delayed reporting arm and the immediate reporting arm respectively. The study also showed that there was an increase in the number of admissions and total bed days among patients in the delayed reporting group. There were 58 patients admitted in the delayed reporting group compared to 44 patients in the immediate reporting group. The total number of bed days was 305 and 245 in the delayed reporting group and in the immediate reporting group respectively. This resulted in an additional total cost of £15,300 for the delayed reporting group which corresponds to a saving of £23.40 per patient in the immediate reporting strategy before the costs of providing the service are taken into account. The key driver of these results was the difference in the number of bed days. In the study, the increase of bed days in the delayed reporting arm was incurred mostly by patients where the ED and radiology reports were concordant, as only 2 patients were wrongly admitted for a total of 4 days. The GDG discussed if the difference in bed days could have been due to differences in injury severity between the two groups. However, no statistically significant differences in injuries were reported in the RCT population. The GDG thought that the difference in bed days may be due to the uncertainty of the ED clinician in making a decision without the aid of the radiology report. For instance they may suspect a minor injury that can be discharged, but without the report, the ED clinician decides to admit the patient until a radiology report is

	available. Also, a patient who is suspected to not have an injury may be admitted as a precaution until a radiology report is available. This study only looked at the service between 8am and 2am and so the GDG did not base the 24 hour recommendation on this evidence alone. The GDG believed that between 2am and 8am hot reporting could continue to be provided by an appropriately trained clinician on site. However, because there are relatively few people presenting with fractures at these hours, another option could be to outsource during these hours. The cost of the outsourcing may be cheaper than having an appropriately reporting trained clinician on site. The study considered the cost savings to a typical NHS hospital trust with 20,000 MSK radiography referrals per annum, which would be £468,000 based on the results of this economic analysis. The authors of the study believed the service could be provided with 6 whole time equivalent reporting radiographers. They assumed an advanced practitioner salary at midpoint Agenda for Change Band 7 (Point 30 - £35,184) and 20% employment on-costs (£7037), making the annual operating cost £253,326. When this operating cost is compared with the expected £468,000 savings, immediate reporting is still cost saving. Although the RCT reported EQ5D scores, the GDG believed they did not show any clinical difference between the two groups. They believed that there was no reason why hot reporting would have a reduction in quality of life and so considered these results as equally effective in terms of this outcome. Overall the GDG believed this service is cost effective as it is likely to decrease costs and improve outcomes in terms of missed fractures.
Quality of evidence	One high quality RCT was included in the review. This study evaluated the clinical and cost effectiveness of hot reporting in a population of patients with suspected musculoskeletal injuries. Although this population is not limited to those patients with a suspected fracture, the GDG decided that this population represented the population that would be treated with hot reporting of X-rays in practice, and therefore the evidence was not downgraded on the basis of indirectness. The included economic study was based on the high quality RCT included in the clinical review; this was assessed as directly applicable with potentially serious limitations. This was because the costs of providing the hot reporting service were not formally monitored, but an estimate of the cost was presented.
Other considerations	All the GDG agreed this is a good recommendation, however there was significant disagreement with the strength of recommendation by a minority of GDG members: • The concerns from the minority of the GDG were: the strength of the recommendation based on a single study; the resource that may be required to implement hot reporting (including the validity of assuming that such a service could be delivered with the number of staff in the study since no formal manpower assessment has been carried out and concerns about the impact of this recommendation on training); and whether the pressure to deliver a definitive report would undermine the quality of the report. • However, the majority of the GDG believed the strength of the recommendation to be right. It is based on high quality evidence where hot reporting was shown to be cost effective. They agreed that there may be difficulty with implementation initially but overall considered this to be in the best interest of the patient and their long term outcomes. The GDG noted that staff other than radiographers and radiologists may provide a definitive report on ED X-rays in some hospitals in the UK. To allow for flexibility in

	the implementation of this recommendation, the GDG chose to recommend that hot reporting should be provided by any clinician trained to provide the definitive written report of X-rays. This may include registrars or nurse practitioners. However, the GDG agreed that the provision of hot reporting should not undermine the quality of the report provided. They also strongly believed that any trained professional working in a suitable environment (for example, an environment that provides the reading screens necessary to adequately view films) who provides the definitive written report of X-rays should follow the standards specified by the Royal College of Radiologists.[26] Finally, the GDG wished to note that hospitals should ensure that junior clinicians who are providing the hot reporting of radiographs are able to discuss complex cases with a senior member of staff. The study did not address the issue of training and audit of radiology reporting which is currently delivered both formally and "on the job" as part of next day reporting. The radiologists on the guideline pointed out that in order to train and maintain skills of the reporting workforce new structures for on the job training would be required if all ED radiographs were "hot reported". There is likely to be an increase in training required to provide the workforce needed to provide hot reporting, however, the costs of this training are not likely to affect the conclusions of the study, as the initial training costs will become small when spread over the course of the radiographer's career. Continuous auditing of reports is not likely to have an effect on the cost as this is required to take place for delayed reports also.

8 Management and treatment plan in the emergency department

8.1 Timing of reduction and imaging guidance – distal radius fractures

8.1.1 Introduction

Dorsally displaced distal radius fractures are very common. Most can be treated with a closed reduction though some require surgery. Of those that require closed reduction, it is uncertain whether this should be done in the ED or in a fracture clinic. If the fracture is reduced in the ED then that would likely be on the day of injury, if reduced at a fracture clinic that would be after the day of injury. Also of interest is whether the reduction should be image-guided or not. It's possible to image the fracture during the reduction procedure to improve the reduction. This is normally done using fluoroscopy or ultrasound, but may increase the duration of the procedure and costs.

8.1.2 Review question: Is the reduction through manipulation of a dorsally displaced distal radius fracture without neurovascular compromise influenced by timing and/or the use of an image intensifier?

For full details see review protocol in Appendix C.

Table 58: PICO characteristics of review question

Population	Adults with a dorsally displaced distal radius fracture (without neurovascular compromise) due to a traumatic incident
Intervention(s)	• Reduction through manipulation with image intensifier on day of injury • Reduction through manipulation without image intensifier on day of injury • Reduction through manipulation with image intensifier after day of injury • Reduction through manipulation without image intensifier after day of injury
Comparison(s)	A comparison of the interventions above
Outcomes	Critical: • Health-related quality of life • Need for re-manipulation • Need for surgical fixation • Patient-reported function – such as: PRWE, DASH Important: • Pain/discomfort • Return to normal activities
Study design	RCTs or systematic reviews of RCTs; cohorts if insufficient RCT evidence is found. If cohorts are used, these must consider all the key confounders chosen by the GDG.

8.1.3 Clinical evidence

No relevant clinical studies were identified. See the study selection flow chart in Appendix D and excluded studies list in Appendix K.

8.1.4 Economic evidence

Published literature

No relevant economic evaluations were identified.

See also the economic article selection flow chart in Appendix E.

8.1.5 Evidence statements

Clinical

No relevant clinical studies were identified.

Economic

No relevant economic evaluations were identified.

8.1.6 Recommendations and link to evidence

Recommendations	**Research recommendation: For patients with displaced fractures of the distal radius, is manipulation with real-time image guidance more clinically and cost effective than manipulation without real-time image guidance?**
Relative values of different outcomes	Critical outcomes were need for health-related quality of life, re-manipulation, need for surgical fixation, and patient-reported function. Important outcomes were pain/discomfort and return to normal activities.
Trade-off between clinical benefits and harms	No clinical evidence was identified for either question.
Economic considerations	No economic evidence was identified for either question. **Timing of reduction** Current practice for patients who present to ED with a distal radial fracture is to perform an initial closed reduction in ED and then refer the patient to the fracture clinic for a decision regarding further surgical treatment. In some patients a closed reduction may be unnecessary prior to the decision for surgery and this increases the burden on the ED and adds unnecessary costs for the treatment time in ED. Due to the lack of clinical evidence, the GDG decided to make a research recommendation. **Image intensification** Using an image intensifier for those who can be reduced in ED is likely to reduce the time to a successful reduction and reduces the need for re-manipulation and reimaging. It also removes the need to administer further anaesthetics for reduction which increases costs. As there is also an additional cost for the equipment required in ED to perform the reduction under image intensification, and without any clinical or economic evidence, the GDG decided that a research recommendation was necessary.
Quality of evidence	No clinical evidence was identified for either question.
Other considerations	No clinical evidence was found on which to base a judgement around timing of reduction or whether fractures should be reduced using an image intensifier (real time image guidance).

	In current practice the issue of timing of reduction is inextricably linked with the use of real time image guidance and expertise of the health professional performing the reduction. Fractures which are reduced early are reduced in the ED and are not done by orthopaedic surgeons or with real time image guidance. Fractures that are reduced late tend to be reduced in a fracture clinic by an orthopaedic surgeon using real time image guidance. The GDG felt in general that dorsally displaced distal radius fractures should be reduced at the earliest opportunity. However the advantages of early reduction could be lost if the reduction is not performed well. The GDG considered that reductions undertaken 'blind' (without the use of real time image guidance) are more likely to require unintended secondary procedures and cause undue discomfort/pain to patients. The GDG agreed that all reductions of dorsally displaced distal radius fractures should include the use of real time image guidance. However ED s do not have access to real time image guidance and mindful of the lack of evidence and cost implications, the GDG did not feel they could recommend this. Therefore the GDG decided it was appropriate to make a research recommendation to answer this question. This review question was not extended to children because the GDG felt that delays to distal fracture reduction in children were not currently a problem.

8.2 Reduction anaesthesia – distal radius fractures

8.2.1 Introduction

Dorsally displaced distal radius fractures are very common. Most are treated with a provisional closed reduction by manipulation in the emergency department (ED) before referral to a fracture clinic the following day for further assessment. The anaesthetic technique used for closed reductions is important because the procedure can be very painful for the patient and the best results are achieved when the arm and wrist are most relaxed. There is currently little consensus on the anaesthetic technique that best meets these requirements.

8.2.2 Review questions:

a) What type of anaesthetic is the most clinically and cost effective for closed reduction of dorsally displaced distal radius fractures in people without neurovascular compromise in the emergency department?

b) What are the rates of serious adverse events for selected anaesthetic techniques used in the emergency department?

This review sought to identify the best anaesthetic technique to use during closed reductions of displaced distal radial fractures when in the emergency department. Initially, a clinical effectiveness review (question A) was developed to answer this question. However, the GDG felt that the studies included in the review were too small and not sufficiently powered to detect rare but serious adverse events associated mainly with intravenous regional anaesthesia (IVRA) and conscious sedation. Therefore, we developed a more inclusive adverse events protocol (question B) to pick up larger studies investigating these anaesthetic techniques in an ED context. Entonox was not included in the second protocol because there are not believed to be serious adverse events associated with its use.

For full details see review protocols in Appendix C.

Table 59: PICO characteristics of clinical effectiveness review (question A)

Population	Adults with a dorsally displaced distal radius fracture (without neurovascular compromise) due to a traumatic incident
Interventions	• Conscious sedation • Entonox • Haematoma block • IVRA • Regional nerve block (including brachial plexus block) • Haematoma block with conscious sedation • Haematoma block with Entonox
Comparison	Compared with each other (between categories only)
Outcomes	Critical: • Health-related quality of life • Pain • Need for re-manipulation • Need for surgical fixation • Patient-reported function PRWE, DASH • Death • Laryngospasm/Respiratory depression • Nausea/vomiting • Cardiac arrhythmias • Nerve damage • Infection • Hallucinations/emergent phenomena Important: • Return to normal activities
Study design	RCTs or systematic reviews of RCTs; cohorts if insufficient RCT evidence is found. If cohorts are used, these must consider all the key confounders chosen by the GDG.

Table 60: PICO characteristics of adverse events review (question B)

Population	Adults undergoing relevant anaesthetic technique in the ED without supervision from an anaesthetist
Interventions	• Haematoma block • IVRA • Regional nerve block (including brachial plexus block) • Conscious sedation - midazolam, fentanyl, ketamine, opiates • Haematoma block with sedation • Haematoma block with Entonox
Comparison	Any suitable control group, or no comparison required if case series
Outcomes	Critical: • Death • Health-related quality of life • Cardiac arrest • Laryngospasm/respiratory depression • Cardiac arrhythmias

	• Nerve damage • Aspiration of gastric contents • Compromised airway/respiration • Methaemoglobinaemia • Convulsions • Other serious adverse event
Indirect populations	Anaesthesia directed by surgeons without anaesthetist supervision will be included as indirect evidence Studies including children will be included as indirect evidence
Study design	RCTs or systematic reviews or cohort studies or case series. Only studies with ≥400 participants were included

8.2.3 Clinical evidence

Clinical effectiveness review

Seven RCTs or quasi-RCTs were included in the review.[6,19,60,66,101,116,190] These are summarised in Table 61 below. Evidence from these studies is summarised in the clinical evidence summary tables below (Table 62 to Table 65). See also the study selection flow chart in Appendix D, study evidence tables in Appendix G, forest plots in Appendix J, GRADE tables in Appendix I and excluded studies list in Appendix K.

Evidence was found for the following comparisons:

- Haematoma block versus IV regional anaesthesia[6,101,190]
- Entonox versus IV regional anaesthesia[60]
- Entonox versus haematoma block[116]
- Haematoma block versus regional nerve block[19,66]

No studies were found that investigated conscious sedation, haematoma block with sedation, or haematoma block with Entonox. Where pain is reported, it is pain during the closed reduction by manipulation. Goh 2002[60] reported the number of patients admitted to hospital, it was inferred that this would be for surgical fixation and has been reported as such.

Table 61: Summary of studies included in the review

Study	Intervention and comparison	Population	Outcomes	Comments
Abbaszadegan 1990[6]	Haematoma block (prilocaine) versus IV regional anaesthesia (prilocain)	Adults with displaced Colles' fractures	• Pain • Need for surgical fixation • Nerve damage	Sweden n=99 No image intensifier
Bajracharya 2002[19]	Haematoma block (lignocaine) versus regional nerve block Reduced 10–15 minutes after administration of anaesthesia	Adults with distal forearm fractures	• Pain • Need for re-manipulation • Laryngospasm/ respiratory depression • Infection	Nepal n=100 No image intensifier After day of injury
Goh 2002[60]	IV regional anaesthesia (lignocaine) versus	Adults with distal radius fractures	• Pain • Need for re-manipulation	Singapore n=67

Study	Intervention and comparison	Population	Outcomes	Comments
	Entonox		• Need for surgical fixation	No image intensifier On day of injury (A&E)
Haasio 1990[66]	Haematoma block (prilocaine) versus regional nerve block (prilocaine) Reduced 15 minutes after administration of anaesthesia	People with Colles' fracture	• Pain	Finland n=35 No image intensifier On day of injury (A&E)
Kendall 1997[101]	Haematoma block (lignocaine) versus IV regional anaesthesia (prilocaine)	People (16 years and over) with Colles' fracture	• Pain • Need for re-manipulation	United Kingdom n=150 No image intensifier On day of injury (A&E)
Man 2010[116]	Haematoma block (lignocaine) versus Entonox	Adults with a distal radius fracture	• Pain	Hong Kong n=67 No image intensifier On day of injury (A&E)
Wardrope 1985[190]	Haematoma block (lignocaine) versus IV regional anaesthesia (prilocaine)	Adults (>45 years) with Colles' fracture	• Pain • Need for re-manipulation	United Kingdom n=79 No image intensifier On day of injury (A&E)

Table 62: Clinical evidence summary: Haematoma block compared with IV regional anaesthesia for reduction of displaced distal radius fractures

Outcome	Number of studies (number of participants)	Imprecision	GRADE rating	Absolute difference	Control event rate (per 1000)	Control event rate for continuous outcomes
Pain score (measured with Visual Analogue Scale)(Better indicated by lower)	2 (n=241)	Serious imprecision	VERY LOW	MD 1.5 higher (0.8 to 2.2 higher)	NA	1.3
Painful/very painful	1 (n=79)	Serious imprecision	VERY LOW	170 more per 1000 (from 31 fewer to 548 more)	262 per 1000	NA
Need for surgical fixation	1 (n=99)	Very serious imprecision	VERY LOW	80 more per 1000 (from 0 more to 170 more)	0 per 1000	NA
Need for re-manipulation	2 (n=223)	No serious imprecision	LOW	196 more per 1000 (from 58 more to 463 more)	85 per 1000	NA
Median nerve decompression	1 (n=99)	Very serious imprecision	VERY LOW	1 more per 1000 (from 34 fewer to 238 more)	40 per 1000	NA

Table 63: Clinical evidence summary: Entonox compared with IV regional anaesthesia for reduction of displaced distal radius fractures

Outcome	Number of studies (number of participants)	Imprecision	GRADE rating	Absolute difference	Control event rate (per 1000)	Control event rate for continuous outcomes
Pain score (measured with Visual Analogue Scale) (Better indicated by lower)	1 (n=67)	Serious imprecision	VERY LOW	MD 3.6 higher (2.38 to 4.82 higher)	NA	2.2
Need for surgical fixation	1 (n=67)	Very serious imprecision	VERY LOW	54 more per 1000 (from 22 fewer to 746 more)	31 per 1000	NA

Outcome	Number of studies (number of participants)	Imprecision	GRADE rating	Absolute difference	Control event rate (per 1000)	Control event rate for continuous outcomes
Need for re-manipulation	1 (n=67)	Serious imprecision	VERY LOW	168 more per 1000 (from 10 fewer to 942 more)	63 per 1000	NA

Table 64: Clinical evidence summary: Entonox compared with haematoma Block for reduction of displaced distal radius fractures

Outcome	Number of studies (number of participants)	Imprecision	GRADE rating	Absolute difference	Control event rate (per 1000)	Control event rate for continuous outcomes
Pain score (measured with Visual Analogue Scale)	1 (n=67)	No serious imprecision	LOW	MD 4.39 higher (3.19 to 5.59 higher)	NA	2.8

Table 65: Clinical evidence summary: Haematoma block compared with regional nerve block for reduction of displaced distal radius fractures

Outcome	Number of studies (number of participants)	Imprecision	GRADE rating	Absolute difference	Control event rate (per 1000)	Control event rate for continuous outcomes
Pain score (measured with Visual Analogue Scale) (Better indicated by lower)	1 (n=100)	No serious imprecision	HIGH	MD 0.38 higher (0.09 to 0.67 higher)	NA	1.7
Moderate/severe pain	1 (n=35)	Serious imprecision	VERY LOW	248 fewer per 1000 (from 422 fewer to 135 more)	563 per 1000	NA
Need for re-manipulation	1 (n=100)	Very serious imprecision	LOW	0 fewer per 1000 (from 19 fewer to 291 more)	20 per 1000	NA
Bronchial spasm	1 (n=100)	Very serious imprecision	LOW	13 fewer per 1000 (from 20 fewer to 140 more)	20 per 1000	NA
Infection (at block	1 (n=100)	Very serious	LOW	20 more per 1000	0 per 1000	NA

Outcome	Number of studies (number of participants)	Imprecision	GRADE rating	Absolute difference	Control event rate (per 1000)	Control event rate for continuous outcomes
site)		imprecision		(from 30 fewer to 70 more)		

Adverse events review

Twelve case series in fourteen papers were included in the review. [13,29,34,36,76,85,86,134,152,153,159,180,181,188] These are summarised in Table 66 below. Evidence from these studies is summarised in the clinical evidence summaries below (Table 67 and Table 68). See also the study selection flow chart in Appendix D, study evidence tables in Appendix G, forest plots in Appendix J, GRADE tables in Appendix I and excluded studies list in Appendix K.

Evidence was found for the following anaesthetic techniques:

- IVRA (3 studies)[29,86,181]
- Conscious sedation (9 studies)[13,34,36,76,85,134,152,153,159,180,188]

No studies fitting the inclusion criterion of over 400 participants were found that investigated haematoma block, haematoma block with sedation, or haematoma block with Entonox, or regional nerve block. One study[192] met the inclusion criteria but did not include any outcomes of interest and was excluded.

Table 66: Summary of studies included in the review

Study	Intervention and comparison	Population	Outcomes	Comments
Andolfatto 2011[13] Case series	Conscious sedation Ketofol Staff: At minimum, an emergency physician (EP), a nurse, and a respiratory therapist. 80% of PSAs performed involved two EPs	Adults given conscious sedation (ketofol) in the ED Age - Median (IQR): 53 (36–70) years	• Cardiac arrhythmias • Other serious adverse event	Canada n=728 Patient's ASA physical status classification: • Class 1/2: 90% • Class 3/4: 10% 68% of procedures were orthopaedic
Bou-merhi 2007[29] Case series	IV regional anaesthesia Lidocaine and double pneumatic cuff Staff: the administering surgeon had basic or advanced cardiac life support qualification. A nurse was present whose only responsibility was to continuously monitor the patient's vital signs and to operate and monitor the pneumatic cuff	Adults and children who underwent a surgical procedure and were administered IVRA by the plastic surgeon Age - Mean (range): 44 (12–85) years	• Cardiac arrest • Other serious adverse event	Canada n=479 operations (on 448 patients) 99.6% of procedures performed on upper extremities Serious indirectness: Children included and anaesthetic administered by a plastic surgeon rather than emergency physician
Burton 2006[34] Case series	Conscious sedation Propofol Staff: depth of sedation was monitored by	Adults and children presenting to the ED with an injury or illness requiring conscious sedation and were treated	• Compromised airway/ respiration	USA n=792 Multicentre (3 EDs) prospective consecutive case series

Study	Intervention and comparison	Population	Outcomes	Comments
	emergency physician and nursing personnel	with propofol as the sedative agent Age - Mean (SD): 41 (22) years		73% of procedures were orthopaedic Serious indirectness: 8% of patients were younger than twelve years old
Campbell 2006[36] Case series	Conscious sedation Propofol/midazolam in combination with fentanyl Staff: drug administration and patient monitoring was conducted by an advanced level paramedic trained in conscious sedation, under the supervision of an emergency physician	People who had procedural sedation in the ED Age - 210 people >65 years of age	• Death • Aspiration of gastric • Compromised airway/ respiration • Endotracheal intubation	Canada n=979 80% of procedures were orthopaedic
Jacques 2011[85] Case series	Conscious sedation Propofol and/or midazolam Staff: sedation delivered in the resuscitation room with at least two doctors and one nurse present. Most senior doctor present: • Consultant or equivalent: 28% • Other grades: 72%	All patients requiring conscious sedation in an ED Age - Mean (range): 50 (13–101) years	• Cardiac arrest • Laryngospasm/ respiratory depression • Cardiac arrhythmias • Aspiration of gastric contents • Compromised airway/ respiration • Other serious adverse event	United Kingdom n=1402 Serious indirectness: Children included in the study. The total number of children was not reported however there were 144 patients <20 years of age 96% of procedures were orthopaedic Maximum sedation score: • 1–3 (light-moderate): 62% • 4 (deep): 26% • 5 (unresponsive): 2% • Unknown: 9%
Jakeman 2013[86] Case series	IV regional anaesthesia (Bier's block) Lidocaine	Patients over 16 years old who were admitted to an ED with wrist trauma Age - Mean: 65 years	• Death • Cardiac arrhythmias • Convulsions/ seizure • Other serious adverse event	United Kingdom n=416 All procedures were orthopaedic
Newstead 2013[134]	Conscious sedation Propofol Staff: sedation	Adults and children requiring conscious sedation within the	• Compromised airway/ respiration	United Kingdom n=1008 77% of procedures

Study	Intervention and comparison	Population	Outcomes	Comments
Case series	carried out under direct observation of a senior emergency physician in whom advanced airway management was part of their training.	ED Mean (range): 58 (15–97) years	• Other serious adverse event	were manipulation under anaesthesia Serious indirectness: Children included in the study
Rodgers 2011[152] & Rodgers 2005[153] Case series	Conscious sedation. Sedation was typically performed using midazolam and fentanyl. Other drugs used were propofol, methohexital, dexamethasone, diphenhydramine, and meperidine. Staff: Administering surgeon was a diplomat of the National Dental Board of Anaesthesia. All assistants were either licensed registered nurses or anaesthesia assistants.	People undergoing conscious sedation for various oral surgical procedures	• Death • Cardiac arrest • Cardiac arrhythmias • Aspiration of gastric contents • Convulsions/ seizure	USA n=6209 Patient's ASA physical status classification: • Class I: 45% • Class II: 53% • Class III: 1% Serious indirectness: anaesthetic administered by an oral surgeon in an oral surgical practice
Sacchetti 2007[159] & Hogan 2006[76] Case series	Conscious sedation Staff: sedation directed by emergency physician (EP). Monitoring was done by an emergency nurse or by another emergency physician. The most commonly used sedation drug(s) were midazolam: 41% of patients, fentanyl: 25%, propofol: 25%, etomidate: 23%, ketamine: 14%.	Adults and children having procedural sedation administered by emergency physicians Age - Median (range): 31 (0–95) years Excluded: Sedation to facilitate intubation or in intubated patients Data from the ProSCED registry, database of EP-directed procedural sedation cases.	• Death • Compromised airway/ respiration • Other serious adverse event	USA n=1028 sedations (980 patients) Multicentre (14 EDs) consecutive case series 60%+ of procedures were orthopaedic Serious indirectness: Children were included Patient's ASA physical status classification: • Class I: 70% • Class II: 26% • Class III+: 4% Patient's level of sedation: • light: 13% • Moderate: 53% • Deep: 34% General (unintended): 0.01%
Taylor 2011[180]	Conscious sedation.	Adults and children who received	• Laryngospasm/ respiratory	Australia n=2623

Study	Intervention and comparison	Population	Outcomes	Comments
Case series	Sedation drug(s) used (data was available for 2146 patients): • Propofol: 63% • Midazolam: 24% • Fentanyl: 30% • Morphine: 8% • Nitrous oxide: 9% • Ketamine: 16% Staff (person in charge of sedation): • Consultant: 59% • Registrar: 40% • Resident: 0.01% • Other: 0.01%	parenteral sedation for a procedure in the ED Age - Median (IQR): 34 (20–60) years	depression • Aspiration of gastric contents • Compromised airway/ respiration • Convulsions/ seizure	50% of procedures were for dislocated shoulder/fractured wrist/fractured ankle Serious indirectness: study included children Multi-centre study of consecutive patients in 11 EDs Observer's assessment of alertness/sedation (OAA/S) scale (data was available for 2146 patients): • level 1: 13% • level 2: 16%, • level 3: 11%, • level 4: 15% • level 5: 21% • level 6: 24%
Thamizhavel l 1996[181] Case series	IV regional anaesthesia Bier's block using prilocaine and double cuff	Patients having various manipulative surgical procedures in the ED Age - Range: 17–92 years. Exclusions: • Patient cannot understand procedure • Known hypersensitivity to local anaesthesia • Peripheral vascular disease • Sickle cell disease	• Death • Convulsions/ seizure	United Kingdom n=915
Vinson 2013[188] Case series	Conscious sedation. Carried out by an emergency physician and emergency nurse specifically trained and certified in procedural sedation. Most reductions carried out using 1 physician, 1 nurse model	ED patients who received conscious sedation for reduction of shoulder dislocation/elbow dislocation/hip dislocation/forearm fracture Age - Median (IQR): Shoulder reduction group: 32 (19–58) years, elbow	• Death • Cardiac arrest • Compromised airway/ respiration • Other serious adverse event	USA n=442 Multicentre of consecutive patients in 3 EDs Patient's ASA physical status classification (where data was available): • Class I: 70% • Class II: 28%

Study	Intervention and comparison	Population	Outcomes	Comments
		reduction group: 21 (16–36) years, hip reduction group: 75 (65–83) years, forearm reduction group: 12 (7–32) years		• Class III: 2%

Table 67: Clinical evidence summary: Adverse events of IVRA

Outcome	Number of studies (number of participants)	Imprecision	GRADE rating	Risk by study	Combined risk
Death	2 (n=1331)	NA	VERY LOW	0/416 (0%) 0/915 (0%)	0/1331 (0%)
Major cardiac event	1 (n=479)	NA	VERY LOW	0/479 (0%)	0/479 (0%)
Arrhythmia	1 (n=416)	NA	VERY LOW	0/416 (0%)	0/416 (0%)
Convulsions/seizure	2 (n=1331)	NA	VERY LOW	0/416 (0%) 1/915 (0.1%)	1/1331 (0.08%)
Operations cancelled due to tourniquet-related technical problems	1 (n=479)	NA	VERY LOW	4/479 (0.8%)	4/479 (0.8%)
Cuff failure (asymptomatic)	1 (n=416)	NA	VERY LOW	1/416 (0.2%)	1/416 (0.2%)

Table 68: Clinical evidence summary: Adverse events of conscious sedation

Outcome	Number of studies (number of participants)	Imprecision	GRADE rating	Risk by study	Combined risk
Death	4 (n=8853)	NA	VERY LOW	0/979 (0%) 0/6209 (0%) 0/1208 (0%) 0/457 (0%)	0/8853 (0%)
Cardiac arrest	3 (n=8068)	NA	VERY LOW	0/1402 (0%) 0/6209 (0%) 0/457 (0%)	0/8068 (0%)
Seizure	3 (n=9383)	NA	VERY LOW	1/6209 (0.02%) 0/1028 (0%) 2/2146 (0.09%)	3/9383 (0.03%)
Laryngospasm	2 (n=3548)	NA	VERY LOW	3/1402 (0.2%)	5/3548 (0.1%)

Outcome	Number of studies (number of participants)	Imprecision	GRADE rating	Risk by study	Combined risk
				2/2146 (0.09%)	
Bronchospasm	1 (n=1402)	NA	VERY LOW	3/1402 (0.2%)	3/1402 (0.2%)
Aspiration/pulmonary aspiration/aspiration of a foreign body	4 (n=10736)	NA	VERY LOW	0/979 (0%) 0/1402 (0%) 0/6209 (0%) 1/2146 (0.05%)	1/10736 (0.009%)
Arrhythmia/dysrhythmia	3 (n=8336)	NA	VERY LOW	1/728 (0.1%) 3/1402 (0.2%) 9/6209 (0.1%)	13/8336 (0.2%)
Endotracheal intubation	3 (n=2228)	NA	VERY LOW	0/792 (0%) 0/979 (0%) 0/457 (0%)	0/2228 (0%)
Bag valve mask ventilation	5 (n=5702)	NA	VERY LOW	15/728 (2%) 31/792 (4%) 32/1008 (3%) 5/1028 (0.5%) 66/2146 (3%)	149/5702 (3%)
Reversal agent used	4 (n=5033)	NA	VERY LOW	22/1402 (2%) 4/1028 (4%) 15/2146 (0.7%) 1/457 (0.2%)	42/5033 (0.8%)
Hypotension (intervention required)	5 (n=5367)	NA	VERY LOW	1/728 (0.5%) 11/1008 (1%) 1/1028 (0.1%) 27/2146 (1%) 2/457 (0.4%)	42/5367 (0.8%)
Hypertension	1 (n=728)	NA	VERY LOW	2/728 (0.3%)	2/728 (0.3%)

Outcome	Number of studies (number of participants)	Imprecision	GRADE rating	Risk by study	Combined risk
(intervention required)					
Over sedation	1 (n=1402)	NA	VERY LOW	4/1402 (0.3%)	4/1402 (0.3%)

8.2.4 Economic evidence

Published literature

No relevant economic evaluations were identified.

See also the economic article selection flow chart in Appendix E

Unit costs

Table 69: Cost of anaesthetic agents

Anaesthetic	Concentration	Dosage	Unit cost per procedure
Conscious sedation			
Midazolam	Midazolam 1 mg/1 ml solution for injection ampoules (5ml ampoule = £0.60)	5mg	£0.60
IVRA			
Prilocaine	Prilocaine hydrochloride 10 mg/ml (50 ml multi-dose vial = £5.06)	240mg[a]	£2.43
Haematoma block			
Prilocaine	Prilocaine hydrochloride 10 mg/ml (50 ml multi-dose vial = £5.06)	240mg[b]	£2.43
Regional nerve block			
Prilocaine	Prilocaine hydrochloride 10 mg/ml (50 ml multi-dose vial = £5.06)	240mg[b]	£2.43
Entonox			
50% nitrous oxide/oxygen mixture		Assuming , on average, 30 litres used per patient	£0.33

Sources: BNF [95]
(a) Based on Abbaszadegan et al. 1990[5,6] and Wardrope et al. 1985[190,190].
(b) Assumed to be the same as IVRA.

Table 70: Cost of healthcare professional time from beginning of procedure to patient discharge from the hospital.

Procedure	HCP needed	Time spent performing the procedure	Time spent monitoring after the procedure is performed (time per patient, assuming two patients are monitored by one nurse)	Unit cost per hour of HCP time	Unit cost per procedure
Conscious sedation	2 x registrar for procedure only 1 x nurse for procedure and monitoring	45 minutes	240 minutes (120 minutes with patient)	£40 per hour for registrar £34 per hour for nurse	£153.50
IVRA	2 x registrar for procedure only[a]	45 minutes	120 minutes (60 minutes with patient)	£40 per hour for registrar	£119.50

Procedure	HCP needed	Time spent performing the procedure	Time spent monitoring after the procedure is performed (time per patient, assuming two patients are monitored by one nurse)	Unit cost per hour of HCP time	Unit cost per procedure
	1 x nurse for procedure and monitoring			£34 per hour for nurse	
Haematoma block	1 x registrar for procedure only 1 x nurse for procedure only	45 minutes	0	£40 per hour for registrar	£55.50
Regional nerve block	1 x anaesthetist for procedure and initial monitoring 1 x registrar for procedure only 1 x nurse for procedure and monitoring	45 minutes	90 minutes (45 minutes with patient; anaesthetist only present for 15 minutes)	£40 per hour for registrar £94 per hour for anaesthetist £34 per hour for nurse	£175.00
Entonox	1 x registrar for procedure only 1 x nurse for procedure only	45 minutes	0	£40 per hour for registrar	£55.50

a) One registrar is needed to ensure the cuff is securely fitted and one is needed to perform the procedure
Sources: GDG opinion, PSSRU[45]

Table 71: Cost of equipment

Equipment	Unit cost per procedure
Conscious sedation	
Cannula (22-14G)	£0.84
10 ml Syringe	£0.53
IVRA	
cannula (22-14G)	£0.84
10 ml syringe	£0.53
Electro-Pneumatic Automatic Tourniquet (£3,090 per machine)	£0.62[a]
Double-type cuff with Velcro and buckle fastening (£124–£236 per cuff)	£1.50[b]
Haematoma block	
10 ml syringe	£0.53
Large bore needle to draw medication	£0.45
Large bore needle for injection	£0.45
Regional nerve block	
10 ml syringe	£0.53

Equipment	Unit cost per procedure
Ultrasound unit (£1,179 per unit)	£0.24[a]
Entonox	
Entonox delivery circuit mask	£5.98
Entonox delivery circuit mouthpiece	£3.95
Entonox mouthpiece filter	£1.48
Demand valve (£280 per unit)	£0.06[a]

a) Assuming 5000 uses per machine
b) Assuming 100 uses per cuff
Source: NHS supply chain [3], GDG opinion

Table 72: Total cost of each procedure[(a)]

Procedure	Anaesthetic costs	Equipment costs	HCP time costs	Total
Conscious sedation	£0.60	£1.37	£153.50	£155.47
IVRA	£2.43	£3.49	£119.50	£125.42
Haematoma block	£2.43	£1.43	£55.50	£59.36
Regional nerve block	£2.43	£0.77	£175.00	£178.20
Entonox	£0.33	£11.48	£55.50	£67.31

a) This excludes costs that occur before the procedure is performed and other costs that will be equal across all procedures.

8.2.5 Evidence statements

Clinical

Haematoma block versus IV regional anaesthesia

Very low quality evidence from 2 RCTs comprising 241 participants showed that haematoma block was clinically harmful relative to IV regional anaesthesia in terms of pain score during reduction, with serious imprecision.

Very low quality evidence from 1 RCT comprising 79 participants showed that haematoma block was clinically harmful relative to IV regional anaesthesia in terms of patients deeming the experience of reduction to be painful or very painful, with serious imprecision.

Very low quality evidence from 1 RCT comprising 99 participants showed that haematoma block was clinically harmful relative to IV regional anaesthesia in terms of need for surgical fixation, with serious imprecision.

Low quality evidence from 2 RCTs comprising 223 participants showed that haematoma block was clinically harmful relative to IV regional anaesthesia in terms of need for re-manipulation, with no serious imprecision.

Very low quality evidence from 1 RCT comprising 99 participants showed that haematoma block was clinically harmful relative to IV regional anaesthesia in terms of median nerve decompression, with serious imprecision.

Entonox versus IV regional anaesthesia

Very low quality evidence from 1 RCT comprising 67 participants showed that Entonox was clinically harmful relative to IV regional anaesthesia in terms of pain score during reduction, with serious imprecision.

Very low quality evidence from 1 RCT comprising 67 participants showed that Entonox was clinically harmful relative to IV regional anaesthesia in terms of need for surgical fixation, with serious imprecision.

Very low quality evidence from 1 RCT comprising 67 participants showed that Entonox was clinically harmful relative to IV regional anaesthesia in terms of need for re-manipulation, with serious imprecision.

Entonox versus haematoma block

Low quality evidence from 1 RCT comprising 67 participants showed that Entonox was clinically harmful relative to haematoma block in terms of pain score during reduction, with no serious imprecision.

Haematoma block versus regional nerve block

High quality evidence from 1 RCT comprising 100 participants showed that haematoma block and regional nerve block did not differ in terms of in terms of pain score during reduction, with no serious imprecision.

Very low quality evidence from 1 RCT comprising 35 participants showed that haematoma block was clinically beneficial relative to regional nerve block in terms of pain during reduction, with serious imprecision.

Low quality evidence from 1 RCT comprising 100 participants showed that haematoma block and regional nerve block did not differ in terms of need for re-manipulation, with very serious imprecision.

Low quality evidence from 1 RCT comprising 100 participants showed that haematoma block and regional nerve block did not differ in terms of bronchial spasm, with very serious imprecision.

Low quality evidence from 1 RCT comprising 100 participants showed that haematoma block and regional nerve block did not differ in terms of infection at block site, with very serious imprecision.

Economic

No relevant economic evaluations were identified.

8.2.6 Recommendations and link to evidence

Recommendations	**11. Consider intravenous regional anaesthesia (Bier's block) when reducing dorsally displaced distal radius fractures in adults (16 or over) in the emergency department. This should be performed by healthcare professionals trained in the technique, not necessarily anaesthetists.** **12. Do not use gas and air (nitrous oxide and oxygen) on its own when reducing dorsally displaced distal radius fractures in the emergency department.**
Relative values of different outcomes	Health-related quality of life is usually regarded as the most critical outcome as it is the most all-encompassing and patient-centred outcome, and can inform health economic decisions. However, in this case, the transient nature of the effects of the interventions made measuring an impact on long term quality of life difficult. Other critical outcomes were pain, need for re-manipulation, need for surgical fixation and patient-reported function. Adverse effects of the anaesthetic drugs were also seen as critical with the most important being death and laryngospasm/respiratory

	depression. Other critical adverse effects were nausea/vomiting, cardiac arrhythmias, nerve damage, infection, and hallucinations/emergent phenomena. Return to normal activities was considered by the GDG to be important.
Trade-off between clinical benefits and harms	**Clinical effectiveness review** **IV regional anaesthesia versus haematoma block** There were clinically important benefits for IV regional anaesthesia relative to haematoma block in terms of pain, need for re-manipulation and need for surgical fixation. There was no clinically important difference between the treatments in terms of median nerve compression. **IV regional anaesthesia versus Entonox** There were clinically important benefits for IV regional anaesthesia relative to Entonox in terms of pain, need for re-manipulation and need for surgical fixation. **Haematoma block versus Entonox** Haematoma block was clinically beneficial relative to Entonox in terms of pain. **Haematoma block versus regional nerve block** The continuous pain score outcome (high quality evidence) showed no clinically important difference, but the dichotomised pain outcome (low quality) showed there were clinically important benefits for haematoma block. There were no clinically important differences between haematoma block and regional nerve block in terms of bronchial spasm need for re-manipulation or infection at block site. **Overall** Overall IV regional anaesthesia was probably the most effective treatment. While IV regional anaesthesia was not compared directly to regional nerve block, it was more effective than haematoma block for nearly all critical outcomes reported, while haematoma block showed similar effectiveness to regional nerve block. Both IV regional anaesthesia and haematoma block were more effective for all reported outcomes in comparison to Entonox. **Additional evidence on adverse events** Because of concern in the GDG that the included comparison papers may have been too small to have picked up important adverse effects, which are anecdotally reported for IV regional anaesthesia in particular, a further search was conducted for large scale cohort and case series covering the anaesthetics. **Adverse events of IV regional anaesthesia** There were no reported instances of death, major cardiac event or arrhythmia. Rates of operations cancelled due to tourniquet related technical problems and asymptomatic cuff failure were 0.8% and 0.2%, respectively. Convulsions/seizure were reported in one patient for an overall rate of 0.08%. This patient was known to have epilepsy. These adverse events do not appear to outweigh the clinical benefits of IV regional intubation. **Adverse events of conscious sedation** There were no reported instances of death, cardiac arrest or endotracheal intubation. Rates of seizure, laryngospasm and aspiration were less than or equal to 0.1%. Rates of bronchospasm, arrhythmia/dysrhythmia, hypertension (requiring intervention) and over sedation were less than or equal to 0.3%. Reversal agents were used in 0.8% of cases and hypotension (requiring intervention) was experienced 0.8% of the time. The rate of bag valve mask ventilation was 3%. These

	adverse events do not appear to be likely to outweigh any advantages that may exist for conscious sedation, although no evidence was found comparing conscious sedation to any of the other anaesthetic options.
Economic considerations	No economic evidence was identified for this question. Conscious sedation and regional nerve blocks are the two most expensive treatments but the evidence suggests that a regional nerve block is only as effective as the much cheaper haematoma block. This suggests that the haematoma block dominates the regional nerve block. There was no evidence in favour of conscious sedation. Entonox was shown to be less effective than a haematoma block and more expensive and so Entonox was also dominated. This means that the question becomes a comparison between a haematoma block and the more expensive and more effective IVRA. IVRA was shown to have an improved pain score compared to haematoma block although over such a small time this is unlikely to affect quality of life enough to make it cost effective based on the intervention cost alone – IVRA costing £66 more. However, the evidence suggested that IVRA reduced the need for surgical fixation in comparison to haematoma block by 80 per 1000. The cost of surgical fixation would then need to be £825 for IVRA to be cost neutral. The GDG believed that surgery would cost more than that and so IVRA may even be cost saving. The GDG considered the uncertainty in the evidence but agreed that IVRA provides enough benefit to justify the increase in cost.
Quality of evidence	All but one outcome were graded as low or very low quality evidence. This was due to risk or bias and/or imprecision. Risk of bias was very serious for most outcomes due to a lack of allocation concealment, or a lack of patient, health-care practitioner and assessor blinding. There was serious or very serious imprecision for most outcomes due to the 95% confidence intervals crossing one or both MIDs.
Other considerations	IV regional anaesthesia was the most effective treatment in the clinical review of RCTs. However the comparative studies were regarded as too small to pick up the rare but very serious adverse events associated with the technique. Additionally the evidence base comparing the use of this technique in reduction of distal radius fractures to other techniques is old, with the most recent included study published in 2002. A further clinical review investigating AEs in IVRA was therefore conducted. The new evidence suggested that, contrary to expectations, adverse events of IVRA did not outweigh the benefits of this approach in terms of reduced pain during manipulation and fewer re-manipulations and surgical fixations. The GDG did not consider haematoma block sufficiently effective in terms of pain relief during reduction to be able to recommend it. However they did note that it is an easy procedure to perform, cheaper than IVRA or regional nerve block, and does not cause any serious adverse events. Regional nerve blocks appeared to be similar in effectiveness to haematoma blocks in the clinical review. However, the GDG noted that the true effectiveness of regional nerve blocks could have been masked by closed reductions being carried out before the full anaesthetic effect had taken effect. In both studies reductions were undertaken 15 minutes after the anaesthetic was administered and a regional nerve block's full effect is often not apparent until an hour after administration. The GDG considered that a 45 minute delay in undertaking a closed reduction may be unworkable in the context of the emergency department setting in terms of pressure on staff time.

	Entonox was not as effective as haematoma block and IVRA in terms of pain relief during reduction. For this reason the GDG considered it to be unacceptable as the sole anaesthetic agent used during a closed reduction of dorsally displaced distal radius fractures. Despite the further review showing that the adverse effects of conscious sedation were unlikely to outweigh any benefits of this approach, the clinical review found no clinical evidence for the efficacy of conscious sedation. The GDG consensus was therefore that there was insufficient evidence to be able to make a recommendation for this technique. Furthermore, the GDG felt that the potential risk of serious adverse events might be too high when an anaesthetist is not present to oversee the procedure, and that this may not have been reflected in the new evidence. After consideration of the relative balance of risks and harms, the quality of the evidence, and economic considerations, the GDG felt that a recommendation encouraging the use of IV regional anaesthesia was warranted. The evidence review question specified only people with fractures without neurovascular compromise however no evidence was excluded on this basis. On reflection the GDG decided to remove the neurovascular compromise caveat from the recommendation on the basis that this does not change management. They did however concede that it would increase urgency for a successful reduction. This review question was not extended to children because the GDG felt that minor distal radius displacements in children resolve with growth and so do not require manipulation. The GDG also thought that when children have a major displacement they will always have a general anaesthetic. The GDG Guideline Development Group also discussed the definition of distal radial displacement and decided it is not possible to give a meaningful definition of displacement that requires reduction. Displacement of a distal radial fracture can include angulation, translation, shortening, rotation, articular involvement of the radiocarpal joint and articular involvement of the radio-ulna joint. Each of these can occur alone or in any combination. The magnitudes of each are continuous variables. Consequently there are an almost infinite number of types of displacement with no clear consensus as to what represents significant displacement. As a consequence in the largest of the studies referred to in the guideline (the DRAFFT trial) it was left to the managing surgeon to determine when displacement was significant enough to require reduction. Consequently, the Guideline Development Group decided to also leave it to the managing surgeon to determine when displacement is significant enough to require reduction.

8.3 Treatment of torus fractures

8.3.1 Introduction

Torus fractures, also known as buckle fractures, are a paediatric fracture commonly caused by a fall on the outstretched hand. The mechanism of injury leads to a compression and subsequent buckling of the dorsal cortex, but the volar cortex is usually unaffected. These are a very common paediatric wrist injury, comprising about 3–4% of all injury-related visits to trauma departments. There is little consensus on the optimal treatment strategy for children who have this injury, and this review aims to synthesise the evidence in this field to inform a recommendation.

8.3.2 Review question: What is the most clinically and cost-effective management strategy for children with torus fractures of the forearm?

For full details see review protocol in Appendix C.

Table 73: PICO characteristics of review question

Population	Children and young people experiencing a torus fracture following a traumatic incident.
Intervention(s)	• Rigid non-removable cast (fibreglass, plaster of Paris) • Soft cast • Removable splint • Bandaging
Comparison(s)	• No immobilisation • A comparison of above
Outcomes	Critical: • pain/discomfort • Patient experience • Return to normal activities • Health-related quality of life • Skin problems • Re-fracture Important: • Number of outpatient visits • Cast changes Population size and directness: • No limitations on sample size • Studies with indirect populations will not be considered.
Study design	RCTs or systematic reviews of RCTs; cohorts if no RCTs. If cohorts are used, these must consider all the key confounders chosen by the GDG.

8.3.3 Clinical evidence

Six studies were included in the review.[100,103,139,145,194,197] These are summarised in Table 74 below. Evidence from these studies is summarised in the clinical evidence summaries below (Table 75 to Table 77). See also the study selection flow chart in Appendix D, study evidence tables in Appendix G, forest plots in Appendix J, GRADE tables in Appendix I and excluded studies list in Appendix K.

Table 74: Summary of studies included in the review

Study	Intervention/ comparison	Population	Outcomes	Comments
Karimi 2012[100]	Rigid cast versus removable splint	Children of mean age 9.5 years from Iran with torus fracture	Pain, convenience, adverse skin effects	-
Oakley 2008[139]		Children <18 years from Australia with torus fracture	Pain, proportion that would choose that treatment in future, return to normal activities, need for re-immobilisation	subgrouped pain outcomes according to initial pain. Both have been reported

Study	Intervention/ comparison	Population	Outcomes	Comments
Plint 2006[145]		Children of mean age 9.5-9.9 years from Canada with torus fracture	Pain, proportion that would choose that treatment in future, re-fracture	-
Williams 2013[197]		Children of mean age 9-9.5 years from USA with torus fracture	Pain, proportion that would choose that treatment in future, convenience	Multiple time points for each outcome, but only 21 day outcome has been included
Khan 2007[103]	Rigid cast versus soft cast	Children of mean age 9.5 years from Ireland with torus fracture	Problems with casts, proportion that would choose that treatment in future, cast complications	Parents were respondents rather than patients
West 2005[194]	Rigid cast versus bandaging	Children of 1 to >10 years from UK with torus fracture	Pain, discomfort, convenience	-

Table 75: Clinical evidence summary: rigid cast versus removable splint

Outcome	Number of studies (n)	Imprecision	GRADE rating	Absolute difference	Control event rate (per 1000)
Mild to moderate pain on activity at 3 weeks	1 (n=137)	Serious imprecision	VERY LOW	109 fewer per 1000 (from 223 fewer to 66 more)	438
Proportion finding treatment convenient at 3 weeks	1(n=137)	No serious imprecision	LOW	0 fewer per 1000 (from 100 fewer to 100 more)	906
Adverse events - skin problems	1(n=84)	No serious imprecision	LOW	152 fewer per 1000 (from 106 fewer to 166 fewer)	172
Adverse events - oedema	1(n=137)	Serious imprecision	VERY LOW	70 more per 1000 (from 10 more to 130 more)	0
Proportion at 2–4 weeks who would choose to continue with same form of immobilisation weeks	3(n=222)	Serious imprecision	VERY LOW	361 fewer per 1000 (from 583 fewer to 49 more)	821
Proportion at 2 weeks resuming normal activities	1(n=137)	Serious imprecision	LOW	287 more per 1000 (from 93 more to 527 more)	667
Proportion at 2 weeks requiring re-immobilisation	1(n=84)	Very serious imprecision	VERY LOW	71 fewer per 1000 (from 124 fewer to 124 more)	143
Adverse events: re-fractures	1(n=87)	No serious imprecision	LOW	not pooled	0/42 (0%)

Table 76: Clinical evidence summary: rigid casts versus soft casts

Outcome	Number of studies (n)	Imprecision	GRADE rating	Absolute difference	Control event rate (per 1000)
Parental problems with casts at 3 weeks	1(n=117)	Serious imprecision	VERY LOW	90 more per 1000 (from 2 fewer to 849 more)	140
Proportion of parents at 3 weeks who would choose that treatment in future	1(n=117)	No serious imprecision	LOW	926 fewer per 1000 (from 798 fewer to 966 fewer)	986

Outcome	Number of studies (n)	Imprecision	GRADE rating	Absolute difference	Control event rate (per 1000)
Cast complications at 3 weeks	1 (n=117)	Serious imprecision	VERY LOW	90 more per 1000 (from 2 fewer to 849 more)	104

Table 77: Clinical evidence summary: rigid casts versus bandaging

Outcome	Number of studies	Imprecision	GRADE rating	Absolute difference	Control event rate (per 1000)
Existence of pain at 4 weeks	1(n=39)	No serious imprecision	LOW	491 more per 1000 (from 67 more to 1000 more)	714
Existence of pain for 2 or more days at 4 weeks	1(n=39)	No serious imprecision	LOW	659 more per 1000 (from 49 more to 1000 more)	714
Proportion of patients with discomfort during treatment period	1(n=39)	No serious imprecision	LOW	516 more per 1000 (from 27 more to 1000 more)	571
Proportion of patients finding treatment convenient at 4 weeks	1(n=39)	No serious imprecision	LOW	803 fewer per 1000 (from 538 fewer to 897 fewer)	143

Narrative review for incompletely reported outcomes

Rigid cast versus removable splint

Williams 2013 reported group medians for pain and perception of convenience but did not include any measure of variability (such as interquartile range). Their point estimates are summarised in the table below.

Table 78: Point estimates in Williams 2013

Outcome	Rigid cast	Removable splint	P
Median pain at 21 days (0–9 scale; higher worse)	0	1	NS
Median perception of convenience at 21 days (0–9 scale; higher better)	3	9	<0.0001

8.3.4 Economic evidence

Published literature

One cost-consequence analysis was identified with the relevant comparison and has been included in this review.[46] This is summarised in the economic evidence profile below (Table 79) and the economic evidence table in Appendix H.

See also the economic article selection flow chart in Appendix E.

Table 79: Economic evidence profile: Removable splint versus plaster cast

Study	Applicability	Limitations	Other comments	Incremental costs	Incremental effects	Cost effectiveness	Uncertainty
Davidson 2001[46] (UK)	Partially applicable[a]	Potentially serious limitations[b]	A within-RCT cost-consequence analysis comparing a removable splint and a plaster cast based. This study was not included in the clinical review as it did not present any relevant clinical outcomes. However, it is a relevant study to include as economic evidence.	Saves £51.23 per person[c]	No difference in radiological outcomes	NA	No sensitivity analyses undertaken

(a) Appropriate comparators from a UK perspective, however, costs are from Alder Hey children's hospital and may not represent UK NHS costs as a whole. Health effects are not expressed in terms of QALYs.

(b) The only outcomes reported are for the radiological union and position of the fracture.

(c) Costs included: Radiograph, clinic attendance, full plaster-of-Paris cast, plaster-of-Paris backslab, Futura splint, temporary splint.

8.3.5 Evidence statements

Clinical

Rigid cast versus removable splint

Very low quality evidence from one RCT comprising 137 participants showed that a rigid cast was clinically effective compared with a removable splint in terms of numbers with mild to moderate pain on activity at 3 weeks, with serious imprecision.

Low quality evidence from one RCT comprising 137 participants showed that a rigid cast was clinically effective compared with a removable splint in terms of skin problems, with no serious imprecision.

Low quality evidence from one RCT comprising 84 participants showed that a rigid cast was clinically effective compared with a removable splint in terms of the proportion resuming normal activities, with serious imprecision.

Very low quality evidence from one RCT comprising 137 participants showed that a rigid cast was clinically harmful compared with a removable splint in terms of oedema, with serious imprecision.

Very low quality evidence from 3 RCTs comprising 222 participants showed that a rigid cast was clinically harmful compared with a removable splint in terms of the proportion at 2–4 weeks who would choose to continue with the same form of immobilisation, with serious imprecision.

Low quality evidence from one RCT comprising 137 participants showed that there was no difference in clinical effectiveness between a rigid cast and a removable splint in terms of the proportion finding treatment convenient at 3 weeks, with no serious imprecision.

Very low quality evidence from one RCT comprising 84 participants showed that there was no difference in clinical effectiveness between a rigid cast and a removable splint in terms of the proportion requiring re-immobilisation, with very serious imprecision.

Low quality evidence from one RCT comprising 87 participants showed that there was no difference in clinical effectiveness between a rigid cast and a removable splint in terms of refractures, with no serious imprecision.

Rigid cast versus removable splint

Very low quality evidence from one RCT comprising 117 participants showed that there was no difference in clinical effectiveness between a rigid cast and a soft cast in terms of the parental problems with casts at 3 weeks, with serious imprecision.

Low quality evidence from one RCT comprising 117 participants showed that a rigid cast was clinically harmful compared with a soft cast in terms of the proportion at 3 weeks who would choose to continue with the same form of immobilisation, with no serious imprecision.

Very low quality evidence from one RCT comprising 117 participants showed that a rigid cast was clinically harmful compared with a soft cast in terms of cast complication, with serious imprecision.

Rigid cast versus bandaging

Low quality evidence from one RCT comprising 39 participants showed that a rigid cast was clinically harmful compared with bandaging in terms of the proportion with pain of any duration at 4 weeks, with no serious imprecision.

Low quality evidence from one RCT comprising 39 participants showed that a rigid cast was clinically harmful compared with bandaging in terms of the proportion with pain lasting more than 2 days at 4 weeks, with no serious imprecision.

Low quality evidence from one RCT comprising 39 participants showed that a rigid cast was clinically harmful compared with bandaging in terms of the proportion with discomfort during the treatment period, with no serious imprecision.

Low quality evidence from one RCT comprising 39 participants showed that a rigid cast was clinically harmful compared with bandaging in terms of the proportion of patients finding treatment convenient at 4 weeks, with no serious imprecision.

Economic

One cost-consequence analysis showed that a removable splint was cost-saving compared with plaster cast immobilisation (removable splints saved £51.23 per person) to treat torus fractures. This study was assessed as partially applicable with potentially serious limitations.

8.3.6 Recommendations and link to evidence

Recommendations	**13. Do not use a rigid cast for torus fractures of the distal radius.** **14. Discharge children with torus fractures after first assessment and advise parents and carers that further review is not usually needed.** **Research recommendation: What is the clinical effectiveness and cost effectiveness of no treatment for torus fractures of the distal radius in children compared with soft splints, removable splints or bandages?**
Relative values of different outcomes	Critical outcomes were: pain/discomfort, as this is probably the most important issue of concern to the patient; health-related quality of life; patient experience; adverse events; and return to normal activities. Important outcomes were the number of outpatient visits and the number of cast changes, as these are good proxies for the comfort and effectiveness of the therapies.
Trade-off between clinical benefits and harms	**Rigid cast versus removable splint** Rigid casts had a relative benefit in terms of pain, a return to normal activities, and the adverse events of skin problems. However, this was partially offset by a relative harm for rigid casts in terms of the proportion who would choose to continue the therapy in future, and the adverse event of oedema. Overall, however, the benefits of rigid casts over removable splints were deemed to outweigh the harms. **Rigid cast versus soft cast** There were no benefits of using rigid casts over soft casts, and thus the relative harms for rigid casts (parents not wishing to choose that treatment in future and cast complications) were unopposed. Overall, then, soft casts were deemed preferable to rigid casts. **Rigid cast versus bandaging** There were no benefits of using rigid casts over bandaging, and thus the relative harms for rigid casts (parents not wishing to choose that treatment in future, pain, and inconvenience) were unopposed. Overall, then, bandaging was deemed preferable to rigid casts. **Summary**

	The evidence suggested that soft casts and bandaging were probably the optimal approaches out of the four considered.
Economic considerations	One within trial analysis of a UK randomised controlled trial[46] showed that a removable splint was cost saving in comparison to plaster-of-Paris. The GDG considered the natural history of a torus fracture of the distal radius and believed it to remain the same whether the arm is immobilised or not. Currently, patients with a torus fracture are often treated in a rigid plaster cast, which involves a return hospital visit for its removal. It was agreed that this treatment is not cost effective as the treatment does not provide any clinical benefit but incurs unnecessary costs from both materials and hospital visits. The GDG therefore agreed that it should be recommended that rigid casts should not be used in the treatment of torus fractures. The GDG were concerned that not providing any treatment may appear to be cost effective but may also cause concern for the parents. They thought that this may lead to further unnecessary hospital attendances for the patients and that a removable bandage or soft cast may provide some benefit and prevent these attendances.
Quality of evidence	**Clinical evidence** Quality was low to very low for all outcomes across all 3 comparisons. The main risk of bias was a lack of allocation concealment, and most outcomes were seriously imprecise. **Economic evidence** This study was assessed as partially applicable with potentially serious limitations. This was because the costs were taken from a single hospital that may not represent the UK as a whole and the study did not report health outcomes in terms of QALYs.
Other considerations	Torus fractures are buckle fractures of the distal radius. These are fractures in which there is cortical deformation but no break in the cortex (and thus should not be confused with greenstick fractures). Torus fractures were considered to be very low risk injuries in the skeletally immature, and were also viewed as fractures which can heal naturally. The main harm associated with the treatment interventions were pain and discomfort. The main benefits were considered to be increased mobility/ability to perform normal activities, which were highest in bandages and soft casts. The GDG discussed that any intervention (such as a rigid or a soft cast, a removable cast or a bandage) may act as a reminder to children to be cautious whilst their torus fracture heals, thus improving parent experience and psychological wellbeing (although no evidence was retrieved for the latter). However, the GDG felt that the evidence in the literature was not compelling enough to indicate that rigid casts should be used. Furthermore, the costs of rigid casts would be higher than other treatments because of the need for follow up for removal of the cast. Removal of the rigid cast usually involves an electric plaster saw which can be distressing to children and parents. Alternatives, such as a soft cast, can be removed without an electrical saw. The GDG agreed that the wording of the recommendation was strong and explicit enough to stop clinicians from using rigid casts. The GDG also noted that because alternatives to rigid casts can be removed at home, there was no real need for follow up. This was reflected in a recommendation stating that parents should be advised there is no need for further follow up and the child can be discharged. The GDG noted that this should be accompanied by children and their parents or carers being given good instructions and advice on the care of their

	bandages or soft casts. Although the GDG questioned the need for any treatment at all, on the basis that torus fractures usually heal naturally, they agreed via consensus methods that it was not appropriate to recommend *no treatment*, as no evidence was retrieved which looked at *no treatment* as a viable intervention strategy. The GDG decided that a research recommendation should be proposed to see if no treatment was as effective as soft casts, bandages or removable splints. Finally, the GDG also acknowledged that good casting skills may not be present in the emergency department. This could affect how well soft casts are fitted, a poor fit possibly resulting in increased discomfort. Hence decisions on any treatment should be made with available expertise in mind. This is a fracture only seen prior to skeletal maturity, and so the population in this review is restricted to children.

8.4 Referral for on-going management from the emergency department

Introduction

After people with non-complex fractures have been discharged home from the emergency department, they will often need to attend an out-patient clinic for re-appraisal of their injury and further management. There is a growing belief that some of the stages in this process are inefficient and costly, both in terms of NHS resources, patients' outcomes and the patients' time. There are several unknown quantities in the process. Firstly, who in the multidisciplinary team is best suited to making decisions about patients' further outpatient management? Secondly, do all patients need to come back for a face to face clinic, or can some be given virtual clinic appointments? Moreover, can some specific patient groups simply be discharged when leaving the emergency department? Finally, should follow up clinics be general or specialist?

Referral pathways were selected as a second priority area for economic modelling in this guideline, looking at different service configurations incorporating the different aspects explained above.

This model was designated as low priority if time permitted, however due to time limitations this did not go ahead. Nevertheless, in this chapter we present the process used to derive and frame the clinical questions that would provide data for such a model and the systematic reviews conducted to provide answers to the questions above, and to inform the model.

Conceptual modelling

The nature of the review topic required iterative methods for question formation, evidence synthesis and interpretation as outlined in the NICE interim methods guide.

Conceptual modelling was the formal technique used to define the clinical questions to provide data for the economic model. In the context of guideline development, conceptual modelling is used to explore and share knowledge between the technical team and the GDG experts with the aim to:

- Establish breadth and complexity of problem
- Enable simplification of the problem
- Agree aim of the evidence review
- Prioritise aspects which would benefit most from research and data synthesis
- Agree scope of question and define the problem

- Define objectives of the evidence review

Developers were asked to define preliminary objectives of service delivery change based on the inputs, content of change and outcomes expected:

- To reduce time to definitive repair of fracture, by reducing the number of complications arising from unhealed fracture, by reducing the referral time to orthopaedic surgery, scheduling review by injury type rather than by a blanket target review time, or keeping current referral times but prioritising minor fracture on rolling trauma lists.

Developers were asked to ratify objectives of service delivery change by using following components: Purpose; Target Performance; Change; Constraints

- To explore reducing the number of patients returning with complications arising from minor fracture (purpose) [to a minimum of 10% of all presenting fractures (target performance)] by reducing the timing of referral to the orthopaedic surgeon (change) to a maximum of 4 hours post arrival, 10 hours post arrival and 24 hours post arrival (constraint)
- To explore reducing the number of patients returning with complications arising from minor fracture (purpose) [to a minimum of 10% of all presenting fractures (target performance)] by prioritising minor fracture surgery on rolling trauma list (change) keeping in mind priority complex fractures represent 10% of all workload and should be prioritised over minor fractures (constraint)

Several aspects of the non-complex fracture scope have service delivery implications and there were several overlapping themes and variables to consider in determining the optimal referral strategy (with reference to timing). With complex and multicomponent strategies, a typical review question structure (i.e. a PICO) where specific interventions are compared may not be appropriate in informing decision making on this topic.

A workshop was designed where an iterative approach to decision making using participatory methods designed to define and structure complex “messy” system/service problems could be developed. The workshop was set up with these objectives in mind:

- Introduce participatory methods (i.e. conceptual and process mapping)
- Explore the decision problem from a variety of perspectives, including:
    - The patient journey through the system (patient flow)
    - Clinical patient status (healing vs. deterioration of fracture)
    - Looking at outcomes from clinical activities undertaken in the system
- Agree what is critical to consider in decision making
- Agree a definition of the problem and write objectives of the review(s).

At subsequent meetings, aims and objectives of the work were refined.

From the conceptual mapping discussion, developers felt the following reviews inform critical parameters of the model:

- Referral pathway decision-maker
- Referral to virtual fracture clinics compared to face to face fracture clinics
- Referral Destinations (specialist versus generalist)

These are presented in the sections below.

8.4.1 Referral pathway decision-makers

8.4.1.1 Introduction

Some people with non-complex fractures (NCFs) who have been discharged home from the emergency department require further referral. This question revolves around what specialism and grade of health professional, or multi-disciplinary team of health professionals, is the most clinically and cost effective at making this referral.

8.4.1.2 Review question: Who are the most clinically and cost-effective referral pathway decision-makers for patients with non-complex fractures?

For full details see review protocol in Appendix C.

Table 80: PICO characteristics of review question (Referral pathway decision-makers (MDT))

Population	People who have been discharged home from ED (i.e. not admitted to hospital) after first attendance with suspected NCF (initial imaging has happened) who require a management plan
Interventions	• Consultant orthopod • Consultant ED • Registrar • Junior or SHO • Nurse • Extended practitioner • Physiotherapist • Locum for each of above
Comparison	Combinations of the above compared to each other
Outcomes	Critical • Patients recalled for change of management • Number of different types of attendances • Unnecessary attendance at a clinic • Time to definitive management plan • Number of referrals to a specialist clinic • Indicator of patient satisfaction (including quality of life) • Other measure of efficiency of management plan process
Study design	RCTs or Systematic reviews of RCTs; observational studies if insufficient RCT evidence is retrieved. If cohorts are used, these must consider all the key confounders chosen by the GDG.

8.4.1.3 Clinical evidence

Two observational studies were included in the review.[50,174] They are summarised in Table 81 below. Evidence from these studies are summarised in the clinical evidence summaries below (Table 82 to Table 93). See also the study selection flow chart in Appendix D, study evidence tables in Appendix G, forest plots in Appendix J, and excluded studies list in Appendix K.

East et al. 2014 reviewed the charts of people diagnosed with non-complex fractures who were referred to a fracture clinic. It noted down the level of the referring health professional and whether the referral was correct. A referral was determined to be incorrect if the person required no orthopaedic follow-up or treatment. The paper provided no details of how decisions were made and whether other health professionals were consulted during the referral process.

Table 81: Summary of studies included in the review

Study	Intervention and comparison	Population	Outcomes	Comments
East 2014[50] Retrospective chart review	Referral to fracture clinics from A&E by • Consultants • Registrars • SHO • Clinical nurse specialists Compared to each other	n=101 Consecutive patients referred from A&E department to an orthopaedic fracture clinic	• Unnecessary attendance at a clinic (i.e. Discharge after one attendance without any further physical management undertaken) • Positive predictive value for each grade of health professional	Conducted in Ireland Orthopaedic injuries included in study where N ≥ 2: • Metacarpal fractures • Radial fractures • Clavicle fractures • Humerus fractures • Metatarsal fractures • Scaphoid fractures • Shoulder dislocations • Fibula fractures • Vertebrae fractures • Ankle sprains • Ulna fractures • Acromioclavicular sprains
Snaith 2014[174] Observational data taken from a larger RCT	Referral to specialist clinics from A&E by • Consultants • Senior doctor • Junior doctor • Emergency nurse practitioner Compared to each other	n=598 Patients discharged from A&E after being imaged	• Number of referrals to specialist clinics	Conducted in UK

Unnecessary attendance at a clinic

Table 82: Clinical evidence summary: consultant versus SHO

Outcome	Number of studies (number of participants)	Imprecision	GRADE rating	Absolute difference	Control event rate (per 1000)	Control event rate for continuous outcomes
No intervention after first attendance at fracture clinic	1 (n=22)	Very serious	Very low	105 more per 1000 (from 50 fewer to 1000 more)	63	NA

Table 83: Clinical evidence summary: consultant versus clinical nurse specialist

Outcome	Number of studies (number of participants)	Imprecision	GRADE rating	Absolute difference	Control event rate (per 1000)	Control event rate for continuous outcomes
No intervention after first attendance at fracture clinic	1 (n=16)	Very serious	Very low	232 fewer per 1000 (from 376 fewer to 764 more)	400	NA

Table 84: Clinical evidence summary: consultant versus registrar

Outcome	Number of studies (number of participants)	Imprecision	GRADE rating	Absolute difference	Control event rate (per 1000)	Control event rate for continuous outcomes
No intervention after first attendance at fracture clinic	1 (n=62)	Very serious	Very low	13 fewer per 1000 (from 154 fewer to 911 more)	179	NA

Table 85: Clinical evidence summary: SHO versus clinical nurse specialist

Outcome	Number of studies (number of participants)	Imprecision	GRADE rating	Absolute difference	Control event rate (per 1000)	Control event rate for continuous outcomes
No intervention after	1 (n=26)	Serious	Very low	336 fewer per 1000	400	NA

Outcome	Number of studies (number of participants)	Imprecision	GRADE rating	Absolute difference	Control event rate (per 1000)	Control event rate for continuous outcomes
first attendance at fracture clinic				(from 392 fewer to 84 more)		

Table 86: Clinical evidence summary: registrar versus SHO

Outcome	Number of studies (number of participants)	Imprecision	GRADE rating	Absolute difference	Control event rate (per 1000)	Control event rate for continuous outcomes
No intervention after first attendance at fracture clinic	1 (n=72)	Very serious	Very low	117 more per 1000 (from 38 fewer to 1000 more)	63	NA

Table 87: Clinical evidence summary: registrar versus clinical nurse specialist

Outcome	Number of studies (number of participants)	Imprecision	GRADE rating	Absolute difference	Control event rate (per 1000)	Control event rate for continuous outcomes
No intervention after first attendance at fracture clinic	1 (n=66)	Serious	Very low	220 fewer per 1000 (from 332 fewer to 60 more)	400	NA

Number of referrals to specialist clinics

Table 88: Clinical evidence summary: consultant versus senior doctor

Outcome	Number of studies (number of participants)	Imprecision	GRADE rating	Absolute difference	Control event rate (per 1000)	Control event rate for continuous outcomes
Number of referrals to specialist clinics	1 (n=242)	Very serious	Very low	7 fewer per 1000 (from 135 fewer to	365	NA

Outcome	Number of studies (number of participants)	Imprecision	GRADE rating	Absolute difference	Control event rate (per 1000)	Control event rate for continuous outcomes
				193 more)		

Table 89: Clinical evidence summary: consultant versus junior doctor

Outcome	Number of studies (number of participants)	Imprecision	GRADE rating	Absolute difference	Control event rate (per 1000)	Control event rate for continuous outcomes
Number of referrals to specialist clinics	1 (n=112)	Very serious	Very low	14 more per 1000 (from 130 fewer to 257 more)	343	NA

Table 90: Clinical evidence summary: consultant versus ENP

Outcome	Number of studies (number of participants)	Imprecision	GRADE rating	Absolute difference	Control event rate (per 1000)	Control event rate for continuous outcomes
Number of referrals to specialist clinics	1 (n=276)	Serious	Very low	84 fewer per 1000 (from 207 fewer to 110 more)	440	NA

Table 91: Clinical evidence summary: Senior doctor versus junior doctor

Outcome	Number of studies (number of participants)	Imprecision	GRADE rating	Absolute difference	Control event rate (per 1000)	Control event rate for continuous outcomes
Number of referrals to specialist clinics	1 (n=270)	Very serious	Very low	21 more per 1000 (from 93 fewer to 185 more)	343	NA

Table 92: Clinical evidence summary: Senior doctor versus ENP

Outcome	Number of studies (number of participants)	Imprecision	GRADE rating	Absolute difference	Control event rate (per 1000)	Control event rate for continuous outcomes
Number of referrals to specialist clinics	1 (n=434)	Serious	Very low	75 fewer per 1000 (from 150 fewer to 22 more)	440	NA

Table 93: Clinical evidence summary: Junior doctor versus ENP

Outcome	Number of studies (number of participants)	Imprecision	GRADE rating	Absolute difference	Control event rate (per 1000)	Control event rate for continuous outcomes
Number of referrals to specialist clinics	1 (n=304)	Serious	Very low	97 fewer per 1000 (from 198 fewer to 48 more)	440	NA

Evidence not suitable for GRADE (Referral pathway decision-makers (MDT))

The study also presented the positive predictive value (PPV) of each level of health professional for correct referrals to a fracture clinic. This was not suitable for GRADE because the outcomes do not fit into the standard diagnostic GRADE table. The PPV is the probability of having the condition in people with a positive index test result. This evidence was assessed to be at very high risk of bias.

Table 94: Positive predictive value of correct referrals to fracture clinics

Level of referring health professional	Number of referrals	Incorrect referrals	PPV
Consultant	6	1	83%
Registrar	56	10	82%
SHO	16	1	94%
Clinical nurse specialist	10	4	60%
Undocumented	20	3	85%

8.4.1.4 Economic evidence

Published literature

No relevant economic evaluations were identified.

8.4.1.5 Evidence statements

Clinical

Very low quality evidence from 1 observational study comprising 22 participants showed that SHOs were clinically effective compared to consultants in terms of unnecessary referral, with very serious imprecision

Very low quality evidence from 1 observational study comprising 16 participants showed that consultants were clinically effective compared to clinical nurse specialists in terms of unnecessary referral, with very serious imprecision

Very low quality evidence from 1 observational study comprising 62 participants showed there was no difference in clinical effectiveness between consultants and registrars in terms of unnecessary referral, with very serious imprecision

Very low quality evidence from 1 observational study comprising 26 participants showed that SHOs were clinically effective compared to clinical nurse specialists in terms of unnecessary referral, with serious imprecision

Very low quality evidence from 1 observational study comprising 72 participants showed that SHOs were clinically effective compared to registrars in terms of unnecessary referral, with very serious imprecision

Very low quality evidence from 1 observational study comprising 66 participants showed that registrars were clinically effective compared to clinical nurse specialists in terms of unnecessary referral, with serious imprecision

Very low quality evidence from 1 observational study comprising 242 participants showed there was no difference between consultants and senior doctors in terms of number of referrals to specialist clinics, with very serious imprecision

Very low quality evidence from 1 observational study comprising 112 participants showed there was no difference between consultants and junior doctors in terms of number of referrals to specialist clinics, with very serious imprecision

Very low quality evidence from 1 observational study comprising 276 participants showed there was no difference between consultants and emergency nurse practitioners in terms of number of referrals to specialist clinics, with serious imprecision

Very low quality evidence from 1 observational study comprising 270 participants showed there was no difference between senior doctors and junior doctors in terms of number of referrals to specialist clinics, with very serious imprecision

Very low quality evidence from 1 observational study comprising 434 participants showed there was no difference between senior doctors and emergency nurse practitioners in terms of number of referrals to specialist clinics, with serious imprecision

Very low quality evidence from 1 observational study comprising 304 participants showed there was no difference between junior doctors and emergency nurse practitioners in terms of number of referrals to specialist clinics, with serious imprecision

Economic

No relevant economic evaluations were identified.

8.4.2 Referral to virtual fracture clinics compared to face to face fracture clinics

8.4.2.1 Review question: What is the clinical and cost effectiveness of referral to virtual fracture clinics compared to face to face fracture clinics for patients with NCF?

For full details see review protocol in Appendix C.

Table 95: PICO characteristics of review question

Population	People who have been discharged home from ED (i.e. not admitted to hospital) after first attendance with suspected NCF (initial imaging has happened) who require a management plan.
Interventions	• Virtual decision • Face to face meeting
Comparison	To each other
Outcomes	Accuracy of achieving appropriate management plan (assume that OT formulated management plan is gold standard): Proxy outcomes are: • Number of recalled patients requiring change of management • Number of different types of attendances (i.e. to show number of times management plan not formulated). • Unnecessary attendance at a clinic (i.e. Discharge after one attendance without any further physical management undertaken.) • Time to definitive management plan (i.e. in person attendance at a fracture clinic vs no attendance needed?) • Number of referrals to a specialist clinic? • Indicator of patient satisfaction (inc.QoL) Population size and directness: • No limitations on sample size • Studies with indirect populations will not be considered.

Study design	RCTs or Systematic reviews of RCTs; cohorts if no RCTs retrieved, before and after studies

8.4.2.2 Clinical evidence

Two non-randomised studies were included in the review.[22,91] These are summarised in Table 96 below. Evidence from these studies is summarised in the narrative review. See also the study selection flow chart in Appendix D, study evidence tables in Appendix G, forest plots in Appendix J, GRADE tables in Appendix I and excluded studies list in Appendix K.

Table 96: Summary of studies included in the review

Study	Intervention and comparison	Population	Outcomes	Comments
Beiri 2006[22]	**Intervention:** Consultant rapid review of patient notes, leading to a decision on which of the following options: routine out-patient clinic, nurse led fracture clinic, and recall for change of management or discharge to GP care. **Comparison:** Routine out-patient fracture clinics	1364 people with musculoskeletal injuries and all sources of referrals at Leicester Royal Infirmary.	Average time to review a patient	Historical cohort study, comparing a cohort receiving intervention in May 2004 to a different cohort receiving comparator in September 2004. Very serious risk of bias, with no adjustments for likely selection bias, and potential attrition and detection bias.
Jenkins 2014[91]	**Intervention:** virtual clinic or ED discharge **Comparison:** Routine out-patient fracture clinics	598 people with fractures. No characteristics reported	Number of appointments per patient Subsequent non-union	Very poor reporting, making it impossible to judge risk of bias – hence very high risk of bias by default/ Only a sub-set of participants with 5th meta-tarsal fractures contributed towards outcomes extracted for this review. These did not experience the main virtual clinic review, instead being discharged straight from ED with information and telephone support. Thus these results are probably very indirect.

Narrative review

Beiri 2006[22] compared the average time taken to review a patient, with a mean (range) of 1 minute (0.42 – 1.86) in the pre-fracture clinics group and 11 minutes (8.2 – 14.1) in the general group. [VERY LOW QUALITY]

Jenkins 2014[91] compared the number of appointments in each group, with 1.76 appointments per patient in the time when face to face clinics were used, and 0.32 appointments per patient in the time when the virtual clinic protocol was in use. This did not appear to adversely affect clinical

outcomes, with no significant effect on the incidence of subsequent reduction and fixation for non-union [OR for face to face versus virtual: 0.72 (95% CIs: 0.17-3.07); p=0.735] [VERY LOW QUALITY].

8.4.2.3 Economic evidence

Published literature

No relevant economic evaluations were identified.

8.4.2.4 Evidence statements

Clinical

Two observational studies comprising 1962 people showed that virtual clinics reduced consultation times and the number of appointments compared to face to face clinics, with very serious imprecision.

Economic

No relevant economic evaluations were identified.

8.4.3 Referral Destinations (specialist versus generalist)

8.4.3.1 Review question: What is the clinical and cost effectiveness of different referral destinations for patients with non-complex fractures?

For full details see review protocol in Appendix C.

Table 97: PICO characteristics of review question: Referral destinations (specialist versus generalist)

Population	People who have been discharged home from ED (i.e. not admitted to hospital) after first attendance with suspected NCF (initial imaging has happened) who require a management plan.
Interventions	• General fracture clinic • Specialist clinic
Comparison	Each other
Outcomes	Accuracy of achieving appropriate management plan (assume that OT formulated management plan is gold standard): Proxy outcomes are: • Number of recalled patients requiring change of management • Number of different types of attendances (i.e. to show number of times management plan not formulated). • Unnecessary attendance at a clinic (i.e. Discharge after one attendance without any further physical management undertaken.) • Time to definitive management plan (i.e. in person attendance at a fracture clinic vs no attendance needed?) • Number of referrals to a specialist clinic? • Indicator of patient satisfaction (inc.QoL) Population size and directness: • No limitations on sample size • Studies with indirect populations will not be considered.

Study design	RCTs or Systematic reviews of RCTs; cohorts if no RCTs retrieved, before and after studies

Clinical evidence:

No eligible randomised or observational studies were found. See the study selection flow chart in Appendix D and excluded studies list in Appendix K.

8.4.3.2 Economic evidence

Published literature

No relevant economic evaluations were identified.

8.4.3.3 Evidence statements

Clinical

No relevant clinical evidence was identified.

Economic

No relevant economic evaluations were identified.

8.4.4 Recommendations and link to evidence

Recommendations	**Research recommendation: What is the clinical and cost effectiveness of virtual new patient fracture clinics compared with next-day consultant-led face-to-face clinics in people presenting with non-complex fractures in the emergency department and thought to need an orthopaedic opinion?**
Relative values of different outcomes	For all three separate questions, the chosen outcomes were the same. Any outcome demonstrating the accuracy of achieving an appropriate management plan was regarded as critical. Possible outcomes, which can all be regarded as of equal priority, include: • Number of recalled patients requiring change of management. • Number of different types of attendances (i.e. to show number of times management plan not formulated). • Unnecessary attendance at a clinic (that is, discharge after one attendance without any further physical management undertaken). • Time to definitive management plan (i.e. in person attendance at a fracture clinic vs. no attendance needed). • Number of referrals to a specialist clinic. • Indicator of patient satisfaction (including quality of life).
Trade-off between clinical benefits and harms	**MDT** One retrospective chart review compared the accuracy of referral from A&E to fracture clinics by consultants, registrars, senior house officers (SHOs), and clinical nurse specialists. This was measured by 'unnecessary attendance' (discharge after one attendance without any further physical management undertaken). SHOs were the least likely to refer people for unnecessary attendance at a fracture clinic, followed by consultants, registrars, and clinical nurse specialists. **Virtual versus face-to-face clinics** Two observational studies showed there was a clinical benefit from virtual clinics in

	terms of shorter consultation times and fewer appointments per person from virtual clinics, and no reported harms. **Specialist clinics versus general fracture clinics** No evidence was found
Economic considerations	No economic evidence was identified for this area. The GDG chose the referral pathways topic as the second modelling priority for the non-complex fractures guideline and a conceptual model was developed with input from the GDG. However, due to a lack of good quality clinical evidence, it was decided that there would be no benefit in continuing to develop the model fully. Three questions were reviewed to inform parameters of the planned model. These assessed the accuracy of the decision by the MDT in ED for referral to the fracture clinic; the clinical effectiveness of virtual fracture clinics compared to face-to-face clinics and the clinical effectiveness of specialist versus general fracture clinic referral. If good quality evidence was available then these would have been used in a model to assess the costs and benefits of the various combinations of strategies from these three questions. So, for example, if the most accurate MDT strategy is used for decision making, there may be no need to have virtual triage as there may be very few unnecessary referrals if the decision is made accurately in the first instance. This could then be compared against a less accurate initial decision but using virtual fractures clinics to reduce the number of unnecessary referrals to the fracture clinic. The number of unnecessary referrals to the fracture clinic will then impact the benefit of general fracture clinics versus specialist fracture clinics. The GDG considered the clinical evidence that was available and believed that, due to its very low quality, a recommendation could not be made based on a model informed by these studies. The GDG agreed that the economic aspects of the referral pathway were largely due to the accuracy of decisions and the number of unnecessary attendances at the fracture clinic as well as the cost of providing additional services such as virtual triage. Therefore, the GDG believed that a research recommendation was necessary to provide better quality evidence to inform a model assessing referral pathways for non-complex fractures.
Quality of evidence	Quality of the observational evidence was graded as very low, largely due to likely selection, performance and detection bias in all observational studies across the three reviews. In addition there was considerable uncertainly around point estimates for all comparative outcomes, and statistical reporting in primary studies was poor.
Other considerations	Taken together, and at face value, the findings from the four reviews suggested that SHOs were the best clinician to appropriately refer patients to fracture clinic, and that a virtual fracture clinic was preferable to a face to face clinic. However, overall the evidence was regarded as too weak and insufficient to inform any recommendations, and the GDG felt a research recommendation would be the optimal approach.

9 Ongoing orthopaedic management

9.1 Non-surgical orthopaedic management of unimalleolar ankle fractures

9.1.1 Introduction

Stable ankle fractures are common traumatic injuries, usually involving fracture of a single malleolus. Currently there is variation in advice given around mobilisation and weight-bearing for people who have this injury as the evidence base is unclear. Early unrestricted weight bearing as tolerated is thought to be beneficial to the patient in terms of avoiding disuse atrophy, and improving ambulatory function and quality of life. However there is also concern amongst some clinicians that early unrestricted weight-bearing may lead to displacement of the fracture, with subsequent malunion or need for surgery. There is therefore a need for a review of the available evidence so that appropriate recommendations can be made.

9.1.2 Review question: What is the most clinically- and cost-effective mobilisation strategy in patients with stable ankle fractures?

For full details see review protocol in Appendix C.

Table 98: PICO characteristics of review question

Population	Children, young people and adults experiencing a stable ankle fracture following a traumatic incident
Intervention(s)	Immediate unrestricted weight bearing (weight bearing as tolerated)
Comparison(s)	Delayed unrestricted weight-bearing (partial weight bearing, touch weight bearing, non-weight bearing, protected weight bearing)
Outcomes	Critical: • Health-related quality of life • Patient-reported outcomes (OMAS, AAOFAS, DRI) • Return to normal activities • Displacement • Need for operative treatment • Non-union/malunion • DVT/PE at 3 months Important: • Number of hospital/out-patient attendances • Length of hospital stay, length till return to normal residence/ step down
Study design	RCTs or systematic reviews of RCTs: cohorts if insufficient RCT evidence found

9.1.3 Clinical evidence

No relevant clinical studies were identified. See the study selection flow chart in Appendix D and excluded studies list in Appendix K.

9.1.4 Economic evidence

Published literature

No relevant economic evaluations were identified.

See also the economic article selection flow chart in Appendix E.

9.1.5 Evidence statements

Clinical

No relevant clinical studies were identified.

Economic

No relevant economic evaluations were identified.

9.1.6 Recommendations and link to evidence

Recommendations	**15. In the non-surgical orthopaedic management of unimalleolar ankle fractures:** • **advise immediate unrestricted weight-bearing as tolerated** • **arrange for orthopaedic follow-up within 2 weeks if there is uncertainty about stability** • **advise all patients to return for review if symptoms are not improving 6 weeks after injury.**
Relative values of different outcomes	Critical outcomes were health-related quality of life, patient reported outcomes (OMAS, AAOFAS, DRI), return to normal activities, displacement, need for operative treatment, non-union/malunion and DVT/PE at 3 months. Important outcomes were the number of hospital/out-patient attendances and the length of hospital stay/length until return to normal residence.
Trade-off between clinical benefits and harms	No evidence was identified for this question and so this recommendation was made based on GDG consensus. The GDG considered a precautionary approach to weight bearing and mobilisation in patients with ankle fractures may unnecessarily delay early return to normal activities. However they recognised that a treating clinician has to make a decision on the likely stability of an ankle fracture. A single fractured malleolus is the most common radiographic presentation of a potentially stable ankle fracture, and if it presents as minimally displaced on initial x-ray without prior intervention it is unlikely to displace under physiological conditions, such as unrestricted weight-bearing while walking. Unimalleolar fractures include Weber Grade A and B fractures of the lateral malleolus and medial malleolar fractures and exclude minor avulsion flake fractures and posterior malleolus fractures. These fractures do not require manipulation. Therefore the GDG made their consensus recommendation in relation to this group. More complex fracture patterns are much less likely to represent a stable injury and they would have a different balance of clinical costs and benefits from early loading and mobilisation. For example, if fractures affect more than one of the malleoli, the injury is more mechanically unstable and therefore more likely to displace when loaded. This latter group were excluded in order to simplify the recommendation while keeping it applicable to the majority of potentially stable fractures.

	In those fractures where the stability of ankle to unrestricted weight-bearing was uncertain, for example where there is bruising around both sides of the ankle, there was a small risk of displacement during loading. In those cases the GDG recommended review with X-ray at one week. The GDG felt that in the rare cases where the fracture had displaced, surgery would still be possible at one week with no increase in the risk of complications. The GDG felt that patients with unimalleolar fractures not requiring surgery were unlikely to have complications related to loading if they were able to walk with unrestricted weight-bearing during the first week. Therefore, routine review of these patients was not required. However, the GDG recommended that people should be encouraged to return for review if no symptomatic improvement had occurred at 6 weeks. Overall, the GDG agreed that the small risk of displacing a unimalleolar fracture that has not been manipulated do not outweigh the benefits gained from immediate mobilisation and so recommended immediate unrestricted weight bearing.
Economic considerations	No economic evidence was found to inform this review. Weight bearing mobilisation is important for the recovery of a patient with a stable ankle fracture. It promotes healing and improves mobility, which can improve functional outcomes and reduce hospital stay. This can therefore reduce costs and improve the quality of life of the patient. If immediate full weight bearing is encouraged early, most patients will benefit. However, in those cases where the stability of the ankle fracture is uncertain, the patient may still require surgery, so there is a trade-off between the benefits of immediate weight-bearing and the increased costs of surgery. Delaying weight bearing will incur greater costs of hospital stay, as well as reducing the functional outcome for patients. This increased hospital stay can also increase the risk of adverse events such as pressure sores, deep vein thrombosis, urinary tract infections and chest infections. These will incur further costs for treatment. The GDG came to the consensus that immediate full weight bearing was more likely to be cost effective as most patients would benefit and this would outweigh the costs and effects of those who do not.
Quality of evidence	No relevant clinical studies were identified.
Other considerations	No other considerations were identified.

9.2 Ankle imaging

9.2.1 Introduction

Ankle fractures are a common injury affecting a significant number of people every year. Outcomes following surgery may have significant implications for patients' long-term function and quality of life, and may also have an additional cost through re-operations. X-rays are the usual first-line imaging choice for diagnosing fractures. While these are effective at ruling out people who do not have a fracture X-rays do not always provide a full picture of the fracture. CT imaging does provide a more complete image but it is unclear whether this is beneficial or cost-effective for planning when an X-ray has already been obtained. This review investigated whether the use of CT scanning in

addition to plain film X-ray was clinically- and cost-effective in improving patient outcome following surgery for ankle fractures.

9.2.2 Review question: Is the use of CT scanning in addition to initial plain film X-ray clinically- and cost-effective for planning surgical treatment of unstable/displaced ankle fractures?

For full details see review protocol in Appendix C.

Table 99: PICO characteristics of review question

Population	Children, young people and adults with ankle fractures following a traumatic incident, in whom surgery is undertaken
Intervention(s)	CT scanning
Comparison(s)	No CT scanning
Outcomes	Critical: • Health-related quality of life • Pain/discomfort • Return to normal activities • Psychological wellbeing • unnecessary imaging • need for revision surgery • functional outcomes Important: • Radiological outcomes – satisfactory fracture reduction.
Study design	RCTs or Systematic reviews of RCTs

9.2.3 Clinical evidence

No relevant clinical studies were identified to answer this review question. See the study selection flow chart in Appendix D and excluded studies list in Appendix K.

9.2.4 Economic evidence

Published literature

No relevant economic evaluations were identified.

See also the economic article selection flow chart in Appendix E.

9.2.5 Evidence statements

Clinical

No relevant clinical studies were identified.

Economic

No relevant economic evaluations were identified.

9.2.6 Recommendations and link to evidence

Recommendation	**Research recommendation: Is CT scanning in addition to initial plain film X-**

	ray clinically effective and cost effective for planning surgical treatment of unstable/displaced ankle fractures compared with plain film X-ray alone?
Relative values of different outcomes	While diagnostic cohort studies can tell us about the relative accuracy of a diagnostic test compared to a reference standard, they do not tell us whether adopting a particular diagnostic strategy improves patient outcomes. Evidence on patient outcomes is only available from diagnostic randomised controlled trials which compare two diagnostic interventions with identical subsequent treatment as indicated by the diagnostic test. No RCTs or diagnostic accuracy studies were found For the RCT outcomes critical outcomes were health-related quality of life, pain/discomfort, return to normal activities, psychological wellbeing, unnecessary imaging, need for revision surgery and functional outcomes. Radiological outcomes that assessed whether a satisfactory reduction was achieved was identified as an important outcome. Sensitivity and specificity were the outcomes for the diagnostic accuracy studies.
Trade-off between clinical benefits and harms	No clinical evidence was found and so the benefits and harms had to be discussed via consensus. The GDG suspected that CT imaging may improve the clinical outcome of surgery by providing surgeons with details about the location and extent of a fracture, and will therefore lead to a more effective reduction.
Economic considerations	No economic evidence was identified for this question. An additional CT scan incurs a cost of around £85 and so there needs to be a clinical benefit in order to justify this increase in cost. The GDG believe that it will be beneficial in planning surgery for ankle fractures, which will allow surgery to be performed more effectively and therefore reduce the recovery time of the patient and therefore reduce hospital stay. They also believe that it can have an effect on the long term outcomes for the patient. Due to the lack of clinical evidence the GDG decided that a research recommendation was necessary as they weren't confident enough to make a consensus recommendation.
Quality of evidence	No clinical evidence was found for this question.
Other considerations	Because CT scanning would incur an additional cost and an increased radiation risk, the GDG did not wish to make a recommendation to use CT scanning prior to surgery for all ankle fractures. The GDG chose to make a research recommendation to definitively investigate if ankle fractures may benefit from CT scanning prior to surgical intervention. The GDG noted that the use of CT imaging prior to surgery may only be clinically and cost effective for use in the planning of surgery for a subset of ankle fractures.

9.3 Timing of surgery – ankle fractures

9.3.1 Introduction

Ankle fractures requiring surgery are common; however, there is uncertainty in clinical practice about the appropriate timing of surgery. Some clinicians delay surgery due to concerns about operating while the injury is swollen and the integrity of the skin may be compromised, while other clinicians may operate quickly to reduce the risk of infection and reduce the need for inpatient care. This review investigated the clinical- and cost-effectiveness of different timings of surgery to guide practice.

9.3.2 Review question: What is the most clinically- and cost-effective timing of surgical treatment of an ankle fracture?

For full details see review protocol in Appendix C.

Table 100: PICO characteristics of review question

Population	Children, young people and adults who have experienced a traumatic incident
Intervention(s)	Surgery: • ≤24 hours post injury • 24–48 hours post injury • 2–7 days post injury • 8–13 days post injury • ≥14 days post injury
Comparison(s)	Comparison of the above
Outcomes	Critical: • Pain/discomfort • Return to normal activities • Psychological wellbeing • Inpatient length of stay • Health-related quality of life • Skin breakdown • Wound infection • VTE Important: • Physiotherapy appointments
Study design	RCTs of systematic reviews of RCTs; cohorts if no RCTs are retrieved. If cohorts are used, these must consider all the key confounders chosen by the GDG.

The aim of this review was to evaluate the optimal timing for scheduling surgery for ankle fractures. The GDG decided to compare the clinical- and cost-effectiveness of timings of ankle surgery that corresponded with the organisation of trauma services, that is, whether surgery should always be performed on the day of, or the day after injury; whether surgery could wait until after the weekend, and/or whether surgery could be delayed by one or two weeks to prioritise surgery for other injuries. In anticipation that some studies may have compared groups receiving surgery at times other than those specified in the review protocol, it was decided that for the purpose of the analysis, such studies would be allocated to groups based on the mean time to surgery as reported in the study. Where the mean time to surgery was not reported in the published report, authors were contacted on a maximum of two occasions to request this data. Where authors did not respond or were unable to access this data, these studies were allocated to the most relevant group for analysis. A significant number of studies meeting the inclusion criteria for this review reported insufficient data for analysis and were excluded from the final report.

9.3.3 Clinical evidence

We searched for studies comparing the clinical effectiveness of different timings of ankle surgery. No randomised trials were identified. Nine cohort studies were subsequently included in the review;[30,77,89,107,117,160,162,172,195] these are summarised in Table 101 below. The majority of the evidence compared surgery within 24 hours with surgery at later time points, and two studies compared surgery between 24–48 hours with surgery at later time points. No relevant clinical studies comparing surgery within 24 hours with surgery within 24–48 hours, or surgery within 2–7 days with surgery at later time points were identified. Evidence from the included studies is summarised in the clinical evidence summary below (Table 101). See also the study selection flow chart in Appendix D, study evidence tables in Appendix G, forest plots in Appendix J, GRADE tables in Appendix I and excluded studies list in Appendix K.

Table 101: Summary of studies included in the review

Study	Intervention/ comparison	Population	Outcomes	Comments
Breederveld 1988[30]	Surgery <24 hours versus surgery within 5–8 days (no mean time to surgery)	Patients (age range not reported) with a unilateral fracture (closed or open) requiring surgery	Inpatient length of stay, wound infection	Inpatient length of stay not analysed due to insufficient data in the published report
Hoiness 2000[77]	Surgery <8 hours versus surgery >5 days (mean time to surgery=8.2 days)	Patients (age range not reported) with a closed ankle fracture	Inpatient length of stay, wound infection, skin breakdown, VTE	–
James 2001[89]	Surgery <24 hours versus surgery within 2–15 days (mean time to surgery=5.5 days)	Patients (age range not reported) with a closed ankle fracture requiring operative treatment	Inpatient length of stay	Standard deviations for the two comparisons were not reported in the paper and were estimated for the purpose of analysis
Konrath 1995[107]	Surgery <5 days (mean time to surgery=1.5 days) versus surgery >5 days (mean time to surgery=13.6 days)	Patients (age range not reported) with closed, unstable Weber B bimalleolar or bimalleolar equivalent ankle fractures	Inpatient length of stay, wound infection	Inpatient length of stay not analysed due to insufficient data in the published report
Manoukian 2013[117]	Surgery <24 hours versus surgery >24 hours (mean time to surgery=3.7 days)	Patients (age range=13–90 years) with ankle fractures requiring surgery	Inpatient length of stay	–
Saithna 2009[160]	Surgery <6 days (mean time to surgery = 1.98 days) versus surgery ≥6 days (mean time to surgery = 9.46 days)	Patients (age range=16.4–82.2 years) with closed ankle fractures	Wound infection	–
Schepers 2013[162]	Surgery <24 hours versus surgery >24 hours (no mean time to surgery)	Patients (age range=16–65 years) with closed ankle fracture treated using plating of the fibula	Wound infection	–
Singh 2005[172]	Surgery <24 hours versus surgery >24 hours (mean time to surgery = 3.1 days)	Skeletally mature patients (age range=19–90 years) with an ankle fracture requiring surgery	Inpatient length of stay, wound infection, wound breakdown	Standard deviations for the two comparisons were not reported in the paper and were estimated for the purpose of

Study	Intervention/ comparison	Population	Outcomes	Comments
				analysis
Westacott 2010[195]	Surgery <24 hours versus surgery 1-7 days (mean time to surgery=2.7 days)	Children and adults (age range=13–88 years) with an isolated closed ankle fracture	Inpatient length of stay	Inpatient length of stay assessed only for the time period after surgery

Table 102: Clinical evidence summary: Surgery <24 hours versus surgery at later time points

Outcome	Number of studies (participants)	Imprecision	GRADE rating	Absolute difference	Control event rate (per 1000)	Control event rate for continuous outcomes
Hospital length of stay (days): <24 hours versus 2–7 days	4(n=318)	No serious imprecision	VERY LOW	MD 3.86 lower (5.21 to 2.52 lower)	-	10
Hospital length of stay (days): <24 hours versus 8–13 days	1(n=84)	No serious imprecision	VERY LOW	MD 12.4 lower (17.39 to 7.41 lower)	-	19.6
Infection: <24 hours versus 2–7 days	2(n=154)	Serious imprecision	VERY LOW	101 fewer per 1000 (from 195 fewer to 8 fewer)	125	-
Infection: <24 hours versus 8–13 days	1(n=84)	No serious imprecision	VERY LOW	147 fewer per 1000 (from 332 fewer to 39 more)	177	-
Infection: <24 hours versus >24 hours	1(n=205)	No serious imprecision	VERY LOW	110 fewer per 1000 (from 167 fewer to 54 fewer)	110	-
Wound breakdown: <24 hours versus 2–7 days	1(n=62)	Serious imprecision	VERY LOW	91 more per 1000 (from 41 fewer to 223 more)	0	-
Wound breakdown: <24 hours versus 8–13 days	1(n=84)	Serious imprecision	VERY LOW	191 fewer per 1000 (from 398 fewer to 17 more	235	-
VTE : <24 hours versus 8–13 days	1(n=84)	Very serious imprecision	VERY LOW	0 fewer per 1000 (from 79 fewer to 79 more)	0	-

Table 103: Clinical evidence summary: surgery within 24–48 hours versus. surgery at later time points

Outcome	Number of studies (participants)	Imprecision	GRADE rating	Absolute difference	Control event rate (per 1000)	Control event rate for continuous outcomes

Outcome	Number of studies (participants)	Imprecision	GRADE rating	Absolute difference	Control event rate (per 1000)	Control event rate for continuous outcomes
Infection: 24–48 hours versus 8–13 days	1(n=85)	Serious imprecision	VERY LOW	172 fewer per 1000 (from 41 fewer to 199 fewer)	207	-
Infection: 24–48 hours versus >14 days (any wound complication; including infection and wound breakdown)	1(n=202)	Very serious imprecision	VERY LOW	14 fewer per 1000 (from 47 fewer to 89 more)	62	-

9.3.4 Economic evidence

Published literature

One comparative cost study was identified with the relevant comparison and has been included in this review.[117] This is summarised in the economic evidence profile below (Table 104) and the economic evidence tables in Appendix H.

See also the economic article selection flow chart in Appendix E.

Table 104: Economic evidence profile: Early versus delayed surgery

Study	Applicability	Limitations	Other comments	Incremental cost[c]	Incremental effects	Cost effectiveness	Uncertainty
Manoukian 2013[117] (UK)	Partially applicable[a]	Potentially serious limitations[b]	Cost comparison based on a retrospective within-group analysis of hospital stay	**>24 hours versus <24 hours** £798 **>48 hours versus <48 hours** £1488	n/a	n/a	No analysis undertaken

(a) Relevant comparison with a UK NHS perspective, however, no health outcomes are included.
(b) Based on a retrospective within-group analysis, which could be prone to bias. Only the cost of inpatient stay is included and not downstream costs such as physiotherapy visits.
(c) Inpatient stay cost used was £227 per day based on NHS Reference Costs 2006–2007.

9.3.5 Evidence statements

Clinical

Surgery within 24 hours versus surgery at later time points

Very low quality evidence from 4 studies comprising 318 participants demonstrated a clinical benefit of surgery within 24 hours compared with surgery within 2–7 days for hospital length of stay, with no serious imprecision.

Very low quality evidence from 1 study comprising 84 participants demonstrated a clinical benefit of surgery within 24 hours compared with surgery between 8–13 days for hospital length of stay, with no serious imprecision.

Very low quality evidence from 2 studies comprising 154 participants demonstrated a clinical benefit of surgery within 24 hours compared with surgery within 2–7 days for infection, with serious imprecision.

Very low quality evidence from 1 study comprising 84 participants demonstrated a benefit of surgery within 24 hours compared with surgery within 8–13 days for infection, with no serious imprecision.

Very low quality evidence from 1 study comprising 205 participants demonstrated a clinical benefit of surgery within 24 hours compared with surgery after 24 hours for infection, with no serious imprecision.

Very low quality evidence from 1 study comprising 62 participants demonstrated a clinical benefit of surgery within 24 hours compared with surgery within 2–7 days for wound brea**k**down, with serious imprecision.

Very low quality evidence from 1 study comprising 84 participants demonstrated a clinical benefit of surgery within 24 hours compared with surgery within 8-13 days for wound breakdown, with serious imprecision.

Very low quality evidence from 1 study comprising 854 participants demonstrated a clinical benefit of surgery within 24 hours compared with surgery within 8–13 days for episodes of VTE, with very serious imprecision.

Surgery within 24-48 hours versus surgery at later time points

Very low quality evidence from 1 study comprising 85 participants demonstrated a clinical benefit of surgery within 24–48 hours compared with surgery within 8–13 days for infection, with serious imprecision.

Very low quality evidence from 1 study comprising 202 participants demonstrated a clinical benefit of surgery within 24–48 hours compared with surgery after 14 days for infection, with very serious imprecision.

Economic

One comparative costing study found that early surgery was cost saving compared to late surgery for treating ankle fractures (£798 saved for within 24 hours versus over 24 hours, and £1,488 saved for within 48 hours versus over 48 hours). This study was assessed as partially applicable with potentially serious limitations.

9.3.6 Recommendations and link to evidence

Recommendations	16. If treating an ankle fracture with surgery, consider operating on the day of injury or the next day.
Relative values of different outcomes	Critical outcomes were pain/discomfort, return to normal activities, psychological wellbeing, inpatient length of stay, health-related quality of life, adverse effects (skin breakdown, wound infection and VTE). The number of physiotherapy appointments was identified as an important outcome as a measure of the success of surgery.
Trade-off between clinical benefits and harms	**Surgery carried out at less than 24 hours versus surgery carried out after 24 hours** There were clinically important benefits for surgery carried out after less than 24 hours in terms of hospital stay, infection, wound breakdown and VTE, compared with later surgery. There were no harms identified for surgery carried out at <24 hours relative to the comparator. **Surgery carried out at 24-48 hours versus surgery carried out at later times** There were clinically important benefits for surgery carried out at 24-48 hours in terms of infection compared to later surgery. There were no harms identified for surgery carried out at 24-48 hours relative to the comparator.
Economic considerations	One economic study[117] which was based on an included clinical study showed an increase in costs due to hospital stay of £1488 per patient for those having surgery after 48 hours compared to before. Prioritising ankle fractures for early surgery will not have a large direct cost as it will just delay less urgent procedures on the surgery list. Early surgery will reduce inpatient stay as well as the risk of adverse events. Deep infection is one potential adverse event that has a higher risk with delayed surgery and therefore can lead to large increases in costs due to the additional surgical procedures, long courses of antibiotics and the additional hospital stay required. The impact on other patients whose procedures will be delayed was also considered by the GDG. They believed that the potential detriment from delayed treatment of ankle fractures was greater than other fractures and so prioritising these was justified and cost effective.
Quality of evidence	**Clinical evidence** Nine cohort studies of very low quality were included in the review, which compared surgery within 24 or 48 hours with surgery at later time points. No evidence was found comparing surgery within 24 hours to surgery within 48 hours. Several papers did not report the mean age of participants, but the age range included in the other studies was 13-90 years. A number of studies included in the review reported insufficient data for some outcomes to be analysed, and these were either estimated or excluded from the review. Because this meant that there may have been serious bias it was suggested that the recommendation should be tentative. In the review protocols, the GDG identified time points that correspond with the way trauma services would provide care. Studies that compared alternative time points were allocated to a time point specified in the protocol based on the mean time to surgery reported in the paper. As some patients in these studies would have received surgery earlier or later than the allocated time point, these studies were downgraded for indirectness. **Economic evidence** The cost comparison included was from a UK perspective but did not include any health benefits. It included the costs of inpatient stay and did not look at any other downstream costs. It was assessed as partially applicable with potentially serious

	limitations.
Other considerations	The GDG agreed that despite the varying presentations and demographics of ankle fractures, all ankle fractures identified as requiring surgery should be treated in a standard way. The GDG chose to recommend that the surgery for ankle fractures should ideally occur on the day of injury but otherwise by the end of the following day in order to minimise adverse effects such as skin breakdown, wound infection and VTE. The GDG felt that for the same recommendation should apply to children, despite of the lack of evidence.

9.4 Timing of surgery – distal radius fractures

9.4.1 Introduction

Delays to distal radius surgery can lead to negative consequences, such as increased pain and impaired healing due to haematoma development. Sometimes minimal delays may have a benefit because the disadvantages of waiting are outweighed by the advantages of ensuring that thorough imaging and planning of surgery take place. It is likely, however, that a point exists after which further delay becomes a disadvantage to the average distal radius surgery patient, and the extent of this may depend on whether the fracture is intra-articular or extra-articular. This review aims to define this time point.

9.4.2 Review question: What is the maximum safe delay in surgical management of fractures of the distal radius before outcome is compromised?

For full details see review protocol in Appendix C.

Table 105: PICO characteristics of review question

Population	Children, young people and adults that require surgery following a distal radial fracture, after experiencing a traumatic incident
Intervention	• ≥14 days post injury • 8–13 days post injury • >48 hours to ≤7 days post injury • Within 48 hours
Comparison	Comparison of the above
Outcomes	Critical: • Health-related quality of life • Need for re-operation • PROMS • Wound infection • Anaesthetic complications • Growth plate arrest Important: • Pain/discomfort • Return to normal activities • Psychological wellbeing Population size and directness:

	• No limitations on sample size • Studies with indirect populations will not be considered
Study design	Systematic reviews/randomised controlled trials. Cohort studies if no RCTs retrieved. If cohorts are used, these must consider all the key confounders chosen by the GDG.

9.4.3 Clinical evidence

No RCTs or cohort studies were found for this review question. See the study selection flow chart in Appendix D and excluded studies list in Appendix K.

9.4.4 Economic evidence

Published literature

No relevant economic evaluations were identified.

See also the economic article selection flow chart in Appendix E.

9.4.5 Evidence statements

Clinical

No relevant clinical evaluations were identified.

Economic

No relevant economic evaluations were identified.

9.4.6 Recommendations and link to evidence

Recommendations	**17. When needed for distal radius fractures, perform surgery:** • **within 72 hours of injury for intra-articular fractures** • **within 7 days of injury for extra-articular fractures.** **18. When needed for re-displacement of distal radius fractures, perform surgery within 72 hours of the decision to operate.**
Relative values of different outcomes	Critical outcomes were health-related quality of life, the need for re-operation; patient reported outcome scores and adverse effects (wound infection, anaesthetic complications and growth plate arrest). Important outcomes were pain/discomfort, return to normal activities and psychological wellbeing.
Trade-off between clinical benefits and harms	No published evidence was found for this question. The GDG felt that if the injury is intra-articular then surgery should be performed within 72 hours from injury. The GDG reported that after 72 hours reduction of intra-articular fragments can become more difficult because of the development of organised haematoma. If the injury is extra-articular than a delay of up to 7 days from decision to operation was regarded as acceptable. The risk of failing to achieve a closed reduction for extra-articular injuries was felt by the GDG to possibly increase after a delay of greater than seven days. Although extra-articular fractures could also be surgically fixed within 72 hours, it was felt that this was not essential as there is no evidence or mechanism for adverse effects from any delay up to 7 days. Making a recommendation that extra-articular fractures should be fixed within 7 days was therefore an attempt to prioritise resources towards ensuring that the more time-

	dependent intra-articular fractures could be fixed within 72 hours. For re-displaced distal radius fractures that had previously been managed with closed reduction and casting the GDG felt that if surgery was indicated it should be done within 72 hours from the diagnosis or redisplacement rather than 7 days from diagnosis for a fresh extra-articular fracture. The rationale is that fractures initially managed by manipulation and casting have their first review X-ray at about one week. Since the redisplacement may have occurred at any time during that week the response needs to allow for this and be more rapid. The 72 hours was considered to be appropriate reflecting clinical urgency whilst allowing sufficient time to arrange the further treatment.
Economic considerations	No economic studies were identified for this question. Delaying surgery for these patients does not have a large direct cost as the patient does not need to stay in hospital awaiting surgery. If surgery can be delayed without compromising outcome then other more urgent procedures on the surgery list can be planned more effectively. Currently there is no defined timescale for treatment of these injuries and so treatment may be delayed until logistically convenient. The downside of delaying surgery is that the patient is likely to have a delay in returning to normal activities and therefore a reduction in quality of life. However, this is likely to be minimal in comparison to the functional outcome. Another issue with delayed surgery is that the fracture can begin to heal. This partially healed fracture then becomes a more complicated injury to performed surgery on and will required an open procedure instead of the less invasive and less expensive K-wire fixation that could be performed if treated sooner. The GDG considered these issues when making a consensus recommendation and believed that the key injuries that need to be treated early are those where there is an intra-articular fracture. Therefore they decided to recommend surgery within 72 hours for these fractures. For extra-articular fractures, they believed 7 days to be the maximum safe delay. The GDG also considered when surgery was required following re-displacement of a distal radial fracture and believed that these should be performed within 72 hours of the decision to operate.
Quality of evidence	No published evidence was available so recommendations were made by consensus.
Other considerations	Despite the lack of clinical evidence, the GDG felt that this was too urgent an issue for a research recommendation. It was felt that at present many intra-articular distal radius surgeries are carried out too late leading to possibly poorer outcomes. Such delays were usually made for non-clinical reasons. It was therefore felt that a clinical recommendation was needed to encourage a change in practice. The time frames suggested are based upon clinical experience, knowledge of physiological healing times, and what is achievable within the NHS.

9.5 Definitive treatment – distal radius fractures

9.5.1 Introduction

Dorsally displaced distal radial fractures are an extremely common injury, and may be caused by a fall on outstretched hands or may appear as a fragility fracture. Dorsally displaced distal radial fractures may cause significant long-term impairments in the function of the wrist. At present, a closed reduction of the fracture may be attempted in the emergency department, however, this may

be hard to achieve. It is unclear whether a closed or open reduction is most effective for the management of dorsally displaced distal radial fractures. Furthermore, there is uncertainty about which method of fixation results in better clinical outcomes. This review sought to evaluate the clinical and cost effectiveness of methods of closed and open reduction and fixation in the definitive treatment of dorsally displaced distal radial fractures.

9.5.2 Review question: What is the most clinically and cost effective definitive treatment for dorsally displaced low-energy fractures of the distal radius?

For full details see review protocol in Appendix C.

Table 106: PICO characteristics of review question

Population	Children, young people and adults experiencing a dorsally displaced fracture of the distal radius (without neurovascular compromise)
Intervention(s)	• Closed reduction and plaster cast immobilisation • Closed reduction and external fixation • Closed reduction and percutaneous wiring • Open reduction and internal fixation (ORIF) • No treatment
Comparison(s)	A comparison of the above

Outcomes	Critical:
	• Health-related quality of life
	• Pain/discomfort
	• Return to normal activities
	• Psychological wellbeing
	• Hand and wrist function
	• Adverse effects
	  ○ Pin-site infection
	  ○ Post traumatic osteoarthritis
	  ○ Complex regional pain syndrome
	
	Important:
	• Need for revision surgery
	• Need for further surgery (for example, removal of metalwork)
	• Number of attendances/bed days
	• Radiological anatomical measures

Study design	RCTs of systematic reviews of RCTs, cohorts if no RCTs retrieved. If cohorts are used, these must consider all the key confounders chosen by the GDG.

This review sought to examine the most clinically and cost effective treatment for dorsally displaced fractures of the distal radius. The analysis compared classes of intervention against each other, and did not include intra-class comparisons (for example, dorsal versus volar plates).

9.5.3 Clinical evidence

Fifty-seven studies (randomised controlled trials (RCTs) and systematic reviews of RCTs) were included in the review[5,7,14,16,18,21,23,24,40,44,51,56,62-65,67,73,75,78,80,82,84,90,97,98,108-112,118,120,121,123-127,147,154-157,166,170,178,179,186,193,42,94,111,196,198,199,201,202] these are summarised in Table 107 below. The majority of evidence investigated methods of definitive treatment in skeletally mature patients; 12 studies compared external fixation with internal fixation, 16 studies compared external fixation with plaster cast, 4 studies compared external fixation with k-wires, 7 studies compared internal fixation with k-

wires, 2 studies compared internal fixation with plaster cast, and 7 studies compared k-wires with plaster cast. Three studies compared k-wires and plaster cast in paediatric patients. Evidence from these studies is summarised in the clinical evidence summaries below (Table 108 to Table 114). See also the study selection flow chart in Appendix D, study evidence tables in Appendix G, forest plots in Appendix J, GRADE tables in Appendix I and excluded studies list in Appendix K.

Sensitivity and subgroup analyses were conducted for 2 meta-analyses (hand and wrist function for the comparisons external fixation versus internal fixation and internal fixation versus percutaneous wiring), which did not resolve heterogeneity in the data. As a consequence, these analyses were conducted using a random effects model.

Table 107: Summary of studies included in the review

Study	Intervention/comparison	Population	Outcomes	Comments
Abbaszadegan 1990[5]	External fixation versus plaster cast	Adults (n=47)	Pain; hand and wrist function; pin site infection; need for further surgery	
Abramo 2009[7] (Landgren 2011[110])	External fixation versus internal fixation	Adults (n=50)	Pain; hand and wrist function; post traumatic osteoarthritis; complex regional pain syndrome; pin site infection; need for further surgery	Both papers reported on the same trial
Arora 2011[14]	Internal fixation versus plaster cast	Adults (n=90)	Pain; hand and wrist function; complex regional pain syndrome	Adults >65 years
Azzopardi 2005[16]	K-wires versus plaster cast	Adults (n=57)	Quality of life; pain; return to normal activities; pin site infection; need for further surgery	Adults >60 years; extra-articular fractures
Bahari-kashani 2012[18]	Internal fixation versus k-wires	Adults (n=114)	Quality of life; pain; hand and wrist function; in site infection	Intra-articular fractures
Bartl 2014[21]	Internal fixation versus plaster cast	Adults (n=149)	Quality of life; function	Intra-articular fractures
Belloti 2010[24] (Belloti 2010[23])	External fixation versus k-wires	Adults (n=100)	Pain; hand and wrist function	Both papers reported on the same trial
Colaris 2013[40]	K-wires versus plaster cast	Children (n=128)	Hand and wrist function; pin site infection	
Costa 2014[42]	Internal fixation versus k-wires	Adults (n=461)	Quality of life; hand and wrist function; infection; need for further surgery	
Cui 2011[44]	External versus internal fixation	Systematic review (n=10 studies)	Hand and wrist function; pin site infection; complex regional pain	Studies extracted and assessed for quality

Study	Intervention/comparison	Population	Outcomes	Comments
			syndrome	independently
Egol 2008[51]	External fixation versus internal fixation	Adults (n=88)	Pain; hand and wrist function; pin site infection; need for further surgery	
Foldhazy 2010[56]	External fixation versus plaster cast	Adults (n=59)	Hand and wrist function; post traumatic osteoarthritis; complex regional pain syndrome	Adults >60 years
Gradl 2013[62]	External fixation versus internal fixation	Adults (n=102)	Pain; hand and wrist function	
Grewal 2005[63]	External fixation versus internal fixation	Adults (n=62)	Quality of life; pain; hand and wrist function; complex regional pain syndrome; pin site infection	Intra-articular fractures
Grewal 2011[64]	External fixation versus internal fixation	Adults (n=53)	Hand and wrist function; complex regional pain syndrome; pin site infection	
Gupta 1999[65]	K-wires versus plaster cast	Adults (n=50)	Hand and wrist function	Extra-articular fractures
Handoll 2007[67]	External fixation versus plaster cast	Systematic review (n=15 studies)	Quality of life; hand and wrist function; pain; complex regional pain syndrome; pin site infection	Studies extracted and assessed for quality independently
Harley 2004[73]	External fixation versus k-wires	Adults (n=50)	Quality of life; hand and wrist function; complex regional pain syndrome; pin site infection	
Hegeman 2004[75]	External fixation versus plaster cast	Adults (n=32)	Pain; hand and wrist function; complex regional pain syndrome	Adults >55 years; intra-articular fractures
Hollevoet 2011[78]	Internal fixation versus k-wires	Adults (n=42)	Hand and wrist function; pin site infection; need for further surgery	Adults >50 years
Howard 1989[80]	External fixation versus plaster cast	Adults (n=50)	Hand and wrist function; complex regional pain syndrome; pin site infection	
Hutchinson 1995[82]	External fixation versus k-wires	Young people and adults	Hand and wrist function; complex regional pain	

Study	Intervention/comparison	Population	Outcomes	Comments
		(n=89)	syndrome; pin site infection	
Ismatullah 2012[84]	External fixation versus plaster cast	Adults (n=30)	Hand and wrist function; complex regional pain syndrome; pin site infection	
Jenkins 1988[90]	External fixation versus plaster cast	Adults (n=106)	Hand and wrist function	
Jeudy 2012 [94]	External fixation versus internal fixation	Adults (n=75)	Hand and wrist function; Return to normal function; Complex regional pain syndrome	
Kapoor 2000[97]	External fixation versus internal fixation versus plaster cast	Adults (n=90)	Hand and wrist function; complex regional pain syndrome; pin site infection	Intra-articular fractures
Karantana 2013[98]	Internal fixation versus k-wires	Adults (n=135)	Quality of life; pain; hand and wrist function; pin site infection; need for further surgery	
Kreder 2006[108]	External fixation versus plaster cast	Adults (n=113)	Quality of life; complex regional pain syndrome; pin site infection	
Lagerstrom 1999[109]	External fixation versus plaster cast	Adults (n=68)	Pain	Adults >45 years
Leung 2008[111]	External fixation versus internal fixation	Adults (n=137)	Hand and wrist function; complex regional pain syndrome; Pin site infection; Osteoarthritis	
Ludvigsen 1997[112]	External fixation versus k-wires	Adults (n=74)	Hand and wrist function; complex regional pain syndrome	
Marcheix 2010[118]	Internal fixation versus k-wires	Adults (n=110)	Hand and wrist function	Adults >50 years
Mardani 2011[120]	K-wires versus plaster cast	Adults (n=198)	Pin site infection; need for further surgery	
Mcfadyen 2011[121]	Internal fixation versus k-wires	Adults (n=56)	Hand and wrist function; complex regional pain syndrome; pin site infection; need for further surgery	Extra-articular fractures
Mclauchlan 2002[122]	K-wires versus plaster cast	Children	Need for further	

Study	Intervention/comparison	Population	Outcomes	Comments
(Mclauchlan 2002[123])		(n=68)	surgery	
Mcqueen 1996[124]	External fixation versus plaster cast	Adults (n=120)	Complex regional pain syndrome; pin site infection	
Merchan 1992[125]	External fixation versus plaster cast	Adults (n=70)	Hand and wrist function; complex regional pain syndrome	Intra-articular fractures
Miller 2005[126]	K-wires versus plaster cast	Children (n=25)	Pin site; need for further surgery	Extra-articular fractures
Moroni 2004[127]	External fixation versus plaster cast	Adults (n=40)	Quality of life; hand and wrist function; need for further surgery	Adults >65 years
Pring 1988[147]	External fixation versus plaster cast	Adults (n=75)	Need for further surgery	
Rodriguez-merchan 1997[154]	K-wires versus plaster cast	Adults (n=40)	Hand and wrist function; complex regional pain syndrome; pin site infection; need for further surgery	Adults >46 years; intra-articular
Roh 2015[155]	Volar plate versus external fixation	Adults (74)	Hand function; complex regional pain syndrome; pin site infection;	Intra-articular fractures
Roumen 1991[156]	External fixation versus plaster cast	Adults (n=43)	Hand and wrist function; complex regional pain syndrome	Adults aged >55 years
Rozental 2009[157]	Internal fixation versus k-wires	Adults (n=45)	Return to normal activities; hand and wrist function; pin site infection	
Shankar 1992[166]	K-wires versus plaster cast	Adults (n=45)	Hand and wrist function; complex regional pain syndrome; pin site infection	Intra-articular fractures
Shukla 2014[170]	External fixation versus internal fixation	Adults (n=110)	Hand and wrist function; complex regional pain syndrome;	Intra-articular fractures
Stoffelen 1998[178] (Stoffelen 1999[179])	K-wires versus plaster cast	Adults (n=98)	Hand and wrist function	Extra-articular fractures
Ur 2012[186]	External fixation versus plaster cast	Adults (n=60)	Pain; complex regional pain syndrome; pin site infection; need for further surgery	Intra-articular fractures

Study	Intervention/comparison	Population	Outcomes	Comments
Wei 2009[193]	External fixation versus internal fixation	Adults (n=46)	Pain; hand and wrist function	Intra-articular fractures
Wilcke 2011[196]	External fixation versus internal fixation	Adults (n=63)	Hand and wrist function; pin site infection; need for further surgery	
Williksen 2013[198]	External fixation versus internal fixation	Adults (n=114)	Pain; hand and wrist function; complex regional pain syndrome; pin site infection	
Wong 2010[199]	K-wires versus plaster cast	Adults (n=60)	Quality of life; hand and wrist function; complex regional pain syndrome; pin site infection	Adults >65 years; extra-articular fractures
Xu 2009[201]	External fixation versus internal fixation	Adults (n=35)	Hand and wrist function; post traumatic osteoarthritis; complex regional pain syndrome; pin site infection	Intra-articular fractures
Young 2003[202]	External fixation versus plaster cast	Adults (n=125)	Pain; hand and wrist function	

Table 108: Clinical evidence summary: External fixation versus internal fixation in adults with dorsally displaced distal radius fracture

Outcome	Number of studies (participants)	Imprecision	GRADE rating	Absolute difference	Control event rate (per 1000)	Control event rate for continuous outcomes
Pain VAS/SF-36/DASH pain subscale (0–10; (Better indicated by lower))	5(n=349)	No serious imprecision	MODERATE	MD 0.23 lower (0.52 lower to 0.06 higher)	-	1.4
Return to normal activities	1(n=75)	Very serious imprecision	VERY LOW	73 fewer per 1000 (from 244 fewer to183 more)	538	-
Hand and wrist function DASH/PRWE/MAYO/Gartland Werley/ Michigan hand questionnaire ((Better indicated by lower))	7(n=501)	Serious imprecision	VERY LOW	SMD 0.17 standard deviations lower (0.19 lower to 0.54 higher)	-	-
Hand and wrist function (poor or fair)	4(n=325)	Very serious	VERY LOW	6 more per 1000 (from 86 fewer to 138 more)	320	-
Pin site infection	11(n=729)	No serious imprecision	LOW	100 more per 1000 (from 60 more to 130 more)	10	-
Post-traumatic osteoarthritis	3(n=84)	Serious	VERY LOW	115 more per 1000 (from 28 more to 232 more)	250	-
Complex regional pain syndrome	11(n=774)	Very serious	VERY LOW	15 more per 1000 (from 3 fewer to 46 more)	28	-
Need for further surgery	3(n=190)	No serious imprecision	LOW	6 more per 1000 (from 51 fewer to 144 more)	91	-

Table 109: Clinical evidence summary: External fixation versus plaster cast in adults with dorsally displaced distal radius fracture

Outcome	Number of studies (participants)	Imprecision	GRADE rating	Absolute difference	Control event rate (per 1000)	Control event rate for continuous outcomes
Quality of life (3 months) SF-36. Scale from 0–100. (Better indicated by higher)	1(n=40)	No serious imprecision	LOW	MD 0.90 lower (7.25 lower to 9.05 higher)	-	66.2
Pain (2 years) SF-36. Scale from 0–100. (Better indicated by lower)	1(n=113)	No serious imprecision	VERY LOW	MD 0.4 higher (0.03 to 0.77 higher)	-	0.1
Pain (3 months–7 years)	3(n=177)	Serious	VERY LOW	69 fewer per 1000 (from 14 fewer to 108 fewer)	204	-
Hand and wrist function (fair/poor) Gartland & Werley/Green & O'Brian/Stewart/Lidstrom/ Sarmiento	10(n=543)	Serious	VERY LOW	71 fewer per 1000 (from 130 fewer to 6 more)	324	-
Pin site infection	7(n=387)	No serious imprecision	LOW	113 more per 1000 (from 65 fewer to 162 more)	0	-
Post-traumatic osteoarthritis	1(n=59)	Very serious	VERY LOW	44 fewer per 1000 (from 173 fewer to 284 more)	258	-
Complex regional pain syndrome	10(n=544)	Serious	VERY LOW	4 more per 1000 (from 24 fewer to 59 more)	56	-
Need for further surgery	4(n=147)	No serious imprecision	LOW	300 fewer per 1000 (from 390 fewer to 211 fewer)	220	-

Table 110: Clinical evidence summary: External fixation versus k-wires in adults with dorsally displaced distal radius fracture

Outcome	Number of studies (participants)	Imprecision	GRADE rating	Absolute Difference	Control event rate (per 1000)	Control event rate for continuous outcomes
Quality of life SF-36. Scale from 0–100 (Better indicated by higher)	1(n=34)	Serious	Very low	MD 3 lower (10.39 lower to 4.39 higher)	-	48
Pain VAS. Scale from 0–10 (Better indicated by lower)	1(n=91)	No serious imprecision	Moderate	MD 0.2 higher (0.4 higher to 0.8 higher)	-	1.2
Hand and wrist function Scale from 0–100 (Better indicated by lower)	2(n=125)	Serious	Low	MD 4.17 higher (1.18 lower to 9.51 higher)	-	12
Hand and wrist function (fair/poor)	2(n=112)	Very serious	Very low	5 more per 1000 (from 65 fewer to 208 more)	-	103
Pin site infection	2(n=86)	No serious imprecision	Low	267 more per 1000 (from 34 more to 916 more)	-	97
Complex regional pain syndrome	3(n=146)	Very serious	Very low	18 more per 1000 (from 11 fewer to 84 more)	-	32

Table 111: Clinical evidence summary: Internal fixation versus k-wires in adults with dorsally displaced distal radius fracture

Outcome	Number of studies (participants)	Imprecision	GRADE rating	Absolute difference	Control event rate (per 1000)	Control event rate for continuous outcomes
Quality of life EQ-5D/SF-36. Scale from 0–100 (Better indicated by	3(n=642)	No serious imprecision	VERY LOW	MD 6.73 higher (5.38 lower to 18.84 higher)	-	68.7

Pain SF-36 (pain subscale). Scale from 0–100 (Better indicated by lower)	1(n=114)	No serious imprecision	LOW	MD 8.5 higher (4.33 to 12.67 higher)	-	54.3
Outcome	**Number of studies (participants)**	**Imprecision**	**GRADE rating**	**Absolute difference**	**Control event rate (per 1000)**	**Control event rate for continuous outcomes**
higher)						
Pain	1(n=130)	Very serious	VERY LOW	1 fewer per 1000 (from 38 fewer to 171 more)	47	-
Return to normal activities mean time until return to work (days)	1(n=42)	Serious	LOW	MD 9 lower (23.63 lower to 5.63 higher)	-	26
Hand and wrist function DASH/QuickDASH/MAYO/ PRWE. Scale from 0–100 (Better indicated by lower)	7(n=893)	Serious	VERY LOW	MD 6.49 lower (10.59 to 2.40 lower)	-	21
Pin site infection	5(n=373)	No serious imprecision	MODERATE	75 fewer per 1000 (from 121 fewer to 30 fewer)	-	143
Complex regional pain syndrome	1(n=56)	-	LOW	Not calculated[a]	0	-
Need for further surgery	4(n=675)	Serious	VERY LOW	49 fewer per 1000 (from 2 fewer to 70 fewer)	85	-

[(a)] *Not calculated as zero events in both arms*

Table 112: Clinical evidence summary: Internal fixation versus plaster cast in adults with dorsally displaced distal radius fracture

Outcome	Number of studies (participants)	Imprecision	GRADE rating	Absolute difference	Control event rate (per 1000)	Control event rate for continuous outcomes
Quality of life - EQ5D utility score (Better indicated by higher)	1 (n=149)	No serious imprecision	LOW	MD 0 higher (0.06 lower to 0.06 higher)	-	0.89

Outcome	Number of studies (participants)	Imprecision	GRADE rating	Absolute difference	Control event rate (per 1000)	Control event rate for continuous outcomes
Quality of life - SF36 mental (Better indicated by higher)	1(n=149)	No serious imprecision	LOW	MD 0.2 higher (2.48 lower to 2.88 higher)		53.6
Quality of life - SF36 physical (Better indicated by higher)	1(n=149)	Serious	VERY LOW	MD 3.3 higher (0.91 lower to 6.79 higher)		45.3
Pain VAS. Scale from 0–10 (Better indicated by lower)	1(n=73)	Serious	VERY LOW	MD 0.1 lower (0.44 to 0.24 higher)	-	0.3
Hand and wrist function (PRWE and DASH). (Better indicated by lower)	2(n=222)	No serious imprecision	LOW	SMD 0.2 lower (0.46 lower to 0.06 higher)	-	19
Hand and wrist function (fair/poor)	1(n=42)	Very serious	VERY LOW	198 fewer per 1000 (from 379 fewer to 169 more)	565	-
Pin site infection	2(n=122)	Very serious	VERY LOW	34 more per 1000 (from 21 fewer to 89 more)	0	-
Complex regional pain syndrome	3(n=195)	Very serious	VERY LOW	16 fewer per 1000 (from 29 fewer to 31 more)	33	-

Table 113: Clinical evidence summary: K-wires versus plaster cast in adults with dorsally displaced distal radius fracture

Outcome	Number of studies (participants)	Imprecision	GRADE rating	Absolute difference	Control event rate (per 1000)	Control event rate for continuous outcomes

Outcome	Number of studies (participants)	Imprecision	GRADE rating	Absolute difference	Control event rate (per 1000)	Control event rate for continuous outcomes
Quality of life WHOQOL and SF-36 (physical component) (Better indicated by higher)	2(n=114)	No serious imprecision	LOW	MD 0.35 standard deviations higher (0.02 lower to 0.73 higher)	-	3.5–38.2
Pain VAS. Scale from 0–10(Better indicated by lower)	1(n=54)	Serious	VERY LOW	MD 0.5 lower (1.28 lower to 0.28 higher)	-	1.2
Return to normal activities Activities of daily living (ADL). Scale from 0–12(Better indicated by higher)	1(n=54)	Serious	VERY LOW	MD 0.3 higher (0.96 lower to 1.56 higher)	-	9.4
Hand and wrist function Cooney modification of Green & O'Brian. Scale from 0–100(Better indicated by lower)	1(n=98)	Serious	VERY LOW	MD 15 lower (29.81 lower to 1.78 higher)	-	34
Hand and wrist function MAYO. Scale from 0–100 (Better indicated by lower)	1(n=60)	Serious	LOW	MD 1.7 lower (5.18 lower to 1.78 higher)	-	19.5
Hand and wrist function (fair/poor) Sarmiento/McBride/Horne (Better indicated by lower)	3(n=135)	No serious imprecision	LOW	310 fewer per 1000 (from 162 fewer to 382 fewer)	450	-

Outcome	Number of studies (participants)	Imprecision	GRADE rating	Absolute difference	Control event rate (per 1000)	Control event rate for continuous outcomes
Pin site infection	5(n=397)	No serious imprecision	LOW	146 more per 1000 (from 96 more to 195 more)	0	-
Complex regional pain syndrome	3(n=145)	Very serious	VERY LOW	28 fewer per 1000 (from 81 fewer to 25 more)	46	-
Need for further surgery	3(n=292)	No serious imprecision	LOW	151 fewer per 1000 (from 210 fewer to 92 fewer)	61	-

Table 114: Clinical evidence summary: K-wires versus plaster cast in children with dorsally displaced distal radius fracture

Outcome	Number of studies (participants)	Imprecision	GRADE rating	Absolute Difference	Control event rate (per 1000)	Control event rate for continuous outcomes
Hand and wrist function ABILHAND. Scale from 0–42 (Better indicated by lower)	1(n=123)	No serious imprecision	Moderate	MD 0.4 higher (0.01 lower to 0.81 higher)	-	41.5
Pin site infection	2(n=157)	Very serious	Very low	53 more per 1000 (from 2 fewer to 108 more)	0	-
Need for further surgery	2(n=102)	No serious imprecision	Low	275 fewer per 1000 (from 399 fewer to 150 fewer)	301	-

9.5.4 Economic evidence

Published literature

One cost-utility analysis was identified comparing volar locking plates with K-wires and has been included in this review.[41] This is summarised in the economic evidence profile below (Table 115) and the economic evidence tables in Appendix H.

One cost-utility analysis relating to this review question was identified but was excluded due to methodological limitations.[167] These are listed in Appendix K, with reasons for exclusion given.

See also the economic article selection flow chart in Appendix E.

Table 115: Economic evidence profile: Volar locking plates versus Kirschner wires for dorsally displaced distal radial fractures

Study	Applicability	Limitations	Other comments	Incremental cost per patient (£)	Incremental effects per patient (QALYs)	Cost effectiveness	Uncertainty
Costa 2015[41] (UK)	Directly applicable[(a)]	Minor limitations[(b)]	Based on an RCT included in the clinical review. Intention-to-treat analysis; incremental analysis using a full trial dataset where missing data was dealt with using two different methods. Firstly, the last number carried forward was used for imputation and then the multiple imputation method was used. QALYs were estimated using the EQ-5D scores at baseline, 3 months, 6 months and 12 months.	726[(c)(d)]	0.008[(c)(e)]	£89,322 per QALY	Probability surgery is cost-effective (£20k/30k threshold): 0%/3% Overall results did not change in the following analyses: – Complete case analysis: only complete data were used. – Societal perspective – Analysis adjusting for baseline age, gender and EQ5D score. – Subgroup analysis by age (<50 versus ≥50). K-wires dominated in the <50 age group.

Abbreviations: QALY: quality-adjusted life years; RCT: randomised controlled trial [Update according to which abbreviations used in table]

(a) UK NHS and PSS perspective

(b) No major limitations observed

(c) Estimated using bootstrapped estimates

(d) 2012 UK pounds; cost components incorporated were surgical intervention (including the costs of the surgical team, implants, consumables and unexpected surgical procedures and inpatient stay), costs of visits to both primary and secondary health-care professionals (e.g. hospital outpatient visits, hospitalisation, physiotherapy appointments), medication, aids and adaptation equipment.

(e) QALYs were based on EQ-5D estimated through patient questionnaires.

9.5.5 Evidence statements

Clinical

External fixation versus internal fixation

Moderate quality evidence from RCTs comprising participants 5 RCTs comprising 349 participants demonstrated no clinical difference between external fixation and internal fixation for pain, with no serious imprecision.

Very low quality evidence from 7 RCTs comprising 75 participants demonstrated no clinical difference between external fixation and internal fixation for hand and wrist function when measured as a continuous variable, with serious imprecision.

Very low quality evidence from 4 RCTs comprising 325 participants demonstrated no clinical difference between external fixation and internal fixation for hand and wrist function when measured in terms of the proportion with fair or poor results, with very serious imprecision.

Low quality evidence from 11 RCTs comprising 729 participants demonstrated a clinical harm of external fixation compared with internal fixation for pin site infection, with no serious imprecision.

Very low quality evidence from 3 RCTs comprising 84 participants demonstrated a clinical harm of external fixation compared with internal fixation for post-traumatic osteoarthritis, with serious imprecision.

Very low quality evidence from 11 RCTs comprising 774 participants demonstrated no clinical difference between external fixation and internal fixation for complex regional pain syndrome, with very serious imprecision.

Low quality evidence from 3 RCTs comprising 190 participants demonstrated no clinical difference between external fixation and internal fixation for need for further surgery, with no serious imprecision.

Very low quality evidence from 1 RCT comprising 75 participants demonstrated no clinical difference between external fixation for return to normal activity, with very serious imprecision.

External fixation versus plaster cast or splint

No evidence was found comparing external fixation with plaster cast or splint in children.

Low quality evidence from 1 RCT comprising 40 participants demonstrated no clinical difference between external fixation and plaster cast or splint for health-related quality of life, with no serious imprecision.

Very low quality evidence from RCTs comprising 113 participants demonstrated no clinical difference between external fixation and plaster cast or splint for pain when measured on a continuous scale, with no serious imprecision.

Very low quality evidence from 3 RCTs comprising 177 participants demonstrated a clinical benefit of external fixation compared with plaster cast or splint for pain when measured on a categorical scale, with serious imprecision.

Very low quality evidence from 10 RCTs comprising 543 participants demonstrated a clinical benefit of external fixation compared with plaster cast/splint for hand and wrist function, with serious imprecision.

Low quality evidence from 7 RCTs comprising 387 participants demonstrated a clinical harm of external fixation compared with plaster cast or splint for pin site infection, with no serious imprecision.

Very low quality evidence from 1 RCT comprising 59 participants demonstrated no clinical difference between external fixation and plaster cast or splint for post-traumatic osteoarthritis, with very serious imprecision.

Very low quality evidence from 10 RCTs comprising 544 participants demonstrated no clinical difference between external fixation and plaster cast or splint for complex regional pain syndrome, with serious imprecision.

Low quality evidence from 4 RCTs comprising 147 participants demonstrated a clinical benefit of external fixation compared with plaster cast or splint for need for further surgery, with no serious imprecision.

External fixation versus percutaneous wiring (K-wires)

No evidence was found comparing external fixation with K-wires in children.

Very low quality evidence from 1 RCT comprising 34 participants demonstrated no clinical difference between external fixation and K-wires for health-related quality of life, with serious imprecision.

Moderate quality evidence from 1 RCT comprising 91 participants demonstrated no clinical difference between external fixation and K-wires for pain, with no serious imprecision.

Very low quality evidence from 4 RCTs comprising 237 participants demonstrated no clinical difference between external fixation and K-wires for hand and wrist function, with serious to very serious imprecision.

Low quality evidence from 2 RCTs comprising 86 participants demonstrated a clinical harm of external fixation compared with K-wires for pin site infection, with no serious imprecision.

Very low quality evidence from 3 RCTs comprising 146 participants demonstrated no clinical difference between external fixation and K-wires for complex regional pain syndrome, with very serious imprecision.

Internal fixation versus percutaneous wiring (K-wires)

No evidence was found comparing internal fixation with K-wires in children.

Very low quality evidence from 3 RCTs comprising 642 participants demonstrated no clinical difference between internal fixation and K-wires for health-related quality of life, with no serious imprecision.

Low quality evidence from 1 RCT comprising 114 participants demonstrated a clinical harm of internal fixation compared with K-wires for pain when measured on a continuous scale, with no serious imprecision

Very low quality evidence from 1 RCT comprising 130 participants demonstrated no clinical difference between internal fixation and K-wires for pain when measured on a categorical scale, with very serious imprecision.

Low quality evidence from 1 RCT comprising 42 participants demonstrated a clinical benefit of internal fixation compared with K-wires for time to return to normal activities, with serious imprecision.

Very low quality evidence from 7 RCTs comprising 893 participants demonstrated no clinical difference between internal fixation and K-wires for hand and wrist function, with serious imprecision.

Moderate quality evidence from 5 RCTs comprising 373 participants demonstrated a clinical benefit of internal fixation compared with K-wires for pin site infection, with no serious imprecision.

Low quality evidence from 1 RCTs comprising 56 participants demonstrated no clinical difference between internal fixation and K-wires for complex regional pain syndrome, with no estimated imprecision.

Very low quality evidence from 4 RCTs comprising 675 participants demonstrated a clinical benefit of internal fixation compared with K-wires for need for further surgery, with serious imprecision.

Internal fixation versus plaster cast or splint

No evidence was found comparing internal fixation with plaster cast or splint in children.

Very quality evidence from 1 RCT comprising 149 participants demonstrated no clinical difference between internal fixation and plaster cast or splint for quality of life in terms of the SF36 physical sub-scale, with serious imprecision.

Low quality evidence from 1 RCT comprising 149 participants demonstrated no clinical difference between internal fixation and plaster cast or splint for quality of life in terms of the SF36 mental sub-scale, with no serious imprecision

Low quality evidence from 1 RCT comprising 149 participants demonstrated no clinical difference between internal fixation and plaster cast or splint for quality of life in terms of the EQ-5D utility score, with no serious imprecision

Very low quality evidence from 1 RCT comprising 73 participants demonstrated no clinical difference between internal fixation and plaster cast or splint for pain, with serious imprecision.

Low quality evidence from 2 RCTs comprising 222 participants demonstrated no clinical difference between internal fixation and plaster cast or splint for hand and wrist function when measured as a continuous variable, with no serious imprecision.

Very low quality evidence from 1 RCT comprising 42 participants demonstrated a clinical benefit of internal fixation compared with plaster cast or splint for hand and wrist function when measured as a categorical variable, with very serious imprecision.

Very low quality evidence from 2 RCTs comprising 122 participants demonstrated no clinical difference between internal fixation and plaster cast or splint for pin site infection, with very serious imprecision.

Very low quality evidence from 3 RCTs comprising 195 participants demonstrated no clinical difference between internal fixation and plaster cast or splint for complex regional pain syndrome, with very serious imprecision.

Percutaneous wiring (K-wires) versus plaster cast or splint

Adults

Low quality evidence from 2 RCTs comprising 114 participants demonstrated no clinical difference between K-wires and plaster cast or splint for health-related quality of life, with no serious imprecision.

Very low quality evidence from 1 RCT comprising 54 participants demonstrated no clinical difference between K-wires and plaster cast or splint for pain, with serious imprecision.

Very low quality evidence from 1 RCT comprising 54 participants demonstrated no clinical difference between K-wires and plaster cast or splint for time to return to normal activities, with serious imprecision.

Very low quality evidence from 1 RCT comprising 98 participants demonstrated a clinical harm of K-wires compared with plaster cast splint for hand and wrist function measured with the Cooney modification of the Green and O'Brian scale, with serious imprecision.

Low quality evidence from 1 RCT comprising 60 participants demonstrated no clinical difference between K-wires and plaster cast or splint for hand and wrist function measured with the Mayo scale, with serious imprecision.

Low quality evidence from 3 RCTs comprising 135 participants demonstrated a clinical benefit of K-wires compared with plaster cast splint for hand and wrist function measured on a categorical scale, with no serious imprecision.

Low quality evidence from 5 RCTs comprising 397 participants demonstrated a clinical harm of K-wires compared with plaster cast or splint for pin site infection, with no serious imprecision.

Very low quality evidence from 3 RCTs comprising 145 participants demonstrated no clinical difference between K-wires and plaster cast/splint for complex regional pain syndrome, with very serious imprecision.

Low quality evidence from 3 RCTs comprising 292 participants demonstrated a clinical benefit of K-wires compared with plaster cast or splint for need for further surgery, with no serious imprecision.

Children

Moderate quality evidence from 1 RCT comprising 123 participants demonstrated no clinical difference between K-wires and plaster cast or splint for hand and wrist function, with no serious imprecision.

Very low quality evidence from 2 RCTs comprising 157 participants demonstrated a clinical harm of K-wires compared with plaster cast or splint for pin site infection, with very serious imprecision.

Low quality evidence from 2 RCTs comprising 102 participants demonstrated a clinical benefit of K-wires compared with plaster cast or splint for need for further surgery, with no serious imprecision.

Economic

One cost utility analysis found that for treating dorsally displaced fractures of the distal radius, volar locking plates were not cost effective in comparison to K-wires (£89,322 per QALY). This study was assessed as directly applicable with minor limitations.

9.5.6 Recommendations and link to evidence

Recommendations	**Adults** **19. Consider manipulation and a plaster cast in adults (skeletally mature) with dorsally displaced distal radius fractures.** **20. When surgical fixation is needed for dorsally displaced distal radius fractures in adults (skeletally mature):** • **offer K-wire fixation if:** – **no fracture of the articular surface of the radial carpal joint is detected, or**

	– **displacement of the radial carpal joint can be reduced by closed manipulation** • **consider open reduction and internal fixation if closed reduction of the radial carpal joint surface is not possible.**
Relative values of different outcomes	Critical outcomes were health-related quality of life, pain-discomfort, return to normal activities, psychological wellbeing, hand and write function, and adverse effects (pin-site infection, post-traumatic osteoarthritis and complex regional pain syndrome). Important outcomes were the need for revision or further surgery, and radiological outcomes. However, due to the volume of evidence for other outcomes and the poor association between radiological outcomes and clinical outcomes (e.g. function, quality of life) the GDG chose not to consider the evidence for radiological outcomes from the identified studies.
Trade-off between clinical benefits and harms	External versus internal fixation The evidence indicated no clinical benefit for external fixation compared to internal fixation, but a clinical harm for external fixation for pin site infection and osteoarthritis. There was no clinical difference between external fixation and internal fixation for pain, hand and wrist function at 6-7 weeks or 1 year, complex regional pain syndrome, and need for further surgery. Overall, given the relative value of different outcomes, both treatments showed a similar balance of harms and benefits. **External fixation versus K-wires** The evidence indicated no clinical benefit of external fixation compared with K-wires, and a clinical harm of external fixation for pin site infection. There was no clinical difference between external fixation and K-wires for quality of life, pain, hand and wrist function and complex regional pain syndrome. Overall, given the relative value of different outcomes, K wires showed a better balance of benefits and harms than external fixation. **External fixation versus plaster cast/splint** The evidence indicated a clinical benefit for external fixation for hand and wrist function and need for further surgery as compared to plaster cast/splint, but a clinical harm of external fixation for pin site infection. There was no clinical difference between external fixation and plaster cast/splint for quality of life, osteoarthritis, and complex regional pain syndrome. One study indicated no clinical difference between external fixation and plaster cast/splint for pain, while three studies indicated a clinical benefit of external fixation for pain. Overall, given the relative value of different outcomes, external fixation showed a better balance of benefits and harms than the plaster cast/splint. **Internal fixation versus K-wires** The evidence indicated a clinical benefit of internal fixation over K-wires for pin site infection, return to normal activities and need for further surgery. There was no clinical difference between internal fixation and K-wires for quality of life, hand and wrist function and complex regional pain syndrome. One study demonstrated a clinical harm of internal fixation compared to K-wires for pain at 1 year, while another study demonstrated no clinical difference between internal fixation and K-wires for pain at 1 year. Although overall the evidence indicated that internal fixation showed a better balance of benefits and harms that K-wires, the GDG noted that the evidence demonstrating a greater need for further surgery in patients treated with K-wires compared to internal fixation related to procedures to remove buried wires conducted under local anaesthetic, and thus did not indicate a failure of the initial approach. The GDG also felt that this procedure was less invasive than further surgical procedures associated with internal fixation, such as the removal of plates. Furthermore, the GDG noted evidence that internal fixation and K-wires

	demonstrated similar efficacy for the two most critical outcomes for patients; health-related quality of life and hand and wrist function. Therefore, the GDG felt that the evidence did not demonstrate sufficient evidence to recommend internal fixation over K-wires, considering the substantial additional cost of internal fixation. **Internal fixation versus plaster cast/splint** The evidence indicated a clinical benefit of internal fixation for hand and wrist function at 6-7 weeks and SF-36 physical as compared to plaster cast/splint, and no clinical harm of internal fixation. There was no clinical difference between internal fixation and plaster cast for SF-36 mental, EQ5D, pain, hand and wrist function at 1 year, pin site infection and complex regional pain syndrome. Overall, given the relative value of different outcomes, internal fixation showed a better balance of benefits and harms than plaster-cast/splint. **K-wires versus plaster cast/splint** There was a clinical benefit of K-wires for need for further surgery compared to plaster cast/splint, but a clinical harm of K-wires for pin site infection. There was no clinical difference between K-wires and plaster cast for quality of life, pain, return to normal activities and complex regional pain syndrome. There was conflicting findings concerning the difference between K-wires and plaster cast/splint for hand and wrist function. One study indicated a clinical harm of K-wires compared to plaster cast/splint, one study indicated no clinical difference between K-wires and plaster cast/splint, and three studies indicated a clinical benefit of K-wires for hand and wrist function. Overall, given the relative value of different outcomes, the GDG felt that K-wires offered the better treatment, due to the reduced need for further surgery.
Economic considerations	One relevant economic study was included for this question Costa 2015[41] compared K-wires to internal fixation with plates and screws in patients who were believed to benefit from fixation by the treating consultant surgeon. This study is an economic analysis alongside a randomised controlled trial which has been included in our clinical review for this question. This study showed that there was a slight benefit of internal fixation over k-wires in terms of QALYs; however, the increased cost of internal fixation was too high to make it cost effective, with an ICER of £89,322. Therefore, this study concludes that K-wires should be used in favour of internal fixation to treat distal radial fractures that require fixation. The GDG agreed that if a satisfactory closed reduction could be made, then there is no need to undergo expensive surgery as a plaster cast, the cheapest intervention, would be sufficient. If the treating surgeon believes that the patient may benefit from surgical fixation to fix the bone in place the GDG considered the evidence for surgical techniques. Since the evidence suggests that internal fixation is not cost effective in comparison to K-wires, the GDG recommended that K-wires should be used. There was some clinical evidence of a need for further surgery for patients who had K-wires, but the GDG believed this to be in cases where the wires had been buried in the initial surgery. This means that they would have to be surgically removed, whereas if they are left exposed, they can be easily removed by a nurse. Leaving the pins exposed can lead to pin site infection, however, the evidence suggests that the risk of this is low and the treatment not costly because the infection is not deep. The GDG considered the patients who require surgical fixation but where a closed reduction of the radial carpal joint could not be achieved, the GDG believed that an open reduction was necessary and so given that an invasive procedure is being performed anyway, then internal fixation should be recommended.
Quality of evidence	**Clinical evidence** The vast majority of the data was at low or very low GRADE quality. Several analyses

	also demonstrated some unexplained heterogeneity. No subgroup analyses were conducted due to too few studies reporting data separately for the specified subgroups (age and location of fracture). **Economic evidence** The included economic study (Costa 2015[41]), comparing k-wires to internal fixation with plates and screws, is a cost utility analysis from a UK NHS perspective. It has been assessed as directly applicable with minor limitations.
Other considerations	The GDG felt that the evidence demonstrated no significant benefit of one method of fixation over another for key patient outcomes, such as health-related quality of life and hand and wrist function. The GDG agreed, therefore, that plaster cast/splint was a sufficient method for treating some dorsally displaced distal radial fractures. Despite plaster cast not being appropriate for all patients, the GDG chose to recommend that clinicians consider the use of plaster cast as they felt that clinicians are able to determine when surgical fixation would be more appropriate. For situations where clinicians decide that surgery is more appropriate, the GDG noted that K-wire fixation is as effective as other more invasive methods of fixation and so is the most preferable option where a closed reduction is possible. However, the GDG also noted that open surgery may be required when a closed reduction of the fracture cannot be achieved. As a consequence, the GDG chose to recommend internal fixation where open reduction is already indicated as the invasive surgery is being performed as a matter of course. The GDG felt that there is no clear evidence in the literature concerning which dorsally displaced distal radial fractures benefit from surgical rather than conservative treatment. The GDG considered making a research recommendation in this area. However this was not done because a review question had not been posed on this specific topic. The GDG believed that the effectiveness of treatment for dorsally displaced distal radial fractures may vary depending on whether the fracture is intra-articular or extra-articular, and this was proposed as a criterion for subgrouping studies where heterogeneity existed in the data. However, the GDG noted that the identification of intra-articular fractures is difficult without CT imaging. At the present time, CT imaging is not used to routinely diagnose and/or plan treatment for dorsally displaced distal radial fractures in the UK. High-energy fractures, often associated with Gustillo Anderson Grade II/III open injuries, or proximal forearm injuries, are rare and not covered by this recommendation.

Recommendations	**Children** **21. In children (skeletally immature) with dorsally displaced distal radius fractures (including fractures involving a growth plate) who have undergone manipulation, consider:** • **a below-elbow plaster cast, or** • **K-wire fixation if the fracture is completely displaced (off-ended).**
Relative values of different outcomes	The GDG identified health-related quality of life, pain-discomfort, return to normal activities, psychological wellbeing, hand and write function, and adverse effects (pin-site infection, post-traumatic osteoarthritis and complex regional pain syndrome) as critical outcomes for the evaluation of definitive treatments for dorsally displaced

	distal radial fractures. The GDG also identified need for revision surgery, need for further surgery, and radiological outcomes as important outcomes. However, the GDG chose not to consider the evidence for radiological outcomes, due to the volume of evidence for other outcomes and the poor association between radiological outcomes and clinical outcomes (for example, function, quality of life).
Trade-off between clinical benefits and harms	The clinical evidence included in the review compared the use of K-wires to plaster cast/splint for the treatment of dorsally displaced distal radius fractures in children. No clinical evidence was found evaluating the other interventions. Consistent with the evidence for adult patients, the evidence indicated no overall benefit of either treatment compared to the other. The GDG felt that the use of a plaster cast would not be appropriate for all children with dorsally displaced distal radial fractures. Using consensus, the GDG therefore chose to recommend the use of K-wire fixation when a fracture is still considered to be unstable following reduction. They chose to recommend plaster cast for children when the fracture is considered to be stable following reduction. The GDG noted that all of the evidence in children used a long arm plaster cast. The GDG discussed evidence in the wider literature that a below-elbow cast is associated with greater clinical benefit than a long arm cast, and therefore used consensus to recommend that only a below elbow cast should be used for children with dorsally displaced distal radial fractures.
Economic considerations	No relevant economic studies were included for this question. The GDG agreed that if a satisfactory closed reduction could be made, then there is no need to undergo expensive surgery as a plaster cast, the cheapest intervention, would be sufficient. If the treating surgeon believes that the patient may benefit from surgical fixation to fix the bone in place the GDG considered the evidence for surgical techniques. Since the evidence from the adult population suggests that internal fixation is not cost effective in comparison to K-wires, the GDG recommended that K-wires should be used. There was some clinical evidence of a need for further surgery for patients who had K-wires, but the GDG believed this to be in cases where the wires had been buried in the initial surgery. This means that they would have to be surgically removed, whereas if they are left exposed, they can be easily removed by a nurse. Leaving the pins exposed can lead to pin site infection, however, the evidence suggests that the risk of this is low and the treatment not costly because the infection is not deep.
Quality of evidence	The clinical evidence was at moderate, low or very low GRADE quality. This was due to risk of bias and imprecision. No evidence was found for the following outcomes: health-related quality of life, pain, return to normal activities, psychological wellbeing, post-traumatic-osteoporosis, complex regional pain syndrome, and number of attendances/bed days. No evidence was found comparing other interventions in this population.
Other considerations	The GDG noted that fixation of fractures involving the growth plate in children may have a greater risk of long-term adverse outcomes. The GDG believed that in such cases, care should be taken to pass the k-wire as centrally through the growth plate as possible. When passing a k-wire across the growth plate, more than one attempt should be avoided in order to minimise damage to the growth plate. The GDG noted that there is no validated method for assessing the stability of dorsally displaced distal radial fractures in children in the operating theatre. As a consequence the GDG chose to recommend that clinicians consider k-wire fixation only for children with completely displaced (off-ended) fractures. The GDG noted that clinicians may also choose to use k-wire fixation based on their own clinical suspicion that a fracture is unstable. High-energy fractures, often associated with grade 2/3 open injuries, or proximal forearm injuries, are rare and not covered by this recommendation.

9.6 Definitive treatment – proximal humerus fractures

9.6.1 Introduction

Fractures of the proximal humerus are common injuries accounting for 5–6% of all fractures in people aged over 65 years. The majority of these are non-displaced or minimally displaced two-part fractures according to the Neer classification, and can be successfully treated with conservative management (immobilisation of the joint, followed by physiotherapy). Treatment of displaced (3-4 Neer classification) fractures is more challenging and may require surgical intervention (internal fixation or humeral head replacement). Despite their increasing use, surgical procedures have not been associated with improved shoulder functionality over the conservative approach. Moreover, the surgical procedure has increased cost implications and may be related to a number of adverse effects, including mortality, in this high-risk group of patients.

9.6.2 Review question: What is the most cost effective definitive treatment for displaced low-energy fractures of the proximal humerus?

For full details see review protocol in Appendix C.

Table 116: PICO characteristics of review question

Population	Adults experiencing a traumatic incident resulting in a fracture of the proximal humerus.
Intervention(s)	Conservative: • Immobilisation in arm sling Operative: • Open reduction and plating • Intramedullary nailing • Hemiarthroplasty • Reverse (geometry) shoulder replacement
Comparison(s)	To each other (across and within conservative and operative groups)
Outcomes	Critical: • Mortality at 1 and 12 months • Health-related quality of life • Functional score (DASH/Constant/Oxford) • Infection • Avascular necrosis (AVN) • Need for further/operative treatment • Nerve damage Important: • Return to normal activities
Study design	RCTs or systematic reviews of RCTs; Cohorts if no RCTs found. If cohorts are used, these must consider all the key confounders chosen by the GDG.

9.6.3 Clinical evidence

We searched for randomised trials comparing the effectiveness of surgical and non-surgical treatments for fractures of the proximal humerus (see protocol above). Seven trials meeting the protocol were identified. Two studies[27,141] were found comparing hemiarthroplasty with conservative

treatments and a further two compared open reduction versus conservative[54,55,203]. A single trial was found comparing hemiarthroplasty and open reduction[35], one trial was found comparing hemiarthroplasty and reverse shoulder replacement[165]. A large RCT comparing multiple surgical techniques with conservative treatment was also found[68,150]. These are summarised in Table 117 below. Evidence from these studies is summarised in the clinical evidence summaries below (Table 118 to Table 122). See also the study selection flow chart in Appendix D, study evidence tables in Appendix G, forest plots in Appendix J, GRADE tables in Appendix I and excluded studies list in Appendix K.

Table 117: Summary of studies included in the review

Study	Intervention/comparison	Population	Outcomes
Boons 2012[27]	Hemiarthroplasty versus conservative	Patients >65 years old with displaced proximal humeral four-part fractures	Mortality at 12 months; Constant score; Infection; Need for further surgery
Cai 2012[35]	Hemiarthroplasty versus open reduction and plating	Elderly patients with acute displaced 4-part fracture of the surgical neck of the humerus	Mortality at 12 months; Quality of life; Need for further operative treatment
Fjalestad 2014a[55],Fjalestad 2012[54]	Open reduction and plating versus conservative	Patients aged 60 or over with a displaced, unstable three or four-part proximal humerus fracture	Mortality at 12 months; Quality of life; Constant Score; AVN; Need for further operative treatment; Nerve Damage
Handoll 2015[68,150]	Surgical (combined) versus conservative	Patients were eligible for inclusion if they were aged 16 years or older and presented within 3 weeks after sustaining a displaced fracture of the proximal humerus that involved the surgical neck	Mortality; Quality of Life; Oxford Shoulder Score; Infection; Need for further operative treatment; Nerve damage; AVN
Olerud 2011[141]	Hemiarthroplasty versus conservative	Patients aged 55 years or older who have sustained a proximal humeral fracture following a low-energy fall	Mortality at 12 months; Quality of Life; Constant Score; DASH Score; Infection; Need for further operative treatment
Sebastia-Forcada 2014[165]	Hemiarthroplasty versus Reverse shoulder replacement	Patients aged 70 years and older with an acute proximal humeral fracture who were candidates for shoulder arthroplasty	Mortality at 12-months; Constant Score; QuickDASH; Infection; Need for further operative treatment
Zyto 1997[203]	Open reduction and plating versus conservative	A displaced three or four part fracture of the humerus not caused by high-energy trauma and not pathological	Constant Score; Infection

Table 118: Clinical evidence summary: Hemiarthroplasty versus conservative

Outcome	Number of studies (participants)	Imprecision	GRADE rating	Absolute difference	Control event rate (per 1000)	Control event rate for continuous outcomes
Mortality	2 (n=103)	Very serious	VERY LOW	5 more per 1000 (from 41 fewer to 212 more)	54	-
Health-related quality of life (EQ-5D; Scale 0–1; better indicated by higher score)	1 (n=49)	Serious	LOW	MD 0.16 higher (0.04 higher to 0.28 higher)	-	0.65
Constant Score (range of scores 0–100; better indicated by higher score)	2 (n=103)	No serious imprecision	MODERATE	MD 1.6 higher (5.47 lower to 8.67 higher)	-	54.8
DASH Score range of scores 0–100; better score indicated by lower score)	1 (n=48)	Serious	LOW	MD 6.7 lower (17.93 lower to 4.53 higher)		36.9
Need for further operative treatment	2 (n=103)	Very serious	LOW	40 more per 1000 (from 23 lower to 263 more)	38	-
Infection	2 (n=103)	Unable to perform pooled analysis				

Table 119: Clinical evidence summary: Hemiarthroplasty versus open reduction

Outcome	Number of studies (participants)	Imprecision	GRADE rating	Absolute difference	Control event rate (per 1000)	Control event rate for continuous outcomes
Mortality	1 (n=28)	Very serious	VERY LOW	60 more per 1000 (from 0 fewer to 230 more)	6.3	-
Health-related quality of life (EQ-5D; Scale 0–1; better indicated by	1 (n=27)	Serious	VERY LOW	MD 0.07 higher (0.01 higher to 0.24 higher)	-	0.74

Outcome	Number of studies (participants)	Imprecision	GRADE rating	Absolute difference	Control event rate (per 1000)	Control event rate for continuous outcomes
higher score)						
Need for further operative treatment	1 (n=28)	Very serious	VERY LOW	74 fewer per 1000 (from 194 fewer to 434 more)	231	-

Table 120: Clinical evidence summary: Open reduction versus conservative

Outcome	Number of studies (participants)	Imprecision	GRADE rating	Absolute difference	Control event rate (per 1000)	Control event rate for continuous outcomes
Mortality	1 (n=50)	Very serious	LOW	80 more per 1000 (from 0 more to 210 more)	0	-
Health-related quality of life (range of score 0-1; better indicated by higher score)	1 (n=48)	Serious	LOW	MD 0.02 higher (0.04 lower to 0.08 higher)	-	0.825
Constant Score (range of scores 0–100; better indicated by higher score)	2 (n=77)	Serious	VERY LOW	MD 3.37 lower (12.71 lower to 5.97 higher)	-	71
AVN	1 (n=48)	Very serious	VERY LOW	78 fewer per 1000 (from 288 fewer to 264 more)	600	-
Need for further operative treatment	1 (n=48)	Very serious	LOW	134 more per 1000 (from 19 fewer to 1000 more)	0	-
Infection	1 (n=48)	Very serious	VERY LOW	140 more per 1000 (from 0 more to 350 more)	0	-
Nerve damage	1 (n=48)	Very serious	LOW	75 more per 1000 (from 75 fewer to 665 more)	200	-

Table 121: Clinical evidence summary: Hemiarthroplasty versus reverse shoulder replacement

Outcome	Number of studies (participants)	Imprecision	GRADE rating	Absolute difference	Control event rate (per 1000)	Control event rate for continuous outcomes
Mortality	1 (n=62)	Very serious	VERY LOW	32 more per 1000 (from 53 fewer to 117 more)	0	-
Constant Score (range of scores 0–100; better indicated by higher score)	1 (n=61)	Serious	LOW	MD 16.1 lower (25.21 to 6.99 lower)	-	56.1
QuickDASH (range of scores 0-55; better indicated by lower score)	1 (n=61)	Serious	LOW	MD 6.9 higher (2.99 to 10.81 higher)	-	17.5
Infection	1 (n=61)	Very serious	VERY LOW	1 more per 1000 (from 30 fewer to 473 more)	32	-
Need for further operative treatment	1 (n=61)	Serious	MODERATE	166 more per 1000 (from 7 fewer to 1000 more)	32	-

Table 122: Clinical evidence summary: Surgical (combined – all surgery types) versus conservative

Outcome	Number of studies (participants)	Imprecision	GRADE rating	Absolute difference	Control event rate (per 1000)	Control event rate for continuous outcomes
Mortality	4 (n=403)	Serious	VERY LOW	28 more per 1000 (from 10 fewer to 113 more)	41	-
Health-related quality of life (EQ-5D; Scale 0–1; better indicated by higher score)	3 (n=315)	No serious imprecision	MODERATE	MD 0.03 higher (0.01 lower to 0.07 higher)	-	0.27
Health-related quality of life (SF-12 physical component; Scale 0–	1 (n=226)	No serious imprecision	MODERATE	MD 1.48 higher (1.83 lower to 4.79 higher)	-	44.2

Outcome	Number of studies (participants)	Imprecision	GRADE rating	Absolute difference	Control event rate (per 1000)	Control event rate for continuous outcomes
100; better indicated by higher score)						
Health-related quality of life (SF-12 mental component; Scale 0–100; better indicated by higher score)	1 (n=226)	No serious imprecision	MODERATE	MD 1.39 lower (4.62 lower to 1.84 higher)	-	50.7
Oxford Shoulder Score range of scores 0–48; better score indicated by lower score)	1 (n=231)	No serious imprecision	MODERATE	MD 0.29 lower (2.44 lower to 1.86 higher)	-	40.4
Constant Score (range of scores 0–100; better indicated by higher score)	4 (n=172)	No serious imprecision	LOW	MD 0.2 higher (5.84 lower to 5.43 higher)	-	62.9
Infection	4 (n=381)	Serious	VERY LOW	21 more per 1000 (from 2 fewer to 44 more)	0	-
AVN	2 (n=298)	Very serious	VERY LOW	21 more per 1000 (from 106 fewer to 237 more)	304	-
Nerve damage	2 (n=294)	Very serious	LOW	21 more per 1000 (from 18 fewer to 61 more)	63	-
Need for further operative treatment	4 (n=410)	Very serious	VERY LOW	11 more per 1000 (from 13 fewer to 58 more)	38	-

9.6.4 Economic evidence

Published literature

One cost utility analysis was identified with the relevant comparison and has been included in this review.[68] This is summarised in the economic evidence profile below (Table 57) and the economic evidence tables in Appendix F.

One cost utility analysis relating to this review question was identified but was excluded due to methodological limitations.[54] This is summarised in Appendix L, with reasons for exclusion given.

See also the economic article selection flow chart in Appendix C.

Table 123: Economic evidence profile: surgical vs conservative treatment for displaced low-energy fractures of the proximal humerus

Study	Applicability	Limitations	Other comments	Incremental cost per patient (£)	Incremental effects per patient (QALYs)	Cost effectiveness	Uncertainty
Handoll 2015[68] (UK)	Directly applicable[(a)]	Minor limitations[(b)]	Based on an RCT included in the clinical review. Intention-to-treat analysis; the incremental analysis was conducted using the multiple imputed data set. The incremental mean utility and the incremental mean cost between the two treatments were estimated through regression equations using the bivariate method. The covariates used to adjust for in the model were age, gender, treatment group and tuberosity involvement (yes/no) at baseline. EQ5D was estimated at baseline, then at 3, 6, 12 and 24 months.	1,758[(c)(d)]	- 0.0101[(c)(e)]	Conservative treatment dominates surgical treatment	Probability surgery is cost-effective (£20k/30k threshold): 6%/15% Overall results did not change in the following analyses: - Complete case analysis: only complete cases data were used. - Analysis using both shoulder- and non-shoulder-related resource use - Analysis using patient questionnaires (rather than hospital forms) as the main source for hospital data.

Abbreviations: QALY: quality-adjusted life years; RCT: randomised controlled trial [Update according to which abbreviations used in table]

(a) UK NHS and PSS perspective

(b) No major limitations observed

(c) Estimated using multiple imputation and OLS regression

(d) 2012 UK pounds; cost components incorporated were surgical intervention (including the costs of the surgical team, implants, consumables and unexpected surgical procedures and inpatient stay), costs of visits to both primary and secondary health-care professionals (e.g. hospital outpatient visits, hospitalisation, physiotherapy appointments).

(e) QALYs were based on EQ-5D estimated through patient questionnaires.

9.6.5 Evidence statements

Clinical

Hemiarthroplasty versus conservative

Very low quality evidence from 2 RCTs comprising 103 participants demonstrated no clinical difference between hemiarthroplasty and conservative treatment with regard to mortality, with very serious imprecision.

Low quality evidence from a single RCT comprising 49 participants demonstrated a clinical improvement with hemiarthroplasty when compared with conservative treatment for health-related quality of life, with serious imprecision.

Moderate quality evidence from 2 RCTs comprising 103 participants demonstrated no clinical difference between hemiarthroplasty and conservative treatment with regard to functional measures (constant score), with no serious imprecision.

Low quality evidence from a single RCT comprising 48 participants demonstrated no clinical difference between hemiarthroplasty and conservative treatment with regard to functional measures (DASH score), with serious imprecision.

Low quality evidence from 2 RCTs comprising 103 participants demonstrated no clinical difference between hemiarthroplasty and conservative treatment for incidence of further operative treatment, with very serious imprecision.

Evidence from 2 RCTs comprising 103 participants demonstrated no clinical difference between hemiarthroplasty and conservative treatment for risk of infection.

Hemiarthroplasty versus open reduction

Very low quality evidence from a single RCT comprising 28 participants demonstrated a clinical harm of hemiarthroplasty when compared with open reduction with regard to mortality at 12 months, with very serious imprecision.

Very low quality evidence from a single RCT comprising 27 participants demonstrated no clinical difference between hemiarthroplasty and open reduction for health-related quality of life, with serious imprecision.

Very low quality evidence from a single RCT comprising 32 participants demonstrated no clinical difference between hemiarthroplasty and open reduction for incidence of further operative treatment, with very serious imprecision.

Clinical evidence summary: open reduction versus conservative

Low quality evidence from a single RCT comprising 50 participants demonstrated a clinical harm of open reduction when compared with conservative with regard to mortality, with very serious imprecision.

Low quality evidence from a single RCT comprising 48 participants demonstrated no clinical difference between open reduction and conservative treatment with regard to health-related quality of life, with serious imprecision.

Very low quality evidence from 2 RCTs comprising 77 participants demonstrated no clinical difference between open reduction and conservative treatment with regard to functional measures (constant score), with very serious imprecision

Very low quality evidence from a single RCT comprising 48 participants demonstrated a clinical benefit with open reduction compared with hemiarthroplasty for incidence of AVN, with very serious imprecision.

Low quality evidence from a single RCT comprising 48 participants demonstrated a clinical harm with open reduction compared to hemiarthroplasty for number of further operative treatments, with very serious imprecision.

Very low quality evidence from a single RCT comprising 29 participants demonstrated a clinical harm with open reduction compared with hemiarthroplasty for incidence of infection, with very serious imprecision.

Low quality evidence from a single RCT comprising 44 participants demonstrated a clinical harm with open reduction compared with hemiarthroplasty for incidence of nerve damage, with very serious imprecision.

Hemiarthroplasty versus reverse shoulder replacement

Very low quality evidence from a single RCT comprising 62 participants demonstrated a clinical harm with hemiarthroplasty compared to reverse shoulder replacement with regard to mortality, with very serious imprecision.

Low quality evidence from a single RCT comprising 61 participants demonstrated a clinical harm with hemiarthroplasty compared to reverse shoulder replacement with regard to functional measures (constant score), with serious imprecision.

Low quality evidence from a single RCT comprising 61 participants demonstrated a clinical harm with hemiarthroplasty compared to reverse shoulder replacement with regard to functional measures (QuickDASH), with serious imprecision.

Very low quality evidence from a single RCT comprising 61 participants demonstrated no clinical difference between hemiarthroplasty and reverse shoulder replacement with regard to incidences of infection, with very serious imprecision.

Moderate quality evidence from a single RCT comprising 61 participants demonstrated a clinical harm with hemiarthroplasty compared to reverse shoulder replacement with regard to need for further operative treatment, with serious imprecision.

Surgical combined versus conservative

Very low quality evidence from 4 studies comprising 403 participants demonstrated a clinical harm with surgical treatment compared to conservative treatment for mortality, with serious imprecision.

Very low quality evidence from 3 studies comprising 315 participants demonstrated no clinical difference between surgical and conservative treatments with regard to health-related quality of life (EQ-5D), with no serious imprecision.

Moderate quality evidence from a single RCT comprising 226 participants demonstrated no clinical difference between surgical and conservative treatments with regard to physical health-related quality of life (SF-12-physical), with no serious imprecision.

Moderate quality evidence from a single RCT comprising 226 participants demonstrated no clinical difference between surgical and conservative treatments with regard to mental health-related quality of life (SF-12-mental) with no serious imprecision.

Moderate quality evidence from a single RCT comprising 231 participants demonstrated no clinical difference between surgical and conservative treatments with regard to functional measures (Oxford Shoulder score) with no serious imprecision.

Low quality evidence from 4 studies comprising 172 participants demonstrated no clinical difference between surgical and conservative treatments with regard to functional measures (Constant score) with no serious imprecision.

Very low quality evidence from 4 RCTs comprising 381 participants demonstrated no clinical difference between surgical and conservative treatment with regard to incidences of infection, with serious imprecision.

Very low quality evidence from 2 RCTs comprising 298 participants demonstrated no clinical difference between surgical and conservative treatment with regard to incidences of AVN, with very serious imprecision.

Low quality evidence from 2 RCTs comprising 294 participants demonstrated no clinical difference between surgical and conservative treatment with regard to incidences of nerve damage, with very serious imprecision.

Very low quality evidence from 4 RCTs comprising 410 participants demonstrated no clinical difference between surgical and conservative treatment with regard to need for further operative treatment, with very serious imprecision.

Economic

One cost-utility analysis found that, in people with a displaced fracture of the proximal humerus that involved the surgical neck, conservative treatment was dominant (less costly and more effective) compared to surgical treatment. This analysis was assessed as directly applicable with minor limitations.

9.6.6 Recommendations and link to evidence

Recommendations	**22. For adults (skeletally mature) with displaced low energy proximal humerus fractures:** • **offer non-surgical management for definitive treatment of uncomplicated injuries** • **consider surgery for injuries complicated by an open wound, tenting of the skin, vascular injury, fracture dislocation or a split of the humeral head.**
Relative values of different outcomes	Critical outcomes were mortality, health related quality of life, functional scores and adverse effects as the critical outcomes for the evaluation of definitive treatments of the proximal humerus; health related quality of life as it could be severely affected following this injury and would be dependent on management; functional scores and adverse effects specific to the management of the fracture (infection, avascular necrosis, need for further /operative treatment, nerve damage) as these would have a clinical and economic consequences; mortality as these patients were generally considered high risk surgical patients due to age and co-morbidities. Return to normal activity was considered an important outcome but this was

	also likely to be captured within health related quality of life.
Trade-off between clinical benefits and harms	The evidence that was presented was according to the protocol, where interventions were compared within surgery as well as between surgery and conservative treatments. However, the GDG felt it would be most appropriate to focus on comparisons between surgery and conservative treatment rather than the comparisons between different surgical approaches. This was because the first issue facing patients and clinicians is the question of whether to offer surgery or not. The type of surgery offered being secondary to this initial decision. **Conservative vs. surgical combined** Four studies comparing surgical and conservative treatments for management of humerus fractures indicated a clinical risk with surgical treatment for mortality. However, the GDG noted the low mortality rates across studies and felt the discrepancies in mortality might be due to chance. Health related quality of life and adverse effects including infection and risk of further operative procedure demonstrated no clinical difference between groups. There was some variation between trials regarding the incidence of avascular necrosis (AVN), although this also failed to demonstrate a clinical difference between groups. The GDG felt that this was likely due to variation in the criteria used to diagnose AVN and felt the outcome was not as useful when combined across studies. The GDG discussed the evidence and concluded that there was no clinical difference between the treatment groups. In particular, they referenced the HTA trial by Handoll et al., which was a well conducted UK based trial. This study found that the there was no significant difference between surgical treatment compared with nonsurgical treatment in patient-reported clinical outcomes over 2 years following fracture. The GDG noted that patients who had 'a clear indication for surgery' such as severe soft-tissue compromise, multiple injuries (upper limb fractures), pathological fracture (other than osteoporotic), were excluded and that this created a degree of subjectivity regarding eligibility. However, the GDG felt that this trial was representative of current UK practice and indicated a strong recommendation should be made for the conservative approach as no additional benefit was indicated with surgery. **Surgical group compared** Several RCTs compared surgical procedures including reverse shoulder arthroplasty, hemiarthroplasty and open reduction with internal fixation using plates. The GDG discussed the evidence but, based on the strong evidence described above, a conservative approach was recommended compared to any form of surgery for this population.
Economic considerations	One cost utility analysis was identified that compared conservative treatment to surgical treatment. [68,69] This study is a within-trial analysis of an RCT which is included in our clinical review for this question. The analysis was from a UK NHS perspective and used the EQ5D as a measure of quality of life, collected at baseline, 3 months, 6 months 12 months and 24 months. The time horizon for the study was 2 years and costs included surgical procedures, consumables and both primary care and secondary care attendances. The results showed a slight increase in QALYs (0.01) for the conservative treatment group as well as a reduction in overall costs (£1,758). The study therefore concluded that conservative treatment dominated surgical

	treatment for fractures of the proximal humerus. This evidence was assessed as directly applicable with minor limitations. The GDG considered the clinical evidence included in our review that compared conservative treatment to surgical treatment and believed that it did not conflict with the conclusions of the included economic evidence. They also believed that the evidence comparing different surgical treatments was of secondary importance given that conservative treatment was shown to dominate surgical treatment. The GDG therefore agreed that conservative treatment should be recommended for people with fractures of the proximal humerus.
Quality of evidence	**Clinical evidence** **Surgery versus Conservative** The clinical evidence was rated from moderate to very low quality. The evidence was downgraded due to high risk of bias as blinding was not possible between surgical and non-surgical interventions. The evidence also demonstrated some inconsistency but we were unable to subgroup by Neer classification as the populations came from a mixture of populations. **Within surgery** Several RCTs compared surgical procedures. The study was not considered of significant quality on which to make a recommendation, for the same reasons as the surgery v conservative studies. **Economic evidence** **Surgery versus conservative** The included study is an economic evaluation alongside an RCT that was specific to our target population and included in our clinical review (Handoll 2015). It is a cost utility analysis from a UK NHS perspective and included all relevant costs and health benefits. It has been assessed as directly applicable with minor limitations.
Other considerations	The GDG noted that most of the evidence was in displaced fractures (Neer-classification type 3 and 4) and generally in an elderly population. The GDG noted that surgical intervention may still be definitively indicated in a small group of patients (e.g. patients with open fractures or those tenting the skin, fractures associated with a vascular injury, fracture-dislocations, and fractures involving a split of the humeral head). This question was restricted to adults and not children, as displaced low energy fractures of the proximal humerus are fragility fractures that are usually only seen in adults.

9.7 Definitive treatment – femoral fractures in children

9.7.1 Introduction

Femoral mid-shaft fractures are relatively common in children, with an annual incidence of 0.19%. In the youngest age groups, such fractures may indicate non-accidental injury, although, road traffic accidents account for 90% of femoral fractures in adolescence. There is little agreement in the literature regarding the most clinically and cost-effective treatment for this injury. This systematic review aims to synthesize the evidence in this area to formulate a recommendation on best practice.

9.7.2 Review question: What is the most clinically and cost-effective treatment for paediatric femoral shaft fractures?

For full details see review protocol in Appendix C.

Table 124: PICO characteristics of review question

Population	Children experiencing a femoral shaft fracture following a traumatic incident.
Intervention(s)	**Conservative treatment:** • Pavlik harness (fabric splint) • Bryant's traction (tape applied to leg and weight to apply traction) • Hip spica casting (plaster down waist and leg) • Gallows traction **Surgical treatment:** • Elastic intramedullary nailing (EIN) • Standard intramedullary nailing (SIN) • External fixation • Traditional open plate fixation • Minimally invasive plate fixation
Comparison(s)	With each other (both between and within the conservative and surgical categories)
Outcomes	Critical: • Health-related quality of life • Number of follow-up/revision surgeries? • PODCI-POSNA score • Mortality • Neurovascular damage • Deformity/limb length discrepancy • Non-union/malunion • Vascular compromise • Avascular necrosis (femoral head) Important: • Pain/discomfort • Return to normal activities • Duration hospital stay • Psychological wellbeing
Study design	RCTs and systematic reviews of RCTs. If no RCTs, cohorts. If cohorts are used, these must consider all the key confounders chosen by the GDG.

9.7.3 Clinical evidence

We searched for randomised trials comparing the effectiveness of any of the treatments listed in the protocol, and 5 were found in total. For the hip spica versus elastic intramedullary nail comparison, 3 studies[81,158,168] were found, for the hip spica versus external fixation comparison one study[200] was found and for the external fixation versus elastic intramedullary nail one study [20] was found.

For the other permutations of protocol treatments where RCTs had not been found, cohort studies were sought. For most of the permutations of treatment none of the studies found were eligible, largely because of group differences in age or other confounders that were not adjusted in a multivariable analysis (see excluded studies list in Appendix L). However, there was one eligible

cohort study found for Bryant's traction versus the Pavlik harness,[189] one for SIN versus submuscular plating,[143] and one cohort study compared the EIN, SIN, external fixation and plating.[149]

The included studies are summarised in Table 125 below. Evidence from these studies is summarised in the clinical evidence summaries below (Table 126 to Table 130). Evidence from the study by Ramseier 2010[149] is given in a narrative section as it was not suitable for a clinical evidence summary table. See also the study selection flow chart in Appendix D, study evidence tables in Appendix G, forest plots in Appendix J, GRADE tables in Appendix I and excluded studies list in Appendix K.

Table 125: Summary of studies included in the review

Study	Intervention/ comparison	Population	Outcomes
Hsu 2009[81]	Hip spica versus elastic intramedullary nail	Age 5-12 years	Hospital stay
Ruhullah 2014[158]		Age 3-13 years	Hospital stay Further treatment Flynn's grading Return to independent ambulation Return to school Return to normal activities Malunion Avascular necrosis
Shemshaki 2011[168]		Age 6-12 years	Parent satisfaction Hospital stay Return to school Return to independent ambulation Nerve injury Malunion
Wright 2005[200]	Hip spica versus external fixation	Age 4-10 years	RAND child health scale AEs requiring further treatment malunion
Bar-on 1997[20]	External fixation versus elastic intramedullary nail	Age 5.2-13.2 years	Parent satisfaction Further treatment Return to school Nerve injury Malunion
Wang 2014[189a]	Bryant's traction versus Pavlik harness	Age 0-1 years	Length of hospital stay Leg length discrepancy malunion
Park 2012[143 a]	SIN versus sub-muscular plating	Age 11-17 years	Flynn grading Return to normal ambulation Need for re-operation Leg length discrepancy Non-union
Ramseier 2010[149a]	EIN versus SIN versus Ext fixation versus plating	Age 11-17.6 years	Malunion Major complications (These were the only relevant outcomes looked at with a multivariable analysis – other outcomes were compared univariately

Study	Intervention/ comparison	Population	Outcomes
			between groups but there were serious baseline differences in key confounders)

(a) Cohort studies. These were required to have group parity in key confounders, or to have conducted a multivariable analysis

Table 126: Clinical evidence summary: Spica versus EIN

Outcome	Number of studies (participants)	Imprecision	GRADE rating	Absolute difference	Control event rate (per 1000)	Control mean value for continuous outcomes
Length of hospital stay (days) (Better indicated by lower values)	3(n=146)	Very serious	VERY LOW	Random effects MD 0.19 lower (12.32 lower to 11.94 higher)		10.15
Return to school (weeks) (Better indicated by lower values)	2(n=95)	No serious imprecision	VERY LOW	Random effects MD 5.73 higher (3.68 to 7.79 higher)		6.65
Return to (independent) ambulation (days) (Better indicated by lower values)	2(n=95)	No serious imprecision	VERY LOW	Random effects MD 36.41 higher (20.44 to 52.37 higher)		40.7
Return to normal activities (weeks) (Better indicated by lower values)	1(n=49)	No serious imprecision	LOW	MD 3.32 higher (1.31 to 5.33 higher)		8.76
Further treatment	1(n=49)	Very serious	VERY LOW	78 fewer per 1000 (from 115 fewer to 253 more)	120	
Flynn grading 'excellent'	1(n=49)	No serious imprecision	LOW	593 fewer per 1000 (from 342 fewer to 692 fewer)	760	
Malunion	2(n=95)	Very serious	VERY LOW	9 fewer per 1000 (from 82 fewer to 1000 more)	83	
Rand child health status (higher worse) (Better indicated by lower values)	1(n=101)	serious	VERY LOW	MD 1 lower (3.9 lower to 1.9 higher)		69
Avascular necrosis	1(n=49)	Very serious	VERY LOW	34 fewer per 1000 (from 40 fewer to 188 more)	40	
Parental satisfaction 'good	1(n=46)	serious	VERY LOW	260 fewer per 1000	1000	

Outcome	Number of studies (participants)	Imprecision	GRADE rating	Absolute difference	Control event rate (per 1000)	Control mean value for continuous outcomes
or excellent'				(from 40 fewer to 420 fewer)		
Nerve injury	1(n=46)	Very serious	VERY LOW	37 fewer per 1000 (from 43 fewer to 193 more)	43	

Table 127: Clinical evidence summary: Spica versus Ext fixation

Outcome	Number of studies (participants)	Imprecision	GRADE rating	Absolute difference	Control event rate (per 1000)	Control mean value for continuous outcomes
Malunion	1(n=101)	No serious imprecision	LOW	291 more per 1000 (from 58 more to 781 more)	156	

Table 128: Clinical evidence summary: Ext fixation versus EIN

Outcome	Number of studies (participants)	Imprecision	GRADE rating	Absolute Difference	Control event rate (per 1000)	Control mean value for continuous outcomes
Parental satisfaction - would choose same treatment again	1(n=20)	serious	VERY LOW	190 fewer per 1000 (from 430 fewer to 140 more)	1000	
Number of follow up revisions	1(n=20)	Very serious	VERY LOW	100 more per 1000 (from 79 fewer to 1000 more)	100	
Foot drop	1(n=20)	Very serious	VERY LOW	85 fewer per 1000 (from 100 fewer to 331 more)	100	
Limb length discrepancy	1(n=20)	Very serious	VERY LOW	200 more per 1000 (from 80 lower to 480	0	

Outcome	Number of studies (participants)	Imprecision	GRADE rating	Absolute Difference	Control event rate (per 1000)	Control mean value for continuous outcomes
				more)		
Length of hospital stay (days) (Better indicated by lower values)	1(n=38)	No serious imprecision	VERY LOW	MD 16.4 higher (9.05 to 23.75 higher)		1.4
Leg length discrepancy (mm) (Better indicated by lower values)	1(n=38)	Very serious imprecision	VERY LOW	MD 0.4 higher (7.35 lower to 8.15 higher)		7.6

Table 129: Clinical evidence summary: Bryant's traction versus Pavlik harness

Outcome	Number of studies (participants)	Imprecision	GRADE rating	Absolute difference	Control event rate (per 1000)	Control mean value for continuous outcomes
Malunion	1(n=38)	No serious imprecision	VERY LOW	not evaluable	0	

Table 130: Clinical evidence summary: SIN versus Plating

Outcome	Number of studies (participants)	Imprecision	GRADE rating	Absolute difference	Control event rate (per 1000)	Control mean value for continuous outcomes
Flynn grading of 'excellent'	1(n=45)	Very serious imprecision	VERY LOW	68 more per 1000 (from 172 fewer to 475 more)	522	
Return to ambulation without limping	1(n=43)	No serious imprecision	VERY LOW	0 fewer per 1000 (from 80 fewer to 90 more)	1000	
Need for reoperation	1(n=43)	Very serious imprecision	VERY LOW	100 more per 1000 (from 50 fewer to 240 more)	0	
leg length discrepancy	1(n=43)	No serious	VERY LOW	not pooled	0	

Outcome	Number of studies (participants)	Imprecision	GRADE rating	Absolute difference	Control event rate (per 1000)	Control mean value for continuous outcomes
>1 cm		imprecision				
Non-union	1(n=43)	Very serious imprecision	VERY LOW	50 more per 1000 (from 70 fewer to 170 more)	0	

Narrative summary

Ramseier 2010[149] compared SIN, EIN, External fixation and plating. Data were not suitable for GRADE as only p values were given. There were serious group discrepancies at baseline for key confounders such as fracture type and age, and so only outcomes analysed via a multivariable analysis were extracted. Relationships between EIN and external fixation were not extracted as these data had previously been gathered from RCTs.

It was found that after adjustment for age, sex, bodyweight, high-energy trauma, polytrauma, increased comminution, fracture level and pattern, and open/closed fracture status, rigid nail and plate fixation were not significantly different from elastic nail fixation with regard to malunion (p=0.99). Measures of effect, such as ORs, were not provided.

A major complication was defined as one or more of the following; loss of reduction, malunion or shortening and/or a re-operation for any reason other than routine hardware removal. After multivariable analysis, the risk of a major complication did not differ significantly among the elastic nail, rigid nail and plate fixation groups.

9.7.4 Economic evidence

Published literature

No relevant economic evaluations were identified.

Three economic evaluations relating to this review question were identified but were excluded due to methodological limitations.[32,74,161]. These are summarised in Appendix L, with reasons for exclusion given.

See also the economic article selection flow chart in Appendix E.

9.7.5 Evidence statements

Clinical

Hip spica versus EIN

Very low quality evidence from 2 RCTs comprising 95 participants showed that the hip spica was clinically harmful relative to the EIN in terms of the time to return to school, with no serious imprecision.

Very low quality evidence from 2 RCTs comprising 95 participants showed that the hip spica was clinically harmful relative to the EIN in terms of the time to return to independent ambulation, with no serious imprecision.

Low quality evidence from 1 RCT comprising 49 participants showed that the hip spica was clinically harmful relative to the EIN in terms of the time to return to normal activities, with no serious imprecision.

Low quality evidence from 1 RCT comprising 49 participants showed that the hip spica was clinically harmful relative to the EIN in terms of the numbers of people with an excellent Flynn grading, with no serious imprecision.

Very low quality evidence from 1 RCT comprising 46 participants showed that the hip spica was clinically harmful relative to the EIN in terms of the numbers of people whose parents were satisfied, with serious imprecision.

Very low quality evidence from 3 RCTs comprising 146 participants showed that the hip spica and the EIN did not differ in terms of length of hospital stay, with very serious imprecision.

Very low quality evidence from 1 RCT comprising 49 participants showed that the hip spica and the EIN did not differ in terms of the need for further treatment, with very serious imprecision.

Very low quality evidence from 1 RCT comprising 49 participants showed that the hip spica and the EIN did not differ in terms of malunion, with very serious imprecision.

Very low quality evidence from 1 RCT comprising 49 participants showed that the hip spica and the EIN did not differ in terms of avascular necrosis, with very serious imprecision.

Very low quality evidence from 1 RCT comprising 46 participants showed that the hip spica and the EIN did not differ in terms of nerve injury, with very serious imprecision.

Spica versus external fixation

Very low quality evidence from 1 RCT comprising 101 participants showed that the hip spica was clinically beneficial relative to external fixation in terms of adverse events requiring other treatment, with no serious imprecision.

Very low quality evidence from 1 RCT comprising 101 participants showed that the hip spica was clinically harmful relative to external fixation in terms of malunion, with no serious imprecision.

Very low quality evidence from 1 RCT comprising 101 participants showed that the hip spica and external fixation did not differ in terms of Rand child health status, with serious imprecision.

External fixation versus EIN

Very low quality evidence from 1 RCT comprising 20 participants showed that external fixation was clinically beneficial relative to EIN in terms of foot-drop, with very serious imprecision.

Very low quality evidence from 1 RCT comprising 20 participants showed that external fixation was clinically harmful relative to EIN in terms of parental satisfaction, with serious imprecision.

Very low quality evidence from 1 RCT comprising 20 participants showed that external fixation was clinically harmful relative to EIN in terms of number of follow-up revisions, with very serious imprecision.

Very low quality evidence from 1 RCT comprising 20 participants showed that external fixation was clinically harmful relative to EIN in terms of limb length discrepancy, with very serious imprecision.

Bryant's traction versus the Pavlik harness

Very low quality evidence from 1 retrospective cohort study comprising 38 participants showed that Bryant's traction was clinically harmful relative to the Pavlik harness in terms of length of hospital stay, with no serious imprecision.

Very low quality evidence from 1 retrospective cohort study comprising 38 participants showed that Bryant's traction and the Pavlik harness did not differ in terms of leg length discrepancy, with very serious imprecision.

Very low quality evidence from 1 retrospective cohort study comprising 38 participants showed that Bryant's traction and the Pavlik harness did not differ in terms of malunion, with no serious imprecision.

SIN versus plating

Very low quality evidence from 1 retrospective cohort study comprising 45 participants showed that SIN and plating did not differ in terms of the number with a Flynn grading of excellent, with very serious imprecision.

Very low quality evidence from 1 retrospective cohort study comprising 43 participants showed that SIN and plating did not differ in terms of the number returning to ambulation without limping, with no serious imprecision.

Very low quality evidence from 1 retrospective cohort study comprising 43 participants showed that SIN and plating did not differ in terms of leg length discrepancy, with no serious imprecision.

Very low quality evidence from 1 retrospective cohort study comprising 43 participants showed that SIN was clinically harmful relative to plating in terms of the need for re-operation, with very serious imprecision.

Very low quality evidence from 1 retrospective cohort study comprising 43 participants showed that SIN was clinically harmful relative to plating in terms of non-union, with very serious imprecision.

Economic

No relevant economic evaluations were identified.

9.7.6 Recommendations and link to evidence

Recommendations	**23. Admit all children (skeletally immature) with femoral shaft fractures and consider 1 of the following according to age and weight:** • **prematurity and birth injuries: simple padded splint** • **0 to 6 months: Pavlik's harness or Gallows traction** • **3 to 18 months (but not in children over 15 kg): Gallows traction** • **1 to 6 years: straight leg skin traction (becomes impractical in children over 25 kg) with possible conversion to hip spica cast to enable early discharge** • **4 to 12 years (but not in children over 50 kg): elastic intramedullary nail** • **11 years to skeletal maturity (weight more than 50 kg): elastic intramedullary nails supplemented by end-caps, lateral-entry antegrade rigid intramedullary nail, or submuscular plating.**
Relative values of different outcomes	Critical outcomes were: health-related quality of life; the number of follow up treatments, as this is a good marker of treatment failure; PODCI-POSNA score as a functional marker; and adverse effects (mortality, neurovascular damage, deformity, non-union, vascular compromise and avascular necrosis). Important outcomes were pain, return to normal activities, duration of hospital stay and psychological wellbeing.
Trade-off between clinical benefits and harms	**Bryant's traction versus Pavlik's harness** Bryant's traction led to a relative harm compared to Pavlik's harness in terms of hospital stay. However other outcomes did not differ. The harms of Bryant's traction thus dominated, although because no critical outcomes were reported, it is unclear which of the two treatments was clinically superior. The GDG noted that a more commonly used term for Bryant's traction is Gallows traction, which is the term used in the recommendation. **Hip Spica versus elastic Intramedullary nailing (EIN)** No clinical benefits were observed for the hip Spica relative to EIN. On the other hand, clinical harms in terms of longer return to normal activities, and lower numbers with an 'excellent' Flynn grading or good/excellent parental satisfaction were observed for the hip Spica relative to the EIN. Hence, after allowing for the relative weights of different outcomes, EIN was regarded as clinically superior in this comparison. **Hip Spica versus external fixation** Hip Spica led to a clinically important level of less adverse events requiring treatment than external fixation, but also greater mal-union. On balance, after allowing for the relative weights of different outcomes, the harms probably balanced the benefits, making the two treatments in this comparison comparable. **External fixation versus EIN** External fixation led to a clinically important level of harm in terms of less parental

	satisfaction, more revisions and greater limb length discrepancy relative to EIN, but had a relatively lower level of footdrop. Overall, the harms of external fixation over EIN outweighed the relative benefits. Hence, after allowing for the relative weights of different outcomes, EIN was regarded as clinically superior in this comparison. **Standard intramedullary nailing (SIN) versus plating** SIN led to a relative harm compared to plating in terms of need for reoperation and non-union. SIN had no relative benefit or harm over plating for Flynn grading, return to normal ambulation or leg length discrepancy. Due to the critical nature of the outcomes for which SIN had a clinical harm, plating appears to have the best balance of benefits and harms. However, it should be noted that the SIN used in this study were modified adult nails and may not reflect the results expected from current intramedullary nails specifically designed for children, which are inserted via a lateral approach.
Economic considerations	No economic evidence was included for this question. Gallows traction is the cheapest intervention as it uses a system of pulleys that will be reused and so incur a minimal cost per use. The child needs to have bandages and a strap to be connected to the equipment and this comes in a kit that costs £5.81. Straight leg traction has a similar cost to Gallows traction. A Pavlik harness has an increased cost of materials at £16.13, while hip spica casting is more expensive still due to the materials and anaesthetist time required. This overall cost is estimated at £40.20. The most expensive intervention cost is for an elastic intramedullary nail due to the cost of the implant. The overall cost differences between these treatments are largely due to the length of hospital stay required. An excess bed day in a paediatric trauma and orthopaedic department is approximately £358. A Pavlik harness allows the patient to be discharged sooner than other treatments – excluding hip Spica casting – and the cost of just one extra bed day will outweigh the increase in costs of the materials compared to Gallows traction. Hip spica casting requires the patient to return to hospital for the removal of the cast and so incurs an additional cost. Premature infants or those with birth injuries will be incubated and so cannot have anything other than a simple padded splint. For children up to 6 months of age, the GDG recommend a Pavlik harness due to the low cost, reduced hospital stay and no other clinical difference compared to gallows traction. Pavlik harness treatment is impractical for children over around 6 months of age as they child will be able to undo the Velcro straps. Therefore, another method is necessary which will probably result in a longer hospital stay. A hip spica cast would allow early discharge but immediate spica treatment for unstable femur fractures is associated with a risk of severe adverse effects and spica application usually requires general anaesthesia, which also comes with a risk of severe adverse effects. Traction requires longer hospital stay until either the fracture is healed or is sufficiently stable for a hip spica to be employed safely. Traction treatment may require an inpatient stay of up to six weeks at a cost of around £15,036. For older children, conservative treatment is impractical and so surgical fixation is required. The GDG agreed that elastic intramedullary nailing should be used due to the better outcomes compared to external fixation and the ability to discharge the patient sooner as a nail does not need to be removed. For children 11 years or above, a stronger method of internal fixation is required and so the GDG agreed that the nail can be supplemented by end caps or either lateral entry antegrade rigid intramedullary nails or submuscular plating could be used.

Quality of evidence	Quality of evidence was low to very low. Risk of bias across all outcomes was very serious, mainly due to a lack of evidence of allocation concealment and blinding. Imprecision was also serious or very serious in the majority of outcomes. In age group 1-6 there was very little evidence available and so a consensus decision was used.
Other considerations	From 0 to 1 years there is an advantage to keeping children with femoral shaft fractures in hospital, to facilitate investigations for non-accidental injury, making Gallows traction a good option for this age group, with its associated longer hospital stay. The GDG noted that the Elastic intramedullary nailing (EIN) used in the literature is also referred to as Elastic Stable Intramedullary Nailing (ESIN) and so the recommendations for EIN also apply to ESIN. The standard intramedullary nailing used in the literature was reported by one GDG member to have severe complications in children. However, it was noted that the standard intramedullary nailing used in the literature was not typical of the standard intramedullary nailing currently used for children, which is inserted via a lateral approach. This lateral approach version of standard intramedullary nailing is termed Lateral Entry Antegrade Rigid Intramedullary Nailing and was regarded by the GDG as having a lower risk of complications. As an alternative to Lateral Entry Antegrade Rigid Intramedullary Nails in children above 11, elastic intramedullary nails supplemented by end caps were suggested. The end caps effectively transform the elastic nails into rigid structures, making them appropriate for this age group.

9.8 Post-operative mobilisation – distal femoral fractures

9.8.1 Introduction

Prolonged immobilisation after a femoral fracture can lead to reduced function secondary to muscle disuse atrophy. This, in turn, can lead to reduced quality of life and sometimes falls, which bring further morbidity or even mortality. A rapid return to normal weight-bearing is therefore desirable, but the perceived risks of disrupting the healing fracture site can often lead to a delay in mobilisation. Current practice varies widely and this review aims to identify the optimal time for unrestricted weight-bearing.

9.8.2 Review question: What is the most clinically and cost-effective weight-bearing strategy in patients with operatively treated fractures of the distal femur?

For full details see review protocol in Appendix C.

Table 131: PICO characteristics of review question

Population	Children, young people and adults who have undergone surgical treatment for traumatic fracture of the distal femur.
Intervention	**Immediate** unrestricted weight bearing (weight bearing as tolerated)
Comparison	**Delayed** unrestricted weight-bearing (partial weight bearing, touch weight bearing, non-weight bearing, protected weight bearing)
Outcomes	Critical: • Mortality • Health-related quality of life

	• Return to pre-injury mobility status/normal activity • Displacement of fracture (angular deformity) • Re-operation (non-union and mal-union) • DVT/PE within 3 months • Chest infections • UTIs Important: • Hospital bed days Population size and directness: • No limitations on sample size • Studies with indirect populations will not be considered
Study design	Systematic reviews/RCTs and cohort studies. If cohorts are used, these must consider all the key confounders chosen by the GDG.

9.8.3 Clinical evidence

No RCTs or cohort studies were found for this review question. See the study selection flow chart in Appendix D and excluded studies list in Appendix K.

9.8.4 Economic evidence

Published literature

No relevant economic evaluations were identified.

See also the economic article selection flow chart in Appendix E.

9.8.5 Evidence statements

Clinical

No relevant clinical evaluations were identified.

Economic

No relevant economic evaluations were identified.

9.8.6 Recommendations and link to evidence

Recommendations	**24. Consider advising immediate unrestricted weight-bearing as tolerated for people who have had surgery for distal femoral fractures.**
Relative values of different outcomes	Critical outcomes were mortality at 30 days and 1 year, health-related quality of life, return to pre-injury mobility status/ normal activity, displacement of fracture (angular deformity), re-operation (non-union and mal-union), DVT/PE within 3 months, chest infections, and urinary tract infections. Hospital bed days was considered as an important outcome.
Trade-off between clinical benefits and harms	There was no evidence available from published sources, and so a consensus recommendation based on hip fracture guidelines was made. The GDG felt that the considerable risks of disuse-related immobility with delayed

	weight bearing outweighed the small risk of fracture fixation failure with early full weight bearing as tolerated. Hence the recommendation with the least risk and better balance of benefits and harms was immediate unrestricted weight-bearing,.
Economic considerations	No economic evidence was found to inform this review. Weight bearing mobilisation is important for the recovery of a patient with a distal femur fracture. It promotes healing, which can improve functional outcomes and reduce hospital stay. This can therefore reduce costs and improve the quality of life of the patient. If full weight bearing is performed early, most patients will benefit. However, there is an increased risk of the fixation failing and the patient requiring further surgery, so there is a trade-off between the reduced costs of hospital stay and the increased costs from further surgery. There is also the same trade-off between improved outcomes of the majority who benefit and the reduced outcomes of those who require further surgery. Delaying weight bearing will increase the healing time of the fracture and incur greater costs of hospital stay, as well as reducing the functional outcome for patients. This increased hospital stay can also increase the risk of adverse events such as pressure sores, deep vein thrombosis, urinary tract infections and chest infections. These will incur further costs for treatment. The GDG came to the consensus that immediate full weight bearing was more likely to be cost effective as most patients would benefit and this would outweigh the costs and effects of those who do not.
Quality of evidence	No clinical evidence was retrieved to inform this review.
Other considerations	Supervision by the physiotherapist was felt to be essential for immediate weight-bearing, and this raised concerns that 'out of hours' physiotherapists should be available. This has resource implications.

9.9 Post-operative mobilisation – ankle fractures

9.9.1 Introduction

Open reduction and internal fixation (ORIF) of the ankle is a commonly carried out operation in the NHS. Currently there is variation in advice given around mobilisation and weight-bearing for people who have undergone this procedure, as there is uncertainty as to whether unrestricted weight bearing as tolerated should be commenced at a very early stage or after a number of weeks. Possible benefits of early unrestricted weight-bearing are thought to include improved ambulatory function and quality of life, but potential harms may include wound infection or disruption of the healing site. A clear recommendation for optimal practice therefore requires a rigorous review of the available evidence.

9.9.2 Review question: What is the most clinically- and cost- effective mobilisation strategy in post-operative patients following internal fixation of ankle fracture?

For full details see review protocol in Appendix C.

Table 132: PICO characteristics of review question

Population	Children, young people and adults who have had internal fixation for an ankle fracture following a traumatic incident

Intervention(s)	**Immediate** unrestricted weight bearing (weight bearing as tolerated) (Unrestricted weight bearing beginning as late as the start of the 3rd post-operative week was considered to be immediate)
Comparison(s)	**Delayed** unrestricted weight bearing (partial weight bearing, touch weight bearing, non-weight bearing, protected weight bearing)
Outcomes	Critical: • Health-related quality of life • Patient-reported outcomes (OMAS, AAOFAS, DRI) • return to normal activities • Displacement • Need for re-operation • Non-union/malunion • DVT/PE at 3 months • Wound infection Important: • Number of hospital/out-patient attendances • Length of hospital stay, length till return to normal residence/ step down
Study design	RCTs or systematic reviews of RCTs: cohorts if insufficient RCT evidence found. If cohorts are used, these must consider all the key confounders chosen by the GDG.

9.9.3 Clinical evidence

Eight RCTs were included in the review;[8-12,53,79,187] these are summarised in Table 133 below. Evidence from these studies is summarised in the clinical evidence summary below Table 134. See also the study selection flow chart in Appendix D, study evidence tables in Appendix G, forest plots in Appendix J, GRADE tables in Appendix I and excluded studies list in Appendix K.

Immediate unrestricted weight bearing was defined as starting from as early as the first post-operative day until the beginning of the third week. Delayed unrestricted weight bearing ranged from the fourth post-operative week until the eighth week. All wound infection outcomes were combined in this review; they were defined in the papers as superficial infection, superficial infection/skin irritation, infection and deep infection. The studies that reported deep infection did not report any incidences in either the immediate unrestricted weight bearing group or the delayed unrestricted weight bearing group.

Table 133: Summary of studies included in the review

Study	Intervention/comparison	Population	Outcomes
Ahl 1986[8]	1st day versus 5th week Both groups had below knee casts for 7 weeks.	n=46 Adults with dislocated fractures of the fibula who had internal fixation. Conducted in Sweden	• Displacement (re-dislocation) • Need for re-operation • Wound infection
Ahl 1987[9]	1st day (with below-the-knee cast) versus 4th week	n=53 Adults with displaced bimalleolar or trimalleolar ankle fractures who had internal fixation. Conducted in Sweden	• Ankle score at 3 and 6 months • Displacement (re-dislocation) • Need for re-operation • Wound infection • Length of hospital stay
Ahl 1988[11]	2nd week (orthosis) versus	n=51	• Displacement (re-

Study	Intervention/comparison	Population	Outcomes
	7th week (dorsal splint) Both groups encouraged to do ankle exercises at least 5 times daily.	Adults with displaced lateral malleolar fractures who had internal fixation. Conducted in Sweden	dislocation) • Need for re-operation • Wound infection
Ahl 1989[12]	1st day versus 4th/5th week	n=99 Adults with dislocated lateral malleolar or bimalleolar fractures who had internal fixation. Conducted in Sweden	• Displacement (re-dislocation)
Ahl 1993[10]	2nd week (orthosis) versus 8th week (dorsal splint) Both groups had plaster casts and no weight bearing for one week. Also encouraged to do ankle exercises at least 5 times daily	n=43 Adults with displaced bimalleolar or trimalleolar ankle fractures who had internal fixation. Conducted in Sweden	• Ankle score at 3 and 6 months • Displacement • Need for re-operation • Wound infection
Finsen 1989[53]	1st day (below knee cast with rubber walker) versus 6th week (POP splint)	n=56 People with an ankle fracture who underwent rigid internal fixation. Conducted in Norway	• Ankle score at 9 weeks, 18 weeks, 36 weeks, 52 weeks
Honigmann 2007[79]	Beginning of 3rd week (orthosis) versus 6th week (bandage). Both groups did partial weight bearing of 15 kg	n=45 Young people and adults with displaced malleolar fracture who had internal fixation. Conducted in Switzerland	• Ankle scores at 6 and 10 weeks • Pain/comfort scores at 6 and 10 weeks • Quality of life (SF12) at 6 and 10 weeks
Van laarhoven 1996[187]	2–5 days (below-knee walking plaster) versus not detailed (crutches) Both groups were treated in a plaster cast for two to five days	n=81 People with ankle fractures who had internal fixation. Conducted in Netherlands	• Ankle score at 10 days, 6 weeks, 3 months, 12 months • Return to normal activities • Displacement (re-dislocation) • Wound infection

No data were found for these outcomes: non-union/malunion, DVT/PE at 3 months, number of hospital/out-patient attendances.

Table 134: Clinical evidence summary: Weight bearing for people with ankle fractures who have had internal fixation

Outcome	Number of studies (number of participants)	Imprecision	GRADE rating	Absolute difference	Control event rate (per 1000)	Control event rate for continuous outcomes
Ankle score at 9 weeks (Better indicated by lower)	1 (n=39)	Serious	VERY LOW	MD 2.8 lower (6.11 lower to 0.51 higher)	NA	11.6
Ankle score at 18 weeks (Better indicated by lower)	1 (n=39)	Very serious	VERY LOW	MD 0.1 higher (2.6 lower to 2.8 higher)	NA	5.3
Ankle score at 36 weeks (Better indicated by lower)	1 (n=39)	Serious	VERY LOW	MD 1.1 higher (0.66 lower to 2.86 higher)	NA	2.2
Ankle score at 52 weeks (Better indicated by lower)	1 (n=39)	Very serious	VERY LOW	MD 0.1 higher (1.57 lower to 1.77 higher)	NA	1.8
Displacement/re-dislocation	6 (n=360)	Very serious	VERY LOW	9 fewer per 1000 (from 19 fewer to 32 more)	22 per 1000	NA
Wound infection	5 (n=267)	Serious	VERY LOW	62 more per 1000 (from 3 more to 225 more)	30 per 1000	NA

Narrative review for outcomes not appropriate for GRADE

Need for re-operation (very high risk of bias)

Four studies[8-11] reported need for re-operation. All studies reported 0 events in all trial arms.

Patient-reported outcomes and quality of life [very high risk of bias]

Four studies[9,10,79,187] reported some form of patient-reported ankle/quality of life score. The results are in Table 135. The papers report a mix of means and medians without any useful measures of variance. P values were reported inconsistently in all but the 1996 paper by van Laarhoven.

The majority of Olerud and Molander/ankle score (linear analogue scale) results indicated no significant difference between intervention and comparator groups. Where significant differences were found, they favoured the immediate unrestricted weight bearing group.

Honigmann 2007[79] reported similar results in both intervention and comparator groups for comfort and pain scores. Walking confidence scores favoured immediate unrestricted weight bearing at 6 weeks and delayed at 10 weeks (p=0.02). The SF12 mental score was significantly better in the delayed unrestricted weight bearing group at 6 weeks (p=0.01) but there was no significant difference at 10 weeks. The SF12 physical score showed no significant difference at either 6 or 10 weeks.

Table 135: Patient-reported outcomes and quality of life

Score and time period	Study	Number of participants	Immediate unrestricted weight bearing	Delayed unrestricted weight bearing	P value
Olerud and Molander: 0–100. High is a good outcome					
At 10 days	van Laarhoven 1996[a]	n=81	45	40	0.47[(c)]
At 6 weeks	Honigmann 2007[b]	n=43	72 (35 to 95)	70 (45 to 90)	0.81
	van Laarhoven 1996[a]	n=81	65	50	0.02[(c)]
At 10 weeks	Honigmann 2007[b]	n=43	80 (40 to 100)	85 (40 to 100)	0.53
At 3 months	Ahl 1987[a]	n=51	54	47	<0.05
	Ahl 1993[a]	n=40	66	53	-
	van Laarhoven 1996[a]	n=81	85	80	0.84[(c)]
At 6 months	Ahl 1987[a]	n=51	70	73	-
	Ahl 1993[a]	n=40	82	76	-
At 12 months	van Laarhoven 1996[a]	n=81	95	95	0.90[(c)]
Ankle score (linear analogue scale: 0–100). High is good outcome					
At 10 days	van Laarhoven 1996[a]	n=81	40	30	0.05[(c)]
At 6 weeks	van Laarhoven 1996[a]	n=81	70	60	0.03[(c)]
At 3 months	van Laarhoven 1996[a]	n=81	80	80	0.82[(c)]

Score and time period	Study	Number of participants	Immediate unrestricted weight bearing	Delayed unrestricted weight bearing	P value
At 12 months	van Laarhoven 1996[a]	n=81	90	90	0.83[(c)]
Comfort (visual analogue scale: 0–10). High is a good outcome					
At 6 weeks	Honigmann 2007[b]	n=43	10 (9 to 10)	9 (8 to 10)	-
At 10 weeks	Honigmann 2007[b]	n=43	9 (8 to 10)	9 (8 to 9.5)	-
Pain (visual analogue scale: 0–10). High is a poor outcome					
At 6 weeks	Honigmann 2007[b]	n=43	0 (0 to 1)	0 (0 to 1.5)	-
At 10 weeks	Honigmann 2007[b]	n=43	0 (0 to 1.5)	1 (0 to 2)	-
Walking confidence (visual analogue scale: 0–10). High is a good outcome					
At 6 weeks	Honigmann 2007[b]	n=43	9 (8 to 10)	8 (7 to 10)	-
At 10 weeks	Honigmann 2007[b]	n=43	9 (8 to 9)	10 (9 to 10)	0.02
SF12 mental score: 0–100. High is good outcome					
At 6 weeks	Honigmann 2007[b]	n=43	52 (44 to 56)	57 (54 to 62)	0.01
At 10 weeks	Honigmann 2007[b]	n=43	55 (54 to 58)	56 (55 to 60)	Not significant
SF12 physical score: 0–100. High is good outcome					
At 6 weeks	Honigmann 2007[b]	n=43	39 (43 to 47)	38 (32 to 46)	Not significant
At 10 weeks	Honigmann 2007[b]	n=43	48 (46 to 52)	49 (46 to 55)	Not significant

(a) Mean scores
(b) Median (range)
(c) Mann–Whitney test

Return to normal activities [very high risk of bias]

Van Laarhoven 1996[187] reported median (range) days until return to full-time work, part-time work and work in a standing job. The differences between groups were stated as not significant; however, the trend showed a benefit for immediate unrestricted weight bearing. The results are reported in Table 136.

Table 136: Return to normal activities (days)

Return to work	Immediate unrestricted weight bearing	Delayed unrestricted weight bearing	P value (Mann–Whitney test)
Return to full-time work	78 (9 to 244)	79 (9 to 356)	0.54
Return to part-time work	24 (7 to 183)	44 (4 to 216)	0.19
Return to work in a standing job	20	40	0.13

Length of hospital stays (very high risk of bias)

Ahl 1987[9] reported mean time spent in hospital as 4 days for both the immediate unrestricted weight bearing arms and delayed unrestricted weight bearing arms. No measure of variance was stated and the results showed no significant differences between the intervention and comparator groups.

9.9.4 Economic evidence

Published literature

No relevant economic evaluations were identified.

See also the economic article selection flow chart in Appendix E.

9.9.5 Evidence statements

Clinical

Very low quality evidence from 1 RCT comprising 39 participants showed that immediate unrestricted weight bearing was clinically beneficial relative to delayed unrestricted weight bearing in terms ankle function at 9 weeks, with serious imprecision.

Very low quality evidence from 1 RCT comprising 39 participants showed that immediate unrestricted weight bearing and delayed unrestricted weight bearing did not differ in terms of ankle function at 18 or 52 weeks , with very serious imprecision.

Very low quality evidence from 1 RCT comprising 39 participants showed that immediate unrestricted weight bearing was clinically harmful relative to delayed unrestricted weight bearing in terms ankle function at 36 weeks , with serious imprecision.

Very low quality evidence from 1 RCT comprising 39 participants showed that immediate unrestricted weight bearing was clinically harmful relative to delayed unrestricted weight bearing in terms of wound infection, with serious imprecision.

Very low quality evidence from 6 RCTs comprising 360 participants showed that the immediate unrestricted weight bearing and delayed unrestricted weight bearing did not differ in terms of displacement/re-dislocation, with very serious imprecision.

Economic

No relevant economic evaluations were identified.

9.9.6 Recommendations and link to evidence

Recommendations	**Research recommendation: What is the most clinically effective and cost-effective strategy for weight-bearing in people who have had surgery for internal fixation of an ankle fracture?**
Relative values of different outcomes	Critical outcomes were health-related quality of life, patient reported outcomes (OMAS, AAOFAS, DRI), return to normal activities, displacement, need for operative treatment, non-union/malunion and DVT/PE at 3 months. Important outcomes were the number of hospital/out-patient attendances and the length of hospital stay/length until return to normal residence.
Trade-off between clinical benefits and harms	There were clinically important benefits for immediate weight bearing relative to delayed weight bearing in terms of short term ankle function, but these were not observed in the longer term. There were clinically significant harms for immediate weight bearing relative to delayed weight bearing in terms of quality of life, although this was a relatively small effect and not borne out over time. There were also clinically significant harms for immediate weight bearing relative to delayed weight bearing in terms of wound infection. However when the outcome reported in the study was *deep* infection, there were no incidences in either intervention or comparator groups. Overall, the evidence did not suggest a clear difference between

	approaches in terms of their balance of benefits and harms.
Economic considerations	Weight bearing mobilisation is important for the recovery of a patient following fixation of an unstable ankle fracture. It promotes healing, which can improve functional outcomes and reduce hospital stay. This can therefore reduce costs and improve the quality of life of the patient. If full weight bearing is performed early, most patients are expected to benefit. However, there is an increased risk of the fixation failing and the patient requiring further surgery, so there is a trade-off between the reduced costs of hospital stay and the increased costs from further surgery. There is also the same trade-off between improved outcomes of those who benefit and the reduced outcomes of those who require further surgery. Delaying weight bearing will increase the healing time of the fracture and incur greater costs of hospital stay, as well as reducing the functional outcome for patients. This increased hospital stay can also increase the risk of adverse events such as pulmonary embolism, deep vein thrombosis, pressure sores, deep vein thrombosis and infections. These will incur further costs for treatment. No economic evidence was found on this question and considering the trade-off between strategies the GDG decided to make a research recommendation.
Quality of evidence	All the evidence was graded as very low quality. Risk of bias was very serious for most outcomes due to a lack of allocation concealment, or a lack of patient, health-care practitioner and assessor blinding. There was serious or very serious imprecision for all outcomes due to the 95% confidence intervals crossing one or both clinical importance thresholds. Finally, there was inconsistency in effect size (direction of effect) for the same outcome measured at different follow-up points.
Other considerations	The GDG decided a research recommendation was appropriate given the very low quality of the evidence and the inconclusive results.

10 Documentation, information and support

10.1 Documentation

10.1.1 Introduction

Accurate, comprehensive and relevant documentation is generally accepted as an essential part of patient care. Unfortunately, this may not always be regarded as a priority in an emergency situation, and there is concern that documentation of the trauma patient and the person with non-complex fractures in particular, is not always optimal. One aspect that is often neglected is safeguarding. Non-complex fractures may often be associated with non-accidental injury, particularly in children, and it is possible that documentation that considers this issue will lead to better outcomes. Comorbidities and falls risk are vital issues in relation to older people with fractures, and documentation of these may help to inform better advice as well as more appropriate care. Finally, fracture classification is essential to inform appropriate management but may often not be recorded. This review aims to evaluate the importance of these four aspects within documentation.

10.1.2 Review question: In patients with non-complex fractures does documentation recording safeguarding, comorbidities, falls risk and fracture classification alongside standard diagnosis documentation improve outcomes compared with standard diagnosis documentation alone?

For full details see review protocol in Appendix C.

Table 137: PICO characteristics of review question

Population	Children, young people and adults experiencing a traumatic incident leading to a non-complex fracture.
Intervention	Documentation recording one or more of safeguarding[a], comorbidities[b], falls risk and fracture classification alongside standard diagnosis.
Comparison	Standard diagnosis documentation. This will normally include the diagnosis (that is, #NOF), with other information NOT including one or more of safeguarding, comorbidities, falls risk or fracture classification.
Outcomes	Critical: • Mortality (short- and long-term) • Health-related quality of life (short- and long-term) • Future fractures • Additional treatments/unplanned surgery Important: • Return to normal activities Population size and directness: • No limitations on sample size • Studies with indirect populations will not be considered
Study design	Systematic reviews/RCTs, dropping down to cohort studies if no RCTs. If cohorts are used, these must consider all the key confounders chosen by the GDG.

(a) Safeguarding includes non-accidental injury, domestic abuse and elder abuse.
(b) Comorbidities to include disorders such as substance abuse, alcohol dependence and smoking.

10.1.3 Clinical evidence

No RCTs or cohort studies were found for this review question. See the study selection flow chart in Appendix D and excluded studies list in Appendix K.

10.1.4 Economic evidence

Published literature

No relevant economic evaluations were identified.

See also the economic article selection flow chart in Appendix E.

10.1.5 Evidence statements

Clinical

No relevant clinical evaluations were identified.

Economic

No relevant economic evaluations were identified.

10.1.6 Recommendations and link to evidence

Recommendations	**25. Consider developing and using standard documentation to prompt the assessment of the following from first presentation in people with fractures:** • **safeguarding** • **comorbidities** • **falls risk** • **nature of fracture, including classification where possible.** **26. Follow a structured process when handing over care within the emergency department (including shift changes) and to other departments. Ensure that the handover is documented.** **27. Ensure that all patient documentation, including images and reports, goes with patients when they are transferred to other departments or centres.** **28. Produce a written summary, which gives the diagnosis, management plan and expected outcome, and:** • **is aimed at and sent to the patient's GP within 24 hours of admission** • **includes a summary written in plain English that is understandable by patients, family members and carers** • **is readily available in the patient's records.**
Relative values of different outcomes	Health-related quality of life was the only critical outcome identified for this review. Important outcomes were pain/discomfort, return to normal activities, and psychological wellbeing.
Trade-off between	No published evidence was found for this review question. The GDG felt that

clinical benefits and harms	documentation of safeguarding, comorbidities, falls risk and fracture classification were important to ensure good patient care, and yet were frequently absent from notes because the standard documentation did not prompt them. It was agreed by the GDG that standard documentation should prompt the recording of these 4 important variables, as it was believed that this would lead to a clinical benefit with no counteracting harms.
Economic considerations	No relevant economic studies were identified. Changes in documentation systems can incur an implementation cost that could be larger, especially if electronic systems are used. However, over time the cost per patient will become negligible. Another cost, however, is the potential increase in staff time due to the increase in information that is needed to be documented. There are potential cost benefits of having standardised documentation though. For instance, repeat examinations could be reduced and there could be a clinical benefit to the patient by minimising the loss of key information that could affect their onward treatment. The GDG also regarded safeguarding as an important issue that is not always documented properly. This can have a great impact on quality of life, especially for children who could be affected in the long term. The GDG agreed that the benefits of standardised documentation would justify the implementation cost and the potential increase in staff time and would therefore be cost effective.
Quality of evidence	No published evidence was found for this review question, so decisions were made by GDG consensus.
Other considerations	The GDG felt the treating clinician should document either a description or classification of a fracture sufficient to justify the clinical decisions at that point in the patient pathway and as a record of the nature of the injury. The GDG presume that as part of routine medical care a history of co-morbidities would be sought. However particular attention should be paid to co-morbidities which have a relevance to the causation or management of a fracture; for example diabetes (affecting healing and infection potential), renal disease (influencing choice of analgesic), and prescribed medications for pre-existing conditions (for example, anticoagulants). In addition, when the bony injury is out of proportion to the reported mechanism an underlying bony pathology should be suspected and any conclusions recorded. A falls assessment may help prevent further injury. It should be documented whether this has been considered and what action has been taken. This applies to a sufficiently large group of fracture patients that it should be considered separately from co-morbidities in general. The GDG also noted there is a NICE guideline on the assessment and prevention of falls in older people.[129] Safeguarding should be considered in people with fractures just as in any patient. However, as fractures generally result from an applied mechanical force the GDG considered there should be greater vigilance. When the fracture patient is considered vulnerable for any reason - for instance, their age, mental health or social circumstance - it should be specifically recorded that this matter has been considered. Any action taken as a result of this consideration should also be documented

10.2 Information and support

10.2.1 Introduction

The NICE guideline on 'Patient Experience' (CG138) has established that people receiving medical care, along with their carers and families, require information about their diagnosis, prognosis and treatment. This is in order to optimise a sense of control and minimise psychological stress, as well as to provide useful practical advice and important warnings. Such information is required from the very early stages of assessment and treatment. Because the optimum information is specific to the person's condition, this chapter describes, through a synthesis of findings from qualitative studies, the specific thoughts and feelings of people with fractures, and their carers and families, concerning the information and support they require.

10.2.2 Review question: What information and support do people with fractures and their families and carers require?

For full details see review protocol in Appendix C.

Table 138: SPICE characteristics of review question

Setting	NHS – primary and secondary care
Population	People with non-complex fractures after trauma
Intervention (phenomenon of interest)	Information
Comparison	Not applicable – this will be a qualitative review
Evaluation	Thoughts and feelings of respondents about the information they require will be collated

10.2.3 Clinical evidence

Four qualitative studies were included in the review;[57,138,140,173] these are summarised in Table 139 below. Evidence from these studies is summarised in a narrative review. A simple thematic analysis was used to pool findings from the different studies. Quality was assessed using a modified version of the NICE qualitative studies appraisal framework.

Issues covered by this quality assessment were:

- Rigour of the research methodology
- Quality of data collection
- Clear description of role of researcher
- Clear description of context
- Trustworthy data collection methods
- Rigorous analysis methods
- Richness of data
- Trustworthy data analysis methods
- Convincing findings
- Relevance to the aims of the study

Limitations of each study in terms of these quality criteria are summarised in Table 139 and a detailed breakdown of the quality assessment is included in Appendix O.

Table 139: Summary of studies included in the review

Study	Population	Methods	Limitations
Forsberg 2014[57]	24–72 year olds in Sweden with a lower limb fracture and reparative surgery	Semi-structured interviews and content analysis	No methods to ensure trustworthiness and long duration after surgery for some. Quality rating: not trustworthy
O'Brien 2010[138]	People with finger fractures and treated with a distraction splint	Semi-structured interview and phenomenological/ grounded theory	Some injuries had occurred up to eight years previously. Quality rating: trustworthy
Okonta 2011[140]	People with fractures treated at a Doctors On Call for Service hospital in the Congo	Free-attitude interviews and content analysis	Unclear if triangulation used. Quality rating: not trustworthy
Sleney 2014[173]	People aged 5 years or older admitted to an ED in Bristol, Surrey and Swansea.	Semi-structured interviews and thematic analysis	Not all participants had fractures. Quality rating: indirect but trustworthy

Narrative review of the evidence

There were 6 main themes concerning the content of information or support desired that emerged from the review of the literature:

- Treatment details
- Outcomes of treatment
- Time schedules
- Information promoting self-efficacy
- Aftercare and home rehabilitation
- Social support

There were also 4 themes concerning the manner in which information should be given:

- Patient-centred
- Consistency
- Non-technical language
- Written information

Content of information

Treatment details

Participants in three studies (Forsberg 2014[57], Sleney 2014[173], O'Brien 2010[138] emphasised the importance of obtaining information on the treatments being administered.

Prior to surgery, Forsberg 2014[57] described how most anxiety stemmed from the lack of understanding of what would happen. During surgery, Forsberg 2014[57] described how participants under regional anaesthesia reported feelings of curiosity about what was occurring. They appreciated the staff saying what they were doing and why:

> *"I heard them banging and I felt when I was…I said what are you doing and they said [orthopaedic] now we are spiking the long nail in".*

Forsberg 2014[57] described how participants wanted information about pain relief, such as "explaining which kind of drug was being administered".

Sleney 2014[173] found that some participants thought information given about treatment or aftercare could inspire confidence:

> *''...the consultant he was...absolutely on the ball and that's one thing I have to say, he instilled confidence...you know he kept me fully informed and made sure that I knew what was going on''*

Similarly, Okonta 2011[140] stated how information about treatment was linked to reassurance:

> *"we need to get information about the steps of treatment…we need reassurance by doctors".*

A lack of information on the treatment sometimes gave the impression that the treatment was somehow 'experimental' or not the established approach. O'Brien 2010[138] described how some participants who were given a distraction splint for a finger fracture believed that they should have received a much simpler treatment, such as an operation to pin the fracture:

> *"I was expecting that firstly they would put some plaster on it. They didn't explain anything [in the Emergency Department]. They were experimenting, I believe, on that day...It seemed like quite a new thing that they were going through, and I didn't really know what the reason was and why they were doing it and all that."*

After surgery Forsberg 2014[57] reported how participants wanted to know about the nature of any implants. Being shown a similar implant or an X-ray was felt to be helpful for understanding the procedure and also helped recall the information that had been given about this. O'Brien 2011[138] described a patient's anxiety after not having been initially informed of the nature of an external splinting device, and how accurate information relieved this worry:

> *"I was told that I would have a distraction splint. I didn't really understand what that involved so I looked it up online and the picture was some huge enormous thing and my big concern was how on earth would I manage with that, and when I learned that the splint I was going to have was a lot more compact I was relieved".*

Sleney 2014[173] also noted that the timing of information about procedures was important. In relation to surgery, some participants stated that they were not necessarily in a fit state to assimilate information before surgery. Some would have liked to receive information about the procedure after the operation:

> *''...I must admit maybe it is just norm but the follow up from the operation was pretty non-existent, in other words I don't know what do you expect? Do you expect the surgeon to come round, sit down and have a long chat with you? I guess he's rather busy. But I must admit he was conspicuous by his absence".*

Outcomes of treatment

Sleney 2014[173] reported how participants desired information on the outcomes of surgery. Participants operated on with a regional anaesthetic reported a 'comfortable feeling' of arriving in the post-surgical ward when aware of their surgical outcome. In contrast, participants who had had a general anaesthetic had a strong 'desire to know the outcome of the surgery'.

Time schedules

Being told about likely time scales was another aspect of information that was sought by participants. Forsberg 2014[57] stated how most participants were not given information on the timings of ward routines or how long they would be staying in a particular ward, and that this was 'a real strain'.

Okonta 2011[140] reported how most of the participants were not given information about the management plan and were therefore unable to take part in any decision making:

"they did not inform me how long the nail will stay in my bone"; "if I was informed about the duration of my hospital stay I would manage my financial resources accordingly".

Self-efficacy

Participants often valued information that empowered them to take control of a situation themselves. For example, Forsberg 2014[57] showed how participants undergoing surgery under regional anaesthesia valued the information that they could request sedatives if being awake during the procedure became too much for them to bear. Forsberg 2014[57] also showed that when staff offered "suggestions of solutions like repositioning the fractured limb to relieve the pain, or informing participants that they could decide when they wanted pain relief, this contributed to a sense of involvement".

Aftercare and home rehabilitation

Forsberg 2014[57] found that participants were anxious about their ability to perform necessary tasks after discharge, such as using their mobility device or how to give blood thinning medication. Participants found that such information was best given slowly and gradually during the practical experience of such tasks.

Sleney 2014[173] also reported how participants wanted information related to treatment or aftercare. Participants wanted answers to questions, such as when improvements would be noticeable, when they could or should use an injured limb as normal and whether mobility and strength would improve with time.

''The hardest thing I thought was not any feedback because there was no one there saying like now you can start lifting light weights, now you can do this. Just after they straightened my arm out they just left me. I was ringing them up and they were just saying 'Just take your time it is a big injury (…..) back on track'. The only thing that has got me back on track is my ambition not so much push myself but made sure I was doing things and made sure my arm was all right and trained it up really. Some guidance might have...If I had some feedback from the doctors I might have been recovered quicker maybe, I don't know.''

Sleney 2014[173] reported how information about physiotherapy was very important to participants. Participants who had not received physiotherapy said that they were unsure how to strengthen or mobilise their injured limb or how fast or complete their recovery of function would be. They also required information on how much strain they could place on the injury, and when they could return to sport or work:

''You don't really know how much you know you have to push it yourself, how much you can bend things and force things to get it going. It was only my daughter mainly because she's got a sports science degree and has been involved with injuries herself and it was only from that experience and her experience that we knew basically what we needed to do anyway.''

Social support

The only study to comment on the support desired after fracture was Sleney 2014.[173] Most participants had some support at home, which was usually a family member, friend or neighbour. One participant, however, with a dislocated knee was without nearby friends or relatives and did not have a telephone. This was not considered during discharge:

''I had nothing, no particular food or anything, my car was left at [name of hospital] Hospital, so and I live four miles from a local shop, I live in a very rural area on my own. There was no questions about that aspect; you know it's all very well discharging people but what are you discharging them to particularly with a massive injury, which it was. In fact it was so debilitating that it – an arm is quite different, you can walk around with your arm – but with a leg, particularly as I had steps to negotiate to my flat as well. I was totally bed bound,

absolutely bed bound, massive pain. [….] I had really minimal support and I think that what is worrying is that the patient is not really looked at as a whole but only, in my respect, I was 'a knee' but you know that knee inhabits a person and that person needs to have some sort of support, whether it's food, just being kept in touch with.''

Manner of communicating information

Patient-centred

Forsberg 2014[57] reported how participants wished to be treated as a person and not as 'the fracture'. They wanted staff members to speak directly to them and not about them and their diagnosis.

Consistency

Forsberg 2014[57] and Sleney 2014[173] showed that for some participants information was gained from several sources, which could be conflicting, as well as difficult to remember. For example, Sleney 2014[173] described how some patients were unsure whether they would receive physiotherapy because of conflicting messages. This was reported as confusing and also upsetting 'in what was already a stressful situation'. Participants in the Forsberg 2014[57] study emphasised the importance of coherent information.

Non-technical language

Sleney 2014[173] reported how some participants felt the language in which information was conveyed was often too technical, although this was not always a barrier to comprehension:

''I had a letter sent to the doctor with everything stating on it and a copy given to me so I could read it as well. Not that I could fully understand all the terms, but I got the gist of it.''

Written information

Forsberg 2014[57] showed how some participants desired written information:

"I lacked information/what is the plan…wanted a document to read…. …."

In particular, individual coherent written information in connection with discharge from the hospital was wanted.

Sleney 2014[173] reported how some participants felt written information they had been given was useful, such as literature explaining how to care for plaster casts. Some participants said that written information was particularly useful to take home because they had found it difficult to assimilate the verbal advice given during their stay in hospital.

10.2.4 Economic evidence

Published literature

No relevant economic evaluations were identified.

See also the economic article selection flow chart in Appendix E.

10.2.5 Evidence statements

Clinical

Four qualitative studies[57,138,140,173] suggested that information should be provided about the following:

- treatment methods

- treatment outcomes
- time schedules
- pain relief
- self-efficacy
- aftercare and home rehabilitation

In addition, social care needs should also be considered before discharge.

These studies also suggested that information should be provided that was:

- patient-centred
- consistent
- non-technical
- Written as well as verbal

Economic

No relevant economic evaluations were identified.

10.2.6 Recommendations and link to evidence

Recommendations	**Providing support** **29. If possible, ask the patient if they want someone (family member, carer or friend) with them.** **Support for children and vulnerable adults** **30. Allocate a dedicated member of staff to contact the next of kin and provide support for unaccompanied children and vulnerable adults.** **31. For a child or vulnerable adult with a fracture, enable their family members or carers to remain within eyesight if appropriate.** **32. Work with family members and carers of children and vulnerable adults to provide information and support. Take into account the age, developmental stage and cognitive function of the child or vulnerable adult.** **33. Include siblings of an injured child when offering support to family members and carers.** **34. Address issues of non-accidental injury before discharge in all children with femoral fractures. This is particularly important for children who are not walking or talking. For more information, see the NICE guideline on when to suspect child maltreatment.** **Support for people having procedures** **35. Reassure people while they are having procedures for fractures under local and regional anaesthesia.**

Communication

36. When communicating with patients, family members and carers:

- **manage expectations and avoid misinformation**
- **answer questions and provide information honestly, within the limits of your knowledge**
- **do not speculate and avoid being overly optimistic or pessimistic when discussing information on further investigations, diagnosis or prognosis**
- **ask if there are any other questions.**

37. Document all key communications with patients, family members and carers about the management plan.

Providing information

38. Explain to patients, family members and carers, what is happening and why it is happening. Provide:

- **information on known injuries**
- **details of immediate investigations and treatment, and if possible include time schedules.**

39. Offer people with fractures the opportunity to see images of their injury taken before and after treatment.

40. Provide people with fractures with both verbal and written information on the following when the management plan is agreed or changed:

- **expected outcomes of treatment, including time to returning to usual activities and the likelihood of any permanent effects on quality of life (such as pain, loss of function or psychological effects)**
- **activities they can do to help themselves**
- **home care options, if needed**
- **rehabilitation, including whom to contact and how (this should include information on the importance of active patient participation for achieving goals and the expectations of rehabilitation)**
- **mobilisation and weight-bearing, including upper limb load-bearing for arm fractures.**

41. Ensure that all health and social care practitioners have access to information previously given to people with fractures to enable consistent information to be provided.

Providing information about transfer from the emergency department

42. For patients who are being transferred from an emergency department to another centre, provide verbal and written information that includes:

- **the reason for the transfer**

	• **the location of the receiving centre and the patient's destination within the receiving centre** • **the name and contact details of the person responsible for the patient's care at the receiving centre** • **the name and contact details of the person who was responsible for the patient's care at the initial hospital.**
Relative values of different outcomes	There were no outcomes specified, as this was a qualitative review. Themes were extracted from the reviewed literature.
Trade-off between clinical benefits and harms	There were no harms noted for the provision of information. On the other hand, information provided on treatment, outcomes, time schedules, and home care, as well as information that promoted self-efficacy, were desired by participants. It was also felt that such information should be given in a respectful, clear, consistent and written form, without technical jargon.
Economic considerations	The duration of time spent with the patient was considered to be the main economic implication. Providing more information than is currently offered will take more staff time and therefore potentially greater costs. It was also considered that any available staff member can offer the information if the consultant is needed elsewhere. Consistent information would need to be recorded and made available for any health professional that may be needed to convey the information. If this can be achieved in an efficient way, then this may not have a noticeable effect on costs. The extra time given to patients is likely to be cost-effective as patients may have increased anxiety if relevant information is not provided, which could lead to unnecessary return visits to hospital from concerned patients. Information regarding mobilisation of injuries, both weight bearing and non-weight bearing, will promote better healing and outcomes for the patient. This could also lead to a reduction in additional attendances. The GDG thought that the benefits of providing this information were sufficient enough to justify any increase in patient contact time and the potential increased cost that this increase could incur. The GDG agreed that providing images to the patient would not have a large effect on costs as most wards already have the facilities to show X-ray images on a portable device and if this is not available, the cost of a hard copy image will be minimal. The provision of these images is believed to help the patients understand the treatment that they have received and any other information that they have received. Therefore they believe this to be cost effective.
Quality of evidence	The qualitative evidence was generally good quality. However in one study (Forsberg 2014) there was no evidence of methods to ensure trustworthiness of findings. In another study the use of such methods was unclear, as the methodology was reported ambiguously (Okonta 2011).
Other considerations	The GDG based some of the recommendations on the evidence derived from the qualitative studies, but the majority of recommendations were made by consensus and by cross-referring to the recommendations from the non-complex fractures and major trauma guidelines. There are frequently barriers to information provision, such as the time available in current practice for giving information, being very limited, and it was suggested by one GDG member that an efficient solution might be to direct patients and carers to specially selected pages on the internet. However, it was also felt that there was always a need for one-to-one communication between the person providing care and the patient and/or carer/family and that this should always be available. All hospitals already have a patient advisory and liaison service who would be able to help. Any written information provided to patients, relatives and carers should

	include contact details of the patient advice liaison service.

11 Access to the skills required for the management of people with fractures

11.1 Introduction

Injuries sustained from trauma may be life threatening and could be life changing. Fractures of any severity can be associated with adverse consequences resulting in long lasting disability. The consequence of poor clinical management from a patient perspective can be devastating and from a societal perspective the burden from lost productivity and NHS costs are substantial.

There is no doubt that the optimal management of a person with any trauma is to have the right staff, with the right skills, in the right place at the right time. Accordingly the scope included the topic, 'skills to be present in the multidisciplinary team '. It was anticipated that each guideline developed in these trauma related guidelines: non-complex, complex fractures, major trauma and spinal injury assessment, would reflect the specific skills required in the multidisciplinary team to deliver the recommendations within the specialist guideline. However as the guidelines were developed together it became clear that trauma care should not be defined by having separate areas of care but as a joined up, connected and coherent service. The concept of a multidisciplinary team that 'belongs' to one area of care is misleading. Some members of the spinal injuries multidisciplinary team will manage and care for people that have other injuries, an example is the emergency department consultant. From a patient perspective, and this is particularly true of people with multiple injuries, their care will span across the trauma service and they have their own unique multidisciplinary team.

With this in mind, access to skills in the multidisciplinary team was addressed across the 4 clinical guidelines (non-complex, complex fractures, major trauma and spinal injury assessment) in the major trauma services guidance taking a trauma systems perspective. See chapter 17 Access to services in the Major Trauma services guidance for a summary of the services and skills recommended in each of the guidelines and the recommendation for the skills required to manage people with trauma.

12 Acronyms and abbreviations

Acronym or abbreviation	Description
ABPI	Ankle brachial pressure index
ADL	Activities of daily living
AIS	Abbreviated Injury Scale
ASIA score	American Spinal Injury Association Impairment score
ATLS	Advanced Trauma Life Support
CI	Confidence interval
CC	Comparative costing
CCA	Cost-consequences analysis
CEA	Cost-effectiveness analysis
CNS	Central nervous system
CT	Computed tomography
CUA	Cost-utility analysis
DASH Score	The Disabilities of the Arm, Shoulder and Hand Score
DVT/PE	Deep vein thrombosis and pulmonary embolism.
eFAST	Extended Focused Assessment with Sonography for Trauma
EMAS	East Midlands Ambulance Service
FAST	Focused assessment with sonography for trauma
GCS	Glasgow coma scale
GOS	Glasgow outcome scale
INR	International normalised ratio
IO	Intraosseous
IR	Interventional radiology
IV	Intravenous
ISS	Injury Severity Score
JRCALC	Joint Royal Colleges Ambulance Liaison Committee
KED	Kendrick Extrication Device
MDCT	Multi-detector computed tomography
MDT	Multidisciplinary team
MRI	Magnetic resonance imaging
MTC	Major Trauma Centre
NEXUS	National Emergency X Radiography Utilization Study
NNT	Number needed to treat
NPV	Negative predictive value
NSAIDS	Non-steroidal anti-inflammatory drugs
ORIF	Open reduction and internal fixation
PACS	Picture Archiving and Communications Systems
PCC	Prothrombin complex concentrate
PPV	Positive predictive value
QALY	Quality-adjusted life year
RCT	Randomised controlled trial
RSI	Rapid Sequence Induction of anaesthesia and intubation

Acronym or abbreviation	Description
TARN	The Trauma Audit & Research Network
TU	Trauma unit
UTI	Urinary tract infection
VKA	Vitamin K antagonist
VTE	Venous thrombosis embolism

13 Glossary

Term	Definition
Abbreviated Injury Scale (AIS)	Injuries are ranked on a scale of 1 to 6, with 1 being minor, 5 severe and 6 an unsurvivable injury. This represents the 'threat to life' associated with an injury and is not meant to represent a comprehensive measure of severity.
Abstract	Summary of a study, which may be published alone or as an introduction to a full scientific paper.
Active Bleeding	Also known as or related to haemorrhage, loss of blood, bleeding, haemorrhage, bleeding
Activities of daily living (ADL)	Routine activities carried out for personal hygiene and health (including bathing, dressing, feeding) and for operating a household.
Acute	A stage of injury or stroke starting at the onset of symptoms. The opposite of chronic.
Advanced Trauma Life Support (ATLS)	A training program for medical professionals in the management of acute trauma cases, developed by the American College of Surgeons.
Algorithm (in guidelines)	A flow chart of the clinical decision pathway described in the guideline, where decision points are represented with boxes, linked with arrows.
Allocation concealment	The process used to prevent advance knowledge of group assignment in a RCT. The allocation process should be impervious to any influence by the individual making the allocation, by being administered by someone who is not responsible for recruiting participants.
Ambulation	Walking with braces and/or crutches.
American Spinal Injury Association Impairment (ASIA) Score	A system to describe spinal cord injury and help determine future rehabilitation and recovery needs. It is based on a patient's ability to feel sensation at multiple points on the body and also tests motor function. Ideally, it's first given within 72 hours after the initial injury. Scored from A-E; A means complete injury; E means complete recovery.
Angiography	Radiography of blood or lymph vessels, carried out after introduction of a radiopaque substance.
Angular deformity	Deformity of limbs by angulation at joints or in the bones themselves.
Ankle brachial pressure index (ABPI)	The ratio of the blood pressure in the lower legs to the blood pressure in the arms. It is used for decision-making in leg ulcer assessment.
Antero-lateral	Directed from the front towards the side.
Antero-posterior	Directed from the front towards the back.
Anticoagulation	The process of hindering the clotting of blood.
Antifibrinolytic agent	Pharmacological agents that inhibit the activation of plasminogen to plasmin, prevent the break-up of fibrin and maintain clot stability. They are used to prevent excessive bleeding.
Applicability	The degree to which the results of an observation, study or review are likely to hold true in a particular clinical practice setting.
Arm (of a clinical study)	Sub-section of individuals within a study who receive one particular intervention, for example placebo arm
Arterial injury	An injury following a traumatic injury which results in a laceration, contusion, puncture, or crush injury to an artery.
Arterial shunts	An artificial passageway introduced through a surgical procedure that allows blood to flow from through the arteries.
Aspiration event	The event of food or drink entering the airway.
Association	Statistical relationship between two or more events, characteristics or other variables. The relationship may or may not be causal.

Term	Definition
Attrition bias	Bias resulting from the loss of data from analysis. Loss of data from analysis causes bias by disrupting baseline equivalence and also because data from people who drop out are often systematically different from data collected from those who don't drop out. Loss of such data therefore distorts the apparent response of a group to a treatment. For example, those who drop out from a treatment may be the worst responders and so if these are not included in the analysis this may make a treatment look better than it really is. Attrition bias may be reduced by following an intention to treat approach (see 'intention to treat').
Avascular necrosis	Avascular necrosis is cellular death of bone components due to interruption of the blood supply.
Baseline	The initial set of measurements at the beginning of a study (after run-in period where applicable), which may be important in demonstrating how much selection bias is present. They may also be compared with subsequent results in certain study designs.
Basic airway manoeuvres	A set of medical procedures performed in order to prevent airway obstruction and thus ensuring an open pathway. Manoeuvres include encouraging the victim to cough, back blows and abdominal thrusts.
Before-and-after study	A study that investigates the effects of an intervention by measuring particular characteristics of a population both before and after taking the intervention, and assessing any change that occurs. Because there is no control group, this approach is subject to considerable bias (see control group). 'Before and after study' is sometimes also used to denote historical cohort studies that compare two groups separated in time, often before and after the initiation of a new treatment strategy. In such cases the control group is the group treated earlier.
Bias	Systematic (as opposed to random) deviation of the results of a study from the 'true' results that is caused by the way the study is designed or conducted.
Blinding	Keeping the study participants, caregivers, and outcome assessors unaware which interventions the participants have been allocated in a study.
Blunt trauma	A traumatic injury caused by the application of mechanical force to the body by a blunt force, object or instrument or an injury in which the body strikes a surface such as a wall or the ground, in which the skin was not penetrated.
Canadian C-Spine Rules	Selective guidelines developed in Canada for the ordering of cervical spine imaging following acute trauma.
Carer (caregiver)	Someone other than a health professional who is involved in caring for a person with a medical condition.
Case-control study	Comparative observational study in which the investigator selects individuals who have experienced a health-related event (cases) and others who have not (controls), and then collects data to determine relative prior exposure to a possible cause.
Case-series	Report of a number of cases of a given disease, usually covering the course of the disease and the response to treatment. There is no comparison (control) group of patients. See 'before and after ' study.
Central nervous system (CNS)	The brain and spinal cord.
Cervical	High-level nervous structure of the spinal cord responsible for controlling the neck muscles, diaphragm, shoulders, wrists, triceps and fingers.
Cervical collar	A cervical collar (also neck brace) is an orthopaedic medical device used to support a patient's neck and head.
Charlson comorbidity index	A comorbidity index which predicts the ten-year mortality for a patient who

Term	Definition
	may have a range of comorbid conditions. The score is helpful in deciding how aggressively to treat a condition.
Chest decompression	A medical procedure to remove air from the pleural cavity and treat tension pneumothorax injuries. A cannula is inserted and advanced in the chest until air is aspirated. The manoeuver effectively converts a tension pneumothorax into a simple pneumothorax.
Chronic spinal cord injury	The stage of spinal cord injury where there is no longer continuing damage or recovery.
Clinical efficacy	The extent to which an intervention produces an overall health benefit when studied under controlled research conditions.
Clinical effectiveness	The extent to which an intervention produces an overall health benefit in routine clinical practice.
Clinician	A healthcare professional providing direct patient care, such as a doctor, nurse or physiotherapist.
Coagulopathy	Coagulopathy is a condition in which the blood's ability to clot (coagulate) is impaired. It can be caused as a result of on-going cycles of dilution and consumption of coagulation factors, hypothermia and acidosis following traumatic incidents.
Cochrane Review	The Cochrane Library consists of a regularly updated collection of evidence-based medicine databases including the Cochrane Database of Systematic Reviews (reviews of randomised controlled trials prepared by the Cochrane Collaboration).
Cohort study	A sample (or cohort) of individuals without a chosen outcome event (such as a disease) are defined on the basis of presence or absence of exposure to one or more suspected risk factors or interventions. The effects of these risk factors or interventions on chosen outcomes are then evaluated at later follow up. Prospective cohort studies are managed by the researchers in real time. This allows the measurement of appropriate potential confounding variables at baseline. Retrospective cohort studies are based on databases that were collected prospectively, often for another purpose, but which are used retrospectively (that is, not in real time) by a researcher. This approach often means that appropriate confounding variables may not have been collected
Comorbidity	One or more additional disorders (other than that being studied or treated) in an individual.
Comparability	Similarity of the groups in characteristics likely to affect the study results (such as health status or age).
Comparative costing (CC)	A type of analysis where costs are compared without the consideration of health benefits
Compartment syndrome	A condition that occurs when the amount of swelling and/or bleeding in a muscle compartment causes pressure that is greater than the capillary pressure and results in tissue ischemia and potential tissue necrosis.
Complete injury	Generally, a spinal cord injury that cuts off all sensory and motor function below the lesion site.
Computed tomography (CT) scan	A scan which produces images of a cross sectional plane of the body. The scan is produced by computer synthesis of X-ray images taken in many different directions in a given plane.
Comminuted fracture	A fracture in which the bone shatters into three or more pieces.
Compound Fracture	A fracture in which broken bone fragments lacerate soft tissue and protrude through an open wound in the skin. This term is synonymous with 'open fracture'. See open fracture

Term	Definition
Conceptual mapping	Activity which involves diagrammatically representing the relationships between different areas and the interactions between interventions and outcomes.
Conceptual modelling	Activity in which the participants' understanding of the decision problem is represented in a mathematical model which can be discussed and agreed by the participants.
Concordance	This is a recent term whose meaning has changed. It was initially applied to the consultation process in which doctor and patient agree therapeutic decisions that incorporate their respective views, but now includes patient support in medicine taking as well as prescribing communication. Concordance reflects social values but does not address medicine-taking and may not lead to improved adherence.
Concussion	Reversible paralysis following brain trauma, usually involving loss of consciousness and/or a transient state of confusion.
Confidence interval (CI)	A range of values for an unknown population parameter with a stated 'confidence' (conventionally 95%) that it contains the true value. The interval is calculated from sample data, and straddles the sample estimate. The 'confidence' value means that if the method used to calculate the interval is repeated many times, then that proportion of intervals will actually contain the true value.
Confounding	In a study, confounding occurs when the effect of an intervention (or risk factor) on an outcome is distorted as a result of one or more additional variables that are able to influence the outcome, and that also have an association with the intervention (or risk factor). Association with the intervention (or risk factor) generally means an imbalance in the confounder across intervention (or risk factor) groups. For example, a sample of coffee drinkers may be observed to have more heart disease than a sample of non-coffee drinkers. If the coffee drinker sample are much older than the non-coffee drinker sample, then differing age may explain the outcome rather than coffee consumption, assuming greater age increases heart disease risk.
Consensus methods	Techniques that aim to reach an agreement on a particular issue. Consensus methods may be used when there is a lack of strong evidence on a particular topic.
Constant-Murley shoulder Outcome Score	A commonly used outcome measure for assessing the outcomes of the treatment of shoulder disorders.
Control group	A group of people in a study who do not receive the treatment or test being studied. Instead, they may receive the standard treatment (sometimes called 'usual care') or a dummy treatment (placebo). The results for the control group are compared with those for a group receiving the treatment being tested. Without a control group it is impossible to know the extent to which a change in outcome in the intervention group is due to the treatment effect or to intervening effects such as the placebo effect , practice effect or natural history effect. However if a control group has very similar characteristics to the treatment group then it can be assumed that it will be exposed to very similar intervening effects. Therefore taking the difference between group outcomes (or the ratio if the outcome is bivariate) allows the intervening effects to largely cancel out, leaving only the differential between-group treatment effect.
Cosmesis	The surgical correction of a disfiguring physical defect.
Cost benefit analysis	A type of economic evaluation where both costs and benefits of healthcare treatment are measured in the same monetary units. If benefits exceed costs,

Term	Definition
	the evaluation would recommend providing the treatment.
Cost-consequences analysis (CCA)	A type of economic evaluation where various health outcomes are reported in addition to cost for each intervention, but there is no overall measure of health gain.
Cost-effectiveness analysis (CEA)	An economic study design in which consequences of different interventions are measured using a single outcome, usually in 'natural' units (For example, life-years gained, deaths avoided, heart attacks avoided, cases detected). Alternative interventions are then compared in terms of cost per unit of effectiveness.
Cost-effectiveness model	An explicit mathematical framework, which is used to represent clinical decision problems and incorporate evidence from a variety of sources in order to estimate the costs and health outcomes.
Cost-utility analysis (CUA)	A form of cost-effectiveness analysis in which the units of effectiveness are quality-adjusted life-years (QALYs).
Credible Interval	The Bayesian equivalent of a confidence interval.
Crush injury	An injury by an object that causes compression of the limb or body.
Cryoprecipitate	A source of fibrinogen, vital to blood clotting.
Damage control surgery	A technique of surgery for critically ill patients involving other sub-specialty services in addition to the trauma surgeon. This technique places emphasis on preventing the "lethal triad", rather than correcting the anatomy. The patient will be stabilised before definitive treatment.
Debridement	The whole process of opening up of a wound, or pathological area (for example, bone infection), together with the surgical excision of all avascular, contaminated, infected, or other undesirable tissue.
Decision analysis	An explicit quantitative approach to decision making under uncertainty, based on evidence from research. This evidence is translated into probabilities, and then into diagrams or decision trees which direct the clinician through a succession of possible scenarios, actions and outcomes.
Deep infection	Deep incisional surgical site infections must meet the following three criteria: • Occur within 30 days of procedure (or one year in the case of implants) • are related to the procedure • involve deep soft tissues, such as the fascia and muscles. In addition, at least one of the following criteria must be met: • Purulent drainage from the incision but not from the organ/space of the surgical site. • A deep incision spontaneously dehisces or is deliberately opened by a surgeon when the patient has at least one of the following signs or symptoms - fever (>38°C), localised pain or tenderness - unless the culture is negative. • An abscess or other evidence of infection involving the incision is found on direct examination or by histopathologic or radiological examination. • Diagnosis of a deep incisional SSI by a surgeon or attending physician.
Definitive closure	The final surgical closing of a wound by suture or staple.
Definitive cover	Final closure of the open fracture wound, using a local flap of skin, or skin grafted from another part of the body.
Definitive (internal or external) fixation	The final surgical implantation of internal or external metalwork for the purposes of repairing a bone and fixing it into place.
Definitive haemorrhage control	A surgical procedure to completely stop bleeding following trauma.

Term	Definition
Definitive treatment	A final treatment, which may conclude prior preparatory stages, which aims to achieve a specific therapeutic effect.
Delayed bone healing	A fracture that takes longer to heal than expected.
Delayed primary amputation	A procedure that is carried out when amputation is chosen as preferable to attempting reconstructive surgery for limb salvage, but is not performed as an emergency operation.
Detection bias	Bias relating to the way in which data is collected. The most common cause of detection bias results from failure to blind outcome assessors. If outcome assessors know the group allocation of a participant this may influence the way that the measurement is carried out.
Diagnostic RCT	A randomised controlled trial that compares outcomes from groups allocated to two or more different forms of diagnostic assessment. Diagnostic RCTs are a pragmatic way of assessing how well diagnostic tests affect outcome through their ability to determine appropriate management of patients. In contrast to diagnostic accuracy studies, they can encompass issues like the duration or comfort of a test, which may be important considerations in the decision concerning which diagnostic test should be used.
The Disabilities of the Arm, Shoulder and Hand (DASH) Score	A patient reported questionnaire to inform on functional capacity of the arm.
Disability rating index	A patient reported clinical tool for assessing physical disability, mainly intended for clinical settings.
Discounting	Costs and perhaps benefits incurred today have a higher value than costs and benefits occurring in the future. Discounting health benefits reflects individual preference for benefits to be experienced in the present rather than the future. Discounting costs reflects individual preference for costs to be experienced in the future rather than the present.
Discrete Event Simulation	A type of model (also known as time-to-event model) based on patient-level simulation where 'time to event' is the key parameter as opposed to 'probability of event occurring' like in a Markov model.
Dislocation	Displacement of one or more bones at a joint.
Dominance	An intervention is said to be dominated if there is an alternative intervention that is both less costly and more effective.
Drop-out	A participant who withdraws from a trial before the end.
Dynamic fluoroscopy	Imaging technique which uses an X-ray tube and a fluoroscopic screen with an image intensifier to create a real-time image of moving objects.
Economic evaluation	Comparative analysis of alternative health strategies (interventions or programmes) in terms of both their costs and consequences.
Effect (as in effect measure, treatment effect, estimate of effect, effect size)	The observed association between interventions and outcomes or a statistic to summarise the strength of the observed association.
Effectiveness	See 'Clinical effectiveness'.
Efficacy	See 'Clinical efficacy'.
Embolization	Therapeutic introduction of a substance into a blood vessel in order to occlude it and prevent active bleeding following trauma.
Emergent phenomena	A stage in recovery from general anaesthesia that includes a return to spontaneous breathing, voluntary swallowing and normal consciousness.
Epidemiological study	The study of a disease within a population, defining its incidence and prevalence and examining the roles of external influences (For example, infection, diet) and interventions.

Term	Definition
EQ-5D (EuroQol-5D)	A standardise instrument used to measure a health outcome. It provides a single index value for health status and measures quality of life
Evidence	Information on which a decision or guidance is based. Evidence is obtained from a range of sources including randomised controlled trials, observational studies, expert opinion (of clinical professionals and/or patients).
Exclusion criteria (literature review)	Explicit standards used to decide which studies should be excluded from consideration as potential sources of evidence.
Exclusion criteria (clinical study)	Criteria that define who is not eligible to participate in a clinical study.
Extended dominance	If Option A is both more clinically effective than Option B and has a lower cost per unit of effect, when both are compared with a do-nothing alternative then Option A is said to have extended dominance over Option B. Option A is therefore more efficient and should be preferred, other things remaining equal.
Extended Focused Assessment with Sonography for Trauma (eFAST)	Extends the viewing area of FAST to include other assessments . It is often used to image the thorax.
External fixation	External fixation involves the placement of pins or screws into the bone on both sides of the fracture. The pins are then secured together outside the skin with clamps and rods, forming an external frame.
Extrapolation	In data analysis, predicting the value of a parameter outside the range of observed values.
Fascia iliaca compartment block	Fascia iliaca block is a low-tech alternative to a femoral nerve or a lumbar plexus block. The mechanism behind this block is that the femoral and lateral femoral cutaneous nerves lie under the iliacus fascia.
Fasciotomy	The surgical division the investing fascial wall of an osseo-fascial muscle compartment, usually to release pathologically high intra-compartmental pressure.
Fibrinolysis	A process within the body that prevents blood clots that occur naturally from growing and causing problems.
Focused assessment with sonography for trauma (FAST)	A rapid bedside ultrasound (see definition) examination performed as a screening test for blood around the heart (pericardial effusion) or abdominal organs (hemoperitoneum) after trauma.
Flap failure	When a mass of tissue used for grafting, only partially removed so that it retains its own blood supply during transfer to another site, does not fully re-vascularise.
Follow-up	Observation over a period of time of an individual, group or initially defined population whose appropriate characteristics have been assessed in order to observe changes in health status or health-related variables.
Frankel classification	Precursor to ASIA scoring system to assess spinal function.
Fresh frozen plasma	The remaining serum of human blood that is frozen after the cellular component has been removed for blood transfusion
Full-body computed tomography (CT)/whole-body CT	A CT scan from the head to below the hips with a form of X-ray imaging that produces cross-sectional images.
Generalisability	The extent to which the results of a study based on measurement in a particular patient population and/or a specific context hold true for another population and/or in a different context. In this instance, this is the degree to which the guideline recommendation is applicable across both geographical and contextual settings. For example, guidelines that suggest substituting one form of labour for another should acknowledge that these costs might vary

Term	Definition
	across the country.
Glasgow coma scale (GCS)	A rating scale devised to assess the level of consciousness following brain damage. The scale assesses eye, verbal and motor responses. The GCS grades on a scale of 1–15, the lower score indicating the greater neurologic impairment.
Glasgow outcome scale (GOS)	A system for classifying the outcome of persons who survive. The scale has eight outcome categories and relates to functional independence and not residual deficits.
Gold standard	See 'Reference standard'
Gustilo Anderson Grade	The Gustilo Anderson Grade open fracture classification system comprises: Type I: clean wound smaller than 1 cm in diameter, appears clean, simple fracture pattern, no skin crushing. Type II: a laceration larger than 1 cm but without significant soft-tissue crushing, including no flaps, degloving, or contusion. Fracture pattern may be more complex. Type III: an open segmental fracture or a single fracture with extensive soft-tissue injury. Also included are injuries older than 8 hours. Type III injuries are subdivided into three types: Type IIIA: adequate soft-tissue coverage of the fracture despite high-energy trauma or extensive laceration or skin flaps. Type IIIB: inadequate soft-tissue coverage with periosteal stripping. Soft-tissue reconstruction is necessary. Type IIIC: any open fracture that is associated with vascular injury that requires repair.
Haematoma block	An analgesic technique used to allow painless manipulation of fractures avoiding the need for full anaesthesia.
Haemodynamic instability	Patients who are non-responders or transient responders to intravenous fluid therapy.
Haemodynamically unstable	A patient requiring frequent interventions to maintain Heart Rate, Blood Pressure, or oxygenation.
Haemodynamic status	The status of blood flow in the circulation, the sum result of cardiac output and blood pressure. Stable haemodynamic status occurs when the circulatory supply of oxygen maintains organ perfusion.
Harms	Adverse effects of an intervention.
Health economics	The study of the allocation of scarce resources among alternative healthcare treatments. Health economists are concerned with both increasing the average level of health in the population and improving the distribution of health.
Health-related quality of life (HRQoL)	A combination of an individual's physical, mental and social well-being; not merely the absence of disease.
Heterogeneity	The term (or 'lack of homogeneity') is used in meta-analyses and systematic reviews when the results or estimates of effects of treatment from separate studies seem to be very different. This can be in terms of the different size of treatment effects or even to the extent that some studies indicate beneficial treatment effects and others suggest adverse treatment effects. Such results may occur as a result of differences between studies in terms of the patient populations, outcome measures, definition of variables or duration of follow-up, although there is also a small probability they may due to random sampling error.
High-energy fracture	A fracture resulting from a direct impact of sufficient energy to cause disruption of bone in anyone regardless of their health or comorbidities. Examples are a motor vehicle accident, a high-height fall, or an industrial

Term	Definition
	accident.
Image intensifier	A medical device that converts X-rays into visible light at higher intensity than fluorescent screens do.
Immobilised	The process of holding a joint or bone in place with a splint, cast or brace. This is done to prevent an injured area from moving while it heals.
Imprecision	Results are imprecise when they have wide confidence intervals around the estimate of effect. This may be partly due to studies including relatively few patients. It also arises as a result of high intrinsic variability in continuous outcome, or a low event rate.
Inclusion criteria (literature review)	Explicit criteria used to decide which studies should be considered as potential sources of evidence.
Incomplete injury	If a person with a spinal cord injury has either some sensation and/or some movement below the level of their spinal cord lesion, their injury is said to be incomplete
Incontinence	Loss of control of bowel or bladder.
Incremental analysis	The analysis of additional costs and additional clinical outcomes with different interventions.
Incremental cost	The mean cost per patient associated with an intervention minus the mean cost per patient associated with a comparator intervention.
Incremental cost effectiveness ratio (ICER)	The difference in the mean costs in the population of interest divided by the differences in the mean outcomes in the population of interest for one treatment compared with another.
Incremental net benefit (INB)	The value (usually in monetary terms) of an intervention net of its cost compared with a comparator intervention. The INB can be calculated for a given cost-effectiveness (willingness to pay) threshold. If the threshold is £20,000 per QALY gained then the INB is calculated as: (£20,000 x QALYs gained) – Incremental cost.
Indirectness	The available evidence is different to the review question being addressed, in terms of the population, intervention, comparison or outcome.
Initial surgery	A patient's first surgical intervention after injury
Injury Severity Score (ISS)	A clinical scale from 1 to 75 (higher score being more serious) which can classify patients following a traumatic incident. Those scoring above 15 are defined as having suffered from major trauma. ISS of 9-15 have moderately severe trauma.
International normalised ratio (INR)	A laboratory test measure of blood coagulation based on prothrombin time.
Intention to treat analysis (ITT)	A strategy for analysing data from a randomised controlled trial. All participants' data are analysed in the arm to which they were allocated, regardless of whether participants received (or completed) the intervention given to that arm or not. Intention-to-treat analysis reflects real-world adherence to the protocol and also prevents bias caused by the loss of participants' data from analysis. (see attrition bias)
Intervention	Healthcare action intended to benefit the patient, for example, drug treatment, surgical procedure, psychological therapy.
Interventional radiology (IR)	Defined by the British Society for Interventional Radiology (IR) it refers to a range of techniques which rely on the use radiological image guidance (X-ray fluoroscopy, ultrasound, computed tomography [CT] or magnetic resonance imaging [MRI]) to precisely target therapy. Most IR treatments are minimally invasive alternatives to open and laparoscopic (keyhole) surgery.
Intramedullary fixation	A surgical technique in which a metal nail provides stability to the bone.
Intraoperative	The period of time during a surgical procedure.

Term	Definition
Intraosseous (IO) access	The process of injecting directly into the marrow of a bone to provide a non-collapsible entry point into the systemic venous system
Intraperitoneal	Intraperitoneal means within or administered through the peritoneum. The peritoneum is a thin, transparent membrane that lines the walls of the abdominal (peritoneal) cavity and contains and encloses the abdominal organs, such as the stomach and intestines
Intravenous	A drug, nutrient solution, or other substance administered into a vein.
Intubation	Insertion of a tube into the trachea for purposes of anaesthesia, airway maintenance and lung ventilation.
Ischaemic damage	Damage caused to tissue or an organ due to insufficient supply of blood to an organ.
Kappa statistic	A statistical measure of inter-rater agreement that assesses the probability that the agreement occurred by chance.
Kendrick Extrication Device (KED)	A device used for extricating and immobilizing patients from auto accidents and other confined spaces.
Laparotomy	A surgical procedure to open the abdomen for diagnosis or in preparation for surgery.
Length of stay	The total number of days a participant stays in hospital.
Lesion	Site of injury or wound to the spinal cord.
Licence	See 'Product licence'.
Life-years gained	Mean average years of life gained per person as a result of the intervention compared with an alternative intervention.
Likelihood ratio	The likelihood ratio combines information about the sensitivity and specificity. It tells you how much a positive or negative result changes the likelihood that a patient would have the disease. The likelihood ratio of a positive test result (LR+) is sensitivity divided by 1- specificity.
Limb salvage	A surgical procedure to maintain a limb following a traumatic incident.
Log roll	Method of turning a patient without twisting the spine.
Long-term care	Residential care in a home that may include skilled nursing care and help with everyday activities. This includes nursing homes and residential homes.
Loss to follow-up	Loss to follow up is usually caused by failure of participants to attend for follow-up outcome assessments, though it can also occur if researchers exclude participants from a study for non-compliance (see 'intention to treat'). Loss to follow up may cause bias if the reason for non-attendance could have affected outcomes. For example, if non-attendance at follow-up is due to the treatment having made the condition worse, then such harm from the treatment is not captured during follow up and thus analysis, making the treatment seem better than it really is.
Low energy fracture	A fracture resulting from mechanical forces that would not ordinarily lead to the bone to fracture, for example, a fall from a standing height. Low-energy fractures may be more common in individuals with bone fragility (e.g. individuals with osteoporosis)
Lumbar	Lower-level area of the spine, lying below the thoracic spine and above the sacral spine. Lumbar nerves are responsible for innervation of the abdomen, parts of the perineum and most of the lower limbs.
Magnetic resonance imaging (MRI)	A medical imaging technique used for medical diagnosis, staging of disease and for follow-up without exposure to ionizing radiation. MRI scanners use magnetic fields and radio waves to form images of the body.
Major haemorrhage	Loss of more than one blood volume within 24 hours (around 70 mL/kg, >5 litres in a 70 kg adult), a 50% of total blood volume lost in less than

Term	Definition
	3 hours, or bleeding in excess of 150 mL/minute.
Major Trauma Centre (MTC)	A specialist hospital responsible for the care of major trauma patients across the region. It is a specialist hospital responsible for the care of the most severely injured patients involved in major trauma. It provides 24/7 emergency access to consultant-delivered care for a wide range of specialist clinical services and expertise. It is optimised for the definitive care of injured patients. In particular, it has an active, effective trauma Quality Improvement programme. It also provides a managed transition to rehabilitation and the community. It takes responsibility for the care of all patients with Major Trauma in the area covered by the Network. It also supports the Quality Improvement programmes of other hospitals in its Network. It provides all the major specialist services relevant to the care of major trauma, that is, general, emergency medicine, vascular, orthopaedic, plastic, spinal, maxillofacial, cardiothoracic and neurological surgery and interventional radiology, along with appropriate supporting services, such as critical care. The Royal College of Surgeons cite research advising that such centres should admit a minimum of 250 critically injured patients per year
Major Trauma Network	A collaboration between the providers commissioned to deliver trauma care services in a geographical area. A trauma network includes all providers of trauma care: pre-hospital services, other hospitals receiving acute trauma admissions (Trauma Units), and rehabilitation services. The trauma network has appropriate links to the social care and the voluntary/community sector. While individual units retain responsibility for their clinical governance, members of the Network collaborate in a Quality Improvement programme.
Malunion	Consolidation of a fracture in a position of deformity.
Markov model	A method for estimating long-term costs and effects for recurrent or chronic conditions, based on health states and the probability of transition between them within a given time period (cycle).
Multi-detector computed tomography (MDCT) scan	A form of computed tomography (CT) technology for diagnostic imaging. In MDCT, a two-dimensional array of detector elements replaces the linear array of detector elements used in typical conventional and helical CT scanners. The two-dimensional detector array permits CT scanners to acquire multiple slices or sections simultaneously and greatly increase the speed of CT image acquisition
Meta-analysis	A statistical technique for combining (pooling) the results of a number of studies that address the same question and report on the same outcomes to produce a summary result. The aim is to derive more precise and clear information from a large data pool. It is generally more likely to confirm or refute a hypothesis than the individual trials.
Methaemoglobinaemia	Methaemoglobin (MetHb) is an altered state of haemoglobin (Hb), reducing its ability to release oxygen. It can be acquired following admission of anaesthesia.
Minimal load bearing	Load-bearing only as much as is required to maintain the best level of independence achievable.
Minimal weight bearing	Weight-bearing only as much as is required to maintain the best level of independence achievable.
Motor function	Ability to perform functional tasks.
Motor recovery	Recovery of the strength and co-ordination of voluntary movement.
Multidisciplinary team (MDT)	Group of experts providing optimal management following Spinal Cord Injury. Teams can consist of Medics, Nurses, Surgical Team Physiotherapists, General

Term	Definition
	Practitioner, Speech and Language Therapist.
Multivariable model	A statistical model for analysis of the relationship between two or more predictor (independent) variables and the outcome (dependent) variable.
Muscle/joint contracture	A permanent shortening of a muscle or joint.
Myoglobinuria	Myoglobinuria is a condition usually the result of rhabdomyolysis or muscle destruction which can be detected by the detection of myglobin in the urine.
National Emergency X Radiography Utilization Study (NEXUS)	Guideline detailing Low-Risk Criteria to rule-out cervical spine injury in patients following acute trauma.
Necrosis	The death of most or all of the cells in an organ or tissue due to disease, injury, or failure of the blood supply.
Neer Classification	The Neer classification of proximal humeral fractures is probably the most frequently used along with the AO classification of proximal humeral fractures. The classification has been variably adapted by multiple authors into 4 main areas: • One-part fracture - fracture lines involve 1-4 parts none of the parts are displaced (that is, <1 cm and <45 degrees). These undisplaced/minimally displaced fractures account for approximately 70-80% of all proximal humeral fractures and are almost always treated conservatively 6-7. • Two-part fracture - fracture lines involve 2-4 parts, one part is displaced (that is, >1 cm or >45 degrees). Four possible types of two-part fractures exist (one for each part): surgical neck, greater tuberosity, anatomical neck, lesser tuberosity: uncommon • Three-part fracture - fracture lines involve 3-4 parts, two parts are displaced (that is, >1 cm or >45 degrees) • Four-part fracture -fracture lines involve parts, three parts are displaced (that is, >1cm or >45 degrees) with respect to the 4th.
Negative predictive value (NPV) [In screening/diagnostic tests:]	A measure of the usefulness of a screening/diagnostic test. It is the proportion of those with a negative test result who do not have the disease, and can be interpreted as the probability that a negative test result is correct.
Neuropathic/spinal cord pain	Neuropathic pain is a problem experienced following Spinal Cord Injury. A sharp pain is the result of damage to the spine and soft tissue surrounding the spine.
Neuroprotective agents	Medications that protect the brain and spinal cord from secondary injury caused by stroke or trauma.
Neurovascular compromise	Injury occurring when vessels and nerves are be disrupted or distorted by a fracture or dislocation and require urgent reduction.
Non-union	Non-union is failure of bone healing. A fracture is judged to be un-united if the signs of non-union are present when a sufficient time has elapsed since injury, during which the particular fracture would normally be expected to have healed by bony union. That period will vary according to age, fracture location and patho-anatomy.
Normotension	Fluid resuscitation with the aim of increasing systemic blood pressure to normal blood pressures.
No weight bearing	Not allowed to walk/stand.
Number needed to treat (NNT)	The number of patients that who on average must be treated to cause a single occurrence of the positive outcome of interest.
Oblique fracture	A fracture with an angled pattern.
Observational study	Retrospective or prospective study in which the investigator observes the natural course of events with or without control groups; for example, cohort

Term	Definition
	studies and case–control studies.
Occlusive dressing	A dressing that seals the wound from air or bacteria
Odds ratio	The odds of an event is the ratio of the number of events occurring (for example, the number of people dying) to the number of non-events (for example, the number of people not dying) within a single group. Odds are distinct from risks (see risk ratio) and are therefore not strictly a measure of probability. Odds are normally compared across two groups as an odds ratio (OR). For example the OR of dying in smokers compared to non-smokers would be calculated by dividing the odds of death in smokers by the odds of death in non-smokers. An odds ratio of 1 would show that the odds of the event is the same for both groups. An odds ratio greater than 1 means the odds of event are greater in the first group. An odds ratio less than 1 means that the odds of the event are less likely in the first group. Sometimes odds can be compared across more than 2 groups – in this case, one of the groups is chosen as the 'reference category', and the odds ratio is calculated for each group compared with the reference category. For example, to compare the odds of dying from lung cancer for non-smokers, occasional smokers and regular smokers, non-smokers could be used as the reference category. Odds ratios would be worked out for occasional smokers compared with non-smokers and for regular smokers compared with non-smokers. See also ‘relative risk’ and ‘risk ratio’.
Open fracture	A fracture associated with a wound. The skin may be pierced by the bone or by a blow that breaks the skin at the time of the fracture. The bone may or may not be visible in the wound. This term is synonymous with ‘compound fracture’.
Open pneumothorax	When there is a pneumothorax associated with a chest wall defect, such that the pneumothorax communicates with the exterior. Usually caused by gunshot or knife wounds to chest.
Open reduction and internal fixation (ORIF)	A method of surgically repairing a fractured bone. Generally, this involves either the use of plates and screws or an intramedullary (IM) rod to stabilize the bone.
Opiates	A class of drugs that includes heroin, morphine, and codeine.
Opportunity cost	The loss of other health care programmes displaced by investment in or introduction of another intervention. This may be best measured by the health benefits that could have been achieved had the money been spent on the next best alternative healthcare intervention.
Osteomyelitis	An acute or chronic inflammatory condition affecting bone and its medullary cavity, usually the result of bacterial (occasionally viral) infection of bone.
Ottawa ankle rules	Ottawa ankle rules are a set of guidelines for clinicians to help decide if a patient with foot or ankle pain should be offered X-rays to diagnose a possible bone fracture.
Outcome	Measure of the possible results that may stem from exposure to a preventive or therapeutic intervention. Outcome measures may be intermediate endpoints or they can be final endpoints. See ‘Intermediate outcome’.
P-value	The probability that an observed difference could have occurred by chance, assuming that there is in fact no underlying difference between the means of the observations. If the probability is less than 1 in 20, the P value is less than 0.05; a result with a P value of less than 0.05 is conventionally considered to be ‘statistically significant’.
Paralysis	Injury or disease to a person's nervous system can affect the ability to move

Term	Definition
	or feel.
Paraplegia	Loss of function and paralysis below the cervical area of the neck; generally, the upper body retains motor and sensory function.
Partial weight bearing	A small amount of weight may be supported by the limb.
Pelvic packing	Pelvic packing is an invasive surgical procedure, used to tamponade sources of pelvic bleeding. Absorbent packs are placed within the preperitoneal and retroperitoneal spaces and must be removed, usually within 48 hours.
Performance bias	Bias resulting from differences in the way different groups are treated, apart from the actual treatment under investigation. This may occur if those caring for participants are not blinded to group allocation. For example, participants in the 'favoured' group may be given better care. Performance bias also relates to participant beliefs about a treatment's efficacy. For example, if a participant knows he/she is in the intervention group then they may experience a placebo effect, which might not be felt by those in a non-treatment group.
Perioperative	The period from admission through surgery until discharge, encompassing the pre-operative and post-operative periods.
Permissive hypotension	The use of restrictive fluid therapy, specifically in the trauma patient, that increases systemic blood pressure without reaching normal blood pressures.
Picture Archiving and Communications Systems (PACS)	PACS enables X-ray and scan images to be stored electronically and viewed on screens.
Pilon	The distal end of the tibia – from the French for a stump, or a pestle. Fractures of the distal tibial metaphysic caused by axial load failure are called "pilon fractures".
Placebo	An inactive and physically identical medication or procedure used as a comparator in controlled clinical trials.
Plantar aspect	Relating to the sole of the foot.
Platelets	Blood cells whose function (along with coagulation factors) is to stop bleeding.
Pneumothorax	A collection of air or gas in the pleural cavity which can cause the lung(s) to collapse.
Polypharmacy	The use or prescription of multiple medications. Polypharmacy is often defined as taking 5 or 10 medications at the same time/
Polytrauma	Patients with associated injury (i.e. two or more severe injuries in at least two areas of the body), or with a multiple injury (i.e. two or more severe injuries in one body area). Also known as multisystem trauma.
Positive predictive value (PPV)	In screening/diagnostic tests: A measure of the usefulness of a screening/diagnostic test. It is the proportion of those with a positive test result who have the disease, and can be interpreted as the probability that a positive test result is correct.
Postoperative	Pertaining to the period after patients leave the operating theatre, following surgery.
Post-test probability	For diagnostic tests. The proportion of patients with that particular test result who have the target disorder
Post-traumatic arthritis	Post-traumatic arthritis is caused by the wearing out of a joint that has had any kind of physical injury. Such injuries can damage the cartilage and/or the bone, changing the mechanics of the joint and making it wear out more

Term	Definition
	quickly.
Power (statistical)	The ability to demonstrate an association when one exists. Power is related to sample size; the larger the sample size, the greater the power and the lower the risk that a possible association could be missed.
Preoperative	The period before surgery commences.
Pressure sore	Skin breakdown due to unrelieved pressure.
Pre-test probability	For diagnostic tests. The proportion of people with the target disorder in the population at risk at a specific time point or time interval. Prevalence may depend on how a disorder is diagnosed.
Primary care	Healthcare delivered to patients outside hospitals. Primary care covers a range of services provided by general practitioners, nurses, dentists, pharmacists, opticians and other healthcare professionals.
Primary outcome	The outcome of greatest importance, usually the one in a study that the power calculation is based on.
Product licence	An authorisation from the MHRA to market a medicinal product.
Prognosis	A probable course or outcome of a disease. Prognostic factors are patient or disease characteristics that influence the course. Good prognosis is associated with low rate of undesirable outcomes; poor prognosis is associated with a high rate of undesirable outcomes.
Prophylactic antibiotics	The prevention of infection complications using antimicrobial therapy (most commonly antibiotics).
Prospective study	A study in which people are entered into the research and then followed up over a period of time with future events recorded as they happen. This contrasts with studies that are retrospective.
Protected load bearing	Encouraged to use limb within load limit set by clinician.
Protected weight bearing	Patient encouraged to walk as normal, but with the use of a walking aid.
Prothrombin complex concentrate (PCC)	A combination of blood clotting factors II, VII, IX and X, as well as protein C and S, prepared from fresh-frozen human blood plasma used to reverse the effects of oral anticoagulation therapy in an actively bleeding patient.
Publication bias	Also known as reporting bias. A bias caused by only a subset of all the relevant data being available. The publication of research can depend on the nature and direction of the study results. Studies in which an intervention is not found to be effective are sometimes not published. Because of this, systematic reviews that fail to include unpublished studies may overestimate the true effect of an intervention. In addition, a published report might present a biased set of results (e.g. only outcomes or sub-groups where a statistically significant difference was found.
Quadriplegia	Scientifically known as tetraplegia; paralysis affecting all four limbs.
Quality of life	See ‘Health-related quality of life’.
Quality-adjusted life year (QALY)	An index of survival that is adjusted to account for the patient’s quality of life during this time. QALYs have the advantage of incorporating changes in both quantity (longevity/mortality) and quality (morbidity, psychological, functional, social and other factors) of life. Used to measure benefits in cost-utility analysis. The QALYs gained are the mean QALYs associated with one treatment minus the mean QALYs associated with an alternative treatment.
Randomisation	Allocation of participants in a research study to two or more alternative groups using a chance procedure, such as computer-generated random numbers. This approach is used in an attempt to ensure there is an even distribution of characteristics across groups, which should minimise selection bias.
Randomised controlled trial	A comparative study in which participants are randomly allocated to

Term	Definition
(RCT)	intervention and control groups and followed up to examine differences in outcomes between the groups.
Rapid Sequence Induction of anaesthesia and intubation (RSI)	A medical procedure prompt involving a prompt administration of general anaesthesia and subsequent intubation of the trachea. The procedure results in rapid unconsciousness (induction) and neuromuscular blockade (paralysis) and is used to maintain a patient's airway following a traumatic incident.
RCT	See 'Randomised controlled trial'.
Receiver operated characteristic (ROC) curve	A graphical method of assessing the overall accuracy of a diagnostic test at several different thresholds of the index measure. Sensitivity is plotted against 1 minus specificity. A perfect test will have a vertical line that extends from the origin to the top left point of the graph, continuing as a horizontal line to the top right portion of the graph. A good test will be somewhere close to this ideal.
Reduction	The replacement or realignment of a body part in normal position or restoration of a bodily condition to normal.
Reference standard	The test that is considered to be the best available method to establish the presence or absence of the outcome – this may not be the one that is routinely used in practice.
Regional nerve block	A deliberate interruption of signals traveling along a nerve, often for the purpose of pain relief
Rehabilitation	Set of services intended to restore maximum function -- physical, psychological, vocational and social - to a person with a disability.
Relative risk (RR)	Risk and probability are synonymous. The risk of an event is the ratio of the number of events occurring (for example, the number of people dying) to the total number of events and non-events (for example, the total number of people dying and staying alive) in a group. Risks are distinct from odds (see odds ratio). Risks are normally compared across two groups as a relative risk, which is also known as a risk ratio (RR). For example the RR of dying in smokers compared to non-smokers would be calculated by dividing the risk of death in smokers by the risk of death in non-smokers. A RR of 1 would show that the risk of the event is the same for both groups. RR ratio greater than 1 means the risk of the event are greater in the first group. A RR less than 1 means that the risk of the event are less likely in the first group. Sometimes risks can be compared across more than 2 groups – in this case, one of the groups is chosen as the 'reference category', and the RR is calculated for each group compared with the reference category. For example, to compare the risk of dying from lung cancer for non-smokers, occasional smokers and regular smokers, non-smokers could be used as the reference category. RRs would be worked out for occasional smokers compared with non-smokers and for regular smokers compared with non-smokers. See also 'odds ratio'.
Reporting bias	See publication bias.
Rescue board	A robust and light construction board for placing patients on following injury. Rescue boards are particularly useful for water rescues but can be also used on land.
Resource implication	The likely impact in terms of finance, workforce or other NHS resources.
Respiratory compromise	An impairment of normal pulmonary gas exchange. If this leads to an arterial PaO2 of <8Kpa this signals the onset of respiratory failure. Respiratory compromise could be due to respiratory depression (see 'respiratory

Term	Definition
	depression') or other causes such as fluid in the lungs.
Respiratory depression	Respiratory depression: Occurs when ventilation is compromised below the level required for normal gas exchange. This is related to both rate (<10 breaths per minute) and depth of breathing. This can be induced by many causes such as excessive analgesia, head injury, intoxication or cervical spine injury.
Restricted weight bearing (active/passive range)	Restricted to range specific to a joint.
Retroperitoneal	The space between the peritoneum and the posterior abdominal wall that contains especially the kidneys and associated structures, the pancreas, and part of the aorta and inferior vena cava.
Retrospective study	A retrospective study deals with the present/ past and does not involve studying future events. This contrasts with studies that are prospective.
Revascularisation	The restoration of perfusion to a body part or organ that has suffered ischemia following surgical intervention.
Review question	In guideline development, this term refers to the questions about treatment and care that are formulated to guide the development of evidence-based recommendations.
Rigid non-removable cast	A non-removable off-bearing cast which is generally made from fibreglass or plaster of Plaster of Paris.
Scoop stretcher	The scoop stretcher is a device used specifically for casualty lifting. It is most frequently used to lift supine patients from the ground, either due to unconsciousness or in order to maintain stability in the case of trauma, especially spinal injury.
Secondary amputation	An amputation that is carried out after an attempted salvage of the limb.
Secondary outcome	An outcome used to evaluate additional effects of the intervention deemed a priori as being less important than the primary outcomes.
Selection bias	A systematic bias in selecting participants for study groups, so that the groups have differences in prognosis and/or therapeutic sensitivities at baseline. Randomisation (with concealed allocation) of patients protects against this bias. In non-randomised studies a multivariable analysis helps to partially adjust for selection bias.
Selective imaging	An imaging method following trauma in which scanning is limited to areas suspected of having injury. Imagining can be undertaken using ultrasound, CT or X-ray.
Selective immobilization	Immobilization following the use of a prediction soon.
Sensitivity	Sensitivity or recall rate is the proportion of true positives which are correctly identified as such. For example in diagnostic testing it is the proportion of true cases that the test detects. See the related term 'Specificity'
Sensitivity analysis	A means of representing uncertainty in the results of economic evaluations. Uncertainty may arise from missing data, imprecise estimates or methodological controversy. Sensitivity analysis also allows for exploring the generalizability of results to other settings. The analysis is repeated using different assumptions to examine the effect on the results. One-way simple sensitivity analysis (univariate analysis): each parameter is varied individually in order to isolate the consequences of each parameter on the results of the study. Multi-way simple sensitivity analysis (scenario analysis): two or more parameters are varied at the same time and the overall effect on the results is evaluated.

Term	Definition
	Threshold sensitivity analysis: the critical value of parameters above or below which the conclusions of the study will change are identified. Probabilistic sensitivity analysis: probability distributions are assigned to the uncertain parameters and are incorporated into evaluation models based on decision analytical techniques (For example, Monte Carlo simulation).
Significance (statistical)	A result is deemed statistically significant if the probability of the result occurring by chance is less than 1 in 20 ($p < 0.05$).
Skeletal maturity	Skeletal maturity is relevant to the consideration of fractures for many reasons. The term is used frequently in the guideline. The anatomy of immature bone is different from mature bone; most obviously in the presence of growth plates, but also in the different pattern of blood supply. Immature bones break in a way different to mature bone, due to the presence of growth plates and the mechanical qualities of the bone itself. Growing bone has a relatively higher fibrous composition to adult bone and so has the ability to deform before it fails and breaks, this results in immature bones displaying very different injury patterns to adult fractures. Immature bone tends to heal more rapidly. The initial injury or its treatment may interfere with normal bone growth. For the whole person the skeleton is mature once all growth plates are closed. For an individual injury skeletal maturity is when the growth plates are closed in the injured bone or bones. Clinical judgement is required during the transition period from immaturity to maturity as to how the bone should be regarded for clinical management purposes.
Skeletal stabilisation	Stabilising an unstable limb, part of limb or pelvis by a method which involves attaching something to the bone. This can be definitive or temporary. Definitive skeletal stabilisation (also referred to as definitive skeletal fixation) will be left in situ throughout the planned healing process, and therefore is durable and precisely applied. Temporary skeletal stabilisation is replaced by a definitive solution before the healing process is complete, and so can be done more quickly, may cross joints, and may not involve such precise reduction.
Softcast	A lightweight splint that is removal and can be applied for immobilisation.
Specificity	The proportion of true negatives that a correctly identified as such. For example in diagnostic testing the specificity is the proportion of non-cases incorrectly diagnosed as cases. See related term ‘Sensitivity’. In terms of literature searching a highly specific search is generally narrow and aimed at picking up the key papers in a field and avoiding a wide range of papers.
Spinal Cord Injury (SCI)	An injury to the spinal cord interferes with messages between the brain and the body and results in paralysis and sensory loss below the level of the injury. The location at which the cord is injured and the severity of the injury determines the physical limitations the person will have.
Spinal shock	Often occurring soon after spinal cord injury, this is a loss of reflexes below the level of injury with associated loss of sensorimotor functions. This condition can last for several hours to days after initial injury.
Stakeholder	Those with an interest in the use of the guideline. Stakeholders include manufacturers, sponsors, healthcare professionals, and patient and carer groups.
Subcutaneous	An injection in which a needle is inserted just under the skin.
Supraglottic device	Medical device that when applied facilitates unobstructed access of

Term	Definition
	respiratory gases to the glottic opening by displacing tissue and sealing off the laryngeal area.
Surgical site infection (SSI)	Defined as being present when pathogenic organisms multiply (SSI) in a wound giving rise to local signs and symptoms, for example heat, redness, pain and swelling, and (in more serious cases) with systemic signs of fever or a raised white blood cell count. Infection in the surgical wound may prevent healing taking place so that the wound edges separate or it may cause an abscess to form in the deeper tissues. The definitions of SSI may vary between research studies but are commonly based on those described by the Centers for Disease Control and Prevention (CDC) although other valid measures have been used, for example the ASEPSIS scoring method for postoperative wound infections and some studies that have focused only on the more serious deep and organ/space infections for which less subjective measures are available. Differences in case definitions should be taken into account when comparing reported rates of SSI.
Surgical wound classification	*Clean* – an incision in which no inflammation is encountered in a surgical procedure, without a break in sterile technique, and during which the respiratory, alimentary and genitourinary tracts are not entered. *Clean-contaminated* – an incision through which the respiratory, alimentary or genitourinary tract is entered under controlled conditions but with no contamination encountered. *Contaminated* – an incision undertaken during an operation in which there is a major break in sterile technique or gross spillage from the gastrointestinal tract, or an incision in which acute, non-purulent inflammation is encountered. Open traumatic wounds that are more than 12–24 hours old also fall into this category. *Dirty or infected* – an incision undertaken during an operation in which the viscera are perforated or when acute inflammation with pus is encountered during the operation (for example, emergency surgery for faecal peritonitis), and for traumatic wounds where treatment is delayed, and there is faecal contamination or devitalised tissue present.
Systems model	A problem-oriented representation of a complex system where parts of the system and their interactions that are relevant to the decision problem are explicitly set out.
Systematic review	Research that summarises the evidence on a clearly formulated question according to a pre-defined protocol using systematic and explicit methods to identify, select and appraise relevant studies, and to extract, collate and report their findings. It may or may not use statistical meta-analysis.
Telemedicine	Delivery of health services via remote telecommunications. This includes interactive consultative and diagnostic services.
Tension band	A format for orthopaedic wiring of fracture fragments either alone or with a screw or Kirschner wire to force fragments together in compression.
Tension pneumothorax	A tension pneumothorax occurs when intrapleural air accumulates progressively in and leads to significant impairment of respiration and/or blood circulation. It is a life threatening occurrence requiring rapid recognition and treatment is required if cardiorespiratory arrest is to be avoided.
Test and treat studies	See ‘diagnostic RCT’.
Thoracic	Portion of the spinal column in the chest, between the cervical and lumbar areas.
Thoracotomy	The construction of an artificial opening through the chest wall, usually for the drainage of fluid or the release of an abnormal accumulation of air. Used

Term	Definition
	to treat pneumothorax.
Tiered team response	Tiered trauma systems aim to better match the personnel and resources of the trauma team to the immediacy of the patients need for care
Time horizon	The time span over which costs and health outcomes are considered in a decision analysis or economic evaluation.
Tracheal intubation	A medical procedure in which a tube is placed into the windpipe (trachea), through the mouth or the nose. In most emergency situations it is placed through the mouth.
Transverse fracture	This type of fracture has a horizontal fracture line.
The Trauma Audit & Research Network (TARN)	An independent monitor of trauma care in England and Wales that is committed to making a real difference to the delivery of the care of those who are injured. They promote improvements in care through national comparative clinical audit.
Trauma coordinator	Typically a nurse recruited into MTCs with experience of trauma care
Trauma Unit (TU)	A hospital that is part of the major trauma network providing care for all except the most severe major trauma patients. When it is not possible to get to the major trauma centre within 45 minutes, or where the patient needs to be stabilised quickly, the patient is taken to the nearest hospital with a local trauma unit for immediate treatment and stabilisation before being transferred on to the major trauma centre.
Traumatic Brain Injury	A non-degenerative, non-congenital insult to the brain from an external mechanical force, possibly leading to permanent or temporary impairment of cognitive, physical, and psychosocial functions, with an associated diminished or altered state of consciousness.
Treatment allocation	Assigning a participant to a particular arm of the trial.
Triage	Triage is the process by which people are classified according to the type and urgency of their symptoms/condition/situation. The aim is to get someone in need to the right place at the right time to see an appropriately skilled person/team.
Ultrasound	Diagnostic ultrasound, also called sonography or diagnostic medical sonography, is an imaging method that uses high-frequency sound waves to produce images of structures within your body.
Univariate	Analysis which separately explores each variable in a data set.
Unrestricted load bearing	Encouraged to use limb as normal.
Unrestricted mobility	Encouraged to use limb as normal.
Unrestricted weight bearing	Encouraged to walk as normal.
Unstable fracture	A fracture with a tendency to displace after reduction.
Utility	A measure of the strength of an individual's preference for a specific health state in relation to alternative health states. The utility scale assigns numerical values on a scale from 0 (death) to 1 (optimal or 'perfect' health). Health states can be considered worse than death and thus have a negative value.
Vacuum mattress	A vacuum mattress is a medical device used for the immobilisation of patients, especially in the case of vertebra, pelvis or limb trauma. The atmospheric pressure enables the mattress to become rigid securing the patient.
Vitamin K antagonist (VKA)	A group of substances that reduce blood clotting by reducing the action of vitamin K.
Whole-Body CT	A scanogram (vertex to toes) followed by a CT scan from vertex to mid-thigh.
Wound photographs	A digital photograph of the wound to kept along kept as documentation with

Term	Definition
	the patients note.
X-ray	A radiograph made by projecting X-rays through organs or structures of the body onto a photographic film. Structures that are relatively radiopaque (allow few X-rays to pass through), such as bones and cavities filled with a radiopaque contrast medium, cast a shadow on the film. Also called X-ray film.

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