National Clinical Guideline Centre

Final

Fractures (complex): assessment and management

Complex fractures: assessment and management of complex fractures

NICE Guideline NG37

Methods, evidence and recommendations

February 2016

Final

Commissioned by the National Institute for Health and Care Excellence

Section 6.10 of this guideline and its related recommendation were updated in 2022 and have been struck through in this guideline. For recommendations relating to the temporary cover of open fractures between debridement and definitive cover please see the 2022 update.

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Contents

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1 Foreword

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 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.

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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 the non-complex fractures are those likely to be treated at the receiving hospital, whereas the complex fractures require transfer or the consideration of transfer of the injured person to a specialist centre.

There are no agreed definitions for complex fractures and so estimating their true incidence is difficult. Complex fractures are considered to make up the minority of the estimated 1.8 million fractures occurring in England each year[23], they are associated with considerable morbidity and are a large burden on healthcare resources. The treatment of complex fractures usually requires interaction between multiple healthcare professionals and specialists and the patient pathway is often complex.

A single guideline covering all aspects of complex fractures is not possible to achieve. Therefore, a unique approach had to be utilised to develop a guideline that would be of benefit to patients, clinicians and healthcare providers in the treatment of complex fractures.

Instead of tracing the pathway of a single type of complex fracture, the guideline uses three injuries to inform various stages on the pathway of patient care. The themes of open fracture, pelvic fracture and pilon fracture were chosen on the basis of their general applicability. The individual topics for each were chosen on the basis of their relevance to particular steps in the patient pathway of care, a perceived variation in current practice or their individual clinical importance. Consequently, the guidelines are not comprehensive for any individual injury. However, it was inherent in the development of the guideline that whilst recommendations are necessarily made only in relation to the individual topics of the scope, these recommendations should where possible be considered as representative of the management of complex fractures in general.

High-energy pelvic fractures may in themselves present a significant mechanical challenge in orthopaedic trauma. However, it is their potential to be associated with life-threatening haemorrhage or other significant injuries that sets them apart. High-energy pelvic fractures are, therefore, used to explore aspects of pre-hospital care, triage, transfer and emergency treatment.

Whilst open fractures may be associated with other serious injuries, it is the combination of a fracture, significant soft issue involvement and the propensity for infection that are pre-eminent with these injuries. There are some particular technical issues in the care of open fractures that are addressed, but much is directed at assessing the required expertise and timing of treatment.

Whilst the practice has evolved where high-energy pelvic fractures and open fractures tend to be transferred to a specialist centre for care at some stage in their management, this is often not the case with pilon fractures. Pilon fractures are injuries of the weight-bearing joint surface of the lower tibia, they are often difficult to manage, complications rates are often high and the outcome of treatment tends to be poor. In addition to the specific issues in their management, they can be used as an example to explore the desirability of concentrating patients or expertise for difficult, less common injuries

In summary, there are particular technical issues addressed for each of the complex fractures considered, but additionally, there are recurring questions across the types relating to the necessary availability of expertise, the urgency of delivering care and logistic consequences of these requirements.

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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: Assessment and management of complex fractures (including pelvic fractures and open fractures of limbs)

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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 complex facture.

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- People with open fractures
- People with pilon fractures
- People with pelvic fractures, including those with acetabular fractures

Key clinical issues that will be covered

- Initial triage by pre-hospital care provider
- Initial assessment and management by pre-hospital care provider
- Acute stage clinical assessment
- Acute stage imaging assessment
- Timing of referral and criteria for acceptance
- Initial management and treatment plan
- Ongoing management
- Skills to be present within the multidisciplinary team
- Documentation of clinical assessments and management for people with complex fracture
- Information and support needs of patients and their families and carers where appropriate.

For further details please refer to the scope in Appendix A and the review questions in Section 4.3

3.3.2 What this guideline does not cover

Groups that will not be covered

Any person with a:

- Non-complex fracture
- Skull fracture
- Hip fracture
- Spinal injury

Clinical issues that will not be covered

- Prevention and follow-up of complex fractures
- Management and follow-up of pathological conditions
- Management and follow-up of dislocations

3.3.3 Relationships between the guideline and other NICE guidance

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.

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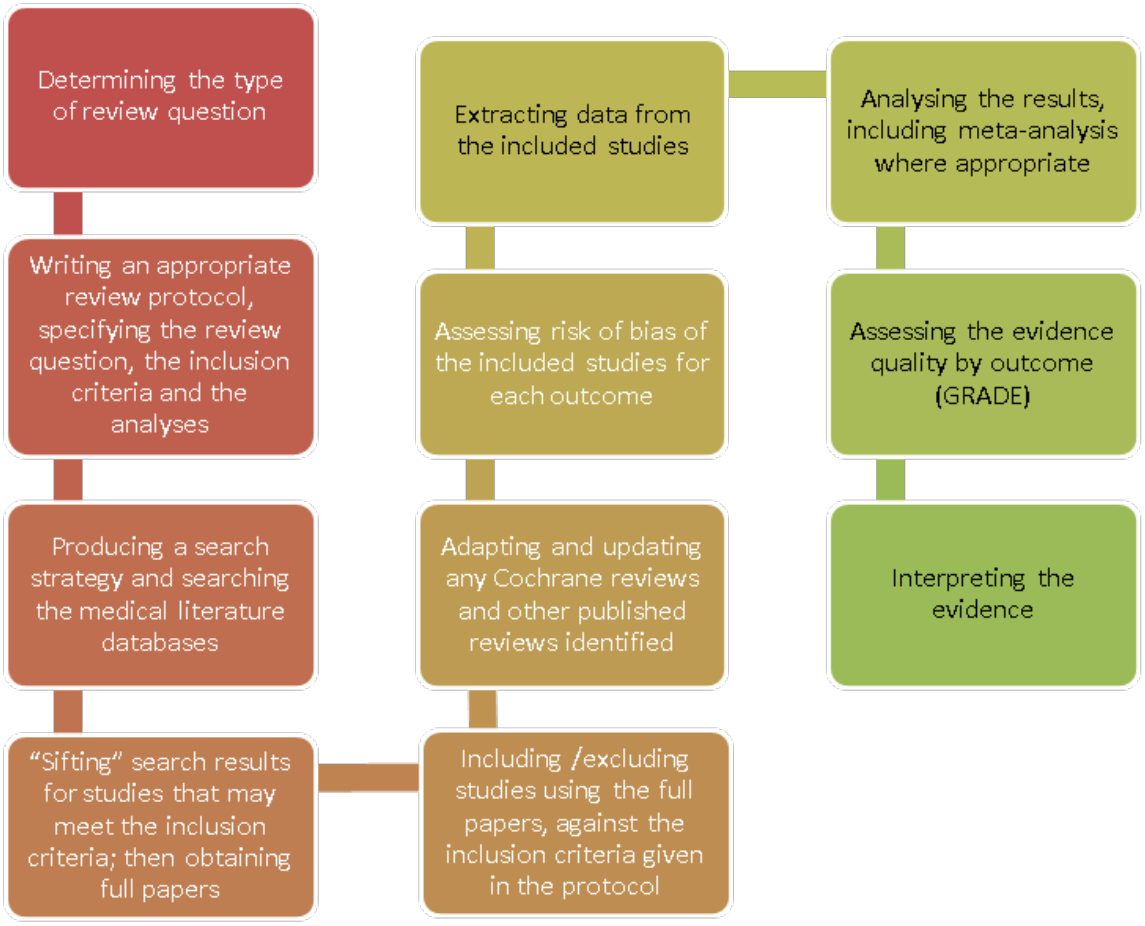
4 Methods

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[68].

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 33 review questions were identified.

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

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Table 1: Review questions

Chapter	Review questions	Outcomes
Open fractures	Is it clinically and cost effective for suspected open limb fractures to be directly transported to a major trauma centre?	Critical: • Mortality up to 12 months • Health-related quality of life • Limb loss • Deep infection • Time to definitive soft tissue closure • Joint orthoplastic debridement • Multiple procedures • Further transfer for plastics • Functional outcome measures • Pain/discomfort • Return to normal activities • Psychological wellbeing Important: • Total hospital length of stay
Open fractures	Which are the best risk prediction tools to predict likelihood of successful limb salvage in people with mangled limbs who are given limb salvage treatment?	Sensitivity and specificity of the risk tool for predicting successful salvage/need for amputation
Open fractures	What is the optimum time to administer prophylactic antibiotics for suspected open fractures?	Critical: • Mortality • Function • Health-related quality of life • Deep infection • Allergy/anaphylaxis • Reoperation (unplanned)/amputation • Wound healing by 6 weeks Important: • Return to normal activities • Superficial infection
Open fractures	What is the most clinically and cost effective dressing type prior to surgical debridement and excision for use in open fractures, pre-hospital and in hospital?	Critical • Function • Health-related quality of life • Deep infection (bone) • Wound infection • Tissue necrosis • Re-operation (unplanned)/amputation • Wound healing by 6 weeks Important: • Return to normal activities
Open fractures	Are arterial shunts followed by later repair more clinically and cost effective compared to	Critical: • Quality of life • Mortality

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Chapter	Review questions	Outcomes
	definitive repair of arterial injuries associated with open fractures?	• Amputation • Deep infection • Compartment decompression • Unplanned re-operation Important • Length of stay • Hospitalisation
Open fractures	Is the presence of an orthopaedic surgeon and plastic surgeon at the initial surgical excision and stabilisation of an open fracture clinically and cost effective?	• Mortality • Health-related quality of life • Deep surgical site infection • Amputation • Flap failure • Time to definitive cover • Unplanned complexity of soft tissue cover • Length of hospital stay • Further unplanned surgery • Return to normal activities
Open fractures	What is the optimal timing of initial debridement of open fractures?	Critical: • Mortality up to 12 months • Health-related quality of life • Return to normal activities • Deep Surgical site infection • Re-operation (unplanned) • Amputation • Functional outcomes Important: • Length of hospital stay
Open fractures	Is the use of initial definitive fixation and cover more clinically and cost effective in the management of open fractures compared with staged fixation and cover?	Critical: • Mortality at 1 and 12 months • Health-related quality of life • Deep surgical site infection (infection involving the bone) • Flap failure (total or partial) Important: • Length of hospital stay • Further unplanned surgery • Return to normal activities
Open fractures	What is the most clinical and cost effective time to achieve definitive soft tissue cover in open fractures?	Critical: • Mortality up to 12 months • Health-related quality of life • deep surgical site infection • Re-operation • Amputation

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Chapter	Review questions	Outcomes
		• Functional outcomes • Partial Flap failure • Complete flap failure Important: • Length of hospital stay • Superficial wound infection • Return to normal activities
Open fractures	What is the most clinically and cost effective temporary dressing or wound therapy in open fractures after wound excision or surgical debridement?	Critical: • Function • Health-related quality of life • Deep infection • Wound infection • Re-operation/amputation • Wound healing by 6 weeks • Tissue necrosis Important: • Return to normal activities
Pelvic fractures	Is it clinically and cost effective for patients with suspected high energy pelvic or acetabular fractures to be transferred directly to a major trauma centre (MTC)?	Critical: • Mortality up to 12 months • Health-related quality of life • Adverse effects (surgical complications) • Further transfer for specialist surgery • Functional outcome measures • Pain/discomfort • Return to normal activities • Psychological wellbeing • Time to definitive surgery Important: • Total hospital bed days • Blood loss
Pelvic fractures	What is the most clinically and cost effective timing for transferring patients with pelvic fractures (including acetabular fractures) to tertiary or specialist services?	Critical: • Mortality at 1 and 12 months • Health-related quality of life • Hip replacement • Need for further surgery • Nerve injury • Sexual function (erectile dysfunction in men; pain during intercourse in women) Important:

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Chapter	Review questions	Outcomes
		• Functional outcomes • Return to normal activities)
Pelvic fractures	Which are the best diagnostic risk tools to predict the presence of a pelvic fracture at the pre-hospital stage?	• Sensitivity and specificity • Area Under the Curve methods (AUC)
Pelvic fractures	What is the most clinically and cost effective duration for pelvic binder use?	Critical: • Mortality to 1 year • Health-related quality of life • Skin necrosis • Breakdown • Blistering • Functional outcome measures • Pain/discomfort • Return to normal activities • Psychological wellbeing • Blood loss (blood components)
Pelvic fractures	What is the safest strategy and timing for log rolling patients with suspected or known pelvic fracture?	Critical: • Mortality • Health-related quality of life • Volume of blood lost/number of transfusions required • Time to definitive control of haemorrhage • Important: • Functional outcome measures • Pain/discomfort • Return to normal activities • Psychological wellbeing • Length of stay
Pelvic fractures	Pelvic imaging (a) What is the most clinically and cost effective imaging modality for assessment of high energy suspected pelvic or acetabular fractures at the initial presentation?	Critical: • Mortality up to 12 months • Health-related quality of life • Missed injury • Need for further diagnostic imaging • Time to whole body CT (for other injuries) • Radiation • Delayed treatment • Functional outcome measures • Pain/discomfort • Return to normal activities • Psychological wellbeing Important: • Time in hospital • Misdiagnosis
Pelvic fractures	Pelvic imaging (b)	Sensitivity and specificity

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Chapter	Review questions	Outcomes
	What is the diagnostic accuracy of CT, CT plus X-ray or X-ray for assessment of high energy pelvic or acetabular fractures for (1) existence of fractures and (2) classification of fractures?	
Pelvic fractures	Cystourethrogram (a) Does a cystourethrogram lead to better outcomes than CT in patients with confirmed or suspected pelvic fracture and suspected bladder and urethral injuries?	Critical: • Mortality up to 12 months • Health-related quality of life • Missed bladder injury • Missed urethral injury • Impotence • Incontinence • Infection of fracture site • Time to definitive diagnosis • Functional outcome measures • Pain/discomfort • Return to normal activities • Psychological wellbeing Important: • Length of stay
Pelvic fractures	Cystourethrogram (b) What is the diagnostic accuracy of cystourethrograms and CT for assessment of bladder injury in patients with confirmed or suspected pelvic fracture?	Sensitivity and specificity

Pelvic fractures	What is the most clinically and cost-effective invasive technique for control of bleeding in pelvic ring fractures?	Critical:
		• Mortality
		• Health-related quality of life
		• Re-bleeding rates
		• Need for further intervention
		• Volume of blood lost/Number of transfusions required
		• Time to definitive control of haemorrhage
		• Need for rescanning
		• Adverse effects
		  ○ Tissue necrosis/muscle infarction
		  ○ Deep infection
		
		Important:
		• Pain/discomfort
		• Return to normal activities
		• Length of stay

Pilon fractures	Is it clinically and cost effective to transfer people with a pilon fracture (equivalent in children: McFarlane fracture) to a specialist centre prior to first surgical procedure?	Critical: • Health-related quality of life • Surgical site infection • Ankle fusion

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Chapter	Review questions	Outcomes
		• Unplanned further surgery (any surgery including for infection, re-intervention, or to correct fusion) Important: • Patient-reported outcomes (return to normal activities).
Pilon fractures	What is the most clinically and cost effective strategy in the surgical management of pilon fractures?	Critical: • Quality of life • Length of stay • Hospitalisation • Mortality • Amputation • Deep infection • Unplanned surgery • Function • Pain Important: • Length of stay • Hospitalisation • Return to normal activities
Pilon fractures	Are fine wire external fixators more clinically and cost effective for managing pilon fractures than internal fixation with plates and screws?	Critical: • Health-related quality of life • Surgical site infection • Ankle fusion • Unplanned further surgery • Wound breakdown Important: • Patient-reported outcomes (return to normal activities)
Other	Identifying arterial injury (a) What is the most effective method of identifying an arterial injury requiring intervention in people with upper and lower limb fractures?	Critical: • Mortality up to 12 months • Health-related quality of life • Limb salvage • Myoglobinuria/renal failure • Proportion requiring fasciotomy • Limb ischaemia/deep infection • Functional outcome measures • Pain/discomfort • Return to normal activities • Psychological wellbeing • Time to revascularisation Important: • Total hospital length of stay

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Chapter	Review questions	Outcomes
Other	Identifying arterial injury (b) What is the most accurate method for diagnosing an arterial injury in a person requiring intervention in people with upper and lower limb fractures?	• Sensitivity and specificity
Other	Compartment syndrome (a) What is the most clinically and cost effective method of identifying compartment syndrome in patients with limb fractures?	Critical: • Health-related quality of life • Neurological dysfunction • Muscle/joint contracture • Amputation • Functional outcome measures • Pain/discomfort • Return to normal activities • Psychological wellbeing • Deep infection • Neuropathic ulcers Important: • Unplanned surgery • Missed compartment syndrome (not including foot compartment) • Length of stay • Cosmesis
Other	Compartment syndrome (b) What is the most accurate method of identifying compartment syndrome in patients with limb fractures?	Sensitivity and specificity

Other	What is the most clinically and cost effective strategy for splinting of lower limb long bone fractures in the pre-hospital setting?	Critical:
		• Mortality up to 12 months
		• Health-related quality of life
		• Function
		• Adverse effects
		  ○ Neurovascular damage
		  ○ Tissue necrosis
		  ○ Pain (various methods)
		
		Important:
		• Return to normal activities
		• Blood pressure (various surrogates)

Other	Does hip dislocation require immediate open reduction in the event of a failed closed reduction?	Critical: • Mortality • Health-related quality of life • Avascular necrosis fem head • Sciatic nerve injury Important: • Pain/discomfort • Return to normal activities

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Chapter	Review questions	Outcomes
		• Psychological wellbeing • Functional scores for hip (Oxford, Harris)
Other	Is it clinically and cost-effective to extend full-body CT to the feet in patients with polytrauma and suspected lower limb injury?	Critical: • Mortality at 12 months • Health-related quality of life • Missed lower limb fracture or vascular injury • Radiation exposure/radiation adverse effects • Functional outcomes • Time to definitive diagnosis Important • Length of stay
Other	For patients with open fractures is documentation that includes wound photographs more clinically and cost effective than documentation without?	Critical: • Mortality at 1, 6 and 12 months • Health-related quality of life • Deep infection • Time to initial surgery • Time to definitive closure Important: • Functional outcome measures • Pain/discomfort • Return to normal activities • Psychological wellbeing
Other	Does documentation recording assessment results of neurovascular status (including interpretations and conclusions) improve outcomes compared with limited recording of neurovascular status in people with complex fractures?	Critical: • Mortality up to 12 months • Health-related quality of life • Pain/discomfort • Amputation • Neuromuscular function Important: • Total hospital bed days • Blood loss • Return to normal activities • Psychological wellbeing • Litigation
Other	What information and support do people with fractures and their families and carers require?	*(qualitative review – no pre-defined outcomes)*

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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].[68] 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 between 25th March and 16 April 2015. No papers 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 16th or 17th April 2015. No papers published 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]).[68]
- 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).

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- 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 sifts of the first three 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 synthesise 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 J. The GDG was consulted about any uncertainty regarding inclusion or exclusion.

The key population inclusion criterion was:

- People of all ages experiencing an open, pelvic or pilon fracture as a result of a traumatic physical event.

The key population exclusion criterion was:

- People with
  - non-complex fractures (this will be covered in another guideline)
  - skull fracture
  - hip fracture
  - spinal injury (this will be covered in another guideline)

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

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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.

4.3.3Contacting 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 timing of debridement review, further data was requested and received from researchers involved in the Davis-Sears, 2012[19] study.

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 age 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 spinal cord injury
- Patient-assessed symptoms

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- 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, American Spinal Injury Association/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)[4] 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) 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.

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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 subunits 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, 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 confidence intervals 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 was synthesised using the same methods for intervention reviews (see dichotomous or continuous outcomes above).

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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®. 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[72,72]). 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, for example, R^2 , if reported was 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 subthemes 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, subthemes would relate to more than one generic theme. A summary evidence table of generic themes and underpinning subthemes was then produced alongside the quality of the evidence.

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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.

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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

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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'

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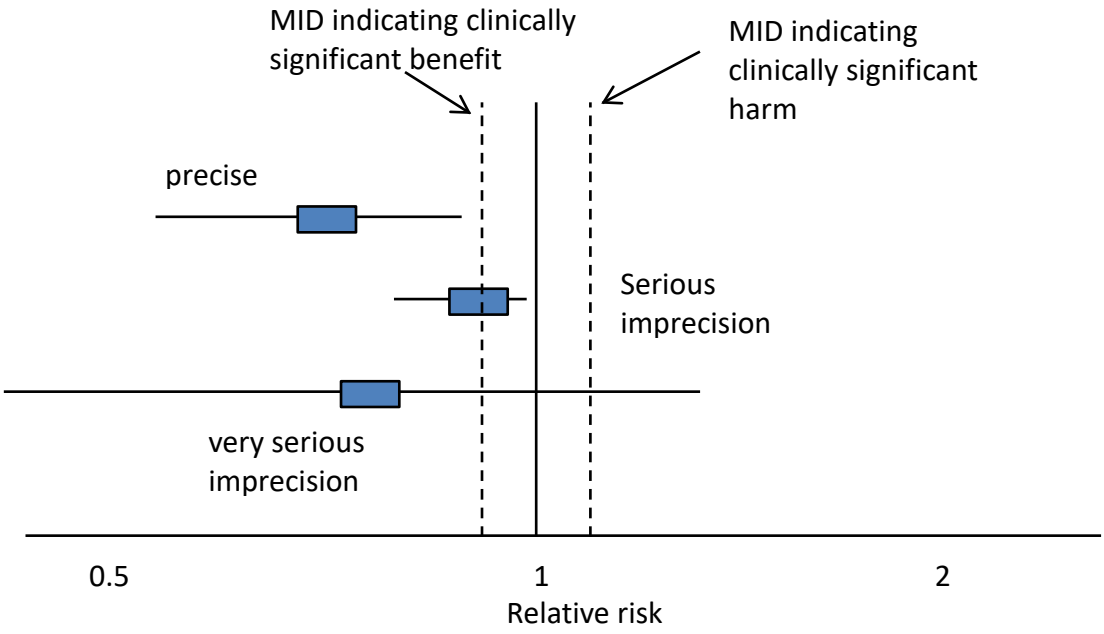
outcome (for example, a VAS pain score). Clinically significant harms will be the converse of these. If baseline values are unavailable, then half the median comparator group standard deviation of that variable will be taken as the MID.

- 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 confidence interval 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 4. The reasons or criteria used for downgrading were specified in the footnotes of the GRADE tables.

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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 4) brought the rating down by one increment to a minimum grade of very low, as explained for interventional studies.

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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 Table 6):

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

Table 6: 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 test and setting)	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 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?	

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4.3.5.4 Qualitative reviews

Table 7 below summarises the factors which were assessed to inform the quality rating for each subtheme. Quality was rated as trustworthy or not trustworthy based on these criteria.

Table 7: 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

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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[69]
- Studies considered eligible but were excluded can be found in Appendix K.

4.4.1.1 Inclusion/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/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, Appendix H[69] 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.

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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 attempted by the Health Economist in priority areas. This was later downgraded to a costing analysis. 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 explored through the use of audit data 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 L 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.[67]

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

- 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
- 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' [67].

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 6-10.
- Forest plots and summary ROC curves (Appendix I)

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- A description of the methods and results of the cost-effectiveness analysis undertaken for the guideline (Appendix L)

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 5.2).

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,[69] 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.

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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.

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5 Guideline summary

5.1 Full list of recommendations

1. Transport people with suspected open fractures:
   - directly to a major trauma centre or specialist centre that can provide orthoplastic care if a long bone, hindfoot or midfoot are involved, or
   - to the nearest trauma unit or emergency department if the suspected fracture is in the hand, wrist or toes, unless there are pre-hospital triage indications for direct transport to a major trauma centre.
2. Do not base the decision whether to perform limb salvage or amputation on an injury severity tool score.
3. Perform emergency amputation when:
   - a limb is the source of uncontrollable life-threatening bleeding, or
   - a limb is salvageable but attempted preservation would pose an unacceptable risk to the person's life, or
   - a limb is deemed unsalvageable after orthoplastic assessment.
4. Base the decision whether to perform limb salvage or delayed primary amputation on multidisciplinary assessment involving an orthopaedic surgeon, a plastic surgeon, a rehabilitation specialist and the person and their family members or carers (as appropriate).
5. When indicated, perform the delayed primary amputation within 72 hours of injury.
6. In the pre-hospital setting, administer prophylactic intravenous antibiotics as soon as possible and preferably within 1 hour of injury to people with open fractures without delaying transport to hospital.
7. In the emergency department, administer prophylactic intravenous antibiotics immediately to people with open fractures if not already given.
8. Do not irrigate open fractures of the long bones, hindfoot or midfoot in pre-hospital settings.
9. Consider a saline-soaked dressing covered with an occlusive layer for open fractures in pre-hospital settings.
10. Do not irrigate open fractures of the long bones, hindfoot or midfoot in the emergency department before debridement.
11. Consider a saline-soaked dressing covered with an occlusive layer (if not already applied) for open fractures in the emergency department before debridement.
12. In people with a devascularised limb following long bone fracture, use a vascular shunt as the first surgical intervention before skeletal stabilisation and definitive vascular reconstruction.
13. Surgery to achieve debridement, fixation and cover of open fractures of the long bone, hindfoot or midfoot should be performed concurrently by consultants in orthopaedic and plastic surgery (a combined orthoplastic approach).

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14. Perform debridement:
    - immediately for highly contaminated open fractures
    - within 12 hours of injury for high-energy open fractures (likely Gustilo–Anderson classification type IIIA or type IIIB) that are not highly contaminated
    - within 24 hours of injury for all other open fractures.
15. Perform fixation and definitive soft tissue cover:
    - at the same time as debridement if the next orthoplastic list allows this within the time to debridement recommended in recommendation 14, or
    - within 72 hours of injury if definitive soft tissue cover cannot be performed at the time of debridement.
16. When internal fixation is used, perform definitive soft tissue cover at the same time.
17. ~~Consider negative pressure wound therapy after debridement if immediate definitive soft tissue cover has not been performed.~~
18. Transport people with suspected pelvic fractures:
    - to the nearest hospital if suspected pelvic fracture is the only pre-hospital triage indication
    - directly to a major trauma centre if they also have other pre-hospital triage indications for major trauma.
19. Immediately transfer people with haemodynamic instability from pelvic or acetabular fractures to a major trauma centre for definitive treatment of active bleeding.
20. Transfer people with pelvic or acetabular fractures needing specialist pelvic reconstruction to a major trauma centre or specialist centre within 24 hours of injury.
21. If active bleeding is suspected from a pelvic fracture following blunt high-energy trauma:
    - apply a purpose-made pelvic binder, or
    - consider an improvised pelvic binder but only if a purpose-made binder does not fit.
22. For people with suspected pelvic fractures and pelvic binders, remove the binder as soon as possible if:
    - there is no pelvic fracture, or
    - a pelvic fracture is identified as mechanically stable, or
    - the binder is not controlling the mechanical stability of the fracture, or
    - there is no further bleeding or coagulation is normal.

    Remove all pelvic binders within 24 hours of application.
23. Before removing the pelvic binder, agree with a pelvic surgeon how a mechanically unstable fracture should be managed.
24. Do not log roll people with suspected pelvic fractures before pelvic imaging unless:

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- an occult penetrating injury is suspected in a person with haemodynamic instability
- log rolling is needed to clear the airway (for example, suction is ineffective in a person who is vomiting).

When log rolling, pay particular attention to haemodynamic stability.

25. Use CT for first-line imaging in adults (16 or over) with suspected high-energy pelvic fractures.

26. For first-line imaging in children (under 16s) with suspected high-energy pelvic fractures:

- use CT rather than X-ray when CT of the abdomen or pelvis is already indicated for assessing other injuries
- consider CT rather than X-ray when CT of the abdomen or pelvis is not indicated for assessing other injuries.

Use clinical judgement to limit CT to the body areas where assessment is needed.

27. For first-line invasive treatment of active arterial pelvic bleeding, use:

- interventional radiology if emergency laparotomy is not needed for abdominal injuries
- pelvic packing if emergency laparotomy is needed for abdominal injuries.

28. Create a definitive management plan and perform initial surgery (temporary or definitive) within 24 hours of injury in adults (skeletally mature) with displaced pilon fractures.

29. If a definitive management plan and initial surgery cannot be performed at the receiving hospital within 24 hours of injury, transfer adults (skeletally mature) with displaced pilon fractures to an orthoplastic centre (ideally this would be emergency department to emergency department transfer to avoid delay).

30. Immediately transfer adults (skeletally mature) with displaced pilon fractures to an orthoplastic centre if there are wound complications.

31. Create a definitive management plan involving a children's orthopaedic trauma specialist within 24 hours of diagnosis in children (skeletally immature) with intra-articular distal tibia fractures.

32. If a definitive management plan and surgery cannot be performed at the receiving hospital, transfer children (skeletally immature) with intra-articular distal tibia fractures to a centre with a children's orthopaedic trauma specialist (ideally this would be emergency department to emergency department transfer to avoid delay).

33. Use hard signs (lack of palpable pulse, continued blood loss, or expanding haematoma) to diagnose vascular injury.

34. Do not rely on capillary return or Doppler signal to exclude vascular injury.

35. Perform immediate surgical exploration if hard signs of vascular injury persist after any necessary restoration of limb alignment and joint reduction.

36. Do not delay revascularisation for angiography in people with complex fractures.

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37. For humeral supracondylar fractures in children (under 16s) without a palpable radial pulse but with a well-perfused hand, consider observation rather than immediate vascular intervention.

38. In people with fractures of the tibia, maintain awareness of compartment syndrome for 48 hours after injury or fixation by:

    - regularly assessing and recording clinical symptoms and signs in hospital
    - considering continuous compartment pressure monitoring in hospital when clinical symptoms and signs cannot be readily identified (for example, because the person is unconscious or has a nerve block)
    - advising people how to self-monitor for symptoms of compartment syndrome, when they leave hospital.

39. 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.

40. Immediately transfer people with a failed closed reduction of a native hip joint to a specialist centre if there is insufficient expertise for open reduction at the receiving hospital.

41. Use whole-body CT (consisting of a vertex-to-toes scanogram followed by CT from vertex to mid-thigh) in adults (16 or over) with blunt major trauma and suspected multiple injuries. Patients should not be repositioned during whole-body CT.

42. Use clinical findings and the scanogram to direct CT of the limbs in adults (16 or over) with limb trauma.

43. Do not routinely use whole-body CT to image children (under 16s). Use clinical judgement to limit CT to the body areas where assessment is needed.

44. All trusts receiving patients with open fractures must have information governance policies in place that enable staff to take and use photographs of open fracture wounds for clinical decision-making 24 hours a day. Protocols must also cover the handling and storage of photographic images of open fracture wounds.

45. Consider photographing open fracture wounds when they are first exposed for clinical care, before debridement and at other key stages of management.

46. Keep any photographs of open fracture wounds in the patient's records.

47. When assessing neurovascular status in a person with a limb injury, document for both limbs:

    - which nerves and nerve function have been assessed and when
    - the findings, including:
    - sensibility
    - motor function using the Medical Research Council (MRC) grading system
    - which pulses have been assessed and when
    - how circulation has been assessed when pulses are not accessible.

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Document and time each repeated assessment.

48. The trauma team structure should include a clear point of contact for providing information to patients, their family members and carers.

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

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

51. Contact the mental health team as soon as possible for patients who have a pre-existing psychological or psychiatric condition that might have contributed to their injury, or a mental health problem that might affect their wellbeing or care in hospital.

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

53. 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.

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

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

56. 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.

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

58. 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 permanent effects on quality of life (such as pain, loss of function and psychological effects)
    - amputation, if this is a possibility
    - 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.

59. 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.

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

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61. 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.

5.1.1 Additional recommendations

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

Pre-hospital settings

- For recommendations on managing airways, recognising and managing chest trauma, controlling external haemorrhage and fluid replacement, see the NICE guideline on major trauma.

Initial pharmacological pain management

- For recommendations on pain assessment in people with suspected complex fractures, see the NICE guideline on major trauma.
- For recommendations on the initial pharmacological management of pain in people with suspected open fractures, see the NICE guideline on major trauma.
- For recommendations on the initial pharmacological management of pain in people with suspected high-energy pelvic fractures, see the NICE guideline on major trauma.
- For recommendations on the initial pharmacological management of pain in adults with suspected low-energy pelvic fractures, see the NICE guideline on hip fracture.
- For recommendations on the initial pharmacological management of pain in adults with suspected pilon fractures and children with suspected intra-articular distal tibia fractures, see the NICE guideline on non-complex fractures.

Providing support

- 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 questions.

Documentation

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

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- includes a summary written in plain English that is understandable by patients, family members and carers
- is readily available in the patient's records.

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, major trauma services and spinal injury assessment.
- Enable each healthcare professional who delivers care to people with fractures to have up-to-date training in the intervention they are required to give.

5.2 Key research recommendations

1. **How accurate is the first CT scan with contrast (trauma scan) for detecting bladder injuries in people with suspected bladder injuries after a traumatic incident?**

2. **In adults with closed pilon fractures, what method of fixation provides the best clinical and cost effectiveness outcomes as assessed by function and incidence of major complications at 2 years (stratified for timing of definitive surgery early [under 36 hours] versus later [over 36 hours])?**

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6 Open fractures

6.1 Immediate destination of people with open fractures

6.1.1 Introduction

Open limb fractures are complex injuries frequently associated with soft tissue loss, contamination and infection. Urgent intervention is often required to clean the area of the injury and to prevent long-term complications, such as deep infection, vascular compromise and complete limb loss. Current UK consensus guidelines (The British Orthopaedic Association and British Association of Plastic, Reconstructive and Aesthetic Surgeons)[11] recommend the use of a multidisciplinary team with senior plastic surgeons and orthopaedic input for early intervention. Co-localisation of these services is a pre-requisite of all UK major trauma centres. These centres carry an additive cost to the NHS, compared with district general hospitals, but the added clinical and cost benefit to patients following open fracture is unknown. This review aims to assess the clinical and cost effectiveness of patients with open fracture being directly transported to a major trauma centre (MTC).

6.1.2 Review question: Is it clinically and cost effective for suspected open limb fractures to be directly transported to a major trauma centre?

For full details see review protocol in Appendix C.

Table 8: PICO characteristics of review question

Population	Children, young people and adults with open fractures.
Intervention	Direct transfer to a MTC/specialist centre for orthoplastic care
Comparison	Direct transfer to the nearest Hospital (non-MTC)
Outcomes	**Critical:** • Mortality up to 12 months • Health-related quality of life • Limb loss • Deep infection • Time to definitive soft tissue closure • Joint orthoplastic debridement • Multiple procedures • Further transfer for plastics • Functional outcome measures • Pain/discomfort • Return to normal activities • Psychological wellbeing **Important:** • Total hospital length of stay
Study design	RCT or systematic review of RCT's

6.1.3 Clinical evidence

No relevant clinical studies comparing were identified. See the search strategy in appendix F, study selection flow chart in Appendix D and excluded studies list in Appendix J.

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6.1.4 Economic evidence

Published literature

No relevant economic evaluations were identified.

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

6.1.5 Evidence statements

Clinical

No relevant clinical evidence was identified.

Economic

No relevant economic evaluations were identified.

6.1.6 Recommendations and link to evidence

Recommendations	**1. Transport people with suspected open fractures:** • **directly to a major trauma centre[a] or specialist centre that can provide orthoplastic care if a long bone, hindfoot or midfoot are involved, or** • **to the nearest trauma unit or emergency department if the suspected fracture is in the hand, wrist or toes, unless there are pre-hospital triage indications for direct transport to a major trauma centre.**
	In addition to this recommendation the Service delivery guideline recommends that specific geographic or patient characteristics may require intermediate care in a trauma unit within the context of a regional trauma network, and that diversion to the nearest trauma unit may be needed for life-saving interventions.
Relative values of different outcomes	Critical outcomes were mortality at 1, 6 and 12 months, health-related quality of life, limb loss and deep infection. Important outcomes were pain/discomfort, return to normal activities, psychological wellbeing, hospital bed days and blood loss.
Trade-off between clinical benefits and harms	No evidence was found in the published literature, so recommendations were made based on consensus. The GDG felt that for long bone or hindfoot and midfoot open fractures the most important feature of the optimal destination was that it should provide orthoplastic care, which would usually mean it would be a MTC or a specialist centre for orthoplastic care. The benefits of getting the patient to orthoplastic care where the expertise exists to treat these patients in the timely manner required were believed to outweigh possible harms in terms of greater time in reaching that destination and the delay to starting treatment. This is supported by other evidence and recommendations in this guideline that advise immediate debridement for some open fractures and that all open fractures should be debrided within 24 hours (see recommendations on initial timing of debridement).

a In some locations or circumstances, intermediate care in a trauma unit might be needed for urgent treatment, in line with agreed practice within the regional trauma network.

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	For patients with other open fractures (including wrist, toe and hand) the need for orthoplastics was deemed less critical, and so the harms of a longer time to destination might not be exceeded by any benefits. Hence for these people it was felt that transport to the nearest emergency department (ED) or trauma unit (TU) would be optimal.
Economic considerations	No economic evidence was identified for this question. There is a trade-off involved in deciding the destination of a patient with an open fracture, as the patient may require skills from an orthoplastic centre which may not be the nearest hospital. Taking the patient directly to the orthoplastic centre may increase the journey time and consequently delay the initial treatment in comparison to taking them directly to the nearest hospital. Conversely, if the patient were to be taken to the nearest hospital, they may require a secondary transfer to the appropriate destination that has the skills available to provide definitive treatment for the open fracture. This will incur unnecessary costs for those who require orthoplastic services. Another consideration is that transporting a large number of open fractures that do not require orthoplastic services directly to the orthoplastic centre could overwhelm the hospital and result in delayed treatment for other patients who do require the expert services. The GDG came to a consensus that patients who require orthoplastic care should be taken directly to a centre that can provide it. This is necessary to accommodate the recommendation for the presence of a plastic surgeon at the initial debridement of open fractures. They believed that recommending direct transport to an orthoplastic centre for people with long bone, hindfoot or midfoot fractures was likely to capture the population who require this expertise and very few of these could be adequately treated without this expertise. They also believed that suspected fractures of the hand, wrist or toes would capture those who can be treated in a TU or ED and very few of these would require secondary transfer to an orthoplastic centre for definitive treatment.
Quality of evidence	No evidence was found.
Other considerations	Replant surgery may not be available in all MTCs and local plans for potential replantation need to be formulated.

6.2 Limb salvage

6.2.1 Introduction

A mangled limb after a complex fracture presents the clinician with a very difficult decision. Functional salvage of the limb is clearly desirable, and so decisions on salvage must be made with the aim of avoiding unnecessary amputation. On the other hand, delay in amputation of a limb that is heavily contaminated or beyond repair may lead to pain, serious infection and even death. Any patient will either have the safe capacity for limb salvage or not, but the ability to predict this at an early stage and thus make the correct decision in time is difficult. A highly accurate prediction tool is required that can identify those patients whose limb can be safely and effectively salvaged, and also identify those for whom salvage would fail or be dangerous. Several prediction tools exist, and the aim of this review is to evaluate which, if any, have adequate sensitivity and specificity to enable appropriate decision-making.

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6.2.2 Review question: Which are the best risk prediction tools to predict likelihood of successful limb salvage in people with mangled limbs who are given limb salvage treatment?

For full details see review protocol in Appendix C.

Table 9: PICO characteristics of review question

Population	Children, young people and adults with mangled extremity who are given limb salvage treatment
Prognostic Risk tools	Any tools used in the literature (There are no confounders with risk prediction tools, as they are a composite of most key variables thought to affect an outcome)
Outcomes	Sensitivity or specificity of the risk tool for predicting successful salvage/need for amputation.

6.2.3 Clinical evidence

Use of a risk prediction tool involves the inputting of variables into an algorithm that predicts the probability of an outcome for a single patient. The variables included in the algorithm, and their weights, are usually found by prior regression analyses of all variables thought likely to affect the outcome in a developmental study. The accuracy of these tools is then evaluated on a sample that is distinct from the sample used for the developmental study.

Such studies evaluating the accuracy of risk tools were sought and 23 retrospective or prospective prognostic risk tool papers were included in the review[6,8-10,12,17,24,26,27,29,39,48,51-53,59,61,65,78,79,82,83,85,86,91]. These are summarised in Table 10. Evidence from this study is summarised in the clinical evidence summaries (Table 11 to Table 35). For evidence where there was sufficient data for meta-analysis, sensitivity/1-specificity graphs have also been presented (Figure 3 and Figure 4). See also the study selection flow chart in Appendix D, study evidence tables in Appendix G, forest plots in Appendix I, GRADE tables in Appendix H and excluded studies list in Appendix J.

Table 10: Summary of studies included in the review

Study	Population	Follow-up time	Risk tools	Comments (positive aspects of study in bold)
Behdad 2012[6]	Grade I, IIB and IIIC open fractures due to trauma; children (age circa 12 years) n=200	1 year	MESS	Unclear if amputation decision based on tool score; no thresholds defined; data did differentiate between primary and secondary amputations; unclear description of rationale for any amputations; follow-up adequate for reasonable assumption that all secondary amputations occurred in this period; Quadas rating: very serious risk of bias
Bonanni 1993[8]	Severely mangled limbs; mean age 32.1 (15.3) years n=89	2 years	MESS MESI PSI LSI	Unclear if amputation decision based on tool score; data did differentiate between primary and secondary amputations; unclear description of rationale for any amputations; follow-up adequate for reasonable assumption that all secondary amputations occurred in this period; Quadas rating: very serious risk of bias
Bosse 2001[9,10]	Type IIIB and C lower limb injuries; 16-69 years n=556	Minimum 6 months	HFS-'97 PSI MESS NISSSA	Amputation decision clearly not based on tool score; data did differentiate between primary and secondary amputations; unclear description of rationale for any amputations; follow-up adequate for reasonable assumption that all secondary

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Study	Population	Follow-up time	Risk tools	Comments (positive aspects of study in bold)
			LSI	amputations occurred in this period; Quadas rating: serious risk of bias
Brown 2009[12]	Abbreviated injury score >1 for lower limb injury; median age 25 years n=86	Unclear	MESS	Unclear if amputation decision based on tool score; data did not differentiate between primary and secondary amputations; unclear description of rationale for any amputations; follow-up unclear so cannot be sure all secondary amputations occurred in this period; Quadas rating: very serious risk of bias
Dagum 1999[17]	Type IIIB and C open tibia fractures; mean age 37 years n=55	7-147 months	MESS MESI PSI LSI	Unclear if amputation decision based on tool score; data did differentiate between primary and secondary amputations; clear description of rationale for any amputations; follow-up adequate for reasonable assumption that all secondary amputations occurred in this period; Quadas rating: serious risk of bias
Doucet 2011[24]	Open tibia fracture with abbreviated injury score >1; military; mean age 24 years n=965	Unclear	MESS	Unclear if amputation decision based on tool score; data did differentiate between primary and secondary amputations; unclear description of rationale for any amputations; follow-up unclear so cannot be sure all secondary amputations occurred in this period; Quadas rating: very serious risk of bias
Durham 1996 [26]	Severe upper and lower limb injuries (Gustilo IIIB or C); mean age 35 (14) years n=74	8 months to 10 years	MESS MESI PSI LSI	Unclear if amputation decision based on tool score; data did differentiate between primary and secondary amputations; clear description of rationale for any amputations; follow-up adequate for reasonable assumption that all secondary amputations occurred in this period; Quadas rating: serious risk of bias
El Sharawy 2005[27]	Upper and lower limb injuries; mean age 29 (12.5) years n=62	1-32 months	MESS MESI	Unclear if amputation decision based on tool score; data did differentiate between primary and secondary amputations; clear description of rationale for any amputations; follow-up adequate for reasonable assumption that all secondary amputations occurred in this period; Quadas rating: serious risk of bias
Fagelman 2002[29]	Children of mean age 9.5 years; open lower extremity long bone fractures n=36	Minimum 1 year	MESS	Unclear if amputation decision based on tool score; tool threshold unclear; data did not differentiate between primary and secondary amputations; unclear description of rationale for any amputations; authors admitted possibility that some amputations may have been avoidable and also that some reported as being salvaged may have been amputated after study follow-up period; follow-up adequate for reasonable assumption that all secondary amputations occurred in this period; Quadas rating: very serious risk of bias
Helfet 1990[39]	Not reported n=26	Unclear	MESS	Unclear if amputation decision based on tool score; data did not differentiate between primary and secondary amputations; unclear description of

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Study	Population	Follow-up time	Risk tools	Comments (positive aspects of study in bold)
				rationale for any amputations; follow-up unclear so cannot be sure all secondary amputations occurred in this period; Quadas rating: very serious risk of bias
Johansen 1990[48]	Not reported n=26	Unclear	MESS	Unclear if amputation decision based on tool score; data did not differentiate between primary and secondary amputations; unclear description of rationale for any amputations; follow-up unclear so cannot be sure all secondary amputations occurred in this period; Quadas rating: very serious risk of bias
Kjorstad 2007[83]	Any extremity injuries; military; age not reported but adult n=60	Unclear	MESS	Likely that amputation decision not based on tool score; data did not differentiate between primary and secondary amputations; unclear description of rationale for any amputations; follow-up unclear so cannot be sure all secondary amputations occurred in this period; Quadas rating: very serious risk of bias
Krettek 2001[51]	All open long bone fractures of upper and lower limbs; age unclear n=182	4 years	HFS '98 HFS MESS NISSSA	Unclear if amputation decision based on tool score; data did not differentiate between primary and secondary amputations; unclear description of rationale for any amputations; follow-up adequate for reasonable assumption that all secondary amputations occurred in this period; Quadas rating: very serious risk of bias
Kumar 2007[52]	Gustilo type IIIA-C femur and type III pilon fractures. Mean age 34.5 years n=36	6 months	MESS	Unclear if amputation decision based on tool score; data did not differentiate between primary and secondary amputations; primary amputation definition very unclear; clear description of rationale for any amputations; follow-up adequate for reasonable assumption that all secondary amputations occurred in this period; Quadas rating: very serious risk of bias
Madhuchnadra 2015[59]	Gustilo type IIIA and B. Mean age 38 years. n=40	Unclear, but until 'completion of treatment'	Ganga	Amputation decision clearly not based on tool score; data did differentiate between primary and secondary amputations; clear description of rationale for any amputations; follow up unclear; Quadas rating: serious risk of bias
McNamara 1994 [61]	Type IIIB and C open tibial fractures; age 3 to 76 years; only one <18 years n=24	Mean 21.6 months	MESS NISSSA	Amputation decision clearly not based on tool score; data did not differentiate between primary and secondary amputations; unclear description of rationale for any amputations; follow-up adequate for reasonable assumption that all secondary amputations occurred in this period; Quadas rating: very serious risk of bias
Mommsen 2010[65]	Traumatic extremity arterial injuries admitted to a level I trauma	Mean 1.7 years	MESS	Unclear if amputation decision based on tool score; data did not differentiate between primary and secondary amputations; unclear description of rationale for any amputations; follow-up adequate for reasonable assumption that all secondary

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Study	Population	Follow-up time	Risk tools	Comments (positive aspects of study in bold)
	centre; mean age 9 years n=44			amputations occurred in this period; Quadas rating: very serious risk of bias
Rajasekeran 2006[78]	Type IIIA and B injuries referred to tertiary referral centre; mean 35 years n=109	36 – 60 months	MESS Ganga	Amputation decision clearly not based on tool score; data did not differentiate between primary and secondary amputations; clear description of rationale for any amputations; follow-up adequate for reasonable assumption that all secondary amputations occurred in this period; Quadas rating: serious risk of bias
Ramasamy 2013A[79]	Lower leg injury from vehicle explosions; military; mean age 26 years n=89	Mean 33.6 months	FASS AIS	Unclear if amputation decision based on tool score; data did not differentiate between primary and secondary amputations; unclear description of rationale for any amputations; follow-up adequate for reasonable assumption that all secondary amputations occurred in this period; Quadas rating: very serious risk of bias
Robertson 1991[82]	All severe lower extremity injuries; age not reported n=152	At least 6 months	MESS	Unclear if amputation decision based on tool score; data did differentiate between primary and secondary amputations; clear description of rationale for any amputations; follow-up adequate for reasonable assumption that all secondary amputations occurred in this period; Quadas rating: serious risk of bias
Sheean 2014[85]	Gustilo type III open tibia fractures; military; median age 23 (19-34) years n=155	Up to 19.6 months	MESS	Unclear if amputation decision based on tool score; data did not differentiate between primary and secondary amputations; unclear description of rationale for any amputations; follow-up adequate for reasonable assumption that all secondary amputations occurred in this period; Quadas rating: very serious risk of bias
Slauterbeck 1994[86]	Open upper limb fractures; age unclear, but likely to be adults n=43	Unclear	MESS	Clear that amputation decision not based on tool score; data did not differentiate between primary and secondary amputations; unclear description of rationale for any amputations; follow-up adequate for reasonable assumption that all secondary amputations occurred in this period; Quadas rating: very serious risk of bias
Stewart 2012[91]	Gustilo type IIIB and C compound fractures; mean age 8.7 years n=20	At least 1 year	MESS LSI PSI NISSSA HFS-'98	Unclear if amputation decision based on tool score; only primary amputations; unclear description of rationale for any amputations; Follow-up adequate for reasonable assumption that all secondary amputations occurred in this period; Quadas rating: very serious risk of bias

The aim of these studies was to assess how accurately the tools could predict whether a patient truly has a need for an amputation or not. There are four important methodological concepts relevant to the quality of these studies, and these are described below.

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1. Clear description of the rationale for amputation

Assessing the prognostic accuracy of the risk tools involves evaluating the extent to which a tool's prediction of amputation soon after injury concurs with a true later need for amputation. The reference standard should therefore be a true need for amputation. Unfortunately, it is never possible to be completely sure that the amputations ultimately carried out in the studies reflected a true need for amputation; once an amputation has been carried out there is no way to know if the amputation could have been avoided or not. Hence for the reference standard to have some validity, it is vitally important that the studies clearly describe a rigorous rationale for amputation decisions, so that the assumption can be made that those given amputation were truly requiring amputation. This assumption is, of course, imperfect, but is necessary for any prognostic accuracy analyses to be attempted. The alternative is to not evaluate these risk tools.

2. Adequate follow-up

In terms of those not having an amputation, that is, those with salvaged limbs, there is less doubt about the reference standard – if a limb remains salvaged for long enough then it becomes increasingly more likely that salvage was the truly correct decision. However, it is vital that there is sufficient follow-up to be sure that all salvaged limbs are truly successful; a short follow-up may fail to record salvages that ended in amputation.

3. Blinding of surgeons from risk tool scores

Another very important issue to bear in mind is whether the actual decision to amputate was influenced by results from the risk tool being evaluated. This would clearly lead to greater observed accuracy than otherwise; if amputation is made in response to results from a risk tool then that risk tool will inevitably be found to be a highly accurate indicator of amputation. Hence blinding of the risk tool results from the people making decisions about amputation was an important factor determining the quality rating of a study.

4. Primary and secondary amputations

Primary amputation usually refers to amputations made before any attempt at salvage – this is reserved for limbs that are clearly unreconstructable. Secondary amputation refers to amputations made after an attempt at salvage has already begun. Studies that focus on secondary amputations have been prioritised in this review, as these involve the cases where a risk tool would be extremely useful to allow an early decision that may avoid painful and potentially life-threatening attempts at salvage. Furthermore, studies that include primary amputations may tend to exaggerate the accuracy of the tools, as the primary cases are likely to have very high-risk tool scores that accord with their amputation status.

Studies were therefore analysed by whether they analysed by secondary amputations or not. In addition, studies involving children were analysed separately. Finally, all studies analysed data for lower limbs (or, in one study, a mixture of upper and lower limbs). However, two studies also analysing data for upper limbs have been presented separately.

6.2.3.1 Secondary amputations – children (upper limbs)

No evidence was found.

6.2.3.2 Secondary amputations – children (lower limbs)

No evidence was found.

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6.2.3.3 Secondary amputations – adults (upper limbs)

MESS

Table 11: MESS as predictor (threshold 7 or more) of the need for secondary amputation in upper limbs. This was not pooled due to insufficient number of studies (less than 5)

No. of studies	n	Risk of bias	Inconsistency	Indirectness	Imprecision	Sensitivity (95% CI)	Specificity (95% CI)	Quality
1	12	Serious[a]	None	None	Very serious[b]	1 (0.29 to 1)	0.89 (0.52 to 1)	VERY LOW

(a) Risk of bias resulted from blinding of tool score from those making decisions on amputation not clear
(b) Precision of sensitivity and specificity poor

MESI

Table 12: MESI as predictor (threshold 20 or more) of the need for secondary amputation in upper limbs. This was not pooled due to insufficient number of studies (less than 5)

No. of studies	n	Risk of bias	Inconsistency	Indirectness	Imprecision	Sensitivity (95% CI)	Specificity (95% CI)	Quality
1	12	Serious[a]	None	None	Very serious[b]	0.67 (0.09 to 0.99)	1 (0.66 to 1)	VERY LOW

(a) Risk of bias resulted from blinding of tool score from those making decisions on amputation not clear
(b) Precision of sensitivity and specificity poor

6.2.3.4 Secondary amputations – adults (lower limbs)

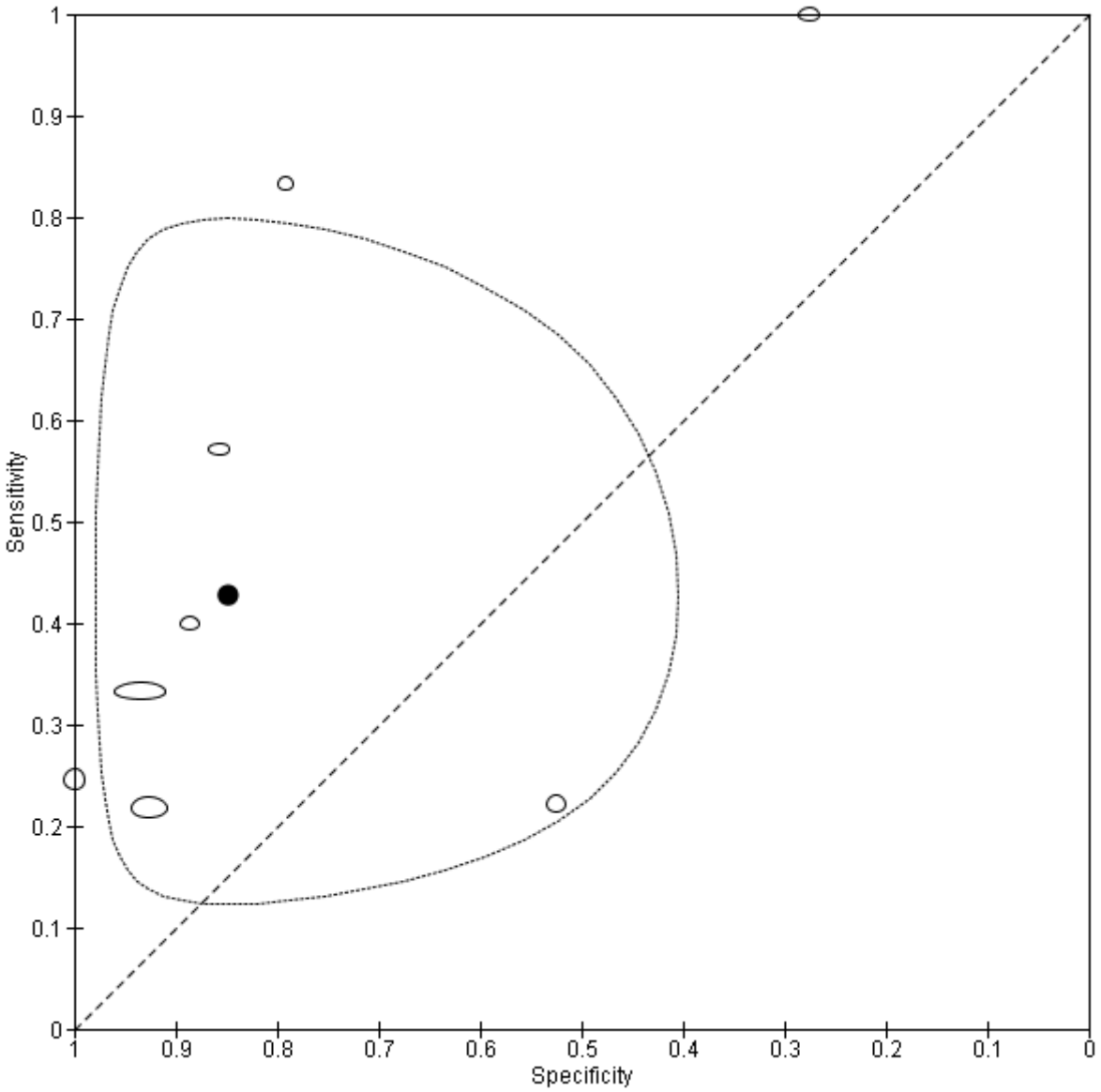
MESS

Table 13: MESS as predictor (threshold 7 or more) of the need for secondary amputation in lower limbs

No. of studies	No. of patients	Risk of bias	Inconsistency	Indirectness	Imprecision	Pooled Sensitivity (95% CI)	Pooled Specificity (95% CI)	Quality
8	1348	Serious[a]	Very serious[b]	None	Very serious[c]	0.43 (0.23 to 0.70)	0.83 (0.61 to 0.95)	VERY LOW

(a) Risk of bias resulted from just one of the following in most studies: blinding of tool score from those making decisions on amputation not clear, or unclear description of rationale for any amputations
(b) More than 0.4 range of differences in point estimates across studies observed in forest plot
(a) Precision of sensitivity and specificity poor

Figure 3: Diagnostic meta-analysis for MESS in detecting the need for secondary amputation in lower limbs.



The solid black circle represents the pooled value of sensitivity and specificity. The dotted curve drawn around this point represents the 95% confidence intervals around this point. The open ovals represent the results of individual studies, and their area is proportional to the study size

Narrative review

One study[6] at very serious risk of bias measured accuracy of the MESS at several different thresholds. An area under curve (AUC) was not calculated but the accuracy data are given below in Table 14.

Table 14: Sensitivity and specificity of the MESS for predicting secondary amputation in adults at different thresholds

Threshold (amputate if >)	Sensitivity	Specificity
2	1	0
4	1	0.133
5.5	0.867	0.333

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Threshold (amputate if >)	Sensitivity	Specificity
6.5	0.733	0.533
7.5	0.533	0.666
8.5	0.267	0.867
9.5	0.133	0.933
11	0	1.0

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MESI

Table 15: MESI as predictor (threshold 20 or more) of the need for secondary amputation in lower limbs. This was not pooled due to insufficient number of studies (less than 5)

No. of studies	n	Risk of bias	Inconsistency	Indirectness	Imprecision	Sensitivity (95% CI)	Specificity (95% CI)	Quality
4	58 40 30 62	Serious[a]	Very serious[b]	None	Very serious[c]	0.06 (0to 0.27) 0 (0-0.52) 0.5(0.12-0.48) 1(0.4-1) Median: 0 (0-0.52)	0.90 (0.76 to 0.97) 0.94(0.81-0.99) 1(0.86-1) 0.34(0.22-0.48) Median: 0.90 (0.76 to 0.97)	VERY LOW

(b) Risk of bias resulted from just one of the following in most studies: blinding of tool score from those making decisions on amputation not clear, or unclear description of rationale for any amputations
(c) More than 0.4 range of differences in point estimates
(d) Precision of sensitivity and specificity generally poor across studies

PSI

Table 16: PSI as predictor (threshold 8 or more) of the need for secondary amputation in lower limbs. This was not pooled due to insufficient number of studies (less than 5)

No. of studies	n	Risk of bias	Inconsistency	Indirectness	Imprecision	Sensitivity (95% CI)	Specificity (95% CI)	Quality
4	58 312 40 30	Serious[a]	Serious[b]	None	Very serious[c]	0.33 (0.13-0.59) 0.36(0.24-0.50) 0.60(0.15-0.95) 0.50(0.12-0.88) Median: 0.36(0.24-0.50)	0.70(0.53-0.83) 0.84(0.79-0.88) 0.94(0.81-0.99) 0.96(0.79-1) Median: 0.84(0.79-0.88)	VERY LOW

(a) Risk of bias resulted from just one of the following in most studies: blinding of tool score from those making decisions on amputation not clear, or unclear description of rationale for any amputations
(b) 0.2-0.4 range of differences in point estimates
(c) Precision of sensitivity and specificity generally poor across studies

LSI

Table 17: LSI as predictor (threshold 6 or more) of the need for secondary amputation in lower limbs. This was not pooled due to insufficient number of studies (less than 5)

No. of studies	n	Risk of bias	Inconsistency	Indirectness	Imprecision	Sensitivity (95% CI)	Specificity (95% CI)	Quality
4	58 312 40 30	Serious[a]	Very serious[b]	None	Very serious[c]	0.61 (0.36-0.83) 0.29(0.18-0.43) 0.60(0.15-0.95) 0.83(0.36-1) Median: 0.60(0.15-0.95)	0.42(0.27-0.59) 0.97(0.94-0.99) 0.83(0.66-0.93) 0.83(0.63-0.95) Median: 0.83(0.63-0.95)	VERY LOW

(a) Risk of bias resulted from just one of the following in most studies: blinding of tool score from those making decisions on amputation not clear, or unclear description of rationale for any amputations
(b) More than 0.4 range of differences in point estimates
(c) Precision of sensitivity and specificity generally poor across studies

NISSSA

Table 18: NISSSA as predictor (threshold 11 or more) of the need for secondary amputation in lower limbs. This was not pooled due to insufficient number of studies (less than 5)

No. of studies	n	Risk of bias	Inconsistency	Indirectness	Imprecision	Sensitivity (95% CI)	Specificity (95% CI)	Quality
1	312	Serious[a]	None	None	None	0.13(0.05-0.24)	0.98(0.96-1)	MODERATE

(a) Risk of bias resulted from unclear description of rationale for any amputations

HFS '97

Table 19: HFS '97 (threshold 9 or more) as predictor of the need for secondary amputation in lower limbs. This was not pooled due to insufficient number of studies (less than 5)

No. of studies	n	Risk of bias	Inconsistency	Indirectness	Imprecision	Sensitivity (95% CI)	Specificity (95% CI)	Quality
1	312	Serious[a]	None	None	None	0.11(0.04-0.22)	0.98(0.96-0.99)	MODERATE

(a) Risk of bias resulted from unclear description of rationale for any amputations

Ganga score

Table 20: Ganga score (threshold 14 or more) as predictor of the need for secondary amputation in lower limbs. This was not pooled due to insufficient number of studies (less than 5)

No. of studies	n	Risk of bias	Inconsistency	Indirectness	Imprecision	Sensitivity (95% CI)	Specificity (95% CI)	Quality
1	40	Serious[a]	None	None	None	1.0(0.3-1.0)	1.0(0.91-1.0)	MODERATE

(a) Risk of bias resulted from unclear follow up

6.2.3.5 Mixed primary/secondary amputations – children (upper limbs)

MESS

Table 21: MESS as predictor (threshold 7 or more) of the need for secondary amputation in upper limbs. This was not pooled due to insufficient number of studies (less than 5)

No. of studies	n	Risk of bias	Inconsistency	Indirectness	Imprecision	Sensitivity (95% CI)	Specificity (95% CI)	Quality
1	17	Very serious[a]	None	None	None	Not estimable	1(0.8-1)	LOW

(a) Risk of bias resulted from blinding of tool score from those making decisions on amputation not clear, or unclear description of rationale for any amputations

6.2.3.6 Mixed primary/secondary amputations – children (lower limbs)

MESS

Table 22: MESS as predictor (threshold 7 or more) of the need for primary/secondary amputation in children. This was not pooled due to insufficient number of studies (less than 5)

No. of studies	n	Risk of bias	Inconsistency	Indirectness	Imprecision	Sensitivity (95% CI)	Specificity (95% CI)	Quality
3	87	Very serious[a]	Very serious[b]	None	Very seriousc	0.5(0.19-0.81) 1(0.63-1) 0.67(0.09-0.99)	1(0.87-1) 0.79(0.54-0.94) 0.86(0.64-0.97)	VERY LOW

No. of studies	n	Risk of bias	Inconsistency	Indirectness	Imprecision	Sensitivity (95% CI)	Specificity (95% CI)	Quality
						Median: 0.67(0.09-0.99)	Median: 0.86(0.64-0.97)	

(a) Risk of bias resulted from at least two of the following in all studies: blinding of tool score from those making decisions on amputation not clear, insufficient follow-up, or unclear description of rationale for any amputations
(b) More than 0.4 range of differences in sensitivity point estimates across studies observed in forest plot
***(c)** Precision of sensitivity very poor*

LSI

Table 23: LSI as predictor (threshold 6 or more) of the need for primary/secondary amputation in children. This was not pooled due to insufficient number of studies (less than 5)

No. of studies	n	Risk of bias	Inconsistency	Indirectness	Imprecision	Sensitivity (95% CI)	Specificity (95% CI)	Quality
1	24	Very serious[a]	None	None	Very serious[b]	0.66(0.12-0.95)	0.81(0.58-0.94)	VERY LOW

(a) Risk of bias resulted from blinding of tool score from those making decisions on amputation not clear, insufficient follow-up, or unclear description of rationale for any amputations
(b) Precision of sensitivity very poor

PSI

Table 24: PSI as predictor (threshold 8 or more) of the need for primary/secondary amputation in children. This was not pooled due to insufficient number of studies (less than 5)

No. of studies	n	Risk of bias	Inconsistency	Indirectness	Imprecision	Sensitivity (95% CI)	Specificity (95% CI)	Quality
1	24	Very serious[a]	None	None	Very serious[b]	1(0.3-1)	0.90(0.7-0.99)	VERY LOW

(a) Risk of bias resulted from blinding of tool score from those making decisions on amputation not clear, insufficient follow-up, or unclear description of rationale for any amputations
(b) Precision of sensitivity very poor

NISSSA

Table 25: NISSSA as predictor (threshold 11 or more) of the need for primary/secondary amputation in children. This was not pooled due to insufficient number of studies (less than 5)

No. of studies	n	Risk of bias	Inconsistency	Indirectness	Imprecision	Sensitivity (95% CI)	Specificity (95% CI)	Quality
1	24	Very serious[a]	None	None	Very serious[b]	0.66(0.12-0.95)	0.81(0.58-0.94)	VERY LOW

(a) Risk of bias resulted from blinding of tool score from those making decisions on amputation not clear, insufficient follow-up, or unclear description of rationale for any amputations
(b) Precision of sensitivity very poor

HFS-98

Table 26: HFS 98 (threshold 11 or more) as predictor of the need for primary/secondary amputation in children. This was not pooled due to insufficient number of studies (less than 5)

No. of studies	n	Risk of bias	Inconsistency	Indirectness	Imprecision	Sensitivity (95% CI)	Specificity (95% CI)	Quality
1	24	Very serious[a]	None	None	Very serious[b]	1(0.3-1)	0.76(0.53-0.92)	VERY LOW

(a) Risk of bias resulted from blinding of tool score from those making decisions on amputation not clear, insufficient follow-up, or unclear description of rationale for any amputations
(b) Precision of sensitivity very poor

6.2.3.7 Mixed primary/secondary amputations – adults upper limb

No evidence found

6.2.3.8 Mixed primary/secondary amputations – adults lower limb

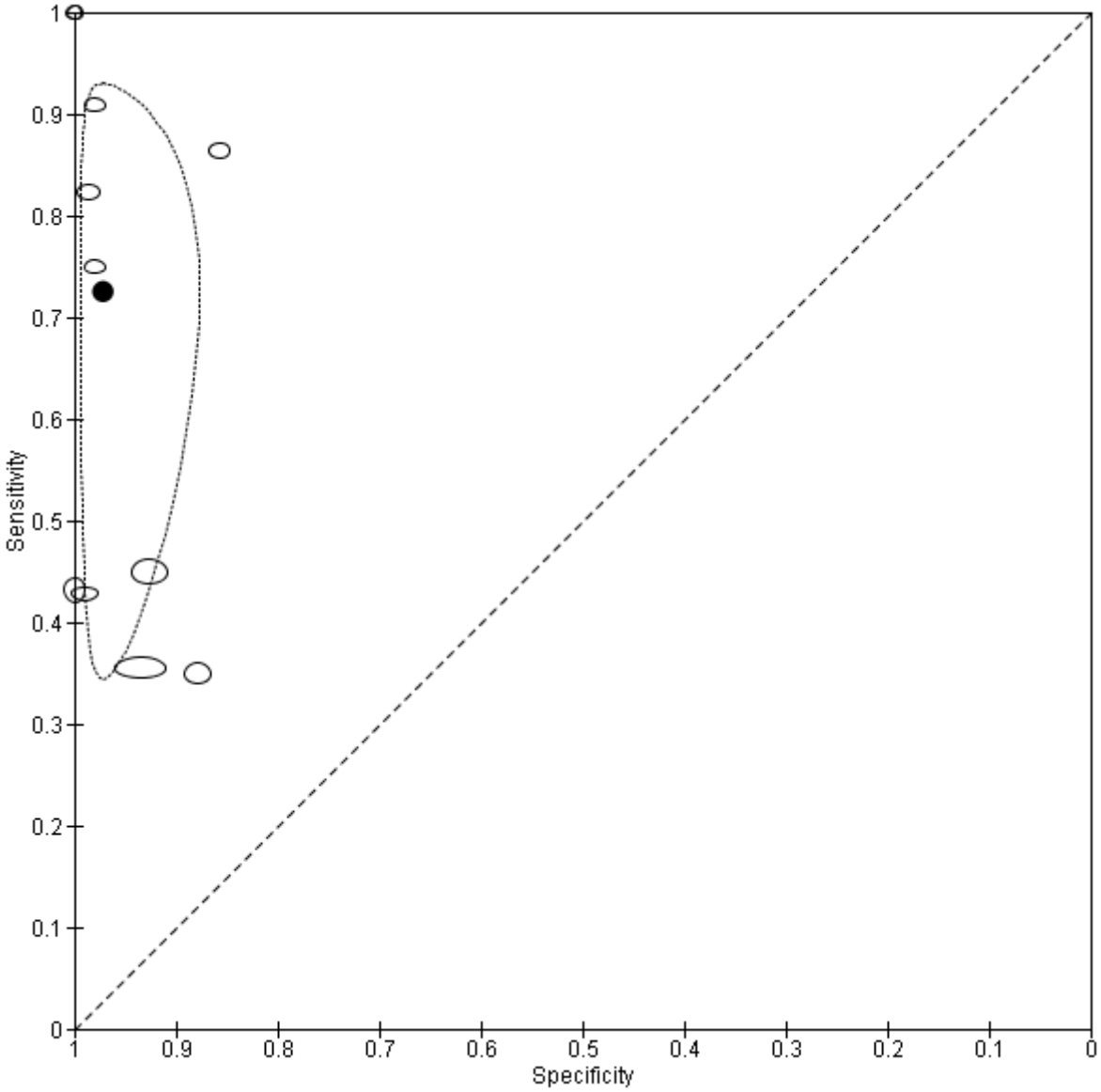
MESS

Table 27: MESS as predictor (threshold 7 or more) of the need for primary/secondary amputation in lower limbs

No. of studies	n	Risk of bias	Inconsistency	Indirectness	Imprecision	Pooled Sensitivity (95% CI)	Pooled Specificity (95% CI)	Quality
11	1805	Very serious[a]	Very serious[b]	None	Very serious[c]	0.71 (0.49 to 0.90)	0.97 (0.93 to 0.99)	VERY LOW

(a) Risk of bias resulted from at least two of the following in most studies: blinding of tool score from those making decisions on amputation not clear, insufficient follow-up, or unclear description of rationale for any amputations
(b) More than 0.4 range of differences in sensitivity point estimates across studies observed in forest plot
(c) Precision of sensitivity poor

Figure 4: Diagnostic meta-analysis for MESS in detecting the need for secondary and primary amputation in lower limbs.



The solid black circle represents the pooled value of sensitivity and specificity. The dotted curve drawn around this point represents the 95% confidence intervals around this point. The open ovals represent the results of individual studies, and their area is proportional to the study size

Narrative review

One study (McNamara) [61]at very serious risk of bias measured accuracy of the MESS at several different thresholds. An AUC was not calculated but the accuracy data are given below in Table 28.

Table 28: Sensitivity and specificity of the MESS for predicting primary or secondary amputation in adults at different thresholds

Threshold (amputate if >)	Sensitivity	Specificity
4	1.0	0.46
5	0.82	0.69
6	0.55	0.92

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Threshold (amputate if >)	Sensitivity	Specificity
7	0.55	1.0
8	0	-

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Ganga scale

Table 29: Ganga scale (threshold 14 or more) as predictor of the need for primary or secondary amputation in lower limbs. This was not pooled due to insufficient number of studies (less than 5)

No. of studies	n	Risk of bias	Inconsistency	Indirectness	Imprecision	Sensitivity (95% CI)	Specificity (95% CI)	Quality
1	109	Serious[a]	None	None	Serious[b]	1(0.59-1)	0.97(0.92-0.99)	LOW

(a) Risk of bias resulted from unclear description of rationale for any amputations
(b) Precision of sensitivity poor

PSI

Table 30: PSI as predictor (threshold 8 or more) of the need for primary or secondary amputation in lower limbs. This was not pooled due to insufficient number of studies (less than 5)

No. of studies	n	Risk of bias	Inconsistency	Indirectness	Imprecision	Sensitivity (95% CI)	Specificity (95% CI)	Quality
1	357	Serious[a]	None	None	Serious[b]	0.47(0.37-0.57)	0.84(0.79-0.88)	LOW

(a) Risk of bias resulted from unclear description of rationale for any amputations
(b) Precision of sensitivity poor

NISSSA

Table 31: NISSSA as predictor (threshold 11 or more) of the need for primary or secondary amputation in lower limbs. This was not pooled due to insufficient number of studies (less than 5)

No. of studies	n	Risk of bias	Inconsistency	Indirectness	Imprecision	Sensitivity (95% CI)	Specificity (95% CI)	Quality
2	446	Very serious[a]	Serious[b]	None	Serious[c]	0.33 (0.24-0.43) 0.71(0.44-0.90) Median: 0.33 (0.24-0.43)	0.98(0.96-1) 0.99(0.92-1) Median: 0.98(0.96-1)	VERY LOW

(a) Risk of bias resulted from unclear description of rationale for any amputations and unclear if amputation decision based on tool score
(b) 0.2-0.4 variation in sensitivity point estimates across studies
Precision of sensitivity poor for one study

Narrative review

One study [61] at very serious risk of bias measured accuracy of the NISSSA at several different thresholds. An AUC was not calculated but the accuracy data are given below in Table 32.

Table 32: Sensitivity and specificity of the NISSSA for predicting primary or secondary amputation in adults at different thresholds

Threshold (amputate if >)	Sensitivity	Specificity
4		0
5		0.08
6		0.46
7	1.0	0.46
8	0.91	0.69
9	0.81	0.92
10	0.54	0.92
11	0.36	1.0
12	0.27	

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LSI

Table 33: LSI as predictor (threshold 6 or more) of the need for primary or secondary amputation in lower limbs. This was not pooled due to insufficient number of studies (<5)

No. of studies	n	Risk of bias	Inconsistency	Indirectness	Imprecision	Sensitivity (95% CI)	Specificity (95% CI)	Quality
1	357	Serious[a]	None	None	Serious[b]	0.51(0.41-0.61)	0.97(0.94-0.99)	LOW

(a) Risk of bias resulted from unclear description of rationale for any amputations
(b) Precision of sensitivity poor

HFS '98

Table 34: HFS 98 as predictor (threshold 11 or more) of the need for primary or secondary amputation in lower limbs. This was not pooled due to insufficient number of studies (less than 5)

No. of studies	n	Risk of bias	Inconsistency	Indirectness	Imprecision	Sensitivity (95% CI)	Specificity (95% CI)	Quality
1	87	Very serious[a]	None	None	Serious[b]	0.82(0.57-0.96)	0.99(0.92-1)	VERY LOW

(a) Risk of bias resulted from unclear description of rationale for any amputations and unclear if amputation decision based on tool score
(b) Precision of sensitivity poor

HFS/HFS '97

Table 35: HFS/HFS 97 as predictor (threshold 9 or more) of the need for primary or secondary amputation in lower limbs. This was not pooled due to insufficient number of studies (less than 5)

No. of studies	n	Risk of bias	Inconsistency	Indirectness	Imprecision	Sensitivity (95% CI)	Specificity (95% CI)	Quality
2	446	Very serious[a]	Serious[b]	None	Serious[c]	0.37(0.28-0.47) 0.88(0.64-0.99) Median: 0.37(0.28-0.47)	0.98(0.96-0.99) 0.96(0.88-0.99) Median: 0.98(0.96-0.99)	VERY LOW

(a) Risk of bias resulted from unclear description of rationale for any amputations and unclear if amputation decision based on tool score
(b) 0.2-0.4 variation in sensitivity point estimates across studies
(c) Precision of sensitivity poor

FASS

Table 36: FASS as predictor of the need for primary or secondary amputation in lower limbs. This was not pooled due to insufficient number of studies (less than 5)

No. of studies	n	Risk of bias	Inconsistency	Indirectness	Imprecision	Area under curve	Quality
1	89	Very serious[a]	None	None	Serious[b]	0.891 (0.807-0.947)	VERY LOW

(a) Risk of bias resulted from unclear description of rationale for any amputations and unclear if amputation decision based on tool score
(b) Precision of sensitivity not optimal

AIS

Table 37: AIS as predictor of the need for primary or secondary amputation in lower limbs. This was not pooled due to insufficient number of studies (less than 5)

No. of studies	n	Risk of bias	Inconsistency	Indirectness	Imprecision	Area under curve	Quality
1	89	Very serious[a]	None	None	Serious[b]	0.783 (0.683-0.863)	VERY LOW

(a) Risk of bias resulted from unclear description of rationale for any amputations and unclear if amputation decision based on tool score
(b) Precision of sensitivity not optimal

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 38: UK costs of an amputation procedure

Procedure	HRG code	Cost
Amputation of Single Limb with CC Score 0-9	YQ22B	£8,589

Source: NHS Reference Costs 2013-2014 [21]

6.2.5 Evidence statements

Clinical

Secondary amputation

Children- upper limb

No evidence was found

Children- lower limb

No evidence was found

Adults – upper limb

Very low quality evidence from one study with 12 adults showed that MESS at a threshold of 7 or more has a sensitivity of 1 (95% CI, 0.29 to 1) and a corresponding specificity of 0.89 (95% CI, 0.52 to 1) for predicting secondary amputation in people with upper limb injuries.

Very low quality evidence from one study with 12 adults showed that MESI at a threshold of 20 or more has a sensitivity of 0.67 (95% CI, 0.09 to 0.99) and a corresponding specificity of 1 (95% CI, 0.66 to 1) for predicting secondary amputation in people with upper limb injuries.

Adults – lower limb

When diagnostic meta-analysis was conducted Very low quality evidence from 8 studies with 1348 adults showed that MESS at a threshold of 7 or more has a pooled sensitivity of 0.43 (95% CI, 0.23 to 0.70) and a corresponding specificity of 0.83(95% CI, 0.61 to 0.95) for predicting secondary amputation in people with lower limb injuries.

Very low quality evidence from 4 studies with 190 adults showed that MESI at a threshold of 20 or more has a median sensitivity of 0 (95% CI 0 to 0.52) and a corresponding median specificity of 0.90 (95% CI, 0.76 to 0.97) for predicting secondary amputation in people with lower limb injuries.

Very low quality evidence from 4 studies with 440 adults showed that PSI at a threshold of 8 or more has a median sensitivity of 0.36 (95% CI, 0.24 to 0.50) and a corresponding median specificity of 0.84 (95% CI, 0.79 to 0.88) for predicting secondary amputation in people with lower limb injuries.

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Very low quality evidence from 4 studies with 440 adults showed that LSI at a threshold of 6 or more has a median sensitivity of 0.60 (95% CI, 0.15 to 0.95) and a corresponding median specificity of 0.83 (95% CI, 0.63 to-0.95) for predicting secondary amputation in people with lower limb injuries.

Moderate quality evidence from one study with 312 adults showed that NISSSA at a threshold of 11 or more has a sensitivity of 0.13 (95% CI, 0.05 to 0.24) and a corresponding specificity of 0.98 (95% CI, 0.96 to 1) for predicting secondary amputation in people with lower limb injuries.

Moderate quality evidence from one study with 312 adults showed that HFS '97 at a threshold of 9 or more has a sensitivity of 0.11 (95% CI, 0.04 to 0.22) and a corresponding specificity of 0.98 (95% CI, 0.96 to 0.99) for predicting secondary amputation in people with lower limb injuries.

Moderate quality evidence from one study with 40 adults showed that Ganga score at a threshold of 14 or more has a sensitivity of 1.0 (95% CI, 0.3 to 1.0) and a corresponding specificity of 1.0 (95% CI, 0.91 to 1.0) for predicting secondary amputation in people with lower limb injuries.

Mixed primary and secondary amputation

Children- upper limb

Low quality evidence from one study with 17 children showed that MESS at a threshold of 7 or more has an inestimable sensitivity and a corresponding specificity of 1 (95% CI, 0.8 to 1) for predicting primary or secondary amputation in children with upper limb injuries.

Children- lower limb

Very low quality evidence from 3 studies with 87 children showed that MESS at a threshold of 7 or more has a median sensitivity of 0.67 (95% CI, 0.09 to0.99) and a corresponding median specificity of 0.86 (95% CI, 0.64 to 0.97) for predicting primary or secondary amputation in children with lower limb injuries.

Very low quality evidence from one study with 24 children showed that LSI at a threshold of 6 or more has a sensitivity of 0.66 (95% CI, 0.12 to 0.95) and a corresponding specificity of 0.81 (95% CI, 0.58 to 0.94) for predicting primary or secondary amputation in children with lower limb injuries.

Very low quality evidence from one study with 24 children showed that PSI at a threshold of 8 or more has a sensitivity of 1 (95% CI, 0.3 to 1) and a corresponding specificity of 0.90 (95% CI, 0.7 to 0.99) for predicting primary or secondary amputation in children with lower limb injuries.

Very low quality evidence from one study with 24 children showed that NISSSA at a threshold of 11 or more has a sensitivity of 0.66 (95% CI, 0.12 to 0.95) and a corresponding specificity of 0.81 (95% CI, 0.58 to 0.94) for predicting primary or secondary amputation in children with lower limb injuries.

Very low quality evidence from one study with 24 children showed that HFS-98 at a threshold of 11 or more has a sensitivity of 1 (95% CI, 0.3 to 1) and a corresponding specificity of 0.76 (95% CI, 0.53 to 0.92) for predicting primary or secondary amputation in children with lower limb injuries.

Adults – upper limb

No evidence found

Adults – lower limb

When diagnostic meta-analysis was conducted Very low quality evidence from 11 studies with 1805 adults showed that MESS at a threshold of 7 or more has a pooled sensitivity of 0.71 (95% CI,

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0.49 to 0.90) and a corresponding specificity of 0.97 (95% CI, 0.93 to 0.99) for predicting primary/secondary amputation in people with lower limb injuries.

Low quality evidence from one study with 109 adults showed that the Ganga scale at a threshold of 14 or more has a sensitivity of 1 (95% CI, 0.59 to 1) and a corresponding specificity of 0.97 (95% CI, 0.92 to 0.99) for predicting primary or secondary amputation in adults with lower limb injuries.

Low quality evidence from one study with 357 adults showed that PSI at a threshold of 8 or more has a sensitivity of 0.47 (95% CI, 0.37 to 0.57) and a corresponding specificity of 0.84 (95% CI, 0.79 to 0.88) for predicting primary or secondary amputation in adults with lower limb injuries.

Very low quality evidence from 2 studies with 446 adults showed that NISSSA at a threshold of 11 or more has a median sensitivity of 0.33 (95% CI, 0.24 to 0.43) and a corresponding median specificity of 0.98 (95% CI, 0.96 to 1) for predicting primary or secondary amputation in adults with lower limb injuries.

Low quality evidence from one study with 357 adults showed that LSI at a threshold of 6 or more has a sensitivity of 0.51 (95% CI, 0.41 to 0.61) and a corresponding specificity of 0.97 (95% CI, 0.94 to 0.99) for predicting primary or secondary amputation in adults with lower limb injuries.

Very low quality evidence from one study with 87 adults showed that HFS '98 at a threshold of 11 or more has a sensitivity of 0.82 (95% CI, 0.57 to 0.96) and a corresponding specificity of 0.99 (95% CI, 0.92 to 1) for predicting primary or secondary amputation in adults with lower limb injuries.

Very low quality evidence from 2 studies with 446 adults showed that HFS/HFS '97 at a threshold of 9 or more has a median sensitivity of 0.37 (95% CI, 0.28 to 0.47) and a corresponding median specificity of 0.98 (95% CI, 0.96 to 0.99) for predicting primary or secondary amputation in adults with lower limb injuries.

Very low quality evidence from one study with 89 adults showed that FASS at a number of thresholds has an AUC of 0.891 (95% CI, 0.807 to 0.947) for predicting primary or secondary amputation in adults with lower limb injuries.

Very low quality evidence from one study with 89 adults showed that AIS at a number of thresholds has an AUC of 0.783 (95% CI, 0.683 to 0.863) for predicting primary or secondary amputation in adults with lower limb injuries.

Economic

No relevant economic evaluations were identified.

6.2.6 Recommendations and link to evidence

Recommendations	**2. Do not base the decision whether to perform limb salvage or amputation on an injury severity tool score.** **3. Perform emergency amputation when:** • **a limb is the source of uncontrollable life-threatening bleeding, or** • **a limb is salvageable but attempted preservation would pose an unacceptable risk to the person's life, or** • **a limb is deemed unsalvageable after orthoplastic assessment.**

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	Include the person and their family members or carers (as appropriate) in a full discussion of the options if this is possible. **4. Base the decision whether to perform limb salvage or delayed primary amputation on multidisciplinary assessment involving an orthopaedic surgeon, a plastic surgeon, a rehabilitation specialist and the person and their family members or carers (as appropriate).** **5. When indicated, perform the delayed primary amputation within 72 hours of injury.**
Relative values of different outcomes	The prognostic risk tool is designed to detect the need for amputation. In this context, a high sensitivity means that a high proportion of those truly needing amputation will be identified as such. This implies only a few people who really need amputation will be offered salvage because the test erroneously suggests they don't need amputation. The dangers of a low sensitivity are that people needing amputation are put through a painful and potentially lethal salvage process that ultimately fails. A high specificity means that a high proportion of those who do **not** need amputation will be identified as such. This implies only a few people who do not need amputation will have their limb needlessly amputated because the tool erroneously indicates it should be amputated. The dangers of a low specificity are that people not needing amputation will lose a limb that could have been salvaged. Some authors have stated that a high specificity is probably more important than a high sensitivity. This is on the basis that needlessly losing a limb is a catastrophic outcome. However, the dangers of delaying an amputation that really needs to be done may be greater in terms of morbidity and mortality. The adage of 'life before limb' may be of relevance here. Hence sensitivity may be at least as important, if not more important, than specificity. Consequently, for the purposes of decision making, sensitivity and specificity are regarded as of roughly equal importance, with perhaps some priority given to sensitivity.
Trade-off between clinical benefits and harms	Few tools were reliably found to have an adequate sensitivity or specificity. Although some promising results were found in some of the earlier studies, these were assisted by the inclusion of detecting primary amputations. In terms of the ability to predict the need for secondary amputations, a meta-analysis of 8 studies showed that the MESS had poor sensitivity (0.43) and only moderate specificity (0.83). This means that 57% of those requiring an amputation would endure needless attempts at salvage, or that 17% of those not requiring an amputation would nevertheless have their limb amputated. Neither of these statistics is probably acceptable. Results for the MESI, PSI, LSI, NISSSA and HFS '97 were qualitatively similar and therefore, also showed they were not adequate for their purpose. In contrast, the Ganga score was found by two studies to have relatively good accuracy.
Economic considerations	No economic evidence was identified for this question. The accuracy of a tool that predicts whether a patient with an open fracture should have an amputation or not affects both treatment costs and the health-related quality of life of patients. Therefore, the cost effectiveness of a prognostic tool is dependent upon the sensitivity and specificity, indicating whether people can be correctly identified as needing or not needing amputation. All else being equal, a diagnostic intervention with a higher sensitivity and specificity than alternatives will be cost effective. See more on this in appendix O.

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	The sensitivity of the tool affects the proportion of people who require amputation that are actually amputated and also, therefore, the proportion that are incorrectly reconstructed. A lower sensitivity increases the number of people expected to have an unsuccessful reconstruction followed by a secondary amputation later. This adds costs for unnecessary reconstruction surgery as well as causing the patient to have a reduced quality of life. The quality of life detriment will be dependent on the timing of the secondary amputation. In some circumstances patients could have a reconstruction performed and have physiotherapy management to improve the function of the limb, for weeks, months or even years, only to have the limb amputated afterwards anyway due to poor outcomes. The time until the secondary amputation will affect the duration of the reduced quality of life as well the value of the increased cost of physiotherapy. The specificity of the tool affects the proportion of people who do not require amputation that are correctly reconstructed and also, therefore, the proportion that are incorrectly amputated. A lower specificity increases the number of people expected to have an amputation where reconstruction would have been successful and beneficial. These patients might not have a reduced quality of life compared with having reconstruction but will incur lifelong recurring costs of replacement limb prosthetics that could have been avoided. The GDG believed that the sensitivity and specificity of the injury severity tool scores were not accurate enough to predict amputation and decided not to recommend them. Instead they agreed on the scenarios where amputation should be performed and also that the decision should be made after a combined orthoplastic assessment.
Quality of evidence	Quality of evidence was generally very low. Most studies failed to clarify if the surgeons were blinded to the risk tool scores when making a decision. In addition, many studies failed to give a clear account of how amputation decisions would be made clinically, thus reducing confidence that those people with an amputation truly required an amputation; this, of course, reduced the validity of the reference standard. Some studies also did not describe the follow-up period adequately, thus prohibiting confidence that those with salvage at the end of follow-up would be likely to continue to have that status. For the two studies reporting good accuracy for the Ganga score, one of these was in a mixed secondary/primary amputation sample, which would thus tend to artificially inflate the accuracy relevant to people where a primary amputation was not indicated. The other study, albeit focussed on secondary amputations, was very small-scale. This meant that imprecision of the diagnostic accuracy data were high. The GDG felt these limitations meant the Ganga was not appropriate for recommendation either.
Other considerations	The GDG felt that given their low specificity and sensitivity, the existing risk tools were not adequate for purpose and so should not be used to decide on the need for amputation. Tools in current use not being adequate for their purpose may be partly due to the methods of development of these tools, none of which were based on a high quality developmental study. It is possible that development of a new tool, based on a large scale cohort study with a multivariable logistic regression, may uncover important variables that need to be added to a tool to make it more accurate. However, an adequately accurate tool may never be realised, as the need for amputation is based on a highly complex array of factors, some of which may not be measurable or even ascertainable on admission. The GDG felt that in the absence of suitable risk tools, decisions on secondary amputations should be made collectively by consultant orthopaedic and plastic

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	surgeons, rehabilitation professionals and the patient as a minimum. The GDG also noted that vascular surgeon input will be required in some cases but that this is not always necessary. The amputation should be made within 72 hours of injury as after this period the risk of deep infection increases. The GDG felt that primary amputations should be considered if salvage was impossible or risky for the patient, or as a means to stop catastrophic life-threatening bleeding. In children, specific considerations should be made regarding level of amputation which differ to that in adults. Due to effects of growth, amputation through joints is preferable where this does not compromise the primary aim of the surgery.

6.3 Antibiotics

6.3.1 Introduction

Prevention of deep infection after an open fracture is essential to avoid tragic sequelae, such as amputation or even death. Prophylactic antibiotics are routinely given, but often this is delayed until the patient has arrived at the emergency department (ED). It is believed that giving antibiotics at the earliest possible stage, either at the scene of the accident or on the way to hospital, may be optimal in terms of reducing infection risk, although, there may be other dangers from pre-hospital administration of antibiotics by non-medical staff.

6.3.2 Review question: What is the optimum time to administer prophylactic antibiotics for suspected open fractures?

For full details see review protocol in Appendix C.

Table 39: PICO characteristics of review question

Population	Children, young people and adults with a suspected open fracture, following a traumatic incident
Intervention(s)	Prophylactic antibiotics delivered within the first 1 hour post injury (that is, pre-hospital)
Comparison(s)	The above compared with any other time-points occurring after the intervention (as reported by studies). If drop down to cohorts, may also use time points as a continuous variable.
Outcomes	Critical: • Mortality • Function • Health-related quality of life • Deep infection • Allergy/anaphylaxis • Reoperation (unplanned)/amputation • Wound healing by 6 weeks Important: • Return to normal activities • Superficial infection
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.

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6.3.3 Clinical evidence

No RCTs were found to meet the inclusion criteria. Three prospective [28,44,45,97,98] and one retrospective [55] cohort studies have been included in the review which looked at the timing of prophylactic antibiotics as a continuous variable. There were no cohort studies that presented the prophylactic antibiotic timings as per the protocol; within the first hour post injury (that is, pre-hospital) compared with other time intervals.

The main reasons why other studies were excluded were due to inadequate adjustment of confounders (age and grade of the injury), or the papers did not analyse by the time antibiotics were given.

Evidence from the included study is summarised in the clinical evidence narrative summary below in Table 40. A narrative summary was used due to poor outcome reporting. See also the study selection flow chart in Appendix D, study evidence tables in Appendix G, and excluded studies list in Appendix J.

Table 40: Summary of included studies

Study and type	Fracture location and grade and patient characteristics	Intervention and comparison	Comments
Enninghorst 2011[28] Prospective cohort study	89 adult patients that met their inclusion criteria of a blunt trauma open tibial shaft fracture. The tibial fractures consisted of different Gustilo grades; grade 1 (n=21), grade 2 (n=27), grade 3a (n=18), grade 3b (n=21) and grade 3c (n=1). The mechanisms of injury were primarily road and traffic injuries (n=55, motor vehicle and motor bike crashes and pedestrians struck by vehicles). 33 (37%) of the patients had multiple injuries. The initial fixation of the fractures were carried out by different methods; intramedullary nailing (n=70), external fixation (n=12), closed reduction and application of plaster (n=3) and percutaneous plating (n=4).	No specific protocol was enforced, but all patients had an initial washout in the ED and antibiotic cover and tetanus prophylaxis. The type of antibiotics given for the different grade of fractures, dose, duration and time intervals was not described. However, the time to prophylactic antibiotics administration was listed as a confounder included in the multivariate analysis (but no data was given, not even at baseline in the univariate analysis).	The definition of infection was 'if the infection required surgical debridement and long term IV antibiotics based on infectious disease and service consultation'. The multivariate analysis is described to have included 18 variables, but it is not clear exactly what was inputted. Interpretation of the paper suggests the following may have been included as factors that may predict deep infection: sex, age, smoking status, ISS, NISS, trauma team activation, high energy mechanism, contamination, time from injury to operating room, time from admission to operating room, grade of fracture, initial stabilisation (none or internal fixation), in-hours (8 am-8 pm), attending surgeon in the operating room, ICU admission, number of procedures, antibiotic

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Study and type	Fracture location and grade and patient characteristics	Intervention and comparison	Comments
			timing and type of fracture.
Weber 2014[97,98] Prospective cohort	686 patients of median age of 39.6 years had open fractures (29% Gustilo grade 1, 37% Gustilo grade 2, 21% Gustilo grade 3a, 12% Gustilo grade 3b and 1% Gustilo grade 3c). Overall, 49% had experienced an MVA, 31% had sustained falls, 18% had received crush injuries, and 2% were the victims of assaults.	Established principles of open fracture management were used, including initial surgical debridement and fracture fixation with copious irrigation (3 litres or more) and debridement of soft tissues and contaminated bone. Surgical fixation was at the surgeon's discretion. This was repeated at intervals of 48 hours until tissues were clean, all non-viable tissue had been removed and delayed wound closure could occur. Timing of debridement or timing of prophylactic antibiotics was at the discretion of the surgeon, and the effects of timing of antibiotics was evaluated using a multivariable regression	Multivariate analysis (MVA) adjusted for timing of surgery, transfusion, fracture location, and Gustilo grade. Age and gender were not included in the model.
Hull, 2014[44,45] Prospective cohort	364 patients of mean age of 40 years had open fractures (12% Gustilo grade 1, 31.6% Gustilo grade 2, 34.9% Gustilo grade 3a, 15.9% Gustilo grade 3b and 5.7% Gustilo grade 3c). 6.3% were gunshot injuries. 23.5% were upper limb injuries and 76.5% were lower limb injuries.	Intravenous antibiotics administered on presentation and continued until the wound is covered definitively, or for at least 24 hours post-operatively in patients with a Gustilo-Anderson G1 fracture. Patients not allergic to penicillin received cefuroxime, and patients with a higher grade fracture received gentamycin and metronidazole/penicillin. Patients allergic to penicillin were given clindamycin or vancomycin rather than cefuroxime. Debridement was undertaken urgently based on the availability of an operating theater. Delays of >6 hours were often encountered due to the lack of availability and/or the physiological instability of the patient. The timing of wound closure and the method of fixation were left to the discretion of the surgeon.	Adjustment was for gross contamination, existence of tibial fracture, time to debridement and grade of fracture (low versus high). Age, gender, mechanism of penetration, ASA class, and ISS score had a non-significant association with the outcome.
Lack, 2015[55] Retrospective cohort	137 patients with Gustilo type II a, b and c open tibial fractures; type b and c in 47% of those not infected and 50% of those infected; mean age	Definitive fracture fixation and wound management followed basic standard principles. Diaphyseal fractures were treated with intramedullary	Adjustment for age, Gustilo-Anderson classification, smoking, presence of diabetes,

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Study and type	Fracture location and grade and patient characteristics	Intervention and comparison	Comments
	(non-infected/infected) 40/40.5 years; mean ISS 10/9.5	fixation. Those with intra-articular extension or at the very distal or proximal metaphysis were usually treated with plate and screw fixation. Those with intra-articular extension or at the very distal or proximal metaphysis were usually treated with plate and screw fixation. The standard regimen for antibiotic prophylaxis was cefazolin (128/137). Other antibiotics used were clindamycin or vancomycin. Temporizing external fixation was used when necessary and definitive fixation was performed as soon as the patient and wound were amenable. Wounds were closed when possible and those not able to be closed were treated with negative pressure dressings pending definitive wound coverage.	time to debridement and time to cover

6.3.3.1 Clinical evidence narrative summary

Enninghorst 2011[28] reported there to be 15 patients (17%) out of the 89 included to have developed deep infections, 4 of which required a late amputation. The paper states that 'all patients got their antibiotic prophylaxis in a timely fashion (1.2±0.3 hours) without statistical difference between infected and non-infected cases'. No data was given in the univariate logistic regression analysis table or for the MVA for the deep infection outcome, but the paper describes there to have been 'no identifiable predictors for infection' in the MVA.

Weber 2014[97,98] found that time to antibiotics did not have any independent effect on the odds of deep infection, with an OR of 1.0 (95% CI, 0.95 to 1.05) for deep infection per increased hour of time to antibiotics, after adjustment for time to surgery, transfusion, fracture location and Gustilo grade.

Hull 2014[44,45] also found that time to antibiotics did not have any independent effect on the odds of deep infection, after adjustment for time to surgery, gross contamination, fracture location and grade of fracture (high versus low).

In contrast, Lack 2015[55] found that time to antibiotic prophylaxis had a strong and significant independent effect on deep infection within 90 days, after adjustment for age, Gustilo-Anderson classification, smoking, presence of diabetes, time to debridement and time to cover. For patients with more than 66 minutes to antibiotics, the adjusted OR for deep infection was 3.78 (95% CI, 1.26 to 14.11), compared with less than 66 minutes to antibiotics. The most likely factor for these contrasting results was the larger numbers with a greater severity of contamination in this study compared to the others.

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6.3.4 Economic evidence

Published literature

No relevant economic evaluations were identified.

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

6.3.5 Evidence statements

Clinical

The very low quality clinical evidence comprising 1276 patients suggests that prophylactic antibiotics given after one hour in highly contaminated (type III) tibial shaft fractures increases the deep surgical site infection rate, but that this is not seen in studies where the average contamination level was less severe.

Economic

No relevant economic evaluations were identified.

6.3.6 Recommendations and link to evidence

Recommendations	**6. In the pre-hospital setting, administer prophylactic intravenous antibiotics as soon as possible and preferably within 1 hour of injury to people with open fractures without delaying transport to hospital.** **7. In the emergency department, administer prophylactic intravenous antibiotics immediately to people with open fractures if not already given.**
Relative values of different outcomes	Critical outcomes were mortality, deep infection, health-related quality of life, allergy/anaphylaxis, amputation (or unplanned reoperation as a proxy) and wound healing by 6 weeks. Important outcomes were return to normal activities and superficial infection.
Trade-off between clinical benefits and harms	The four included studies only looked at one outcome – deep infection – and three suggested that the timing of antibiotics has no effect on this outcome. However, the other study showed a clinical benefit from more rapid administration, within approximately one hour. One reason for this discrepancy between studies may be that the study showing an effect was restricted to a population with grade III open fractures, whereas the other three papers included patients with lower grades of injury. The GDG interpreted this as indicating that the benefits of antibiotics may be more easily detected in a population with significant wound contamination.
Economic considerations	No economic evidence was identified for this question. The cost of giving prophylactic antibiotics is the same regardless of the time they are given; however, they may differ because of staff implications if provided by different staff pre-hospital and in hospital. They can be given pre-hospital or in hospital and there would be no delay to treatment if given in transit. However, it is not standard practice all over the country for paramedics to carry antibiotics, and there is a possibility of it inducing delays on scene. Paramedics also may not have knowledge on full patient history, such as allergies, which means there is an element of risk in administering antibiotics pre-hospital. This implies there is a trade-off between the risk of infection if antibiotics are delayed, and the risk of having severe adverse events, such as allergic reaction, outside of a hospital where treatment cannot be

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	provided immediately. Severe infection could lead to amputation and further resource use, such as increased length of stay. The GDG felt that there was a benefit of early antibiotic prophylaxis that outweighed the risk of severe adverse events, and that this should be considered as soon as possible. This recommendation is likely to lead to a change in practice as it is uncommon for antibiotics to be issued so early, particularly in the pre-hospital setting.
Quality of evidence	Evidence was graded as very low overall, largely due to the inherent bias resulting from the observational nature of the research. Furthermore, in one study reporting of the analyses was poor, and the same study had <10 events per variable, potentially reducing the validity of findings. Furthermore, the range of timings was either not adequately reported or very narrow, the latter making any significant conclusions highly unlikely.
Other considerations	Given the serious limitations of some of the evidence, the GDG felt that the results from the three inconclusive studies should be regarded as absence of evidence rather than evidence of absence. This meant that these three studies were not necessarily seen as contradicting the conclusive study. Thus, a stronger recommendation was possible. The GDG felt that prophylactic antibiotics should ideally be provided immediately in the pre-hospital setting. However, they decided to recommend that they were given within one hour rather than 'immediately' to prevent pre-hospital providers opting not to give them once the 'immediate' point had already passed (as in emergency situations where threats to life had been immediately paramount). The GDG also felt that recommending they were used 'as soon as possible' was not ideal, as it would give providers the option to delay their administration beyond an hour if practical (but not insurmountable) constraints made it seem not 'possible'. If patients arrived in acute care without initiation of antibiotic prophylaxis it was felt vital that no further delay was acceptable and the recommendation was therefore made that antibiotics should be given immediately. The GDG acknowledged concerns about dealing with serious adverse effects when the antibiotics were given pre-hospital, but concluded that these would be outweighed by the potential benefits.

6.4 Dressings before debridement

6.4.1 Introduction

A fracture is 'open' when a broken bone is exposed through the skin. These fractures present a high risk of infection due to the open wound and wound contamination that may be present. Open fractures require immediate treatment and an operation is often required to clean the area of the fracture. This is called wound debridement or excision and involves the surgical cleaning of the wound of foreign material, such as dirt or clothing, as well as non-viable soft tissue. An important aspect of infection control is the dressing of the wound both prior to and post debridement.

6.4.2 Review question: What is the most clinically and cost effective dressing type prior to surgical debridement and excision for use in open fractures, pre-hospital and in hospital?

For full details see review protocol in Appendix C.

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Table 41: PICO characteristics of review question

Population	Children, young people and adults with an open fracture after a traumatic incident
Intervention(s)	• Antiseptic dressing • Saline dressing • Dry dressing • Occlusive antiseptic dressing • Occlusive saline dressing • Antiseptic dressing (with prior wound irrigation) • Saline dressing (with prior wound irrigation) • Dry dressing (with prior wound irrigation) • Occlusive antiseptic dressing (with prior wound irrigation) • Occlusive saline dressing (with prior wound irrigation)
Comparison	To each other
Outcomes	Critical • Function • Health-related quality of life • Deep infection (bone) • Wound infection • Tissue necrosis • Re-operation (unplanned)/amputation • Wound healing by 6 weeks Important: • Return to normal activities
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.

6.4.3 Clinical evidence

No relevant clinical studies were identified. See the search strategy in appendix F, study selection flow chart in Appendix D and excluded studies list in Appendix J.

6.4.4 Economic evidence

Published literature

No relevant economic evaluations were identified.

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

Unit costs

Table 42: UK costs of pre-debridement dressings

Dressing type	Unit cost
Dry dressing[a]	£0.56
Saline dressing[b]	£1.62
Antiseptic dressing[c]	£3.37

Sources: SP services; a supplier used by the East Midlands Ambulance Service
(a) Sterile dressing, 275 mmx 200 mm, high specification bandage. £80.35 for a pack of 144.
(b) Dry dressing plus 200 ml of Sodium Chloride 0.9% w/v at £2.65 for a 500 ml bottle.

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(c) Antimicrobial dressing, 4.5 inchesx4.1 yards, contains polyhexamethylene biguanide. £201.95 for a pack of 60.

6.4.5 Evidence statements

Clinical

No clinical studies were identified.

Economic

No relevant economic evaluations were identified.

6.4.6 Recommendations and link to evidence

Recommendations	**8. Do not irrigate open fractures of the long bones, hindfoot or midfoot in pre-hospital settings.** **9. Consider a saline-soaked dressing covered with an occlusive layer for open fractures in pre-hospital settings.** **10. Do not irrigate open fractures of the long bones, hindfoot or midfoot in the emergency department before debridement.** **11. Consider a saline-soaked dressing covered with an occlusive layer (if not already applied) for open fractures in the emergency department before debridement.**
Relative values of different outcomes	Critical outcomes were: health-related quality of life; deep (bone) infection and wound, the primary purpose of these dressings is to prevent infection; unplanned re-operation or amputation; function, wound healing and tissue necrosis. Return to normal activities was considered to be important but not critical as it is a proxy for function.
Trade-off between clinical benefits and harms	No clinical evidence was found to evaluate the trade-off between clinical benefits and harms of dressings for open fractures prior to debridement. In the absence of evidence, recommendations were made by consensus. The GDG considered simplicity and speed of application to be important drivers in the decision of what dressing to use for open fractures as this will happen primarily in the pre-hospital setting. The consensus recommendation was that a saline-soaked dressing with an occlusive layer is an effective way of reducing desiccation of the wound and also reduces the likelihood of further contamination. The GDG saw no advantage in the addition of antiseptic to the dressing. The GDG considered wound lavage/irrigation to be time-consuming and potentially harmful as it may disseminate already present contamination throughout the wound.
Economic considerations	No economic evidence was identified for this question. The cost of a standard dressing is small at £0.56 and to soak this in saline adds an extra £1.06 for 200 ml of saline making that £1.62 in total. An antiseptic dressing is the most expensive and costs £3.37. An occlusive layer can be added using bandage and tape and so this will incur only a small additional cost. The GDG believed that the saline-soaked dressing with an occlusive layer prevents desiccation of the wound and reduces the likelihood of further contamination and so is worth the small additional cost in comparison to a standard dressing. The GDG did not believe there was any benefit to the more expensive antiseptic dressing.

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	A small cost would also be incurred for irrigation with saline. However, the GDG believed there may be harm from irrigation due to contamination being washed into the wound rather than out as well as there being a delay in transporting the person to hospital. Therefore, the GDG believed that irrigating prior to applying a dressing was not cost effective.
Quality of evidence	No relevant clinical studies were identified.
Other considerations	The GDG agreed that the re-dressing of the wound in hospital prior to surgery was unnecessary.

6.5 Arterial shunts

6.5.1 Introduction

Complex fractures may often lead to vascular injury, which if severe, can threaten the survival of a limb or even lead to death. Rapid management of serious vascular injury is therefore essential. Currently, vascular shunts may be used as a temporary measure to restore blood flow quickly, prior to definitive repair. However, sometimes shunts are not used, and definitive vascular repair may occur immediately or directly after skeletal stabilisation, and it is unclear which is the optimal approach. This review evaluates the relative clinical and cost effectiveness of these different strategies.

6.5.2 Review question: Are arterial shunts followed by later repair more clinically and cost effective compared to definitive repair of arterial injuries associated with open fractures?

For full details see review protocol in Appendix C.

Table 43: PICO characteristics of review question

Population	Children, young people and adults experiencing a traumatic incident
Interventions	• Vascular shunt, definitive skeletal stabilisation, definitive vascular repair • Definitive skeletal stabilisation, definitive vascular repair • Definitive vascular repair, definitive skeletal stabilisation • Temporary skeletal stabilisation, definitive vascular repair, definitive skeletal stabilisation
Comparison	To each other
Outcomes	Critical: • Quality of life • Mortality • Amputation • Deep infection • Compartment decompression • Unplanned re-operation Important • Length of stay • Hospitalisation
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.

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6.5.3 Clinical evidence

We searched for randomised trials comparing two or more of the following treatment approaches:

- Vascular shunt, definitive skeletal stabilisation, definitive vascular repair
- Definitive skeletal stabilisation, definitive vascular repair
- Definitive vascular repair, definitive skeletal stabilisation
- Temporary skeletal stabilisation, definitive vascular repair, definitive skeletal stabilisation

No RCTs were found, and so observational trials were sought. One retrospective cohort study was found.[22] This study is summarised in Table 44 below. It contained three groups, which spanned all four of the protocol groups (Table 43), as one of the groups was definitive *or* temporary skeletal stabilisation followed by definitive vascular repair. However, only the other two groups were equally matched for the key confounder of ischaemia time. As no adjustments were made for this variable in the study the other group involving definitive *or* temporary skeletal stabilisation followed by definitive vascular repair was excluded from this review. Hence, the only comparison included was shunt followed by definitive skeletal stabilisation and definitive vascular repair versus definitive vascular repair followed by definitive skeletal stabilisation.

Evidence from this study is summarised in the clinical evidence summary (Table 45). See also the study selection flow chart in Appendix D, study evidence tables in Appendix G, forest plots in Appendix K, GRADE tables in Appendix I and excluded studies list in Appendix K.

Summary of included studies

Table 44: Summary of studies included in the review

Study	Intervention and comparison	Population	Outcomes	Comments
Desai 2012[22]	Shunt, definitive skeletal stabilisation, definitive vascular repair versus definitive vascular repair, definitive skeletal stabilisation	People aged 6-80 years (mean age 33 years) with combined lower extremity traumatic injuries requiring both orthopaedic and vascular surgical repair	• Mortality • Amputation • Unplanned surgery • Compartment syndrome	Key confounder of ischaemic time was similar between groups (180 versus 195 minutes). Age, ISS, GCS and MESS also reasonably similar.

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Table 45: Clinical evidence summary: Shunt, definitive skeletal stabilisation, definitive vascular repair versus definitive vascular repair, definitive skeletal stabilisation

Outcome	No. of studies	Imprecision	GRADE rating	Absolute difference	Control event rate (per 1000)	Control event rate for continuous outcomes
Mortality	1 (n=22)	Very serious	VERY LOW	42 fewer per 1000 (from 59 fewer to 589 more)	59	
Amputation	1 (n=22)	Very serious	VERY LOW	94 fewer per 1000 (from 265 fewer to 1000 more)	294	
Compartment syndrome	1 (n=22)	Very serious	VERY LOW	84 fewer per 1000 (from 116 fewer to 386 more)	118	
Other vascular surgery	1 (n=22)	Very serious	VERY LOW	210 fewer per 1000 (from 379 fewer to 852 more)	412	

6.5.4 Economic evidence

Published literature

No relevant economic evaluations were identified.

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

Unit costs

Table 46: UK costs of an amputation procedure

Procedure	HRG code	Cost
Amputation of Single Limb with CC Score 0-9	YQ22B	£8,589

Source: NHS Reference Costs 2013-2014 [21]

6.5.5 Evidence statements

Clinical

Very low quality evidence from one observational study comprising 22 people showed that use of a shunt had clinically important benefits in terms of mortality compared with immediate definitive vascular repair, with very serious imprecision.

Very low quality evidence from one observational study comprising 22 people showed that use of a shunt had clinically important benefits in terms of amputation compared with immediate definitive vascular repair, with very serious imprecision.

Very low quality evidence from one observational study comprising 22 people showed that use of a shunt had clinically important benefits in terms of compartment syndrome compared with immediate definitive vascular repair, with very serious imprecision.

Very low quality evidence from one observational study comprising 22 people showed that use of a shunt had clinically important benefits in terms of other vascular surgery compared with immediate definitive vascular repair, with very serious imprecision.

Economic

No relevant economic evaluations were identified.

6.5.6 Recommendations and link to evidence

Recommendations	**12. In people with a devascularised limb following long bone fracture, use a vascular shunt as the first surgical intervention before skeletal stabilisation and definitive vascular reconstruction.**
Relative values of different outcomes	Critical outcomes were quality of life, mortality, amputation, deep infection, compartment decompression and unplanned re-operation. Important outcomes were length of stay and hospitalisation.
Trade-off between clinical benefits and harms	There were clinically important benefits in terms of mortality, amputation, compartment syndrome and the need for other vascular surgery in the group using a

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	shunt as the first intervention compared to the group using definitive vascular repair as the first intervention. No relative harms were reported.
Economic considerations	No economic evidence was identified for this question. Two of the interventional strategies compare the order in which definitive restoration of the circulation and definitive skeletal stabilisation are performed and so there is no difference in the cost of the strategies. Another strategy starts with the temporary restoration of the circulation using a vascular shunt followed by definitive skeletal stabilisation and then definitive restoration of the circulation, so there is the small additional cost of a shunt. The fourth strategy being compared has the more expensive additional cost of surgery time for temporary skeletal stabilisation before definitive restoration of the circulation and definitive skeletal stabilisation are performed. The potential adverse events for people with a devascularised limb are serious as they include amputation, compartment syndrome and death. Amputation incurs a large surgical cost as well as long-term prosthetics and rehabilitation costs. The patient also has a reduction in health-related quality of life due to the impact on the patient's mobility, usual activities and their ability to self-care. Compartment syndrome incurs a surgical cost if identified and can require amputation if not. These complications are therefore key outcomes that heavily influence the cost effectiveness of the intervention. Temporary shunting can permit establishment of the circulation and a decision can then be made whether a primary amputation would lead to the best long term functional result. The only clinical evidence that was included compared a shunt followed by definitive skeletal stabilisation and definitive vascular repair to definitive vascular repair followed by definitive skeletal stabilisation. This evidence suggests that there are clinically important benefits of using a shunt for temporary restoration of the circulation and the GDG believed that these benefits would far outweigh the cost of using vascular shunts for all patients with a devascularised limb. The GDG believed that, from the included clinical evidence, it could be inferred that using a vascular shunt for temporary restoration of the circulation was more clinically and cost effective than the other strategies too. This is because the other strategies delay restoration of the circulation and so the GDG believed that the risk of complications was higher and so the costs of treatment and the overall detriment to health-related quality of life would favour using a vascular shunt to restore the circulation as the first operative procedure.
Quality of evidence	The study was non-randomised but there was adequate similarity in key confounders. Imprecision was extremely high, meaning that great care should be taken when interpreting clinical benefit from the point estimates. Therefore, there is a possibility that a shunt could cause harm in terms of the outcomes.
Other considerations	The GDG were aware of the limitations of the evidence but decided overall that temporary shunts would benefit the patient by reducing the time for restoration of the circulation. The GDG was cognisant that ischaemic times longer than 3-4 hours can lead to irreparable muscle and nerve damage and that delayed reperfusion can result in renal failure and death. Therefore, the priority should be to re-establish the circulation as soon as possible after the injury and this can only be achieved by insertion of a vascular shunt. The GDG were sufficiently certain of the construct validity of this conclusion that they felt a strong recommendation was warranted. After restoration of circulation, viability of the severely injured limb can then be assessed. Where optimal function would be preserved by limb reconstruction, this is achieved by skeletal stabilisation after shunt insertion, followed by definitive vascular reconstruction. If the limb were not viable following insertion of the shunt

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	or considered to be too severely injured, consideration should be given to primary amputation. The GDG initially considered shunts in the context of open fractures but after discussion felt that shunts are also appropriate for patients presenting with a devascularised limb following knee, ankle or elbow dislocations. This was reflected in the wording of the recommendation. The GDG defined skeletal stabilisation as stabilising an unstable limb, part of limb or pelvis by a means which involves attaching something to the bone.

6.6 Orthoplastic approaches for open fractures

6.6.1 Introduction

For patients with open fractures there is a need to deal with not only the fracture but also the open wound, ensuring that soft tissue healing takes place with optimal reductions in the likelihood of amputation, infection risk and tissue loss. The traditional approach has been for the orthopaedic surgeon to attend to debridement and fracture stabilisation first, and for the plastic surgeon to only become involved later, necessitating an open wound for some time. More recently, collaboration between orthopaedic and plastic surgeons in the initial surgery has become part of practice in certain areas. It is suggested that such joint initial management may improve outcomes, and this review aims to evaluate the efficacy and cost-effectiveness of such an approach.

6.6.2 Review question: Is the presence of an orthopaedic surgeon and plastic surgeon at the initial surgical excision and stabilisation of an open fracture clinically and cost effective?

For full details see review protocol in Appendix C.

Table 47: PICO characteristics of review question

Population	Children, young people and adults experiencing a traumatic incident and open fracture
Intervention(s)	Combined orthopaedic and plastic surgery teams at the initial procedure **or** orthopaedic surgeon present and plastic surgeon available via phone **or** no plastic surgeon input at initial procedure
Comparison(s)	Each compared with each other
Outcomes	• Mortality • Health-related quality of life • Deep surgical site infection • Amputation • Flap failure • Time to definitive cover • Unplanned complexity of soft tissue cover • Length of hospital stay • Further unplanned surgery • Return to normal activities
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.

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6.6.3 Clinical evidence

No RCTs were found and so the type of study design was extended to cohort studies. One cohort study was included in this review[66].

Naique 2006 comprised 72 adults with open fractures. Twenty-five patients who had been initially treated with a combined orthoplastic approach to surgery were compared with 47 patients who had initially been treated with a solely orthopaedic approach in another centre prior to being transferred to the hospital where the research was being conducted for a combined approach. Hence allocation was on the basis of the source of patients – those who had been directly sent to the research hospital and those who had arrived via the other centre. This is likely to have led to group differences in patient characteristics, such as socioeconomic status or trauma severity. The study failed to report baseline characteristics of the groups, and no attempts were made to adjust for any confounding. Some outcomes were not adequately reported; for example, further unplanned surgery was reported for the study as a whole but not for each group. This study was therefore judged to be at very high risk of bias. Evidence from this study is summarised in the clinical evidence summary below (Table 48).

See also the study selection flow chart in Appendix D, study evidence tables in Appendix G, forest plots in Appendix I, GRADE tables in Appendix H and excluded studies list in Appendix J.

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Table 48: Clinical evidence summary: Combined versus non-combined

Outcome	Number of studies (n)	Imprecision	GRADE rating	Absolute difference	Control event rate (per 1000)	Control value for continuous outcomes
Amputations	1 (n=72)	Very serious imprecision	VERY LOW	3 fewer per 1000 (from 39 fewer to 377 more)	43	
flap failure	1 (n=72)	Serious imprecision	VERY LOW	130 fewer per 1000 (from 240 fewer to 20 fewer)	128	
Deep infection	1 (n=72)	Very serious imprecision	VERY LOW	66 fewer per 1000 (from 101 fewer to 216 more)	106	
Enneking limb score (Better indicated by lower values)	1 (n=72)	Serious imprecision	VERY LOW	MD 1 higher (6.71 lower to 8.71 higher)		74

6.6.4 Economic evidence

Published literature

No relevant economic evaluations were identified.

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

New cost-effectiveness analysis

This area was prioritised for new cost-effectiveness analysis.

The model explores a combination of the timing of the initial debridement of open fractures and the presence of a plastic surgeon.

Initially audit data (Trauma Audit and Research Network [TARN]) was explored as a data source to measure treatment effects for this model. However, this method proved difficult and was abandoned after exploration of TARN from the major trauma guideline, which identified that TARN was not an appropriate source of data. Please see Appendix N in the major trauma guideline for further detail on how TARN was explored.

Thus, the planned model was downgraded to a cost analysis. There was some clinical evidence identified from the guideline reviews to incorporate into the analysis, and the GDG felt this analysis would be useful in informing recommendations.

The costing analysis was split into three parts, encompassing other guideline questions:

- Timing of debridement with and without a plastic surgeon (incorporating staff costs if staff need to be on call to debride earlier and the adverse event risks of waiting longer for debridement).
- Timing of cover (incorporating the costs of additional lists needed if covering within a certain time frame and the adverse event risks of waiting longer for cover).
- Multiple theatre sessions (incorporating the costs of theatre time and preparation time if the management pathway of debridement, fixation and cover, is done in one or several theatre slots).

Please see Table 49 for a summary of the results.

For further detail on the analyses, please see Appendix L.

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Table 49: Summary of results: Original cost analysis for treatment of open fractures

Analysis section	Applicability	Limitations	Other comments	Cost per patient (£)	Uncertainty
Timing of debridement with and without a plastic surgeon present	Directly applicable[a]	Potentially serious limitations[b]	This analysis looked at the timing of debridement and the presence of a plastic surgeon at debridement. It looked at the costs of all theatre staff involved in debridement as well as the costs of deep infection, amputation and prosthetics based on the data found in the guideline clinical review and assumptions.	**Without plastic surgeon** Debridement <6 hours: £3,137 Debridement 6-12 hours: £3,370 Debridement 12-24 hours: £4,043 Debridement >24 hours: £6,345 **With plastic surgeon** Debridement <6 hours: £2,978 Debridement 6-12 hours: £2,988 Debridement 12-24 hours: £3,166 Debridement >24 hours: £4,041	Various one-way sensitivity analyses were performed to assess uncertainty. None of these changed the conclusion and the presence of a plastic surgeon remained cost saving.
Timing of soft tissue cover	Directly applicable	Potentially serious limitations	This analysis compared the costs of staffing for additional theatre lists that would be required to provide definitive soft tissue cover within a reduced timeframe. The costs of deep infection, amputation and prosthetics based on the data found in the guideline clinical review and assumptions. This cost was estimated per person based on a population of people with open fractures who require plastic surgery.	7 lists per week (1-day delay): £27,212 4 lists per week (2-days delay): £18,796 3 lists per week (3-days delay): £16,351 2 lists per week (4-days delay): £13,906 1 list per week (7-days delay): £12,543	Various one-way sensitivity analyses were performed to assess uncertainty. These did not have a large effect on the results.
Multiple theatre sessions	Directly applicable	Potentially serious limitations	This analysis looked at the cost implications of performing debridement, fixation and cover in one theatre session compared with staged fixation and/or staged cover. The trade-offs here are the additional staff time required to	**Plastic surgeon present at debridement:** 1. Debridement, fixation and cover in one theatre session: £6,035 2. Debridement and definitive fixation in the first session; definitive cover in the second: £6,156	No sensitivity analyses were performed for this analysis.

Analysis section	Applicability	Limitations	Other comments	Cost per patient (£)	Uncertainty
			prepare multiple theatre sessions and the inefficient cost of the unused plastic surgeon for the duration of definitive fixation when definitive cover is performed immediately. No complication costs were included.	3. Debridement and temporary fixation in the first session; definitive fixation and definitive cover in the second: £8,260 4. Debridement and temporary fixation in the first session; definitive fixation in the second session; definitive cover in the third: £8,380 **Plastic surgeon not present at debridement:** 1. Debridement, fixation and cover in one theatre session: £6,035 2. Debridement and definitive fixation in the first session; definitive cover in the second: £5,561 3. Debridement and temporary fixation in the first session; definitive fixation and definitive cover in the second: £7,665 4. Debridement and temporary fixation in the first session; definitive fixation in the second session; definitive cover in the third: £7,786	

Abbreviations: QALY: quality-adjusted life years;

(a) UK NHS and PSS perspective, directly applicable to questions

(b) Health benefits not included, many assumptions made including; the trend line of risks to find line of best fit for clinical data was assumed, full lifetime costs of resource use for amputation not included, assumption made about what time of day complex fracture might arrive at the hospital, no mortality assumed after injury.

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The costing analysis aimed to assist the GDG in making recommendations for the entire open fracture treatment pathway, and incorporates clinical review data to capture the trade-off between reduced time to interventions meaning reduced risk of adverse events but more expensive staff time, and also the trade-off around the presence of an orthopaedic surgeon and the impact this may have on adverse events.

The population in question are people who have suffered an open fracture as a result of trauma. For the purposes of the timing of cover analysis, where costs were also calculated on a population level, it was estimated that there are 105 open fractures per year requiring plastic surgery. See Appendix L for further details.

The costing analyses found that:

- The presence of a plastic surgeon reduces the cost of debridement at all time points, as the increase in staff costs are outweighed by the reduction in adverse events from the plastic surgeon being present. Debriding earlier is also less costly because fewer complications develop the earlier the wound is debrided.
- The more lists a hospital has per week, the more expensive this will be.
- With a plastic surgeon present at debridement, performing all the interventions in one stage is the cheapest strategy. Without a plastic surgeon present, debridement and fixation in one theatre session and cover in a second session is the cheapest. This is because the additional preparation time for a second theatre session for definitive cover outweighs the inefficient use of the plastic surgeon while definitive fixation is performed between debridement and definitive cover.

Please refer to the LETR in section 6.9.6 for further discussion on the relation between the different parts of the analysis and how this was used in GDG decision making.

However this analysis has limitations. It did not include any health benefit such as QALYS as it only focused on the acute treatment period. Data on adverse events were taken from single studies from the clinical review. It also included assumptions about; the distribution of data when fitting a line of best for the clinical review data, the proportion of people requiring an amputation following deep infection, no mortality was assumed post injury.

Therefore although no health benefits were included in the analysis, meaning no firm conclusions can be made on the cost effectiveness of the interventions, there are some outputs from the analysis which show cost savings. The analysis was felt to be sufficient for the purposes of decision making by the GDG.

6.6.5 Evidence statements

Clinical

Very low quality evidence from one study comprising 72 participants showed that a combined and non-combined approach to surgery of open fractures did not differ in terms of amputation rates, with very serious imprecision

Very low quality evidence from one study comprising 72 participants showed that a combined approach to surgery of open fractures was clinically beneficial in terms of flap failure compared with a non-combined approach, with serious imprecision

Very low quality evidence from one study comprising 72 participants showed that a combined approach to surgery of open fractures was clinically beneficial in terms of deep infection compared with a non-combined approach, with very serious imprecision

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Very low quality evidence from one study comprising 72 participants showed that a combined and non-combined approach to surgery of open fractures did not differ in terms of Enneking limb scores, with serious imprecision

Economic

An original cost analysis showed that a combined orthoplastic approach to debridement is cost saving in comparison with an orthopaedic surgeon alone. This analysis was assessed as directly applicable with potentially serious limitations.

6.6.6 Recommendations and link to evidence

See LETR in section 6.9.6.

6.7 Optimal timing of debridement

6.7.1 Introduction

Debridement is an essential step in the management of a patient with an open fracture. Debridement involves the removal of debris and damaged tissue from the area of injury in an attempt to reduce deep contamination of the wound. The timing of debridement may be an important factor in influencing deep infection rates and may therefore also affect amputation and mortality rates. Theoretically, the earlier that debridement is instituted, the lower the chances of a deep infection becoming established. However, sometimes later debridement may be required to allow initial stabilisation of the patient and essential investigations to be carried out, and so the effects of timing of debridement on outcomes are not clear cut. Furthermore, there may be cost implications implied by a policy of early debridement. Empirical findings from studies are required to inform the most clinically and cost-effective practice.

6.7.2 Review question: What is the optimal timing of initial debridement of open fractures?

For full details see review protocol in Appendix C.

Table 50: PICO characteristics of review question

Population	Children, young people and adults who have experienced an open fracture following a traumatic incident
Intervention(s)	Surgical treatment (time from injury <6, 6-12, 12-24 hours)
Comparison(s)	Comparison of the above and later than 24 hours
Outcomes	Critical: • Mortality up to 12 months • Health-related quality of life • Return to normal activities • Deep surgical site infection • Re-operation (unplanned) • Amputation • Functional outcomes Important: • Length of hospital stay
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.

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6.7.3 Clinical evidence

No RCTs were found to meet the inclusion criteria so cohort studies have also been included. Nine cohort studies, seven retrospective and two prospective, were included in the review.[15,19,28,35,45,55,60,71,97] These are summarised in Table 51 below. Evidence from these studies is summarised in the clinical evidence summary below (Table 52). See also the study selection flow chart in Appendix D, study evidence tables in Appendix G, forest plots in Appendix K, GRADE tables in Appendix I and excluded studies list in Appendix L.

Four of the studies are based on open tibial fractures[15,19,28,55], four on open long bone fractures (femur, tibia/fibula, humerus and forearm)[35,45,60,97] and one open femoral shaft fractures[71].

All of the studies carried out multivariate analysis (MVA) but included different variables. The outcomes that were reported include deep surgical site infection, re-operation (unplanned) and amputation. There were no studies that reported mortality up to 12 months, health-related quality of life, return to normal activities, functional outcomes or length of stay that were appropriately adjusted for confounders. The majority of the other studies were excluded due to inadequate adjustment of confounders. Some did not even provide basic baseline characteristic data on age and grade of the open fractures.

Only four of the studies[35,45,60,71] specified the type of antibiotics used for different grades of fractures, with only one study[71] reporting the bacteria that was found in the deep surgical site infections.

Most of the studies had fewer than 10 events per variable included in the MVA reducing the validity of the results.

6.7.3.1 Summary of included studies

Table 51: Summary of studies included in the review

Study and type	Fracture location and grade and patient characteristics	Intervention/ comparison	Outcomes	Comments
Charalambous 2005A[15] Retrospective cohort	Open tibial fractures (n=383) Adult and child population (range 3-88 years) Grade 1, 2, 3A and 3B (7.6%, 10.3%, 59.3%, 22.8% in the early group and 9.5%, 9.5%, 69.8% and 11.2% in the delayed group).	Group 1: Early debridement (<6 hours) Group 2: Delayed/late debridement (>6 hours)	Deep surgical site infection Re-operation (unplanned)	No pre-defined protocol used. Type of antibiotic used and bacteria found not described. MVA used to control for confounders. It was not clear what was included but thought to be age, sex, mechanism of injury, fracture site, fracture pattern, Gustilo grade, average time to initial antibiotics, length of antibiotic administration, most senior surgeon present at initial surgery, primary surgical procedure and

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Study and type	Fracture location and grade and patient characteristics	Intervention/ comparison	Outcomes	Comments
				definitive surgical procedure.
Davissears 2012[19] Retrospective cohort	Open tibial fractures (n=7560) Adult population (18 years and older) Grade: not reported as ICD codes were used. Arterial injury, nerve injury and presence of a complex wound based on ICD codes were recorded.	Group 1: Debridement on day 0 Group 2: Debridement on day 1 Group 3: Debridement on day 2 Group 4: Debridement on days 3-4 Group 5: Debridement on day 5 or greater Group 6: Debridement timing not specified	Amputation	Analysis based on ICD coding No pre-defined protocols described. Type of antibiotic used and bacteria found not described MVA used to control for confounders (age, sex, race, economic characteristics, Injury severity scale score, comorbidities, associated injuries/procedure (arterial injury, tibial nerve injury, complicated open wound, fasciotomy, dislocation (knee or ankle), admission type, location, bed size, hospital teaching status, hospital volume open tibial fractures per year, median household income, mechanism of injury.
Enninghorst 2011[28] Prospective cohort	Blunt trauma open tibial shaft fractures (n=89) Adult population (>18 years) Grade of injuries: grade 1 (n=21), grade 2 (n=27), grade 3a (n=18), grade 3b (n=21), grade 3c (n=1).	Group 1: Early debridement (<6 hours) Group 2: Delayed/late debridement (>6 hours)	Deep surgical site infection	No pre-defined protocols described Antibiotic cover and tetanus (type and dosing not described) MVA used to control for confounders. 18 variables, unclear what the full list was. Thought to be: sex, age, smoking status, ISS, NISS, Trauma team activation, high energy mechanism, contamination, time from injury to operating room, time from admission to

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Study and type	Fracture location and grade and patient characteristics	Intervention/ comparison	Outcomes	Comments
				operating room, grade, initial stabilization, in hours or not, attending surgeon in the operating theatre, ICU admission, number of procedure, antibiotic timing and type of fracture.
Harley 2002[35,36] Retrospective cohort	Open long bone (femur, tibia/fibula, humerus and forearm) fractures (n=215) Grade of injuries: grade 1 (n=60), grade 2 (n=90), grade 3 (n=65)	Group 1: Early debridement (≤8 hours) Group 2: Delayed/late debridement (>8 hours)	Deep surgical site infection	Informal protocol used. Antibiotics used were cephalosporin for a minimum of 48 hours (plus aminoglycosides for grade 3 injuries, or if definitive treatment was >8 hours) MVA used to control for confounders: Male gender, age, time to definitive treatment and Gustilo grade.
Hull 2014[44,45] Retrospective cohort	Open fractures – no clear information given on type or location of fractures	Continuous risk factor: Odds ratio of deep infection (compared to previous hour of delay to debridement).	Deep surgical site infection	Adjustment for gross contamination, existence of tibial fracture and grade of fracture (low versus high). Age, gender, mechanism of penetration, ASA class, ISS score and time of antibiotic administration were not included in the final model as they had a non-significant association with the outcome
Malhotra 2014[60] Retrospective cohort	Blunt trauma extremity fracture (404 patients with n=415 fractures) No age restriction described Grade of injuries: grade 1 (n=86), grade 2 (n=162), grade 3a (n=112),	Group 1: Early debridement (<8 hours) Group 2: Delayed/late debridement (>8 hours)	Deep surgical site infection	No pre-defined protocol described. Antibiotics used were for Grade 1, a cephalosporin, grade 2 and 3 cephalosporin and aminoglycoside. Extensive contamination penicillin would also be

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Study and type	Fracture location and grade and patient characteristics	Intervention/ comparison	Outcomes	Comments
	grade 3b (n=47) and grade 3c (n=8)			given or clindamycin if there was an allergy. MVA used to control for confounders. The entire data set is said to have been included; age, ISS, RTS, SBP, lactate and Gustilo grade.
Noumi 2005[71] Retrospective cohort	88 patients with n=89 open femoral shaft fractures. No age restriction described. Range 15-62 years. Grade of injuries: grade 1 (n=22), grade 2 (n=43), grade 3a (n=12), grade 3b (n=7) and grade 3c (n=5).	Group 1: Early debridement (≤6 hours) Group 2: Delayed/late debridement (>6 hours)	Deep surgical site infection	Basic protocol used. Antibiotics given were cephalosporin for 72 hours which was sometimes combined with an aminoglycoside. MVA used to control for confounders: age, sex, Gustilo grade, fracture grade by AO type, fracture site, reamed versus undreamed nailing, debridement time, existence of multiple trauma and existence of floating knee injury.
Weber 2014[97,98]	Median 39.6 years (range 17-93 years). 49% MVA, 31% falls, 18% crush injuries, 2% assaults. 29% Gustilo G1, 37% Gustilo G2, 21% G3a, 12% G3b and 1% G3c.	Continuous risk factor: Odds ratio of deep infection (compared with previous hour of delay to debridement).	Deep infection	Multivariable regression adjusting for time to antibiotics, transfusion, fracture location, and Gustilo grade. Age and gender were not included in the model.
Lack 2015[55]	137 patients with Gustilo Type II a, b and c open tibial fractures; Type b and c in 47% of those not infected and 50% of those infected; mean age (non-infected/infected) 40/40.5; mean ISS 10/9.5	Unclear, but timing of debridement included as a predictive factor in the model	Deep infection	Adjustment for age, Gustilo-Anderson classification, smoking, presence of diabetes, time to debridement and time to cover

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Table 52: Clinical evidence summary: early versus delayed/late debridement

Outcome	Number of studies (participants)	Imprecision	GRADE RATING	Absolute difference	Control event rate (per 1000)	Control group value for continuous outcomes
Deep surgical site infection (≤6 hours versus >6 hours)	1 (n=89)	Very serious	VERY LOW	51 more per 1000 (from 74 fewer to 824 more)	77	
Deep surgical site infection (≤8 hours versus >8 hours)	1 (n=215)	Very serious	VERY LOW	5 fewer per 1000 (from 62 fewer to 118 more)	100	
Deep surgical site infection (<8 hours versus >8 hours)	1 (n=415)	Serious	VERY LOW	100 fewer per 1000 (from 4 fewer to 147 fewer)	195	
Deep surgical site infection (continuous time)	2 (1100)	Serious	VERY LOW	Adjusted random effects OR: 1.01 (0.95-1.07) per increased hour of delay	-	
Amputation (Day 0 versus Day 1)	1 (n=3975)	No serious imprecision	VERY LOW	16 fewer per 1000 (from 9 fewer to 19 fewer)	22	
Amputation (Day 0 versus Day 2)	1 (n=3494)	No serious imprecision	VERY LOW	17 fewer per 1000 (from 8 fewer to 20 fewer)	22	
Amputation (Day 0 versus Days 3+4)	1 (n=3487)	No serious imprecision	VERY LOW	19 fewer per 1000 (from 11 fewer to 23 fewer)	25	
Amputation (Day 0 versus Day 5 or greater)	1 (n=3693)	No serious imprecision	VERY LOW	57 fewer per 1000 (from 52 fewer to 60 fewer)	63	
Amputation (Day 0 versus no specified time)	1 (n=5283)	Very serious	VERY LOW	2 more per 1000 (1 fewer to 9 more)	3.2	

Narrative summary for incompletely reported data

Deep surgical site infection

Enninghorst 2011[28] prospectively reviewed 89 blunt trauma patients with open tibial shaft fractures. The paper does not report any data from the MVA but describes there to have been 'no identifiable predictors for infection', of which the timing to surgery (time to debridement) had been included as a continuous variable. 'Infection' in this study refers to a deep surgical site infection by definition.

Hull 2014[44,45] stratified their analysis by the grade or contamination status of tibial fractures, and found that the deleterious effect of delay on deep infection increased with the grade and contamination. However, no data were provided other than a low resolution figure.

Lack 2015[55] found a non-significant effect of debridement time after adjustment for confounders. Adjustment was made for age, Gustilo-Anderson classification, smoking, presence of diabetes, time to antibiotics and time to cover (risk of bias, very high; indirectness of outcome, no indirectness).

Unplanned surgery

Charalambous 2005A[15] reported no significant difference between the early, and delayed or late debridement treatment groups (fewer than 6 hours and more than 6 hours) for unplanned surgery (need of secondary surgical procedure to promote bone union) in open tibial fractures (n=383) with p=0.53. No other MVA data and confidence intervals were provided.

6.7.4 Economic evidence

Published literature

No relevant economic evaluations were identified.

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

New cost-effectiveness analysis

This area was prioritised for economic analysis.

Please see section 6.6.4 for a summary of this analysis.

6.7.5 Evidence statements

Clinical

Very low quality evidence from two studies (n=89, n=215) suggested that there was no clinical difference in deep surgical site infection between early and delayed (late) debridement of open fractures (6 hours or less versus more than 6 hours for open femoral shaft fractures, 8 hours or less and more than 8 hours for open long bone fractures, respectively), with very serious imprecision.

Very low quality evidence from one study (n=415) suggested that early debridement (less than 8 hours) may have a lower deep surgical site infection rate compared with delayed (late) debridement (more than 8 hours) in open extremity fractures, with serious imprecision.

Very low quality evidence from one study (n=7560) suggested early debridement on day 0 has a lower amputation rate compared with delayed (late) debridement (day 1, day 2, days 3 and 4 or, day 5 or greater) for open tibial fractures, with no serious imprecision.

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Very low quality evidence from 3 studies (n=1237) suggested the time of debridement is not an important predictor of deep infection, with serious imprecision.

Economic

An original cost analysis showed that debridement in less than 6 hours is less costly than debridement within 6-12 hours, 12-24 hours, and after 24 hours. This analysis was assessed as directly applicable with potentially serious limitations.

6.7.6 Recommendations and link to evidence

See LETR in section 6.9.6.

6.8 Staging of fixation and cover

6.8.1 Introduction

Open fractures require debridement, fixation and cover. There is a variation in practice throughout England and Wales in terms of the timing and staging of these procedures. Sometimes all three stages may be performed in one sitting with a joint orthopaedic and plastic surgery approach. However, it is common for other approaches to be used as well. For example, fixation may be staged with an initial external fixation prior to definitive fixation later. Cover may also be performed on a separate session after definitive fixation. There is uncertainty amongst clinicians as to the optimal approach and the aim of the following two reviews to determine the optimal approach and timing of fixation and cover.

6.8.2 Review question: Is the use of initial definitive fixation and cover more clinically and cost effective in the management of open fractures compared with staged fixation and cover?

For full details see review protocol in Appendix C.

Table 53: PICO characteristics of review question

Population	Children, young people and adults with open fractures
Intervention(s)	Definitive fixation (internal or external) and immediate cover Definitive fixation (internal or external) and staged cover Staged fixation (external initially and then internal or external) and staged cover
Comparison(s)	Compared with each other
Outcomes	Critical: • Mortality at 1 and 12 months • Health-related quality of life • Deep surgical site infection (infection involving the bone) • Flap failure (total or partial) Important: • Length of hospital stay • Further unplanned surgery • Return to normal activities
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.

6.8.3 Clinical evidence

We searched for randomised controlled trials comparing three separate comparisons:

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Definitive fixation and immediate cover versus definitive fixation and staged cover

Only one RCT[7] met the inclusion criteria and was included in the review[7].

As this study was felt to have a very specific population (low contamination rate), cohort studies were also included for this comparison to allow a broader and more clinically relevant population to be considered. Four additional retrospective cohort studies[32,33,47,84,99,100] were therefore included, most of which included patients who had high contamination rates.

The studies' methodologies are summarised in Table 54, and evidence from these studies are summarised in the clinical evidence summary in Table 56 and Table 57. See also the study selection flow chart in Appendix D, study evidence tables in Appendix G, forest plots in Appendix I, GRADE tables in Appendix H and excluded studies list in Appendix J.

Definitive fixation and immediate cover versus staged fixation and staged cover

No eligible RCT studies were identified and so cohort studies were sought. Two cohort studies were found.[40,41,56,57] The studies' methodologies are summarised in Table 55, and evidence from these studies are summarised in the clinical evidence summary in Table 58. See also the study selection flow chart in Appendix D, study evidence tables in Appendix G, forest plots in Appendix I, GRADE tables in Appendix H and excluded studies list in Appendix J.

Definitive fixation and staged cover versus staged fixation and staged cover

No eligible RCT studies were identified and so cohort studies were sought. However, no cohort studies were found (see exclusion list in Appendix J).

6.8.3.1 Summary of included studies

Table 54: Summary of studies included in the review for definitive fixation and immediate cover versus definitive fixation and staged cover

Study and type	Fracture location and grade and patient characteristics	Intervention/ comparison	Comments
Benson 1983[7], RCT	Information on the type of fixation was unclear with patients labelled as having metal or no metal. There was no formal grading system used. The surgeons subjectively assessed the wounds to be clean (no visible signs of contamination, n=14), slightly dirty/contaminated (small amounts of clothing or other foreign material in the superficial tissues, n=42), moderately dirty (more foreign	Group 1: primary closure (with 5 days of cefazolin) Group 2: delayed closure (with 5 days of cefazolin) Group 3: primary closure (with 5 days of Clindamycin) Group 4: delayed closure (with 5 days of Clindamycin) As the type of antibiotic made no difference to outcome, results in this review are not subgrouped for antibiotic type.	Restricted inclusion criteria: no wounds which were open for >24 hours, wounds contaminated by river or lake water, lawnmower injuries, high velocity gunshot wounds (previous study showed high infection rate when closed primarily), if closure of the wound was deemed physically impossible. The randomization was done by 'a random selection of numbers', there were no reports of allocation concealment, and there were very limited baseline characteristics given for each group. Thirteen moderately or grossly dirty wounds were present in each of the early and delayed cover groups, and these groups had very similar time from injury to debridement (5.4[3.5] hours for early and 5.5[3.1] hours for late). Internal fixation was used in 41% of the early cover patients and 34% of the delayed cover

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Study and type	Fracture location and grade and patient characteristics	Intervention/ comparison	Comments
	material, particularly grass or dirt deep in the open fracture area, n=15) and grossly dirty (open fractures with ground in dirt, grass or other foreign material, and/or muscle damage with necrosis, n=11). Fracture site was described as lower extremities (n=44), upper extremities (n=31) and a combination of both upper and lower extremities (n=3).		patients. The study was described as double blind, and although this was true for the antibiotic comparison, this would not have been possible for the main comparison of early versus delayed cover, and it is also unclear if this included assessor blinding. There was some attrition, with 4/40 lost to follow-up in the early group and 2/38 lost to follow-up in the late group. Reasons for loss to follow-up were not given, and as these rates were more than the deep infection event rate they may present a high risk of attrition bias. Overall risk of bias was therefore very high.
Jenkinson 2014[47] Retrospective cohort	146 patients with open fractures. Age 38.6/37.8 years; male sex 76.7%/73.9%; ASA class >2: 9.6%/11%; tibial fracture: 41%/45%; Grade 1 5.5%/5.5%; Grade II 30.1%/37%; Grade IIIA 64.4%/57.5%	Primary closure versus delayed closure. Second look debridement after 48 hours was performed routinely in delayed closure group	To adjust for confounding by indication a propensity score matched cohort study was developed from the original dataset of 262 with primary closure and 87 with delayed closure. Injury characteristics were used in a logistic regression to predict the likelihood of the need for treatment with delayed wound closure. Factors included in the propensity scoring were: age, sex, debridement delay, grade of fracture, contamination, site of fracture and ASA class.
Schemitsh 2012[84] Retrospective cohort using prospective RCT trial data	n=1226 patients with tibial fractures were included in the study (open and closed fractures) of which n=392 where open. Proximal and proximal middle tibial fracture (n=131), distal and distal middle tibial fracture (n=792), and middle tibial fractures (n=293). AO/OTA fracture classification; grade A n=687, grade B n=362, and grade C n=177. Open fractures were fixed by IMN	Primary closure at time of IMN (time not specified) versus delayed closure (time not specified)	Multivariate analysis (MVA) adjusted for: type of nailing (reamed or unreamed), nail material, age, mechanism of injury, smoking, NSAID use, isolated or additional injuries, fracture classification, location of fracture, open/closed surgery, fracture gap, time from injury to surgery and post-operative weight-bearing status. This paper did not report the primary versus delayed cover comparison directly. Instead both primary and delayed cover were compared with a common comparator (additional soft tissue reconstruction). An indirect treatment comparison method has therefore been used to estimate the primary versus delayed effect from the two reported comparisons. As the two reported comparisons were both adjusted for all key confounders, both can be regarded as essentially 'unbiased'. Hence the indirect

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Study and type	Fracture location and grade and patient characteristics	Intervention/ comparison	Comments
	(reamed n=206, undreamed n=194)		estimate of immediate versus delayed cover can also be regarded as unbiased.
Gopal 2004[32,33] Retrospective cohort	34 grade IIIB and IIIc severe open tibial fractures. Age: adults, 48 years; children, 13 years; Gender: 25 men/4 women and 2 boys and 2 girls	Primary closure in a single fix and flap procedure, comprising radical debridement, skeletal stabilisation (normally internal) with a muscle flap. Delayed closure: Immediate debridement and internal fixation with soft tissue cover between 48-72 hours. For 8 subjects cover was only attempted at 72 hours plus because of severe head injury	No MVA, but both groups were adequately similar for age and grade of fracture. The high head injury prevalence in the delayed group could be a serious confounder.
Wei 2014[99,100] Retrospective cohort	49 Grade IIIA and B open tibial fractures. Age: 36-43 years; About 70% male.	Primary closure with internal fixation versus delayed closure with internal fixation with cover at about 1 week	No MVA, but both groups were adequately similar for age and grade of fracture and other non-key confounders.

Table 55: Summary of studies included in the review for definitive fixation and immediate cover versus staged fixation and staged cover

Study and type	Fracture location and grade and patient characteristics	Intervention/comparison	Comments
Hertel 1999[40,41] prospecti ve cohort	29 people with grade IIIb and IIIc open lower leg fractures; Mostly car or motorbike accidents, but some train, gunshot and industrial accidents; age: 28/27; male79%/80%	Definitive fixation and immediate cover - adequate debridement, definitive skeletal stabilisation in 11 and preliminary external stabilisation in 3. Immediate soft tissue coverage was done with a local muscle flap in 8 and a free muscle flap in 7. In 5 a primary cancellous bone graft was added. Staged fixation and staged cover – primary debridement, mostly preliminary stabilisation with an external fixator and soft tissue reconstruction between days 1 and 9 after injury. Soft tissue coverage was achieved	No MVA, but both groups were adequately similar for age and grade of fracture. They were also similar for sex, type of trauma, associated general injuries, type of fracture, arterial lesions, tendon ruptures and soft tissue reconstruction.

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Study and type	Fracture location and grade and patient characteristics	Intervention/comparison	Comments
		with a local muscle flap in 7 and a free muscle flap in 8. Definitive skeletal stabilisation was obtained immediately in 3, at the time of cover in 1 and at a third intervention in 12 patients. No cancellous bone graft was used.	
Liu 2012[56,57] Retrospective cohort	n=103 open limb fractures with n=42 deep metal exposures with free flap constructions. Injuries were in the proximal 1/3, middle 1/3 and distal 1/3 of the tibia/ fibular or the foot. All of the injuries were Gustilo and Anderson grade III (a, b, and c) Fractures were fixed by internal fixation or external then internal.	Mixture of definitive and staged fixation and ≤1 day delay to free flap reconstruction compared with a mixture of definitive and staged fixation with >7 days delay to free flap reconstruction (given in terms of days of exposed metalwork in paper). There was another group, with 2-7 days delay, but multivariable results were not given for this group compared with the other two groups.	MVA adjusted for: age, gender, smoking, ISSS, GA and ASA scores, injury location, flap type, method of fracture fixation and use of NPWT. Evaluated the similar variable of time from injury to cover. However, because patients may have had different times from injury to fixation, this variable was not felt to be as directly relevant to this review, and so was not used in this review. Also collected data on the effects of duration of exposed metalwork on osteomyelitis and deep metal infection, but results from the MVA were not given.

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Table 56: Clinical evidence summary: RCT- Definitive fixation with immediate (primary) versus definitive fixation with staged (delayed) cover of open fractures (fracture type unknown)

Outcome	Number of studies (participants)	Imprecision	GRADE rating	Absolute difference	Control event rate (per 1000)	Control mean (for continuous outcomes)
Deep surgical site infection– overall	1 (n=76)	Very serious	VERY LOW	49 fewer per 1000 (from 55 fewer to 47 more)	56	

Table 57: Clinical evidence summary: Cohorts- Definitive fixation with immediate (primary) versus definitive fixation with staged (delayed) cover of open fractures

Outcome	Number of studies (participants)	Imprecision	GRADE rating	Absolute Difference	Control event rate (per 1000) for binary outcomes	Control mean (for continuous outcomes)
Deep infection	3 (n=225)	Serious imprecision	VERY LOW	112 fewer per 1000 (from 36 fewer to 146 fewer)	178	
Further unplanned surgery	1 (n=49)	Very serious	VERY LOW	Not available Adjusted OR(95% CIs), estimated using indirect treatment comparison methods: 0.62 (0.23 to 1.70)	-	
Amputation	1 (n=49)	Very serious imprecision	VERY LOW	99 fewer per 1000 (132 fewer to 194 more)	136	

Table 58: Clinical evidence summary: Cohorts- Definitive fixation with immediate (primary) versus staged fixation with staged (delayed) cover of open fractures

Outcome	No. of studies (participants)	Imprecision	GRADE rating	Absolute difference	Control event rate (per 1000) for binary outcomes	

					OR Control mean (for continuous outcomes)	Control mean (for continuous outcomes)
Deep infection	1 (n=29)	No serious imprecision	VERY LOW	270 fewer per 1000 (from 500 fewer to 30 fewer)	267	
Flap failure (total or partial)	2 (n=28)	No serious imprecision	VERY LOW	500 fewer per 1000 (from 770 lower to 230 lower) [based on raw, unadjusted, data] Adjusted OR (95% CIs): 0.09 (0.01 to 0.59)	0	
Number of further treatments	1(n=29)	Only range given for each group so imprecision unclear	VERY LOW	-2.3 operations		3.9 operations
Return to weight bearing	1 (n=29)	Only range given for each group so imprecision unclear	VERY LOW	-4.6 months		9.6 months
Amputation	1 (n=29)	Unclear	VERY LOW	Not estimable	0	

6.8.4 Economic evidence

Published literature

No relevant economic evaluations were identified.

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

New cost-effectiveness analysis

This area was prioritised for economic analysis.

Please see section 6.6.4 for a summary of this analysis.

6.8.5 Evidence statements

Clinical

Definitive fixation and immediate cover versus definitive fixation and staged cover

Very low quality evidence from one randomised study comprising 76 patients suggested that definitive fixation with immediate closure has a clinically important lower rate of deep infection compared with definitive fixation with staged closure, with very serious imprecision.

Very low quality evidence from three cohort studies comprising 256 patients suggested that definitive fixation with immediate closure has a clinically important lower rate of deep infection compared with definitive fixation with staged closure, with no serious imprecision.

Very low quality evidence from on cohort study comprising 806 patients suggested that definitive fixation with immediate closure has a clinically important lower rate of amputation compared with definitive fixation with staged closure, with no serious imprecision.

Very low quality evidence from one cohort study comprising 392 patients suggested that definitive fixation with immediate closure has a clinically important lower rate of further unplanned surgery compared with definitive fixation with staged closure, with very serious imprecision.

Definitive fixation and immediate cover versus staged fixation and staged cover

Very low quality evidence from one cohort study comprising 29 patients suggested that definitive fixation with immediate closure has a clinically important lower rate of deep infection compared with staged fixation with staged closure, with very serious imprecision.

Very low quality evidence from two cohort studies comprising 100 patients suggested that definitive fixation with immediate closure has a clinically important lower rate of flap failure compared with definitive fixation with staged closure, with no serious imprecision.

Very low quality evidence from one cohort study comprising 29 patients suggested that definitive fixation with immediate closure has a clinically important lower number of further unplanned operations compared with staged fixation with staged closure, with unclear imprecision.

Very low quality evidence from one cohort study comprising 29 patients suggested that definitive fixation with immediate closure has a clinically important lower time to return to normal weight bearing activity compared with staged fixation with staged closure, with unclear imprecision.

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Very low quality evidence from one cohort study comprising 29 patients suggested that definitive fixation with immediate closure and staged fixation with staged closure do not differ in their effects on amputation, as there were no events in either group.

Economic

An original cost analysis showed that with a plastic surgeon present at debridement, performing all the interventions in one theatre session is less costly than; debridement and definitive fixation in the first session and definitive cover in the second, debridement and temporary fixation in the first session and definitive fixation and definitive cover in the second, and debridement and temporary fixation in the first session and definitive fixation in the second and definitive cover in the third. Without a plastic surgeon present, debridement and definitive fixation in the first session and definitive cover in the second is less costly than; performing all the interventions in one theatre session, debridement and definitive fixation in the first session and definitive cover in the second, and debridement and temporary fixation in the first session and definitive fixation in the second and definitive cover in the third. This analysis was assessed as directly applicable with potentially serious limitations.

6.8.6 Recommendations and link to evidence

See LETR in section 6.9.6.

6.9 Timing of cover

6.9.1 Introduction

The previous chapter on staging of fixation and cover provided some inferences on the optimal timing of cover, as staging has implications for the timing of cover. However, the previous review did not provide specific information on the optimal timing of cover. Hence this additional review question on timing of cover has been included, as it may help to provide clear indications of the maximal acceptable delay from injury to cover.

6.9.2 Review question: What is the most clinical and cost effective time to achieve definitive soft tissue cover in open fractures?

For full details see review protocol in Appendix C.

Table 59: PICO characteristics of review question

Population	Children, young people and adults experiencing a traumatic incident.
Intervention(s)	Immediate soft tissue cover (immediately after early debridement) Soft tissue cover at later times post injury or admission (1,3,7 and >7 days)
Comparison(s)	Compared with each other
Outcomes	Critical: • Mortality up to 12 months • Health-related quality of life • deep surgical site infection • Re-operation • Amputation • Functional outcomes • Partial Flap failure • Complete flap failure

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	Important: • Length of hospital stay • Superficial wound infection • Return to normal activities 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. If cohorts are used these must consider all the key confounders chosen by the GDG.

6.9.3 Clinical evidence

We searched for randomised controlled trials comparing immediate cover of open fractures at the time of early debridement and cover delayed by approximately 1,3, 7 or more than 7 days. One eligible RCT was found[7], but the population in this study was regarded as unrepresentative of people with more severely contaminated open fractures, so cohort studies were also sought. Nine eligible cohort studies were found [16,32,40,42,55,57,76,96,99,100] and overall, these covered a more diverse range of the levels of wound contamination expected in people with open fractures.

No studies compared immediate cover with one day, but two[32,33] [40,41] compared immediate cover with 3 days (2 to 3 days and 4.4 days), two[7,99,100] compared immediate cover with 7 days (5.9 and 7 days, respectively) and one[42] compared immediate cover with more than 7 days (9.3 days). In addition, one compared more than 7 days with 3 days and less[56,57], one compared less than 3 days with more than 3 days [96], one compared 1 to 7 days with more than 7 days[16], one compared 5 days and less with more than 5 days [55] and one [75,76] looked at timing as a continuous variable and so did not compare discrete groups.

The studies' methodologies are summarised in Table 60, and evidence from these studies are summarised in the clinical evidence summary in Table 61 to Table 67. See also the study selection flow chart in Appendix D, study evidence tables in Appendix G, forest plots in Appendix I, GRADE tables in Appendix H and excluded studies list in Appendix J.

Summary of included studies

Table 60: Summary of studies included in the review for timing of cover

Study and type	Fracture location and grade and patient characteristics	Intervention	comparison	Comments
Benson 1983[7], RCT	Information on the type of fixation was unclear. There was no formal grading system used. The surgeons subjectively assessed the wounds to be clean (no visible signs of contamination, n=14), slightly	Immediate cover (after debridement carried out at mean of 5.4 hours) (with 5 days of cefazolin or clindamycin[a])	Delayed cover at mean of 5.9 days after injury (with 5 days of cefazolin or clindamycin[a])	Restricted inclusion criteria: no wounds which were open for >24 hours, wounds contaminated by river or lake water, lawnmower injuries, high velocity gunshot wounds or if closure of the wound was deemed physically impossible. The randomization was done by 'a random selection of numbers', there were no reports of

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Study and type	Fracture location and grade and patient characteristics	Intervention	comparison	Comments
	dirty/contaminated (small amounts of clothing or other foreign material in the superficial tissues, n=42), moderately dirty (more foreign material, particularly grass or dirt deep in the open fracture area, n=15) and grossly dirty (open fractures with ground in dirt, grass or other foreign material, and/or muscle damage with necrosis, n=11). Fracture site was described as lower extremities (n=44), upper extremities (n=31) and a combination of both upper and lower extremities (n=3).			allocation concealment, and there were very limited baseline characteristics given for each group. Thirteen moderately or grossly dirty wounds were present in each of the early and delayed cover groups, and these groups had very similar time from injury to debridement (5.4[3.5] hours for early and 5.5[3.1] hours for late). Internal fixation was used in 41% of the early cover patients and 34% of the delayed cover patients. The study was described as double blind, and although this was true for the antibiotic comparison, this would not have been possible for the main comparison of early versus delayed cover, and it is also unclear if this included assessor blinding. There was some attrition, with 4/40 lost to follow-up in the early group and 2/38 lost to follow-up in the late group. Reasons for loss to follow-up were not given, and as these rates were more than the deep infection event rate they may present a high risk of attrition bias. Overall risk of bias was therefore very high.
Gopal 2004[32,33] Retrospective cohort	34 grade IIIB and IIIc severe open tibial fractures. Age: adults, 48 years, children, 13 years; Gender: 25 men/4 women	Immediate closure in a single fix and flap procedure, comprising radical debridement, skeletal stabilisation (normally internal) with a muscle flap.	Delayed closure: Immediate debridement and internal fixation with soft tissue cover between 48-72 hours after injury.	No multivariate analysis (MVA), but both groups were adequately similar for age and grade of fracture.

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Study and type	Fracture location and grade and patient characteristics	Intervention	comparison	Comments
	and 2 boys and 2 girls	Cover always completed in <24 hours after injury	Another group with cover at >3 days was not included as this could have included people with cover ranging up to >7 days.	
Hertel 1999[40] prospecti ve cohort	29 people with Grade IIIb and IIIc open lower leg fractures; Mostly car or motorbike accidents, but some train, gunshot and industrial accidents; age: 28/27; male79%/80%	Definitive fixation and immediate cover - adequate debridement, definitive skeletal stabilisation in 11 and preliminary external stabilisation in 3. Immediate soft tissue coverage was done with a local muscle flap in 8 and a free muscle flap in 7. In 5 a primary cancellous bone graft was added.	Delayed cover at a mean of 4.4 days. This group had staged fixation and staged cover – primary debridement, mostly preliminary stabilisation with an external fixator and soft tissue reconstruction between days 1 and 9 after injury. Soft tissue coverage was achieved with a local muscle flap in 7 and a free muscle flap in 8. Definitive skeletal stabilisation was obtained immediately in 3, at the time of cover in 1 and at a third intervention in 12 patients. No cancellous bone graft was used.	No MVA, but both groups were adequately similar for age and grade of fracture. They were also similar for sex, type of trauma, associated general injuries, type of fracture, arterial lesions, tendon ruptures and soft tissue reconstruction.
Hohman 2007[42] Retrospe ctive cohort	95 patients aged 30.2/33.4 years with open tibial fractures. 38 grade I, 35 grade 2, 7 grade 3a; 15 gunshot fractures to tibial shaft	Primary cover (mean 7.2 hours after admission), done at Helen Josef Hospital by a single surgeon. Fracture stabilised with unreamed AO nail after early initial debridement and primary wound closure.	Delayed cover at mean 9.3 days post debridement (which was at about 5 hours after injury) done at Johannesburg hospital by one surgeon. Early surgical debridement and stabilisation in a plaster splint. Repeat debridement at	No MVA, but both groups were adequately similar for age and grade of fracture and other potentially confounding variables that were measured

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Study and type	Fracture location and grade and patient characteristics	Intervention	comparison	Comments
			48 hours with closure if possible (but mean cover was at 9.3 days after injury) and unreamed AO nail inserted for fracture stabilisation.	
Liu 2012[56,57] Retrospective cohort	103 patients with 105 open limb fractures. Mean age was approximately 40 years; M:F was 91:14.	≤3 days to soft tissue cover. Resuscitation, debridement and fracture stabilisation in theatre. Serial debridement in theatre until wound vitality was adequate, then free-flap transfer. IV antibiotics given from presentation to at least 72 hours post wound closure.	4-7 days and >7 days delay to soft tissue cover. However in the MVA the analysis covered ≤3 days to >14 days. Resuscitation, debridement and fracture stabilisation in theatre. Serial debridement in theatre until wound vitality was adequate, then free-flap transfer. IV antibiotics given from presentation to at least 72 hours post wound closure.	In the MVA the analysis covered ≤3 days to >14 days. This may represent an outcome reporting bias. MVA adjusted for age, gender, smoking, ISS (injury severity score), GA (Gustilo and Anderson score) and ASA (American Society of Anaesthesiology) scores, injury location, flap type, method of fracture fixation and use of NPWT.
Webb 2007[96] Retrospective cohort	n=105 patients with Gustilo type-IIIA-C tibial open fractures, who underwent limb salvage	≤3 days to soft tissue cover. Most cover was performed with free or rotational muscle flaps; only 3 were performed with fasciocutaneous flap but group make-up unclear. No other details of care given in the paper	>3 days to soft tissue cover. Most cover was performed with free or rotational muscle flaps; only 3 were performed with fasciocutaneous flap but group make-up unclear. No other details of care given in the paper	Not well reported but MVA adjusted for time to debridement, sociodemographic variables, injury characteristics and severity (all available injury descriptors). Hence all likely confounders were almost certainly well-covered. However, the requirement of 10 events per variable in the MVA was clearly not met.
D'Alleyrand 2014[16] Retrospective cohort	69 patients with tibial (n=45), plateau (n=17) and pilon (n=12) open fractures	1-7 days to soft tissue cover. No other details of care given in the paper	>7 days to soft tissue cover. No other details of care given in the paper	Adjustment for confounding carried out by propensity scores calculated for propensity to go into each of the two soft tissue cover groups. It included: gender, age, ISS, zone of injury, mechanism

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Study and type	Fracture location and grade and patient characteristics	Intervention	comparison	Comments
				of injury, use of negative wound pressure therapy, use of antibiotic bead pouch and rotational nature of the flap. Further analysis using logistic regression included fracture classification. The results were not analysed by group; rather the effect of one extra day of flap delay on the odds of infection was looked at for the 1-7 day period and the >7 day period separately.
Pollak 2010[75,76]	315 patients with high energy lower extremity injury and open fracture	The time to soft tissue cover was one of the covariates in the MVA. All patients were managed by a protocol that included aggressive fracture debridement, antibiotic coverage, fracture stabilisation, repeat debridement and early soft-tissue coverage		Not well reported but confounders adjusted in the MVA included time to debridement, sociodemographic variables, health habits and fracture classification. However, the requirement of 10 events per variable in the MVA was possibly not met.
Wei 2014[99,100]	49 Grade IIIA and B open tibial fractures. Age: 36-43 years; About 70% male.	Primary closure with internal fixation versus delayed closure with internal fixation with cover at about 1 week		No MVA but both groups were adequately similar for age and grade of fracture and other non-key confounders.
Lack, 2015[55] Retrospective cohort	137 patients with Gustilo Type II a, b and c open tibial fractures; Type b and c in 47% of those not infected and 50% of those infected; mean age (non-infected/infected) 40/40.5; mean ISS 10/9.5	Definitive fracture fixation and wound management followed basic standard principles. Diaphyseal fractures were treated with intramedullary fixation. Those with intra-articular extension or at the very distal or proximal metaphysis were usually treated with plate and screw fixation. Those with intra-articular extension or at the very distal or proximal metaphysis were usually treated with plate and screw fixation. The standard regimen for antibiotic prophylaxis was Cefazolin (128/137). Other antibiotics used were clindamycin or vancomycin. Temporizing external fixation was used when necessary and definitive fixation was performed as soon as the patient and wound were amenable. Wounds were closed when possible and those not able to be closed were treated with negative		Adjustment for age, Gustilo-Anderson classification, smoking, presence of diabetes, time to debridement and time to cover

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Study and type	Fracture location and grade and patient characteristics	Intervention	comparison	Comments
		pressure dressings pending definitive wound coverage.		

(a) As the type of antibiotic made no difference to outcome, results in this review are not subgrouped for antibiotic type.

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Table 61: Clinical evidence summary: timing of cover – Immediate versus 3 day (actual comparators were 1-3 days and 4.4 days)

Outcome	Number of studies (participants)	Imprecision	GRADE rating	Absolute difference	Control event rate (per 1000)
Deep infection	2 (n=51)	Very serious imprecision	VERY LOW	200 fewer per 1000 (from 380 fewer to 10 fewer)	200
Flap failure (total or partial)	1(n=28)	Unclear	VERY LOW	Not estimable	0
Number of further treatments	1(n=29)	Only range given for each group so imprecision unclear	VERY LOW	-2.3 operations	3.9 operations
Return to weight bearing	1(n=29)	Only range given for each group so imprecision unclear	VERY LOW	-4.6 months	9.6 months
Amputation	1(n=29)	Unclear	VERY LOW	Not estimable	0

Table 62: Clinical evidence summary: timing of cover – Immediate versus 7 days (actual comparator was 6 days) [RCT data]

Outcome	Number of studies (participants)	Imprecision	GRADE rating	Absolute difference	Control event rate (per 1000)
Deep infection	1 (n=76)	Very serious	VERY LOW	49 fewer per 1000 (from 55 fewer to 47 more)	56

Table 63: Clinical evidence summary: timing of cover – Immediate versus 7 days (actual comparator was 6 days) [cohort data]

Outcome	Number of studies (participants)	Imprecision	GRADE rating	Absolute difference	Control event rate (per 1000)
Deep infection	1 (n=49)	Very serious	VERY LOW	87 fewer per 1000 (from 207 fewer to 254 more)	273
Amputation	1 (n=49)	Very serious	VERY LOW	99 fewer per 1000 (from 132 fewer to 194 more)	136

Table 64: Clinical evidence summary: timing of cover – Immediate versus more than 7 days (actual comparator was 9.3 days)

Outcome	Number of studies (participants)	Imprecision	GRADE rating	Absolute difference	Control event rate (per 1000)
Time to discharge	1 (n=95)	Only range given for each group so imprecision unclear	VERY LOW	-6.8 days	15.4 days

Outcome	Number of studies (participants)	Imprecision	GRADE rating	Absolute difference	Control event rate (per 1000)
Infection (not specified if deep)	1(n=95)	Very serious	VERY LOW	23 more per 1000 (from 16 fewer to 443 more)	20 per 1000

Table 65: Clinical evidence summary: timing of cover – 3 days or less versus more than 7 days (actual comparator was more than 14 days)

Outcome	Number of studies (participants)	Imprecision	GRADE rating	Adjusted OR (95% CIs) for <3 days compared with >14 days (Absolute difference not calculable)	Control event rate (per 1000)
Deep infection	1 (n=103)	No serious imprecision	VERY LOW	0.14(0.028 -0.641)	NA
Osteomyelitis	1 (n=103)	Serious imprecision	VERY LOW	0.095(0.01-0.90)	NA
Higher flap take-backs	1 (n=103)	Serious imprecision	VERY LOW	0.087(0.009-0.84)	NA

Table 66: Clinical evidence summary: timing of cover – 5 days or less versus more than 5 days

Outcome	Number of studies (participants)	Imprecision	GRADE rating	Adjusted OR (95% CIs) for >14 days compared with <3 days (Absolute difference not calculable)	Control event rate (per 1000)
Deep infection	1 (n=137)	No serious imprecision	VERY LOW	0.135(0.037-0.394)	NA

Table 67: Clinical evidence summary: timing of cover – 1-7 days versus more than 7 days (timing used as continuous variable in actual analysis)

Outcome	Number of studies (participants)	Imprecision	GRADE rating	Adjusted OR (95% CIs) for each extra day delay (Absolute difference not calculable)	Control event rate (per 1000)
Deep infection (subgroup with cover between 1-7 days)	1 (n=63)	Very serious imprecision	VERY LOW	0.94(0.65-1.36)	NA
Deep infection (subgroup with cover at >7 days)	1 (n=45)	Serious imprecision	VERY LOW	1.155(1.03-1.29)	NA

Narrative results for outcomes where no data were reported.

Days in hospital and total number of surgical procedures

No data were presented for relevant outcomes, but Webb 2007[96] reported that: 'timing of soft-tissue coverage (3 days or less after the injury as compared with more than 3 days after the injury had no apparent effect on clinical or functional outcome'. Outcomes investigated of relevance to this review's protocol included days in hospital and total number of surgical procedures.

Infection

After MVA adjustment, Pollak 2010[75,76] indicated that the effect of timing of cover was not an independent predictor of the development of serious infection requiring rehospitalisation. The mean (unadjusted) time from debridement to cover of those with major infection was 4.4 (3.3) days and 5.7 (4.9) days for those without major infection. This lack of a clear effect may relate to the relative homogeneity of cover time across the sample.

6.9.4 Economic evidence

Published literature

No relevant economic evaluations were identified.

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

New cost-effectiveness analysis

This area was prioritised for economic analysis.

Please see section 6.6.4 for a summary of this analysis.

6.9.5 Evidence statements

Clinical

Immediate versus 1 day

No evidence was found for this comparison.

Immediate versus 3 days

Very low quality evidence from two cohort studies comprising 51 people with open fractures showed that immediate cover had clinically important benefits in terms of deep infection compared with cover at 3 days, with very serious imprecision.

Very low quality evidence from one cohort study comprising 29 people with open fractures showed that immediate cover had clinically important benefits in terms of the number of further treatments compared with cover at 3 days, with unclear imprecision.

Very low quality evidence from one cohort study comprising 29 people with open fractures showed that immediate cover had clinically important benefits in terms of return to weight-bearing compared with cover at 3 days, with unclear imprecision.

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Very low quality evidence from one cohort study comprising 29 people with open fractures showed that immediate cover and cover at 3 days did not differ in terms of amputation, with unclear imprecision.

Very low quality evidence from one cohort study comprising 29 people with open fractures showed that immediate cover and cover at 3 days did not differ in terms of flap failure, with unclear imprecision.

Immediate versus 7 days

Very low quality evidence from one RCT comprising 78 people with open fractures showed that immediate cover had clinically important benefits in terms of deep infection compared with cover at 7 days, with very serious imprecision.

Very low quality evidence from one cohort study comprising 80 people with open fractures showed that immediate cover had clinically important benefits in terms of deep infection compared with cover at 7 days, with very serious imprecision.

Very low quality evidence from one cohort study comprising 80 people with open fractures showed that immediate cover had clinically important benefits in terms of amputation compared with cover at 7 days, with very serious imprecision.

Immediate versus more than 7 days

Very low quality evidence from one cohort study comprising 95 people with open fractures showed that immediate cover had clinically important benefits in terms of time to discharge compared with cover at more than 7 days, with unclear imprecision.

Very low quality evidence from one cohort study comprising 95 people with open fractures showed that immediate and delayed cover did not differ in terms of unspecified infection, with unclear imprecision.

Less than 3 days versus more than 7 days

Very low quality evidence from one cohort study comprising 103 people with open fractures showed that cover at 3 days or less had clinically important benefits in terms of deep infection compared with cover at more than 14 days, with no serious imprecision.

Very low quality evidence from one cohort study comprising 103 people with open fractures showed that cover at 3 days or less had clinically important benefits in terms of osteomyelitis compared with cover at more than 14 days, with serious imprecision.

Very low quality evidence from one cohort study comprising 103 people with open fractures showed that cover at 3 days or less had clinically important benefits in terms of a higher rate of flap take-backs compared with cover at more than 14 days, with serious imprecision.

Less than 5 days versus more than 5 days

Very low quality evidence from one cohort study comprising 137 people with open fractures showed that cover at 5 days or less had clinically important benefits in terms of deep infection compared with cover at more than 5 days, with no serious imprecision.

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Between 1 and 7 days versus more than 7 days (timing used as continuous variable in actual analysis)

Very low quality evidence from a subgroup of one cohort study comprising 63 people with open fractures that were covered between 1 and 7 days showed that each day of delay in cover does not make a clinically important difference to the odds of deep infection, with very serious imprecision.

Very low quality evidence from a subgroup of one cohort study comprising 45 people with open fractures that were covered after 7 days showed that each day of delay in cover does not make a clinically important difference to the odds of deep infection, with serious imprecision.

Economic

An original cost analysis showed that covering the open fracture within a shorter timeframe is more costly than delaying the intervention. This analysis was assessed as directly applicable with potentially serious limitations.

6.9.6 Recommendations and link to evidence

Recommendations	**13. Surgery to achieve debridement, fixation and cover of open fractures of the long bone, hindfoot or midfoot should be performed concurrently by consultants in orthopaedic and plastic surgery (a combined orthoplastic approach).** **14. Perform debridement:** • **immediately for highly contaminated open fractures** • **within 12 hours of injury for high-energy open fractures (likely Gustilo–Anderson classification type IIIA or type IIIB) that are not highly contaminated** • **within 24 hours of injury for all other open fractures.** **15. Perform fixation and definitive soft tissue cover:** • **at the same time as debridement if the next orthoplastic list allows this within the time to debridement recommended in recommendation 14, or** • **within 72 hours of injury if definitive soft tissue cover cannot be performed at the time of debridement.** **16. When internal fixation is used, perform definitive soft tissue cover at the same time.**
Relative values of different outcomes	**Multidisciplinary team (MDT)** Critical outcomes were mortality, health-related quality of life, deep surgical site infection, amputation, flap failure, and time to definitive cover. Important outcomes were unplanned complexity of soft tissue cover, length of hospital stay, further unplanned surgery and return to normal activities. **Timing of debridement** Critical outcomes were mortality up to 12 months, amputation, deep surgical site infection, health-related quality of life, re-operation (unplanned), return to normal activities and functional outcomes. Length of hospital stay was considered as an important outcome.

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	Staging of fixation and/or cover Critical outcomes were mortality, health-related quality of life, deep surgical site infection and flap failure. Important outcomes were length of hospital stay, further unplanned surgery and return to normal activities. **Timing of cover** Critical outcomes were mortality, health-related quality of life, deep surgical site infection, re-operation, amputation, functional outcomes, partial flap failure and complete flap failure. Important outcomes were length of hospital stay, superficial wound infection and return to normal activities.
Trade-off between clinical benefits and harms	**MDT** The evidence showed clinically important benefits for a combined orthoplastic approach in terms of less flap failure and less deep infection, compared with an approach where a plastic surgeon was not initially present. No relative harms for a combined orthoplastic approach were identified. **Timing of debridement** Overall, the evidence demonstrated that there were clear benefits from early debridement in terms of lower rates of amputation. There were clear benefits for early debridement in terms of deep infection in two studies, but harm in one study and equivocal results in the other 5 studies. Methodological or population-based factors that might explain these differing results could include differing debridement methods across studies, the timing and type of antibiotics given and differences in fixation. Other outcomes were not evaluated in the studies. Overall, the greater importance of the outcome of amputation over deep infection meant that early debridement was regarded as offering more benefits than harms. **Staging of fixation and/or cover** The evidence showed a clinical benefit for definitive fixation and *immediate* cover (over definitive fixation and *delayed* cover and also over *staged* fixation and *delayed* cover) in terms of deep infection, flap failure, further unplanned surgery, and return to normal weight bearing activity. No harms from immediate cover were observed. **Timing of cover** **Immediate versus 1 day** No evidence was found for this comparison **Immediate versus 3 days** There were clinically important benefits for immediate cover (compared with cover at approximately 3 days) in terms of deep infection, number of further treatments and return to weight-bearing. No harms from immediate cover were reported. Hence immediate cover appears to be more clinically effective than cover at 3 days. **Immediate versus 7 days** There were clinically important benefits for immediate cover (compared with cover at approximately 7 days) in terms of deep infection. No harms from immediate cover were reported. Hence immediate cover appears to be more clinically effective than cover at 7 days. **Immediate versus more than7 days**

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	There were clinically important benefits for immediate cover (compared with cover at >7 days) in terms of time to discharge. No benefits in terms of infection were found for immediate cover. No harms from immediate cover were reported. Hence immediate cover appears to be more clinically effective than cover at >7 days. **Less than 3 days versus more than 7 days** There were clinically important benefits for earlier cover in terms of deep infection, osteomyelitis and flap take backs. No harms from earlier cover were reported. Hence earlier cover appears to be more clinically effective than cover at >7 days. **Less than 5 days versus more than 5 days** There were clinically important benefits for earlier cover in terms of deep infection. No harms from earlier cover were reported. Hence earlier cover appears to be more clinically effective than cover at >5 days. **Other data** One study showed an increase in risk of deep infection with increasing delay for cover done from >7 days onwards, but no effect when cover was done from 1-7 days. Two other studies also did not show any effect of increasing delay on the risk of deep infection, at any period. These studies were, however, characterised by a relatively small range of cover times.
Economic considerations	No published economic evaluations were identified for any of these questions; however, it was identified as a priority area for economic modelling. Three cost analyses were developed to help quantify the cost implications of: • debridement at different times, with and without a plastic surgeon in theatre; • the additional theatre lists required to perform soft tissue cover at different times; • the trade off in costs between the more efficient use of surgeon time with separate specialty lists and the reduced theatre preparation time when multiple procedures are performed in a theatre session. These analyses looked at the cost implications of staffing changes as well as the costs incurred from treating deep infection, amputation and the long-term costs of prosthetics. The risks of adverse events (deep infection and amputation) were derived from the guideline clinical reviews. This model was assessed as being directly applicable with potentially serious limitations. Please see Appendix L for more detail on the analyses. **Timing of debridement and presence of plastic surgeon** The first analysis showed that as the time to debridement increased, the overall costs increased due to the increase in complications when debridement is performed later. The increased staff cost for early debridement was relatively small as only a proportion of patients would have surgery performed out of hours. This cost was far outweighed by the increasing cost of complications. The analysis also showed similar results for the presence of a plastic surgeon at debridement. Although there was an increased staff cost for a plastics consultant and registrar to be present in theatre, the reduction in complications was large enough to outweigh the additional staffing cost and actually make the strategy cost-saving overall for all timings of debridement. When considering the uncertainty around the results, of particular concern was the relative risk of deep infection when the plastic surgeon is present, which was from a

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very low quality study[66]. This was a key parameter in the analysis; however it was subject to a threshold analysis to find the value at which the strategy becomes cost neutral. It is important to note that this parameter had a large confidence interval (0.047 – 3.037) and therefore the RR used in the analysis and in turn the impact on results is uncertain. However, it was felt by the clinical experts that there are benefits that have not been taken account of in this analysis such as the detriment to quality of life. Therefore, this relative risk could increase further, resulting in a more costly approach if the plastic surgeon is present, yet still remain a *cost effective* strategy.

Timing of cover

The second analysis quantified the costs of providing cover within 1, 2, 3, 4 and 7 days. The cost of providing an 8-hour orthoplastic theatre list was estimated to be £6,035. At this cost, and using the risk estimates from the clinical review (cross ref) for the timing of cover question, the increase in staffing needed to provide more lists, to reduce time to cover, far outweighs the cost savings from reduced complications. In other words, the more lists provided, the more expensive this is.

The GDG noted that although the costs appeared high, these need to be compared to the current baseline, which was believed to be two dedicated theatre lists per week, costing a hospital an estimated £627,682 per year. This can only guarantee soft tissue cover within four days and the estimated complication cost for this is £834,056 per year.

It was recognised that having a theatre list in operation every day was not feasible, because of cost and staffing implications, thus immediate cover is not always possible. The appropriate number of lists also had to be balanced against the relatively low incidence of open fractures. The GDG felt that 3 lists per week would allow open fractures to be covered within 72 hours, and possibly less depending on the day the patient came in. This coincides with the clinical evidence stating that providing cover within 3 days had a clinical benefit.

Increasing the number of lists to three per week at an annual cost of £941,524 is estimated to reduce the cost of complications to £777,194. The overall annual costs for two and three lists per week, respectively, are £1,461,739 and £1,718,718. There is, therefore, an increase in costs overall for performing soft tissue cover within 72 hours (incremental cost of £256,979 per hospital) but this needs to be considered along with the health-related quality of life benefits that come with the reduction in complications.

The analysis estimated the mean number of patients who present to a major trauma centre (either directly or indirectly) with an open fracture requiring plastic surgery as 105. On the assumption that these surgery lists will only be used for these patients, the estimated cost per patient for two lists and three lists per week, respectively, would be £13,906 and £16,351; an increase of £2,445 per patient for the additional list. This would require a mean increase in QALYs per patient of at least 0.12 in order to be cost effective. For the estimated life years remaining of 38 years that was used in the model, this equates to a mean difference in utility of 0.003 each year. The GDG believed this to be achievable given the severe life changing complications involved. Also, taking into account the fact that this is based on the assumption that staff are only working when a patient arrives, this is a conservative estimate. In reality, the staff can perform other work that can be cancelled at short notice to accommodate any emergency arrivals. In other words, indirect populations that may also benefit from an additional list have not been included here, and therefore, cost effectiveness could be underestimated.

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Multiple theatre sessions

The third analysis aimed to quantify the costs of undertaking all stages of surgery in a single theatre session compared with multiple sessions. This showed that, when a plastic surgeon is present at debridement, performing all procedures in one session (strategy 1) was cost saving compared with staging fixation and/or cover due to the additional preparation time required for the additional theatre sessions. This analysis did not take into account the additional cost of an external fixator for staged fixation which supports the single session approach further. The GDG noted that current practice generally involves the surgical strategy whereby three theatre sessions are needed.

If definitive fixation was performed in the first session and leaving just the definitive cover for the second session (strategy 2), this would reduce costs compared with the staged fixation (strategy 3) from staff costs (and fixator device costs). However, the GDG believed from the evidence that having metal work exposed following invasive definitive fixation will increase the risk of deep infection and subsequent amputation. They believed that the costs saved overall would be lower than those shown in this analysis and agreed that this surgical strategy was not likely to be a cost effective strategy.

Summary

When considering all these analyses together, it will not always be possible to perform all the procedures in one session as this will require dedicated orthoplastic surgery lists on every day, which is unlikely to be cost effective due to the relatively low incidence of open fractures. To use these services in a cost effective way, the GDG believed that the initial debridement should be prioritised as an emergency procedure but with the less severe fractures allowing up to 24 hours for surgery to be performed. This allows for the option of an all-in-one procedure (strategy 1) to be performed if the patient arrives within 24 hours of a dedicated surgery list. For those where this cannot be achieved, temporary fixation will be required (strategy 3: debridement and temporary fixation in one session and definitive fixation and definitive cover in a second session). Within this strategy, having plastic surgeons present at debridement adds approximately £600 to the cost. However, from the first analysis, having a plastic surgeon present reduces complication costs which would partly outweigh this additional staff cost. Additionally, as some patients would receive the all in one strategy, the cost per person of the theatre strategies was likely to be an average of strategies 1 and 3, which is still less costly than current practice of strategy 4. These cost savings will also help to offset the costs from the additional theatre list.

The GDG believed that if a patient is to be given internal fixation, definitive soft tissue cover should be performed immediately after because the invasive open procedure increases the risk of deep infection if not covered immediately. This circumstance implies that if cover cannot be achieved on the same day as debridement, then staged fixation must be used so that definitive internal fixation can be delayed until a day that immediate cover can be performed. Without this staging of fixation, a dedicated orthoplastic surgery list would need to be provided every day in order to guarantee providing cover immediately after the internal fixation procedure.

The GDG believed that although staged fixation was not cost effective when considered solely as a fixation strategy, it would not be cost effective to provide an every-day orthoplastic surgery service to allow for early debridement followed immediately by definitive fixation and definitive cover. Therefore, the GDG agreed that the most likely cost effective strategy was to provide immediate debridement for highly contaminated open fractures from a combined orthoplastic team and

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	definitive soft tissue cover within 72 hours. For slightly less severe fractures (likely to be classified as type IIIA and type IIIB after debridement) immediate debridement is likely to be unnecessary and so 12 hours was agreed as the maximum delay for high energy open fractures and 24 hours was the maximum for all other open fractures. The recommendations made for debridement, along with cover within 72 hours, and a combined orthoplastic approach, mean that depending on whether the patient arrives on a day when a surgery list was in place, the patient is most likely to have only 1 or 2 procedures for the entire treatment needed (debridement, fixation, cover). These are cheaper strategies than what currently happens in practice, and could also have fewer adverse events if treatment is provided quicker. These recommendations are likely to have a cost impact from the additional theatre list being implemented. However, this may be offset by the less costly surgical strategies recommended, and also the benefit to indirect populations, which have not been taken account of here.
Quality of evidence	**MDT** Evidence was Very low quality. All outcomes had very serious risk of bias, due to a lack of randomisation and little attempt to adjust for confounding. All outcomes were seriously or very seriously imprecise except deep infection. **Timing of debridement** Evidence was all graded as Very low. All 8 studies were cohort studies, 6 of which were retrospective. All included key potential confounding variables in their meta-analyses. **Staging of fixation and/or cover** All evidence had very serious risk of bias. The RCT was limited by possible selection, performance and attrition bias. Three of the cohorts conducted a MVA, adjusting for both key confounders and other potential confounders. However, there were insufficient events per variable for adequate validity of analyses. The other 3 cohort studies did not conduct a MVA, but all had acceptable parity between groups for the key confounders. **Timing of cover** Quality of evidence was Very low. The RCT had no allocation concealment or adequate blinding, while three of the cohort studies did not contain any MVAs or purposeful matching strategies. However, in all three of these cohort studies there were no potentially confounding between-group baseline differences in the key confounders of age and fracture type. The intractable confounding in some studies, where the timing of cover was associated with another difference in surgical practice (such as staging of fixation) was noted by the GDG. **Economic model** This model was assessed as being directly applicable with potentially serious limitations. Limitations include; the analysis was a costing analysis which did not incorporate quality of life. Downstream costs have not been fully captured as no lifetime care costs for amputees have been included; however, inclusion of this is likely to improve cost effectiveness. Additionally; there is uncertainty about some of the inputs, no assumptions were made about mortality, assumptions were made for the estimated trend lines for the risks in the second analysis, and on the proportion of amputations post infection. Although cost effectiveness remains uncertain as effects were not included, cost effectiveness was ascertained using the costs, clinical data, and qualitative

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	judgements. The GDG felt the analysis was sufficient for the purposes of decision making.
Other considerations	**Other** All supplementary information considered by the GDG supported the evidence from the included papers. **MDT** The GDG felt that the benefits of a combined approach over a non-combined approach shown in the literature agreed with their own clinical experience, warranting a strong recommendation for an orthoplastic approach. Therefore the recommendation was based on a combination of very low quality evidence, which was analysed in the HE model and tested in a threshold analysis for the relative risk of deep infection in the cost analysis, and GDG consensus. **Timing of debridement** The GDG discussed current practice, which involves debridement within around 6 hours. The GDG felt that for highly contaminated open fractures, debridement should be immediate. It was also noted that injuries in an aquatic or marine environment are likely to be highly contaminated although they may not look like it. The GDG further discussed one of the included papers[45] that had looked at the relationship between infection rates and time to debridement at different levels of contamination. This showed that at the lower grades of contamination the increased risk of infection per unit of delay was small and therefore, did not justify immediate debridement in those cases, due to issues such as pressure on theatre time. However, in the higher grades of contamination, the effect of increased delay on increased infection rates was very strong, warranting immediate debridement. Higher grades of contamination were believed to be more likely with visible macroscopic contamination and agricultural and aquatic contamination. Overall, findings do suggest that debridement carried out as early as possible in highly contaminated open fractures may be important in reducing amputation rates. In less highly contaminated fractures, the need for immediate debridement is reduced. The GDG originally put Gustilo-Anderson grades as criteria for the timing of debridement. However, the GDG reflected that Gustilo-Anderson grades are only validated as post-debridement classifications, and therefore, cannot be used prior to debridement to decide on debridement timing. It was felt that the term 'high energy' in place of type IIIA and B open fractures would be sufficient to ensure that this group was characterised as those with severe trauma but without excessive contamination. In terms of the GDG's assessment of the model results, there was discussion around the RR of deep infection if a plastic surgeon is present. The GDG were happy that plastic surgeons could reduce the risk of deep infection by as much as the paper implied, however, the actual relative risk may be higher given the large confidence interval. In particular the orthopaedic surgeons felt they can perform debridement much more effectively with the help of a plastic surgeon. The study used was the only one identified from the clinical review, and the fact that the cost analysis showed it was cost saving gives a fair amount of leeway for uncertainty in the data. The GDG felt that recommendation on combined orthoplastic approach would not be controversial because an orthoplastic approach is the way that current practice is

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	heading anyway due to the BOAST4 guidelines. Also, the Major Trauma Centre service specification includes plastic surgery, but services can be variable. Thus the GDG felt that this recommendation emphasises what is already expected of a fully operational MTC service and would hope to improve standardisation. There are benefits for the plastic surgeon also, as they can plan the soft tissue cover better by being present at debridement, so it was felt strongly by the group that this rec will be supported by both orthopaedics and plastics. **Staging of fixation and/or cover** The GDG felt the evidence supported the use of cover immediately after fixation, and that this fixation should ideally be non-staged. **Timing of cover** The evidence for the timing of cover question was expected to agree with the evidence for the staging of cover question, as of course staging implies a later timing of cover. Despite this overlap, the additional question on timing of cover was felt by the GDG to be important, as it helped to provide clear indications of the maximal acceptable delay from injury to cover, which was not derived from the staging review. For example, although the staging review showed that non-staged fixation and cover were optimal, it did not give any indications of the maximal acceptable time to cover if staging of fixation, and therefore, delayed cover was clinically indicated. The GDG agreed that the data from the timing of cover question showed that in such a case, the maximum delay to cover should be 72 hours, except in exceptional circumstances. The GDG recognised that there will be clinical circumstances where definitive fixation/cover will not be possible within 72 hours; for instance multi-injury patients requiring organ support in the ITU. The intractable confounding in some studies, where the timing of cover was associated with another difference in surgical practice (such as staging of fixation) was noted by the GDG.

~~6.10 Definitive dressings after debridement~~

~~6.10.1 Introduction~~

~~A fracture is 'open' when a broken bone is exposed through the skin. These fractures present a high risk of infection due to the open wound and wound contamination that may be present. Open fractures require immediate treatment and an operation is often required to clean the area of the fracture. This is called wound debridement or excision and involves the surgical cleaning of the wound of foreign material, such as dirt or clothing, as well as non-viable soft tissue. An important aspect of infection control is the dressing of the wound both prior to and post debridement.~~

~~6.10.2 Review question: What is the most clinically and cost effective temporary dressing or wound therapy in open fractures after wound excision or surgical debridement?~~

~~For full details see review protocol in Appendix C.~~

~~Table 68: PICO characteristics of review question~~

~~Population~~	~~Children, young people and adults with an open fracture after a traumatic incident~~
~~Intervention(s)~~	~~• Antibiotic dressing~~ ~~• Negative pressure wound therapy (NPWT)~~ ~~• Negative pressure and antibiotic dressing~~ ~~• Standard dry/saline/antiseptic dressing~~

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Comparison	To each other
Outcomes	Critical: • Function • Health-related quality of life • Deep infection • Wound infection • Re-operation/amputation • Wound healing by 6 weeks • Tissue necrosis Important: • Return to normal activities
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.

6.10.3 Clinical evidence

Two RCTs were included in the review;[80,90] these are summarised in Table 69 below. Evidence from these studies is summarised in the GRADE clinical evidence summary in Table 70. See also the study selection flow chart in Appendix D, study evidence tables in Appendix G, forest plots in Appendix I, GRADE tables in Appendix H and excluded studies list in Appendix J.

Evidence was found for one comparison; NPWT compared with standard dressing.

Table 69: Summary of studies included in the review

Study	Intervention and comparison	Population [All grading is by the Gustilo and Anderson classification]	Outcomes	Comments
Rasool 2013[80]	NPWT versus saline-soaked dressing	n=50 Children, young people and adults with grade II, IIIA, IIIB open tibial fractures	• Wound healing	• Conducted in Pakistan • RCT
Stannard 2009[90]	NPWT versus saline wet to moist dressing	n=58 Adults with severe open fractures (heavily contaminated grade II/IIIA, severe soft tissue injury grade IIIA, all grade IIIB and IIIC)	• Quality of life • Deep infection • Wound healing • Length of stay in hospital	• Conducted in United Kingdom • RCT

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~~Table 70: Clinical evidence summary: NPWT compared with standard dressing for open fractures after debridement~~

~~Outcome~~	~~Number of studies (number of participants)~~	~~Imprecision~~	~~GRADE RATING~~	~~Absolute difference~~	~~Control event rate (per 1000)~~	~~Control event rate for continuous outcomes~~
~~Deep infection at 11 weeks~~	~~1 (n=58)~~	~~Serious~~	~~VERY LOW~~	~~246 fewer per 1000 (from 52 fewer to 292 fewer)~~	~~304 per 1000~~	~~NA~~
~~Wound healed within 30 days~~	~~1 (n=50)~~	~~No serious imprecision~~	~~LOW~~	~~463 more per 1000 (from 156 more to 905 more)~~	~~520 per 1000~~	~~NA~~
~~Quality of life at 3 months~~	~~1 (n=58)~~	~~Serious~~	~~VERY LOW~~	~~MD 11.4 higher (2.67 to 20.13 higher)~~	~~NA~~	~~32.4~~

Narrative review of results not suitable for analysis in GRADE

NPWT versus standard dressing

Quality of life (very high risk of bias)

One study[90] with 58 participants reported full results for the SF-36 physical component at 3 months and these are in Table 70. This study also reported no significant difference between NPWT and standard dressing for the SF-36 physical component at 12 months.

The same study reported no significant difference between the two groups in the SF-36 mental health component at 3 or 12 months.

Wound healing (very high risk of bias)

One study[90] with 58 participants reported time taken for wounds to reach Gustilo and Anderson grade A and so be ready for closure. The mean time for the NPWT group was 4 days (range 2-11 days) and the mean time for the standard dressing group was 3.2 days (range 2-9 days).

Length of stay in hospital (very high risk of bias)

One study[90] with 58 participants reported mean length of stay in hospital. The mean length of stay was 9.5 days for the NPWT group and 11.7 days for the standard dressings group. No measure of spread was reported for these data.

6.10.4 Economic evidence

Published literature

No relevant economic evaluations were identified.

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

Unit costs

Table 71: Intervention costs

Dressing type	Description	Cost	Source
Antibiotic beads	20 beads containing gentamicin	£132	NHS Supply Chain[3]
NPWT	Large dressing with port, large canister and use of a pump system [a]	£66	NHS Supply Chain
Negative pressure and antibiotic dressing	NPWT with 20 antibiotic beads [b]	£198	NHS Supply Chain
Standard dry/saline/antiseptic dressing	Dry dressing [c]	£0.56	SP Services [d]
	Saline dressing [e]	£1.62	SP Services
	Antiseptic dressing [f]	£3.93	SP Services

(a) See Table 72 below for further detail
(b) £132+£66
(c) Sterile dressing, 275 mmx200 mm, high specification bandage. £80.35 for a pack of 144.
(d) A supplier used by the East Midlands Ambulance Service
(e) Dry dressing plus 200 ml of sodium chloride 0.9% w/v at £2.65 for a 500 ml bottle.

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(f) Antimicrobial dressing, 4.5 inchesx4.1 yards, contains polyhexamethylene biguanide. £201.95 for pack 60 plus dry dressing.

Table 72: Negative pressure pump systems for non-disposable negative pressure dressings

Equipment type	Unit cost[b]	Source
Large gauze dressing with port	£30.60	NHS Supply Chain [3]
Re-usable portable pump system[a]	£5.46	NHS Supply Chain
Large disposable canister	£30	NHS Supply Chain
Total	£66	

(a) £5,455, assumed lifespan of 1000 uses.

Table 73: Hospital bed day cost

Bed day type	Cost per day	Source
Excess bed day[a] from Intermediate Foot Procedure for Trauma	£252	HRG: HA33Z, Trauma and Orthopaedics. NHS Reference costs 2012-2013[20]

(a) Excess bed day on a trauma ward for the HRG associated with the debridement of an open tibial fracture.

6.10.5 Evidence statements

Clinical

NPWT versus standard dressing

Very low quality evidence from 1 RCT comprising 58 participants showed that NPWT was clinically beneficial relative to standard dressing in terms of deep infection at 11 weeks, with serious imprecision.

Low quality evidence from 1 RCT comprising 50 participants showed that NPWT was clinically beneficial relative to standard dressing in terms of wound healed at 30 days, with no serious imprecision.

Very low quality evidence from 1 RCT comprising 58 participants showed that NPWT was clinically beneficial relative to standard dressing in terms of quality of life at 3 months, with serious imprecision.

Economic

No relevant economic evaluations were identified.

6.10.6 Recommendations and link to evidence

Recommendations	17. Consider negative pressure wound therapy after debridement if immediate definitive soft tissue cover has not been performed.
Relative values of different outcomes	Critical outcomes were: health-related quality of life; deep (bone) infection and wound, the primary purpose of these dressings is to prevent infection; unplanned re-operation or amputation; function, wound healing and tissue necrosis. Return to normal activities was considered to be important but not critical as it is a proxy for function.
Trade-off between clinical benefits and harms	There were clinically important benefits for NPWT relative to standard dressing in terms of deep infection and wound healing. There were also clinically important benefits for NPWT relative to standard dressing in the SF-36 physical component at 3 months. However, there was no significant difference at 12 months, and there were no significant differences in the SF-36 mental health component at either 3 or

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	~~12 months. One paper reported incomplete data on time taken for wounds to heal ready for closure and length of stay in hospital, and both outcomes favoured NPWT.~~
~~Economic considerations~~	~~No economic evidence was identified for this question.~~ ~~NPWT has an increased cost compared with standard dressings and antibiotic dressings due to the need for a pump system and disposable canisters required to collect the fluid produced by the wound. The evidence for NPWT compared with standard dressings has shown a reduction in the risk of deep infection, which can cause increased costs due to further surgical procedures and length of hospital stay. Deep infection also causes a reduction in quality of life for the patient and it can also lead to amputation if the infection is severe. This incurs further costs and reduces the patient's quality of life further. The GDG believed that the additional cost of NPWT was likely to be offset by the costs saved by the reduced risk of deep infection as well as the reduced length of stay. NPWT was therefore considered to be cost effective in comparison with other dressings following debridement.~~ ~~There was no evidence for NWPT used in combination with antibiotic dressings and given the large increase in cost for antibiotic beads the GDG could not recommend this due to a lack of evidence.~~
~~Quality of evidence~~	~~All evidence was graded either Low or Very low quality. This was due to risk or bias and imprecision. Risk of bias was very serious for all outcomes due to a lack of allocation concealment, or a lack of patient, healthcare practitioner and assessor blinding. There was serious or very serious imprecision for most outcomes as well.~~ ~~The outcomes with incomplete data in the narrative review were all at very high risk of bias.~~
~~Other considerations~~	~~While the GDG did consider NPWT to be the most effective dressing, the imprecision of the studies were too high for a stronger recommendation. The Wound management of Open Lower Limb Fractures (WOLLF) study that is currently on-going is expected to add significantly to the evidence base in this clinical area. The WOLLF study is anticipated to end in March 2017.~~

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7 Pelvic fractures

7.1 Initial destination for people with pelvic fractures

7.1.1 Introduction

Pelvic fractures can be a life-threatening injury in some people if they lead to severe bleeding within the pelvic ring. There are therefore clinical advantages for sending such patients directly to a major trauma centre (MTC). However, many people suspected of pelvic fractures do not have haemorrhage severe enough to cause haemodynamic instability, and sending such patients to a MTC may place an unnecessary burden on MTCs, increasing costs and distracting resources from those more in need. The optimal strategy is therefore unclear, and so this review aims to assess the relative clinical and cost effectiveness of sending patients with suspected pelvic fractures direct to a MTC compared with sending them to the nearest hospital, with later transfer to a MTC if necessary.

7.1.2 Review question: Is it clinically and cost effective for patients with suspected high energy pelvic or acetabular fractures to be transferred directly to a major trauma centre (MTC)?

This review sought to identify the optimal place of care for people with high energy pelvic or acetabular fractures. The question was set to gather evidence that would aid decision making regarding direct transfer to a major trauma centre compared with an indirect transfer to the nearest hospital followed by delayed transfer to a specialist centre. For full details see review protocol in Appendix C.

Table 74: PICO characteristics of review question

Population	Children, young people and adults with suspected high energy (fall from more than standing height) pelvic fractures.
Intervention	Direct transfer to a MTC/specialist centre
Comparison	Direct transfer to the nearest hospital (followed by definitive diagnosis of pelvic fracture and delayed transfer to MTC if necessary)
Outcomes	Critical: • Mortality up to 12 months • Health-related quality of life • Adverse effects (surgical complications) • Further transfer for specialist surgery • Functional outcome measures • Pain/discomfort • Return to normal activities • Psychological wellbeing • Time to definitive surgery Important: • Total hospital bed days • Blood loss
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.

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7.1.3 Clinical evidence

Summary of included studies

No relevant clinical studies were identified. See the search strategy in appendix F, study selection flow chart in Appendix D and excluded studies list in Appendix J.

7.1.4 Economic evidence

Published literature

No relevant economic evaluations were identified.

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

7.1.5 Evidence statements

Clinical

No relevant clinical studies were identified.

Economic

No relevant economic evaluations were identified.

7.1.6 Recommendations and link to evidence

Recommendations	**18.Transport people with suspected pelvic fractures:** • **to the nearest hospital if suspected pelvic fracture is the only pre-hospital triage indication** • **directly to a major trauma centre[b] if they also have other pre-hospital triage indications for major trauma.**
	In addition to this recommendation the Service delivery guideline recommends that specific geographic or patient characteristics may require intermediate care in a trauma unit within the context of a regional trauma network, and that diversion to the nearest trauma unit may be needed for life-saving interventions.
Relative values of different outcomes	Critical outcomes were mortality, health-related quality of life, adverse effects, further transfer to specialist surgery, functional outcomes and time to definitive surgery. Important outcomes were blood loss and total hospital bed days.
Trade-off between clinical benefits and harms	No clinical evidence was identified for this question. The GDG therefore made recommendations on consensus. It was felt that transporting all people **suspected** of pelvic fracture to a MTC would involve transporting large numbers of people **without** an actual pelvic fracture to a MTC. Furthermore, the majority of pelvic fractures are low-energy fragility injuries and do not require specialist pelvic management. Transporting these patients would unnecessarily inconvenience patients and unnecessarily increase pressure on the MTC. The GDG thought that only a small group of people with a suspected pelvic facture needed to go to a MTC. Of these, many would be identified in the pre-hospital setting on the basis of the other factors triggering major trauma triage (such as

b In some locations or circumstances, intermediate care in a trauma unit might be needed for urgent treatment, in line with agreed practice within the regional trauma network.

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	major haemorrhage or associated injury). Therefore, the GDG felt that patients with isolated pelvic fracture and no significant bleeding can be managed in the nearest trauma unit.
Economic considerations	No economic evidence was identified for this question. There is a trade-off involved in terms of: • travelling further to a MTC where the specialist skills are available to manage the suspected pelvic fracture, but risk compromising the patient on the journey, • versus going directly to another destination (perhaps if there are other injuries that need immediate management, such as airway difficulties) then being transferred onto a MTC, which delays the treatment of the fracture which also has risks. In terms of trying to identify the populations affected by this question, it is important to think about, out of suspected pelvic fractures, how many people would need the specialist service, and how many of these would be compromised by a journey elsewhere. It is also important to think about capacity and opportunity cost, in terms of how many and who would be displaced by suspected pelvic fractures going to a major trauma centre. The GDG felt that we want to make sure we are picking up patients with a pelvic fracture who are bleeding, as these would benefit from immediate treatment. However, most trauma patients are likely to have multiple injuries and are therefore going to be triaged to a MTC based on another indication. Therefore, the patients that this question really relates to are those patients who have not triggered that major trauma triage tool. The accuracy of the identification of the pelvic fracture is an important factor, as if this is fairly over cautious and inclusive, then this could result in the following patients being transferred to a MTC unnecessarily: • patients who turn out not have fractures (false positives), and • patients who have fractures which do not need surgical management. By being taken to the nearest hospital first, this could act as an additional triage step as patients will be imaged here as well and thus, a transfer would be agreed with the MTC only for those patients who need the specialist skills available at the MTC. However, this may delay treatment for those patients who would have benefitted from early intervention. The additional transfer will result in the cost of a transfer, however, this needs to be weighed up against the cost of the specialist staff from taking the patient straight to the MTC, and the opportunity cost of their time as they could have been treating patients which were more severe in this time. No clinical evidence was identified to inform the question of whether the cost of taking all suspected pelvic fractures to a MTC will be outweighed by the benefit to the small proportion who have the type of pelvic fracture that would benefit from specialist treatment at MTCs. The GDG concluded that the patients that had a pelvic injury that would benefit from being taken to a MTC are also likely to be polytrauma patients as we are talking about high-energy pelvic fractures, in other words; pelvic fractures in the context of blunt major trauma. Therefore, isolated fractures accompanied by injuries that are not severe enough to be taken to a MTC are likely to be managed appropriately within a trauma unit, and taking these patients directly to a MTC would have an impact on resources that would outweigh the benefit to these patients. The

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	recommendation on between hospital transfers for patients with pelvic fractures would then allow the appropriate transfer and management of these patients should they need further specialist expertise.
Quality of evidence	No evidence was identified
Other considerations	There were no additional considerations.

7.2 Timing of transfer for patients with pelvic fractures

7.2.1 Introduction

Some patients with pelvic fractures may have been transported to a local hospital, but may require transfer to a major trauma centre (MTC) because of developing haemodynamic instability, or to a specialist centre because of the need for specialist pelvic reconstruction. The timing of transfer is crucial because delays may worsen the prognosis of both haemodynamically compromised patients and those requiring reconstruction. However, very early transfer before the patient has been partially stabilised may be associated with adverse effects during transfer. This review aims to evaluate the most clinically and cost effective timing of transfer.

7.2.2 Review question: What is the most clinically and cost effective timing for transferring patients with pelvic fractures (including acetabular fractures) to tertiary or specialist services?

For full details see review protocol in Appendix C.

Table 75: PICO characteristics of review question

Population	Children, young people and adults with a pelvic or acetabular fracture following a traumatic incident.
Intervention(s)	• Early transfer to tertiary services (<6 hours) • Transfer to tertiary services between 6 and 48 hours following injury • Transfer to tertiary services between 2-7 days following injury • Transfer to tertiary services >1 week following injury
Comparison(s)	No transfer to tertiary services Comparison to each other
Outcomes	Critical: • Mortality at 1 and 12 months • Health-related quality of life • Hip replacement • Need for further surgery • Nerve injury • Sexual function (erectile dysfunction in men; pain during intercourse in women) Important: • Functional outcomes (return to normal activities)
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.

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7.2.3 Clinical evidence

No relevant RCTs, systematic reviews or cohort studies comparing different transfer times to tertiary services were identified. See the search strategy in appendix F, study selection flow chart in Appendix D and excluded studies list in Appendix J.

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

No relevant clinical evidence was identified

Economic

No relevant economic evaluations were identified.

7.2.6 Recommendations and link to evidence

Recommendations	**19. Immediately transfer people with haemodynamic instability from pelvic or acetabular fractures to a major trauma centre for definitive treatment of active bleeding.** **20. Transfer people with pelvic or acetabular fractures needing specialist pelvic reconstruction to a major trauma centre or specialist centre within 24 hours of injury.**
	This recommendation was developed by the complex fractures GDG taking into account the reviews and recommendations on pelvic haemorrhage control in this guideline (7.8.6) and interventional radiology in the Major Trauma guideline and the service delivery guidance (see chapter 6 in the Major Trauma guideline and Major Trauma services guidance for details on the development of the recommendations). In addition to this recommendation the Service delivery guideline recommends that a protocol is provided for the safe and rapid transfer of patients who need definitive specialist intervention.
Relative values of different outcomes	Critical outcomes were mortality at 1 and 12 months, health-related quality of life, hip replacement, need for further surgery, nerve injury and sexual function (erectile dysfunction in men; pain during intercourse in women). An important outcome was return to normal activities.
Trade-off between clinical benefits and harms	No evidence was found in the published literature, so recommendations were made by consensus. We have previously recommended in chapter 7.1 that patients with pelvic fractures who have not got any indications for major trauma should be initially transported to the nearest hospital or trauma unit (TU). The GDG felt that a large group of these patients will not develop haemodynamic instability or the need for specialist

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	reconstructive surgery, and so do not require later transfer to a MTC or specialist unit as the hospital/TU should be able to cater for their clinical needs. However, some patients initially transported to hospital/TUs may demonstrate haemodynamic instability and require invasive haemorrhage control techniques. The most effective haemorrhage control care is provided at MTCs and the outcomes of care are very sensitive to delays. Therefore, the GDG considered that all such patients should be transferred immediately. The potential risk, however, in transferring a patient who is severely haemodynamically unstable is that they may die during transfer. This is a difficult decision and a judgement must be made by the clinician. The GDG felt that the risk of adverse events in transfer could be reduced by facilitating rapid transfer using emergency department (ED)–to-ED systems without prior consultation between inpatient surgical teams. It is then anticipated that the receiving hospital would be able to prepare to receive and manage patients. A further group of patients will require transport to a centre for planned specialist pelvic reconstruction. The GDG believed patients undergoing delayed pelvic reconstruction experience significantly worse outcomes in terms of pain, thromboembolic events and mobility than patients undergoing early reconstruction. To enable preoperative planning and scheduling of a specialist pelvic reconstruction operating list, the GDG felt transfer should be achieved within 24 hours of injury.
Economic considerations	No economic evidence was identified for this question. The transfer described in this question is likely to be from a TU to a MTC, which has the capability to provide pelvic reconstruction or definitive haemorrhage control techniques. It may also be from one MTC to another. However, it is also important to note that the location of pelvic reconstruction services around the country is variable (some are at TUs in some major trauma networks). The population that would benefit from transfer would be patients for whom surgery is contemplated, either if they need specialist care for definitive treatment of their pelvic fracture and/or if they are haemodynamically unstable and need definitive haemorrhage control. The most cost-effective timing of transfer will depend upon the benefits, risks and costs of staying where the patient is versus where they will be transferred to. If transfer to the appropriate destination for definitive haemorrhage control is delayed then this could lead to a risk of mortality. Surgery to fix the pelvis also becomes more complicated if there is a delay (for example, above 48 hours was discussed), the risk of thromboembolic events, chest infections and nerve injury also increase. The risks of delaying transfer were felt to outweigh the benefit of staying in the first receiving hospital. A potential trade-off however, is whether you transfer a patient who is severely haemodynamically unstable to somewhere where there are appropriate skills to manage their condition, but risk them dying during transfer. This is a difficult decision needing clinician judgement. However, it was highlighted that the transfer needs to be agreed with the hospital the patient is being transferred to, as not all patients with a pelvic transfer need surgery or specialist orthopaedic care that a specialist centre can provide, and unnecessary transfers want to be avoided. It was also discussed how once a decision to transfer is made, care stops because the patient is theoretically now the responsibility of the tertiary hospital. Thus, patients needing treatment would benefit from being transferred as quickly as possible, as

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	the GDG felt that while the patients are awaiting treatment they should be doing this in the hospital they have been transferred to, where the skills are available to manage any potential deterioration. The GDG felt that transferring patients who would benefit from specialist care, immediately in the case of bleeding patients, and within 24 hours for patients needing pelvic reconstruction, would be appropriate and is likely to be cost effective given the risks associated with delaying transfer.
Quality of evidence	No evidence was found.
Other considerations	A further consideration is that once the decision to transfer to a MTC has been made, the focus naturally shifts from intervention to preparation for transfer. Delays at this stage therefore can be harmful. Thus, the GDG recommended an immediate critical transfer to a MTC if it were required. During the transport the GDG anticipated that resuscitation and pelvic splintage will be on going. The GDG felt it was likely that pelvic surgery expertise will increasingly and appropriately become concentrated in MTCs.

7.3 Decision for pelvic binders

7.3.1 Introduction

This review question was ultimately aimed at evaluating the patient characteristics that determine the need for a pelvic binder. Pelvic binders are specifically applied to a patient to control serious pelvic bleeding, so the key factor determining the need for a pelvic binder is the existence of clinically important pelvic bleeding. Unfortunately, pelvic bleeding can be difficult to assess as it is usually internal. There are two key indicators of clinically important pelvic bleeding: high-energy pelvic fractures and haemodynamic instability. However, each one alone is not a reliable predictor. Clinically important pelvic bleeds are possible if there is a pelvic fracture, but this is not always the case as not all pelvic fractures will cause vascular injury. Similarly, serious pelvic bleeding is possible if haemodynamic instability is detected, but in the absence of a pelvic fracture it is very likely that the haemodynamic instability would have arisen from bleeding in places other than the pelvis. In contrast, if a high-energy pelvic fracture and haemodynamic instability occur together, the probability that pelvic bleeding has occurred increases greatly. It therefore follows that the need for a pelvic binder is likely if a patient has both a high-energy pelvic fracture and signs of haemodynamic instability.

Since there are already established strategies for evaluating haemodynamic instability, the key unknown is the existence of a pelvic fracture. This review question is therefore focussed on evaluating risk tools that can be used at the roadside to diagnose a pelvic fracture. High sensitivity of these tools is vital to ensure that diagnosis of patients with a pelvic fracture are not missed, which is important because patients with a pelvic fracture are those with the potential to have pelvic bleeding. High specificity is also of some importance, as binders are associated with an economic cost as well as adverse effects such as pressure sores, and so misdiagnosis of pelvic fractures with subsequent over-use of binders is potentially costly.

In summary, this question aims to establish the accuracy of tools to diagnose pelvic fractures at the roadside. If any such tools are sufficiently accurate they may be used alongside established methods for detecting haemodynamic instability to infer the likelihood of clinically important pelvic bleeding and thus the need for a pelvic binder.

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7.3.2 Review question: Which are the best diagnostic risk tools to predict the presence of a pelvic fracture at the pre-hospital stage?

For full details see review protocol in Appendix C.

Table 76: PICO characteristics of review question

Population	Children, young people and adults
Diagnostic prediction tools	Any diagnostic prediction tools[a] identified in the literature
Outcomes	• Sensitivity and specificity • AUC
Study design	Diagnostic accuracy studies

(a) Prediction tools are being sought as these are designed to inform a decision. These incorporate all competing predictors in their design, and are the result of studies conducting multivariable analyses to evaluate these predictors and the weighting given to each.

7.3.3 Clinical evidence

One diagnostic study was included in the review.[34] This had very indirect forms of evidence. Gross 2005 evaluated the diagnostic accuracy of a simple pelvic fracture prediction rule, but used physicians in the emergency department (ED) rather than pre-hospital practitioners at the scene of the accident.

This study is summarised in Table 77 below, while evidence from this study is summarised in the clinical evidence summary below (Table 78). See also the study selection flow chart in Appendix D, study evidence tables in Appendix G, forest plots in Appendix I, GRADE tables in Appendix H and excluded studies list in Appendix J.

Summary of included studies

Table 77: Summary of studies included in the review

Study	Population	Risk tool	Reference standard	Comments
Gross 2005[34]	'Level one' trauma patients, defined as people brought in by the emergency services.	This tool involved 5 criteria: • GCS <14 • Complaint of pelvic pain • Pelvic tenderness on examination • Distracting injury • Clinical intoxication If one or more were present the test was positive for pelvic fracture. In this study the tool was used to predict who should be sent for X-ray.	Antero-posterior X-ray	This study looked at sensitivity and specificity of this risk tool in the ED. Thus it is indirect evidence.

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Table 78: Clinical evidence summary: diagnostic accuracy of risk tool against reference standard of X-ray

Number of studies	n	Risk of bias	Inconsistency	Indirectness	Imprecision	Sensitivity (95% CI)	Specificity (95% CI)	Quality
All fractures								
1	973	Serious[a]	None	Serious[b]	NA	0.97 (0.89-0.99)	0.48 (0.44-0.51)	LOW
Clinically important fractures								
1	973	Serious[a]	None	Serious[b]	NA	1.0 (0.94-1.0)	0.48 (0.44-0.51)	LOW

(a) Lack of blinding
(b) Performed in ED (not pre-hospital) by physician rather than pre-hospital personnel

7.3.4 Economic evidence

Published literature

No relevant economic evaluations were identified.

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

7.3.5 Evidence statements

Clinical

Low quality evidence from one diagnostic study comprising 973 people showed that a risk tool had a sensitivity of 0.97 (95% CI, 0.89 to 0.99) and specificity of 0.48 (95% CI, 0.44 to 0.51) compared with X-ray for detecting any pelvic fracture

Low quality evidence from one diagnostic study comprising 973 people showed that a risk tool had a sensitivity of 1 (95% CI, 0.94 to 1) and specificity of 0.48 (95% CI, 0.44 to 0.51) compared with X-ray for detecting a clinically important pelvic fracture

Economic

No relevant economic evaluations were identified

7.3.6 Recommendations and link to evidence

Recommendations	**21. If active bleeding is suspected from a pelvic fracture following blunt high-energy trauma:** • **apply a purpose-made pelvic binder, or** • **consider an improvised pelvic binder but only if a purpose-made binder does not fit.**
	In addition to the complex fracture GDG reviewing the accuracy of risk tools for the use of pelvic binders, the major trauma GDG reviewed the clinical and cost effectiveness of pelvic binders (Major Trauma clinical guideline see section 10). These recommendations were developed and supported by evidence reviews addressing pelvic binders. Developing the recommendations The pelvic binder recommendations were developed across the two guidelines by all members of both GDGs. Evidence reviews were completed for all the guidelines and the separate GDGs reviewed the evidence and drafted recommendations. The overall guideline population of patients with pelvic bleeding meant that similarities and duplication between the draft recommendations were inevitable. The recommendations were taken to the project executive team (PET) for coherence and consistency checking, the PET also had the advantage of identifying gaps in the separate guidelines that had been addressed in another guideline. The PET agreed on a core set of draft recommendations. The core set of recommendations were taken back to each of the separate GDGs for review and agreement. The GDG had access to both evidence reviews.
Relative values of different outcomes	This review question focussed on evaluating risk tools to diagnose a pelvic fracture. A diagnostic RCT approach was not relevant because the aim was not to evaluate the tools for their effect on outcome, but instead was specifically to assess the

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	diagnostic accuracy of the tools. Hence, a diagnostic accuracy approach involving diagnostic outcomes was relevant. Sensitivity was regarded as more important than specificity. Sensitivity was critical as failure to detect a true case could lead to a patient being denied a pelvic binder, which could lead to serious consequences. In the standard clinical scenario, where a risk tool is not used and the trigger for binder use is suspicion based on mechanism, sensitivity is extremely high and so **any** deficiency in sensitivity by the index test, which is applied to the same population with suspicion based on mechanism, would indicate harm relative to standard care. Specificity was important, as the extremely low specificity of using suspicion based on mechanism was the reason for this review question. However, it did not need to be perfect, since the aim was merely to choose a diagnostic method that would improve specificity from a very low level. For example, a specificity of 0.5 would represent an important improvement over the standard care specificity. This would still result in a lot of patients being given a binder unnecessarily, but considerably less than before.
Trade-off between clinical benefits and harms	Taking the results from the single included paper, the high sensitivity means the fracture diagnostic tool would probably pick up all clinically important pelvic fractures amongst the population who are suspected of pelvic fracture based on mechanism. If all those with pelvic fractures are detected by this tool, then theoretically, all those with actual pelvic bleeding should be picked up as well, on the basis that bleeding into the pelvis is unlikely to occur without a pelvic fracture. The specificity of 0.48 would also mean only 52% of those without a fracture would be treated as if they had one. This method would therefore have the benefits of reduced resource use and less adverse events from pelvic binders than using standard care (suspicion based on mechanism). Note, however, that because not all people with a pelvic fracture would have pelvic bleeding, the actual specificity of this tool for detecting those with pelvic bleeding would be considerably lower than 0.48. In line with the arguments described in the 'relative values of different outcomes' section The GDG therefore agreed that to avoid unnecessary use of binders, those predicted to have a fracture would **also** need to have signs of active bleeding(which would imply pelvic bleeding in the presence of a pelvic fracture).
Economic considerations	Risk scores are likely to have minimal costs on the intervention itself, however, they are likely to have staff costs in terms of time taken to assess the patient and look for signs listed on the risk score. This may be part of the usual assessment of injuries. More accurate prediction will pick up likely pelvic fractures, and the action that will follow from this, such as the application of a pelvic binder and potential triage to a major trauma centre (MTC), will likely being benefit to the patient. Using a risk tool, as opposed to blanket strategy of using pelvic binders on all major trauma patients, or even going simply by mechanism of injury, will also reduce downstream resource use, such as unnecessary imaging in hospital which generally happens when patients arrive with a pelvic binder in order to clear the pelvis. This is because a risk tool will lower the number of binders applied because it is increasing the specificity of the diagnosis. The clinically relevant fractures are the ones that it would be cost effective to identify because the benefit of a diagnostic tool comes from the impact of treatment.

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	The GDG agreed that appropriate identification of suspected pelvic fractures pre-hospital is key in order to reduce the current overuse of pelvic binders. The population that would benefit from a pelvic binder was felt likely to be patients suspected of a fracture from within the major trauma population who are suspected of active bleeding. A pelvic binder should be used for haemorrhage control rather than as a splint. It was discussed how education and training may be needed as to the use of pelvic binders, because pre-hospital care is delivered by a range of providers with varying competencies. In children, it was acknowledged that signs of bleeding may not always present until later, which could be en route to the hospital. Current practice varies across the country, however, usually involves using a combination of mechanism of injury and clinical signs. Therefore, this recommendation is likely to be cost saving as it will reduce the amount of pelvic binders applied with subsequent downstream savings from additional investigations avoided in those unlikely to have a pelvic fracture.
Quality of evidence	Quality of evidence was very low. Blinding of examiners was not well-reported and the study had serious indirectness with the tests being used by hospital clinicians in the ED setting. The relevance of these findings to the pre-hospital context is therefore limited, although, the GDG felt that the evidence could still be taken into account because the tool could be effectively applied in different contexts by trained personnel. The sensitivity of the tool in the study may have been artificially enhanced for two main reasons. Firstly, patients deemed by a clinician to be without a clinical indication for X-ray were not given an X-ray. This meant that these patients had to be excluded from the study because X-ray was the reference test. Importantly, the clinician may have made the decision not to X-ray based on similar criteria to the tested tool, such as pelvic tenderness. It is not impossible that some of these excluded people may have actually had fractures, and, given that they were not picked up by the clinician using a similar assessment procedure to the tool, it is also possible that the tool would not have picked these up as fractures either. Had these cases actually been given an X-ray, they may therefore have shown up as false negatives on exposure to the tool, and sensitivity would therefore have been lower. Hence their exclusion implies a relative exaggeration of sensitivity. The study authors felt this was highly unlikely, but did not give a convincing explanation for this view. Secondly, X-ray may not have been an ideal gold standard as it is not as sensitive as CT. Again, sensitivity of the tool may have been artificially increased; this time because the group who actually had fractures but were not picked up by X-ray would automatically be regarded as either false positives or true negatives, rather than false negatives. However, the GDG felt that the subgroup with fractures not picked up by X-ray would be unlikely to have fractures severe enough to warrant a pelvic binder, so this limitation was regarded as less of a concern. Hence because the high sensitivity of the tool was in doubt primarily for the former reason, the GDG decided that the recommendation should not include use of the studied tool. If sensitivity of the tool were in actual fact less than that reported in the study (as the GDG feared was likely) and therefore pelvic fractures were being missed, this could mean that someone with pelvic bleeding secondary to a pelvic fracture would not receive a pelvic binder. It is important to note that any detected haemodynamic instability in such a patient would not lead to the use of a binder as

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	in the absence of a detected pelvic fracture the source of bleeding would not be identified as the pelvis.
Other considerations	Given that the evidence was very low quality and the GDG had concerns about applicability in the pre-hospital setting (see quality of evidence section above), the GDG used consensus to form the recommendation. Given the lack of a pelvic fracture diagnostic tool of undisputed high sensitivity and good specificity, the GDG felt that an acceptable alternative could be suspicion of pelvic fracture based on high-energy blunt trauma. Such a broad diagnostic criterion would almost certainly have equal or even better sensitivity than the tool (given that the tool was tested in that same group of people with a suspicion based on mechanism), though would have far lower specificity. The GDG agreed that without pelvic bleeding, a pelvic binder was probably unnecessary even if a fracture existed, meaning that any harms (such as skin breakdown) would be unopposed by any benefits. In line with this, the GDG noted that pelvic binders tend to be used erroneously as an orthopaedic splint rather than as a tool for haemorrhage control and therefore, their use was increasing unnecessarily. Furthermore, the unnecessary presence of a pelvic binder may further increase over triage to MTCs, potentially increasing costs. The GDG considered that pelvic bleeding could be best indicated by any systemic signs of haemodynamic instability in the presence of a possible pelvic fracture. In particular, significant pelvic bleeding that can be controlled by a pelvic binder was thought to be unlikely without some signs of haemodynamic instability. In summary, the GDG considered that the patients that should be protected with a pelvic binder were those with a mechanically unstable pelvis and haemodynamic instability. The GDG, therefore, felt that binders should be used on suspicion of a pelvic fracture following high energy trauma and suspected active pelvic bleeding.

7.4 Pelvic binder duration

7.4.1 Introduction

Two major concerns when managing patients with pelvic fractures are haemodynamic status and ring stability. Early stabilisation of pelvic fractures is an effective way of controlling venous bleeding through facilitation of clot formation and prevention of further vascular damage, and may contribute to saving patients' lives. One practical way to attain pelvic fracture stability in the pre-hospital stage is through circumferential wrapping with the use of a pelvic binder. Whilst pelvic binders are extremely useful they do have potential harms, such as local ischaemia and skin breakdown. The duration of their use thus needs to be limited, but it is unclear what the optimal duration is.

7.4.2 Review question: What is the most clinically and cost effective duration for pelvic binder use?

For full details see review protocol in Appendix C.

Table 79: PICO characteristics of review question

Population	Children, young people and adults for a confirmed pelvic fracture following a traumatic incident.
Intervention(s)	• In-situ ≤ 4 hours • In situ >4 and ≤12 hours • In situ >12 and ≤24 hours

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	• In situ >24 hours
Comparison(s)	Comparison of the above
Outcomes	Critical: • Mortality to 1 year • Health-related quality of life • Skin necrosis • Breakdown • Blistering • Functional outcome measures • Pain/discomfort • Return to normal activities • Psychological wellbeing • Blood loss (blood components)
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

No relevant RCTs, systematic reviews or cohort studies comparing different durations of pelvic binder use were identified in the search. See the search strategy in appendix F, study selection flow chart in Appendix D and excluded studies list in Appendix J.

7.4.4 Economic evidence

Published literature

No relevant economic evaluations were identified.

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

7.4.5 Evidence statements

Clinical

No relevant clinical evidence was identified

Economic

No relevant economic evaluations were identified.

7.4.6 Recommendations and link to evidence

Recommendations	**22. For people with suspected pelvic fractures and pelvic binders, remove the binder as soon as possible if:** • **there is no pelvic fracture, or** • **a pelvic fracture is identified as mechanically stable, or** • **the binder is not controlling the mechanical stability of the fracture, or** • **there is no further bleeding or coagulation is normal.**

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	Remove all pelvic binders within 24 hours of application. **23. Before removing the pelvic binder, agree with a pelvic surgeon how a mechanically unstable fracture should be managed.**
Relative values of different outcomes	Critical outcomes were mortality, health-related quality of life, skin necrosis/breakdown/blistering, nerve injury, functional outcomes and blood loss.
Trade-off between clinical benefits and harms	No evidence for this review question was found in the literature. The GDG therefore discussed the benefits and harms through consensus. It was felt that whilst an overly short duration of binder use might lead to re-bleeding, any haemostatic benefit from binders diminishes after 24 hours. Furthermore, it was discussed that with greater binder duration adverse effects such as pressure sores (particularly in the context of de-gloving injuries) and contamination leading to infection become more likely. For example, some members of the GDG reported that after 7 days of binder use pressure necrosis is commonly seen in clinical practice. Although the balance of benefits and harms might vary with age, the general consensus was that binders had no benefit if imaging showed no fracture or if the pelvic fracture was stable with a low likelihood of bleeding, therefore, causing the harms to dominate, or there was no bleeding and coagulation was normal. Even if there were pelvic instability, leading to the risk of re-bleeding, binders would have reduced benefit after 24 hours, leading to gradual dominance of harms. The GDG also felt that if pelvic instability exists, but 24 hours was approaching, the pelvic surgeon should be consulted before removal of the binder to ensure that there were informed plans in place to prevent unnecessary movements of the pelvic fragments prior to surgery. By this stage, any patient with an unstable pelvic fracture and haemodynamic instability should be in a major trauma centre under the care of a pelvic surgeon. (see Timing of transfer for patients with pelvic fractures).
Economic considerations	No economic evidence was identified for this question. Ideally, a pelvic binder would be taken off as early as possible, however, for multiply injured patients, such as patients with head and/or chest injuries, treating the other injuries may be the priority and therefore, the binder may be left on to stabilise the pelvis until this can be treated. Adverse events associated with leaving a binder on include pressure sores/pressure necrosis, soft tissue damage. Hygiene is also an important factor as if a patient soils their binder this can lead to infection. The risk of adverse events is quite rare and the GDG's opinion was that most evidence on this is anecdotal; however, the severity of events such as pressure sores can vary from minor to requiring plastic surgery. Additionally, pressure sores could result from the binder making the initial injury worse rather than causing the pressure sores. Removing the binder too early may also cause a re-bleed as the binder helps to hold the pelvis in place until surgery can be performed. In some cases, if the clinician is concerned about the pelvis but definitive fixation is delayed if treating the other injuries, than external fixation may be applied. Delaying surgery too long also leads to more complications and can make the surgery more difficult.

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	The GDG felt that a recommendation informing about the potential adverse events from binders and recommending their removal as early as possible, but seeking the opinion of a pelvic surgeon if the fracture is unstable, would be appropriate.
Quality of evidence	No published evidence was found.
Other considerations	The GDG described how binders can be removed and reapplied or moved, and are effective when applied from mid-thigh to the greater trochanter. Current practice involves removing the binder every 4 hours, and then leaving the binder off if signs of re-bleeding do not recur.

7.5 Timing of log roll

7.5.1 Introduction

Rotational movement of a patient with a pelvic fracture may be required for clinical examination or nursing care, but this is often dangerous because of the risk of causing or exacerbating pelvic bleeding. For this reason, rotational movements are carefully controlled with a 'log roll' movement, designed to rotate all body segments together as a whole, thus limiting potentially damaging torsion around the pelvis. Nevertheless, even a log rolling strategy may lead to negative sequelae if it is not performed properly or the pelvis is very unstable. For this reason, some clinicians advocate delaying log rolling until after imaging, so that the log roll can be planned based on knowledge of the position of the fracture fragments. However, this may cause delays in essential examination, and so the optimal approach is unclear. This review aims to evaluate the most clinically and cost effective approach.

7.5.2 Review question: What is the safest strategy and timing for log rolling patients with suspected or known pelvic fracture?

For full details see review protocol in Appendix C.

Table 80: PICO characteristics of review question

Population	Children, young people and adults experiencing a traumatic incident.
Intervention(s)	Log roll before imaging
Comparison(s)	Log roll after assessment of imaging
Outcomes	Critical: • Mortality • Health-related quality of life • Volume of blood lost/number of transfusions required • Time to definitive control of haemorrhage • Important: • Functional outcome measures • Pain/discomfort • Return to normal activities • Psychological wellbeing • Length of stay
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.

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7.5.3 Clinical evidence

No relevant RCTs, systematic reviews, cohort or case control studies comparing a log roll before imaging with a log roll after assessment of imaging were identified in the search. See the search strategy in appendix F, study selection flow chart in Appendix D and excluded studies list in Appendix J.

7.5.4 Economic evidence

Published literature

No relevant economic evaluations were identified.

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

7.5.5 Evidence statements

Clinical

No relevant clinical evidence was identified

Economic

No relevant economic evaluations were identified.

7.5.6 Recommendations and link to evidence

Recommendations	**24. Do not log roll people with suspected pelvic fractures before pelvic imaging unless:** • **an occult penetrating injury is suspected in a person with haemodynamic instability** • **log rolling is needed to clear the airway (for example, suction is ineffective in a person who is vomiting).** **When log rolling, pay particular attention to haemodynamic stability.**
Relative values of different outcomes	Critical outcomes were mortality, health-related quality of life, volume of blood lost/number of transfusions required and time to definitive control of haemorrhage. Important outcomes were pain/discomfort, return to normal activities and length of stay.
Trade-off between clinical benefits and harms	No evidence was found in the literature, and so decisions on the recommendations were made by consensus. The GDG discussed how there is a potential risk of inducing haemodynamic instability from log rolling, as movement of an unstable pelvis may lead to further bleeding. The GDG felt that, therefore, log rolling prior to imaging should only be considered in exceptional circumstances, such as the need to search for suspected occult penetrating injuries or the need to clear an airway that is refractory to other methods. The GDG felt that during such an emergency manoeuvre, haemodynamic stability should be carefully monitored to ensure that any consequent pelvic bleeding could be rapidly managed.

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	The GDG noted how after imaging it is usually possible to identify onto which side the patient can be log rolled most safely and so log rolling after imaging was regarded as far safer.
Economic considerations	No economic evidence was identified for this question. The same number of resources would be needed whether log rolling is undertaken before or after imaging (around 5 staff members). However, the consequences are likely to differ if it is done before or after imaging, as log rolling patients who have a pelvic fracture can worsen the injury and potentially result in further bleeding. The bleeding population is the key population for this question as log rolling has been used as a diagnostic technique to spot a bleed underneath the patient and for this purpose has been done prior to the imaging, however, log rolling before imaging may make the injury worse when the extent of the injury has not yet been ascertained. Thus, for early log rolling, there is a trade-off between making the bleeding from the pelvic fracture worse versus identifying other potential sources of bleeding. The patient will most likely need to be log rolled at some point (although imaging may rule this out), and current practice tends to await the imaging results before log rolling. The GDG agreed with this. If specialist equipment is available, then this eliminates the need to log roll to move the patient onto a piece of equipment that can go into the CT scanner. For example, plastic scoops as extrication devices can go into the CT scanner. Or special mattresses are available that the patient can be placed on (after removing the scoops – which does not involve having to move the patient very much only 15 degrees) which can go in the CT scanner. Although this equipment may result in additional expense for hospitals, the scoops are widely used by ambulance services. On a per patient basis, new equipment such as these will be of low cost as they can be re-used. Staff time will also be saved by avoiding unnecessary log rolling for the purposes of placing the patient on another piece of equipment to transfer to the CT scanner. However, there were scenarios discussed where it may be of use to log roll the patient prior to imaging. These include when there is a suspicion of a penetrating injury. The GDG felt that if there is such a suspicion, then log rolling the patient to have a look if they are bleeding would be important because this should be identified as soon as possible. Additionally, if there is a risk to the patient's airway that cannot be dealt with in any other way then log rolling could be lifesaving. However, it is important to also monitor the patient's haemodynamic stability when log rolling in case this does further damage.
Quality of evidence	No evidence was found in the literature.
Other considerations	The GDG discussed how the use of appropriate equipment should avoid the need to log roll early purely for logistic reasons. Examples given were a CT compatible plastic scoop and a transfer mattress (which can come with a heating element).

7.6 Pelvic imaging

7.6.1 Introduction

Clinically significant pelvic or acetabular fractures can lead to severe haemorrhage and may also present considerable challenges during reconstruction. Accurate imaging of pelvic fractures is therefore essential to prevent catastrophic bleeding and to help plan definitive reconstruction. Currently, X-rays are still used in some areas as the first line imaging modality, despite CT scanning being established as the gold standard. X-ray may have certain advantages in terms of lower

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radiation dose and reduced cost, and so it is necessary to know the relative harms and benefits of both, which was the first aim of this review. This review also aimed to determine whether X-rays are an adequate proxy measure for the gold standard of CT imaging, in terms of having sufficiently high diagnostic accuracy to enable its radiation and cost advantages to outweigh the accurate but relatively costly and harmful CT.

7.6.2 Review question:

a) What is the most clinically and cost effective imaging modality for assessment of high energy suspected pelvic or acetabular fractures at the initial presentation?

b) What is the diagnostic accuracy of CT, CT plus X-ray or X-ray for assessment of high energy pelvic or acetabular fractures for (1) existence of fractures and (2) classification of fractures?

This review sought to identify the optimum imaging strategy for patients with a suspected pelvic or acetabular fracture at initial presentation. 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 81. A second review protocol to examine the diagnostic accuracy of each of the imaging strategies, summarised in Table 82, 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 81: PICO characteristics of diagnostic RCT review question (a)

Population	Children, young people and adults experiencing a high-energy suspected pelvic fracture following a traumatic incident.
Interventions	• CT • CT with contrast • Plain X-ray • Plain film X-ray plus CT • Plain film X-ray plus CT with contrast
Comparison	Each other
Outcomes	Critical: • Mortality up to 12 months • Health-related quality of life • Missed injury • Need for further diagnostic imaging • Time to whole body CT (for other injuries) • Radiation • Delayed treatment • Functional outcome measures • Pain/discomfort • Return to normal activities • Psychological wellbeing Important: • Time in hospital • Misdiagnosis
Study design	RCTs or Systematic reviews of RCTs

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Table 82: PICO characteristics of diagnostic accuracy review question (b)

Population	Children, young people and adults experiencing a high-energy suspected pelvic fracture following a traumatic incident.
Index tests	• CT • Plain X-ray • Plain film X-ray +plus CT (CT with or without contrast)
Reference test	Later clinical findings, including further imaging
Outcomes	Sensitivity and specificity
Study design	Diagnostic accuracy studies

7.6.3 Clinical evidence

No clinical evidence was identified as relevant for the diagnostic RCT review question to examine the clinical and cost-effectiveness of the different imaging strategies. Two studies were included in the diagnostic accuracy review;[54,94] these are summarised in Table 83 below. Evidence from these studies is summarised in the clinical evidence summary below (Table 84 to Table 86). See also the study selection flow chart in Appendix D, study evidence tables in Appendix G, forest plots in Appendix I, GRADE tables in Appendix H and excluded studies list in Appendix J.

The GDG identified later clinical findings, including further imaging, as the reference standard to examine the diagnostic accuracy of initial imaging strategies for pelvic or acetabular fractures. The included study evaluated the diagnostic accuracy of X-ray and CT, as compared with the gold standard of expert review of composite imaging strategies and clinical findings, for detecting the existence of a pelvic or acetabular fracture. However, the GDG decided that the CT imaging used in the study was too old to be relevant to the CT images used in practice today. As a consequence, the GDG only considered the evidence for the diagnostic accuracy of X-ray in this study. No clinical evidence was identified for identifying the classification of the fracture.

Table 83: Summary of studies included in the review

Study	Population	Index test(s)	Reference test	Comments
Vannier 1991[94]	Patients (age range, 18-87 years) with known or suspected pelvic fractures	X-ray	Expert review of all imaging (X-ray, CT, 3DCT), clinical history, surgical findings, and follow-up clinical findings	Evidence for the identifying the existence of a fracture. Most patients (n=16) have known or suspected fractures to both hips. All patients received surgery for their fracture.
Kwok 2015[54]	Children of mean age 12.9 years with blunt torso trauma	X-ray	Expert opinion of diagnosis before ED or hospital discharge	Only sensitivity data collected.

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Imaging for detecting the existence of fractures in adults

Table 84: Clinical evidence profile: X-ray for detecting the existence of pelvic fracture

Number of studies	n	Risk of bias	Inconsistency	Indirectness	Imprecision	Sensitivity (95% CI)	Specificity (95% CI)	Quality
X-ray for detecting the existence of pelvic fractures (with expert review of imaging and clinical findings as the gold standard) in adults								
1	17	Very serious[a]	N/A[b]	Serious[c]	N/A[b]	N/A[d]	N/A[d]	VERY LOW

(a) Risk of bias mainly due to bias in availability of images and missing output data
(b) Could not be calculated as no meta-analysis
(c) Sample may represent a subsample of patients with more complex injuries
(d) Insufficient data reported in the paper to calculate

Table 85: Clinical evidence profile: X-ray for detecting the existence of comminuted pelvic fracture

Number of studies	n	Risk of bias	Inconsistency	Indirectness	Imprecision	Sensitivity (95% CI)	Specificity (95% CI)	Quality
X-ray for detecting the existence of comminuted pelvic fractures (with expert review of imaging and clinical findings as the gold standard) in adults								
1	9[a]	Very serious[b]	N/A[c]	Serious[d]	N/A[c]	0.77	0.67	VERY LOW

(a) Sample size estimated. Total n=17; 18/33 fractured hips were comminuted.
(b) Risk of bias mainly due to bias in availability of images and indirectness
(c) Could not be calculated as no meta-analysis
(d) Sample may represent a subsample of patients with more complex injuries

Imaging for detecting the existence of fractures in children

Table 86: Clinical evidence profile: X-ray for detecting the existence of pelvic fracture

Number of studies	n	Risk of bias	Inconsistency	Indirectness	Imprecision	Sensitivity (95% CI)	Specificity (95% CI)	Quality
X-ray for detecting the existence of pelvic fractures (with expert review of imaging and clinical findings as the gold standard) in children aged 0-17								
1	382	Very serious[a]	None	None	None	0.78 (0.73 to 0.82)	No data	LOW
X-ray for detecting the existence of pelvic fractures (with expert review of imaging and clinical findings as the gold standard) in children aged 0-12								
1	382	Very serious[a]	None	None	None	0.73 (0.66 to 0.79)	No data	LOW
X-ray for detecting the existence of pelvic fractures (with expert review of imaging and clinical findings as the gold standard) in children aged 13-17								

Number of studies	n	Risk of bias	Inconsistency	Indirectness	Imprecision	Sensitivity (95% CI)	Specificity (95% CI)	Quality
1	382	Very serious[a]	None	None	None	0.82 (0.76 to 0.87)	No data	LOW

(a) Risk of bias mainly due to bias in availability of images and use of reference standard that included the index test

Narrative findings

The study reported the area under ROC for X-ray, when compared with expert review of imaging and clinical findings as the gold standard. The area under ROC was reported as 0.92 for X-ray. This evidence is at very high risk of bias.

7.6.4 Economic evidence

Published literature

Two economic evaluations relating to this review question were identified but were excluded due to a combination of limited applicability and methodological limitations.[5,30]

These are listed in Appendix K, with reasons for exclusion given.

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

Unit costs

Table 87: Diagnostic modality costs [20]

Imaging modality	Description	Cost
X-ray	Direct access plain film	£28
CT	CT scan, one area, no contrast, 19 years and over	£60
	CT scan, one area, with post contrast only, 19 years and over	£71

Economic considerations

Both of these selectively excluded papers are looking at whether omitting an X-ray prior to a CT in haemodynamically normal patients was cost saving. Barleban 2011[5] was slightly more detailed in terms of whether the X-ray changed the management of the patient (which it did for 2 patients – one had blood given and the other had a pelvic binder placed), it also reported that no complications occurred in the CT scanner. Thus, using the modality, which takes a bit more time, did not have an adverse effect on the patient. The other study, Feeney 2011[30], retrospectively identified people who had an X-ray in the trauma room (some also had a CT after the X-ray) and compared the accuracy of the two modalities. Both studies found that not doing an X-ray first saved on costs with little or no impact on patients.

7.6.5 Evidence statements

Clinical

One Very low quality diagnostic study comprising 9 adults showed that pelvic X-rays have a sensitivity of 0.77 (no CIs available)and a corresponding specificity of 0.67 (no CIs available) for detecting comminuted pelvic fractures.

One Very low quality diagnostic study comprising 451 children showed that pelvic X-rays have a sensitivity of 0.78 (95 CI, 0.73 to 0.82) for detecting pelvic fractures.

Economic

No relevant economic evaluations were identified.

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7.6.6 Recommendations and link to evidence

Recommendations	**25. Use CT for first-line imaging in adults (16 or over) with suspected high-energy pelvic fractures.** **26. For first-line imaging in children (under 16s) with suspected high-energy pelvic fractures:** • **use CT rather than X-ray when CT of the abdomen or pelvis is already indicated for assessing other injuries** • **consider CT rather than X-ray when CT of the abdomen or pelvis is not indicated for assessing other injuries.** **Use clinical judgement to limit CT to the body areas where assessment is needed.**
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 such RCTs were identified and so diagnostic accuracy studies were used for this review. The GDG identified both the sensitivity and specificity of index tests as critical outcomes in evaluating the diagnostic accuracy of imaging strategies for pelvic fractures. Low sensitivity of imaging strategies resulting in missed injuries may be associated with a higher risk of mortality and reduced health outcomes, as a missed pelvic fracture may result in internal haemorrhage. Poor specificity of imaging, resulting in false positive diagnoses of pelvic fractures is also harmful, as these patients may receive invasive surgical intervention unnecessarily.
Trade-off between clinical benefits and harms	No clinical evidence was identified for the diagnostic RCT review examining the clinical outcomes of imaging for pelvic fractures. No clinical evidence was identified to evaluate the diagnostic accuracy of CT or X-ray plus CT. One included study evaluated the diagnostic accuracy of X-ray for identifying (i) pelvic fractures and (ii) comminuted pelvic fractures in adults. The authors did not report the sensitivity or specificity of X-ray for identifying any pelvic fracture, but reported that X-ray was excellent at distinguishing between patients with and without pelvic fractures as indicated by the area under ROC. However, the paper reported that for patients with comminuted pelvic fractures, imaging X-ray would result in 23% false negative and 33% false positive diagnoses. The other included study showed poor results for X-ray in children, with false negative rates of 18-27%.
Economic considerations	No economic evidence was identified for this question. The most costly intervention is X-ray followed by a CT. The accuracy of a modality will be impacted by sensitivity and specificity of the test, as well as the prevalence of the injury (see appendix O for more on this), however, the prevalence of pelvic injuries in a trauma population was felt to be unknown. The cost effectiveness will be impacted by the treatment that follows on from the diagnosis, as this is where the benefit from the diagnosis will come from. For pelvic

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	injuries, this may be an invasive surgical intervention or rehabilitation. This may also depend on the type and specific location of the pelvic injury. As a CT would already be indicated, an X-ray prior to this adds no benefit and would not change management, therefore, undertaking it would only add additional time onto the pathway. For children, it was also felt that if the suspected pelvic fracture was caused by a high-energy trauma, this population would also be indicated for a CT, and where CT is also indicated for the assessment of other injuries, there would be no benefit to an X-ray prior to CT in these scenarios. This recommendation is likely to be cost-saving in a number of ways. Through reducing the number of X-rays undertaken in addition to a CT scan (which already occurs in practice for this population). The goal in this recommendation was to reduce the unnecessary use of X-ray where CT is already indicated, not to increase the use of CT. This would also decrease radiation risk, as well as potentially have opportunity cost savings on staff time because if an X-ray is not needed (for either pelvis or other areas) then a radiographer's time can potentially be spent elsewhere.
Quality of evidence	The evidence in this review was at very high risk of bias. In one study this was due to not all patients receiving the index test, missing output data and indirectness of the study population. The study authors noted that all patients included in the study received surgery for their pelvic fracture, and therefore, these data may only be generalised to patients with complex high-energy pelvic fractures. The GDG noted that patients with complex pelvic fractures following a high-energy trauma would likely receive CT imaging for the detection of other injuries. Therefore, the GDG felt that these data had limited applicability to current practice. In the study on children, the decision to X-ray was done at the clinician's discretion. It was thus possible that some fractures were not included, which may have affected results, if there was an association between clinical suspicion and X-ray detection. It also appears that X-rays were included as part of the composite reference test, which may have increased concordance between index and reference tests.
Other considerations	The GDG felt that CT imaging can be used to detect both the existence of a fracture and the classification of the fracture, without the need for additional X-ray. The GDG also noted that the CT imaging would be multidetector CT accompanied by multiplanar reformatting. The GDG discussed the important issue of the consequences of missed pelvic fractures. The main consequence was felt to be greater risk of haemodynamic instability, particularly if a binder were removed inappropriately. The GDG initially believed that missed pelvic fractures tend to be those that are not clinically important, and that therefore, missed injuries are not usually a concern in terms of haemodynamic instability. However, discussion of one of the included papers showed that occult injuries can actually be very serious. The GDG concluded that the consequences of missing a fracture would outweigh the radiation risk even of CT imaging. Hence using the far less sensitive X-ray instead of the gold standard CT was felt to be potentially harmful. This recommendation only relates to high-energy injuries in both adults and children. This was in order to avoid less potentially serious pelvic fractures having an unnecessary CT. For children, the GDG felt that the radiation risks precluded a stronger recommendation to use first-line CT, and so 'consider' was used rather than 'use',

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	together with a recommendation to use clinical judgement in limiting exposure to as small part of the body as possible. However, for children due to undergo CT for other injuries (such as abdominal injuries), the GDG felt a stronger recommendation was appropriate, as pelvic CT would not lead to much greater radiation than would be received anyway. Furthermore, in relation to both adults and children, the GDG also discussed how the use of CT as the first-line investigation of suspected pelvic fractures may result in reduced exposure to radiation due to not using additional X-rays amongst patients with high energy abdominal/pelvic trauma who would require CT imaging anyway. The GDG noted that a definitive radiology report should be available at the time of management and be provided by a clinician trained to provide the definitive written report.

7.7 Pelvic cystourethrogram

7.7.1 Introduction

Urological injuries are common secondary to pelvic fractures. This question investigates the best imaging strategy to diagnose urological injury in people with suspected or confirmed pelvic fractures after trauma. The current standard is for a patient to receive an abdominal-pelvic CT with contrast, and if urological injury is suspected, then this is followed by either CT cystourethrogram or fluoroscopic cystourethrogram. This is perceived to be a relatively accurate strategy for diagnosing urological injury. However, the time taken for this imaging strategy to be performed could impact on patient outcomes. The contrast used for the initial CT is not considered sufficient for the cystourethrogram and the bladder must be refilled between each stage of imaging and the time spent refilling the bladder may affect patient outcomes. Possible alternative strategies include not refilling the bladder between initial CT and cystourethrogram or beginning with an initial cystourethrogram for people with a strong suspicion of urological injury.

7.7.2 Review questions:

a) Does a cystourethrogram lead to better outcomes than CT in patients with confirmed or suspected pelvic fracture and suspected bladder and urethral injuries?

This review sought to identify the most clinically and cost effective method of identifying urological injury in patients who have suspected or confirmed pelvic fracture after a traumatic incident. Initially, a diagnostic RCT review protocol was developed to examine the clinical and cost effectiveness of the different testing modalities (question A). However, insufficient RCT evidence was identified and as per the review protocol, a second question was drafted to find the diagnostic accuracy (question B) of tests to identify bladder injury. For full details of both protocols, see Appendix C.

Table 88: PICO characteristics of review question a

Population	Children, young people and adults with suspected or confirmed pelvic fracture after experiencing a traumatic incident.
Interventions	• Fluoroscopic cystourethrogram • CT cystourethrogram • CT (with contrast) • CT (without contrast) • CT (with contrast) followed by fluoroscopic cystourethrogram • CT (with contrast) followed by CT cystourethrogram • CT (without contrast) followed by fluoroscopic cystourethrogram

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	• CT (without contrast) followed by CT cystourethrogram
Comparison	To each other

Outcomes	Critical:
	• Mortality up to 12 months
	• Health-related quality of life
	• Missed bladder injury
	• Missed urethral injury
	• Impotence
	• Incontinence
	• Infection of fracture site
	• Time to definitive diagnosis
	• Functional outcomes
	  ○ Pain/discomfort
	  ○ Return to normal activities
	  ○ Psychological wellbeing
	
	Important
	• Length of stay

Study design	RCTs or Systematic reviews of RCTs
Exclusions	Single detector CT

b) What is the diagnostic accuracy of cystourethrograms and CT for assessment of bladder injury in patients with confirmed or suspected pelvic fracture?

Table 89: PICO characteristics of review question b

Population	Children, young people and adults with suspected or confirmed pelvic fracture after experiencing a traumatic incident.
Interventions	• Fluoroscopic cystourethrogram • CT cystourethrogram • CT (with contrast) • CT (without contrast) • CT (with contrast) followed by fluoroscopic cystourethrogram • CT (with contrast) followed by CT cystourethrogram • CT (without contrast) followed by fluoroscopic cystourethrogram • CT (without contrast) followed by CT cystourethrogram
Reference test	Surgical findings and clinical follow-up
Outcomes	Sensitivity and specificity
Study design	Diagnostic accuracy studies
Exclusions	Single detector CT

7.7.3 Clinical evidence

Diagnostic RCT review

No relevant clinical studies were identified.

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Diagnostic accuracy review

Three studies were included in the review.[14,43,77] These are summarised in Table 90 below. Only the fluoroscopic cystourethrogram results were extracted and presented from Horstman 1991[43] and Quagliano 2006[77]; the CT results were not valid for this review because single detector CT was used. Evidence from these studies is summarised in the clinical evidence summary below (Table 91). See also the study selection flow chart in Appendix D, study evidence tables in Appendix G, forest plots in Appendix I, GRADE tables in Appendix H and excluded studies list in Appendix J.

Accuracy data was found for:

- CT (with contrast) followed by CT cystourethrogram
- Fluoroscopic cystourethrogram
- CT (with contrast) followed by fluoroscopic cystourethrogram

Table 90: Summary of studies included in the review

Study	Index test	Reference standard	Population	Comments
Chan 2006[14]	CT with contrast followed by CT cystography 4-MDCT and 16-MDCT used	Operative findings and the progress of the patient's clinical condition during hospital stay and subsequent clinical follow-up[(a)]	Trauma patients with suspected bladder rupture after an initial CT Mean (range) age: 42 (3-94) years 163 (70%) patients had pelvic fractures	n=224 USA Retrospective cohort study Level 1 Trauma Center
Horstman 1991[43]	Conventional cystography (unclear what, if any, imaging happened beforehand)	Operative findings, later imaging, and clinical follow-up[a]	People with blunt trauma Age range: 6-81 years 4 of 5 (80%) people with bladder rupture had pelvic fracture	n=25 USA Retrospective cohort study All patients also had CT cystography but radiographers interpreting conventional cystography were blinded to CT results
Quagliano 2006[77]	Abdominal/ pelvic CT (single/dual/ quadruple) followed by conventional retrograde cystogram	Surgical findings, later imaging and clinical follow-up[a]	Haemodynamically stable people with blunt torso trauma with suspected bladder injury after initial CT	n=212 USA Prospective cohort study Trauma Center Patients also had a CT cystogram in between initial CT and conventional cystogram. It was not stated whether radiologist interpreting conventional cystogram was blinded to CT cystogram results

(a) Length of follow-up unclear

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Table 91: Clinical evidence profile: accuracy of CT and cystography to find bladder injury

Number of studies	n	Risk of bias	Inconsistency	Indirectness	Imprecision	Sensitivity (95% CI)	Specificity (95% CI)	Positive predictive value	Negative predictive value	Quality
CT with contrast followed by CT cystography to detect bladder injury										
1	224	Serious[a]	No inconsistency	None	None	1.0 (0.81-1.0)	1.0 (0.98-1)	1.0	1.0	MODERATE
CT with contrast followed by CT cystography to detect extraperitoneal bladder injury										
1	224	Serious[a]	No inconsistency	None	Serious imprecision[c]	0.92 (0.62-1.0)	1.0 (0.98-1.0)	1.0	1.0	LOW
CT with contrast followed by CT cystography to detect intraperitoneal bladder injury										
1	224	Serious[a]	No inconsistency	None	Very serious imprecision[c]	1.0 (0.48-1.0)	1.0 (0.98-1.0)	0.83	1.0	VERY LOW
Conventional cystography to detect bladder injury										
1	25	Very serious[b]	No inconsistency	None	Very serious imprecision[c]	1.0 (0.48-1.0)	0.95 (0.75-1.0)	0.83	1.0	VERY LOW
CT with contrast followed by conventional cystography to detect bladder injury										
1	212	Very serious[b]	No inconsistency	None	Serious imprecision[c]	0.95 (0.74-1.0)	1.0 (0.98-1.0)	1.0	1.0	VERY LOW
CT with contrast followed by conventional cystography to detect extraperitoneal bladder injury										
1	212	Very serious[b]	No inconsistency	None	Serious imprecision[c]	0.93 (0.66-1.0)	1.0 (0.98-1.0)	1.0	1.0	VERY LOW
CT with contrast followed by conventional cystography to detect intraperitoneal bladder injury										
1	212	Very serious[b]	No inconsistency	None	Very serious imprecision[c]	1.0 (0.48-1.0)	1.0 (0.98-1.0)	1.0	1.0	VERY LOW

(a) Risk of bias due to the reference standard; length of clinical follow-up was not specified and diagnosis was only definitively confirmed through surgery for some patients
(b) Risk of bias mainly due to an unreliable reference standard and selection bias
(c) The judgement of precision was assessed using the confidence interval of the sensitivity value. A range of 0-0.2 was considered not imprecise, 0.2-0.4 serious, and more than 0.4 very serious imprecision.

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7.7.4 Economic evidence

Published literature

No relevant economic evaluations were identified.

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

Unit costs

The below examples include the cost of individual components of the diagnostic techniques in Table 92, and these costs are summed in Table 93 to give the cost of the interventions being compared.

Table 92: Costs of individual parts of interventions

Imaging modality	Description	Cost	Source
CT without contrast[a]	CT Scan, one area, no contrast, 19 years and over	£80	NHS reference costs 2013/14[21]
CT with contrast	CT Scan, one area, with post contrast only, 19 years and over	£91	NHS reference costs 2013/14
Fluoroscopy	Contrast Fluoroscopy Procedures, less than 20 minutes	£69	NHS reference costs 2013/14
Urinary catheter set	Suprapubic Foley Seldinger Catheter Introducing Set: • 18 g hypodermic needle • 3 stage guide wire • dilator and peelable sheath • silicone foley catheter 43 cm 14 fg	£50	NHS Supply Chain [3]

(a) Please see appendix O for more information on NHS reference costs

Table 93: Cost of interventions

Interventions	Detail	Cost
Fluoroscopic cystourethrogram	Fluoroscopy plus catheter	£119
CT cystourethrogram	CT with contrast plus catheter	£141
CT (with contrast)	CT with contrast	£91
CT (without contrast)	CT without contrast	£80
CT (with contrast) followed by fluoroscopic cystourethrogram	CT with contrast plus fluoroscopy plus catheter	£210
CT (with contrast) followed by CT cystourethrogram	CT with contrast plus CT with contrast plus catheter	£232
CT (without contrast) followed by fluoroscopic cystourethrogram	CT without contrast plus fluoroscopy plus catheter	£199
CT (without contrast) followed by CT cystourethrogram	CT without contrast plus CT with contrast plus catheter	£221

The above examples of costs are based on CT for adults, and this could vary for children and also depending on whether fluoroscopy takes more than 20 minutes, as this is a separate cost category.

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7.7.5 Evidence statements

Clinical

Moderate quality evidence from one diagnostic study comprising 224 participants showed CT with contrast followed by CT cystography has a median sensitivity of 1.0 (95% CI, 0.81 to 1.0) and median specificity of 1.0 (95% CI, 0.98 to 1.0) in detecting bladder injury when compared with the reference standard of operative findings and clinical follow-up.

Low quality evidence from one diagnostic study comprising 224 participants showed CT with contrast followed by CT cystography has a median sensitivity of 0.92 (95% CI, 0.62 to 1) and median specificity of 1.0 (95% CI, 0.98 to 1.0) in detecting extraperitoneal injury when compared with the reference standard of operative findings and clinical follow-up.

Very low quality evidence from one diagnostic study comprising 224 participants showed CT with contrast followed by CT cystography has a median sensitivity of 1.0 (95% CI, 0.48 to 1.0) and median specificity of 1.0 (95% CI, 0.98 to 1.0) in detecting intraperitoneal injury when compared with the reference standard of operative findings and clinical follow-up.

Very low quality evidence from one diagnostic study comprising 25 participants showed conventional cystography has a median sensitivity of 1.0 (95% CI, 0.48 to 1.0) and median specificity of 0.95 (95% CI, 0.75 to 0.95) in detecting bladder injury when compared with the reference standard of operative findings, later imaging, and clinical follow-up.

Low quality evidence from one diagnostic study comprising 212 participants showed CT with contrast followed by conventional cystography has a median sensitivity of 0.95 (95% CI, 0.74 to 1) and median specificity of 1.0 (95% CI, 0.98 to 1.0) in detecting bladder injury when compared with the reference standard of operative findings, later imaging, and clinical follow-up.

Low quality evidence from one diagnostic study comprising 212 participants showed CT with contrast followed by conventional cystography has a median sensitivity of 0.93 (95% CI, 0.66 to 1) and median specificity of 1.0 (95% CI, 0.98 to 1.0) in detecting extraperitoneal injury when compared with the reference standard of operative findings, later imaging, and clinical follow-up.

Low quality evidence from one diagnostic study comprising 212 participants showed CT with contrast followed by conventional cystography has a median sensitivity of 1.0 (95% CI, 0.48 to 1.0) and median specificity of 1.0 (95% CI, 0.98 to 1.0) in detecting intraperitoneal injury when compared with the reference standard of operative findings, later imaging, and clinical follow-up.

Economic

No relevant economic evaluations were identified.

7.7.6 Recommendations and link to evidence

Recommendations	Research recommendation: How accurate is the first CT scan with contrast (trauma scan) for detecting bladder injuries in people with suspected bladder injuries after a traumatic incident?
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 such RCTs were identified and so diagnostic accuracy studies were used for this review.

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	The critical outcomes for this diagnostic review question are sensitivity and specificity of the index tests relative to a reference test (which is assumed to give the 'true' diagnosis). The consequences of missing a true injury were regarded as more serious than the consequences of making a false diagnosis, so sensitivity was regarded as a higher priority outcome for decision-making.
Trade-off between clinical benefits and harms	**Diagnostic RCT evidence** No clinical evidence. **Diagnostic accuracy evidence** CT with contrast followed by CT cystography was found to be very accurate for diagnosing bladder injury with a sensitivity and specificity of 1. The sensitivity and specificity for diagnosing intraperitoneal bladder injury was also 1. The sensitivity and specificity for diagnosing extraperitoneal bladder injury was 0.92 and 1, respectively. This implies that using CT with contrast followed by CT cystography should not miss intraperitoneal bladder injury, but may miss up to 8% of extraperitoneal injuries. It also implies that this test will not lead to misdiagnoses in either intra or extraperitoneal bladder injuries. Conventional cystography was found to be accurate for diagnosing bladder injury with a sensitivity of 1 and specificity of 0.95. This implies that conventional cystography should not miss intraperitoneal bladder injury, but may misdiagnose up to 5% of people without injuries. CT with contrast followed by conventional cystography was found to be accurate for diagnosing bladder injury with a sensitivity of 0.95 and specificity of 1. The sensitivity and specificity for diagnosing intraperitoneal bladder injury was 1. The sensitivity and specificity for diagnosing extraperitoneal bladder injury was 0.93 and 1, respectively. This implies that using CT with contrast followed by conventional cystography may miss 5% of cases with intraperitoneal bladder injury, and may miss up to 8% of cases with extraperitoneal injuries. It also implies that this test will not lead to misdiagnoses in either intra or extraperitoneal bladder injuries.
Economic considerations	No economic evidence was identified for this question. The GDG were presented with costs of the different interventions on the protocol based on the type of imaging that was included (with or without contrast) and whether a cystourethrogram was part of the intervention. The most expensive intervention was CT with contrast followed by CT cystourethrogram at £232 per patient. The cost effectiveness of a diagnostic modality stems from how accurately it can identify people with the injury and rule out people without the injury, as well as the true prevalence of the condition within the population being imaged. It was estimated by the GDG that around 1 in 10 pelvic fractures will have a bladder injury. Cystourethrograms take longer than CT and this could have an important impact if these are time critical injuries. There may be a trade-off here between accuracy of a strategy and the additional time involved in getting that diagnosis which could be particularly important in a multiply injured patient. It is not always the case that a bladder injury would need intervention, in most cases the treatment would involve a catheter needing to be inserted.

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	The clinical review showed that all the papers looking at different strategies had high sensitivity and specificity. However, CT with contrast followed by CT cystourethrogram had 100% sensitivity and specificity when identifying bladder injuries as a whole. This was the most expensive strategy; however, as the diagnostic accuracy is very similar between the three methods identified from the papers, cost effectiveness remains uncertain and is dependent on the consequences; of missed injuries and from using a more time intensive method. Current practice is variable but generally involves some additional image following on from the initial trauma CT. For example, this could be a contrast CT followed by an X-ray. Or the surgeon in theatre could undertake the cystourethrogram themselves by inserting contrast into the bladder and undertaking a fluoroscopy, however, this technique can lead to difficulties in theatre because the contrast in the bladder then affects imaging quality when imaging to check the position of the pelvis for surgery. The GDG noted how evidence was lacking on the sensitivity and specificity of CT with contrast alone (that is, the initial trauma CT), and this is an intervention of interest because the opinion was that if the bladder injury is severe enough, it would most likely show up on that initial CT, and this is the intervention that it would be useful to have information on because this can then negate the use of further imaging and free up time later. For a bladder injury to occur, this would be in the context of a high-energy pelvic fracture, which in turn would occur in a multiply injured patient, and a trauma CT (head to pelvis with contrast) would always be undertaken in this case, and therefore, can that first CT diagnose a bladder injury with enough accuracy to not warrant further investigation? This was the question the GDG felt has remained unanswered, and therefore, a research recommendation was decided.
Quality of evidence	**Diagnostic RCT evidence** No clinical evidence. **Diagnostic accuracy evidence** Risk of bias of diagnostic accuracy studies was assessed using the QUADAS 2 tool. The diagnostic accuracy evidence varied in quality between outcomes. One outcome was graded as Moderate quality due to risk of bias (reference standard). All others were graded as Low or Very low quality due to risk of bias (reference standard) and imprecision. Although specificity measures were not imprecise, the imprecision of sensitivity measures was generally very serious, with the lower limit of the confidence interval venturing as low as 0.48 for all comparisons. This indicates that the results in the study samples may not be a particularly accurate indicator of the value we might observe in the whole population and so caution is required when interpreting these results.
Other considerations	The GDG agreed that because no relevant studies were found for the diagnostic RCT review, no recommendation for diagnosing bladder and urethral injuries could be made based on that review. In addition, the GDG did not consider that the studies included in the diagnostic accuracy review covered all of the important imaging strategies for diagnosing bladder injuries. The current standard for detection of bladder injuries is the first trauma CT with IV contrast followed by another visit to either the CT or fluoroscopy suite for a retrograde cystogram. The GDG agreed that this was an accurate strategy for diagnosis of bladder injuries but felt that there were advantages to a strategy that did not involve a second set of images.

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	The strategy which was not covered in the evidence that was of most interest to the GDG was whether the first trauma CT with IV contrast (trauma scan) that nearly all major trauma patients receive after arrival to hospital could accurately diagnose bladder injuries. The rationale for the viability of this strategy is that the IV contrast will gather in the bladder and allow for identification of bladder injury during the pelvis trauma scan. The GDG stated that no extra time should be spent waiting for the contrast to arrive in the bladder and as such, this strategy should not delay completion of the trauma scan. The GDG felt that, if accurate, this strategy would lead to better outcomes for major trauma patients. The better outcomes would be realised through faster diagnosis of bladder injury, no dedicated further imaging for bladder injury that could impede or delay treatment of the patient and give the patient an increased radiation burden. The GDG decided a research recommendation to investigate this imaging strategy was appropriate.

7.8 Pelvic haemorrhage control

7.8.1 Introduction

Pelvic haemorrhage can be fatal, and so optimal management strategies are of vital importance. There is currently variation in the methods used to control pelvic haemorrhage. Since these may differ in efficacy, it follows that in some areas, less effective strategies are being employed, which may have an impact on morbidity and mortality. To ensure that the optimal strategy is universally applied, this review aims to evaluate the clinical and cost effectiveness of arterial embolisation, anterior external fixation, pelvic C-clamps and open pelvic packing.

7.8.2 Review question: What is the most clinically and cost-effective invasive technique for control of bleeding in pelvic ring fractures?

For full details see review protocol in Appendix C.

Table 94: PICO characteristics of review question

Population	Children, young people and adults experiencing a traumatic incident.
Interventions	• Arterial embolisation (interventional radiology) • Anterior external fixation • Pelvic C-clamps • Open pelvic packing
Comparisons	Any other intervention
Outcomes	Critical: • Mortality • Health-related quality of life • Re-bleeding rates • Need for further intervention • Volume of blood lost/number of transfusions required • Time to definitive control of haemorrhage • Need for rescanning • Adverse effects ○ Tissue necrosis/muscle infarction

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	○ Deep infection Important: • pain/discomfort • return to normal activities • Length of stay
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.

7.8.3 Clinical evidence

One study was included in the review[49], methodological details of which are summarised in Table 95 below. Evidence from this study is summarised in the clinical evidence summary below (Table 96). See also the study selection flow chart in Appendix D, study evidence tables in Appendix G, forest plots in Appendix I, GRADE tables in Appendix H and excluded studies list in Appendix J.

Table 95: Summary of studies included in the review

Study	Intervention and comparison	Population	Outcomes	Comments
Katsura 2013[49]	Any other intervention (laparotomy [LAP]) vs. arterial embolisation LAP vs. transarterial embolisation (TAE)	Study population that had both pelvic fractures and positive FAST results n=317 Eligible patient were restricted to those that had LAP or TAE as the initial therapeutic intervention LAP group n=123 TAE group n=194	In-hospital mortality	• Study conducted in Japan • 6-year retrospective cohort study based on data from the Japan Trauma Data • Bank • Although study did not adjust for source of bleeding and fracture type (two key confounders), a two model rigorous regression analysis was performed adjusting for age, gender, number of co-morbidities, systolic blood pressure (SBP),Glasgow coma scale (GCS), injury Severity Score (ISS) and abbreviated injury scale (AIS).AIS included pelvic AIS, head AIS, thoracic AIS and abdominal AIS. • It was assumed that source of bleeding and fracture type would be adjusted for in the incorporation of ISS and AIS in the analysis

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Table 96: Clinical evidence summary: laparotomy (open pelvic packing) versus Transarterial embolisation (interventional radiology)

Outcome	Number of studies (number of participants)	Imprecision	GRADE rating	Adjusted relative effects	Absolute difference (Field versus ED)	Control event rate (per 1000)	Control event rate for continuous outcomes
Mortality	1 (n=317)	Very serious	VERY LOW	OR: 1.13 (95% CI: 0.63 to 2.01)a	NA	NA	NA

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7.8.4 Economic evidence

Published literature

No relevant economic evaluations were identified.

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

Unit costs

Table 97: Intervention costs

Intervention	Detail	Cost per patient	Source
Arterial embolisation (interventional radiology)	Percutaneous Transluminal Embolisation of Blood Vessel	**£5,620**	Weighted for complications and co morbidities for HRG codes: YR21A and YR21B; as recorded for Non-Elective Inpatients long stay [21]
Anterior external fixation	Hoffmann II pelvic fixator 5 mm non-sterile reusable[b] Plus 1 hour of theatre time[a]	£2,523 £1,978 **Total =£4,501**	NHS Supply Chain [3]
Pelvic C-clamps	Pelvic C-clamp complete non-sterile re-useable[b] Plus 1 hour of theatre time[a]	£1,272 £1,978 **Total=£3,250**	NHS Supply Chain
Open pelvic packing	1 hour of theatre time[a]	**£1,978**	GDG contact

(a) Through GDG contact on the Major Trauma guideline. This is based on a cost per minute (£16.48) multiplied by 60 minutes. The theatre cost includes nursing, surgical equipment, overheads, an anaesthetist and a consultant.
(b) Assumed that the re-usable equipment can be re-used 3 times (total cost=£7,568)

7.8.5 Evidence statements

Clinical

Very low quality evidence from 1 study comprising 317 people with pelvic fractures and positive FAST results showed that laparotomy and arterial embolisation did not differ in terms of in-hospital control of pelvic haemorrhage, with very serious imprecision

Economic

No relevant economic evaluations were identified.

7.8.6 Recommendations and link to evidence

Recommendations	**27.For first-line invasive treatment of active arterial pelvic bleeding, use:**

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	• **interventional radiology if emergency laparotomy is not needed for abdominal injuries** • **pelvic packing if emergency laparotomy is needed for abdominal injuries.**
	In addition to the complex fracture GDG reviewing the most clinically and cost effectiveness invasive technique for control of bleeding in pelvic ring fractures, the major trauma GDG reviewed the clinical and cost effectiveness of the use of interventional radiology for definitive control. Developing the recommendations Evidence reviews were completed for all the guidelines and the separate GDGs reviewed the evidence and drafted recommendations. The same evidence was identified for both reviews. The overall guideline population of patients with pelvic bleeding meant that similarities and duplication between the draft recommendations were inevitable. The recommendations were taken to the project executive team (PET) for coherence and consistency checking. The PET agreed with the recommendations in both of the guidelines.
Relative values of different outcomes	Critical outcomes were mortality, health-related quality of life, re-bleeding rates, need for further intervention, volume of blood lost/number of transfusions required, time to definitive control of haemorrhage, need for rescanning, adverse effects, such as tissue necrosis/muscle infarction and deep infection. Important outcomes were pain/discomfort, return to normal activities and length of hospital stay.
Trade-off between clinical benefits and harms	The only included study showed no clinically important difference in in-hospital mortality between interventional radiology and pelvic packing. Although these two interventions might truly not differ in their effects on mortality, they might differ in more subtle ways, such as the re-operation rate, adverse effects or length of stay. Hence the GDG felt that the single available outcome of mortality was insufficient to allow a conclusion more refined than the fact that the two approaches carried the same risk of mortality.
Economic considerations	No economic evidence was identified to inform this question. Interventional radiology uses angiography to guide treatment and is performed by inserting tubes of a wide range of sizes (depending on the treatment being performed) into blood vessels, most commonly via the groin. Interventional radiology requires specialist X-ray imaging equipment and an interventional radiology team (radiologist, radiology scrub nurse and radiographer) to be available and thus, may take more time to prepare when teams are on-call. Interventional radiology doesn't usually take place in theatre, however, hybrid theatre and interventional radiology suites are becoming increasingly common. The procedure is not as invasive as surgery (less physiological insult), and the costs of setting up the theatre (for example, theatre staff, including surgeons and anaesthetists) are likely to be similar to those of preparing the interventional radiology in hybrid theatres. Additionally, only interventional radiology is likely to be a definitive procedure if successful. In surgery fixation, clamps and packing are temporary measures of haemorrhage control and likely to involve subsequent operations to definitively control the haemorrhage.

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	In terms of costs, both surgery and interventional radiology can cost thousands of pounds depending on the time taken due to the complexity of individual cases, and the staff needed. The cost of embolization is variable depending on the agent used and the number of bleeding sites treated. Embolisation of aneurysm of a blood vessel can cost around £5,000 to £6,000 (NHS reference costs). Whereas surgery (damage control followed by definitive surgery if costed by theatre time) costs under £5,000. The success rate of interventional radiology will determine if further operations are needed. Assuming that embolisation is successful in 95% of cases. Then 5% will require an operation after embolisation. If definitive haemorrhage control takes 3 hours (which equates to roughly £3,000), then the cost of embolisation would actually be £5,620 + (0.05*£3,000) = £5,770. When factoring in the costs of the re-operations that are likely to be needed for definitive control from other interventions, then interventional radiology may be cheaper than other interventions. Additionally, if the interventional radiology is done within theatre or in an adjoining suite surgery can continue on from the interventional radiology if necessary. This reduces the re-operation cost further, as the costs of setting up the theatre and the staff involved would already apply for the interventional radiology. The GDG felt that it is quite rare that interventional radiology fails, and therefore, the cost is likely to be lower than demonstrated here. The complication rates of the two methods also need to be taken into account, which can vary depending on the location of the bleed as mentioned above and the patient's physiological status. As interventional radiology is a less invasive method, the opinion of the GDG was that this is likely to result in less downstream resource use and fewer adverse events than the surgical methods. Surgery is associated with complications and also could have an impact on the patient in terms of recovering from anaesthesia, therefore, although interventional radiology could also have adverse events, it was felt that simply due to the nature of the more invasive procedures, these are likely to have more adverse events and downstream resource use compared with interventional radiology. The GDG also felt that interventional radiology would take a similar amount of time to arrange as surgery, however, in current practice, there is a delay in deciding between surgery or interventional radiology. Thus, a clear recommendation encouraging IR, and equalising access to IR to that of surgery, would inevitably speed up the delivery of potentially life-saving interventions. The GDG opinion was that interventional radiology is a worthwhile procedure and did not feel that the clinical evidence identified was strong enough to dissuade them from their expert opinion on the interventions. The most cost effective intervention depends on the likelihood of the success of the embolisation, as well as considering the adverse events and downstream resource use of the procedures being compared. The GDG felt that interventional radiology was likely to be cost effective.
Quality of evidence	The evidence had very serious risk of bias. The cohort study was limited by possible selection and attrition bias. The study conducted a propensity score-adjusted regression analysis, adjusting for age, ISS and other potential confounders. Unfortunately, key confounders, such as source of bleeding and fracture type, were not directly adjusted for in the analysis. However, the GDG agreed that the

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	adjustments made for ISS would probably have ensured that sources of bleeding and fracture type would be indirectly adjusted for.
Other considerations	In the absence of convincing or clear evidence, the GDG used consensus to form their recommendations. The GDG felt that because interventional radiology was less invasive, with consequent lower risks of adverse events, it was probably the most appropriate method to use if an emergency LAP was not needed. However, if an emergency LAP was already needed, pelvic packing would not increase the invasiveness of existing management, and so would be an appropriate approach that would not greatly increase the duration of treatment. The GDG felt that for any patient there was a chance that either intervention approach would be used, depending on the need for a LAP. Hence the GDG felt that rapid access to both interventions was very important. The GDG recognised that delay to any intervention was potentially harmful, and felt that the aim of the review question was to help rapid decision making and decrease indecision around variation of current practice. The GDG, therefore, felt that proximity of the interventional radiology facility to theatres for open surgery was important to reduce delay. It was also recognised that hybrid theatres, where either procedure can be carried out, have the particular advantage that management can be better adapted to an evolving clinical situation.

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8 Pilon fractures in adults and intra-articular distal tibia fractures in children

8.1 Pilon transfer

8.1.1 Introduction

Pilon fractures are a rare type of fracture of the distal tibia. They are associated with high-energy trauma, such as falls from a significant height or motor vehicle accidents, and occur when the talus is directed forcefully into the tibial plafond impacting the articular surface. The high energy characters of traumatic incidents mean patients often have additional injuries that require treatment. For this reason, pilon fractures may be difficult to fixate and are associated with high rates of complications and poor outcomes. These complications include wound healing problems, osteomyelitis, malunion, non-union, infections and hardware failure.

8.1.2 Review question: Is it clinically and cost effective to transfer people with a pilon fracture (equivalent in children: McFarlane fracture) to a specialist centre prior to first surgical procedure?

For full details see review protocol in Appendix C.

Table 98: PICO characteristics of review question

Population	Children and young people with McFarlane fractures or adults with pilon fractures following a traumatic incident
Interventions	• Transfer to specialist centre (as designated by a major trauma network) prior to first surgical procedure • Delayed transfer following initial stabilisation surgery
Comparisons	To each other or no transfer
Outcomes	Critical: • Health-related quality of life • Surgical site infection • Ankle fusion • Unplanned further surgery (any surgery including for infection, re-intervention, or to correct fusion) Important: • Patient-reported outcomes (return to normal activities).
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.

8.1.3 Clinical evidence

No relevant clinical studies comparing were identified. See the search strategy in appendix F, study selection flow chart in Appendix D and excluded studies list in Appendix J.

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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	**Adults** **28. Create a definitive management plan and perform initial surgery (temporary or definitive) within 24 hours of injury in adults (skeletally mature) with displaced pilon fractures.** **29. If a definitive management plan and initial surgery cannot be performed at the receiving hospital within 24 hours of injury, transfer adults (skeletally mature) with displaced pilon fractures to an orthoplastic centre (ideally this would be emergency department to emergency department transfer to avoid delay).** **30. Immediately transfer adults (skeletally mature) with displaced pilon fractures to an orthoplastic centre if there are wound complications.**
Relative values of different outcomes	Critical outcomes were health-related quality of life, surgical site infection, ankle fusion, unplanned further surgery and return to normal activities.
Trade-off between clinical benefits and harms	No evidence was found in the literature so recommendations were made on the basis of consensus. The GDG described how the complication rate for pilon fractures is high and complications can be serious. Hence sufficient expertise is essential for adequate care of these patients. Many centres have the necessary expertise. However, the GDG felt that if there is insufficient expertise in a centre, early transfer should be considered. If a patient with a pilon fracture is deemed suitable for transfer, the GDG considered what sort of centre the patient should be transferred to. Several specialist centres exist. However, not all of these centres have plastic surgery facilities on site. The GDG felt that specialist centres without plastic surgeons on site would continue to successfully manage the great majority of pilon fractures admitted directly to that centre. However, if the decision was made to transfer a patient from a non-specialist centre, then it seemed sensible to transfer the patient to an orthoplastic centre, where any wound complications could be dealt with directly.

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	The GDG also felt that delays in initiating management can reduce benefits and increase harms, and that patients should have a clear treatment plan within 24 hours, and this proviso should apply 7 days a week. The GDG discussed that although physical transfer may be delayed, initial information can be sent to the referral centre by phone to facilitate an early management plan.
Economic considerations	No economic evidence was identified for this question. There is a trade-off between the benefits, risks and costs of a patient with a displaced pilon fracture; remaining in the receiving hospital following initial surgery versus being taken to an orthoplastics centre prior to initial surgery. The GDG believed that the complication rate for pilon fractures is high and these complications can require revision surgery, which incurs additional treatment costs. They also believed that delayed initial treatment of these fractures increased the risk of complications and so the GDG felt they needed to be treated within 24 hours of injury. Pilon fracture surgery requires expertise that is not available at all hospitals and so the patient needs to be transferred to an orthoplastics centre if that expertise is not available at the receiving hospital within this 24 hour period. The GDG believed that the additional cost of transfer would be outweighed by the reduction in costs for the treatment of complications and so recommended that all people with a displaced pilon fracture should be transferred if a definitive management plan and initial surgery could not be performed within 24 hours of injury. If a patient were being transferred, the GDG believed that, given the high rate of complications associated with pilon fractures, it would reduce costs to send the patients to an orthoplastics centre directly, rather than a specialist centre without plastic surgery on site. That way, any wound complications could be treated without the need for a further transfer. They also believed that early transfer would give the potential for early definitive fixation for suitable cases, which is likely to result in reduced hospital stay and therefore reduce costs further.
Quality of evidence	No evidence was found.
Other considerations	The GDG discussed how some receiving centres may not deal with pilon fractures at all. For this they felt that an immediate emergency department (ED)-to-ED transfer to a specialist centre should be carried out to reduce delays. Other receiving centres may have the expertise to deal with pilon fractures, but there might be a lack of resources at certain times. For this scenario the GDG felt that immediate referral to an orthoplastics centre would be optimal.

Recommendations	**Children** **31. Create a definitive management plan involving a children's orthopaedic trauma specialist within 24 hours of diagnosis in children (skeletally immature) with intra-articular distal tibia fractures.** **32. If a definitive management plan and surgery cannot be performed at the receiving hospital, transfer children (skeletally immature) with intra-articular distal tibia fractures to a centre with a children's orthopaedic trauma specialist (ideally this would be emergency department to emergency department transfer to avoid delay).**

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Relative values of different outcomes	Critical outcomes were health-related quality of life, surgical site infection, ankle fusion, unplanned further surgery and return to normal activities.
Trade-off between clinical benefits and harms	No evidence was found in the literature so recommendations were made on the basis of consensus. The paediatric specialist reported how accurate initial diagnosis was essential for optimal management. Intra-articular fractures in children usually involve damage to the growth plate and injuries that may initially appear innocuous need careful evaluation and follow-up because of the risk of premature growth arrest. In addition, unrecognised mechanical instability can lead to early deformity, functional loss and increased risk of serious late onset problems, such as growth disturbance. It is recognized that the majority of children's trauma is managed appropriately by trauma surgeons who are not dedicated children's surgeons, but uncommon injuries with potential complications warrant specialist opinion. Hence timely discussion with a children's orthopaedic trauma specialist or transfer to a site with appropriate children's orthopaedic trauma expertise was essential. The GDG suggest that a management plan is determined within 24 hours of diagnosis rather than within 24 hours of injury in recognition of the fact that the true extent of these injuries is not always appreciated on first presentation.
Economic considerations	No economic evidence was identified for this question. Intra-articular fractures in children are relatively rare and the potential for a poor outcome may not be immediately apparent. Similarly to adult pilon fractures, they have a risk of developing severe long-term complications if treatment is delayed. For this reason, the GDG believed that a definitive management plan involving a children's orthopaedic trauma specialist should be made within 24 hours of diagnosis. If a definitive management plan and initial surgery cannot be performed at the receiving hospital, the GDG agreed that the patient should be transferred to a centre where there is a children's orthopaedic trauma specialist. This was a consensus decision based on the small cost of transferring this small group of people who could have a detrimental effect to health if not transferred in a timely manner. Should deformity and growth disturbance occur as a result of delayed treatment, the cost of revision surgery including increased length of stay and the potential for repeated interventions is considerable. The GDG also realised that not all intra-articular fractures are severe, but due to the difficulty in diagnosing those that are severe, and the low overall numbers, the GDG believed this was a cost effective strategy.
Quality of evidence	No evidence was found.
Other considerations	These are injuries which have a moderate risk of late complications independent of initial treatment and thus need adequate follow up by children's orthopaedic surgeons.

8.2 Staging of pilon fixation

8.2.1 Introduction

Pilon fractures are a complex injury involving damage to the articular surface of the distal tibia at the ankle joint. They are caused by falls from height and high-speed motor vehicle accidents. As well as the damage to the ankle joint, pilon fractures also involve considerable damage to the soft tissues of the lower leg, including the nerves and blood supply. Therefore, although they are not common injuries, they have life-long implications for patients' function and quality of life, and usually incur long-term costs through the need for further surgery and rehabilitation. A review of this area to identify the optimal management strategy, both in terms of the type of fixation and its timing, is therefore highly relevant.

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8.2.2 Review question: What is the most clinically and cost effective strategy in the surgical management of pilon fractures?

For full details see review protocol in Appendix C.

Table 99: PICO characteristics of review question

Population	Adults with a traumatic pilon fracture
Intervention	• Definitive fixation within 24 hours • Temporary fixation and then definitive fixation from >24 hours to 7 days • Temporary fixation and then definitive fixation at >7 days • POP and then definitive fixation from >24 hours to 7 days • POP and then definitive fixation at >7 days
Comparison	To each other
Outcomes	Critical: • Quality of life • Mortality • Amputation • Deep infection • Unplanned surgery Function Pain • Return to normal activities Important: • Length of stay • Hospitalisation • Return to normal activities
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.

8.2.3 Clinical evidence

We searched for randomised studies comparing the timing of definitive fixation and type of temporary stabilisation. No randomised studies were found, but four eligible cohort studies were identified and included in the review. [18,37,50,92,93] These are summarised in Table 100 below. Evidence from these studies is summarised in the clinical evidence summaries below (Table 101 and Table 102). See also the study selection flow chart in Appendix D, study evidence tables in Appendix G, forest plots in Appendix I, GRADE tables in Appendix H and excluded studies list in Appendix J.

Although one of the studies had a relatively rigorous design [92,93], there were serious problems with the applicability and quality of three included studies[18,37,50]. None were designed to evaluate the review question directly, and all were confounded by the method of definitive fixation. Hence, it is unclear if the differences in outcome between groups were a result of the differences in timing of definitive fixation or if these differences were wholly or partly influenced by the differences in definitive fixation method. Reporting of methods was poor, with surgical methods and timing often unclear. Furthermore, whilst Tang 2014 [92,93] restricted the population to closed pilon fractures, the other three studies had mixed open and closed cohorts [18,37,50]. Although this did not cause bias, because groups were matched for open and closed fractures, this does affect the external validity of the results.

The results of Tang 2014 [92,93] were dealt with separately to the other three studies, as the protocol had dictated that studies should be stratified by whether the population reported was open or closed or mixed.

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8.2.3.1 Summary of included studies

Table 100: Summary of studies included in the review

Study	Intervention and comparison	Population	Outcomes	Comments
Davidovitch 2011[18]	Definitive fixation within 24 hours[a] versus temporary fixation (mainly external fixation but also some splinting) and then definitive fixation at >7 days	Adults of mean age 42.5 years with acute fractures of the distal tibial plafond (OTA type 43 C fractures). n=46	Deep infection Unplanned surgery Function	Retrospective cohort study. Key confounder (open/closed fractures) balanced between groups. However, no adjustment was made for the type of definitive fixation, which differed between the groups. The group with definitive fixation at <24 hours had external fixation with limited internal fixation, and the group with definitive fixation at >7 days had internal fixation.
Harris 2006[37]	Temporary fixation (splinting) followed by definitive fixation from >24 hours to 7 days versus temporary fixation (splinting) followed by definitive fixation at >7 days	Adults of mean age 25 years with fractures of the distal tibial plafond. n=79	Deep infection Unplanned surgery Function	Retrospective cohort study. Key confounder (open/closed fractures) balanced between groups. However, no adjustment was made for the type of definitive fixation, which differed between the groups. The group with definitive fixation at >24 hours to 7 days had external fixation, and the group with definitive fixation at >7 days had internal fixation.
Koulouvaris 2007[50]	Definitive fixation within 24 hours versus temporary fixation (external fixation) followed by definitive fixation at >7 days	Adults of unknown mean age with fractures of the distal tibial plafond. n=55	Unplanned surgery Return to normal activities	Retrospective cohort study. Key confounder (open/closed fractures) balanced between groups. However, no adjustment was made for the type of definitive fixation,

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Study	Intervention and comparison	Population	Outcomes	Comments
				which differed between the groups. The group with definitive fixation at <24 hours had external fixation or external fixation combined with open reduction internal fixation (ORIF), and the group with definitive fixation at >7 days had internal fixation with a plate.
Tang 2014 [92,93]	Temporary fixation (splinting) followed by definitive fixation from >24 hours to 7 days versus temporary fixation (splinting) followed by definitive fixation at >7 days	Adults of age 45 years with closed pilon fractures	Deep infection Hospital stay Function	Retrospective study; All had closed fractures; groups very well matched for main confounders. Both groups had ORIF as definitive fixation.

(a) Timing of definitive fixation in intervention group unclear. No mention of any temporary fixation in that group and yet mention was made of definitive fixation being at a mean of 4.6 days which is unlikely if there had been no temporary fixation – it is possible, however, that this time point just relates to the limited internal fixation or the fibular fixation

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Mixed open/closed fractures

Table 101: Clinical evidence summary: Definitive fixation within 24 hours versus temporary fixation plus definitive fixation at more than 7 days

Outcome	No. of studies (n)	Imprecision	GRADE rating	Absolute difference	Control event rate (per 1000)	Control value for continuous outcomes
Number of surgeries (Better indicated by lower values)	1(n=46)	Serious	VERY LOW	MD 0.6 lower (1.03 to 0.17 lower)	-	2.1
Function - American Orthopaedic Foot and Ankle Society (AOFAS)(Better indicated by higher values)	1(n=46)	Serious	VERY LOW	MD 4.7 higher (5.55 lower to 14.95 higher)	-	72.4
Function - Short Musculoskeletal Function Assessment (SMFA) (Better indicated by lower values)	1(n=46)	Serious	VERY LOW	MD 8.5 lower (18.41 lower to 1.41 higher)	-	2.1
People with unplanned surgery	1(n=55)	Very serious	VERY LOW	76 fewer per 1000 (from 77 fewer to 32 more)	77	-
Return to normal activities	1(n=55)	Serious	VERY LOW	92 fewer per 1000 (from 249 fewer to 102 more)	923	-

Table 102: Clinical evidence summary: Temporary fixation plus definitive fixation at more than 24 hours to 7 days versus temporary fixation and definitive fixation at more than 7 days

Outcome	No. of studies (n)	Imprecision	GRADE rating	Absolute difference	Control event rate (per 1000)	Control value for continuous outcomes
Deep infection	1(n=79)	Serious	VERY LOW	60 more per 1000 (from 70 less to 200 more)	0	-
unplanned surgery	1(n=79)	Serious	VERY LOW	187 more per 1000 (from 6 more to 829 more)	63	-

Outcome	No. of studies (n)	Imprecision	GRADE rating	Absolute difference	Control event rate (per 1000)	Control value for continuous outcomes
Foot function index (Better indicated by lower values)	1(n=79)	Serious	VERY LOW	MD 0.17 higher (0 to 0.34 higher)	-	0.23
musculoskeletal function assessment score (Better indicated by lower values)	1(n=79)	Serious	VERY LOW	MD 13.1 higher (0.21 to 25.99 higher)	-	20.9

Closed fractures

Table 103: Clinical evidence summary: Definitive fixation more than 24 hours to 7 days hours versus temporary fixation plus definitive fixation at more than 7 days

Outcome	No. of studies (n)	Imprecision	GRADE rating	Absolute difference	Control event rate (per 1000)	Control value for continuous outcomes
Deep infection	1(n=46)	Very serious	VERY LOW	38 fewer per 1000 (from 44 fewer to 195 more	44	-
Function – poor/fair	1(n=46)	NA	VERY LOW	None	-	-
Hospital stay	1(n=46)	None		7.6 lower (from 9.62 lower to 5.58 lower)		15.2 days

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 104 below shows the additional equipment that is required for the temporary fixation and POP in the strategies where definitive fixation is delayed. Temporary fixation involves a device with re-usable components. These are assumed to incur a small additional cost and so only the disposable components have been presented here.

See section 8.3.4 for details of definitive fixation costs.

Table 104: UK costs of temporary external fixation equipment

Equipment	Unit cost
4 K-wires single use	£51
POP bandage pack of 12	£10

Source: NHS Supply Chain [3]

8.2.5 Evidence statements

Clinical

Mixed closed or open stratum

Definitive fixation within 24 hours versus temporary fixation and definitive fixation at more than 7 days

Very low quality evidence from one study comprising 46 adults with tibial pilon fractures showed that definitive fixation within 24 hours had a clinical benefit in terms of number of surgeries compared with temporary fixation and definitive fixation at more than 7 days, with serious imprecision

Very low quality evidence from one study comprising 46 adults with tibial pilon fractures showed that definitive fixation within 24 hours and temporary fixation and definitive fixation at more than 7 days did not differ in their effects on function as defined by the AOFAS, with very serious imprecision

Very low quality evidence from one study comprising 46 adults with tibial pilon fractures showed that definitive fixation within 24 hours and temporary fixation and definitive fixation at more than 7 days did not differ in their effects on function as defined by the SMFA, with very serious imprecision

Very low quality evidence from one study comprising 55 adults with tibial pilon fractures showed that definitive fixation within 24 hours had a clinical benefit in terms of unplanned surgery compared with temporary fixation and definitive fixation at more than 7 days, with very serious imprecision

Very low quality evidence from one study comprising 55 adults with tibial pilon fractures showed that definitive fixation within 24 hours had a clinical harm in terms of return to normal activities

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compared with temporary fixation and definitive fixation at more than 7 days, with serious imprecision

Temporary fixation and definitive fixation at more than 24 hours to 7 days versus temporary fixation and definitive fixation at more than 7 days

Very low quality evidence from one study comprising 79 adults with tibial pilon fractures showed that temporary fixation and definitive fixation at more than 24 hours to 7 days had a clinical harm in terms of deep infection compared with temporary fixation and definitive fixation at more than 7 days, with serious imprecision

Very low quality evidence from one study comprising 79 adults with tibial pilon fractures showed that temporary fixation and definitive fixation at more than 24 hours to 7 days had a clinical harm in terms of unplanned surgery compared with temporary fixation and definitive fixation at more than 7 days, with serious imprecision

Very low quality evidence from one study comprising 79 adults with tibial pilon fractures showed that temporary fixation and definitive fixation at more than 24 hours to 7 days had a clinical harm in terms of function as defined by the Foot Function Index compared with temporary fixation and definitive fixation at more than 7 days, with serious imprecision

Very low quality evidence from one study comprising 79 adults with tibial pilon fractures showed that temporary fixation and definitive fixation at more than 24 hours to 7 days had a clinical harm in terms of function as defined by the musculoskeletal function assessment score compared with temporary fixation and definitive fixation at more than 7 days, with serious imprecision

Closed stratum

Temporary fixation and definitive fixation at more than 24 hours to 7 days versus temporary fixation and definitive fixation at more than 7 days

Very low quality evidence from one study comprising 46 adults with closed tibial pilon fractures showed that temporary fixation and definitive fixation at more than 24 hours to 7 days did not differ with temporary fixation and definitive fixation at more than 7 days in terms of deep infection, with very serious imprecision

Very low quality evidence from one study comprising 46 adults with closed tibial pilon fractures showed that temporary fixation and definitive fixation at more than 24 hours to 7 days did not differ with temporary fixation and definitive fixation at more than 7 days in terms of function, with inestimable imprecision

Very low quality evidence from one study comprising 46 adults with closed tibial pilon fractures showed that temporary fixation and definitive fixation at more than 24 hours to 7 days had a clinical benefit in terms of hospital stay compared with temporary fixation and definitive fixation at more than 7 days, with no serious imprecision

Economic

No relevant economic evaluations were identified.

8.2.6 Recommendations and link to evidence

See LETR in section 8.3.6.

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8.3 Type of pilon fixation

8.3.1 Introduction

Pilon fractures are a complex injury involving damage to the articular surface of the distal tibia at the ankle joint. They are caused by falls from height and high-speed motor vehicle accidents. As well as the damage to the ankle joint, pilon fractures also involve considerable damage to the soft tissues of the lower leg, including the nerves and blood supply. Therefore, although they are not common injuries, they have life-long implications for patients' function and quality of life, and usually incur long-term costs through the need for further surgery and rehabilitation. A review of this area to identify the optimal management strategy, both in terms of the type of fixation and its timing, is therefore highly relevant.

8.3.2 Review question: Are fine wire external fixators more clinically and cost effective for managing pilon fractures than internal fixation with plates and screws?

For full details see review protocol in Appendix C.

Table 105: PICO characteristics of review question

Population	Adults with a pilon fracture requiring fixation, following a traumatic incident
Intervention(s)	Fine wire external fixation (circular fixators or wire fixators)
Comparison(s)	Open reduction and internal fixation (ORIF) without a circular frame
Outcomes	Critical: • Health-related quality of life • Surgical site infection • Ankle fusion • Unplanned further surgery • Wound breakdown Important: • Patient-reported outcomes (return to normal activities)
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.

8.3.3 Clinical evidence

Two RCTs were included.[95,101] The first study by Wang et al. [95] compared external fixation with ORIF after all the patients had calcaneal traction and was restricted to closed type B3 and C pilon fractures. The second study by Wyrsch et al.[101] included all patients with a confirmed intra-articular fracture of the pilon. For outcomes specified in the protocol and not reported with RCT data we included observational studies. We also included a single prospective cohort study in the analysis[81] as this provided quality of life data.

The three studies included in the review are summarised in Table 106 below. Evidence from these studies is summarised in the clinical evidence summary below (Table 107 and Table 108). See also the study selection flow chart in Appendix D, study evidence tables in Appendix G, forest plots in Appendix I, GRADE tables in Appendix H and excluded studies list in Appendix J.

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Table 106: Summary of studies included in the review

Study and type	Fracture type/ grade and patient characteristics	Intervention/ comparison	Outcomes	Comments
Richards2012[81] Prospective cohort	n=45 Type: C1-3, open or closed Age 18 years or older	Staged treatment Staged ORIF: Initial bridging external fixation with delayed joint fixation. Limited exposure of distal tibia surface, percutaneous plating and screw fixation. External fixation: 2 weeks post injury visualisation of the joint by incision. Screws for restabilisation. Removal of fixator once fracture healed.	• Health-related quality of life (SF-36 – Physical Function)	No assessor blinding 31% and 21% lost to follow-up for the external and stage ORIF groups respectively at 12 months No significant difference found at baseline for age, smoking status comorbidities, open fractures, mechanism of injury or OTA fracture classification
Wang2010[95] RCT	n=60 fractures Type: Closed B3 and C Adults older than 18 years	Stage 1: Calcaneal skeletal traction Stage 2: ORIF or external fixation	• Surgical site infection • Osteomyelitis	No allocation concealment No patient or assessor blinding Balanced baseline characteristics (gender, age, cause of injury, smoking, fracture classification, AO grading)
Wyrsch 1996[101] RCT	n=49 All patients with a confirmed intra-articular fracture of the tibial plafond. Adults 18 years or older	ORIF group: Dynamic compression plate, cloverleaf plate, mini-fragment T-plate).Post-operatively the lower extremity was immobilised for 2-3 weeks in a plaster splint Group 2 - External fixation group: A limited internal fixation combined with external fixation; an Orthofix fixator (EBI Medical, Parsippany, New Jersey) or a Synthes AO fixator (Paoli, Pennsylvania. The fixator was kept in place	• Surgical site infection • Osteomyelitis • Ankle Fusion • Unplanned Surgery • Wound breakdown • Amputation	No allocation concealment No patient or assessor blinding Balanced baseline characteristics (gender, age, fracture classification, AO grading)

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Study and type	Fracture type/ grade and patient characteristics	Intervention/ comparison	Outcomes	Comments
		for an average of 10 weeks and removed once evidence of bone callus formation was found.		

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Table 107: **Clinical evidence summary: ORIF versus external fixation (RCT)**

Outcome	No. of studies (n)	Imprecision	GRADE rating	Absolute difference	Control event rate (per 1000)	Control event rate for continuous outcomes
Surgical site infection	2 (n=95)	Serious	VERY LOW	107 more per 1000 (from 1 fewer to 695 more)	25	
Osteomyelitis	2(n=95)	Serious	VERY LOW	90 more per 1000 (from 0 fewer to 180 more)	0	
Ankle Fusion	1(n=39)	Very serious	VERY LOW	45 more per 1000 (from 53 fewer to 234 more)	53	
Unplanned further surgery - Additional surgery per patient (continuous)	1(n=39)	Serious	VERY LOW	MD 1.17 higher (0.18 to 2.16 higher)	-	0.3
Unplanned further surgery (dichotomous)	1(n39=)	Serious	VERY LOW	274 more per 1000 (from 26 fewer to 1000 more)	200	
Wound breakdown	1(n=39)	None	LOW	320 more per 1000 (from 10 more to 520 more)	0	
Amputation	1(n=39)	None	LOW	160 more per 1000 (from 0 more to 340 more)	0	

Table 108: Clinical evidence summary: ORIF versus external fixation (Cohort)

Outcome	No. of studies	Imprecision	GRADE rating	Absolute difference	Control event rate (per 1000)	Control event rate for continuous outcomes
Health-related quality of life – SF-36	1(n=45)	Serious	VERY LOW	MD 24.2 higher (10.13 to 38.27 higher)	-	25.5

Narrative summary for incompletely reported data

Richards2012[81,81] also reported SF-36, health-related quality of life data (see the clinical evidence summary data above for the 6-month follow-up data). No data was given for the time points of 3 and 12 months follow-up, but the paper reported that there was no significant difference between the two groups.

8.3.4 Economic evidence

Published literature

No relevant economic evaluations were identified.

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

Unit costs

The unit costs in Table 109 below show the individual unit costs of the components used for a definitive external fixation device. The number of each type of component required can vary depending on the injury and so an estimate of the total cost is given at the bottom of the table.

Table 109: UK costs of external fixation equipment

Device	Unit cost
Full ring non-sterile[a]	£182-£240
Half ring non-sterile[a]	£116-£141
Foot plate non-sterile[a]	£157-£215
4 K-wires single use	£51
Wire clamp	£87
Wire bolt	£45
Half pin bolt	£46
Half pin	£117
TOTAL (estimate)	£2,500

Source: NHS Supply Chain[3]
(a) Cost ranges indicate different sizes

Table 110: UK costs of ORIF equipment

Device	Unit cost
Contoured Plate	£235
Eight screws	£240
TOTAL	£475

Source: NHS Supply Chain[3]

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8.3.5 Evidence statements

Clinical - RCT

Very low quality evidence from two studies comprising 95 pilon fractures showed that ORIF may have a clinically important higher rate of surgical site infection compared with external fixation following, with serious imprecision.

Very low quality evidence from two studies comprising 95 pilon fractures showed that ORIF compared with external fixation traction may increase the osteomyelitis occurrence, with serious imprecision.

Very low quality evidence from a single RCT comprising 39 pilon fractures showed no clinical difference between ORIF and external fixation traction for the incidence of ankle fracture, with very serious imprecision.

Very low quality evidence from a single RCT comprising 39 pilon fractures showed a clinically significant increase in number of unplanned surgeries for ORIF compared with external fixation traction, with serious imprecision (dichotomous and continuous).

Low quality evidence from a single RCT comprising 39 pilon fractures showed a clinically significant increase in incidence of wound breakdown for ORIF compared with external fixation traction, with serious imprecision.

Low quality evidence from a single RCT comprising 39 pilon fractures showed a clinically significant increase in incidence of amputation with ORIF compared with external fixation traction.

Clinical - Cohort

Very low quality evidence from one study comprising 45 pilon fractures showed that following temporary external fixation, ORIF had a clinically important higher health-related quality of life compared with external fixation, with serious imprecision.

Economic

No relevant economic evaluations were identified.

8.3.6 Recommendations and link to evidence

Recommendations	Research recommendation: In adults with closed pilon fractures, what method of fixation provides the best clinical and cost effectiveness outcomes as assessed by function and incidence of major complications at 2 years (stratified for timing of definitive surgery early [under 36 hours] versus later [over 36 hours])?
Relative values of different outcomes	**Pilon fixation staging** Critical outcomes were quality of life, mortality, amputation, deep infection, unplanned surgery, function and pain. Important outcomes were length of stay, hospitalisation and return to normal activities. **Pilon fixation - type**

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	Critical outcomes were quality of life, surgical site infection, unplanned surgery, ankle fusion, wound breakdown. Important outcomes were hospitalisation and return to normal activities.
Trade-off between clinical benefits and harms	**Pilon fixation staging** **Mixed open and closed stratum** **Definitive fixation within 24 hours versus temporary fixation and definitive fixation at more than 7 days** There were clinically important benefits for definitive surgery carried out at less than 24 hours over later definitive surgery in terms of the number of surgeries and return to normal activities. There were no harms noted for definitive surgery carried out at <24 hours. Hence on this basis early definitive surgery appears to have the better balance of benefits and harms. **Temporary fixation and definitive fixation at more than 24 hours to 7 days versus temporary fixation and definitive fixation at more than 7 days**. There were clinically important harms for definitive surgery carried out between 24 hours and 7 days over later definitive surgery in terms of deep infection, unplanned surgery and function. Hence on this basis later definitive surgery appears to have the better balance of benefits and harms. This apparent conflict between the comparisons, with earlier definitive fixation being superior in one comparison to a relatively later definitive surgery, but inferior in the other comparison, is unlikely to be a result of the confounding arising from the type of definitive fixation in the studies, as both comparisons had internal fixation done at the later stage and external fixation at the earlier stage. A technical member of the GDG felt that this conflict could be explained by the fact that earlier fixation is only of relative benefit if it is not preceded by temporary fixation, but this explanation was formed to fit the evidence rather than being an a priori mechanism, and is therefore, probably spurious. **Closed stratum** **Temporary fixation and definitive fixation at more than 24 hours to 7 days versus temporary fixation and definitive fixation at more than 7 days.** There were clinically important benefits for definitive surgery carried out between 24 hours and 7 days over later definitive surgery in terms of hospital stay, but no difference between treatments in terms of deep infection. Hence on this basis earlier definitive surgery appears to have the better balance of benefits and harms. **Pilon fixation type** **ORIF versus external fixation** RCT data demonstrated clinically important benefits of external fixation compared with ORIF in terms of surgical site infection, unplanned surgery and wound breakdown. In addition, the studies reported a relative clinical benefit in terms of amputation and osteomyelitis for external fixation. These latter outcomes were not specified in the protocol but the GDG considered these to be significant and therefore chose to include these. A single cohort study was also included and reported only health-related quality of life (SF-36 functional score). This study demonstrated a clinical benefit from the ORIF strategy at 6 months compared with external fixation. However, the study also

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	indicated that there was no significant difference at 12 months between ORIF and external fixation. The GDG discussed the evidence and noted that external fixation demonstrated a clear clinical benefit across most of the RCT data. The GDG pointed out that there was limited soft tissue exposure with the external fixation procedure compared with the more invasive ORIF. The GDG indicated that the soft tissue around the area was particularly susceptible to infection and wound breakdown, and that this might partly explain the higher frequencies of complications following open reduction. The GDG also considered the cohort evidence for health-related quality of life which demonstrated a relative benefit for the internal procedure at 6 but not 12 months. The GDG noted that this could be explained by the fact that the external fixator, which might interfere with quality of life, would be kept on for up to, or over, 6 months, but probably less than 12 months.
Economic considerations	**Pilon staging** No economic evidence was identified for this question. In comparison to immediate definitive fixation, initial temporary stabilisation has an added intervention cost. Temporary fixation has the added cost of the disposable components of an external fixator, and an initial plaster cast has the added cost of the required materials. There is also the increased surgical time for two procedures to be performed, which adds a cost to the strategies with an initial temporary stabilisation. Other cost implications, in addition to the intervention costs, are the cost of complications, such as deep infection and amputation, as well as any unplanned surgical procedures required. These complications are expensive, especially amputation, which requires the lifetime use of prosthetics that require regular replacement. There is also an increase in pre-surgery hospital stay if definitive fixation is delayed and the GDG believe there is also likely to be an increase in post-surgery recovery time. Therefore, the clinical evidence is an important factor in assessing the overall economic impact of these interventions. Due to the Very low quality of the included clinical evidence, as well as the conflicting results, the GDG felt that the only recommendation that could be made was for further research. **Pilon fixation** No economic evidence was identified for this question. The GDG estimated the cost of a single use external ring fixator to be around £2,500 and the GDG were presented with the cost of a plate with eight screws for internal fixation at £475. The external fixator is much more expensive than internal fixation but the evidence suggests that there is an increase in the risk of deep infection and amputation, which can add a large cost to the internal fixation strategy. Evidence from the included cohort studies showed an improvement in health-related quality of life for internal fixation but thought it was likely to be due to the use of the external fixator for up to 6 months or more affecting usual activities rather than an effect on bone healing. The GDG did not feel they could make a recommendation for clinical practice based on the included clinical evidence as the spanning external fixator used in the study is

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	not used in clinical practice in the UK. They were also uncertain about the potential long-term health-related quality of life differences between internal and external fixation. Therefore, they decided that a research recommendation should be made.
Quality of evidence	**Pilon staging** Quality of evidence was very Low. All studies were non-randomised, increasing the risk of selection bias. Three of the non-randomised studies were confounded by definitive fixation type being different across the groups. **Pilon fixation** The quality of evidence ranged from Low to Very low for all outcomes. The two RCTs used an external procedure (spanning external fixation) which is not common practice within the NHS. The GDG noted this as a limitation but felt it was important to consider and include it as a comparator for a research recommendation. Moreover, the study by Wrysch et al. used an ORIF procedure which is no longer used in the NHS as it has been associated with a higher incidence of complication such as wound breakdown. The cohort study was at a very high risk bias, due to inevitable selection bias and also high attrition. It also did not specify the exact external device used making any recommendation based on this study difficult to apply. Evidence for all outcomes included in the review was very imprecise. Overall, the GDG felt the Low quality of the evidence underlined the need for research in this area.
Other considerations	The review questions concerning pilon fixation and stabilisation were not extended to children because the GDG recognised that the technical details of treatment of the paediatric version of the pilon fracture are not particularly contentious and that the risk of immediate catastrophic complications is negligible, in contrast with the adult pattern of the injury. So, the critical step is bringing the injured child to the attention of a specialist as soon as possible. The critical issues with regard to the children's fractures are: an appreciation that the seemingly innocuous X-ray is associated with an unstable injury which may lead to early and late deformity; surgical treatment which confers stability without endangering growth; and recognizing that the injury must be kept under observation long after it has healed. These points should be evident to a specialist children's surgeon. **Pilon staging** The GDG felt that the conflicting evidence also warranted a research recommendation. **Pilon fixation** The GDG indicated that the evidence was not applicable to current management of NHS patients. They noted that an external ring fixation device (most commonly used in the NHS) was not compared in the clinical evidence. They were therefore unable to make a recommendation based on the evidence or consensus and felt a research recommendation was appropriate. They suggested it would be important to compare this specifically against the spanning external fixation method as part of the research recommendation. **Overall**

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	The GDG formulated a research recommendation that encapsulated both review questions.

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9 Other

9.1 Identifying vascular compromise

9.1.1 Introduction

Arterial injury can lead to the loss of the limb or even death if not evaluated and treated as soon as possible. Two factors other than definitive treatment are essential in effective management. First, the method of diagnosis of vascular injury must be as accurate as possible. Second, these methods of diagnosis must be rapid and efficient enough to enable timely intervention; even a perfectly accurate diagnostic method is of little use if it does not give a definitive diagnosis until ischaemic damage is irreversible. This review therefore aimed to compare both accuracy and speed of delivery of the currently used assessment methods.

9.1.2 Review questions

a) What is the most effective method of identifying an arterial injury requiring intervention in people with upper and lower limb fractures?

b) Review question: What is the most accurate method for diagnosing an arterial injury in a person requiring intervention in people with upper and lower limb fractures?

Table 111: PICO characteristics of RCT review question a

Population	Children, young people and adults experiencing a traumatic limb incident. May use indirect evidence including non-fractures (because this will not affect accuracy of measurement) if there are no direct studies.
Intervention(s)	• Clinical assessment only • Doppler (standard) • ABPI (doppler used in a specific way) • Angiography with X-ray • Angiography done with initial CT • Combination of the above
Comparison	Any comparison of the above
Outcomes	Critical: • Mortality up to 12 months • Health-related quality of life • Limb salvage • Myoglobinuria/renal failure • Proportion requiring fasciotomy • Limb ischaemia/deep infection • Functional outcome measures • Pain/discomfort • Return to normal activities • Psychological wellbeing

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	• Time to revascularisation Important: • Total hospital length of stay
Study design	RCTs

Table 112: PICO characteristics of review question b

Population	Children, young people and adults experiencing a traumatic incident.
Index tests	• Clinical assessment only • Doppler (standard) • ABPI (doppler used in a specific way) • Angiography done with X-ray • Angiography done with initial CT • Combination of the above
Reference test	Later clinical/surgical outcomes or invasive catheter angiography/arteriography
Outcomes	Sensitivity and specificity
Study design	Diagnostic studies (direct evidence included >50% of the population having a complex fracture)

9.1.3 Clinical evidence

Diagnostic RCT review

No relevant RCTs were identified. Therefore the diagnostic protocol was followed.

Diagnostic accuracy review

Four diagnostic studies were included in the review;[13,58,64,89] these are summarised in Table 113 below. Evidence from these studies is summarised in the GRADE clinical evidence profiles below (Table 114 to Table 116). See also the study selection flow chart in Appendix D, study evidence tables in Appendix G, forest plots in Appendix I, GRADE tables in Appendix H and excluded studies list in Appendix J.

All of the studies had a mixed adult and child or young person population and it was not possible to stratify the results into the protocol-specified age groups. Although some of the studies use a mixture of reference tests, they have been included as the true outcome of whether the patient had an arterial injury or not was thought to have been identified through these methods. None of the studies were fully blinded and they all had a population which had less than 50% of the included patients with an extremity fracture. Hence they were all downgraded for indirectness

Summary of included studies

Table 113: Summary of studies included in the review

Study	Population	N	Index test(s)	Reference test	Comments
Busquets 2004[13]	>16 years who had a CT angiogram (CTA)for a suspected	97	• CTA	• For the 25 positive on CTA, the ref standard was invasive arteriography,	Very limited baseline characteristics Not blinded

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Study	Population	N	Index test(s)	Reference test	Comments
Retrospective cohort	vascular injury to the upper or lower extremities			invasive arteriography and surgery or surgery alone. • For the 72 negative on CTA the ref standard was later clinical observations for 62 and arteriography for 10	Only36% with fractures Mixed adult and young person population
Soto 1999[89] Prospective cohort	16-60 years with suspected limb arterial injury n=45 (43 after exclusion of 2)	43	• CTA	Conventional catheter angiography (that is, invasive)	Index testers blinded to reference test findings but no mention of reference testers being blinded to index. Mixed adult and young person population 2 excluded as index tests not of diagnostic standard Only 15.6% had fractures
Lynch 1991[58] Prospective cohort	Trauma victims with blunt or penetrating extremity trauma Adults and children (age range 11-62 years)	100 injured limbs in 93 patients	• Doppler (ABPI) <0.90	• Contrast arteriography using invasive transfemoral Seldinger technique • Later clinical outcomes	Not blinded Mixed population (22% with fractures or dislocations) Mixed adult and child population Contrast arteriography was shown by surgery to be incorrect in 2 cases (both FP) Thus only clinical outcome taken as ref test for this review.
Mills2004[64] Prospective cohort	Knee dislocations with potential vascular injury Age 15-74 years	38	• Doppler (ABPI) <0.90 • Clinical examination (Pulse)	• For those positive on doppler, the ref standard was arteriography or surgery (all	No set gold standard Not blinded Only 45%, 5/11) with fractures

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Study	Population	N	Index test(s)	Reference test	Comments
				ended up needing surgical treatment) • For those negative on doppler, the ref standard was admission for serial examination and delayed arterial duplex evaluation	Mixed adult and child population

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Index test: Computed Tomographic Angiography (CTA)

Table 114: Diagnostic accuracy profile of CTA for detecting arterial injury

Number of studies	n	Risk of bias	Inconsistency	Indirectness	Imprecision	Sensitivity (95% CI)	Specificity (95% CI)	Quality
CTA for detecting arterial injury (mixed gold standard[a]) in adults and young people								
1	97	Very serious[b]	NA	Serious	Not evaluable	1 (0.86-1)	1 (0.95-1)	VERY LOW
CTA for detecting arterial injury (conventional catheter angiography gold standard) in adults and young people								
1	43	Very serious[b]	NA	Serious	Not evaluable	R1: 0.9(0.80-0.99) R2: 1 (0.99-1) Cons: 1 (0.99-100)	1 (0.99-1) 1 (0.99-1) 1 (0.99-1)	VERY LOW

Abbreviations: *R1, reader1; R2, reader2; Cons, consensus decision of two index testers*

(a) Patients had different procedures; surgery, arteriography, combination of surgery and arteriography for those with positive CTA or clinical follow up or arteriography for negative CTA.

(b) No blinding, mixed population (less than 50% fractures, adults and young people, no fixed gold standard

Index test: Doppler (ABPI)

Table 115: Diagnostic accuracy profile of doppler (ABPI) less than 0.90 for detecting arterial injury

Number of studies	n	Risk of bias	Inconsistency	Indirectness	Imprecision	Sensitivity (95% CI)	Specificity (95% CI)	Quality
Doppler (ABPI) < 0.90 for detecting arterial injury (angiography and later clinical outcomes/duplex ultrasonography gold standard) in adults and children								
1	38	Very serious[b]	NA	Serious	Not evaluable	1 (95% CIs: 0.71-1)	1 (95% CIs: 0.71-1)	VERY LOW
Doppler (ABPI) less than 0.90 for detecting arterial injury (later clinical outcomes gold standard) in adults and children								
1	100	Very serious[c]	NA	Serious	Not evaluable	0.95 (95% CIs: 0.76-0.99%)	0.97 (95% CIs: 0.91-0.99)	VERY LOW

(a) Patients with less than 0.9 ABI underwent angiography, more than 0.9 had daily clinical examination and arterial duplex ultrasonography

(b) No blinding, mixed population (less than 50% fractures, adults and children), no fixed gold standard
(c) No blinding, mixed population (less than 50% fractures, adults and children)

Index test: Clinical assessment only (pulse)

Table 116: Diagnostic accuracy profile of clinical assessment only (pulse) for detecting arterial injury

Number of studies	n	Risk of bias	Inconsistency	Indirectness	Imprecision	Sensitivity (95% CI)	Specificity (95% CI)	Quality
Clinical assessment only (pulse) for detecting arterial injury (later clinical outcomes/duplex ultrasonography gold standard) in adults and children								
1	38	Very serious[a]	NA	None	Not evaluable	0.91 (95% CIs: 0.59-0.98%)	0.89 (95% CIs: 0.71-0.98)	VERY LOW

(a) No blinding, mixed population (less than 50% fractures, adults and children)

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

Very low quality evidence from two studies comprising 140 patients suggests that CT angiography for assessing arterial damage in upper and lower extremity injuries has a median sensitivity of 1 (95% CI, 0.86 to-1) and a corresponding specificity of 1 (95% CI, 0.95 to 1) when measured against the reference standard of a combination of procedures (surgical, arteriography, surgical and arteriography and clinical assessment).

Very low quality evidence from two studies comprising 138 patients suggests that Doppler (ABPI) for assessing arterial damage in upper and lower extremity injuries has a median sensitivity of 0.95 (95% CI, 0.76 to 0.99) and a corresponding specificity of 0.97 (95% CI, 0.91 to 0.99) when measured against the reference standard of later clinical findings.

Very low quality evidence from one study comprising 38 patients suggests that clinical assessment (pulse) for assessing arterial damage in knee dislocation injuries has a sensitivity of 0.91 (95% CI, 0.59 to 0.98) and a corresponding specificity of 0.89 (95% CI, 0.71 to 0.98) when measured against the reference standard of later clinical findings with duplex ultrasonography.

Economic

No relevant economic evaluations were identified.

9.1.6 Recommendations and link to evidence

Recommendations	**33. Use hard signs (lack of palpable pulse, continued blood loss, or expanding haematoma) to diagnose vascular injury.** **34. Do not rely on capillary return or Doppler signal to exclude vascular injury.** **35. Perform immediate surgical exploration if hard signs of vascular injury persist after any necessary restoration of limb alignment and joint reduction.** **36. Do not delay revascularisation for angiography in people with complex fractures.** **37. For humeral supracondylar fractures in children (under 16s) without a palpable radial pulse but with a well-perfused hand, consider observation rather than immediate vascular intervention.**
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

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	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 such RCTs were identified and so diagnostic accuracy studies were used for this review. The outcomes for this diagnostic review question are sensitivity and specificity of the index tests relative to a reference test (which is assumed to give the 'true' diagnosis). Sensitivity is an important outcome, because poor sensitivity may result in people with vascular injury being undiagnosed and therefore, untreated. In contrast, low specificity, leading to incorrect positive diagnoses, will lead to unnecessary treatments. Though carrying a risk of unnecessary adverse events and higher costs, such additional treatments secondary to misdiagnoses are unlikely to be as much of a risk to the patient as missed diagnoses.
Trade-off between clinical benefits and harms	**CTA** Overall, CTA had clear benefits in terms of very high (100%) sensitivity and specificity, meaning it should not miss vascular injuries and also be able to avoid any misdiagnosis. However, in one study one radiologist missed an injury, and although this error was resolved after consultation, this shows that CTA may not be 100% sensitive for all raters. One potential harm not derived from the studies, was the radiation risk. The benefits of CTA would probably dominate the radiation risk. This would apply to children as well as adults. **Doppler (ABPI>0.9)** Although one study showed that Doppler (ABPI<0.9) had 100% sensitivity and specificity, a larger (possibly more valid) study showed that sensitivity and specificity were only about 95% and 97%, respectively, meaning that about 5% of people with an injury would be missed, and 3% of people without an injury would be misdiagnosed. Although the misdiagnosis rate (false positives) is probably acceptable given the relatively less serious consequences of a false positive finding, the missed diagnosis rate (false negatives) of 1 in 20 is almost certainly not acceptable, given the serious consequences of missing a vascular injury such as losing the limb or death. Hence even though there are no radiation risks, the harms probably outweigh the benefits for this test. **Clinical assessment (pulse)** Sensitivity was 91%, indicating that 9% of those with an injury would be missed. Specificity was 89%, meaning a misdiagnosis rate of 11%. Harms clearly dominate benefits here. However, the GDG considered that a range of hard signs, including pulse and expanding haematoma, was likely to yield adequate sensitivity to detect those cases requiring immediate intervention rather than clinical pulse alone as used in the study.
Economic considerations	No economic evidence was identified for this question. The most expensive intervention is likely to be CT angiography. Some modalities, such as CT may take more time (from time of presentation) to undertake than others, particularly when issues such as scheduling and reporting are taken into account. Thus, there is potentially a trade-off around the quicker (and sometimes more readily available modalities) yet less accurate modalities, versus taking a bit more time for a more precise diagnosis. Practicality may also be a consideration as ABPI has limited use if the patient's limb is multiply injured, which may prevent the clinician from being able to place a blood pressure cuff.

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	A consequence of missing an injury or delay of getting to theatre is likely to be amputation, and also re-vascularising the limb late could lead to renal failure. Timing is critical for vascular injury because there is a limited time (a window of 3 to 4 hours) to get the patient to theatre, and therefore, the GDG felt that we want to try and remove the parts of the pathway that delay treatment, and felt strongly that imaging can cause delays and potentially deaths. Timing was particularly important to the GDG as mentioned above and thus, the trade-off between time and accuracy is an important one for this question, as you want to re-vascularise in the shortest time possible. The downstream costs come from delay in getting to theatre, and therefore, picking up the injuries where intervention is required quickly is considered more of a priority than using a modality that takes longer but has slightly higher accuracy. From the clinical review data, we can infer that clinical assessment is likely to be the least sensitive and specific, with CTA and doppler (ABPI) being the most sensitive and specific, although, for some studies, the reference test is a combination of interventions. However, the GDG felt that a vascular injury would be suspected on clinical parameters alone, and also, it was felt that the injuries that were missed through clinical assessment are likely to be those that would not require immediate intervention, and thus would be picked up later by clinical assessment. The false positives (from a modality with a low specificity) were felt to not use resources unnecessarily because if they have a fracture then they would be operated on anyway, so you wouldn't be operating on people unnecessarily. In summary, the GDG recommend using clinical assessment to identify those injuries that need to be dealt with quickly, thus avoiding using modalities which were likely to pick up less urgent injuries but delay treatment for the most urgent injuries, which can have health and cost consequences. The emphasis on delay was particularly important, and thus, the GDG felt they did not want to make specific recommendations about imaging modalities which could cause delays. However, it was acknowledged that angiography can be helpful in rare scenarios where the site of the injury is unknown, or if a CT is already taking place – then a CTA would be of benefit to look for vascular injury (which was the most sensitive and specific intervention).
Quality of evidence	All evidence was graded Very low. There was inadequate blinding of those doing the index test to the reference test results, or vice versa. All studies were indirect evidence as all had fracture rates of <50%. In one study (Mills), the population only had knee dislocations, but this was not felt to be a problem as the limb is devascularised irrespective of whether it is caused by a fracture or dislocation. So unless joint reduction restores the circulation, they will behave in the same way.
Other considerations	The GDG made recommendations based not only on diagnostic accuracy but also the requirement for immediate intervention. If an investigation, however sensitive, was felt likely to result in a delay, the GDG placed great emphasis on the likely negative impact of a delay to intervention. Accordingly, the GDG decided against making specific recommendations for angiography, despite angiography having a high sensitivity, on the basis that the time delay involved in angiography made it potentially dangerous. The GDG felt that the time delay could, on occasions, lead to the loss of a limb or even life, and felt that by omitting recommendations for angiography they would be able to emphasise the importance of focussing on getting a patient with suspected vascular compromise into surgery immediately. The GDG did, however, discuss certain caveats for the use of angiography, and although these have not been made into recommendation for the reasons discussed above, they are outlined below.

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	The GDG felt that CTA could be used if the site of injury was unclear (for example, multiple level fractures, shot gun injuries) or there are only soft signs of vascular injury (reduced pulse compared with the contralateral uninjured limb). However, this was regarded as extremely rare and unlikely to be a consideration in most cases. The GDG placed great importance on the marginal time taken to get the results. Thus, in a patient already undergoing CT scanning for other reasons, extending this to include an extremity CTA would result in minimal additional delay. The GDG therefore felt that CT angiography could be used when CT is performed as part of the initial trauma assessment, although as this would still create a small additional delay it was not felt to be ideal. On-table angiography was also discussed if CTA would delay revascularisation, but again would create some delay and was therefore, not regarded as optimal. For children, the GDG felt that current guidelines, in the absence of good evidence, show that children with pulseless well-perfused hands after reduction of supracondylar fracture should have surgical exploration only if injury is associated with neurological compromise initially.

9.2 Detecting compartment syndrome

9.2.1 Introduction

Compartment syndrome is a potentially serious condition and occurs when there is an increase in pressure within enclosed osteofascial compartments of the extremities. It can compromise circulation and eventually lead to ischaemic necrosis of the enclosed muscles. For this reason, early identification of compartment syndrome is essential. Currently there is little consensus on the best method for identifying compartment syndrome. It can be identified using clinical symptoms, intra-compartmental pressure measurement or a combination of the two. The most frequently cited clinical symptoms to diagnose compartment syndrome are pain out of proportion to the injury, pallor, sensory deficit and motor deficit. The alternative diagnostic option is measurement of intra-compartmental pressure. This pressure measurement can be used alone or in combination with diastolic blood pressure or mean arterial pressure to diagnose compartment syndrome.

9.2.2 Review questions:

a) What is the most clinically and cost effective method of identifying compartment syndrome in patients with limb fractures?

b) What is the most accurate method of identifying compartment syndrome in patients with limb fractures?

This review sought to identify the most clinically and cost effective method of identifying compartment syndrome in patients with limb fractures. Initially, a diagnostic RCT review protocol was developed to examine the clinical effectiveness of the different testing modalities (question A). However, insufficient RCT evidence was identified and as per the review protocol, a second question was drafted to find the diagnostic accuracy (question B) of tests to identify compartment syndrome. For full details of both protocols, see Appendix C.

Table 117: PICO characteristics of diagnostic RCT review question a

Population	Children, young people and adults with a limb fracture after experiencing a traumatic incident
Interventions	• Intra-compartmental pressure measurement

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	• Intra-compartmental pressure measurement combined with clinical assessment • Clinical assessment
Comparison	Compared with each other
Outcomes	Critical: • Health-related quality of life • Neurological dysfunction • Muscle/joint contracture • Amputation • Functional outcome measures • Pain/discomfort • Return to normal activities • Psychological wellbeing • Deep infection • Neuropathic ulcers Important: • Unplanned surgery • Missed compartment syndrome (not including foot compartment) • Length of stay • Cosmesis
Study design	RCTs or systematic reviews of RCTs

Table 118: PICO characteristics of diagnostic accuracy review question b

Population	Children, young people and adults with a limb fracture after experiencing a traumatic incident
Index tests	• Intra-compartmental pressure measurement • Intra-compartmental pressure measurement combined with clinical assessment • Clinical assessment
Reference standard	Surgical findings/later clinical outcomes
Outcomes	• Sensitivity • Specificity
Study design	Diagnostic accuracy studies

9.2.3 Clinical evidence

Diagnostic RCT review

One RCT was included in the review[37,38] and is summarised in Table 119 below. Evidence from these studies is summarised in the clinical evidence summary below (Table 120). See also the study selection flow chart in Appendix D, study evidence tables in Appendix G, forest plots in Appendix I, GRADE tables in Appendix H and excluded studies list in Appendix J.

This RCT compared the effectiveness of continuous compartment pressure monitoring for 36 hours postoperatively versus routine post-operative examination. In both groups, the definitive diagnosis of compartment syndrome was made through clinical examination. In the former, compartment pressure was a trigger for this examination to be carried out, and in the latter, clinical examination was undertaken as part of the post-operative routine.

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Table 119: Summary of studies included in the review

Study	Intervention and comparison	Population	Outcomes	Comments
Harris 2006[37,38]	**Continuous compartment pressure monitoring** (surgical team was called if ΔP[a] <30 mmHg. Compartment syndrome then diagnosed by clinical examination) **versus** **no continuous compartment pressure monitoring** (routine post-operative examination. Compartment syndrome was diagnosed by clinical examination)	197 people (all over 10 years of age) with 200 extra-articular fractures of the tibia. Mean age was 37 years in monitored group and 31 years in unmonitored Average follow-up was 8 months (3-24 months).	• Sensory loss (neurological dysfunction) • Contracture (muscle/joint contracture) • Length of stay	Conducted in the UK 6 patients in monitored and 3 in unmonitored were unconscious. Unconscious patients in both groups diagnosed by ΔP <30 mmHg

(a) ΔP is difference between diastolic blood pressure and compartment pressure

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Table 120: Clinical evidence summary: continuous compartment pressure monitoring versus no compartment pressure monitoring

Outcome	Number of studies (number of participants)	Imprecision	GRADE rating	Absolute difference (Field versus ED)	Control event rate (per 1000)	Control event rate for continuous outcomes
Sensory loss	1 (n=155)	Very serious	VERY LOW	11 more per 1000 (from 38 fewer to 175 more)	60 per 1000	NA
Contracture	1 (n=155)	Very serious	VERY LOW	22 fewer per 1000 (from 35 fewer to 98 more)	36 per 1000	NA

Narrative review of results not suitable for analysis in GRADE

Continuous compartment pressure monitoring versus no compartment pressure monitoring

Length of stay (very high risk of bias)

One study[37,38] with 197 participants reported length of stay in hospital (important outcome) for each group. The median length of stay was 8 days for the compartment monitoring group and 6 days for unmonitored group. No measure of spread was reported for these data.

Diagnostic accuracy review

Two studies were included in the review;[46,63] they are summarised in Table 121 below. Evidence from these are summarised in the clinical evidence profile below (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.

One paper[46,46] is a prospective diagnostic accuracy study conducted in a hospital in Belgium. It investigates the accuracy of varying compartment pressure thresholds for detecting the presence of compartment syndrome. The other[62,63] is a retrospective study using data from a trauma unit database in the UK to investigate the accuracy of compartment pressure monitoring. Both studies faced the same problem; that confirmation of compartment syndrome after fasciotomy is unreliable. This presents difficulties in creating a good reference standard against which to compare the reference test. Janzing et al. (2001)[46] dealt with this by making the assumption that all patients who underwent fasciotomy had compartment syndrome. McQueen et al. (2013)[63] approached it by using surgical findings to confirm or refute diagnosis in those undergoing fasciotomy.

Table 121: Summary of studies included in the review

Study	Study design and target condition	Index test	How diagnostic accuracy was assessed (reference standard)	Comments
Janzing 2001[46]	Prospective diagnostic accuracy study n=100 (104 fractures) Children, young people and adults with tibial fractures (including polytrauma)	Compartment pressure monitoring and/or clinical judgment After the study was completed, various criteria were investigated to find their accuracy in diagnosing compartment syndrome. All patients were assigned as compartment syndrome-	• Clinical symptoms and compartment pressure monitored for all patients • Patients followed normal hospital protocols for compartment syndrome diagnosis and treatment • Data set created where patients assigned as either positive or negative for compartment syndrome • Data set used to investigate the accuracy of various criteria in diagnosing compartment syndrome **Positive compartment syndrome** • All those who underwent fasciotomy • Those who did not undergo fasciotomy but later developed residual symptoms (sequelae)	Conducted in Belgium There were unclear criteria for undertaking fasciotomy Mean follow-up for residual symptoms: 393 days

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Study	Study design and target condition	Index test	How diagnostic accuracy was assessed (reference standard)	Comments
		positive or compartment syndrome-negative	consistent with compartment syndrome **Negative compartment syndrome** • Those who did not undergo fasciotomy or have residual compartment syndrome symptoms during follow-up	
McQueen 2013[62,63]	Retrospective diagnostic accuracy study (trauma unit database) n=850 Children, young people and adults with tibial diaphyseal fractures	Compartment pressure monitoring Patients with a positive test (ΔP^a <30 mmHg for 2 hours) received a fasciotomy	**True positives** Escape of muscles at fasciotomy was seen along with colour change in the muscles or muscle necrosis (documented by the operating surgeon) **False positives** It was possible to close the fasciotomy wounds primarily at 48 hours **False negatives** Those who had residual symptoms (sequelae) consistent with compartment syndrome during follow-up **True negatives** Those who did not undergo fasciotomy or have residual symptoms during follow-up	Conducted in the UK High rate of attrition (129 patients lost to follow-up) Mean follow-up for residual symptoms: 59 weeks

(a) ΔP is difference between diastolic blood pressure and compartment pressure

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Table 122: Clinical evidence profile: diagnostic accuracy of compartment pressure monitoring

Index test (threshold)	No of studies	n	Risk of bias	Inconsistency	Indirectness	Imprecision	Sensitivity % (95% CI)	Specificity % (95% CI)	Quality
Janzing 2001[46,46]									
Clinical symptoms	1 (n=104)	104	Serious risk of bias[a]	Not applicable	No serious indirectness[b]	Very serious imprecision[c]	0.67 (0.41 to 0.87)	0.89 (0.79 to 0.95)	VERY LOW
Compartment pressure monitoring (ICP >30 mmHg)	1 (n=104)	104	Serious risk of bias[a]	Not applicable	No serious indirectness	Serious imprecision[c]	0.83 (0.59 to 0.96)	0.42 (0.31 to 0.53)	LOW
Compartment pressure monitoring (DBP-ICP <30 mmHg)	1 (n=104)	104	Serious risk of bias[a]	Not applicable	No serious indirectness	Serious imprecision[c]	0.89 (0.65 to 0.99)	0.65 (0.53 to 0.75)	LOW
Compartment pressure monitoring (DBP-ICP <20 mmHg)	1 (n=104)	104	Serious risk of bias[a]	Not applicable	No serious indirectness	Very serious imprecision[c]	0.61 (0.36 to 0.83)	0.81 (0.71 to 0.89)	VERY LOW
Compartment pressure monitoring (MAP-ICP <30 mmHg)	1 (n=104)	104	Serious risk of bias[a]	Not applicable	No serious indirectness	Very serious imprecision[c]	0.39 (0.17 to 0.64)	0.92 (0.84 to 0.97)	VERY LOW
Compartment pressure monitoring (MAP-ICP <30 mmHg for more than 1 hour)	1 (n=104)	104	Serious risk of bias[a]	Not applicable	No serious indirectness	Very serious imprecision[c]	0.33 (0.13 to 0.59)	0.99 (0.93 to 1)	VERY LOW
Clinical symptoms & Compartment pressure monitoring (DBP-ICP <30 mmHg)	1 (n=104)	104	Serious risk of bias[a]	Not applicable	No serious indirectness	Serious imprecision[c]	0.61 (0.36 to 0.83)	0.97 (0.91 to 1)	LOW
Clinical symptoms & Compartment pressure monitoring (MAP-ICP <30 mmHg)	1 (n=104)	104	Serious risk of bias[a]	Not applicable	No serious indirectness	Very serious imprecision[c]	0.28 (0.1 to 0.53)	0.99 (0.93 to 1)	VERY LOW

Index test (threshold)	No of studies	n	Risk of bias	Inconsistency	Indirectness	Imprecision	Sensitivity % (95% CI)	Specificity % (95% CI)	Quality
McQueen 2013[62,63]									
Compartment pressure monitoring (DBP-ICP <30 mmHg) for more than 2 hours	1	850	Very serious risk of bias[a]	Not applicable	No serious indirectness[b]	No serious imprecision[c]	0.94 (0.89 to 0.97)	0.98 (0.97 to 0.99)	LOW

Note: GRADE was conducted with emphasis on test sensitivity as this was the primary measure discussed in decision making

Abbreviations: ICP, intracompartmental pressure; DBP, diastolic blood pressure; MAP, mean arterial pressure; ΔP, difference between diastolic blood pressure and compartment pressure

(a) Risk of bias was assessed using the QUADAS-II checklist. Janzing 2001 was at serious risk of bias due to an uncertain reference standard and McQueen 2013 was at very serious risk of bias due to an uncertain reference standard and attrition (loss of patients during follow-up).

(b) Indirectness was assessed using the QUADAS-II checklist items referring to applicability.

(c) The judgement of precision was assessed using the confidence interval of the sensitivity value. A range of 0-20% of differences in point estimates of sensitivity was considered not imprecise, 20-40% serious and more than 40 very serious.

9.2.4 Economic evidence

Published literature

No relevant economic evaluations were identified.

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

Unit costs

Table 123: UK costs of disposable components for compartment pressure monitoring

Equipment	Cost per use
Disposable syringe	£0.25
Disposable needle	£0.07

Source: SP services

Table 124: UK costs of compartment syndrome complications

Procedure	Cost per use	Comments [a]
Fasciotomy	£3,477	HRG code: HA25C
Amputation	£8,589	HRG code: YQ22B

Source: NHS Reference costs 2013-2014 [21]
(a) See appendix O for further detail on these costs.

9.2.5 Evidence statements

Clinical

Diagnostic RCT

Very low quality evidence from 1 RCT comprising 155 participants showed that there was no difference in clinical effectiveness between continuous compartment pressure monitoring and no compartment pressure monitoring in terms of sensory loss, with very serious imprecision

Very low quality evidence from 1 RCT comprising 155 participants showed that there was no difference in clinical effectiveness between continuous compartment pressure monitoring and no compartment pressure monitoring in terms of contracture, with very serious imprecision

Diagnostic accuracy

One Very low quality diagnostic study comprising 104 participants showed clinical symptoms has a median sensitivity of 0.67 (95% CI, 0.41 to 0.87) and median specificity of 0.89 (95% CI, 0.79 to 0.95) in detecting compartment syndrome when compared with the reference standard of operative findings and clinical follow-up.

One Low quality diagnostic study comprising 104 participants showed compartment pressure monitoring (cut-off: ICP more than 30 mmHg) has a median sensitivity of 0.83 (95% CI, 0.59 to 0.96) and median specificity of 0.42 (95% CI, 0.31 to 0.53) in detecting compartment syndrome when compared with the reference standard of operative findings and clinical follow-up.

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One Low quality diagnostic study comprising 104 participants showed compartment pressure monitoring (cut-off: DBP-ICP less than 30 mmHg) has a median sensitivity of 0.89 (95% CI, 0.65 to 0.99) and median specificity of 0.65 (95% CI, 0.53 to 0.75) in detecting compartment syndrome when compared with the reference standard of operative findings and clinical follow-up.

One Very low quality diagnostic study comprising 104 participants showed compartment pressure monitoring (cut-off: DBP-ICP less than 20 mmHg) has a median sensitivity of 0.61 (95% CI, 0.36 to 0.83) and median specificity of 0.81 (95% CI, 0.71 to 0.89) in detecting compartment syndrome when compared with the reference standard of operative findings and clinical follow-up.

One Very low quality diagnostic study comprising 104 participants showed compartment pressure monitoring (cut-off: MAP-ICP less than 30 mmHg) has a median sensitivity of 0.39 (95% CI, 0.17 to 0.64) and median specificity of 0.92 (95% CI, 0.4 to 0.97) in detecting compartment syndrome when compared with the reference standard of operative findings and clinical follow-up.

One Very low quality diagnostic study comprising 104 participants showed compartment pressure monitoring (cut-off: MAP-ICP less than 30 mmHg for more than 1 hour) has a median sensitivity of 0.33 (95% CI, 0.13 to 0.59) and median specificity of 0.99 (95% CI, 0.93 to 1) in detecting compartment syndrome when compared with the reference standard of operative findings and clinical follow-up.

One Low quality diagnostic study comprising 104 participants showed compartment pressure monitoring (cut-off: DBP-ICP less than 30 mmHg) has a median sensitivity of 0.61 (95% CI, 0.36 to 0.83) and median specificity of 0.97 (95% CI, 0.91 to 1) in detecting compartment syndrome when compared with the reference standard of operative findings and clinical follow-up.

One Very low quality diagnostic study comprising 104 participants showed clinical symptoms and compartment pressure monitoring (cut-off: MAP-ICP less than 30 mmHg) has a median sensitivity of 0.28 (95% CI, 0.1 to 0.53) and median specificity of 0.99 (95% CI, 0.93 to 1.0) in detecting compartment syndrome when compared with the reference standard of operative findings and clinical follow-up.

One Low quality diagnostic study comprising 850 participants showed compartment pressure monitoring (cut-off: DBP-ICP less than 30 mmHg for more than 2 hours) has a median sensitivity of 0.94 (95% CI, 0.89 to 0.97) and median specificity of 0.98 (95% CIs,0.97 to 0.99) in detecting compartment syndrome when compared with the reference standard of operative findings and clinical follow-up.

Economic

No relevant economic evaluations were identified.

9.2.6 Recommendations and link to evidence

Recommendations	**38. In people with fractures of the tibia, maintain awareness of compartment syndrome for 48 hours after injury or fixation by:** • **regularly assessing and recording clinical symptoms and signs in hospital** • **considering continuous compartment pressure monitoring in hospital when clinical symptoms and signs cannot be readily identified (for example, because the person is unconscious or has a nerve block)**

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	• **advising people how to self-monitor for symptoms of compartment syndrome, when they leave hospital.**
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 RCT was identified but because this did not evaluate all the tests, diagnostic accuracy studies were also used for this review. **Diagnostic RCT review** Health-related quality of life was regarded as a critical outcome as it is the most all-encompassing and patient-centred outcome, and can inform health economic decisions. Other critical outcomes were neurological dysfunction, muscle/joint contracture, amputation, functional outcomes, deep infection and neuropathic ulcers. Unplanned surgery, missed compartment syndrome, length of stay and cosmesis were considered by the GDG to be important. **Diagnostic accuracy review** The critical outcomes for this diagnostic review question are sensitivity and specificity of the index tests relative to a reference test (which is assumed to give the 'true' diagnosis). Sensitivity is the most critical outcome, because poor sensitivity may result in people with compartment syndrome being undiagnosed and at risk of significant complications. In contrast, poor specificity would lead to incorrect positive diagnoses and therefore, unnecessary fasciotomies. Fasciotomies can lead to wound healing complications, neurological or vascular injury, and infection, but these effects of misdiagnosis were not thought to be as serious as the sequelae of missed diagnosis.
Trade-off between clinical benefits and harms	**Diagnostic RCT evidence** There was no clinically important difference in sensory loss or contracture when comparing continuous compartment pressure testing versus routine postoperative observation as a trigger for clinical assessment of compartment syndrome. **Diagnostic accuracy evidence** For compartment pressure monitoring, the diagnostic threshold with the best reported sensitivity (0.94) and specificity (0.98) was a difference between diastolic pressure and compartment pressure (ΔP) of less than 30 mmHg for more than 2 hours (moderate quality evidence). A different study tested ΔP of less than 30 mmHg without a 2-hour time threshold and found the sensitivity to be 0.89 and specificity to be 0.65 (low quality evidence). The same study also evaluated clinical symptoms combined with a compartment pressure monitoring ΔP of less than 30 mmHg and found the sensitivity to be 0.61 and specificity to be 0.97 (low quality evidence).
Economic considerations	No economic evidence was identified. To monitor compartment pressure different types of equipment can be used. Handheld compartment pressure monitors are now available or a more complex setup using a manometer, a syringe and some tubing can be used. Both methods use reusable equipment and so the overall cost per use will become negligible over time. Both methods will require a single use needle and so there is a very small cost per patient in comparison to clinical assessment alone.

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	The accuracy of a diagnostic modality stems from how accurately it can identify people with a condition and rule out people without a condition. The prevalence is also important (see more on this in appendix O). The prevalence of compartment syndrome is uncertain because once a fasciotomy has been undertaken it is difficult to tell if compartment syndrome was actually present. If compartment syndrome is missed then it is likely to result in the need for amputation, which incurs an initial cost of surgery as well as a high lifetime cost of prosthetics and other NHS resource use associated with amputations. There will also be a detriment to the health-related quality of life of the patient and so an intervention with a low sensitivity will reduce the cost effectiveness of the intervention. If compartment syndrome is falsely diagnosed as positive, then there will be an unnecessary surgery cost in performing a fasciotomy to release the compartment pressure. The detriment to quality of life is likely to be less than that for missing compartment syndrome. However, there are complications, such as infection and other injuries that can lead to further treatment and an extended hospital stay. An intervention with a lower specificity will also lead to a reduction in cost effectiveness. The GDG believed that the evidence showed that clinical assessment was the most sensitive and specific method for identifying compartment syndrome and, therefore, was cost effective in comparison to pressure monitoring or both. The GDG considered that different levels of seniority could impact the sensitivity and specificity of clinical assessment but still believed it should be the recommended method. The GDG also considered patients whose clinical signs could not be assessed, for instance those who have been anaesthetised or are unconscious. It is essential to use compartment pressure monitoring for these patients as clinical signs are not reliable. The duration of assessment and monitoring was considered by the GDG and they believed that compartment syndrome was more likely to occur after the first 24 hours and reached a consensus that awareness should be maintained for 48 hours after fracture fixation or diagnosis if fixation is not performed.
Quality of evidence	**Diagnostic RCT evidence** Both outcomes were graded as Very low quality evidence due to risk of bias and imprecision. Risk of bias was serious or very serious due to a lack of allocation concealment, or a lack of patient, health-care practitioner and assessor blinding. The evidence was for tibial fractures only, and so findings cannot necessarily be extrapolated to all limb fractures. **Diagnostic accuracy evidence** Risk of bias of diagnostic accuracy studies was assessed using the QUADAS 2 tool. The diagnostic accuracy evidence varied in quality between studies. One study was graded as Moderate quality due to risk of bias (attrition). All others were graded as Low or Very low quality due to risk of bias (inappropriate reference standard) and imprecision. The evidence was for tibial fractures only, and so findings cannot necessarily be extrapolated to all limb fractures.
Other considerations	The GDG did not consider the reference standards used in either diagnostic accuracy study adequate to gain a true assessment of the sensitivity and specificity of

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	compartment pressure monitoring for diagnosing compartment syndrome. The key issue of confirmation of compartment syndrome after fasciotomy is yet to be resolved within the current evidence base. Janzing et al. (2001) assumed all those who underwent fasciotomy were positive for compartment syndrome while noting that for some patients this may not have been true. The GDG considered that this potentially faulty assumption could have significantly affected the results of the study. In contrast, McQueen et al. (2013) used colour change in muscles or muscle necrosis during fasciotomy to confirm compartment syndrome. In addition, the diagnosis was considered incorrect if it was possible to close the fasciotomy wounds primarily at 48 hours. The GDG recognised that the methods used by McQueen at al. (2013) represent the most sophisticated attempt to overcome the problem of confirming compartment syndrome after fasciotomy. However, they felt that the inter-rater reliability of diagnosis between different surgeons and grades of surgeon without prospectively implemented quality control measures would be low. The GDG was also concerned that the criteria for diagnosis - colour change in muscles or muscle necrosis during fasciotomy and whether the fasciotomy wounds can be closed primarily at 48 hours - are currently untested and unproven. For these reasons the GDG felt that the evidence was unreliable and thus felt unable to recommend compartment pressure monitoring for all patients. However, they felt it had a role in the obtunded patient and all other cases where clinical signs cannot be reliably identified. The GDG considered that vigilance of the signs and symptoms of compartment syndrome should be maintained for people with tibial fractures for 48 hours after diagnosis, or from fixation (if performed). This could be done primarily in hospital by health professionals but could also be self-assessed at home. Self-assessment could be assisted through patient information leaflets. The GDG recommends that future studies should concentrate on diagnosing compartment syndrome on a cellular level as current compartment pressure monitoring is a surrogate for compromise of cellular viability.

9.3 Splinting of lower limb long bone fractures

9.3.1 Introduction

Splinting of long bone fractures at the scene of the accident is regarded as an effective way of reducing pain and preventing secondary damage to neurovascular structures and other soft tissues. A variety of splinting techniques are currently in use and it is unclear which is the most effective. The vacuum splint is a relatively new device that may theoretically offer greater comfort and stability than traction splints as it can conform to any shape and may relieve pressure at the site of injury. This review aims to evaluate the most clinically and cost effective techniques.

9.3.2 Review question: What is the most clinically and cost effective strategy for splinting of lower limb long bone fractures in the pre-hospital setting?

For full details see review protocol in Appendix C.

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Table 125: PICO characteristics of review question

Population	Children, young people and adults with a lower limb long bone fracture (open or closed) following a traumatic incident
Intervention	Box splint
Comparisons	Vacuum splint (bean bag from which air is removed) Traction splint (pneumatic and non-pneumatic)

Outcomes	Critical:
	• Mortality up to 12 months
	• Health-related quality of life
	• Function
	• Adverse effects
	  ○ Neurovascular damage
	  ○ Tissue necrosis
	  ○ Pain (various methods)
	
	Important:
	• Return to normal activities
	• Blood pressure (various surrogates)

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.

9.3.3 Clinical evidence

No relevant clinical studies comparing box splints, vacuum splints or traction splints were identified. See the search strategy in appendix F, study selection flow chart in Appendix D and excluded studies list in Appendix J.

9.3.4 Economic evidence

Published literature

No relevant economic evaluations were identified.

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

Unit costs

Table 126: UK costs of long bone splinting equipment

Equipment	Unit cost	Additional information
Box splint (adult)	£36	PVC box splint with Velcro straps.
Box splint (paediatric)	£28	Smaller sized PVC box splint with Velcro straps.
Vacuum splint	£350	Includes wrist/ankle splint, arm splint, leg splint and pump.
Pneumatic traction splint	£345	Different versions for adults and children with the same price.
Non-pneumatic traction splint	£110	This traction splint can be used if the patient also has a fractured pelvis. One device used for adults and children.

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Source: SP services – a supplier used by the East Midlands Ambulance Service.

9.3.5 Evidence statements

Clinical

No relevant studies were identified.

Economic

No relevant economic evaluations were identified.

9.3.6 Recommendations and link to evidence

Recommendations	**39. 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.**
Relative values of different outcomes	The GDG identified mortality, health-related quality of life, function, adverse effects (neurovascular damage, tissue necrosis and pain) as critical outcomes. Important outcomes were return to normal activities and blood pressure.
Trade-off between clinical benefits and harms	No evidence was found relevant to this question and so recommendations were based on consensus. The GDG noted that traction splints are thought to be more comfortable, and may be associated with less pain and a reduction in blood loss. However, the GDG also argued that these benefits should be weighed against the relative advantages of the vacuum splint for other outcomes. For example, time taken to apply a vacuum splint is less than that to apply a traction splint, and the GDG believed that this may reduce the pre-hospital duration which may be associated with a better clinical outcome for some patients. Vacuum splints may also make it easier for pre-hospital staff to examine other injuries, and may be more suitable for injuries below the knee because they allow less movement at the ankle, reducing pain. These can be applied quickly with little training, and are the least expensive intervention. Therefore, for open long bone fractures below or close to the knee, the GDG decided to recommend the use of a vacuum splint. The GDG felt that a box splint was not as useful as a vacuum splint as it would be less comfortable due to providing less support and padding to the fractured limb. Above the knee, the GDG decided to recommend any of the considered splints - a traction splint or splinting the injured leg to the other leg. This was because it was felt that for such fractures there were few advantages of one type of splint over another.
Economic considerations	No economic evidence was identified for this question. The GDG were presented with the costs of the interventions. Box splints are the cheapest (£36), followed by non-pneumatic (£110) and pneumatic traction splints (£345), and vacuum splints (£350).

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	In the absence of any clinical evidence the GDG came to the consensus that a vacuum splint was the most effective intervention for splinting a fracture below the knee. They believed that a box splint did not secure the limb sufficiently, which can increase pain and therefore, also increase the requirement for further analgesia. The vacuum splint is around ten times more expensive than a box splint, but given that they can both be re-used a large number of times, the incremental cost per person is likely to be small and so the GDG believed that it was likely to be cost effective. They also considered the durability of the interventions and realised that if a vacuum splint was punctured then it would need to be replaced, whereas a box splint is more robust to small levels of damage. The GDG believed that puncturing was unlikely and so still agreed that the vacuum splint was cost effective. The GDG also took into consideration that vacuum splints are already widely used and so this would not be a large change to current practice. A non-pneumatic traction splint is cheaper than a pneumatic traction splint, but are only applicable to fractures above the knee. The GDG regarded this as a better option than the pneumatic traction splint for these fractures as it can also be applied if the patient has a pelvic fracture as well. The GDG also considered that for fractures above the knee, it may be just as effective to use adjacent leg splinting, which can be done using straps at a lower cost.
Quality of evidence	No evidence was found.
Other considerations	No other considerations.

9.4 Hip reduction

9.4.1 Introduction

Hip dislocation requires rapid treatment to prevent irreversible damage to local neural and vascular structures. Most hip dislocations can be managed with a closed reduction, but in some cases this does not work and an open reduction is required. To avoid the neurovascular harms of delay, many trusts recommend an open reduction within four hours, but this often means that there is insufficient time to call in adequately qualified staff or transfer the patient to another centre, so the procedure has to be carried out by surgeons with inadequate expertise. It is possible that the effects of sub-optimal surgical technique performed earlier may actually be more harmful than later surgery performed by someone with adequate expertise. Hence this review aims to evaluate the clinical and cost effectiveness of open reduction at different time points.

9.4.2 Review question: Does hip dislocation require immediate open reduction in the event of a failed closed reduction?

For full details see review protocol in Appendix C.

Table 127: PICO characteristics of review question

Population	Children, young people and adults experiencing a traumatic incident.
Intervention(s)	• Open reduction within 4 hours of injury • Open reduction >4 and <12 hours after injury • Open reduction >12 hours after injury
Comparison(s)	To each other

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Outcomes	Critical: • Mortality • Health-related quality of life • Avascular necrosis fem head • Sciatic nerve injury Important: • Pain/discomfort • Return to normal activities • Psychological wellbeing • Functional scores for hip (Oxford, Harris) 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. If cohorts are used these must consider all the key confounders chosen by the GDG.

9.4.3 Clinical evidence

No eligible studies were found and so none were included in the review. See the search strategy in appendix F, study selection flow chart in Appendix D and excluded studies list in Appendix J.

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 clinical evidence was identified.

Economic

No relevant economic evaluations were identified.

9.4.6 Recommendations and link to evidence

Recommendations	**40. Immediately transfer people with a failed closed reduction of a native hip joint to a specialist centre if there is insufficient expertise for open reduction at the receiving hospital.**
Relative values of different outcomes	Critical outcomes were mortality, health-related quality of life, avascular necrosis of the femoral head and sciatic nerve injury. Important outcomes were

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	pain/discomfort, return to normal activities, psychological well-being and functional scores.
Trade-off between clinical benefits and harms	No evidence was found in the literature, so GDG recommendations were made by consensus. The GDG reported that failed closed reductions are quite rare, and thus the number of clinicians with adequate experience of these cases is low. Furthermore, the complexity of open hip reduction is high and the risks of adverse effects severe. The GDG therefore felt that if there is insufficient expertise for proper surgical management, the patient should be woken up after the failed closed reduction and transferred to a centre with expertise. Current practice may lead to pressure to perform an open reduction even if there is insufficient expertise because of the perception that severe long term problems may ensue after 6 hours of open reduction delay, such as avascular necrosis and sciatic nerve damage. However, it was agreed by the GDG that inexpert open reduction can lead to even worse problems.
Economic considerations	No economic evidence was identified for this question. The consequences of delaying an open reduction for longer following a closed reduction include avascular necrosis, nerve palsy, bleeding or even death. If a closed reduction has failed but the clinician is not a skilled hip surgeon (as perhaps the patient is not in a major trauma centre (MTC) or the closer to the time of injury then the more likely that a more junior clinician is present) then either the clinician can attempt an open reduction or transfer the patient to somewhere with the expertise to reduce the fracture surgically. Thus, there is a trade-off around allowing further time delay versus attempting an earlier open reduction which could have more complications if not undertaken by the correctly skilled individual. Complications could include adverse events, but also impacting the quality of future treatment such as the pelvic reconstruction. Thus, there are risks to both carrying out the intervention early by a less skilled member of staff who has failed a closed reduction, and also to delaying the procedure. The population in question is likely to be very small as it was discussed how it is relatively rare that a closed reduction fails. The GDG were in consensus that if a closed reduction has failed, the patient should be transferred to somewhere where this can be carried out with more confidence. Although the current practice leads to pressure for doctors to attempt an open reduction if a closed reduction has failed, the GDG felt strongly that these members of staff should not be coerced into doing something that they do not normally do, and they stated this current practice stems from an informal standard that is in place which is not evidence based (should be done in 6 hours). It was also highlighted that these injuries are likely to be in the context of multiple trauma, therefore, these patients would be triaged to a MTC where the appropriate expertise is available. In the rare cases that these are isolated injuries and have been taken to a non-trauma centre, then following a failed reduction, these patients should be transferred.

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	It was felt that the risk of inexpert repair is likely to outweigh the risk of delay.
Quality of evidence	No evidence was found in the literature.
Other considerations	The GDG considered what should be done if there was an isolated hip injury, and whether such cases should go directly to a MTC for a closed reduction. This would avoid delay to an open reduction if there was a closed reduction failure. However, the GDG felt that the probability of a failed closed reduction was too low to warrant such a recommendation.

9.5 Whole-body CT

9.5.1 Introduction

Currently, it is common practice to distally extend CT only as far as to the pelvis for patients with polytrauma. This often means that fractures distal to the pelvis have to be imaged separately, and may even remain initially undetected. Separate imaging carries harms, such as delays in definitive treatments, as well as greater costs, and undetected injuries may lead to greater pain for the patient as well as complications, such as delayed healing or infection. There is thus a feeling amongst emergency clinicians that CT scanning should be routinely applied to the feet in people suspected of lower limb injury. Possible disadvantages of this strategy include increased radiation exposure, which may be particularly important in children and young people. This review aims to assess the clinical benefits and harms, and cost-effectiveness, of both approaches.

9.5.2 Review question: Is it clinically and cost-effective to extend full-body CT to the feet in patients with polytrauma and suspected lower limb injury?

For full details see review protocol in Appendix C.

Table 128: PICO characteristics of review question

Population	Children, young people and adults with polytrauma and suspected lower leg injury
Intervention	Full-body CT to feet for all polytrauma patients with suspected lower limb high-energy fracture
Comparison	Full-body CT to pelvis for all polytrauma patients, with imaging below pelvis to feet done separately as required
Outcomes	Critical: • Mortality at 12 months • Health-related quality of life • Missed lower limb fracture or vascular injury • Radiation exposure/radiation adverse effects • Functional outcomes • Time to definitive diagnosis Important • Length of stay
Study design	RCT or systematic review of RCTs

9.5.3 Clinical evidence

No relevant clinical studies comparing were identified. See the search strategy in appendix F, study selection flow chart in Appendix D and excluded studies list in Appendix J.

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9.5.4 Economic evidence

Published literature

No relevant economic evaluations were identified.

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

Unit costs

Table 129: Diagnostic modality costs [20]

Imaging modality	Description	Cost[b]
CT[a]	CT scan, one area, no contrast, 19 years and over	£60
	CT scan, one area, with post contrast only, 19 years and over	£71
	CT scan, one area, pre and post contrast	£301
	CT scan, two areas without contrast	£58
	CT scan, two areas with contrast	£76
	CT scan, more than three areas (FULL BODY)	£146
X-ray	Direct access plain film	£28

(a) All CT costs included for comparison.
(b) The costs are sourced from NHS reference costs 2012/13 [20]. Further detail on the costs such as the ranges and number of submissions can be found in appendix O.

9.5.5 Evidence statements

Clinical

No clinical evidence was identified.

Economic

No relevant economic evaluations were identified.

9.5.6 Recommendations and link to evidence

Recommendations	**41. Use whole-body CT (consisting of a vertex-to-toes scanogram followed by CT from vertex to mid-thigh) in adults (16 or over) with blunt major trauma and suspected multiple injuries. Patients should not be repositioned during whole-body CT.** **42. Use clinical findings and the scanogram to direct CT of the limbs in adults (16 or over) with limb trauma.** **43. Do not routinely use whole-body CT to image children (under 16s). Use clinical judgement to limit CT to the body areas where assessment is needed.**

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	Although the complex fracture GDG reviewed the question of full body CT these recommendations were developed and supported by the evidence reviews addressing the scope area on imaging in each of the four clinical guidelines: • Complex fractures: assessment and management of complex fractures (including pelvic fractures and open fractures of limbs) • 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. • Spinal injury assessment: assessment and imaging, and early management for spinal injury (spinal column or spinal cord injury) In particular the Spinal injuries clinical guideline chapter 10 on radiation and risk should be read in conjunction with this chapter. **Developing the recommendations** Imaging recommendations were developed across the trauma guidelines suite by all the individual GDGs. Evidence reviews were completed for all the guidelines and the separate GDGs reviewed the evidence and drafted recommendations. The overall guideline population of patients with traumatic injuries meant that similarities and duplication between the draft recommendations were inevitable. This needed careful consideration when evaluating all the imaging recommendations with particular thought to the person with multiple injuries. The recommendations were taken to project executive team (PET) for coherence and consistency checking, the PET also had the advantage of identifying gaps in the separate guidelines that had been addressed in another guideline. The PET agreed on a core set of draft recommendations. The core set of recommendations were taken back to each of the separate GDGs for review and agreement. The GDGs had access to the reviews underpinning the recommendations.
Relative values of different outcomes	Critical outcomes were mortality, health-related quality of life, missed lower limb fracture or vascular injury, radiation exposure/radiation adverse effects, functional outcomes and time to definitive diagnosis. An important outcome was length of stay.
Trade-off between clinical benefits and harms	No published evidence was found for this review question. Decisions were therefore made by consensus. The GDG felt that extending CT all the way to the feet rather than extending CT only as far as the pelvis (with more distal imaging carried out later as indicated) would increase speed of diagnosis in everyone. However, the GDG felt that CT to feet for all people with merely a suspicion of lower limb injury (the intervention in this review) was not optimal because of concerns about radiation exposure, particularly in children. Furthermore, they felt that the other approach of CT to pelvis with additional imaging (the comparator in this review) was also suboptimal, for reasons of excessive time consumption. Thus, instead of recommending either the intervention or comparator they suggested a middle-ground 'compromise' approach, using the scanogram. The GDG felt that prior use of the scanogram, which can give a low resolution image of the entire body at a radiation cost of approximately one X-ray, would be a useful way of demonstrating if injuries were truly present. It could thus show if the

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	radiation burden of a CT to feet for more detailed imaging and diagnosis was warranted. For example, gross signs of vascular injury or fracture below the pelvis would usually be evident on a scanogram, and for such people, a full CT to feet would be indicated. On the other hand, if no signs were evident on the scanogram, a CT to feet would not be carried out for a patient, even though that patient was suspected of lower limb injury. Given that this patient would previously have had a CT to feet, using suspicion as the indicator, this new approach would therefore reduce needless radiation exposure from CT in the population as a whole. It is important to note that the GDG felt that the scanogram should always be used in conjunction with clinical examination, with a positive finding in either indicating the need to extend CT to the feet. This was to minimise people with a true lower limb injury being missed by the scanogram, the sensitivity of which is unknown, but which is unlikely to have 100% sensitivity. Requiring a positive finding in either (rather than both) might slightly increase the number given CTs to the feet unnecessarily, but certainly not to the extent observed if clinical suspicion alone were used without the scanogram/clinical examination filter. Despite this attempt to minimise missed lower limb injuries, a concern remained that the overall approach of using the scanogram/clinical examination filter would still lead to actual injuries being missed, and thus reduce overall sensitivity relative to the approach of everyone suspected of lower limb injury getting a CT to feet. However, this reduction in sensitivity was felt to be acceptable in the light of 1) the radiation risk from giving everyone suspected of an injury a CT being regarded as a greater harm, and 2) the fact that missed injuries would not normally be life threatening, and that the only likely negative sequelae of missed injuries would be the need for further imaging at a later time. In summary, the use of the scanogram with clinical examination as a triage tool to decide on CT to the feet was regarded as a compromise which was better than the two original treatment options outlined in the review protocol. In other words, it would be better than: • having CT to the feet for all suspected of injury, because CT to feet to all would have a considerable radiation burden. • having CT to the pelvis only, with later imaging, because this approach would lead to important time delays. In children, it was agreed that radiation dangers from CT would be much higher and that, therefore, the decision to extend any CT scan to the feet would need to be made by a senior clinician.
Economic considerations	No economic evidence was identified for this question. If the patient is already having a CT scan for other injuries then continuing this to look for suspected lower limb injuries is likely to be less costly and less time consuming than undertaking an additional image specifically for the lower limbs at a later point. It was noted that the ease of scanning the limbs during the same session depends upon the size of the scanner, as the patient may need to be turned around to scan the limbs, which could add delays, however this is generally the case with older scanners which are becoming less common. For the reason of delay, the GDG felt that patients should not be repositioned to undertake the scanogram. If scanning the limbs is done later, then taking the patient back for more imaging at a later point in time causes discomfort and further time delay as treatment is more beneficial if undertaken earlier, and re-aggregating staff to assess and image the lower leg also adds more time. Treatment of other life-threatening injuries may also be delayed if waiting for additional scanning of lower limbs. There is a small window of

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	opportunity with lower limb injuries to treat the injury before swelling increases. If patients have to be transferred between departments within the hospital to have additional imaging then this also often wastes a large amount of time. However, radiation dose from a CT is higher than that of other modalities, and more so the more regions that are scanned. A whole-body scan will also need some time potentially getting the patients' limbs aligned and in the right position, however, this also depends upon the definition of 'whole-body' scan. The accuracy of later modalities used to assess the lower limb injury (if other than CT) also may not be as accurate as CT and could lead to missed injuries. A large proportion of polytrauma patients have a lower limb injury. The GDG felt that a compromise would be to first undertake a full-body scanogram (an initial two dimensional image used to target subsequent CT), and along with clinical examination, make a decision as to whether there is an indication for CT of the lower limbs as well as the body. If the clinical exam or the scanogram indicate a potential lower limb injury then this will be an indication for CT. It may be possible that if the lower limb injury was not suspected at the indication for CT stage then it might still go on to be missed afterwards when it is too late, however, the GDG felt that injuries missed by CT initially would not be life threatening. Thus, incorporating a scanogram may lead to more patients having a CT to the lower limbs; however, this is likely to pick up injuries that could have had lifelong consequences. Consequences of missing an injury include lifelong functional limitations, impacting quality of life. Commonly missed injuries initially are foot and ankle injuries. Around 30% of midfoot injuries are likely to be missed initially (GDG estimate). Consequences are not just about missed injury but time delay, waiting for additional images of injuries that may become clinically apparent later leads to a delay in decision making about management. The scanogram may also pick up injuries that are not clinically relevant, however picking up the missed injuries in order to treat these in an appropriate timeframe is likely to outweigh this. This recommendation is likely to have a small cost impact as scanning additional body regions does have an increased cost. However, extending the CT would only be done on polytrauma patients in whom you would undertake a CT of the torso anyway, so should not lead to additional patients being scanned.
Quality of evidence	No published evidence was found for this review question.
Other considerations	There was some discussion about the interpretation of the scanogram and the skill of the person doing so, and the impact this may have on the decision to extend CT down to the lower limbs. If the room is too small to allow full excursion of the patient through the scanner, the GDG felt that patients should not be repositioned in order to perform he scanogram. Overall, it was felt that the disadvantages of the additional scanogram, with its small amount of extra radiation, would be compensated by the patient getting earlier treatment to other injuries or the potential lower limb injury.

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9.6 Documentation of open fracture wound photographs

9.6.1 Introduction

Visual observation of the open fracture wound is an essential part of the assessment process. However, removal of dressings over a wound to permit observation may increase the risk of nosocomial infection. Photographs of the wound prior to dressings are therefore regarded as an integral part of good clinical documentation, but a recent survey [88,88] showed that 21 out of 51 accident and emergency departments (EDs) were unable to carry out this procedure. High level evidence of the benefits of wound photography may be required to encourage better clinical practice. The purpose of this review was to determine if the inclusion of wound photographs in documentation led to better clinical outcomes than documentation without wound photographs.

9.6.2 Review question: For patients with open fractures is documentation that includes wound photographs more clinically and cost effective than documentation without?

For full details see review protocol in Appendix C.

Table 130: PICO characteristics of review question

Population	Children, young people and adults experiencing an open fracture from a traumatic incident.
Intervention	Documentation, including photographs of the wound
Comparison	Documentation, not including photographs of the wound
Outcomes	Critical: • Mortality at 1, 6 and 12 months • Health-related quality of life • Deep infection • Time to initial surgery • Time to definitive closure Important: • Functional outcome measures • 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	RCTs or Systematic reviews of RCTs

9.6.3 Clinical evidence

No RCTs or cohort studies were found for this review question. See the search strategy in appendix F, study selection flow chart in Appendix D and excluded studies list in Appendix J.

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9.6.4 Economic evidence

Published literature

No relevant economic evaluations were identified.

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

Unit costs

Table 131: Camera equipment cost

Device	Unit cost	Source
Digital camera with 4GB memory card	£128.32	NHS Supply Chain [3]

Table 132: Cost per fracture

Parameter	Value	Source
Number of cameras needed	1	Assumption
Lifetime of each camera	1 year	Conservative assumption taking into account potential for loss and theft.
Cost per hospital per year	£128.32	N/A
Number of NHS trusts that provide an A&E service.	58	NHS Trust Development Authority Winter Report 2014[70]
Cost for EDs	£7,443	Calculated from above
Number of open fractures in UK each year	2,779	Calculated using incidence data from a BOA/BAPS report[25,25] and population statistics from the 2011 census[2].
Cost per fracture	£2.68	Calculated from above

Table 133: Dressing cost

Device	Unit cost	Source
Saline dressing[(a)]	£1.62	SP Services[b]

(a) Dry dressing plus Sodium Chloride 0.9% w/v at £2.65 for a 500ml bottle.
(b) A supplier used by the East Midlands Ambulance Service.

9.6.5 Evidence statements

Clinical

No relevant clinical evidence was identified.

Economic

No relevant economic evaluations were identified.

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9.6.6 Recommendations and link to evidence

Recommendations	**44. All trusts receiving patients with open fractures must have information governance policies in place that enable staff to take and use photographs of open fracture wounds for clinical decision-making 24 hours a day. Protocols must also cover the handling and storage of photographic images of open fracture wounds.** **45. Consider photographing open fracture wounds when they are first exposed for clinical care, before debridement and at other key stages of management.** **46. Keep any photographs of open fracture wounds in the patient's records.**
Relative values of different outcomes	Critical outcomes were mortality at 1, 6 and 12 months, health-related quality of life, deep infection, time to initial surgery, and time to definitive closure. Important outcomes were pain/discomfort, return to normal activities and psychological wellbeing.
Trade-off between clinical benefits and harms	No evidence was found for this question in the published literature and so recommendations were made by consensus. The GDG discussed the common practice of repeated removal of dressings from wounds to allow inspection of the wound, and felt that it was undesirable as it may increase the risk of infection. The GDG felt it was not necessary to repeatedly uncover the wound for repeated observations over the period from admission to debridement, as significant changes in the wound were not expected in the relatively short period prior to debridement in the absence of any other active treatment of the wound. Therefore, in the context of open fractures, a single observation in the form of a photograph would suffice to provide relevant visual information of the wound to new members of staff on duty, or to refresh the memories of returning staff. The GDG felt this would reduce the tendency for the wound to be needlessly uncovered and thus improve outcomes due to reduced risk of infection. The GDG also discussed the possibility that a single observation of the wound could miss serious changes, such as those due to a fulminant infection, but it was agreed that this would be evident from other signs, and not dependent on visual observations. In line with this, the GDG also stressed the need to not remove dressings solely to take the photograph, and that the photograph should, therefore, be taken at a point where the wound was exposed for another essential purpose. The GDG felt that in many settings pre-hospital photos would be helpful, as the pre-hospital phase may be the only time the wound is necessarily exposed. The GDG thought it was also important to record the condition of the wound at each key stage of its management. The key stages are before and after debridement, after initial closure and at review during the healing phase. This would be analogous to a radiographic record of a fracture. One harm of taking an image was the risk of contravening privacy-based legislation. Hence it was suggested that images should be uploaded to a secure location (and/or printed) immediately, and deleted from the camera. In addition, it was felt that the camera should be the property of the treatment centre and not belong to any staff, to further avoid any possibility that privacy issues would become a problem.

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Economic considerations	No economic evidence was identified for this question. The cost of providing equipment to take photographs is expected to be small per patient given that a camera can be reused many times. The purpose of taking the photograph when the wound is already exposed is in order to refer to the photograph to remember how the injury looked, and to share this with other clinicians to plan management. Taking photographs is therefore expected to reduce the need to reapply dressings and so a small cost can also be saved here and may cover the cost of the camera equipment over time. Eliminating the need to remove dressings also reduces the risk of acquiring an infection, which can be costly to treat and have adverse health consequences. Photographing open fracture wounds is already part of current practice in some NHS hospitals. However, there are often problems with availability and access to camera equipment that prevents imaging from being performed or causes staff to use personal camera phones and risk contravening privacy-based legislation. According to the GDG, some NHS hospitals now have systems in place where personal camera phones can have an application installed that allows an image to be taken, uploaded to the hospital system securely and deleted from the user's personal device. This system provides an easily accessible way to photograph wounds securely and therefore without breaching the patient's right to privacy. The cost of providing this service is currently unknown, however, this is in place at some NHS hospitals and therefore the software has already been developed and extending this across the NHS is unlikely to have a large cost of implementation. The GDG therefore believe it is cost effective to provide images, when the wound is first exposed and at other key stages, within patient records, and that a protocol should be in place for a hospital to provide photographic imaging in an easily accessible and secure way.
Quality of evidence	No evidence was found, and decisions were therefore made by consensus.
Other considerations	The British Orthopaedic Association and British Association of Plastic Surgeons Working Party has recommended, by consensus, that wound photographs should be taken before dressings.[88,88] The GDG were aware that a lot of clinicians are already using personal telephones to take images of open fractures and help reduce infection rates by unnecessary exposure of the wound. This has been reported in the literature. The GDG were also aware that patient consent would need to be sought and this would also need to be addressed in trust protocols.

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9.7 Documentation of neurovascular compromise

9.7.1 Introduction

One possible outcome of a traumatic fracture is neurovascular compromise. Neurovascular compromise is defined as excessive pressure on the nerves or blood vessels and is most prevalent after displaced fractures or fracture dislocations. It can result in a reduction or interruption of blood flow, vascular injury, tissue trauma, excessive oedema, thrombus formation, hypovolaemia and nerve damage or dysfunction. Monitoring neurovascular status is thus essential in early recognition of neurovascular deterioration or compromise. This questions asks the whether documentation of neurovascular status affects clinical outcomes.

9.7.2 Review question: Does documentation recording assessment results of neurovascular status (including interpretations and conclusions) improve outcomes compared with limited recording of neurovascular status in people with complex fractures?

For full details see review protocol in Appendix C.

Table 134: PICO characteristics of review question

Population	Children, young people and adults with suspected complex fractures
Intervention	• Documentation recording neurovascular status, including which tests were done (before and after treatments)
Comparisons	• Limited documentation – yes/no (before and after treatments) • No neurovascular documentation
Outcomes	Critical: • Mortality up to 12 months • Health-related quality of life • Pain/discomfort • Amputation • Neuromuscular function Important: • Total hospital bed days • Blood loss • Return to normal activities • Psychological wellbeing • Litigation
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.

9.7.3 Clinical evidence

No relevant clinical studies were identified. See the search strategy in appendix F, study selection flow chart in Appendix D and excluded studies list in Appendix J.

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9.7.4 Economic evidence

Published literature

No relevant economic evaluations were identified.

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

9.7.5 Evidence statements

Clinical

No clinical evidence was identified

Economic

No relevant economic evaluations were identified.

9.7.6 Recommendations and link to evidence

Recommendations	**47. When assessing neurovascular status in a person with a limb injury, document for both limbs:** • **which nerves and nerve function have been assessed and when** • **the findings, including:** – **sensibility** – **motor function using the Medical Research Council (MRC) grading system** • **which pulses have been assessed and when** • **how circulation has been assessed when pulses are not accessible.** **Document and time each repeated assessment.**
Relative values of different outcomes	Critical outcomes were mortality, health-related quality of life, pain/discomfort, amputation and neuromuscular function. Important outcomes were total hospital bed days, blood loss, return to normal activities, psychological wellbeing and litigation.
Trade-off between clinical benefits and harms	No relevant clinical studies were identified so the GDG decided to make recommendations based on consensus. The GDG discussed the specific requirements for appropriate documentation of neurovascular status. A specific recommendation was made around this because it was considered that recording specific clinical findings was superior to a generic comment, such as 'neurovascularly intact'. Recording specific findings should encourage and help direct appropriate examination. It should also increase subsequent confidence that as the recorded examinations were specific they can more reliably be used to identify trends in the neurovascular status. The GDG discussed the frequency of documentation and agreed that repeated appropriate documentation would help avoid delayed diagnosis.

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Economic considerations	No economic evidence was identified for this question. The GDG believed documenting neurovascular status could reduce the risk of missing injuries and therefore could reduce unnecessary treatment for complications as well as prevent a reduced health-related quality of life in these patients who have delayed treatment. The GDG considered the implementation cost involved to change current documentation but believed it was a small cost when considered over the long term and the benefits that would accrue over time.
Quality of evidence	No relevant clinical studies were identified.
Other considerations	The MRC grading system is a method of describing the strength of muscle contractions: • Grade 5: Muscle contracts normally against full resistance. • Grade 4: Muscle strength is reduced but muscle contraction can still move joint against resistance. • Grade 3: Muscle strength is further reduced such that the joint can be moved only against gravity with the examiner's resistance completely removed. As an example, the elbow can be moved from full extension to full flexion starting with the arm hanging down at the side. • Grade 2: Muscle can move only if the resistance of gravity is removed. As an example, the elbow can be fully flexed only if the arm is maintained in a horizontal plane. • Grade 1: Only a trace or flicker of movement is seen or felt in the muscle. • Grade 0: No movement is observed. The GDG considered what should be done if both limbs were injured and hence there was no contralateral normal limb for comparison. In such a case, it was deemed that clinicians should use their experience to decide what was normal.

9.8 Information and support

9.8.1 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.

9.8.2 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.

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Table 135: SPICE characteristics of review question

Setting	NHS – primary and secondary care
Population	People with complex fractures after trauma
Intervention (phenomenon of interest)	Information
Comparison	Not applicable – this will be a qualitative review
Evaluation	Qualitative data will be collated into themes

9.8.3 Clinical evidence

Four qualitative studies were included in the review;[31,73,74,87] these are summarised in Table 136 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 136 and a detailed breakdown of the quality assessment is included in Appendix Q.

Table 136: Summary of studies included in the review

Study	Population	Methods	Limitations
Forsberg 2014[31]	Age range 24–72 years 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[73]	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[74]	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

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Study	Population	Methods	Limitations
Sleney 2014[87]	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 or support desired

Treatment details

Participants in three studies (Forsberg 2014[31], Sleney 2014[87], O'Brien 2010[73] emphasised the importance of obtaining information on the treatments being administered.

Prior to surgery, Forsberg 2014[31] described how most anxiety stemmed from the lack of understanding of what would happen. During surgery, Forsberg 2014[31] 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[31] described how participants wanted information about pain relief, such as 'explaining which kind of drug was being administered'.

Sleney 2014[87] 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[74] stated how information about treatment was linked to reassurance:

> *"we need to get information about the steps of treatment …we need reassurance by doctors".*

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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[73] described how some participants 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[31] 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 of the information that had been given about this. O'Brien 2011[73] 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[87] 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[87] 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[31] 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[74] 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".*

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Self-efficacy

Participants often valued information that empowered them to take control of a situation themselves. For example, Forsberg 2014[31] 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[31] 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[31] 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[87] 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[87] reported how information about physiotherapy was very important to participants. Participants who had not received 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.[87] 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*

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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[31] 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[31] and Sleney 2014[87] 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[87] 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[31] study emphasised the importance of coherent information.

Non-technical language

Sleney 2014[87] 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[31] 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[87] 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.

9.8.4 Economic evidence

Published literature

No relevant economic evaluations were identified.

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

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9.8.5 Evidence statements

Clinical

Four qualitative studies[31,73,74,87] suggested that information should be provided about:

- 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.

9.8.6 Recommendations and link to evidence

Recommendations	**Providing support** **48. The trauma team structure should include a clear point of contact for providing information to patients, their family members and carers.** **49. If possible, ask the patient if they want someone (family member, carer or friend) with them.** **Support for children and vulnerable adults** **50. Allocate a dedicated member of staff to contact the next of kin and provide personal support for unaccompanied children and vulnerable adults.** **51. Contact the mental health team as soon as possible for patients who have a pre-existing psychological or psychiatric condition that might have contributed to their injury, or a mental health problem that might affect their wellbeing or care in hospital.** **52. For a child or vulnerable adult with a complex fracture, enable their family members or carers to remain within eyesight if appropriate.**

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53. **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.**

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

Support for people having procedures

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

Providing information

56. **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.**

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

58. **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 permanent effects on quality of life (such as pain, loss of function and psychological effects)**
- **amputation, if this is a possibility**
- **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.**

59. **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.**

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

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	Providing information about transfer from an emergency department **61. 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.**
	These recommendations were developed and supported by the evidence reviews addressing the scope area, ' Information and support needs of patients and their families and carers when appropriate' in each of the four clinical guidelines: • Complex fractures: assessment and management of complex fractures (including pelvic fractures and open fractures of limbs) • 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. • Spinal injury assessment: assessment and imaging, and early management for spinal injury (spinal column or spinal cord injury) and ,' provision of information and support for families and carers ' in the Major trauma services guidance scope area. The chapters on information and support in these guidelines should be read in conjunction with this chapter. **Developing the recommendations** Information and support recommendations were developed across the trauma guidelines suite by all the individual GDGs. Each GDG was asked to define a clinical question to address the scope area that was specific and important to the population in their scope. Evidence reviews were completed for all the guidelines and the separate GDGs reviewed the evidence and drafted recommendations. The overall guideline population of patients with traumatic injuries meant that similarities and duplication between the draft recommendations were inevitable. The recommendations were taken to Project Executive Team for coherence and consistency checking, the PET also had the advantage of identifying gaps in the separate guidelines that had been addressed in another guideline. The PET agreed on a core set of draft recommendations that encompassed the meaning from the separate recommendations. These recommendations are a key set of principles that underline best practice in providing information and support to a patient with traumatic injuries. and their families and/or carers Where there were recommendations that were specific to the guideline these were kept separate for publication in that guideline. For example, the spinal injury guideline has a recommendation highlighting the importance of eye contact with a person with suspected spinal injury to avoid movement of their neck.

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	The core set of recommendations and were taken back to each of the separate GDGs for review and agreement. The GDGs had access to the reviews underpinning the recommendations. Some of the recommendations listed here are directed at organisations responsible for commissioning. The recommendation ,'ensure there is a protocol for providing information and support for patients, their families and carers.' is a clear instruction for the organisations in a trauma networks to out a protocol in place. In addition the service delivery recommendations are supplemented with advice to clinical staff to support their practice and to indicate to commissioning bodies what is required to successfully implement the service delivery recommendations. The PET and the GDGs agreed that the service delivery and clinical recommendations were more coherent if they were presented together as a set of recommendation in each guideline rather than separating them across the guidelines. The LETR in this chapter summarises the decision making of the fractures GDG.
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). In addition the applicability of some of the evidence was limited – for example the study by O'Brien (2010) included finger fractures.

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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.

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10 Access to the skills required for the management of people with complex fractures

10.1 Introduction

Injuries sustained from trauma may be life threatening and could be life changing. A complex fracture can be associated with adverse consequences resulting in long-term 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 and potentially life changing injuries 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 fractures, 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 fractures, 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.

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11 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

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Acronym or abbreviation	Description
RCT	Randomised controlled trial
RSI	Rapid Sequence Induction of anaesthesia and intubation
TARN	The Trauma Audit & Research Network
TU	Trauma unit
UTI	Urinary tract infection
VKA	Vitamin K antagonist
VTE	Venous thrombosis embolism

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12 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.

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Term	Definition
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.
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.

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Term	Definition
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 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.

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Term	Definition
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
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.

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Term	Definition
	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, 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:

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Term	Definition
	• 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.
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.

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Term	Definition
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.
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.

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Term	Definition
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 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.

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Term	Definition
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 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.

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Term	Definition
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.
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.

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Term	Definition
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 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.

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Term	Definition
	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 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.

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Term	Definition
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 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

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Term	Definition
	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.
Orthoplastics centre	A hospital with a dedicated, combined service for orthopaedic and plastic surgery in which consultants from both specialties work simultaneously to treat open fractures as part of regular, scheduled, combined orthopaedic and plastic surgery operating lists. Consultants are supported by combined review clinics and specialists nursing teams.
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 or feel.

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Term	Definition
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

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Term	Definition
	bone, changing the mechanics of the joint and making it wear out more 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

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Term	Definition
	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 (RCT)	A comparative study in which participants are randomly allocated to 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.

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Term	Definition
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 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'

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Term	Definition
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. 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’.

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Term	Definition
	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 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.

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Term	Definition
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 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.

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Term	Definition
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 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.

ISBN: 978-1-4731-4829-1

References

1 GRADEprofiler [Computer program]. Version 3.6. GRADE Working Group, 2007

2 2011 Census: Population Estimates for the United Kingdom, 27 March 2011. Office For National Statistics. 2012;1-14

3 NHS Supply Chain Catalogue 2013. 2013. Available from: http://www.supplychain.nhs.uk/ [Last accessed: 24 April 2013]

4 Review Manager (RevMan) [Computer program]. Version 5. Copenhagen. The Nordic Cochrane Centre, The Cochrane Collaboration, 2014. Available from: http://tech.cochrane.org/Revman

5 Barleben A, Jafari F, Rose JJ, Dolich M, Malinoski D, Lekawa M et al. Implementation of a cost-saving algorithm for pelvic radiographs in blunt trauma patients. Journal of Trauma. 2011; 71(3):582-584

6 Behdad S, Rafiei MH, Taheri H, Behdad S, Mohammadzadeh M, Kiani G et al. Evaluation of Mangled Extremity Severity Score (MESS) as a predictor of lower limb amputation in children with trauma. European Journal of Pediatric Surgery. 2012; 22(6):465-469

7 Benson DR, Riggins RS, Lawrence RM, Hoeprich PD, Huston AC, Harrison JA. Treatment of open fractures: a prospective study. Journal of Trauma. 1983; 23(1):25-30

8 Bonanni F, Rhodes M, Lucke JF. The futility of predictive scoring of mangled lower extremities. Journal of Trauma. 1993; 34(1):99-104

9 Bosse MJ, Brumback RJ, Hash C. Medical cost containment: analysis of dual orthopedic/radiology interpretation of X-rays in the trauma patient. Journal of Trauma. 1995; 38(2):220-222

10 Bosse MJ, MacKenzie EJ, Kellam JF, Burgess AR, Webb LX, Swiontkowski MF et al. A prospective evaluation of the clinical utility of the lower-extremity injury-severity scores. Journal of Bone and Joint Surgery American Volume. 2001; 83-A(1):3-14

11 British Orthopaedic Association and British Association of Plastic RaAS. British Orthopaedic Association Standards for Trauma (BOAST) 4. the management of severe open lower limb fractures, 2009. Available from: https://www.boa.ac.uk/wp-content/uploads/2014/12/BOAST-4.pdf

12 Brown KV, Ramasamy A, McLeod J, Stapley S, Clasper JC. Predicting the need for early amputation in ballistic mangled extremity injuries. Journal of Trauma. 2009; 66(4 Suppl):S93-S98

13 Busquets AR, Acosta JA, Colon E, Alejandro KV, Rodriguez P. Helical computed tomographic angiography for the diagnosis of traumatic arterial injuries of the extremities. Journal of Trauma. 2004; 56(3):625-628

14 Chan DPN, Abujudeh HH, Cushing GLJ, Novelline RA. CT cystography with multiplanar reformation for suspected bladder rupture: experience in 234 cases. AJR American Journal of Roentgenology. 2006; 187(5):1296-1302

ISBN: 978-1-4731-4829-1

15 Charalambous CP, Siddique I, Zenios M, Roberts S, Samarji R, Paul A et al. Early versus delayed surgical treatment of open tibial fractures: effect on the rates of infection and need of secondary surgical procedures to promote bone union. Injury. 2005; 36(5):656-661

16 D'Alleyrand JC, Manson TT, Dancy L, Castillo RC, Bertumen JB, Meskey T et al. Is time to flap coverage of open tibial fractures an independent predictor of flap-related complications? Journal of Orthopaedic Trauma. 2014; 28(5):288-293

17 Dagum AB, Best AK, Schemitsch EH, Mahoney JL, Mahomed MN, Blight KR. Salvage after severe lower-extremity trauma: are the outcomes worth the means? Plastic and Reconstructive Surgery. 1999; 103(4):1212-1220

18 Davidovitch RI, Elkhechen RJ, Romo S, Walsh M, Egol KA. Open reduction with internal fixation versus limited internal fixation and external fixation for high grade pilon fractures (OTA type 43C). Foot and Ankle International. 2011; 32(10):955-961

19 Davis Sears E, Davis MM, Chung KC. Relationship between timing of emergency procedures and limb amputation in patients with open tibia fracture in the United States, 2003 to 2009. Plastic and Reconstructive Surgery. 2012; 130(2):369-378

20 Department of Health. NHS reference costs 2012-13. 2013. Available from: https://www.gov.uk/government/publications/nhs-reference-costs-2012-to-2013 [Last accessed: 12 March 2015]

21 Department of Health. NHS reference costs 2013-14. 2014. Available from: http://www.gov.uk/government/publications/nhs-reference-costs-2013-to-2014 [Last accessed: 12 March 2015]

22 Desai P, Audige L, Suk M. Combined orthopedic and vascular lower extremity injuries: sequence of care and outcomes. American Journal of Orthopedics. 2012; 41(4):182-186

23 Donaldson LJ, Reckless IP, Scholes S, Mindell JS, Shelton NJ. The epidemiology of fractures in England. Journal of Epidemiology and Community Health. 2008; 62(2):174-180

24 Doucet JJ, Galarneau MR, Potenza BM, Bansal V, Lee JG, Schwartz AK et al. Combat versus civilian open tibia fractures: the effect of blast mechanism on limb salvage. Journal of Trauma. 2011; 70(5):1241-1247

25 Duckworth T, Morgan BP. A Report by the BOA/BAPS Working Party onThe Management of Open Tibial Fractures. British Orthopaedic Association and British Association of Plastic Surgeons. 1997;1-45

26 Durham RM, Mistry BM, Mazuski JE, Shapiro M, Jacobs D. Outcome and utility of scoring systems in the management of the mangled extremity. American Journal of Surgery. 1996; 172(5):569-4

27 Elsharawy MA. Arterial reconstruction after mangled extremity: injury severity scoring systems are not predictive of limb salvage. Vascular. 2005; 13(2):114-119

28 Enninghorst N, McDougall D, Hunt JJ, Balogh ZJ. Open tibia fractures: timely debridement leaves injury severity as the only determinant of poor outcome. Journal of Trauma. 2011; 70(2):352-357

ISBN: 978-1-4731-4829-1

29 Fagelman MF, Epps HR, Rang M. Mangled extremity severity score in children. Journal of Pediatric Orthopedics. 2002; 22(2):182-184

30 Feeney J, Jayaraman V, Luk S, Shapiro D, Virk M, Twohig M et al. Retrospective review of the costs of routine pelvic X-rays in a trauma setting. American Surgeon. 2011; 77(3):337-341

31 Forsberg A, Soderberg S, Engstrom A. People's experiences of suffering a lower limb fracture and undergoing surgery. Journal of Clinical Nursing. 2014; 23(1-2):191-200

32 Gopal S, Giannoudis PV, Murray A, Matthews SJ, Smith RM. The functional outcome of severe, open tibial fractures managed with early fixation and flap coverage. Journal of Bone and Joint Surgery - British Volume. 2004; 86(6):861-867

33 Gopal S, Majumder S, Batchelor AG, Knight SL, De Boer P, Smith RM. Fix and flap: the radical orthopaedic and plastic treatment of severe open fractures of the tibia. Journal of Bone and Joint Surgery - British Volume. 2000; 82(7):959-966

34 Gross EA, Niedens BA. Validation of a decision instrument to limit pelvic radiography in blunt trauma. Journal of Emergency Medicine. 2005; 28(3):263-266

35 Harley BJ, Beaupre LA, Jones CA, Dulai SK, Weber DW. The effect of time to definitive treatment on the rate of nonunion and infection in open fractures. Journal of Orthopaedic Trauma. 2002; 16(7):484-490

36 Harley JD, Mack LA, Winquist RA. CT of acetabular fractures: Comparison with conventional radiography. American Journal of Roentgenology. 1982; 138(3):413-417

37 Harris AM, Patterson BM, Sontich JK, Vallier HA. Results and outcomes after operative treatment of high-energy tibial plafond fractures. Foot and Ankle International. 2006; 27(4):256-265

38 Harris IA, Kadir A, Donald G. Continuous compartment pressure monitoring for tibia fractures: does it influence outcome? Journal of Trauma. 2006; 60(6):1330-1335

39 Helfet DL, Howey T, Sanders R, Johansen K. Limb salvage versus amputation. Preliminary results of the Mangled Extremity Severity Score. Clinical Orthopaedics and Related Research. 1990;(256):80-86

40 Hertel R, Lambert SM, Muller S, Ballmer FT, Ganz R. On the timing of soft-tissue reconstruction for open fractures of the lower leg. Archives of Orthopaedic and Trauma Surgery. 1999; 119(1-2):7-12

41 Hertel R, Strebel N, Ganz R. Amputation versus reconstruction in traumatic defects of the leg: outcome and costs. Journal of Orthopaedic Trauma. 1996; 10(4):223-229

42 Hohmann E, Tetsworth K, Radziejowski MJ, Wiesniewski TF. Comparison of delayed and primary wound closure in the treatment of open tibial fractures. Archives of Orthopaedic and Trauma Surgery. 2007; 127(2):131-136

43 Horstman WG, McClennan BL, Heiken JP. Comparison of computed tomography and conventional cystography for detection of traumatic bladder rupture. Urologic Radiology. 1991; 12(4):188-193

ISBN: 978-1-4731-4829-1

44 Hull JB, Bell MJ. Modern trends for external fixation of fractures in children: a critical review. Journal of Pediatric Orthopaedics B. 1997; 6(2):103-109

45 Hull PD, Johnson SC FAU, Stephen DJ FAU, Kreder HJ FAU, Jenkinson RJ. Delayed debridement of severe open fractures is associated with a higher rate of deep infection. Bone and Joint Journal. 2014; 96B(3):379-384

46 Janzing HM, Broos PL. Routine monitoring of compartment pressure in patients with tibial fractures: Beware of overtreatment! Injury. 2001; 32(5):415-421

47 Jenkinson RJ, Kiss A, Johnson S, Stephen DJG, Kreder HJ. Delayed wound closure increases deep-infection rate associated with lower-grade open fractures: a propensity-matched cohort study. Journal of Bone and Joint Surgery - American Volume. 2014; 96(5):380-386

48 Johansen K, Daines M, Howey T, Helfet D, Hansen STJ. Objective criteria accurately predict amputation following lower extremity trauma. Journal of Trauma. 1990; 30(5):568-3

49 Katsura M, Yamazaki S, Fukuma S, Matsushima K, Yamashiro T, Fukuhara S. Comparison between laparotomy first versus angiographic embolization first in patients with pelvic fracture and hemoperitoneum: a nationwide observational study from the Japan Trauma Data Bank. Scandinavian Journal of Trauma, Resuscitation and Emergency Medicine. 2013; 21:82

50 Koulouvaris P, Stafylas K, Mitsionis G, Vekris M, Mavrodontidis A, Xenakis T. Long-term results of various therapy concepts in severe pilon fractures. Archives of Orthopaedic and Trauma Surgery. 2007; 127(5):313-320

51 Krettek C, Seekamp A, Kontopp H, Tscherne H. Hannover Fracture Scale '98--re-evaluation and new perspectives of an established extremity salvage score. Injury. 2001; 32(4):317-328

52 Kumar MK, Badole C, Patond K. Salvage versus amputation: Utility of mangled extremity severity score in severely injured lower limbs. Indian Journal of Orthopaedics. 2007; 41(3):183-187

53 Kumar S, O'Connor A, Despois M, Galloway H. Use of early magnetic resonance imaging in the diagnosis of occult scaphoid fractures: the CAST Study (Canberra Area Scaphoid Trial). New Zealand Medical Journal. 2005; 118(1209):U1296

54 Kwok MY, Yen K, Atabaki S, Adelgais K, Garcia M, Quayle K et al. Sensitivity of plain pelvis radiography in children with blunt torso trauma. Annals of Emergency Medicine. 2015; 65(1):63-71

55 Lack WD, Karunakar MA, Angerame MR, Seymour RB, Sims S, Kellam JF et al. Type III open tibia fractures: immediate antibiotic prophylaxis minimizes infection. Journal of Orthopaedic Trauma. 2015; 29(1):1-6

56 Liu CJ, Zhang WZ, Zhu PC. Surgical treatment of tibia Pilon fractures. Zhongguo Gu Shang = China Journal of Orthopaedics and Traumatology. 2010; 23(2):128-130

57 Liu DSH, Sofiadellis F, Ashton M, MacGill K, Webb A. Early soft tissue coverage and negative pressure wound therapy optimises patient outcomes in lower limb trauma. Injury. 2012; 43(6):772-778

ISBN: 978-1-4731-4829-1

58 Lynch K, Johansen K. Can Doppler pressure measurement replace "exclusion" arteriography in the diagnosis of occult extremity arterial trauma? Annals of Surgery. 1991; 214(6):737-741

59 Madhuchandra P, Rafi M, Devadoss S, Devadoss A. Predictability of salvage and outcome of Gustilo and Anderson type-IIIA and type-IIIB open tibial fractures using Ganga Hospital Scoring system. Injury. 2015; 46(2):282-287

60 Malhotra AK, Goldberg S, Graham J, Malhotra NR, Willis MC, Mounasamy V et al. Open extremity fractures: impact of delay in operative debridement and irrigation. Journal of Trauma and Acute Care Surgery. 2014; 76(5):1201-1207

61 McNamara MG, Heckman JD, Corley FG. Severe open fractures of the lower extremity: a retrospective evaluation of the Mangled Extremity Severity Score (MESS). Journal of Orthopaedic Trauma. 1994; 8(2):81-87

62 McQueen MM, Hajducka C, Court-Brown. Redisplaced unstable fractures of the distal radius. Journal of Bone and Joint Surgery - British Volume. 1996; 78(3):404-409

63 McQueen MM, Duckworth AD, Aitken SA, Court-Brown C. The estimated sensitivity and specificity of compartment pressure monitoring for acute compartment syndrome. Journal of Bone and Joint Surgery - American Volume. 2013; 95(8):673-677

64 Mills WJ, Barei DP, McNair P. The value of the ankle-brachial index for diagnosing arterial injury after knee dislocation: a prospective study. Journal of Trauma. 2004; 56(6):1261-1265

65 Mommsen P, Zeckey C, Hildebrand F, Frink M, Khaladj N, Lange N et al. Traumatic extremity arterial injury in children: epidemiology, diagnostics, treatment and prognostic value of Mangled Extremity Severity Score. Journal of Orthopaedic Surgery and Research. 2010; 5:25

66 Naique SB, Pearse M, Nanchahal J. Management of severe open tibial fractures: the need for combined orthopaedic and plastic surgical treatment in specialist centres. Journal of Bone and Joint Surgery - British Volume. 2006; 88(3):351-357

67 National Institute for Health and Clinical Excellence. Social value judgements: principles for the development of NICE guidance. 2nd edition. London: National Institute for Health and Clinical Excellence; 2008. Available from: http://www.nice.org.uk/media/C18/30/SVJ2PUBLICATION2008.pdf

68 National Institute for Health and Clinical Excellence. The guidelines manual. London: National Institute for Health and Clinical Excellence; 2012. Available from: http://publications.nice.org.uk/the-guidelines-manual-pmg6/

69 National Institute for Health and Clinical Excellence. Developing NICE guidelines: the manual. London: National Institute for Health and Clinical Excellence; 2014. Available from: http://www.nice.org.uk/article/pmg20/

70 NHS Trust DevelopmentAuthority (TDA). Winter report NHS Trust Performance Report August 2013 - January 2014, 2014. Available from: http://www.ntda.nhs.uk/wp-content/uploads/2014/03/winter_report_web-FINAL.pdf

ISBN: 978-1-4731-4829-1

71 Noumi T, Yokoyama K, Ohtsuka H, Nakamura K, Itoman M. Intramedullary nailing for open fractures of the femoral shaft: evaluation of contributing factors on deep infection and nonunion using multivariate analysis. Injury. 2005; 36(9):1085-1093

72 Novielli N, Cooper NJ, Abrams KR, Sutton AJ. How is evidence on test performance synthesized for economic decision models of diagnostic tests? A systematic appraisal of Health Technology Assessments in the UK since 1997. Value in Health. 2010; 13(8):952-957

73 O'Brien L, Presnell S. Patient experience of distraction splinting for complex finger fracture dislocations. Journal of Hand Therapy. 2010; 23(3):249-260

74 Okonta HI, Malemo KL, Ogunbanjo GA. The experience and psychosocial needs of patients with traumatic fractures treated for more than six months at doctors on call for service hospital, Goma, Democratic republic of Congo. South African Family Practice. 2011; 53(2):189-192

75 Pollak AN, McCarthy ML, Burgess AR. Short-term wound complications after application of flaps for coverage of traumatic soft-tissue defects about the tibia. The Lower Extremity Assessment Project (LEAP) Study Group. Journal of Bone and Joint Surgery - American Volume. 2000; 82-A(12):1681-1691

76 Pollak AN, Jones AL, Castillo RC, Bosse MJ, MacKenzie EJ, LEAP Study Group. The relationship between time to surgical debridement and incidence of infection after open high-energy lower extremity trauma. Journal of Bone and Joint Surgery - American Volume. 2010; 92(1):7-15

77 Quagliano PV, Delair SM, Malhotra AK. Diagnosis of blunt bladder injury: A prospective comparative study of computed tomography cystography and conventional retrograde cystography. Journal of Trauma. 2006; 61(2):410-412

78 Rajasekaran S, Naresh Babu J, Dheenadhayalan J, Shetty AP, Sundararajan SR, Kumar M et al. A score for predicting salvage and outcome in Gustilo type-IIIA and type-IIIB open tibial fractures. Journal of Bone and Joint Surgery - British Volume. 2006; 88(10):1351-1360

79 Ramasamy MA, Hill AM, Phillip R, Gibb I, Bull AMJ, Clasper JC. FASS is a better predictor of poor outcome in lower limb blast injury than AIS: implications for blast research. Journal of Orthopaedic Trauma. 2013; 27(1):49-55

80 Rasool G, Ahmed MU, Iqbal M, Khwaja Z. Vacuum assited wound closure and normal saline dressing in treatment of Gustilo type II, type IIIa and IIIb open fracture of tibia. Rawal Medical Journal. 2013; 38(4):382-384

81 Richards JE, Magill M, Tressler MA, Shuler FD, Kregor PJ, Obremskey WT et al. External fixation versus ORIF for distal intra-articular tibia fractures. Orthopedics. 2012; 35(6):e862-e867

82 Robertson PA. Prediction of amputation after severe lower limb trauma. Journal of Bone and Joint Surgery British Volume. 1991; 73(5):816-818

83 Rush RM, Kjorstad R, Starnes BW, Arrington E, Devine JD, Andersen CA. Application of the Mangled Extremity Severity Score in a combat setting. Military Medicine. 2007; 172(7):777-781

84 Schemitsch EH, Bhandari M, Guyatt G, Sanders DW, Swiontkowski M, Tornetta P et al. Prognostic factors for predicting outcomes after intramedullary nailing of the tibia. Journal of Bone and Joint Surgery - American Volume. 2012; 94(19):1786-1793

ISBN: 978-1-4731-4829-1

85 Sheean AJ, Krueger CA, Napierala MA, Stinner DJ, Hsu JR, Skeletal Trauma and Research Consortium (STReC). Evaluation of the mangled extremity severity score in combat-related type III open tibia fracture. Journal of Orthopaedic Trauma. 2014; 28(9):523-526

86 Slauterbeck JR, Britton C, Moneim MS, Clevenger FW. Mangled extremity severity score: an accurate guide to treatment of the severely injured upper extremity. Journal of Orthopaedic Trauma. 1994; 8(4):282-285

87 Sleney J, Christie N, Earthy S, Lyons RA, Kendrick D, Towner E. Improving recovery - Learning from patients' experiences after injury: A qualitative study. Injury. 2014; 45(1):312-319

88 Solan MC, Calder JD, Gibbons CE, Ricketts DM. Photographic wound documentation after open fracture. Injury. 2001; 32(1):33-35

89 Soto JA, Munera F, Cardoso N, Guarin O, Medina S. Diagnostic performance of helical CT angiography in trauma to large arteries of the extremities. Journal of Computer Assisted Tomography. 1999; 23(2):188-196

90 Stannard JP, Volgas DA, Stewart R, McGwin J, Alonso JE. Negative pressure wound therapy after severe open fractures: A prospective randomized study. Journal of Orthopaedic Trauma. 2009; 23(8):552-557

91 Stewart DA, Coombs CJ, Graham HK. Application of lower extremity injury severity scores in children. Journal of Children's Orthopaedics. 2012; 6(5):427-431

92 Tang J, Guo Wc, Yu L, Zhao Sh. Clinical efficacy of artificial skin combined with vacuum sealing drainage in treating large-area skin defects. Chinese Journal of Traumatology. 2010; 13(5):289-292

93 Tang X, Liu L, Tu CQ, Li J, Li Q, Pei FX. Comparison of early and delayed open reduction and internal fixation for treating closed tibial pilon fractures. Foot and Ankle International. 2014; 35(7):657-664

94 Vannier MW, Hildebolt CF, Gilula LA, Pilgram TK, Mann F, Monsees BS et al. Calcaneal and pelvic fractures: diagnostic evaluation by three-dimensional computed tomography scans. Journal of Digital Imaging. 1991; 4(3):143-152

95 Wang C, Li Y, Huang L, Wang M. Comparison of two-staged ORIF and limited internal fixation with external fixator for closed tibial plafond fractures. Archives of Orthopaedic and Trauma Surgery. 2010; 130(10):1289-1297

96 Webb LX, Bosse MJ, Castillo RC, MacKenzie EJ, Kellam JE, Travison TG et al. Analysis of surgeon-controlled variables in the treatment of limb-threatening type-III open tibial diaphyseal fracture. Journal of Bone and Joint Surgery - American Volume. 2007; 89(5):923-928

97 Weber D, Dulai SK FAU - Bergman J, Bergman JF, Buckley RF, Beaupre LA. Time to initial operative treatment following open fracture does not impact development of deep infection: a prospective cohort study of 736 subjects. Journal of Orthopaedic Trauma.: 1531-2291 (Electronic). 2014; 28(11):613-619

ISBN: 978-1-4731-4829-1

98 Weber JE, Jackson RE, Peacock WF, Swor RA, Carley R, Larkin GL. Clinical decision rules discriminate between fractures and nonfractures in acute isolated knee trauma. Annals of Emergency Medicine. 1995; 26(4):429-433

99 Wei DH, Raizman NM, Bottino CJ, Jobin CM, Strauch RJ, Rosenwasser MP. Unstable distal radial fractures treated with external fixation, a radial column plate, or a volar plate. A prospective randomized trial. Journal of Bone and Joint Surgery - American Volume. 2009; 91(7):1568-1577

100 Wei Sj, Cai Xh, Wang Hs, Qi Bw, Yu Ax. A comparison of primary and delayed wound closure in severe open tibial fractures initially treated with internal fixation and vacuum-assisted wound coverage: a case-controlled study. International Journal of Surgery. 2014; 12(7):688-694

101 Wyrsch B, McFerran MA, McAndrew M, Limbird TJ, Harper MC, Johnson KD et al. Operative treatment of fractures of the tibial plafond. A randomized, prospective study. Journal of Bone and Joint Surgery - American Volume. 1996; 78(11):1646-1657

ISBN: 978-1-4731-4829-1