National Clinical Guideline Centre

Final

Spinal injury: assessment and initial management

Spinal injury assessment: assessment and imaging for spinal injury

NICE Guideline NG41

Methods, evidence and recommendations

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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.

2 Introduction

Approximately 1000 people sustain a new spinal cord injury (SCI) each year in the UK. These injuries are associated with serious neurological damage, and can result in paraplegia, quadriplegia or death. Currently there are no 'cures' for SCI and in the UK there are 40,000 people living with long term disabilities as a result of such injuries.

Care of an acutely spinally injured patient is aimed towards the preservation of function and prevention of disability. Whilst primary prevention of SCI is not within the scope of this guideline, the avoidance of secondary injury, both mechanical and physiological, is crucial in limiting the effects of acute SCI.

Spinal injuries do not always occur in isolation and the acute management of the patient with multiple injuries is covered in the NICE clinical guideline on major trauma and will be cross referred to when appropriate.

This guideline addresses both cord and column injury. While approximately 15% of people with a spinal column fracture or dislocation will have a cord injury, the majority of people with a cord injury will have an accompanying column injury. Of particular importance is the avoidance of secondary SCI in the presence of an unstable spinal column. Avoidance of a cord injury mandates an awareness of the possibility of column injury and resultant protection of the spinal cord from the time of injury. This requires a standardised and effective approach for spinal immobilisation in both the pre-hospital and hospital phases.

Spinal injuries can be the result of a wide range of events and the injury may not be immediately obvious. The mechanism of injury ranges from a fall from a standing position in the elderly to an axial load to the head (by diving or in a high-speed motor vehicle collision). As a result, the assessment and the recognition of potential spinal column and cord injuries can be challenging.

Across the UK there is variation in pre-hospital spinal immobilisation strategies. Effective immobilisation is pivotal to spinal protection and must be carried out and maintained from the injury site to definitive care. Carrying out full in-line spinal immobilisation can be challenging in the pre-hospital environment with fewer trained personnel available at the injury site than in the hospital resuscitation room.

Accurate assessment and documentation of the spinal injury that includes motor and sensory function is important to provide a baseline for on-going care and this guideline sets out the vital assessments and data collection parameters.

The devastating effects of SCI are well known to the public, which makes providing accurate information to patients, carers and their relatives of particular importance. Information about the process of care should be provided early but inaccurate prognostic prediction either pessimistic or optimistic can be devastating.

The scope of this guideline is the assessment, imaging and early management of spinal injury and does not address rehabilitation. It is important to recognise that early management is intrinsically connected to rehabilitation and some later complications may be avoided with changes in early care. Early and ongoing collaborative multidisciplinary care across a trauma network is vital in ensuring that the patient with a spinal injury receives the best possible care.

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 imaging of patients at high risk of spinal injury.

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 Dr David Skinner 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

All adults, young people and children who present with suspected spinal column or spinal cord injury secondary to a traumatic event.

Key clinical issues that will be covered

- Initial triage and management by pre-hospital care staff
- Acute-stage clinical assessment
- Acute-stage clinical management of early medical intervention (such as anti-inflammatories, antioxidants and anti-excitotoxins)
- Acute-stage imaging assessment of different imaging modalities such as: X-ray, CT and MRI
- Timing of referral and the criteria for acceptance by tertiary services
- Skills to be present within the multidisciplinary team
- Documentation of clinical assessments and management for people with spinal injuries
- Information and support needs of patients and their families and carers when appropriate.

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

3.3.2 What this guideline does not cover

Groups that will not be covered

People whose spinal injury is caused by disease, rather than a traumatic event.

Clinical issues that will not be covered

- Prevention of traumatic spinal injury
- Management of spinal injury in a tertiary centre
- Management and follow-up of pathological conditions predisposing to spinal injury (such as osteoporosis and osteoarthritis)

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).

Head injury. NICE clinical guideline 176 (2014).

Safe staffing for nursing in adult inpatient wards in acute hospitals. NICE safe staffing guideline 1 (2014).

Falls in older people. NICE quality standard 86 (2015).

Related NICE guidance currently in development:

Major trauma. NICE clinical guideline. Publication expected Feb 2016.

Fractures. NICE clinical guideline. Publication expected Feb 2016.

Complex fractures. NICE clinical guideline. Publication expected Feb 2016.

Major trauma services. NICE clinical guideline. Publication expected Feb 2016.

4 Methods

This chapter sets out in detail the methods used to review the evidence and to generate the recommendations that are presented in subsequent chapters. This guidance was developed in accordance with the methods outlined in the NICE guidelines manual 2012[85].

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 17 review questions were identified.

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

Table 1: Review questions

Chapter	Review questions	Outcomes
Protecting the spine	What is the clinical and cost effectiveness of routine spinal protection of all children, young people and adults experiencing trauma compared to selective protection, based on the use of a risk tool/clinical assessment at the scene of the incident/presentation?	Critical: • Mortality • Quality of life • Rates of SCI • Missed spinal column/cord injury, spinal cord neurological function (American Spinal Injury Association [ASIA] and Frankel) • Adverse effects (pressure ulcers, airway compromise, raised ICP, neurological deterioration [ASIA]) associated with spinal protection/immobilisation Important: • Unnecessary imaging • Patient-reported outcomes (pain/discomfort, return to normal activities, psychological wellbeing)
Spinal injury assessment risk tools	What tools are most predictive of spinal injury in people with suspected traumatic spinal injury when trying to exclude spinal cord injury (with or without spinal column injury) or isolated spinal column injury?	• Diagnostic accuracy (sensitivity, specificity, positive predictive value, negative predictive value, likelihood ratios)
Immobilising the spine: pre -hospital strategies	What pre-hospital strategies to protect the spine in people with suspected spinal injury are the most clinically and cost effective during transfer from the scene of the incident to acute medical care?	Critical: • Mortality at 1 month • Mortality at 6 months • Mortality at 12 months • Health-related quality of life • Rates of SCI • Missed spinal column/cord injury • Spinal cord neurological function at 1 month(including ASIA and Frankel) • Spinal cord neurological function at 6 months(including ASIA and Frankel) • Spinal cord neurological function at 12 months (including ASIA and Frankel) • Adverse effects: • Pressure ulcers • Airway compromise • Raised ICP • Neurological deterioration [ASIA]) associated with spinal protection/immobilisation. Important: • Pain/discomfort

Chapter	Review questions	Outcomes
		• Return to normal activities • Psychological wellbeing
Destination (immediate)	What is the optimal immediate destination of a person at risk of a traumatic spinal column injury?	Critical: • Mortality at 1, 6 and 12 months and 2 years • Health-related quality of life • Missed diagnosis • Misdiagnosis • Adverse events: changes in neurology Important: • Length of hospital stay • Discharge destination and transitional • Patient-reported outcomes (pain/discomfort, return to normal activities, psychological wellbeing, psychosocial wellbeing) Population size and directness: • No limitations on sample size • Studies with indirect populations will not be considered
Destination (immediate)	What is the optimal immediate destination of a person at risk of a traumatic spinal cord injury?	Critical: • Mortality at 1, 6 and 12 months and 2 years • Health-related quality of life • Missed diagnosis • Misdiagnosis • Adverse events: changes in neurology • Important: • Length of hospital stay • Discharge destination and transitional • Patient-reported outcomes (pain/discomfort, return to normal activities, psychological wellbeing, psychosocial wellbeing) Population size and directness: • No limitations on sample size • Studies with indirect populations will not be considered
	a) What is the diagnostic accuracy of i) X-ray, ii) dynamic fluoroscopy, iii) CT and iv) MRI, for people with spinal cord injury (with or without column injury)?	• Diagnostic accuracy (sensitivity, specificity, positive predictive value, negative predictive value, likelihood ratios) • Adverse events: effects of radiation

Chapter	Review questions	Outcomes
	b) What is the diagnostic accuracy of i) X-ray, ii) dynamic fluoroscopy, iii) CT and iv) MRI, for people with isolated spinal column injury?	

Radiation risk	For people with clinical signs of spinal injury what are the radiation risks of having a X-ray(s) and/or CT scans?	Critical
		• Mortality (including all-cause mortality)
		• Genetic mutational risk
		• Non-cancer (cataracts, radiation skin changes)
		• Cancer (lag of ≥10 years)
		  ○ Breast cancer
		  ○ Brain tumours
		  ○ Cancers of the gonads
		  ○ Leukaemia
		  ○ Lymphoma
		  ○ Thyroid cancer
		
		Confounders
		• Current cancer diagnosis
		• Previous cancer
		• Age

Further imaging	For people who have clinical signs of traumatic spinal cord or column injury, but who have normal or indeterminate findings on imaging, what is the most clinically and cost effective further imaging strategy?	Critical: • Mortality at 1, 6 and 12 months • Health-related quality of life • Rates of SCI Important: • Adverse events: effects of radiation, effects of sedation/anaesthetic • Delay in treatment of other injuries whilst re-imaging • Patient-reported outcomes (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
Spinal cord decompression	What is the clinical and cost-effectiveness of emergency closed reduction of cervical facet joint dislocation of the cervical spine?	Critical: • Mortality at 1, 6 and 12 months • Health-related quality of life • Spinal cord neurological function at 1, 6 and 12 months (including ASIA and Frankel) • Adverse effects (deterioration in neurological function, acute cervical disc prolapse) Important:

Chapter	Review questions	Outcomes
		• Patient-reported outcomes (pain/discomfort, return to normal activities, psychological wellbeing)
Timing of referral to tertiary services	Is there a benefit of early liaison and referral (within 4 hours) to spinal cord injury centres compared to delayed liaison?	Critical: • Mortality • Quality of life Important: • Pain levels (immediate, 1 week) • Function and ADL (1 month, 3 months, 1 year, 3 years, 5 years) • Length of SCIC stay • Adverse events after transfer (immediate) • For example altered neurological function • Complications – pressure sores, contractures, stones, urological complications, poor spinal outcome • Duration of admission
Referral to a Spinal Cord Injury Centre	What are the clinical factors associated with a positive outcome after transfer to an SCIC for patients with spinal trauma?	Critical: • Mortality after transfer (time to event) • Quality of life after transfer (at 1 week, 1 month, 3 months) Important: • Pain levels after transfer (immediate, 1 week) • Function and ADL (1 month, 3 months, 1 year, 3 years, 5 years) • Length of hospital stay
Neuroprotective pharmacological interventions	What is the clinical and cost-effectiveness of neuroprotective pharmacological interventions (such as anti-inflammatories, antioxidants and anti-excitotoxins) in people with spinal cord injury during the acute stage?	Critical: • Mortality (at 1, 6 and 12 months) • Health-related quality of life • Spinal cord neurological function (at 1, 6 and 12 months). (including ASIA and Frankel) • Adverse effects (GI bleeding, infection including ventilator associated pneumonia, thrombosis, hyperglycaemia) Important: • Patient-reported outcomes (pain/discomfort, return to normal activities, psychological wellbeing)
Neuropathic pain	What are the optimum strategies given in the acute management stage to prevent later neuropathic pain in people with traumatic spinal cord injury?	Critical: • Mortality at 1, 6 and 12 months • Neuropathic pain at 1, 6 and

Chapter	Review questions	Outcomes
		12 months • Health-related quality of life • Adverse events: ○ Dizziness and visual disturbance ○ Nausea and vomiting ○ Lethargy Important: • Patient-reported outcomes (pain/discomfort, psychological wellbeing)
Information and support	a) What information and support do people with suspected traumatic spinal cord/column injury and their families want in the early stages after trauma before a definitive diagnosis has been made? b) What information and support do people with a confirmed traumatic spinal cord/column injury and their families want in the early stages after trauma before transfer to specialist care?	Critical outcomes: • Health-related quality of life • Patient and carer psychological distress. Population size and directness: • No limitations on sample size • Studies with indirect populations will not be considered.
Documentation	What documentation tool should be routinely used to record baseline neurological function in people with spinal injuries?	Critical: • Mortality at 1, 6 and 12 months • Health-related quality of life • Spinal cord neurological function at 1, 6 and 12 months (including ASIA and Frankel) Important: • Patient-reported outcomes (pain/discomfort, return to normal activities, psychological wellbeing).

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].[85] Databases were searched using medical subject headings and free-text terms. Foreign language studies were not reviewed and, where possible, searches were restricted to articles published in the English language. All searches were conducted in MEDLINE, Embase, and the Cochrane Library, and were updated for the final time on 27th March 2015. No papers added to the databases after this date were considered.

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

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

4.2.2 Health economic literature search

Systematic searches were undertaken to identify relevant health economic evidence within the published literature. The NHS Economic Evaluation Database (NHS EED), the Health Economic Evaluations Database (HEED) and Health Technology Assessment (HTA) database were searched using broad population terms and no date restrictions. A search was also run in MEDLINE and Embase using a specific economic filter with population terms. Where possible, searches were restricted to articles published in the English language. Economics search strategies are included in Appendix F. All searches were updated for the final time on 31st March 2015 except in HEED which ceased production in 2014. No papers added to the databases after this date were considered.

4.3 Evidence gathering and analysis

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

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

- correct methods were used to synthesis data
- a sample of the risk of bias assessments.

4.3.1 Inclusion and exclusion criteria

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

The key population inclusion criterion was:

- People of all ages experiencing an acute spinal injury (column and/or cord) as a result of a traumatic physical event.

The key population exclusion criterion was:

- People with spinal injury directly resulting from a disease process, without any concomitant traumatic event.

Conference abstracts were not automatically excluded from any review. 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, 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 appropriate for the question, 'What pre-hospital strategies to protect the spine in people with suspected traumatic spinal injury are the most clinically and cost effective during transfer from the scene of the incident to acute medical care?' If non-randomised studies were appropriate for inclusion, that is, non-drug trials with no randomised evidence, the GDG identified a priori in the protocol the variables which must either be equivalent at baseline or that the analysis had to adjust for any baseline differences. If the study did not fulfil either criterion it was excluded. Please refer to Appendix C for full details on the study design of studies selected for each review question.

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

4.3.3 Contacting authors

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

The GDG did not need to do this for any primary studies. However, the authors of a Cochrane systematic review were contacted in relation to the pharmacological interventions review. Additional data that had not been reported in either the original study papers or Cochrane review were obtained from the authors of the Cochrane review. This was done for the following outcomes:

- sensory function at 6 weeks/6 months for the comparison of high-dose methylprednisolone and no treatment[89]

- motor function at 6 weeks for the comparison of high-dose methylprednisolone and no treatment[89],
- motor function at 1 year for the comparison of nimodpine versus no treatment[93].
- sensory function at 1 year for the comparison of nimodpine versus no treatment [93].

In addition, data from five studies in the pharmacological interventions review[15,17,20,89,93] were extracted from the Cochrane group systematic review[14]. The original papers did not have these outcomes and the Cochrane group had contacted the study authors for the data.

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.[2]

All analyses were stratified for age (under 18 years and 18 years or over), which meant that different studies with predominant age-groups 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 9 sub-strata categories) which would be analysed separately.

Analysis of different types of data

Dichotomous outcomes

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

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

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

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

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

Continuous outcomes

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

- Heath-Related Quality of Life (HRQL)
- Length of stay (hospital/SCIC)
- Symptom scales (normally VAS)
- Spinal cord neurological function (for example, ASIA/Frankel)

- Function and activities of daily living

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

The means and standard deviations of continuous outcomes are required for meta-analysis. However, in cases where standard deviations were not reported, the standard error was calculated, if the p values or 95% confidence intervals (CIs) were reported, and meta-analysis was undertaken with the mean and standard error using the generic inverse variance method in Cochrane Review Manager software (Version 5.3. Copenhagen: The Nordic Cochrane Centre, The Cochrane Collaboration, 2014).

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.[2] 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 <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.

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

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

If all pre-defined strategies of subgrouping were unable to explain statistical heterogeneity within each derived subgroup, then a random effects (DerSimonian and Laird) model was employed to the

entire group of studies in the meta-analysis. A random-effects model assumes a distribution of populations, rather than a single population. This leads to a widening of the CIs around the overall estimate, thus providing a more realistic interpretation of the true distribution of effects across more than 1 population. If, however, the GDG considered the heterogeneity was so large that meta-analysis was inappropriate, then the results were described narratively.

Complex analysis /further analysis

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

Where studies had used a cross-over design, paired continuous data were extracted where possible, and forest plots were generated in RevMan5[2] with the Generic Inverse Variance function. When a cross-over study had categorical data, the standard error (of the log RR) was calculated using the simplified Mantel Haenszel method for paired outcomes, when the number of subjects with an event in both interventions was known. Forest plots were generated in RevMan5[2] with the Generic Inverse Variance function. If paired continuous or categorical data were not available from the cross-over studies, the separate group data were analysed in the same way as data from parallel groups, on the basis that this approach would over-estimate the CIs and thus artificially reduce study weighting resulting in a conservative effect. Where a meta-analysis had a mixture of studies using both paired and parallel group approaches, all data were entered into RevMan5[2] using the Generic Inverse Variance function.

4.3.4.2 Data synthesis for diagnostic test accuracy reviews

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

Diagnostic RCTs

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

Diagnostic accuracy studies

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

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

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

Coupled forest plots of sensitivity and specificity with their 95% CIs across studies (at various thresholds) were produced for each test, using RevMan5.[2] 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®[74]. 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 [88]). For scores with less than five studies, median sensitivity and the paired specificity were reported where possible. If an even number of studies were reported the lowest value of the two middle pairs was reported.

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

4.3.4.3 Data synthesis for risk prediction rules

Evidence reviews on risk prediction rules/tools results were presented separately for discrimination and calibration. The discrimination data was analysed according to the principles outlined under the section on data synthesis for diagnostic accuracy studies. Calibration data, such as, R^2, if reported, were presented separately to the discrimination data. The results were presented for each study separately along with the quality rating for the study. Inconsistency and imprecision were not assessed.

4.3.4.4 Data synthesis for qualitative reviews

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

4.3.5 Appraising the quality of evidence by outcomes

4.3.5.1 Interventional studies

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

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

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

Quality element	Description
Risk of bias	Limitations in the study design and implementation may bias the estimates of the

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

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

Risk of bias

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

Table 3: Principle domains of bias in RCTs

Limitation	Explanation
Selection bias – sequence generation and allocation concealment	If those enrolling patients are aware of the group to which the next enrolled patient will be allocated, either because of a non-random sequence that is predictable, or because a truly random sequence was not concealed from the researcher, this may translate into systematic selection bias. This may occur if the researcher chooses not to recruit a participant into that specific group because of 1) knowledge of that participant's likely prognostic characteristics and 2) a desire for one group to do better than the other.
Performance and detection bias - Lack of patient and health care professional	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

Limitation	Explanation
blinding	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 in the included studies are dissimilar to those defined in the inclusion criteria for the reviews. Indirectness is important when these differences are expected to contribute to a difference in effect size, or may affect the balance of harms and benefits considered for an intervention. As for risk of bias, each outcome had its indirectness assessed within each paper first. For each paper, if there were no sources of indirectness, indirectness was given a rating of 0. If there was indirectness in just one source (for example, in terms of population), indirectness was given a 'serious' rating of -1, but if there was indirectness in two or more sources (for example, in terms of population and treatment) the indirectness was given a 'very serious' rating of -2. A weighted average score was then calculated across all studies contributing to the outcome, by taking into account study precision. For example, if the most precise studies tended to have an indirectness score of -1 each for that outcome, the overall score for that outcome would probably tend towards -1.

Inconsistency

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

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

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, so are not amenable to patient-centred 'anchor' methods.

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

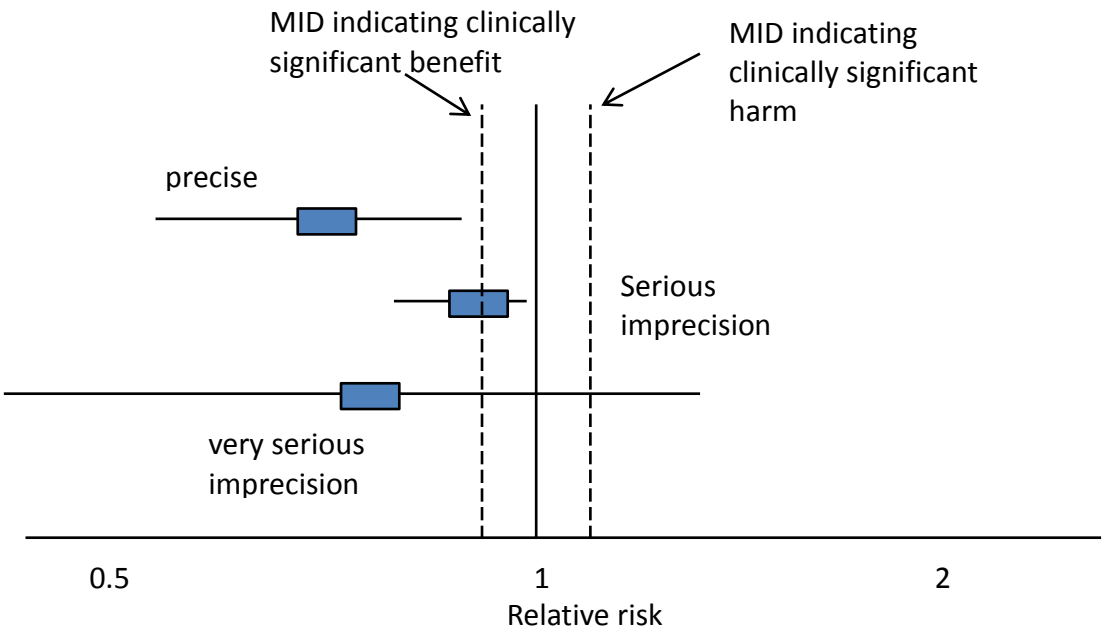
- For categorical outcomes the MIDs are taken as risk ratios (RRs) of 0.75 and 1.25. For 'positive' outcomes, such as 'patient satisfaction', the RR of 0.75 is taken as the line denoting the boundary between no clinically important effect and a clinically significant harm, whilst the RR of 1.25 is taken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

The default MID value was subject to amendment after discussion with the GDG. If the GDG decided that the MID level should be altered, after consideration of absolute as well as relative effects, this

was allowed, provided that any such decision was not influenced by any bias towards making stronger or weaker recommendations for specific outcomes.

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

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



Overall grading of the quality of clinical evidence

Once an outcome had been appraised for the main quality elements, as above, an overall quality grade was calculated for that outcome. The scores from each of the main quality elements (0, −1 or −2) were summed to give a score that could be anything from 0 (the best possible) to −8 (the worst possible). However, scores were capped at −3. This final score was then applied to the starting grade that had originally been applied to the outcome by default, based on study design. For example, all RCTs started as High and the overall quality became Moderate, Low or Very low if the overall score was −1, −2 or −3 points, respectively. The significance of these overall ratings is explained in Table 4. The reasons or criteria used for downgrading were specified in the footnotes of the GRADE tables.

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

Table 4: Overall quality of outcome evidence in GRADE

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

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

4.3.5.2 Prognostic studies

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

Table 5: Description of quality elements for prospective studies

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

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

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

4.3.5.3 Diagnostic studies

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

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?	

4.3.5.4 Qualitative reviews

Table 7 below summarises the factors which were assessed to inform the quality rating for each sub-theme.

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 sub-themes 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 per thousand 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.

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

4.3.7 Clinical evidence statements

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

- The number of studies and the number of participants for a particular outcome.
- An indication of the direction of clinical importance (if one treatment is beneficial or harmful compared with 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 [86]
- Studies considered eligible but were excluded can be found in Appendix K.

4.4.1.1 Inclusion and exclusion

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

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

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

For more details about the assessment of applicability and methodological quality see the economic evaluation checklist (The Guidelines Manual, Appendix H [86] and the health economics research protocol in Appendix C.

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

4.4.2 Undertaking new health economic analysis

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

Additional data for the analysis was identified as required through additional literature searches undertaken by the Health Economist and discussion with the GDG. Model structure, inputs and

assumptions were explained to and agreed by the GDG members during meetings, and they commented on subsequent revisions.

See Appendix 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 [84].

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

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

If the GDG recommended an intervention that was estimated to cost more than £20,000 per QALY gained, or did not recommend one that was estimated to cost less than £20,000 per QALY gained, the reasons for this decision are discussed explicitly in the 'from evidence to recommendations' section of the relevant chapter with reference to issues regarding the plausibility of the estimate or to the factors set out in the 'Social value judgements: principles for the development of NICE guidance' [84].

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 6-20.
- Forest plots and summary ROC curves (Appendix I)
- 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 clinical 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 ?).

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, NICE will consider whether the evidence base has progressed sufficiently to alter the guideline recommendations and warrant an update.

4.5.4 Disclaimer

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

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

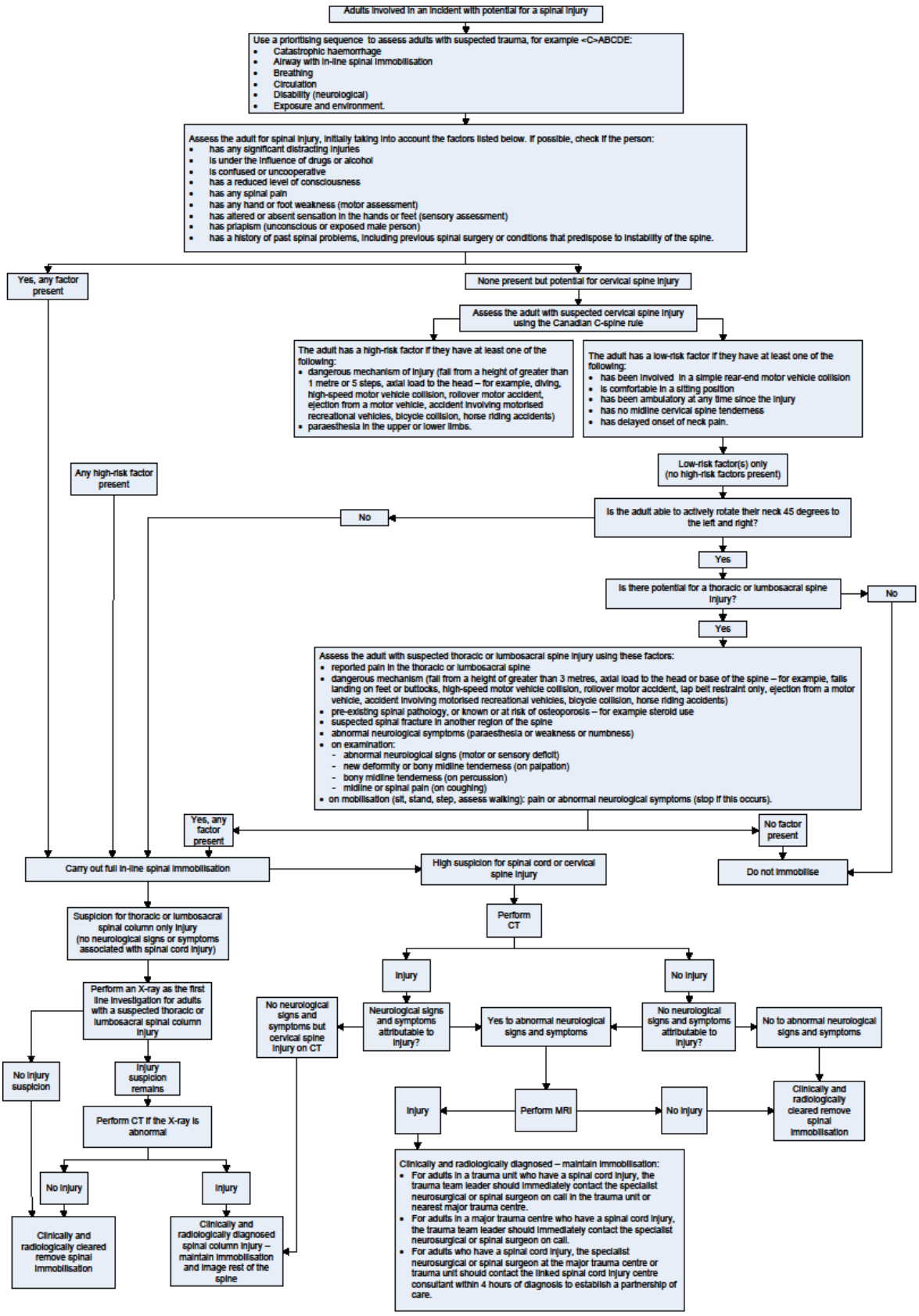
4.5.5 Funding

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

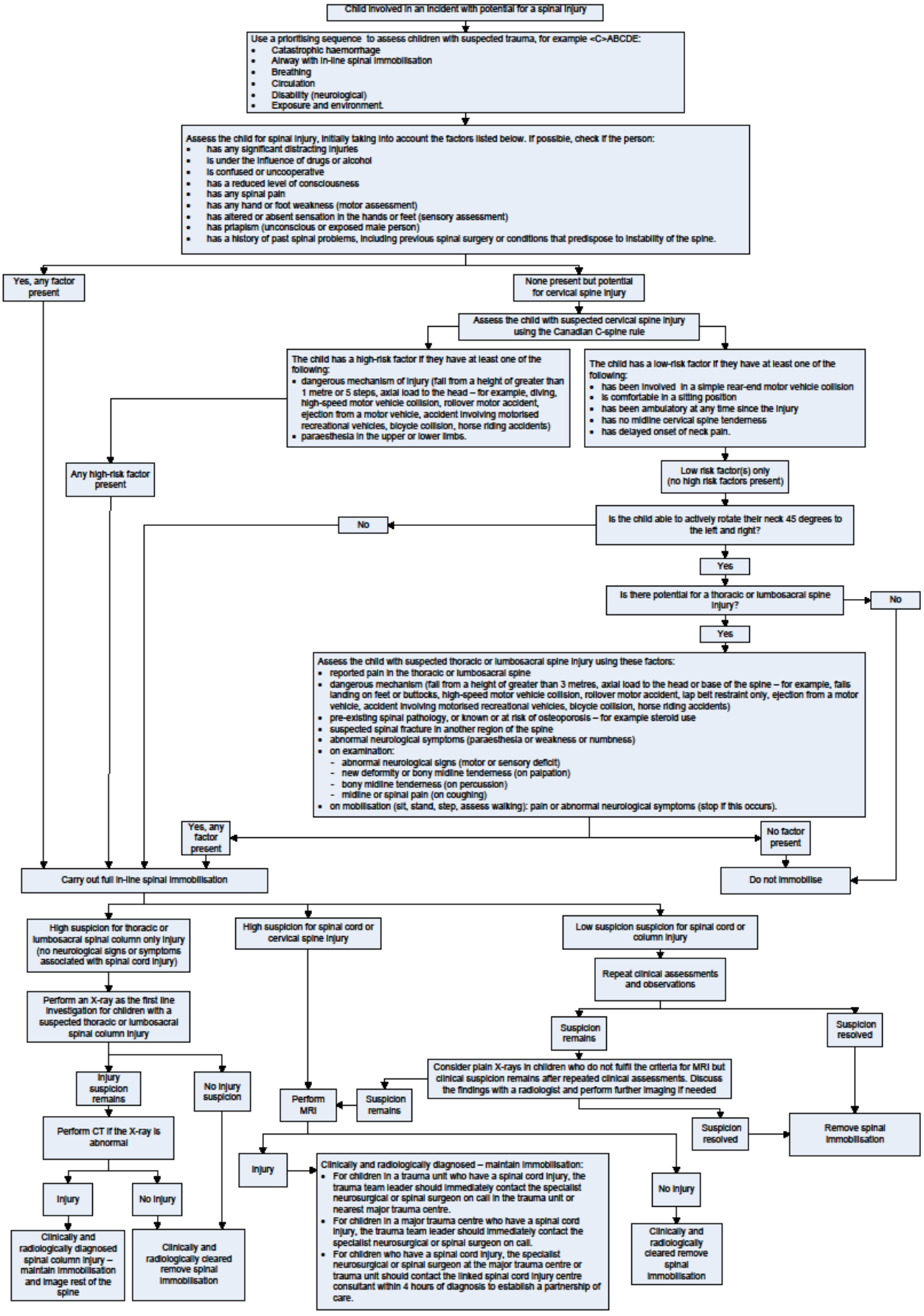
5 Guideline summary

5.1 Algorithms

5.1.1 Assessment and imaging of the spine – Adults



5.1.2 Assessment and imaging of the spine – Children



5.2 Full list of recommendations

1. On arrival at the scene of the incident, use a prioritising sequence to assess people with suspected trauma, for example <C>ABCDE:
    - catastrophic haemorrhage
    - airway with in-line spinal immobilisation (for guidance on airway management refer to the NICE guideline on major trauma)
    - breathing
    - circulation
    - disability (neurological)
    - exposure and environment.
2. At all stages of the assessment:
    - protect the person's cervical spine with manual in-line spinal immobilisation, particularly during any airway intervention and
    - avoid moving the remainder of the spine.
3. Assess the person for spinal injury, initially taking into account the factors listed below. Check if the person:
    - has any significant distracting injuries
    - is under the influence of drugs or alcohol
    - is confused or uncooperative
    - has a reduced level of consciousness
    - has any spinal pain
    - has any hand or foot weakness (motor assessment)
    - has altered or absent sensation in the hands or feet (sensory assessment)
    - has priapism (unconscious or exposed male)
    - has a history of past spinal problems, including previous spinal surgery or conditions that predispose to instability of the spine.
4. Carry out full in-line spinal immobilisation if any of the factors in recommendation 3 are present or if this assessment cannot be done.
5. On arrival at the emergency department use a prioritising sequence for assessing people with suspected trauma (see recommendation 1).
6. Protect the person's cervical spine as in recommendation 2 or maintain full in-line spinal immobilisation.
7. Assess the person for spinal injury as in recommendation 3.
8. Carry out or maintain full in-line spinal immobilisation in the emergency department if any of the factors in recommendation 3 are present or if this assessment cannot be done.
9. Assess whether the person is at high, low or no risk for cervical spine injury using the Canadian C-spine rule as follows:

- the person is at high risk if they have at least one of the following high-risk factors:
  - age 65 years or older
  - dangerous mechanism of injury (fall from a height of greater than 1 metre or 5 steps, axial load to the head – for example diving, high-speed motor vehicle collision, rollover motor accident, ejection from a motor vehicle, accident involving motorised recreational vehicles, bicycle collision, horse riding accidents)
  - paraesthesia in the upper or lower limbs
- the person is at low risk if they have at least one of the following low-risk factors:
  - involved in a minor rear-end motor vehicle collision
  - comfortable in a sitting position
  - ambulatory at any time since the injury
  - no midline cervical spine tenderness
  - delayed onset of neck pain
- the person remains at low risk if they are:
  - unable to actively rotate their neck 45 degrees to the left and right (the range of the neck can only be assessed safely if the person is at low risk and there are no high-risk factors)
- the person has no risk if they:

10. Be aware that applying the Canadian C-spine rule to children is difficult and the child's developmental stage should be taken into account.

11. Assess the person with suspected thoracic or lumbosacral spine injury using these factors:
    - age 65 years or older and reported pain in the thoracic or lumbosacral spine
    - dangerous mechanism of injury (fall from a height of greater than 3 metres, axial load to the head or base of the spine – for example falls landing on feet or buttocks, high-speed motor vehicle collision, rollover motor accident, lap belt restraint only, ejection from a motor vehicle, accident involving motorised recreational vehicles, bicycle collision, horse riding accidents)
    - pre-existing spinal pathology, or known or at risk of osteoporosis – for example steroid use
    - suspected spinal fracture in another region of the spine
    - abnormal neurological symptoms (paraesthesia or weakness or numbness)
    - on examination:
      - abnormal neurological signs (motor or sensory deficit)
      - new deformity or bony midline tenderness (on palpation)
      - bony midline tenderness (on percussion)
      - midline or spinal pain (on coughing)

- on mobilisation (sit, stand, step, assess walking): pain or abnormal neurological symptoms (stop if this occurs).

12. Be aware that assessing children with suspected thoracic or lumbosacral spine injury is difficult and the child's developmental stage should be taken into account.

13. Carry out or maintain full in-line spinal immobilisation if:

- a high-risk factor for cervical spine injury is identified and indicated by the Canadian C-spine rule
- a low-risk factor for cervical spine injury is identified and indicated by the Canadian C-spine rule and the person is unable to actively rotate their neck 45 degrees left and right
- indicated by one or more of the factors listed in recommendation 11.

14. Do not carry out or maintain full in-line spinal immobilisation in people if:

- they have low-risk factors for cervical spine injury as identified and indicated by the Canadian C-spine rule, are pain free and are able to actively rotate their neck 45 degrees left and right
- they do not have any of the factors listed in recommendation 11.

15. Assess the person with suspected cervical spine injury using the Canadian C-spine rule (see recommendations 9 and 10).

16. Assess the person with suspected thoracic or lumbosacral spine injury using the factors listed in recommendation 11 and 12.

17. Carry out or maintain full in-line spinal immobilisation and request imaging if:

- a high-risk factor for cervical spine injury is identified and indicated by the Canadian C-spine rule or
- a low-risk factor for cervical spine injury is identified and indicated by the Canadian C-spine rule and the person is unable to actively rotate their neck 45 degrees left and right or
- indicated by one or more of the factors listed in recommendation 11.

18. Do not carry out or maintain full in-line spinal immobilisation or request imaging for people if:

- they have low-risk factors for cervical spine injury as identified and indicated by the Canadian C-spine rule, are pain free and are able to actively rotate their neck 45 degrees left and right
- they do not have any of the factors listed in recommendation 11.

19. When immobilising the spine tailor the approach to the person's specific circumstances (see recommendations 20 and 24 to 26).

20. The use of spinal immobilisation devices may be difficult (for example in people with short or wide necks, or people with a pre-existing deformity) and could be counterproductive (for example increasing pain, worsening neurological signs and symptoms). In uncooperative, agitated or distressed people, including children, think about letting them find a position where they are comfortable with manual in-line spinal immobilisation.

21. When carrying out full in-line spinal immobilisation in adults, manually stabilise the head with the spine in-line using the following stepwise approach:

- Fit an appropriately sized semi-rigid collar unless contraindicated by:
  - a compromised airway
  - known spinal deformities, such as ankylosing spondylitis (in these cases keep the spine in the person's current position).
- Reassess the airway after applying the collar.
- Place and secure the person on a scoop stretcher.
- Secure the person with head blocks and tape, ideally in a vacuum mattress.

22. When carrying out full in-line spinal immobilisation in children, manually stabilise the head with the spine in-line using the stepwise approach in recommendation 21 and consider:
    - involving family members and carers if appropriate
    - keeping infants in their car seat if possible
    - using a scoop stretcher with blanket rolls, vacuum mattress, vacuum limb splints or Kendrick extrication device.
23. When there is immediate threat to a person's life and rapid extrication is needed, make all efforts to limit spinal movement without delaying treatment.
24. Consider asking a person to self-extricate if they are not physically trapped and have none of the following:
    - significant distracting injuries
    - abnormal neurological symptoms (paraesthesia or weakness or numbness)
    - spinal pain
    - high-risk factors for cervical spine injury as assessed by the Canadian C-spine rule.
25. Explain to a person who is self-extricating that if they develop any spinal pain, numbness, tingling or weakness, they should stop moving and wait to be moved.
26. When a person has self-extricated:
    - ask them to lay supine on a stretcher positioned adjacent to the vehicle or incident
    - in the ambulance, use recommendations 1 to 4, 9 to 14, and 19 to 21 to assess them for spinal injury and manage their condition.
27. Do not transport people with suspected spinal injury on a longboard or any other extrication device. A longboard should only be used as an extrication device.
28. When carrying out or maintaining full in-line immobilisation refer to recommendations 19 to 22.
29. Transport people with suspected acute traumatic spinal cord injury (with or without column injury), with full in-line spinal immobilisation, to a major trauma centre irrespective of transfer time, unless the person needs an immediate lifesaving intervention.

30. Ensure that time spent at the scene is limited to giving life-saving interventions.

31. Divert to the nearest trauma unit if a patient with suspected acute traumatic spinal cord injury (with or without column injury), with full in-line spinal immobilisation, needs an immediate life-saving intervention, such as rapid sequence induction of anaesthesia and intubation, that cannot be delivered by the pre-hospital teams.

32. Do not transport people with suspected acute traumatic spinal cord injury (with or without column injury), with full in-line spinal immobilisation, directly to a spinal cord injury centre from the scene of the incident.

33. Transport adults with suspected spinal column injury without suspected acute traumatic spinal cord injury, with full in-line spinal immobilisation, to the nearest trauma unit, unless there are pre-hospital triage indications to transport them directly to a major trauma centre.

34. Transport children with suspected spinal column injury (with or without spinal cord injury) to a major trauma centre.

35. Be aware that the optimal destination for patients with major trauma is usually a major trauma centre. 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.

36. Imaging for spinal injury should be performed urgently, and the images should be interpreted immediately by a healthcare professional with training and skills in this area.

37. Perform MRI for children (under 16s) if there is a strong suspicion of:

    - cervical spinal cord injury as indicated by the Canadian C-spine rule and by clinical assessment or
    - cervical spinal column injury as indicated by clinical assessment or abnormal neurological signs or symptoms, or both.

38. Consider plain X-rays in children (under 16s) who do not fulfil the criteria for MRI in recommendation 37 but clinical suspicion remains after repeated clinical assessment.

39. Discuss the findings of the plain X-rays with a consultant radiologist and perform further imaging if needed.

40. For imaging in children (under 16s) with head injury and suspected cervical spine injury, follow the recommendations in section 1.5 of the NICE guideline on head injury.

41. Perform CT in adults (16 or over) if:

    - imaging for cervical spine injury is indicated by the Canadian C-Spine rule or
    - there is a strong suspicion of thoracic or lumbosacral spine injury associated with abnormal neurological signs or symptoms.

42. If, after CT, there is a neurological abnormality which could be attributable to spinal cord injury, perform MRI.

43. For imaging in adults (16 or over) with head injury and suspected cervical spine injury, follow the recommendations in section 1.5 of the NICE guideline on head injury.

44. Perform AP and lateral X-rays as the first-line investigation for people with suspected spinal column injury without abnormal neurological signs or symptoms in the thoracic or lumbosacral regions (T1–L3).

45. Perform CT if the X-ray is abnormal or there are clinical signs or symptoms of a spinal column injury.

46. If a new spinal column fracture is confirmed, image the rest of the spinal column.

47. 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.

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

49. If a person with suspected spinal column injury has whole-body CT carry out multiplanar reformatting to show all of the thoracic and lumbosacral regions with sagittal and coronal reformats.

50. 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.

51. For people in a trauma unit who have a spinal cord injury, the trauma team leader should immediately contact the specialist neurosurgical or spinal surgeon on call in the trauma unit or nearest major trauma centre.

52. For people in a major trauma centre who have a spinal cord injury, the trauma team leader should immediately contact the specialist neurosurgical or spinal surgeon on call.

53. For people who have a spinal cord injury, the specialist neurosurgical or spinal surgeon at the major trauma centre or trauma unit should contact the linked spinal cord injury centre consultant within 4 hours of diagnosis to establish a partnership of care.

54. All people who have a spinal cord injury should have a lifetime of personalised care that is guided by a spinal cord injury centre.

55. The management of a spinal cord injury should be agreed between spinal surgery and spinal cord injury specialists for each person.

56. Do not use the following medications, aimed at providing neuroprotection and prevention of secondary deterioration, in the acute stage after acute traumatic spinal cord injury:

    - methylprednisolone
    - nimodipine
    - naloxone.

57. Do not use medications in the acute stage after traumatic spinal cord injury to prevent neuropathic pain from developing in the chronic stage.

58. When communicating with patients, family members and carers:

    - manage expectations and avoid misinformation
    - answer questions and provide information honestly, within the limits of your knowledge

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

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

60. Make eye contact and be in the patient's eye line to ensure that you are visible when communicating with this person to avoid them moving their head.

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

62. If the patient agrees, invite their family member, carer or friend into the resuscitation room. Ensure that they are accompanied by a member of staff and their presence does not affect assessment, diagnosis or treatment.

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

64. 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.

65. For a child or vulnerable adult with spinal injury, enable their family members and carers to remain within eyesight if appropriate.

66. 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.

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

68. Explain to patients, family members and carers what is wrong, 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
- information about 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 or psychological effects.

69. Provide information at each stage of management (including the results of imaging) in face-to-face consultations.

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

71. 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. Provide information on the linked spinal cord

injury centre (in the case of cord injury) or the unit the patient will be transferred to (in the case of column injury or other injuries needing more immediate attention)

- the name and contact details of the person who was 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.

The LETR in this chapter summarises the decision making of the spinal GDG.

72. Record the following in people with suspected spinal injury in pre-hospital settings:
    - <C>ABCDE (catastrophic haemorrhage, airway with in-line spinal immobilisation, breathing, circulation, disability [neurological], exposure and environment)
    - spinal pain
    - motor function, for example hand or foot weakness
    - sensory function, for example altered or absent sensation in the hands or feet
    - priapism in an unconscious or exposed male.
73. If possible, record information on whether the assessments show that the person's condition is improving or deteriorating.
74. Record pre-alert information using a structured system and include all of the following:
    - the patient's age and sex
    - time of incident
    - mechanism of injury
    - injuries suspected
    - signs, including vital signs and Glasgow Coma Scale
    - treatment so far
    - estimated time of arrival at emergency department
    - special requirements
    - the ambulance call sign, name of the person taking the call and time of call.
75. A senior nurse or trauma team leader in the emergency department should receive the pre-alert information, and determine the level of trauma team response according to agreed and written local guidelines.
76. The trauma team leader should be easily identifiable to receive the handover and the trauma team ready to receive the information.
77. The pre-hospital documentation, including the recorded pre-alert information, should be quickly available to the trauma team and placed in the patient's hospital notes.
78. Record the items listed in recommendation 72 as a minimum, for the primary survey.

79. Record the secondary survey results, including a detailed neurological assessment and examination for any spinal pain or spinal tenderness.

80. If spinal cord injury is suspected in people aged over 4 years, complete an ASIA chart (American Spinal Injury Association) as soon as possible in the emergency department, and record:
    - vital capacity for people over 7 years
    - ability to cough.

81. One member of the trauma team should be designated to record all trauma team findings and interventions as they occur (take 'contemporaneous notes').

82. The trauma team leader should be responsible for checking the information recorded to ensure that it is complete.

83. 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.

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

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

5.2.1 Additional recommendations

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

When to carry out or maintain full in-line spinal immobilisation

- Do not carry out or maintain full in-line spinal immobilisation in people if:
  - They have low-risk factors for cervical spine injury as identified and indicated by the Canadian C-spine rule, are pain free and are able to actively rotate their neck 45 degrees left and right
  - They do not have any of the factors listed in recommendation 9.

Pain assessment

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

Pain relief

- Offer medications to control pain in the acute phase after spinal injury.

- For people with spinal injury use intravenous morphine as the first-line analgesic and adjust the dose as needed to achieve adequate pain relief.
- If intravenous access has not been established, consider the intranasal[a] route for atomised delivery of diamorphine or ketamine.
- Consider ketamine in analgesic doses as a second-line agent.

Early management in the emergency department after traumatic spinal cord injury

- All trauma networks should have network-wide written guidelines for the immediate management of a person with spinal cord injury and these should be agreed with the linked spinal cord injury centre.

Training and skills

- Ensure that each healthcare professional within the major trauma service has the training and skills to deliver, safely and effectively, the interventions they are required to give, in line with this guideline and the NICE guidelines on non-complex fractures, complex fractures and major trauma.
- Enable each healthcare professional who delivers care to patients with trauma have up-to-date training in the interventions they are required to give.
- Provide education and training courses for healthcare professionals who deliver care to children with major trauma that include the following components:
  - safeguarding
  - taking into account the radiation risk of CT to children when discussing imaging for them
  - the importance of the major trauma team, the roles of team members and the team leader, and working effectively in a major trauma team
  - managing the distress families and carers may experience and breaking bad news
  - the importance of clinical audit and case review.

5.3 Key research recommendations

1. **What is the clinical and cost effectiveness of emergency reduction of cervical spine dislocations following acute traumatic cervical spine injury?**

2. **Does early treatment with a centrally acting analgesic (for example pregabalin) reduce the frequency or severity of neuropathic pain in people with spinal cord injury?**

3. **After injury, what is the best method of clinical assessment to determine who needs imaging of the thoracic and lumbar spine to exclude injury to the spinal column or cord, and who is safe to discharge without risk of missing significant injury?**

a At the time of publication (February 2016), neither intranasal diamorphine nor intranasal ketamine had a UK marketing authorisation for this indication. The prescriber should follow relevant professional guidance, taking full responsibility for the decision. Informed consent should be obtained and documented. See the General Medical Council's Prescribing guidance: prescribing unlicensed medicines for further information.

6 Protecting the spine

6.1 Introduction

There is variation across the UK in the decision and the approach to protecting the spine. The decision to carry out full in-line spinal immobilisation of a person with the potential for a spinal injury is complex and the assessment is based on clinical assessment usually followed by the use of risk tools. This initial decision is dependent on the healthcare professionals present when the person is assessed; this is most likely to be at the scene of the incident but also can be in the emergency department (ED). Practice in both locations has been to err on the side of caution and this may result in continued immobilisation in people that do not have a spinal injury. Using a risk tool may help to identify people that do not need continued immobilisation. In the initial assessment of a person with traumatic injuries, it is important to quickly protect the spine to ensure a spinal injury is not caused or exacerbated. One approach is to routinely immobilise everyone, another is to use a selective approach only immobilising people where there is an assessed concern. This chapter looks at the impact of a routine or selective approach to protecting the spine regardless of the risk tool used.

6.2 Review question: What is the clinical and cost effectiveness of routine spinal protection of all children, young people and adults experiencing trauma compared to selective protection, based on the use of a risk tool/clinical assessment at the scene of the incident/presentation?

For full details see review protocol in Appendix C.

Table 8: PICO characteristics of review question

Population	Children, young people and adults experiencing a traumatic incident
Intervention/s	Routine spinal protection (of everyone assessed as having a traumatic incident)
Comparison/s	Selective spinal protection based on a a) risk tool (Canadian C-spine rules [CCR], JRCALC, BTS gl) and/or b) clinical assessment (Hoffman 2000)
Outcomes	Critical: • Mortality • Quality of life • Rates of spinal cord injury (SCI) • Missed spinal column/cord injury, spinal cord neurological function (American Spinal Injury Association [ASIA] and Frankel) • Adverse effects (pressure ulcers, airway compromise, raised ICP, neurological deterioration [ASIA]) associated with spinal protection/immobilisation Important: • Unnecessary imaging • Patient-reported outcomes (pain/discomfort, return to normal activities, psychological wellbeing)
Study design	SR, RCTs, cohort, case-control

No studies were identified that compared routine stabilisation with selective stabilisation. Evidence was included from studies that reported on outcomes associated with the application of a selective stabilisation protocol. The evidence review was restricted to prospective observational studies only.

6.3 Clinical evidence

Six studies were included in the review.[7;27;40;39;81;112] Evidence from these are summarised in Table 9 below. See also the study selection flow chart in Appendix D, forest plots in Appendix I, study evidence tables in Appendix G and exclusion list in Appendix J.

Data was only available for the outcome of 'missed spinal column or cord injury'.

All of the studies are prospective observational studies, which do not directly compare the stabilisation of everyone with selective stabilisation. The majority of studies do not report on a surveillance period to capture missed injuries that are reported after discharge. The quality of these studies is therefore graded as Very low.

Table 9: Summary of studies included in the review

Study	n (forms/protocols complete), country	Protocol	Follow-up	Comments
Armstrong 2007[7]	103, UK	Algorithm based on National Emergency X-Radiography Utilization Study criteria and NICE guidelines. Neck pain and/or suspicion of C-spine injury then Inspection: Significant intrusion of vehicle, significant distracting injury, age less than 16 years or older than 65 years, dangerous mechanism of injury (fall from a height of >1 metre or 5 stairs, axial load to head, vehicle roll-over ejection from a motor vehicle, high speed vehicle collision >65 mph, accident involving motorised recreational vehicles, bicycle collision. If yes to any triple immobilisation If no then GCS <15 at time of examination, intoxication with drugs or alcohol, immediate onset of neck pain, paraesthesia in the extremities, focal neurological deficit, presence of midline C-spine tenderness, patient unable to rotate neck through 45 degrees to left and right. If yes to any, then triple immobilisation. If no then C-spine cleared Based on the CCR.	Reports to the ED or ambulance service by patients, other EDs, GPs regional neurological centres or coroners offices	Possible selection bias Patients may have reported C-spine injury to healthcare facilities not being followed up One district general ED
Burton 2005[27]	2220, USA	Revised emergency medical services spine assessment protocol	Hospital data from the state health data	Possible selection bias No access to in

Study	n (forms/protocols complete), country	Protocol	Follow-up	Comments
		(REMSSAP) Four-step assessment sequence based on patient assessment findings: patient unreliability (intoxicated, altered level of consciousness, not calm or uncooperative), presence of an abnormal motor or sensory neurologic examination, and presence of spine tenderness or complaint of spine pain. The protocol directed EMS providers to attempt spine immobilisation in the presence of any of the four considerations	organisation (MHDO). All hospitals are mandated to report clinical and financial data to the MHDO	hospital patient records Multicentre
Domeier 2002[40]	8975, USA	Altered mental status, neurologic deficit, spine pain or tenderness, evidence of intoxication or suspected extremity fracture – the absence of which identify pre-hospital trauma patients without a significant spine injury Based on local protocol.	Medical records	Multicentre trial The decision to immobilise was based on existing protocols and not the study protocol
Domeier 2005[39]	13,483, USA	If any one positive: Altered mental status, evidence of intoxication, neurologic deficit, suspected extremity fracture, and spine pain or tenderness To be completed only on trauma patients with a mechanism of injury with potential for causing spine injury and omit the assessment for patients with insufficient mechanisms Based on local protocol	Hospital records	Reviewers of hospital records were not blinded to clinical findings or immobilisation status before hospital record review No surveillance Multicentre
Muhr 1999[81]	281, USA	Patient mentation: (if yes immobilise) Decreased level of conscious, intoxication/drug impairment, loss of consciousness involved Subjective assessment: (if yes immobilise) spine pain, numbness/tinting/weakness/burning sensation Objective assessment (if yes immobilise): Spine tenderness, other severe injury, pain with	ED chart	No surveillance Multicentre

Study	n (forms/protocols complete), country	Protocol	Follow-up	Comments
		spine range of motion Based on local protocol		
Vaillancourt 2009[112]	1949, Canada	Immobilisation if: Any one of the high risk factors present: Age 65 years or over or dangerous mechanism or numbness or tingling in extremities. No to these questions then go one to: Any one low risk factors which allows safe assessment of range of motion: Simple rear-end motor vehicle collision, ambulatory at any time at scene, no neck pain at scene, absence of midline C-spine tenderness. Answer yes to any of these question then go on to: Patient voluntarily able to actively rotate neck 45 degrees left and right when requested, regardless of pain Answer yes then no C-spine immobilisation Based on the CCR.	Radiography and telephone follow-up	Multicentre Telephone follow-up in absence of radiographs but no other surveillance

Table 10: Missed spinal column cord injury

Study	Injury	Incidence of injury (%)	No. of injuries/No. of patients not immobilised
Armstrong 2007[a]	Cervical spine injury	Not reported[a]	0/Not stated
Burton 2005[b]	Cervical spine fracture	7/2220 (0.3)	0/1,301
Domeier 2002[d]	Spinal injury	295/8975 (3.3)	15/Not stated[b]
Domeier 2005[c]	Spinal injury	415/13,357 (3.1)	33/5171[c,d]
Muhr 1999[e]	Spinal injury	6/281(2.1)	1/98[c]
Vaillancourt 2009[g]	Cervical spine injury	18/1,949 (0.9)	0/731 negative assessments

(a) 34/103 did not have their C-spine cleared at the scene
(b) 2/15 patients received more than basic immobilisation or pain control
(c) No case of SCI
(d) Some patients with negative assessments were immobilised, some of the patients with positive assessments were not immobilised
(e) Economic evidence

6.4 Economic evidence

Published literature

No relevant economic evaluations were identified. There were no excluded studies. See also the economic article selection flow diagram in Appendix E.

Unit costs

Please refer to Appendix M for costs on full in-line immobilisation of suspected spinal injury patients based on the number of patients immobilised from the TARN database in 2012.

A total of 11,166 patients were identified in TARN as being given some form of immobilisation.

The cost for full immobilisation of all these patients including vacuum mattress was estimated at £57,951.54 (£5.19 per person).

The cost for the various immobilisations that were actually used on these patients was £47,892.28 (£4.29 per person). If staff time and a vacuum mattress were included in this cost, it would rise to £6.64 per person.

6.5 Evidence statements

Clinical

Very low quality evidence from six observational studies comprising 26,782 people with suspected spinal injuries showed that of the 7301 people who were selectively not given immobilisation there were 34 spinal injuries, a missed injury rate of 0.56%. When assessed by the risk tool used, there were no missed injuries for the ones based on the CCR and REMSSAP.

Economic

No relevant economic evaluations were identified.

6.6 Recommendations and link to evidence

Recommendations	**Initial assessment pre-hospital** **1. On arrival at the scene of the incident, use a prioritising sequence to assess people with suspected trauma, for example <C>ABCDE:** • **catastrophic haemorrhage** • **airway with in-line spinal immobilisation (for guidance on airway management refer to the NICE guideline on major trauma)** • **breathing** • **circulation** • **disability (neurological)** • **exposure and environment.** **2. At all stages of the assessment:** • **protect the person's cervical spine with manual in-line spinal immobilisation, particularly during any airway intervention and** • **avoid moving the remainder of the spine.** **3. Assess the person for spinal injury, initially taking into account the factors listed below. Check if the person:** • **has any significant distracting injuries**

	• **is under the influence of drugs or alcohol** • **is confused or uncooperative** • **has a reduced level of consciousness** • **has any spinal pain** • **has any hand or foot weakness (motor assessment)** • **has altered or absent sensation in the hands or feet (sensory assessment)** • **has priapism (unconscious or exposed male)** • **has a history of past spinal problems, including previous spinal surgery or conditions that predispose to instability of the spine.** **4. Carry out full in-line spinal immobilisation if any of the factors in recommendation 3 are present or if this assessment cannot be done.** **Initial assessment in hospital** **5. On arrival at the emergency department use a prioritising sequence for assessing people with suspected trauma (see recommendation 1).** **6. Protect the person's cervical spine as in recommendation 2 or maintain full in-line spinal immobilisation.** **7. Assess the person for spinal injury as in recommendation 3.** **8. Carry out or maintain full in-line spinal immobilisation in the emergency department if any of the factors in recommendation 3 are present or if this assessment cannot be done.**
Relative values of different outcomes	The outcomes critical to decision making were mortality, quality of life, rates of SCI, missed spinal column/cord injury, spinal cord neurological function (ASIA and Frankel) and adverse effects, including pressure ulcers, airway compromise, raised intracranial pressure and neurological deterioration (ASIA) associated with spinal protection/immobilisation. Important outcomes were unnecessary imaging and patient-reported outcomes (pain/discomfort, return to normal activities, psychological wellbeing).
Trade-off between clinical benefits and harms	The evidence from this review question did not provide data concerning the benefits of routine spinal protection versus selective protection. The studies were not comparative and did not include routine protection. Hence any harms of routine protection (such as pressure sores in a greater proportion of people than otherwise) could not be evaluated. The evidence for using risk tools was conflicting and it is clear that all risk tools may not be as effective as each other in identifying people with spinal injuries. The studies using the CCR and REMSSAP risk tools did not report any missed injuries but the risk tools reported in Domeier2002, Domeier 2005 and Muhr 1999 showed missed injuries. The clinical and health economic harms associated with a missed injury are considerable. The number of missed cervical injuries was considered to be small but the GDG believed there are a much larger number of missed thoracic

	and lumbar injuries. The lack of comparative data meant that GDG could not make a recommendation on which was the better approach in the initial assessment. It is clear if there is any potential that someone may have a spinal injury their spine must be protected immediately. In the patient with traumatic injuries there may be life threatening injuries that need prioritising before full in-line spinal immobilisation can be implemented. The GDG considered it was important to recommend that in the case of a person with traumatic injuries they should be assessed for life threatening injuries using a prioritising sequence such as <C>ABCDE while their spine is protected and until further spinal assessment and immobilisation can be implemented. The GDG also noted there are factors that indicate that the spine should be immobilised immediately and there is no need to use a risk tool. These factors either indicate that the assessment would be invalid (for example, they have a reduced level of consciousness) or there is strong indication of the presence of a column or cord injury or a high possibility of such an injury in association with pre-existing spinal conditions.
Economic considerations	No published economic evidence was found to inform the use of pre-hospital risk tools for spinal injury compared with routine immobilisation. The use of risk tools is associated with initial costs, such as those associated with staff time in training and performing the assessment appropriately. However, this could lead to cost savings if there are improvements in outcomes, with the high health benefit and reduction of costly adverse outcomes likely to be driving the cost effectiveness of any risk tool used. For example, the risk tool can assist the early identification of patients at high risk of spinal injury and ensure appropriate use of spinal protective measures at the scene of the incident. Consideration was given to the ease and use of a risk tool compared with its accuracy. The easier a risk tool is to use, the less costly it is likely to be. Accuracy is also important when considering the health and cost consequences of the risk tool being incorrect, that is, unnecessary spinal protective measures and associated anxiety associated with this. Accuracy should not be sacrificed when it comes to identifying patients at high risk of spinal injury due to the potential catastrophic consequences The incidence of spinal injury that requires protection was considered in that the higher the true incidence, the more cost effective routine stabilisation would be. On the other hand, where it is a rare event that a person actually requires protection, routine stabilisation may subject many people to the potential of adverse events (such as discomfort or pressure sores) unnecessarily. Considering the balance between the potential for many to have minor adverse events with stabilisation, and the catastrophic and highly costly consequences of missed injury, the GDG felt that an over cautious but a selective approach was likely to be optimal. Overall, a better understanding of the risk factors for spinal injury at the scene of a traumatic incident is likely to result in accurate identification of patients at risk and the possible prevention of SCI or a reduction in its severity. A further important consideration is the effectiveness of the equipment used for stabilisation and the costs thereof. A routine stabilisation strategy is more

	likely to be cost effective if the stabilisation equipment is effective, low cost (or reusable) and has few to no adverse costs. The cost of immobilising (both pre-hospital and downstream) was a concern to the group when making these recommendations. Further consideration of the costs of the equipment used for stabilisation can be found in appendix M. The cost effectiveness of use in the recommendations remain unclear due to insufficient evidence. However, stabilisation as outlined in the recommendation was not thought to deviate from currently understood best practice, and therefore, the GDG thought that the recommendations were likely to have a cost-neutral impact. The GDG considered the estimated costs of £6.64 for full in-line immobilisation per person as reasonable compared with the potential costs resulting from a spinal injury. The total cost of immobilising trauma patients depends upon the risk tools used to decide who should be immobilised. If a person is immobilised inappropriately then this will drive up the cost due to unnecessary use of resources. On the other hand, an accurate risk tool which identifies those most likely to have a spinal injury will lead to fewer immobilisations.
Quality of evidence	All of the data came from observational studies, which were graded as Very low quality. All of the studies reported on the number of missed injuries (either cervical or other spinal) resulting from the application of a selective spinal stabilisation protocol. The majority of studies did not adopt a surveillance period to identify missed injuries post discharge. All of the studies reported on protocols that were used by land ambulance personnel. Only one of the studies was from a UK population.
Other considerations	The GDG felt that the importance of adequate spinal immobilisation during the early, potentially lifesaving stages of assessment cannot be over emphasised. The consequences of inadequate immobilisation potentially result in deteriorating neurological function and in some cases death. However, the GDG noted that prolonged in-line spinal immobilisation can result in airway and/or respiratory compromise, pain and other complications. Immobilisation can also impede management of on-going haemorrhage and may worsen pre-existing conditions, such as ankylosing spondylitis, or risk further injury in combative patients. Hence, continued immobilisation is not necessarily ideal. Although some tools were clearly not fit for purpose, the CCR and REMSSAP tools appeared safe, and may have a role in selective stabilisation. The GDG recommended that initial clinical assessment of a person with traumatic injuries should routinely include manual in line immobilisation. The next chapter reviews the risk tools that may be useful to identify a potential spinal injury and to maintain full in-line spinal immobilisation. The GDG noted that the assessment in the ED was the same as in the pre-hospital and cross referred to the pre-hospital recommendations in the ED setting.

7 Spinal injury assessment risk tools

7.1 Introduction

If a person has the potential for a spinal injury their spine should be routinely protected during the assessment for life threatening injuries. This does not mean, however, that routine immobilisation should be continued after the point at which a risk tool can be applied. This has an impact on ambulance service and emergency department's (EDs) resources. It has also been suggested that unnecessary spinal immobilisation may lead to some adverse effects, such as discomfort or skin breakdown. It is important for healthcare practitioners assessing people for spinal injuries to have access to a risk tool that can accurately predict those patients who 1) have an injury and therefore require immobilisation and imaging and 2) do not have an injury and therefore do not need further immobilisation or imaging of the spine. The previous chapter showed that although some tools lead to missed injuries, some appear to be safe, and are thus useful in reducing the side effects, and costs, of unnecessary immobilisation. This chapter explores further which tools are accurate in predicting spinal injury and the need for immobilisation and imaging.

7.2 Review question: What tools are most predictive of spinal injury in people with suspected traumatic spinal injury when trying to exclude spinal cord injury (with or without spinal column injury) or isolated spinal column injury?

For full details see review protocol in Appendix C.

Table 11: PICO Characteristics of review question

Population	Children, young people and adults with suspected traumatic spinal injury
Clinical assessment tool	• Canadian C-Spine Rules (CCR) • National Emergency X-Radiography Utilization Study (NEXUS) • Australian SPINEX card • American Spinal Injury Association [ASIA] • REMSSAP • Any tools relevant to the thoracic or lumbosacral spine.
Reference standard	• Later imaging findings • Later surgical findings • Later clinical findings • Autopsy
Outcomes	Diagnostic accuracy (sensitivity, specificity, positive predictive value, negative predictive value, likelihood ratios)
Study design	Cohort studies

7.3 Clinical evidence

This review was initially framed by area of the spine (cervical or thoracic and lumbosacral spine) and then type of spinal injury: 1) clinical decision tools for ruling out spinal **cord** injury (SCI) (with or without spinal column injury), and 2) clinical decision tools for ruling out isolated spinal **column** injury (with no associated cord injury). Only 2 clinical decision tools were identified with diagnostic evidence; these were the CCR derived by Stiell et al., 2001[105] and the NEXUS low-risk criteria derived by Hoffman et al., 1992.[63] Both of these clinical decision tools focus specifically on suspected injuries

of the cervical spine. The NEXUS and CCR do not distinguish between type of suspected spinal injury (cord or column), therefore, information provided in the identified papers does not allow us to analyse the diagnostic accuracy of these tools to rule out specifically cord or specifically column injuries. Instead, we can only provide the diagnostic accuracy of CCR and NEXUS for excluding injury (cord or column) of the cervical spine. No tools which focus on suspected injury of the thoracic and/or lumbar spine were identified.

Details of the included rules are in Table 12. Evidence from these included studies are summarised in the clinical evidence profile in Table 14.

Where appropriate, diagnostic meta-analysis was conducted (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®.[74] The bivariate method uses logistic regression on the true positives, true negatives, false positives and false negatives reported in the studies. sROC curves were constructed and confidence regions plotted. See also the study selection flow chart in Appendix D, study evidence tables in Appendix G, paired sensitivity/specificity plots and diagnostic meta-analysis plot in Appendix I and exclusion list in Appendix J.

Table 12: Summary of clinical decision rules identified: imaging for suspected cervical spine injury

Decision rule	Criteria	Study testing rule
CCR (for patients with trauma who are alert [GCS >15] and in a stable condition and in whom cervical spine injury is a concern)	1. Any high-risk factor that mandates X-ray? Age > 65 years, or dangerous mechanism of injury (fall from elevation ≥3 feet/5 stairs, axial load to head for example diving, MVC high speed (>100 km/hour), rollover, ejection, motorized recreational vehicles, bicycle struck or collision), or paraesthesia in extremities. Yes to any of these → X-ray. 2. Any low-risk factor that allows safe assessment of range of motion? Simple rear-end motor vehicle collision (pushed into oncoming traffic, hit by bus/large truck, rollover, hit by high speed vehicle), or sitting position in the ED, or ambulatory at any time, or delayed onset of neck pain, or absence of midline cervical-spine tenderness. No to these → X-ray. 3. Able to rotate neck actively? Unable to rotate neck 45˚ left and right → X-ray. Able to rotate neck 45˚ left and right → no X-ray.	Derivation: Stiell 2001 Validation: Coffey 2011 Ehrlich 2009 Duane 2011 Duane 2013 Griffith 2013 Stiell 2003
NEXUS low risk criteria	Cervical spine X-ray is indicated for patients with trauma unless they meet all of the following criteria: 1. No posterior midline cervical-spine tenderness 2. No evidence of intoxication 3. A normal level of alertness 4. No focal neurologic deficit, and 5. No painful distracting injury. (Pilot NEXUS criteria does not have focal neurological deficit in the criteria and excludes patients with whiplash).	Derivation: Hoffman 1992 Validation: Ehrlich 2009 Dickinson 2004 Duane 2013 Griffith 2011 Griffith 2013 Hoffman 2000 Stiell 2003 Touger 2002 Viccellio 2001

Adults

Eleven studies Duane2013[44], Duane2011[43], Griffith2013[52], STIELL2001 [105], STIELL2003[104], COFFEY2011[32], DICKINSON2004[38], HOFFMAN2000[62], TOUGER2002, [110]} were identified in adults investigating the diagnostic accuracy of cervical spine injury (CSI) clinical decision rules. Two of these studies included patients of all ages. Hoffman 1992 was the NEXUS derivation study and Hoffman 2000 was NEXUS validation. Viccellio 2001 was a sub-study of children (under 18 years) from the Hoffman 2000 NEXUS validation study, therefore, it was possible to separate the information for adults (18 years and over) from Hoffman 2000 for analysis separately. Touger 2002 was another sub-study of Hoffman 2000, looking at the diagnostic accuracy of NEXUS in the older adult population (over 65 years). The other eight studies included cover adults either 16 years and over or 18 years and over.

Both the CCR and NEXUS criteria derivation studies assessed the decision rules against a reference standard of plain X-rays (with some additional CT or MRI scanning requested at the discretion of the treating physician and telephone follow-up for those who did not undergo imaging). It is noted that Duane et al., 2011 and 2013, and Griffith et al., 2011 and 2013 tested the NEXUS low-risk criteria and CCR (and modifications of the CCR) using a reference standard of patients having a cervical spine CT.

Children and infants

Two studiesEHRLICH2009[45] , VICCELLIO2001[113] were identified in children investigating the diagnostic accuracy of CSI clinical decision rules.

Ehrlich et al., 2009 is a retrospective case-matched study applying CCR and NEXUS criteria to the medical records of patients 10 years and under in two cohorts, those who underwent C-spine imaging as part of their initial ED work-up and those who did not. Only data from the imaged children cohort is presented in this review. Viccellio et al., 2001 is a subgroup of patients younger than 18 years from the NEXUS validation study.

Table 13: Summary of studies included in the review

Study	Population	Index test(s)	Reference test	Comments
Coffey 2011 [32]	1420 alert and stable adults >16 years following blunt trauma to the head and/or neck in 2 UK hospitals.	CCR	Radiography or nurse follow-up by telephone (14 days later)	Prospective cohort. There were 202 'indeterminate' cases, in which doctors did not evaluate the range of motion as required by the decision rule. Report fracture information only.
Dickinson 2004 [38]	8924 consecutive adults ≥16 years following acute blunt trauma to the head and/or neck in 10 Canadian hospitals.	NEXUS approximations	Radiography or nurse follow-up by telephone (14 days later)	Retrospective cohort. The CCR group (Stiell 2003) retrospectively interpreting their CCR data in light of the NEXUS criteria. Report fracture information and those that developed neurology.
Duane 2011 [43]	2606 adults >16 years following blunt trauma in one USA level 1 trauma centre.	Modified CCR	Complete C-spine CT	Prospective cohort. Modified CCR excluded active rotation (45°) of the neck (as the trauma facility felt this was too much of a risk for the C-spine). Report fracture information only.

Study	Population	Index test(s)	Reference test	Comments
Duane 2013 [44]	5182 adults >16 years following blunt trauma in one USA level 1 trauma centre.	NEXUS and CCR	Complete C-spine CT	Prospective cohort. Evaluated the individual criteria of both NEXUS and CCR. Report fracture information only.
Ehrlich 2009 [45]	Medical records for 125 children (≤10 years) following trauma in one USA level 1 trauma centre.	NEXUS CCR	Plain C-spine radiography and/or CT.	Retrospective chart review cohort, potential for selection bias. Report fracture information only.
Griffith 2011 [51]	1589 patient examination records from one USA level 1 trauma centre.	NEXUS	CT or medical records	Retrospective cohort. 2x2 table provides details of 1589 individual medical record examinations, but patient characteristics are provided only for the 1552 patients (age, gender info) and mechanism of injury and results are provided for the 1589 individual radiography exams. Simply state CSI– do not clarify whether fracture or cord injury.
Griffith 2013 [52]	507 adults ≥18 years following blunt trauma in one USA level 1 trauma centre.	NEXUS and abbreviated CCR	CT	Prospective cohort. Abbreviated CCR composed of high risk factors (>65 years, dangerous mechanism and paraesthesia in extremities) and inability to rotate neck (excluded low-risk criteria). Simply state CSI – do not clarify whether fracture or cord injury.
Hoffman 1992 [63]	974 adults and children (17 months to 98 years) following blunt trauma in an USA emergency medicine centre.	Pilot NEXUS	Radiography and possibly CT	Prospective cohort. Not possible to calculate 2x2 table. Report fracture information only.
Hoffman 2000 [62]	34069 adults and children (1-101 years) following blunt trauma in 21 USA EDs.	NEXUS	Plain film radiography, and possibly CT and/or MRI	Prospective validation cohort. n (≥18 years)=31004 n (<18 years)=3065 (see Viccellio 2001) n (>65 years)=2943 (see Touger 2002) Report numbers for both fracture and cord injuries.
Stiell 2001 [105]	8924 adults (≥16 years) following blunt trauma in 10 Canadian EDs.	CCR	Plain film radiography and possibly CT, or follow-up at 14 days	Prospective derivation cohort. Report fracture information and those that developed neurology.
Stiell 2003 [104]	7438 adults (≥16 years)	CCR	Plain film radiography	Prospective cohort. Report fracture information and those that

Study	Population	Index test(s)	Reference test	Comments
	following acute trauma to the head or neck in nine Canadian EDs.	NEXUS	and possibly CT, or follow-up at 14 days	developed neurology.
Touger 2002 [110]	2943 older patients (>65 years) with blunt trauma in 21 USA EDs.	NEXUS	Plain film radiography, and possibly CT and/or MRI	Prospective cohort. Sub-study of Hoffman 2000 in older adult population. Report numbers for both fracture and cord injuries.
Viccellio 2001 [113]	3065 children (<18 years) with blunt trauma in 21 USA EDs.	NEXUS	Plain film radiography, and possibly CT and/or MRI	Prospective cohort. Sub-study of Hoffman 2000 in children. Report numbers for both fracture and cord injuries.

Quality of evidence

Risk of bias for each outcome was determined by the QUADAS-2 criteria (see chapter 4). This informed the risk of bias rating given on the GRADE table in Appendix I. The QUADAS-2 covers four domains: patient selection, the index test, the reference standard and flow and timing. Each domain is assessed for risk of bias, and the first 3 are also assessed for applicability (in reference to the review protocol). If there were 2 or more major limitations according to the QUADAS criteria, a rating of very serious limitations was given. If there was a single major limitation a rating of serious limitations was given.

Table 14: Clinical evidence profile: diagnostic accuracy for decision rules for people with a suspected traumatic cervical spine injury

Number of studies	Population (n) (In study order)	Risk of bias	Inconsistency	Indirectness	Imprecision	Sensitivity (95% CI)	Specificity (95% CI)	Quality
NEXUS decision tool – all adults								
5 Pooled data	45720 adults following trauma	NS	S [b]	NS	VS[d]	0.94 (0.78-0.98)	0.25 (0.12-0.46)	VERY LOW
4	22964 adults following blunt trauma	NS	S [b]	NS	NS	1.00 (0.63-1.00) 1.00 (0.99-1.00) 1.00 (0.98-1.00) 0.99 (0.97-1.00) Median 1.00 (0.63 to 1.00)	0.33 (0.31-0.36) 0.01 (0-0.01) 0.43 (0.42-0.44) 0.45 (0.44-0.46) Median 0.33 (0.31 to 0.36)	VERY LOW
NEXUS – children								
2	108 paediatric (≤10 years) medical records 3065 paediatric (<18 years) trauma patients	NS	S [b]	S[c]	S[d]	0.57 (0.18-0.90) 1.00 (0.88-1.00) Median 0.57 (0.18 to 0.90)	0.35 (0.25-0.45) 0.20 (0.18-0.21)	VERY LOW
CCR – children								
1	109 paediatric (≤10 years) medical records	VS [a]	-	S[c]	VS	0.86 (0.42-100)	0.15 (0.08-0.23)	VERY LOW
NEXUS – adults and children								
1	34069 children and adults following blunt trauma	NS	-	NS	NS	1.00 (0.99-1.00)	0.13 (0.13-0.13)	LOW
NEXUS – 65 years and over								

Number of studies	Population (n) (In study order)	Risk of bias	Inconsistency	Indirectness	Imprecision	Sensitivity (95% CI)	Specificity (95% CI)	Quality
1	2943 older adults (>65 years) following blunt trauma	NS	-	S[c]	S[d]	1.00 (0.63-1.00)	0.14 (0.13-0.15)	VERY LOW
NEXUS – pilot adults and children								
1	974 children and adults following blunt trauma	NS	-	NS	NS	1.00 (0.87-1.00)	52 (0.49-0.55)	LOW
NEXUS – approximations								
1	8924 adults (≥16 years) following blunt trauma	VS[a]	-	VS[c]	NS	0.93 (0.87-0.96)	0.38 (0.37-0.39)	VERY LOW
CCR - modified (minus neck rotation)								
1	2606 adults (≥16 years) following blunt trauma	VS[a]	-	VS[c]	NS	0.83 (0.76-0.88)	0.46 (0.44-0.48)	VERY LOW
CCR - modified (minus low-risk factors)								
1	507 adults following blunt trauma	NS	-	VS[c]	VS[d]	1.00 (0.40-1.00)	0.29 (0.25-0.34)	VERY LOW

GRADE was conducted with emphasis on test sensitivity as this was the primary outcome for decision making

(a) Risk of bias was assessed using the QUADAS-II checklist. Outcomes were downgraded by one if the weighted (by sample size [n]) average number of QUADAS-II domains (patient selection, index test, reference standard and flow and timing) with methodological limitations was one. Outcomes were downgraded by two if the weighted average number of QUADAS-II domains with methodological limitations was more than one

(b) Inconsistency was assessed by inspection of the sensitivity/specificity RevMan 5[2] plots, or summary area under the curve (AUC) plots

(c) Reasons for indirectness included incomplete NEXUS or CCR processes (missing out criteria) or using proxy criteria

(d) The judgement of precision for sensitivity and specificity separately was based on visual inspection of the confidence region in the diagnostic meta-analysis. 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 imprecision. The very wide confidence region which expands more than 0.2 from the summary sensitivity and specificity on both axes and crosses the line of no effect increases the uncertainty of the actual diagnostic accuracy of the NEXUS decision tool for all adults.

7.4 Economic evidence

Published literature

No relevant economic evaluations comparing the CCR and the NEXUS clinical decision rules for selecting patients with head injury and suspected CSI for initial imaging with an X-ray or CT scan were identified. There were no excluded studies.

New cost-effectiveness analysis

This area was prioritised for new cost-effectiveness analysis. A summary of the analysis can be seen in Table 15. The GDG identified non-imaging assessment and acute stage imaging for spinal injury as key areas which would benefit from de novo modelling. These questions were looked at in combination to inform components of an overall strategy to clear the spine.

This area has been identified as a high economic priority due to the high economic costs and harms associated with variation in practice around imaging and unnecessary imaging.

However, the clinical reviews of these relevant areas revealed a major paucity of data. Treatment pathways were also constructed with assistance of clinical experts, it was clear that many tenuous assumptions would have to be made. For these reasons in depth formal economic modelling was considered to be not useful in decision making.

Instead of a formal economic model, a simple model was constructed which assisted the GDG to understand the economic implications and trade-offs given different assumptions regarding the accuracy of a diagnostic modality. This model needed to be simple given that downstream treatments were varied and outside the scope of the guideline.

The GDG were able to enter a given prevalence of spinal injury within the trauma population (adult patients that arrive at A&E with suspected spinal column injury) as well as an assumed accuracy for an imaging modality. Accuracy estimates were selected from the clinical evidence review. With costs of different imaging modalities provided, the tool is able to estimate the cost of a particular diagnostic outcome (such as for missed injury), QALY gain per patient and number of missed injuries in a particular strategy to name a few.

This model addresses diagnostic accuracy of decision rules and imaging modalities in patients with column injury ONLY – it however, does take into account patients who convert to a cord injury as a result of their column injury. Isolated SCI was not addressed in this model due to the lack of data. The clinical review did not find accuracy data for X-ray or CT scan for cord injuries. Only MRI accuracy data for cord injuries was identified. Expert opinion supports that if a trauma patient arrives in A&E with neurological signs and symptoms associated with a cord injury an MRI will always be required. The clinical review also highlighted MRI as the Gold standard diagnostic investigation for suspected cord injuries.

The perspective adopted was that of the NHS. The time horizon of the model included the 4 hours in A&E and any extra time to realise the short term outcomes. To calculate QALYs a lifetime horizon was used. A total of 18 strategies were compared, blanket strategies that involved imaging all patients suspected of a spinal injury with either X-ray, CT scan or MRI, combinations of these were also included, such as X-ray plus CT and CT plus MRI, and selective strategies in which a decision rule is applied to determine if a patient should be imaged by one or a combination of these modalities. The prevalence of spinal column injury combined with the performance of prediction rules and the performance of diagnostic imaging techniques determined the number of patients correctly provided treatment (TP), incorrectly provided treatment (FP), correctly left untreated (TN) and incorrectly left

untreated (FN). With costs of different imaging modalities provided, the tool is able to estimate the cost of a particular diagnostic outcome (that is, for missed injury), QALY gain per patient and number of missed injuries in a particular strategy. Litigation costs associated with a missed injury, both column and column injuries that convert to a cord, were included in the base-case analysis.

Base-case probabilistic analysis identified that CCR + CT scan dominated all other strategies and was therefore optimal in a population of suspected column injury. This strategy remained optimal in sensitivity analyses; such as certain variations in the accuracy estimates, when litigation costs were included, when the QALY loss associated with false negatives was increased, when the time horizon was extended, when the risk and consequences of radiation exposure were included and discounting applied. At the assumed prevalence rates and accuracy data, CT scans in combination with a decision rule are most likely to be cost effective. CT scanning only those with a positive X-ray at the assumed prevalence and accuracy rates results in many missed injuries.

The results of the base-case and sensitivity analysis clearly point out that decision rules are important tools in clearing spinal injuries. It highlights the importance of clinical expertise and the role of the medical professional in deciding on imaging a patient with suspected spinal injury.

Although CCR featured among the top ranked strategies in the base case and the HI model, the sensitivity and specificity of the decision rules made an impact on the results. In varying the accuracy estimates of the decision rules a strategy with a decision rule still featured in terms of most cost effective strategy compared to all other strategies. It can be concluded that although results support the use of the CCR, in general the use of a decision rule is recommended.

The economic analysis conducted in the Head Injury guideline concluded that for patients with head injury and suspected cervical spinal injury, the CCR for CT scan was cost effective for selecting patients for diagnostic imaging[83]. This supports the results presented in this analysis.

It has to be acknowledged that the analysis undertaken in this guideline does not fully account or quantify all of the trade-offs involved in the diagnostic decision on which this analysis is based. No weighting or penalty was given to outcomes such as false positive (although the cost of observation and treatment is taken into account), there are no indeterminate images, patients are cleared or found to have an injury, only spinal column injured patients who are missed (FN) can convert to a cord injury. TP's do not convert to cord injuries in the model. The same conversion rate to cord injury is applied to patients with bony column injury or ligamentous column injuries. The analysis also assumed that patients would remain well and experience no deterioration after treatment or no treatment.

The time horizon adopted in this analysis focused on relatively short-term outcomes. QALYs were estimated using utilities from proxy conditions and long-term spinal cord injured patients. The adverse events associated with spinal clearance strategies and the decision to remove spinal protective measures was not fully explored in this analysis. The adverse events associated with spinal protection methods, such as pressure sores, raised intracranial pressure and pneumonia, were not included. Radiation risk associated with imaging modalities is also an important long-term consideration not included; however, this was included in a sensitivity analysis.

It is, therefore, necessary to interpret this analysis to have potentially serious limitations. However, the GDG felt that despite the limitations, the analysis is sufficient for purposes of decision making as it explicitly shows and attempts to quantify the parameters, assumptions and structure underpinning the clinical decision.

See also Appendix L for full write up.

Table 15: Economic evidence profile: Diagnosis of traumatic spinal injury (NCGC model)

Study	Applicability	Limitations	Other comments	Total cost (per person)	Total QALYs (per person)	Total Net Benefit [Rank]	Uncertainty
NCGC model Intervention: 1. X-ray 2. CT 3. MRI 4. X-ray+CT 5. CT+MRI 6. MRI+CT 7. CCR+X-ray 8. CCR+CT 9. CCR+MRI 10. NEXUS+X-ray 11. NEXUS+CT 12. NEXUS+MRI 13. CCR+X-ray+CT 14. CCR+CT+MRI 15. CCR+MRI+CT 16. Nexus+X-ray+CT 17. Nexus+CT+MRI 18. Nexus+MRI+CT	Directly Applicable[a]	Potentially Serious Limitations[b]	Cost-Effectiveness Analysis assessed the clearance strategies available if a person is suspected of column injury, which may be a bony or ligaments injury. Where injury is missed (FN), there is potential for deterioration and possibly conversion to cord injury.	1. £158 2. £121 3. £191 4. £127 5. £129 6. £187 7. £111 8. £81 9. £121 10. £146 11. £111 12. £173 13. £95 14. £89 15. £121 16. £119 17. £119 18. £170	1. 20.85252 2. 20.85275 3. 20.85270 4. 20.85251 5. 20.85268 6. 20.85268 7. 20.85252 8. 20.85275 9. 20.85270 10. 20.85252 11. 20.85274 12. 20.85269 13. 20.85251 14. 20.85267 15. 20.85267 16. 20.85251 17. 20.85267 18. 20.85267	1. £416,892 [14] 2. £416,934 [7] 3. £416,863 [18] 4. £416,923 [12] 5. £416,924 [11] 6. £416,867 [17] 7. £416,940 [5] 8. £416,974 [1] 9. £416,932 [9] 10. £416,904 [13] 11. £416,944 [4] 12. £416,880 [16] 13. £416,956 [3] 14. £416,965 [2] 15. £416,933 [8] 16. £416,931 [10] 17. £416,934 [6] 18. £416,884 [15] CCR+CT dominates all other strategies as it has the lowest cost and the highest QALY.	Various sensitivity analyses and threshold analyses were undertaken on all important parameters within the model. CCR + CT remained the most cost effective option in the majority of analyses, notably when: • radiation risk was taken into account • quality of life for cord injury was varied • litigations costs were included

(a) The analysis was conducted from a UK NHS perspective using NHS costs. QALYs were used as the measure of health benefit.

(b) Various assumptions have been made to simplify the analysis. GDG best estimates were used where data was unavailable, such as downstream litigations costs, and the prevalence of the injury.

7.5 Evidence statements

Adults

NEXUS low-risk criteria

A meta-analysis of 5 diagnostic cohorts in 45,720 adults showed that the NEXUS low-risk criteria had pooled high sensitivity (95% CI) of 0.94 (0.78 to 0.98) and a very poor specificity (SD) of 0.25 (0.12 to 0.46) relative to plain film radiography and/or CT at picking up a CSI in adults, however, there was high variability in these results (Very low quality evidence).

One diagnostic sub-study in 2963 adults aged 65 years and over showed that the NEXUS low-risk criteria had a sensitivity of 1.00 (95% CI, 0.63 to 1.00) and specificity of 0.14 (95% CI, 0.13 to 0.15) relative to plain film radiography, CT and/or MRI at picking up a CSI in older adults (Very low quality evidence).

CCR

Four diagnostic cohorts in 22,964 adults showed that the CCR had a median sensitivity of 1.00 (95% CI, 0.63 to 1.00) and a median specificity of 0.33 (95% CI, 0.31 to 0.36) relative to plain film radiography and/or CT at picking up a CSI in adults (Very low quality evidence).

Modified NEXUS or CCR

One diagnostic cohort in 8924 adults aged 16 years and over showed that reinterpreting CCR criteria within the NEXUS framework had a sensitivity of 0.93 (95% CI, 0.87 to 0.96) and a specificity of 0.38 (95% CI, 0.37 to 0.39) relative to radiography at picking up a CSI in adults (Very low quality evidence).

One diagnostic cohort in 2606 adults aged 16 years and over showed that a modified CCR excluding the neck rotation criterion had a sensitivity of 0.83 (95% CI, 0.76 to 0.88) and a specificity of 0.46 (95% CI, 0.44 to 0.48) relative to complete cervical-spine CT at picking up a CSI in adults (Very low quality evidence).

One diagnostic cohort in 507 adults showed that a modified CCR excluding the low-risk factors criteria had a sensitivity of 1.00 (95% CI, 0.40 to 1.00) and a specificity of 0.29 (95% CI, 0.25 to 0.34) relative to CT at picking up a CSI in adults (Very low quality evidence).

NEXUS – all patients

The NEXUS derivation and validation studies included both children and adults. The derivation study of 974 children and adults found that when the NEXUS criteria included midline neck tenderness, altered level of alertness or intoxication and excluded whiplash mechanism it had a sensitivity of 1.00 (95% CI, 0.87 to 1.00) and a specificity of 0.52 (0.49 to 0.55) (Low quality evidence). The much larger validation study of 34,069 children and adults showed that the NEXUS had a sensitivity of 1.00 (95% CI, 0.99 to 1.00) and a specificity of 0.13 (0.13 to 0.13) relative to radiography, and possibly CT and/or MRI at picking up a CSI in children and adults (Low quality evidence).

Children and infants

NEXUS low-risk criteria

Two diagnostic cohorts with 3173 children showed that the NEXUS low-risk criteria has a median sensitivity of 0.57 (95% CI, 0.18 to 0.90) and median specificity of 0.20 (95% CI, 0.18 to 0.21) relative to plain film radiography and/or CT at picking up a CSI in children (Very low quality evidence).

CCR

One diagnostic cohort of 109 children showed that the CCR has a sensitivity of 0.86 (95% CI, 0.42 to 1.00) and minimal specificity of 0.15 (95% CI, 0.08 to 0.23) relative to plain film radiography and/or CT at picking up a CSI in children (Very low quality evidence).

Economic

No relevant economic evaluations were identified.

An original health economic model found that, for patients with suspected spinal column injury, the CCR (followed by a CT scan) was part of the most cost-effective diagnostic pathway to clear the spine. This analysis is directly applicable with potentially serious limitations.

7.6 Recommendations and link to evidence

Recommendations	**Pre-hospital assessment and management** **9. Assess whether the person is at high, low or no risk for cervical spine injury using the Canadian C-spine rule as follows:** • **the person is at high risk if they have at least one of the following high-risk factors:** – **age 65 years or older** – **dangerous mechanism of injury (fall from a height of greater than 1 metre or 5 steps, axial load to the head – for example diving, high-speed motor vehicle collision, rollover motor accident, ejection from a motor vehicle, accident involving motorised recreational vehicles, bicycle collision, horse riding accidents)** – **paraesthesia in the upper or lower limbs** • **the person is at low risk if they have at least one of the following low-risk factors:** – **involved in a minor rear-end motor vehicle collision** – **comfortable in a sitting position** – **ambulatory at any time since the injury** – **no midline cervical spine tenderness** – **delayed onset of neck pain** • **the person remains at low risk if they are:** – **unable to actively rotate their neck 45 degrees to the left and right (the range of the neck can only be assessed safely if the person is at low risk and there are no high-risk factors)**

	• **the person has no risk if they:** – have one of the above low-risk factors and – are able to actively rotate their neck 45 degrees to the left and right **10. Be aware that applying the Canadian C-spine rule to children is difficult and the child's developmental stage should be taken into account.** **11. Assess the person with suspected thoracic or lumbosacral spine injury using these factors:** • **age 65 years or older and reported pain in the thoracic or lumbosacral spine** • **dangerous mechanism of injury (fall from a height of greater than 3 metres, axial load to the head or base of the spine – for example falls landing on feet or buttocks, high-speed motor vehicle collision, rollover motor accident, lap belt restraint only, ejection from a motor vehicle, accident involving motorised recreational vehicles, bicycle collision, horse riding accidents)** • **pre-existing spinal pathology, or known or at risk of osteoporosis – for example steroid use** • **suspected spinal fracture in another region of the spine** • **abnormal neurological symptoms (paraesthesia or weakness or numbness)** • **on examination:** – **abnormal neurological signs (motor or sensory deficit)** – **new deformity or bony midline tenderness (on palpation)** – **bony midline tenderness (on percussion)** – **midline or spinal pain (on coughing)** • **on mobilisation (sit, stand, step, assess walking): pain or abnormal neurological symptoms (stop if this occurs).** **12. Be aware that assessing children with suspected thoracic or lumbosacral spine injury is difficult and the child's developmental stage should be taken into account.** **13. Carry out or maintain full in-line spinal immobilisation if:** • **a high-risk factor for cervical spine injury is identified and indicated by the Canadian C-spine rule** • **a low-risk factor for cervical spine injury is identified and indicated by the Canadian C-spine rule and the person is unable to actively rotate their neck 45 degrees left and right** • **indicated by one or more of the factors listed in recommendation 11.** **14. Do not carry out or maintain full in-line spinal immobilisation in people if:** • **they have low-risk factors for cervical spine injury as identified and**

	indicated by the Canadian C-spine rule, are pain free and are able to actively rotate their neck 45 degrees left and right • **they do not have any of the factors listed in recommendation 11.** **Hospital assessment and management** **15. Assess the person with suspected cervical spine injury using the Canadian C-spine rule (see recommendations 9 and 10).** **16. Assess the person with suspected thoracic or lumbosacral spine injury using the factors listed in recommendation 11 and 12.** **17. Carry out or maintain full in-line spinal immobilisation and request imaging if:** • **a high-risk factor for cervical spine injury is identified and indicated by the Canadian C-spine rule or** • **a low-risk factor for cervical spine injury is identified and indicated by the Canadian C-spine rule and the person is unable to actively rotate their neck 45 degrees left and right or** • **indicated by one or more of the factors listed in recommendation 11.** **18. Do not carry out or maintain full in-line spinal immobilisation or request imaging for people if:** • **they have low-risk factors for cervical spine injury as identified and indicated by the Canadian C-spine rule, are pain free and are able to actively rotate their neck 45 degrees left and right** • **they do not have any of the factors listed in recommendation 11.**
Relative values of different outcomes	Although the objective of this review focuses on excluding those without spinal cord and/or column injury from unnecessary immobilisation and imaging the primary outcome for this evidence review was sensitivity (an indication of the false negative rate). False negatives (a negative test result when there is a spinal injury) may cause considerable clinical and health economic harms. For example, failure to pick up an unstable cervical column injury could lead to conversion to a SCI. The GDG also considered specificity, as false positive results present harm to the patient both in exposure to imaging-related radiation and in terms of the adverse effects of spinal protection. This is of particular importance in children who have a lower rate of spinal injury and where unnecessary immobilisation may lead to imaging. Although the harms resulting from suboptimal specificity were considered serious, they were not regarded as important as the harms resulting from suboptimal sensitivity, so sensitivity was the more important outcome.
Trade-off between clinical benefits and harms	**Cervical spine** The GDG discussed the sensitivity of the two identified decision tools. It was agreed that greater clinical benefit would be gained by prioritising sensitivity in order to minimise false negatives (missing a cervical spine cord or column injury) than concentrating on specificity (minimising radiation risk of unnecessary imaging for those without injury).

	While unable to compare a meta-analysis of the diagnostic accuracy of CCR with NEXUS, the CCR studies are generally more precise with consistently higher sensitivity ratings compared with the NEXUS studies. No harms were noted for CCR or Nexus. **Thoracic and lumbosacral spine** No evidence concerning the diagnostic accuracy of decision tools designed for the thoracic and lumbosacral spine was found. The benefits of having a set of criteria to identify a thoracic and lumbosacral spinal injury and to avoid missed injuries and unnecessary imaging is clear. A consensus assessment criteria was developed by the GDG as a basis for the recommendation. **Children** Most of the evidence was in adults, but limited evidence suggested such tools have lower sensitivity in children, with a high variability between studies. The difficulties of applying the risk tools to children are well known and the CCR is not validated for use in children under eight years. The benefits of using a risk tool, particularly in avoiding unnecessary imaging, in children outweigh the risks of not using a tool.
Economic considerations	The original economic analysis conducted for this guideline based on accuracy evidence for decision rules from the clinical review identified the CCR and CT scan strategy to be optimal. It was found to dominate all other strategies in the model. This result was robust to various assumptions if mean accuracy data retrieved from the systematic review is felt credible. Throughout all sensitivity analyses, use of some form of decision rule was better than moving directly to imaging to clear the spine. At the assumed prevalence rates and accuracy data, CT scans in combination with a decision rule are most likely to be cost effective. The results of the base-case and sensitivity analysis clearly point out that decision rules are important tools in clearing spinal injuries. It highlights the importance of clinical expertise and the role of the medical professional in deciding on imaging a patient with suspected spinal injury. Although CCR featured among the top ranked strategies in the base case, the sensitivity and specificity of the decision rules made an impact on the results. In varying the accuracy estimates of the decision rules, a strategy with a decision rule (either CCR or NEXUS) still featured in terms of the most cost effective strategy. It can be concluded that although the base-case results support the use of the CCR, in general, the use of a decision rule is recommended. The economic analysis conducted in the Head Injury guideline concluded that for patients with head injury and suspected cervical spinal injury, the CCR for CT scan was cost effective for selecting patients for diagnostic imaging. This reassuringly supports the results presented here. For further discussion on the findings of the model please refer to Appendix L. The model was in the adult population and the GDG felt the results could not be extrapolated to children which are likely to differ in terms of epidemiology of the injury. However a sensitivity analysis was undertaken in the model whereby; the proportion of ligamentous injuries was varied, and also radiation risk was incorporated which is more of a concern in children. The result showed that again a decision rule was included in the most optimal clearance strategy (CCR), with the optimal imaging modality following this depending on the proportion of ligamentous injuries (if this is more than around 27%, MRI is cost effective).

Quality of evidence	The observational nature of the studies available and variation in sensitivity and specificity found across studies (inconsistency) led to the evidence being rated as Very low for both the CCR and NEXUS. The GDG recognised that evidence for currently available clinical decision tools focussed specifically on suspected injuries of the cervical spine. No tools which focus on suspected injury of the thoracic and/or lumbar spine were identified.
Other considerations	The GDG noted that the CCR is a tool designed for decision to image. The GDG considered that it is also a proxy for the identification of a potential column (or cord) injury and can be used for assessment as well as imaging. People that need imaging will need to be immobilised. Once someone is trained to use the CCR it is easy and quick to apply and the GDG considered that it could also be applied in the pre-hospital setting to assess spinal injury and not only in the ED. The GDG recognised that training in the use of the CCR was of utmost importance if it is to be applied properly. **Thoracic and lumbosacral spine** Despite the absence of evidence, the GDG agreed there was an urgent need for assessment criteria to support healthcare professionals in identifying thoracic or lumbosacral spinal injury. Through consensus, the GDG agreed on a set of criteria that could be used as a guide to assessment rather than a definitive predictor. The GDG were keen to emphasise that the criteria had not been validated for use as a risk tool. The criteria for identifying thoracic or lumbosacral spinal injury was extrapolated from the CCR and adjusted to suit the region of the spine. The CCR indicates a fall from 1 metre and the thoracic or lumbosacral spinal criteria 3 metres, more energy is needed to disrupt the thoracic or lumbosacral spine than the cervical spine. The thoracic or lumbosacral spinal criteria suggest a high-risk factor is both being over 65 years and reported pain, and not just over 65 years as in the CCR, in this age group the risks of precautionary immobilisation outweigh the benefits of routine immobilisation. In the case of the cervical spine, the risks of missed injury are greater. In addition, specific criteria for the thoracic or lumbosacral spinal region on examination have been added. This outlines the need for concern in those people with focal signs as well as exacerbation of pain on movement. **Children and young people** There are no validated risk tools for children and young people and the GDG agreed that the CCR could be extrapolated to and used in this population. The GDG were keen to make a recommendation highlighting the need for caution when using the rule. Some of the assessments (such as pain assessment or controlled exploratory movements) cannot be carried out in very young children. The GDG make it clear that the child's developmental age should be taken in to account when assessing for spinal injury. The GDG noted that the assessment in the ED was the same as in the pre-hospital and cross referred to the pre-hospital recommendations in the ED setting. The recommendations to carry out immobilisation based on the assessment also state the need to image in the ED as this is the only way to confirm or exclude a

	spinal injury. However this is not relevant to the pre-hospital setting.

8 Immobilising the spine: pre-hospital strategies

8.1 Introduction

Chapters 7 and 8 have established when to immobilise the spine. The practice of how to immobilise the spine safely and effectively is no less complex or controversial. There is variation in the methods used to immobilise the spine during transportation to hospital from the scene of an accident. Full in-line spinal immobilisation can include a cervical collar, head restraints and either a long spinal board or scoop stretcher. The different methods of spinal protection vary in their capacity to protect the spine, as well as their capacity to cause harm. Other considerations in the use of pre-hospital spinal immobilisation methods may include the cost of equipment and the time and training of pre-hospital clinicians to apply the devices. These factors may influence the variation in equipment that is available to use at an incident. In addition the situation and the injured person's circumstances have to be considered when deciding on the best approach to carry out immobilisation. This chapter aims to identify the optimal strategies to carry out full in-line spinal immobilisation.

8.2 Review question: What pre-hospital strategies to protect the spine in people with suspected spinal injury are the most clinically and cost effective during transfer from the scene of the incident to acute medical care?

For full details see review protocol in Appendix C.

Table 16: PICO characteristics of review question

Population	Children, young people and adults experiencing a traumatic incident. If no evidence is identified the indirect population of healthy volunteers will be considered
Intervention/s	• Spinal boards (long or short) • Rescue board • Scoop stretcher • Spinal extrication devices • Back boards • Collar and back board combinations • Vacuum mattress • Mattress splints • Collars (rigid or soft) • Manual stabilization • Sand bags, straps and tapes, head blocks, aqua board • Kendrick Extrication Device (KED) • Or any combinations of the above
Comparison/s	• Standard care • Do nothing • Each other or combinations of above
Outcomes	Critical: • Mortality at 1 month • Mortality at 6 months • Mortality at 12 months

	• Health-related quality of life • Rates of spinal cord injury (SCI) • Missed spinal column/cord injury • Spinal cord neurological function at 1 month (including American Spinal Injury Association [ASIA] and Frankel) • Spinal cord neurological function at 6 months (including ASIA and Frankel) • Spinal cord neurological function at 12 months (including ASIA and Frankel) • Adverse effects: • Pressure ulcers • Airway compromise • Raised ICP • Neurological deterioration [ASIA]) associated with spinal protection/immobilisation. Important: • Pain/discomfort • Return to normal activities • Psychological wellbeing
Study design	RCTs or Systematic reviews of RCTs; cohorts or case-controls if no RCTs retrieved.

8.3 Clinical evidence

Thirteen studies were included in the review.[12,29,31,34,49,55,60,66,73,75,108,109,114] Six of these studies did not have any relevant outcomes are not considered further.[31,49,55,66,75,108] Evidence from the remaining seven studies are summarised in the clinical evidence summary table below (Table 18). See also clinical GRADE evidence profiles in Appendix H, study selection flow chart in Appendix D, forest plots in Appendix I, study evidence tables in Appendix G and exclusion list in Appendix J.

The population of the studies was indirect; all of the studies were in healthy volunteers.

The included studies compared the following classes of intervention:

- Collars versus collars [12]
- Spinal boards versus spinal boards[29,34,60,114]
- Spinal boards versus vacuum splints[55,109]
- Head blocks (padded versus hard)[73]

A summary of the seven included studies is presented below (Table 17).

Table 17: Summary of studies included in the review

Study	Intervention/comparison	Population	Outcomes	Comments
Black 1998[12]	Collars: Philadelphia versus Aspen	20 healthy volunteers	Pressure Skin humidity	Crossover
Chan 1996[29]	Spinal boards: Collar + backboard versus mattress splint	37 healthy volunteers	Pain	Prospective, randomised, crossover
Cordell 1995[34]	Spinal boards+/-mattresses	20 healthy volunteers	Pain (VAS) Pressure levels Perception of immobilisation Reports p values only	Prospective crossover
Hauswald 2000[60]	Spinal boards: Hardboard versus hardboard +	22 healthy volunteers	Comfort	Prospective non-blinded

Study	Intervention/comparison	Population	Outcomes	Comments
	Mattress versus hardboard + blanket versus hardboard + mattress + blanket			
Lerner 1998[73]	Collars + spinal boards (neck support): towels (padded) versus plywood (unpadded)	39 healthy volunteers	Pain (neck and occipital) Comfort Reports median (range) for pain intensity	Prospective, randomised, crossover
Totten 1999[109]	Spinal boards: Control versus hardboard versus vacuum mattress	39 healthy volunteers	Comfort Respiratory function measures Comfort levels	Random-number crossover
Walton 1995[114]	Spinal boards: Padded long spine board versus unpadded long spine board	30 healthy volunteers	Discomfort (VAS) Transcutaneous tissue O_2 tension	Prospective, randomised, crossover

Table 18: Clinical evidence summary: methods of spinal immobilisation

Outcome	Number of studies (no. of participants)	Imprecision	GRADE rating	Absolute difference	Control event rate (%)	Control event rate for continuous outcomes mean (SD)
Aspen collar versus Philadelphia collar						
Temperature (degrees centigrade)	1 (n=20)	Serious	VERY LOW	MD 2 higher (0.23 lower to 4.23 higher)	-	96 (1)
Percentage relative skin humidity	1 (n=20)	No imprecision	VERY LOW	MD 30 higher (21.23 to 38.77 higher)	-	83 (16)
Occipital pain (VAS score)	1 (n=20)	Very serious	VERY LOW	MD 4 higher (5.32 lower to 13.32 higher)	-	43 (16)
Board versus board/vacuum mattress						
Respiratory outcomes (FVC): Backboard versus vacuum	1 (n=39)	No imprecision	VERY LOW	MD 0.01 higher (0.42 lower to 0.44 higher)	-	2.34 (0.91)
Respiratory outcomes (FEV): Backboard versus vacuum	1 (n=39)	No imprecision	VERY LOW	MD 0.11 higher (0.25 lower to 0.47 higher)	-	1.94 (0.84)
Respiratory outcomes (PEF): Backboard versus vacuum	1 (n=39)	Serious imprecision	VERY LOW	MD 0.01 lower (0.88 lower to 0.86 higher)	-	3.83 (1.9)
Respiratory outcomes (FEF): Backboard versus vacuum	1 (n=39)	Serious imprecision	VERY LOW	MD 0.17 higher (0.37 lower to 0.71 higher)	-	2.13 (1.27)
Comfort: Wooden board versus vacuum	1 (n=39)	No imprecision	VERY LOW	MD 2 lower (2.49 to 1.51 lower)	-	2.81 (1.26)
Pain (VAS): Padded board versus unpadded board	1 (n=30)	No imprecision	LOW	MD 2.90 lower (4.71 lower to 1.09 lower)	-	2.5 (2.1)

Outcome	Number of studies (no. of participants)	Imprecision	GRADE rating	Absolute difference	Control event rate (%)	Control event rate for continuous outcomes mean (SD)
Any symptom- first exposure: Backboard versus vacuum mattress	1 (n=30)	Serious imprecision	VERY LOW	402 more per 1000 (from 29 more to 992 more)	18/18 (100%)	-
Any symptom- second exposure: Backboard versus vacuum mattress	1 (n=35)	Serious imprecision	VERY LOW	401 more per 1000 (from 10 more to 1000 more)	10/19 (52.6%)	-
Occipital pain- first exposure: Backboard versus vacuum mattress	1 (n=37)	No imprecision	LOW	731 more per 1000 (from 153 more to 1000 more)	16/18 (88.9%)	-
Occipital pain- second exposure: Backboard versus vacuum mattress	1 (n=35)	No imprecision	LOW	470 more per 1000 (from 240 more to 710 more)	9/19 (47%)	-
Lumbosacral pain- first exposure: Backboard versus vacuum mattress	1 (n=36)	No imprecision	LOW	540 more (280 more to 790 more)	10/17 (58.8%)	-
Lumbosacral pain- second exposure: Backboard versus vacuum mattress	1 (n=35)	Very serious imprecision	VERY LOW	32 more per 1000 (from 95 fewer to 706 more)	3/19 (15.8%)	-
Cervical pain- first exposure: Backboard versus vacuum mattress	1 (n=35)	Very serious imprecision	VERY LOW	200 fewer per 1000 (from 430 fewer to 20 more)	1/17 (5.9%)	-
Cervical pain- second	1 (n=35)	No	LOW	0 per 1000 (110 fewer to	0/19	-

Outcome	Number of studies (no. of participants)	Imprecision	GRADE rating	Absolute difference	Control event rate (%)	Control event rate for continuous outcomes mean (SD)
exposure: Backboard versus vacuum mattress		imprecision		110 more)	(0%)	
Scapular pain- first exposure: Backboard versus vacuum mattress	1 (n=36)	Very serious imprecision	VERY LOW	10 more per 1000 (140 fewer to 160 more)	1/17 (5.9%)	-
Scapular pain- second exposure: Backboard versus vacuum mattress	1 (n=35)	Very serious imprecision	VERY LOW	50 more per 1000 (from 90 fewer to 190 more)	1/19 (5.3%)	-
Comfort: backboard versus backboard + blanket	1 (n=22)	No imprecision	VERY LOW	MD 2.5 lower (3.17 to 1.83 lower)	-	0.8 (0.2255)
Comfort: Backboard versus backboard+ mattress	1 (n=22)	No imprecision	VERY LOW	MD 6.2 lower (6.77 to 5.63 lower)	-	0.8 (0.2255)
Comfort: Backboard versus backboard + mattress + eggcrate foam	1 (n=22)	No imprecision	VERY LOW	MD 8.8 lower (9.47 to 8.13 lower)	-	0.8 (0.2255)
Comfort: Backboard + mattress versus backboard + blanket	1 (n=22)	No imprecision	VERY LOW	MD 3.7 higher (2.83 to 4.57 higher)	-	7 (1.3533)
Comfort: Backboard + mattress versus backboard + mattress + eggcrate foam	1 (n=20)	No imprecision	VERY LOW	MD 2.6 lower (3.47 to 1.73 lower)	-	7 (1.3533)
Comfort: Backboard + blanket versus backboard +	1 (n=20)	No imprecision	VERY LOW	MD 6.3 lower (7.23 to 5.37 lower)	-	3.3 (1.2788)

Outcome	Number of studies (no. of participants)	Imprecision	GRADE rating	Absolute difference	Control event rate (%)	Control event rate for continuous outcomes mean (SD)
mattress + eggcrate foam						
Head support padded versus unpadded						
Pain (number of people reporting)- immediately following intervention – head (rear)	1 (n=39)	Very serious	VERY LOW	103 more per 1000 (from 74 fewer to 451 more)	14/39 (35.9%)	-
Pain (number of people reporting)- immediately following intervention – neck	1 (n=39)	Serious	VERY LOW	154 fewer per 1000 (from 269 fewer to 77 more)	9/39 (23.1%)	-
Pain (number of people reporting)- immediately following intervention - shoulder	1(n=39)	Very serious	VERY LOW	25 fewer per 1000 (from 68 fewer to 213 more)	2/39 (5.1%)	-
Pain (number of people reporting)- immediately following intervention - lumbar	1(n=39)	Serious	VERY LOW	153 more per 1000 (from 53 fewer to 510 more)	19/39 (48.7%)	-
Pain (number of people reporting)- immediately following intervention - buttock	1(n=39)	Serious	VERY LOW	154 fewer per 1000 (from 221 fewer to 44 more)	4/39 (10.3%)	-
Pain (number of people reporting)- immediately following intervention - ankle	1(n=39)	Very serious	VERY LOW	77 fewer per 1000 (from 134 fewer to 132 more)	3/39 (7.7%)	-
Pain (number of people reporting)- immediately following intervention - head (front)	1(n=39)	Very serious	VERY LOW	0 fewer per 1000 (70 fewer to70 more)	1/39 (2.6%)	-

Outcome	Number of studies (no. of participants)	Imprecision	GRADE rating	Absolute difference	Control event rate (%)	Control event rate for continuous outcomes mean (SD)
Pain (number of people reporting)- immediately following intervention - arm	1(n=39)	Very serious	VERY LOW	0 fewer per 1000 (70 fewer to 70 more)	1/39 (2.6%)	-
Pain (number of people reporting)- immediately following intervention - thoracic	1(n=39)	Very serious	VERY LOW	30 more per 1000 (from60 fewer to 110 more)	2/39 (5.1%)	-
Pain (number of people reporting)- immediately following intervention - thigh	1(n=39)	Very serious	VERY LOW	30 more per 1000 (from60 fewer to 110 more)	2/39 (5.1%)	-
Pain (number of people reporting)- immediately following intervention - knee	1(n=39)	Very serious	VERY LOW	50 more per 1000 (from50 fewer to 150 more)	3/39 (7.7%)	-
Pain (number of people reporting)- immediately following intervention - calf	1(n=39)	Very serious	VERY LOW	50 more per 1000 (from50 fewer to 150 more)	3/39 (7.7%)	-
Pain (number of people reporting)- immediately following intervention - feet	1(n=39)	No imprecision	LOW	0 more per 1000 (from 50 fewer to 50 more)	0/39 (0%)	-
Pain (number of people reporting)- 24 hours following intervention - neck	1(n=39)	Very serious	VERY LOW	51 fewer per 1000 (from 109 fewer to 172 more)	3/39 (7.7%)	-
Pain (number of people reporting)- 24 hours	1(n=39)	Very serious	VERY LOW	0 fewer per 1000 (from 44 fewer to 295 more)	2/39 (5.1%)	-

Outcome	Number of studies (no. of participants)	Imprecision	GRADE rating	Absolute difference	Control event rate (%)	Control event rate for continuous outcomes mean (SD)
following intervention - thoracic						
Pain (number of people reporting)- 24 hours following intervention - lumbar	1(n=39)	No imprecision	LOW	143 fewer per 1000 (from 120 fewer to 151 fewer)	4/399 (1%)	-
Pain (number of people reporting)- 24 hours following intervention - head (front)	1(n=39)	Very serious	VERY LOW	30 fewer per 1000 (from 90 fewer to 490 more)	0/39 (0%)	-
Pain (number of people reporting)- 24 hours following intervention - head (rear)	1(n=39)	Very serious	VERY LOW	50 more per 1000 (from 50 fewer to 150 more)	3/39 (7.7%)	-
Pain (number of people reporting)- 24 hours following intervention - shoulder	1(n=39)	Very serious	VERY LOW	30 fewer per 1000 (from 90 fewer to 40 more)	0/39 (0%)	-
Pain (number of people reporting)- 24 hours following intervention - arm	1(n=39)	Very serious	VERY LOW	30 fewer per 1000 (from 90 fewer to 40 more)	0/39 (0%)	-
Pain (number of people reporting)- 24 hours following intervention - buttock	1(n=39)	Very serious	VERY LOW	50 fewer per 1000 (from 130 fewer to 30 more)	0/39 (0%)	-
Pain (number of people reporting)- 24 hours following intervention - thigh	1(n=39)	Serious	VERY LOW	80 more per 1000 (from 20 fewer to 170 more)	3/39 (7.7%)	-

Outcome	Number of studies (no. of participants)	Imprecision	GRADE rating	Absolute difference	Control event rate (%)	Control event rate for continuous outcomes mean (SD)
Pain (number of people reporting)- 24 hours following intervention - knee	1(n=39)	Very serious	VERY LOW	30 fewer per 1000 (from 110 fewer to 60 more)	1/39 (2.6%)	-
Pain (number of people reporting)- 24 hours following intervention - calf	1(n=39)	Very serious	VERY LOW	30 more per 1000 (from 40 fewer to 90 more)	1/39 (2.6%)	-
Pain (number of people reporting)- 24 hours following intervention - ankle	1(n=39)	Very serious	VERY LOW	0 fewer per 1000 (from 50 fewer to 50 more)	0/39 (0%)	-
Pain (number of people reporting)- 24 hours following intervention - feet	1	Very serious	VERY LOW	0 fewer per 1000 (from 70 fewer to 70 more)	1/39 (2.6%)	-

8.4 Economic evidence

Published literature

No relevant economic evaluations were identified.

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

Unit costs

Relevant unit costs are provided below to aid consideration of cost effectiveness.

Table 19: Costs of stabilisation devices

Category of device	Details	Cost	Source
Spinal boards (long)		£195	East Midlands Ambulance Service (EMAS) [(b)]
Scoop stretcher		£295	EMAS
Spinal extrication devices	KED	£83.50	EMAS
Banana board		£57.90	DS Medical[a]
Collar and back board combinations	Ambu head wedge	£5.25	Lincolnshire and Nottinghamshire Air Ambulance, and EMAS
Vacuum mattress	RedVac EMS system	£444.95	Lincolnshire and Nottinghamshire Air Ambulance
Mattress splints	RedVac (3 splints + pump)	£325	EMAS
Collars (rigid or soft)	Rigid collar	£4.80	EMAS
	Clini cervical collar	£2.40	Drug tariff
	Eesiness soft cervical foam collar	£2.62	Drug tariff
	Miami J collar	£38.44	NHS supply chain
	Philadelphia collar 2 piece design hypo-allergenic plastazote tracheotomy opening rear velcro closure X-ray and MRI compatible	£7.64	NHS supply chain
	Philadelphia collar	£14.82	NHS supply chain
Manual stabilization	Done by a competent person at the scene instead of using sand bags and tape	N/A	EMAS
Aqua board	Including sand bags, straps and head blocks	£534.19	SP Services[a]

(a) Suppliers used by EMAS
(b) Through personal contact in 08/2013

8.5 Evidence statements

Clinical

Aspen collar versus Philadelphia collar

Very low quality evidence from 1 crossover study comprising 20 participants showed that the Aspen collar was clinically effective compared with the Philadelphia collar in terms of temperature, with serious imprecision.

Very low quality evidence from 1 crossover study comprising 20 participants showed that the Aspen collar was clinically effective compared with the Philadelphia collar in terms of percentage relative skin humidity, with no imprecision.

Very low quality evidence from 1 crossover study comprising 20 participants showed that there was no difference in clinical effectiveness between the Aspen collar and the Philadelphia collar in terms of occipital pain, with very serious imprecision.

Board versus vacuum mattress

Very low quality evidence from 1 crossover RCT study comprising 28 participants showed that the there was no difference in clinical effectiveness between board versus board/vacuum mattress for the respiratory outcomes (FVC, FEV, PEF and FEF) with no serious to serious imprecision.

Wooden board versus vacuum

Very low quality evidence from 1 RCT crossover study comprising 48 participants showed that the vacuum was more clinically effective compared with the wooden board in terms of comfort, with no imprecision.

Padded versus unpadded board

Low quality evidence from 1 RCT crossover study comprising 30 participants showed that the padded board was more clinically effective compared with the unpadded board in terms of pain (VAS), with serious imprecision.

Backboard versus vacuum mattress

Very low quality evidence from 1 RCT crossover study comprising 30 to 35 participants showed that the vacuum mattress was more clinically effective compared with the backboard in terms of any symptom – first exposure and second exposure, with serious imprecision.

Low quality evidence from 1 RCT crossover study comprising 37 participants showed that the vacuum mattress was more clinically effective compared with the backboard in terms of occipital pain – first exposure, with no imprecision.

Low quality evidence from 1 RCT crossover study comprising 35 participants showed that the vacuum mattress was more clinically effective compared with the backboard in terms of occipital pain – second exposure, with no imprecision.

Low quality evidence from 1 RCT crossover study comprising 36 participants showed that the vacuum mattress was more clinically effective compared with the backboard in terms lumbosacral pain – first exposure, with no imprecision.

Very low quality evidence from 1 RCT crossover study comprising 35 participants showed that there was no difference in clinical effectiveness between the backboard and vacuum mattress in terms of lumbosacral pain – second exposure, with very serious imprecision.

Very low quality evidence from 1 RCT crossover study comprising 35 participants showed that the backboard was more clinically effective compared with the vacuum mattress in terms of cervical pain – first exposure, with no imprecision.

Low quality evidence from 1 RCT crossover study comprising 35 participants showed that there was no difference in clinically effectiveness between the vacuum mattress and backboard in terms of cervical pain – second exposure, scapular pain – first and second exposure, with very serious imprecision.

Comfort backboard versus backboard plus blanket

Very low quality evidence from 1 RCT crossover study comprising 22 participants showed that backboard and blanket was more clinically effective compared with backboard and blanket in terms of comfort, with no imprecision.

Comfort backboard versus backboard plus mattress

Very low quality evidence from 1 RCT crossover study comprising 22 participants showed that backboard and mattress was more clinically effective compared with comfort backboard in terms of comfort, with no imprecision.

Comfort backboard versus backboard plus mattress plus eggcrate foam

Very low quality evidence from 1 RCT crossover study comprising 22 participants showed that backboard, mattress and eggcrate foam was more clinically effective compared with comfort backboard in terms of comfort, with no imprecision.

Backboard + mattress versus backboard plus blanket

Very low quality evidence from 1 RCT crossover study comprising 22 participants showed that backboard and mattress was more clinically effective compared with backboard and blanket in terms of comfort, with no imprecision.

Backboard + mattress versus backboard plus mattress plus eggcrate foam

Very low quality evidence from 1 RCT crossover study comprising 22 participants showed that backboard, mattress and eggcrate foam and blanket was more clinically effective compared with backboard and mattress in terms of comfort, with no imprecision.

Backboard + blanket versus backboard plus mattress plus eggcrate foam

Very low quality evidence from 1 RCT crossover study comprising 22 participants showed that backboard, mattress and eggcrate foam was more clinically effective compared with backboard and blanket in terms of comfort, with no imprecision.

Head support – unpadded versus padded

Very low quality evidence from 1 RCT crossover study comprising 37 participants showed that the padded headrest was more clinically effective compared with unpadded headrest in terms of pain (head) immediately following the intervention, with very serious imprecision.

Very low quality evidence from 1 RCT crossover study comprising 37 participants showed that the unpadded headrest was more clinically effective compared with padded headrest in terms of pain (neck) immediately following the intervention, with serious imprecision.

Very low quality evidence from 1 RCT crossover study comprising 37 participants showed that the unpadded headrest was more clinically effective compared with padded headrest in terms of pain (shoulder) immediately following the intervention, with very serious imprecision.

Very low quality evidence from 1 RCT crossover study comprising 37 participants showed that the padded headrest was more clinically effective compared with unpadded headrest in terms of pain (lumbar) immediately following the intervention, with serious imprecision.

Very low quality evidence from 1 RCT crossover study comprising 37 participants showed that the unpadded headrest was more clinically effective compared with padded headrest in terms of pain (buttock) immediately following the intervention, with serious imprecision.

Very low quality evidence from 1 RCT crossover study comprising 37 participants showed that the there was no difference in clinical effectiveness between padded and unpadded headrests in terms of pain (ankle, head [front]) immediately following the intervention, with very serious imprecision.

Very low quality evidence from 1 RCT crossover study comprising 37 participants showed that the there was no difference in clinical effectiveness between padded and unpadded headrests in terms of pain (neck, thoracic) 24 hours following the intervention, with very serious imprecision.

Very low quality evidence from 1 RCT crossover study comprising 37 participants showed that the unpadded headrest was more clinically effective compared with padded headrest in terms of pain (lumbar) 24 hours following the intervention, with very serious imprecision.

Very low quality evidence from 1 RCT crossover study comprising 37 participants showed that the there was no difference in clinical effectiveness between padded and unpadded headrests in terms of pain (head [rear], shoulder, arm, buttock, thigh, knee, calf, ankle, feet) 24 hours following the intervention, with serious to very serious imprecision.

Economic

No relevant economic evaluations were identified.

8.6 Recommendations and link to evidence

Recommendations	**Pre-hospital in-line spinal Immobilisation** **19. When immobilising the spine tailor the approach to the person's specific circumstances (see recommendations 20 and 24 to 26).** **20. The use of spinal immobilisation devices may be difficult (for example in people with short or wide necks, or people with a pre-existing deformity) and could be counterproductive (for example increasing pain, worsening neurological signs and symptoms). In uncooperative, agitated or distressed people, including children, think about letting them find a position where they are comfortable with manual in-line spinal immobilisation.** **21. When carrying out full in-line spinal immobilisation in adults, manually stabilise the head with the spine in-line using the following stepwise approach:** • **Fit an appropriately sized semi-rigid collar unless contraindicated by:** – **a compromised airway** – **known spinal deformities, such as ankylosing spondylitis (in these cases keep the spine in the person's current position).** • **Reassess the airway after applying the collar.** • **Place and secure the person on a scoop stretcher.** • **Secure the person with head blocks and tape, ideally in a vacuum mattress.** **22. When carrying out full in-line spinal immobilisation in children, manually stabilise the head with the spine in-line using the stepwise approach in recommendation 21 and consider:** • **involving family members and carers if appropriate** • **keeping infants in their car seat if possible** • **using a scoop stretcher with blanket rolls, vacuum mattress, vacuum limb splints or Kendrick extrication device.** **23. When there is immediate threat to a person's life and rapid extrication is needed, make all efforts to limit spinal movement without delaying treatment.** **24. Consider asking a person to self-extricate if they are not physically trapped and have none of the following:** • **significant distracting injuries** • **abnormal neurological symptoms (paraesthesia or weakness or numbness)** • **spinal pain** • **high-risk factors for cervical spine injury as assessed by the Canadian C-spine rule.**

	25. Explain to a person who is self-extricating that if they develop any spinal pain, numbness, tingling or weakness, they should stop moving and wait to be moved. **26. When a person has self-extricated:** • **ask them to lay supine on a stretcher positioned adjacent to the vehicle or incident** • **in the ambulance, use recommendations 1 to 4, 9 to 14, and 19 to 21 to assess them for spinal injury and manage their condition.** **27. Do not transport people with suspected spinal injury on a longboard or any other extrication device. A longboard should only be used as an extrication device.** **Hospital in-line spinal Immobilisation** **28. When carrying out or maintaining full in-line immobilisation refer to recommendations 19 to 22.**
Relative values of different outcomes	The outcomes critical to decision making were mortality, quality of life, rates of SCI, missed spinal column/cord injury, spinal cord neurological function (ASIA and Frankel) and adverse effects, including pressure ulcers, airway compromise, raised intracranial pressure, and neurological deterioration (ASIA) associated with spinal protection/immobilisation. Important outcomes were unnecessary imaging and patient-reported outcomes (pain/discomfort, return to normal activities, psychological wellbeing).
Trade-off between clinical benefits and harms	The GDG felt that the importance of adequate spinal immobilisation cannot be over emphasised with inadequate protection potentially resulting in deteriorating neurological function possibly leading to death. The GDG noted that there should always be supervision of someone who is fully immobilised. The GDG noted that despite the protective advantages of spinal immobilisation there are situations where a standard one size fits all immobilisation approach could be harmful or delay treatment. Full in-line spinal immobilisation may impede management of the airway, on-going haemorrhage control and may worsen pre-existing conditions, such as ankylosing spondylitis. Collars may result in airway and/or respiratory compromise, and spinal boards can cause pain and prolonged use may lead to pressure sores. All the evidence compared different types of equipment; no evidence was identified that compared the use of different strategies with not using any equipment. The majority of the evidence reported outcomes related to the comfort of the patient and it should be noted that the population in these studies are healthy volunteers and sponsored by the manufacturers. It is difficult to make a conclusion from this evidence about the risk and benefits of different types of strategies when immobilising a person with suspected spinal injuries who may also have other injuries that could be life threatening. The population in the studies were compliant healthy volunteers and do not reflect the real-life situation of the healthcare professional (both in the pre - hospital and emergency department [ED] situation) assessing and treating people in a stressful and frightening situation. It is not unusual for patients to

	be combative, agitated or frightened and a standard approach can result in further injury. As a result, the GDG made recommendations that emphasise the need to approach spinal immobilisation taking into account the patient's specific situation, particularly noting the difficulties in uncooperative, agitated or distressed people, including children. Pre-hospital practitioners are often faced with difficult situations where people are trapped and the GDG agreed a consensus recommendation on the process of immobilisation during extrication was important. The GDG use the example of a person trapped in a vehicle, however, the principles apply to any trapped situation. In these circumstances, the patient may have an immediate threat to life (for example, catastrophic haemorrhage), full in-vehicle assessment may be impossible and there may be added life threatening dangers (to both the patient and attending emergency services), such as fire or flooding. In these situations, to expedite extrication the routine immobilisation of all trapped patients cannot be justified and rapid or self-extrication may be necessary. Supporting a person to self-extricate can be beneficial in a number of ways. Self-extrication is likely to reduce the time to definitive care, potentially improving the outcomes for many patients. It may also reduce the anxiety a person experiences in an entrapment situation. In addition it reduces use of resources for all the emergency services. Inviting a patient to remove themselves from a car is not a declaration of an uninjured cervical spine, and so immobilisation must still be used, in line with local policy, once the patient is out of the vehicle. **Long boards** A longboard is the terminology used for the boards that are used to as extrication device. The purpose of the longboard is to allow the safe transfer of a patient to a transport stretcher. These devices are rigid and uncomfortable. Prolonged time on a long spine board or prolonged time on scene applying these devices may be detrimental leading to pressure sores and can result in a poor patient outcome. In addition spinal immobilisation is not optimal on longboards. In order to minimize these negative occurrences, patients should be removed from the long spine board as soon as it is safe and practical to do so.
Economic considerations	**Pre-hospital stabilisation strategies** No economic evidence was found comparing different devices. The GDG were presented with a cost analysis of the various devices alongside economic considerations. This analysis was based on data from the Trauma Audit and Research Network (TARN), which included the number of different spinal protections used for each patient and the number of each type of protection, that are used pre-hospital, in the ED and in-hospital. This data did not have a breakdown of the type of protections used in combination for each patient so an overall cost per person immobilised was calculated based on all the devices used for the TARN population (average cost of spinal protection was £5.49 per person). It was thought that costs could be reduced by limiting the number of protections that patients could have, so as a comparison, the GDG were presented with the cost per person of a single application of full spinal protection. On the assumption that patients do not need re-immobilisation, the cost of full spinal protection per person is slightly lower than the average cost of protection in current practice (£4.97 per person). However, full spinal protection involves a combination of devices and as such, is the most

	expensive single measure for immobilisation. The vast majority of these costs come from the single use collar, which costs around £4.80 each. For reusable equipment, such as a vacuum mattress, even with a conservative lifetime usage estimate of 2000, the effect on the cost per person is minimal. The GDG took into consideration that the TARN population is a specific population with a higher severity of condition compared with the general trauma population and therefore, does not necessarily fully reflect the trauma population as a whole. The GDG agreed that the clinical review evidence was lacking in terms of informing the group about which device was better at immobilising people and not exacerbating an existing spinal injury. A consensus recommendation was reached using the expertise and guidance of the GDG on the devices which could be seen as the most appropriate. As a full immobilisation involves a combination of devices, this leads to a higher cost, however, it could prevent the need for re-immobilisation and potentially reduce the overall cost. The GDG agreed that the equipment listed in the recommendation was cost-effective due to the small cost per use and the important benefits of having the necessary equipment to provide appropriate protection for patients with spinal injury.
Quality of evidence	Seven parallel RCTs or randomised crossover trials reporting on outcomes specified in the protocol were identified. All of the studies were in the indirect population of healthy volunteers. The outcomes were graded as Low or Very low quality. **Aspen collar versus Philadelphia collar** There were clinically important benefits for the Aspen collar in terms of temperature and percentage relative humidity, and no harms were reported. **Padded board versus unpadded board** There were clinically important benefits for the padded board in terms of pain, and no harms were reported. **Board versus vacuum** There were clinically important harms for the board in terms of comfort, occipital pain, lumbosacral pain and any symptom at first exposure. **Backboard versus backboard and mattress plus foam/blanket** There were clinically important harms for the backboard in terms of comfort. **Unpadded head support versus padded head support** There were clinically important benefits for the unpadded head support in terms of immediate neck pain, immediate shoulder pain, immediate buttock pain and lumbar pain at 24 hours. However, there were also harms in terms of immediate head and immediate lumbar pain.
Other considerations	**Immobilisation methods** The GDG acknowledged there was a call for advice on how to immobilise the spine but noted that methods used to immobilise the spine are dependent on the circumstances and it is difficult to cover all scenarios in this guideline. Equally it is impossible to describe a, 'one fits all' situation without being appearing prescriptive and this could be potentially counterproductive if rigidly adhered to. To address this the GDG have listed the key principles of

immobilising the spine in the recommendations but also noted the methods and practices to carry out spinal immobilisation are well documented in detail elsewhere (for example, ATLS, and in 'Moving and handling patients with actual or suspected spinal cord injuries (SCI) produced by the Spinal Cord Injury Centres of the United Kingdom and Ireland).

The GDG noted the following points about commonly used spinal immobilisation equipment. In general spinal immobilisation equipment in the hospital setting should not comprise of non-CE marked items e.g. rolled up towels, saline bags and tape. Such items are likely not to be fit for purpose and also can significantly reduce image quality.

Collars

A collar should be sized and fitted correctly (not too tightly and should be loosened if necessary, avoiding hyper-extension). For patients with ankylosing spondylitis and rheumatoid arthritis, manual in-line stabilisation is an appropriate substitute for a collar. This may also apply to people with short and wide necks. For patients with a suspected head injury, a collar may increase intracranial pressure and should be applied with caution.

Vacuum mattress and scoop stretcher

The GDG noted that when placing someone on a scoop it was important to minimise movement. To minimise movement of the spine utilise a 10 degrees tilt to left and right while two hemi scoops are inserted. This should ideally be undertaken by 5 people.

The GDG considered that the vacuum mattress had particular benefits in terms of keeping patients warm, providing protection from adverse environments, providing secure immobilisation for extrications (for example, upstairs), allowing carriage over a distance to the hospital transport and providing additional security to a scoop stretcher, allowing patients to 'feel secure'.

The availability of a vacuum mattress on a helicopter and/or an ambulance may be down to space, weight and/or cost. It may not necessary place the scoop inside the vacuum mattress for every incident. If the journey to the receiving hospital is more than 45 minutes, the patient should be placed inside the vacuum mattress and the scoop removed. Some examples of when the scoop would be placed inside the vacuum mattress would be if there was a short distance carrying the patient to either the helicopter or the ambulance; carrying the patient down the stairs; or keeping the patient warm.

The GDG noted a possible disadvantage of the scoop stretcher in terms of the need to be removed from it as soon as possible to avoid pressure-related injuries, despite the competing need for minimising movement at this stage.

9 Destination (immediate)

9.1 Introduction

Until recently, patients with spinal injury, either column or cord, have been transferred from the scene of the accident to the nearest emergency department (ED). With the recent development of trauma networks with major trauma centres (MTCs), local protocols for the management of patients with spinal injury may recommend transfer to MTCs in preference to the nearest ED, but this is not routine.

The initial choice of destination for a person presenting with actual or potential spinal injury is therefore often made by the healthcare practitioners attending the incident scene. A substantial variation in NHS trauma service provision and facilities exists between potential destination hospitals as much as their geographical distance from scene. The attending team are required to calculate destination depending upon the presence of immediate life-threatening injuries, transport modes available, the proximity and scope of local ED and supporting trauma facilities, and the potential for the person to deteriorate during transportation.

There is a need for guidance to facilitate optimal decision-making on the destination for the person with spinal injuries. This chapter contains the results of two reviews – one for spinal column injury and one for spinal cord injury (SCI). These have been dealt with separately as the needs, and the destination requirements, of people with these two conditions differ considerably.

9.2 Review question: What is the optimal immediate destination of a person at risk of a traumatic spinal column injury?

For full details see review protocol in Appendix C.

Table 20: PICO characteristics of review question

Population	Children, young people and adults at risk of a traumatic spinal column injury with and without neurology and without other life threatening injuries
Intervention/s	Major trauma centre (combined and/or isolated)
Comparison/s	• ED of district general hospital • Trauma unit (TU)
Outcomes	Critical: • Mortality at 1, 6 and 12 months and 2 years • Health-related quality of life • Missed diagnosis • Misdiagnosis • Adverse events: changes in neurology Important: • Length of hospital stay • Discharge destination and transitional • Patient-reported outcomes (pain/discomfort, return to normal activities, psychological wellbeing, psychosocial wellbeing) Population size and directness: • No limitations on sample size

	• Studies with indirect populations will not be considered
Study design	Retrospective and prospective cohorts

9.3 Clinical evidence

No relevant studies were identified for this question.

9.4 Economic evidence

Published literature

No relevant economic evaluations were identified.

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

9.5 Evidence statements

Clinical

No relevant clinical studies were identified.

Economic

No relevant economic evaluations were identified.

9.6 Review question: What is the optimal immediate destination of a person at risk of a traumatic spinal cord injury?

For full details see review protocol in Appendix C.

Table 21: PICO characteristics of review question

Population	Children, young people and adults at risk of a traumatic SCI with and without neurology and without other life threatening injuries
Intervention/s	SCI centre (SCIC)
Comparison/s	Major trauma centre (combined and/or isolated)
Outcomes	Critical: • Mortality at 1, 6 and 12 months and 2 years • Health-related quality of life • Missed diagnosis • Misdiagnosis • Adverse events: changes in neurology Important: • Length of hospital stay • Discharge destination and transitional • Patient-reported outcomes (pain/discomfort, return to normal activities, psychological wellbeing, psychosocial wellbeing) Population size and directness: • No limitations on sample size • Studies with indirect populations will not be considered

Study design	Retrospective and prospective cohorts

9.7 Clinical evidence

One retrospective cohort study was included in the review[36]. Evidence from this study is summarised in the clinical evidence summary table below (Table 23). See also the clinical GRADE evidence profile in Appendix H, study selection flow chart in Appendix D, study evidence tables in Appendix G and exclusion list in Appendix J.

One study [36] in the USA compared outcomes in trauma patients admitted to level I trauma centre compared with a level II trauma centre. Level I and level II trauma centres are the equivalent of MTCs and a trauma unit, respectively. A level I trauma centre is a comprehensive regional resource that is a tertiary care facility central to the trauma system. They are capable of providing total care for every aspect of injury – from prevention through rehabilitation. A level 1 centre will have 24-hour in-house coverage by general surgeons, and prompt availability of care in specialties such as orthopaedic surgery, neurosurgery, anaesthesiology, emergency medicine, radiology, internal medicine, plastic surgery, oral and maxillofacial, paediatric and critical care. A level II trauma centre is able to initiate definitive care for all injured patients. Elements of Level II centres include 24-hour immediate coverage by general surgeons, as well as coverage by the specialties of orthopaedic surgery, neurosurgery, anaesthesiology, emergency medicine, radiology and critical care. Tertiary care needs such as cardiac surgery, haemodialysis and microvascular surgery may be referred to a Level I centre.

Only the subgroup of patients with quadriplegia is reported here.

Table 22: Summary of studies included in the review

Study	Intervention/comparison	Population	Outcomes	Comments
Demetriades 2005[36]	American College of Surgeons (ACS) level I centre n=648 Essential characteristics: General surgery residency program, Advanced Trauma Life Support provide/participate, research, extramural educational presentation, cardiac surgery, microvascular/replant surgery, trauma admissions greater than or equal to 1200/year with greater than or equal to 240 patients with ISS >15 or 35 patients/surgeon with ISS >15, operating room and personnel immediately available 24 hours/day, surgical ICU physician in-house 24 hours/day, surgically directed and staffed ICU service, in-house CT technician, MRI, acute haemodialysis. ACS level II centre	Patients older than 14 years of age who were alive on admission to the hospital and had at least one of the following severe injuries: aortic, vena cava, iliac vessels, grade IV/V liver injuries, penetrating cardiac injuries, quadriplegia, or complex pelvic fractures. 1996 to 2003	Mortality Incidence of severe disability	Subgroup of patients with quadriplegia reported here

Study	Intervention/comparison	Population	Outcomes	Comments
	n=244 Characteristics as for level 1 except these are desirable rather than essential.			

Table 23: Clinical evidence summary: Level I versus level II trauma centre

Outcome	Number of studies	Imprecision	GRADE rating	Absolute difference	Control event rate (per 1000)	Control event rate for continuous outcomes
Mortality	1 (892)	Serious	VERY LOW	30 fewer per 1000 (from 89 fewer to 37 more)	262	-
Incidence of severe disability	1 (320)	Very serious	VERY LOW	60 fewer per 100 (from 184 fewer to 32 more)	824	-

9.8 Economic evidence

Published literature

No relevant economic evaluations were identified.

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

9.9 Evidence statements

Clinical

Very low quality evidence from one study comprising 892 people showed that level I trauma centres had a clinically important benefit in terms of mortality compared with level II centres, with serious imprecision.

Very low quality evidence from one study comprising 320 people showed that level I trauma centres had a clinically important benefit in terms of incidence of severe disability compared with level II centres, with very serious imprecision.

Economic

No relevant economic evaluations were identified.

9.10 Recommendations and link to evidence

Recommendations	**29. Transport people with suspected acute traumatic spinal cord injury (with or without column injury), with full in-line spinal immobilisation, to a major trauma centre irrespective of transfer time, unless the person needs an immediate lifesaving intervention.** **30. Ensure that time spent at the scene is limited to giving life-saving interventions.** **31. Divert to the nearest trauma unit if a patient with suspected acute traumatic spinal cord injury (with or without column injury), with full in-line spinal immobilisation, needs an immediate life-saving intervention, such as rapid sequence induction of anaesthesia and intubation, that cannot be delivered by the pre-hospital teams.** **32. Do not transport people with suspected acute traumatic spinal cord injury (with or without column injury), with full in-line spinal immobilisation, directly to a spinal cord injury centre from the scene of the incident.** **33. Transport adults with suspected spinal column injury without suspected acute traumatic spinal cord injury, with full in-line spinal immobilisation, to the nearest trauma unit, unless there are pre-hospital triage indications to transport them directly to a major**

	trauma centre. **34. Transport children with suspected spinal column injury (with or without spinal cord injury) to a major trauma centre.** **35. Be aware that the optimal destination for patients with major trauma is usually a major trauma centre. 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.**
	Refer to Major trauma: Service delivery chapter 6 for the evidence review on appropriate destination for the major trauma patient.
Relative values of different outcomes	The outcomes for column and cord injury are the same. The GDG agreed that the critical outcomes to inform decision making for the immediate destination of people with isolated spinal column injuries are mortality up to 2 years, health-related quality of life, missed and misdiagnosis, and changes in neurology. These outcomes were chosen to evaluate the associated complications of spinal column injuries. These complications can result in disability leading to a devastating impact on a person's long-term wellbeing. The group acknowledged that although the prevalence of mortality is low for spinal column injuries, it should be considered in the decision making if reported by any studies. The other important outcomes chosen to reflect whether patients were transported to the correct destination and also to inform the cost impact were length of hospital stay, discharge destination, pain/discomfort, return to normal activities, psychological wellbeing and psychosocial wellbeing.
Trade-off between clinical benefits and harms	**SCI** One study on people with SCI and the immediate destination was identified. There were clinically important benefits in terms of mortality and incidence of severe disability (which was a proxy for changes in neurology) from being sent to a level 1 trauma centre compared with a level II trauma centre. No harms of being sent to a level 1 trauma centre were identified. People rarely have SCIs in isolation and transfer directly to SCIC for a suspected SCI was considered by the GDG to result in an increased risk of mortality and morbidity rates. This is as a result of a SCIC not having the access to services to adequately manage a multiply injured patient. If a person with a suspected SCI is considered stable (for example, their airway, breathing and circulation are not presenting life-threatening problems) they should be transferred directly to a MTC, where they can receive the most appropriate definitive care. This is contrary to the current practice of diverting to a TU if the distance to travel is over 45 minutes to a MTC. See recommendations 6, 7 and 8 in chapter 6 of the Major trauma service delivery full guideline. The GDG discussed the risks of travelling the extra distance to a MTC against the benefits. The GDG agreed that a MTC should have all the services are required to manage a person with a SCI as set out in The NHS standard contract for Major trauma services (2013).

	TUs do not have the same level of service to manage a person with a SCI. This includes the assessments and treatment plans necessary for effective long-term management. The GDG discussed the benefits of a reduction in inter-hospital transfers and particularly noted that patients would receive definitive care quicker and would have rapid access to specialist care. **Spinal column injury** No studies were identified on people with spinal column injury. In adults, the majority of isolated column injuries do not require the specialities located at a MTC and can be adequately managed by a TU with advice from a MTC. It is not always possible for ambulance staff to assess if a person has an isolated column fracture and in these circumstances, the person should be transferred to a MTC. Children and young people should be transferred to a MTC because they require immediate access to the expertise of a paediatric spinal surgeon. These surgeons are usually based or easily accessed in MTCs and not in a TU.
Economic considerations	No economic evidence was found relating to the immediate destination of people with spinal injuries. For a person with multiple injuries, initial surgical treatment may be required from an MTC, with later secondary transfer to a SCIC. This is likely to be clinically efficacious for patients with time critical conditions requiring management from an array of subspecialists. Such treatment at the earliest opportunity may reduce poor health outcomes, overall hospital stay and costs. However, secondary transfer from the MTC to the SCIC would incur the additional costs of an ambulance and crew. On the other hand, delaying treatment from an SCIC could lead to deterioration in neurological condition and an increase in recovery time. This will incur further costs of hospital stay, as well as potentially incurring the cost of additional treatment for adverse events, such as pressure sores, which developers felt were more likely to occur in non-specialist units. The optimal time of referral is discussed further in chapter 14. If a SCIC is the appropriate final destination (directly or indirectly) for all people with suspected spinal injury, the overall cost of an indirect transfer strategy could be higher than a direct transport for reasons outlined above. This said, if the SCIC is not the final destination for all people with suspected spinal injury, direct transport to the SCIC from the scene could result in the inappropriate use of SCIC specialist beds as well as incurrence of costs from secondary transfer to the MTC, TU or local hospital. Capacity at a SCIC is likely to be an issue because of the specialist nature of the centre and there is therefore likely to be limited capacity. The opportunity cost of using capacity in the SCIC is important and there may be other patients who are waiting to be transferred to use these expert resources. Overall, taking into account that not all people suspected with SCI will require the services of SCIC and that the MTC may be better equipped to manage a range of trauma injuries, it was felt the balance was in favour of directing patients to the MTC, rather than direct transfer to the SCIC. For adults with an isolated column injury, the GDG thought that a substantial proportion of this population would be elderly people who have had a fall. It is

	current practice to treat these patients in a TU and it was thought there would be little additional clinical benefit in sending these patients directly to a MTC. Also, as resources (bed capacity) are constrained at MTCs, and other patients would benefit more from these specialist resources, it was felt cost effective to send adults with an isolated column injury to the TU. It is common policy for patients with SCI to be triaged and sent to a MTC, the recommendation does not deviate from current practice and the cost impact of this recommendation is expected to be neutral.
Quality of evidence	One retrospective cohort study rated as Very low quality was identified comparing the optimal immediate destination of a person at risk of a traumatic SCI. Although the study was from the USA, the GDG thought that the level I and level II trauma centres were the UK equivalent of a major TU and ED in a district general hospital. Although the study population was wider than the review question, covering injuries characteristic of major trauma rather than just SCI, the evidence used for this review was a sub-group with quadriplegia, which fits within the review population. Hence evidence was viewed as direct evidence. Odds ratios adjusted for the main confounders were reported in the study. The confidence intervals for both the relative and absolute effect were relatively imprecise around the estimate of effect, reducing confidence in the point estimates. No relevant studies were retrieved which looked at the optimal immediate destination of a person at risk of a traumatic spinal column injury
Other considerations	Despite the absence of good quality evidence, the GDG considered it was important to make a recommendation on the immediate destination of a person with a suspected spinal cord or column injury. This is a strong recommendation in the context of an absence of evidence, however, the GDG wanted to highlight that this recommendation comes at the beginning of the clinical pathway for the SCI person and the management has not only an immediate but an enduring impact on a person's health-related quality of life.

10 Diagnostic imaging

10.1 Introduction

Spinal injury is a general term which can be divided into 'spinal column injury' where there has been a fracture, dislocation or subluxation affecting the vertebral column (this includes bony injury and/or injury to the associated ligaments); or a 'spinal cord injury' (SCI) where damage to the spinal cord has occurred. SCIs are usually, though not always, associated with a spinal column injury. The incidence of a SCI is less than that of spinal column injury, but frequently has severe and long-lasting sequelae.

It is important to quickly diagnose spinal column injuries to avoid the potential of conversion to a SCI. The need to image to confirm injury in the unconscious patient is obvious and although SCIs are usually evident clinically in the conscious patient, imaging is important to define the level of the injury. This chapter evaluates the diagnostic accuracy of each of the currently available imaging modalities at diagnosing a spinal column or SCI.

10.2 Review question:

a) What is the diagnostic accuracy of i) X-ray, ii) dynamic fluoroscopy, iii) CT and iv) MRI, for people with spinal cord injury (with or without column injury)?

b) What is the diagnostic accuracy of i) X-ray, ii) dynamic fluoroscopy, iii) CT and iv) MRI, for people with isolated spinal column injury?

For full details see review protocol in Appendix C.

Table 24: PICO characteristics of review question

Population	Children, young people and adults with suspected SCI (with or without column injury) or suspected isolated spinal column injury
Index test	• X-ray • Dynamic fluoroscopy • CT • MRI
Reference test	• Surgical findings • Later clinical findings • Autopsy findings MRI and CT may serve as gold standards for X-ray and dynamic fluoroscopy. CT may serve as gold standard for any index test designed to detect bony injuries. MRI may serve as gold standard for any index test designed to detect SCIs.
Outcomes	Diagnostic accuracy (sensitivity, specificity, positive predictive value, negative predictive value, likelihood ratios) Adverse events: effects of radiation
Study type	Cross-sectional, retrospective and prospective cohorts

For this review, studies evaluating the diagnostic accuracy of cervical imaging in people with concurrent head injury were not included, as they have already been reviewed as part of the Head Injury guideline. Cross-referral to the Head Injury guideline will therefore occur to cover diagnostic accuracy of that particular group.

This review has been separated into 2 main sections: diagnostic accuracy in a) adults and b) children. Each of these has been further subdivided into 4 main sections: 1) SCIs in the cervical region, 2) SCIs in the thoracolumbar region, 3) isolated spinal column injuries in the cervical region, 4) isolated spinal column injuries in the thoracolumbar region.

None of the studies reported adverse effects.

10.3 Clinical evidence

10.3.1 Adults

SCI in the cervical region (adults)

No articles were found.

SCI in thoracolumbar region (adults)

A total of 3 articles were found[103,107,111]. These all dealt with the index test of CT compared with the reference test of MRI for cord (or associated) pathology. These studies included children, but as the majority of participants were adults, no subgrouping was performed within any of the studies.

Table 25: Summary of studies included in the review

Study	Population	Index test(s)	Reference test	Comments
Silberstein 1992B [103]	People with spinal trauma n=34	CT (soft tissue)	MRI (soft tissue)	Rigorous study
Tarr 1987[107]	People with suspected recent spinal trauma n=14	CT (soft tissue)	MRI (soft tissue)	Mostly thoracolumbar, but some cervical trauma included. Gold standard not described in study, but has been imposed by the reviewer, based on choice of reference standards in other studies.
Tracy 1989[111]	People with acute spinal injury n=13	CT (soft tissue)	MRI (soft tissue)	Gold standard not described in study. Gold standard has been imposed by the reviewer, based on choice of reference standards in other studies.

Quality of evidence

Risk of bias for each outcome was determined by the QUADAS-2 criteria, as shown in Chapter 4. This has informed the risk of bias rating given in the GRADE clinical evidence profile tables (Table 26 to Table 51). If there were 2 or more major limitations according to the QUADAS criteria, a rating of very serious limitations was given. If there was a single major limitation a rating of serious limitations was given. These ratings contributed to the overall GRADE ratings reported in Table 26 to Table 51.

Diagnostic accuracy of CT for SCI

Table 26: Clinical evidence profile: Studies evaluating CT in relation to the reference test of MRI for SCI

Number and name of studies	Population (n) [In study order]	Risk of bias	Inconsistency	Indirectness	Imprecision	Sensitivity (95% CI) [In study order]	Specificity (95% CI)	Quality
Diagnostic accuracy CT in relation to the reference test of MRI for disc herniation								
3 Silbertstein (1992B) Tracy (1989) Tarr (1987)	People with trauma (34) People with acute spinal injury (27) People with suspected spinal trauma (14)	VS[a]	N	N	NA	0 (0-0.41) 0 (0-0.71) 0.4 (0.05-0.85) Median 0 (0 to 0.71)	1.0 (0.87-1) 1.0 (0.8-1) 1(0.66-1) Median 1 (0.66 to 1)	LOW
Diagnostic accuracy CT in relation to the reference test of MRI for extramedullary haematoma								
1 Silbertstein (1992B)	People with trauma (34)	N	NA	N	NA	0 (0-0.23)	1.0 (0.83-1)	HIGH
Diagnostic accuracy CT in relation to the reference test of MRI for epidural haematoma								
2 Tracy 1989 Tarr 1987	People with acute spinal injury (27) People with suspected spinal trauma (14)	VS[b]	N	N	NA	0 (0-0.84) 0 0-0.71) Median 0 (0. To 0.71)	1(0.72-1) 1(0.81-1) Median 1 (0.72 to 1.0)	LOW
Diagnostic accuracy CT in relation to the reference test of MRI for spinal cord oedema/haemorrhage or haematoma								

Number and name of studies	Population (n) [In study order]	Risk of bias	Inconsistency	Indirectness	Imprecision	Sensitivity (95% CI) [In study order]	Specificity (95% CI)	Quality
2 Tracy 1989 Tarr 1987	People with acute spinal injury (27) People with suspected spinal trauma (14)	VS[b]	N	N	NA	0 (0-0.6) 0 (0-0.84) Median: 0 (0 to 0.84)	1 (0.69-1) 1(0.81-1) Median 1 (0.69 to 1)	LOW
Diagnostic accuracy CT in relation to the reference test of MRI for transection of spinal cord								
1 Tracy 1989	People with acute spinal injury (27)	VS[c]	NA	N	NA	0 (0-0.71)	1(0.8-1)	Low
Diagnostic accuracy CT in relation to the reference test of MRI for cord compression/cord or thecal sac impingement								
2 Silbertstein (1992B) Tarr 1987	People with trauma (34) People with suspected spinal trauma (14)	S[d]	S[e]	N	NA	0 (0-0.26) 0.5 (0.07-0.93) Median 0 (0 to 0.26)	1.0 (0.74-1) 1.0 (0.69-1) Median 1 (0.69 to 1.0)	Low

Abbreviations: N, no serious limitations; S, serious limitations; VS, very serious limitations; NA, not applicable

(a) No reports of blinding, and up to 5 day interval between different tests in Tracy1989. No reports of blinding, and up to 2.5 week interval between different tests in Tarr1987. No flaws in Silbertstein1992B. Overall very serious limitations for outcome

(b) No reports of blinding, and up to 5 day interval between different tests in Tracy1989. No reports of blinding, and up to 2.5 week interval between different tests in Tarr1987. Overall very serious limitations for outcome

(c) No reports of blinding, and up to 5 day interval between different tests

(d) No reports of blinding, and up to 2.5 week interval between different tests in Tarr1987. No flaws in Silbertstein1992B, so overall serious limitations for outcome

(e) Inconsistency across studies in sensitivity

Isolated spinal column injury in the cervical region (adults)

Twenty one[3,5,8,9,24,26,33,41,42,48,50,57,58,70,72,76,77,80,94,97,106] articles were found. The outcomes from these studies have been sub-divided into groups evaluating the diagnostic accuracy of:

- X-ray, in relation to
  - the reference test of CT
  - the reference test of MRI
  - discharge diagnosis
  - composite findings (such as later clinical outcomes/discharge diagnosis, plus other imaging findings)
- CT, in relation to
  - the reference test of MRI, for soft tissue (non-cord) spinal column injuries
  - discharge diagnosis
  - composite findings (such as later clinical outcomes/discharge diagnosis, plus other imaging findings)
- MRI, in relation to
  - the reference test of CT, for bony non-cord injuries
  - final clinical diagnosis

Table 27: Summary of studies included in the review

Study	Population	Index test(s)	Reference test	Comments
Adams 2006[3]	Adults with significant blunt trauma n=97	CT	MRI	
Antevil 2006[5]	Adults with trauma n=319	CT	Composite findings	A small proportion (<10%) had adjunctive X-rays as part of the index test
Awan 2011[8]	Adults with trauma n=200	X-rays	CT	Different resolution of X-ray images compared
Bailitz 2009[9]	Adults with trauma and NEXUS criteria n=50	X-ray OR CT	Clinical outcome	
Brohi 2005[24]	Adult unconscious and intubated trauma patients n=442	CT OR X-ray	MRI and/or clinical outcome, OR CT	CT used as 'gold standard' for X-ray, but MRI/clinical outcome used as gold standard for CT
Brown 2010[26]	Adults with blunt trauma n=106	CT	MRI	Images from medical notes not re-interpreted for purposes of study – the actual diagnosis given in real time was used
Cohn 1991[33]	Adults with trauma n=60	X-ray	Composite findings	Gold standard unclearly described
Duane 2008[42]	People with blunt trauma aged >16 years n=1004	X-ray	CT	
Duane 2010[41]	Adults with blunt trauma n=49	F/E X-rays	MRI	
Goodnight	Adults sustaining blunt	F/E X-rays	Composite	

Study	Population	Index test(s)	Reference test	Comments
2008[48]	trauma n=379	OR CT	evidence, including MRI	
Griffen 2003[50]	Adults with blunt trauma n=116	X-ray OR CT	Clinical outcome	
Harris 2008[57]	Obtunded adults with blunt trauma n=367	CT	Composite findings	Only people with a negative index test were included, so only negative predictive value calculable
Hashem 2009[58]	Adults with a positive diagnosis of cervical spine injury n=215	X-ray OR CT	Clinical outcome	Only sensitivity calculable as only those with gold standard diagnosis included
Klein 1999[70]	Mainly adults (youngest 15 years) with trauma n=42	MRI	CT	Clear blinding
Lee 2001[72]	Adults with trauma presenting at emergency department n=604	X-rays	Helical CT	Data only provided for those with true diagnosis
Macdonald 1990[76]	Adults with trauma from motor vehicle crashes n=775	X-ray	Composite tests	
Mathen 2007[77]	Adults with trauma n=667	X-rays OR CT	Composite tests	
Mower 2001[80]	Adults and children (mean age 37) with blunt trauma n=818	X-ray	Final diagnosis	Only TP and FN data available
Ptak 2001[94]	Adults with multi-trauma n=676	Helical scanning CT	Clinical diagnosis and final outcome	Unclear to what extent the gold standard depended in the index test (thus introducing possibility that measures of diagnostic accuracy would be artificially enhanced)
Resnick 2014[97]	Adults with blunt trauma	Helical scanning CT	Clinical diagnosis and final outcome	Looked at both clinically important injuries and all injuries. Blinding unclear
Takami 2014[106]	Adults with trauma n=179	X-ray	Whole spine CT	

Quality of evidence

Risk of bias for each outcome was determined by the QUADAS-2 criteria, as shown in chapter 4. This has informed the risk of bias rating given in the GRADE clinical evidence profile tables (Table 28 to Table 35). If there were two or more major limitations according to the QUADAS criteria, a rating of very serious limitations was given. If there was a single major limitation a rating of serious limitations was given. These ratings contributed to the overall GRADE ratings reported in Table 28 to Table 35.

Diagnostic accuracy of X-ray for cervical fractures/injuries

Table 28: Clinical evidence profile: Studies evaluating X-ray in relation to the reference test of CT for cervical fractures/injuries

Number and name of studies	Population (n) [IN STUDY ORDER]	Risk of bias	Inconsistency	Indirectness	Imprecision	Sensitivity (95% CI)	Specificity (95% CI)	Quality
Diagnostic accuracy of X-ray in relation to the reference test of CT for cervical fractures in adults								
4 Lee 2001	Adult trauma unit patients (604)	VS[a]	S[b]	N	NA	0.33 (0.19-0.51)	-	VERY LOW
Duane2008	Blunt trauma patients aged >16 years (1004)					0.19 (0.11-0.29)	0.99 (0.98-1)	
Awan 2011	Adult trauma unit patients (200)					0.74 (no raw data to allow estimation)	0.79 (no raw data to allow estimation)	
Takami 2014	Adult trauma (179)					0.625 (0.35-0.85) Median 0.625 (0.35 to 0.85)	-	
Diagnostic accuracy of X-ray in relation to the reference test of CT for cervical injuries in adults								
1 Brohi 2005	Unconscious intubated adults trauma patients (442)	VS[c]	NA	N	NA	0.72 (0.59-0.83)	0.94 (0.91-0.96)	LOW

Abbreviations: n, no serious limitations; S, serious limitations; VS, very serious limitations; NA, not applicable

(a) Unclear blinding and unclear time between index and reference tests for Lee 2001, Takami 2014 and Duane 2008, but unclear blinding alone for Awan 2011; overall, very serious limitations

(b) Inconsistency between studies for sensitivity

(c) Unclear blinding and unclear time between index and reference tests

Table 29: Clinical evidence profile: Studies evaluating X-ray in relation to the reference test of MRI for cervical ligament injuries

Number and name of studies	Population (n)	Risk of bias	Inconsistency	Indirectness	Imprecision	Sensitivity (range)	Specificity (range)	Quality
Diagnostic accuracy of X-ray in relation to the reference test of MRI for cervical ligament injuries in adults								
1 Duane 2010	Adult blunt trauma patients (49)	VS[a]	NA	N	NA	0 (0-0.37)	0.98(0.87-1)	LOW

Abbreviations: n, no serious limitations; S, serious limitations; VS, very serious limitations; NA, not applicable

(a) Unclear blinding and unclear time between index and reference tests

Table 30: Clinical evidence profile: Studies evaluating X-ray in relation to the reference test of discharge diagnosis for cervical injuries

Number and name of studies	Population (n) [in study order]	Risk of bias	Inconsistency	Indirectness	Imprecision	Sensitivity (95% CI) [in study order]	Specificity (95% CI)	Quality
Diagnostic accuracy of X-ray in relation to the reference test of later outcomes – cervical injuries in adults								
5 Mower 2001	Adults with blunt trauma (818)	VS[a]	S[b]	N	NA	0.61(0.57-0.64)	-	VERY LOW
McDonald 1990	Adults with trauma from MVC (818)					0.83 (0.73-0.9)	0.97 (0.96-0.98)	
Bailitz 2009	Adults with trauma (50)					0.36(0.23-0.51)	-	
Hashem 2009	Adults with a positive diagnosis of cervical spine injury (215)					0.61 (0.52-0.7)	-	
Griffen 2003	Adults with blunt trauma (116)					0.65 (0.55-0.73) Median 0.61 (0.52 to 0.7)	-	

Abbreviations: n, no serious limitations; S, serious limitations; VS, very serious limitations; NA, not applicable

(a) Unclear blinding and unclear time between index and reference tests for Mower2001, Hashem2009 and Griffen2003, and only unclear time between tests for McDonald1990 and Bailitz2009; overall very serious limitations
(b) Some inconsistency in sensitivity (mainly between Bailitz2009 and all others)

Table 31: Clinical evidence profile: Studies evaluating X-ray in relation to the reference test of composite outcomes for cervical fractures

Number and name of studies	Population (n) [in study order]	Risk of bias	Inconsistency	Indirectness	Imprecision	Sensitivity (95% CI) [in study order]	Specificity (95% CI)	Quality
Diagnostic accuracy X-ray in relation to the reference test of composite outcomes – adult ligamentous cervical injuries								
1 Goodnight 2008	Adults with blunt trauma(379)	VS[A]	NA	N	NA	1(0.54-1)	0.97 (0.95-0.99)	LOW
Diagnostic accuracy X-ray in relation to the reference test of composite outcomes – adult cervical injuries								
2 Mathen 2007 Cohn 1991	 Adult trauma patients (667) Adult trauma patients (60)	VS[B]	NA	N	NA	0.45 (0.32-0.58) 0.63(0.24-0.91) Median 0.45(0.32 to 0.58)	0.97 (0.96-0.98) 1(0.95-1) Median 0.97 (0.96 to 0.98)	LOW

Abbreviations: n, no serious limitations; S, serious limitations; VS, very serious limitations; NA, not applicable

(a) Unclear blinding and unclear time between index and reference tests
(b) Unclear time between index and reference tests

Diagnostic accuracy of CT for cervical fractures/injuries

Table 32: Clinical evidence profile: Studies evaluating CT in relation to the reference test of discharge diagnosis for cervical fractures

Number and name of studies	Population (n) [in study order]	Risk of bias	Inconsistency	Indirectness	Imprecision	Sensitivity (95% CI) [In study order]	Specificity (95% CI)	Quality
Diagnostic accuracy of CT in relation to the reference test of later outcomes – cervical fractures in adults								

Number and name of studies	Population (n) [in study order]	Risk of bias	Inconsistency	Indirectness	Imprecision	Sensitivity (95% CI) [In study order]	Specificity (95% CI)	Quality
2 Ptak 2001 Antevil 2006	Multi-trauma adult patients (676) Adults with trauma (319)	VS[a]	N	N	NA N	0.98 (0.91-1) 1 (0.9-1) Median 0.98 (0.91 to 1.0)	1(0.99-1) -	LOW
Diagnostic accuracy of CT in relation to the reference test of later outcomes – cervical injury in adults								
4 Bailitz 2009 Hashem 2009 Griffen 2003 Resnick 2014	Adult trauma (50) Adults with a positive diagnosis of cervical spine injury (215) Adults with blunt trauma (116) Adults with blunt trauma (824)	VS[b]	N	N	NA	1(0.93-1) 1(0.97-1) 1(0.97-1) 0.91 (0.85-0.95) Median 1 (0.93 to 1.0)	- - - 1(0.99-1)	LOW
Diagnostic accuracy of CT in relation to the reference test of later outcomes – clinically important cervical injury in adults								

Number and name of studies	Population (n) [in study order]	Risk of bias	Inconsistency	Indirectness	Imprecision	Sensitivity (95% CI) [In study order]	Specificity (95% CI)	Quality
1 Resnick 2014	Adults with blunt trauma (824)	VS[b]	N	N	NA	1(0.98-1)	1(0.99-1)	LOW

Abbreviations: *n, no serious limitations; S, serious limitations; VS, very serious limitations; NA, not applicable*

(a) Unclear blinding and unclear time between index and reference tests for Antevil2006, and unclear time between tests for Ptak2001; overall very serious limitations
(b) Unclear blinding and unclear time between index and reference tests for Hashem2009 , Resnick 2014 and Griffen2003, unclear time between tests for Bailitz2009; overall very serious limitations.

Table 33: Clinical evidence profile: Studies evaluating CT in relation to the reference test of composite outcomes for cervical injuries

Number and name of studies	Population (n) [in study order]	Risk of bias	Inconsistency	Indirectness	Imprecision	Sensitivity (95% CI) [in study order]	Specificity (95% CI) [in study order]	Quality
Diagnostic accuracy CT in relation to the reference test of composite outcomes – cervical ligamentous injuries								
1 Goodnight 2008	Adults sustaining blunt trauma (379)	VS[a]	NA	N	NA	1(0.54-1)	0.97(0.94-0.98)	LOW
Diagnostic accuracy CT in relation to the reference test of composite outcomes – cervical injuries								
1 Brohi 2005	Unconscious and intubated patients with trauma (442)	VS[a]	NA	N	NA	0.98 (0.9-1)	0.99(0.97-1)	LOW

Abbreviations: *n, no serious limitations; S, serious limitations; VS, very serious limitations; NA, not applicable*

(a) Unclear blinding and unclear time between index and reference tests

Table 34: Clinical evidence profile: Studies evaluating CT in relation to the reference test of MRI for cervical injuries

Number and name of studies	Population (n) [in study order]	Risk of bias	Inconsistency	Indirectness	Imprecision	Sensitivity (95% CI) [in study order]	Specificity (95% CI)	Quality
Diagnostic accuracy CT in relation to the reference test of MRI for cervical fracture								
1 Adams 2006	People with significant blunt trauma (97)	VS[a]	NA	N	NA	0.94 (no raw data to allow estimation)	0.88 (no raw data to allow estimation)	LOW

Abbreviations: *n, no serious limitations; S, serious limitations; VS, very serious limitations; NA, not applicable*

(a) Unclear blinding and unclear time between index and reference tests

Diagnostic accuracy of MRI for cervical injuries

Table 35: Clinical evidence profile: Studies evaluating MRI in relation to the reference test of CT for cervical fractures

Number and name of studies	Population (n) [in study order]	Risk of bias	Inconsistency	Indirectness	Imprecision	Sensitivity (95% CI) [in study order]	Specificity (95% CI)	Quality
Diagnostic accuracy MRI in relation to the reference test of CT for anterior element cervical fracture								
1 Klein	People with trauma (42)	S[a]	NA	N	NA	0.36 (0.25-0.5)	0.98(0.92-1)	MODERATE
Diagnostic accuracy MRI in relation to the reference test of CT for posterior element cervical fracture								
1 Klein	People with trauma (42)	S[a]	NA	N	NA	0.12(0.06-0.21)	0.97(0.89-1)	MODERATE

Abbreviations: *n, no serious limitations; S, serious limitations; VS, very serious limitations; NA, not applicable*

(a) Unclear time between index and reference tests

Isolated spinal column injury in the thoracolumbar region (adults)

Eighteen articles[10,11,25,28,35,59,64,65,68,71,92,98,99,102,103,107,111,115] were found. The outcomes from these studies have been sub-divided into groups evaluating the diagnostic accuracy of:

- X-ray, in relation to
  - the reference test of CT
  - the reference test of MRI
  - discharge diagnosis
  - composite findings (such as later clinical outcomes/discharge diagnosis, plus other imaging findings)
- CT, in relation to
  - the reference test of MRI, for soft tissue (non-cord) spinal column injuries
  - discharge diagnosis
  - composite findings (such as later clinical outcomes/discharge diagnosis, plus other imaging findings)
- MRI, in relation to
  - the reference test of CT, for bony non-cord injuries
  - surgery, for soft tissue (non-cord) spinal column injuries

Table 36: Summary of studies included in review

Study	Population	Index test(s)	Reference test	Comments
Ballock 1992[10]	People with traumatic wedge compression or burst thoracolumbar fractures n=25	X-ray	CT	Subgrouped for orthopaedic surgeons and radiologists. Differentiated burst fracture from wedge compression fracture rather than burst fracture compared with no fracture.
Berry 2005[11]	People with blunt trauma n=103	X-ray CT	Composite outcomes (imaging, discharge summary, consult notes)	Unclear if the gold standard diagnosis was made completely independently of the previous index scanning.
Brown 2005A[25]	People with traumatic lumbar and thoracic fractures n=178	X-ray CT	Composite outcomes (imaging, discharge summary, consult notes)	Subgrouped to lumbar fractures/thoracic fractures. Unclear if the gold standard diagnosis was made completely independently of the previous index scanning.
Campbell 1995[28]	People with traumatic lumbar spine fractures n=53	X-rays	CT	No indication of interval between interval and reference tests.
Dai 2008[35]	People with traumatic compression or burst thoracolumbar fractures n=73	X-ray	CT	Subgrouped for residents and spine surgeons. Differentiated burst fracture from compression fracture rather than burst fracture compared with no fracture.
Hauser 2003[59]	People with high risk of traumatic	X-ray	CT	Unclear if different radiologists carried out index and reference

Study	Population	Index test(s)	Reference test	Comments
	thoracolumbar spine injury n=215			tests. No blinding.
Ito 2006[65]	People with vertebral fragility fractures caused by weak external force n=120	X-ray	MRI	Long interval between X-ray and MRI imaging (up to 4 weeks).
Karul 2013[68]	People with minor trauma n=107	X-rays	CT	Reference tests could have been unblinded to index tests.
Krueger 1996[71]	People with trauma to lumbar spine transverse processes, evident on X-ray n=28	X-ray (for ANY lumbar fracture)	CT (for ANY lumbar fracture)	Gold standard not defined, but for purposes of this review we have designated CT findings as the gold standard. The patients who have transverse process fractures visible on X-ray may also tend to have more visibility of OTHER fractures on X-ray than the general population of those with transverse process fractures. Hence sensitivity may be overestimated.
Pizones 2013[92]	People with suspected acute traumatic thoracolumbar fracture n=58	MRI	Surgery	No reports of blinding
Rhea 2001[98]	People with multiple trauma n=125	X-rays CT	Composite outcomes (imaging, discharge summary, consult notes)	Non-rigorous gold standard: if index tests agreed this agreed status was automatically taken as gold standard. Only if they disagreed was further information used to form the definitive diagnosis.
Rhee 2002[99]	People with blunt trauma n=115	X-rays CT	Composite outcomes (imaging, discharge summary, consult notes)	Only sensitivity data collected. No blinding reported. Unclear if the gold standard diagnosis was made completely independently of the previous index scanning.
Sheridan 2003[102]	People with traumatic thoracolumbar fractures n=78	CT X-rays	Discharge diagnosis	Lack of blinding of the CT results when reviewing X-ray results. All had fractures so sensitivity data only.
Silberstein 1992B[103]	People with spinal trauma n=34	MRI (bony injury) CT (soft tissue injury)	CT MRI	Rigorous study
Takami 2014	Adults with trauma n=179	X-ray	Whole spine CT	
Tarr 1987[107]	People with suspected recent spinal trauma	MRI (bony)	CT (bony)	Mostly thoracolumbar, but some cervical trauma included. Gold

Study	Population	Index test(s)	Reference test	Comments
	n=14			standard not described in study. This has been imposed by the reviewer, based on choice of reference standards in other studies.
Tracy 1989[111]	People with acute spinal injury n=13	MRI (bony) CT (soft tissue)	CT (bony) MRI (soft tissue)	Gold standard not described in study. This has been imposed by the reviewer, based on choice of reference standards in other studies.
Wintermark 2003[115]	People with severe blunt trauma n=100	X-rays CT	Composite outcomes (imaging, discharge summary, consult notes)	Subgrouped for stability of fracture, and also by anterior/middle/posterior column fractures.

Quality of evidence

Risk of bias for each outcome was determined by the QUADAS-2 criteria, as shown in chapter 4. This has informed the risk of bias rating given in the GRADE clinical evidence profiles (Table 37 to Table 45). If there were 2 or more major limitations according to the QUADAS criteria, a rating of very serious limitations was given. If there was a single major limitation a rating of serious limitations was given. These ratings contributed to the overall GRADE ratings reported in Table 37 to Table 45.

Diagnostic accuracy of X-ray for thoracolumbar fractures/injuries

Table 37: Clinical evidence profile: Studies evaluating X-ray in relation to the reference test of CT for thoracolumbar fractures

Number and name of studies	Population (n) [in study order]	Risk of bias	Inconsistency	Indirectness	Imprecision	Sensitivity (95% CI)	Specificity (95% CI)	Quality
Diagnostic accuracy of X-ray in relation to the reference test of CT for thoracolumbar burst fractures in adults (in a restricted population with ONLY burst fractures or wedge compression fractures)								
2 Ballock 1992	Trauma unit patients with either a burst thoracolumbar fracture or a wedge compression fracture (25)	VS[a]	N	N	NA	0.79 (0.60-0.92)	0.87(no raw data to allow estimation)	LOW
Dai 2008	Patients with either a burst thoracolumbar fracture or a compression fracture (73)					0.80 (0.66-0.91) Median 0.79 (0.6o to 0.92)	0.89 (0.71-0.98) Median 0.89 (0.71 to 0.98)	
Diagnostic accuracy of X-ray in relation to the reference test of CT for thoracolumbar fractures in adults								

Number and name of studies	Population (n) [in study order]	Risk of bias	Inconsistency	Indirectness	Imprecision	Sensitivity (95% CI)	Specificity (95% CI)	Quality
2 Hauser 2003 Takami 2014	People with trauma (394)	VS[b]	S	N	NA	0.58(0.41-0.75) 0.86 (0.72-0.95) Median 0.58 (0.41 to 0.75)	0.93(0.89-0.97)	VERY LOW
Diagnostic accuracy of X-ray in relation to the reference test of CT for thoracic fractures in adults								
1 Karul 2013	People with mild trauma (107)	VS[c]	NA	N	NA	0.49(0.37-0.62)	0.55(0.39-0.70)	LOW
Diagnostic accuracy of X-ray in relation to the reference test of CT for unstable lumbar fractures in adults								
1 Campbell 1995	People with traumatic wedge-compression fractures (53)	S[d]	NA	N	NA	0.82(0.66-0.92)	0.79(0.49-0.95)	MODERATE
Diagnostic accuracy of X-ray in relation to the reference test of CT for any lumbar fractures in adults with a transverse lumbar fracture (on X-ray)								
1 Krueger 1996	People with traumatic lumbar transverse process fractures (28)	VS[e]	NA	N	NA	0.75(0.55-0.89)	-	LOW

Abbreviations: *n, no serious limitations; S, serious limitations; VS, very serious limitations; NA, not applicable*

(a) In Ballock and Dai, the group without the diagnosis of interest (burst fracture) themselves had an alternative diagnosis (wedge compression fracture). None had no diagnosis. There might be a difference in the ease of diagnosis when differentiating between two competing diagnoses than between one diagnosis and no diagnosis. Also, interval between index and reference tests not clear in either study. Thus overall the outcome was graded as very serious limitations

(b) Unclear blinding of index test when carrying out reference test in Hauser 2003 and Takami 2014; reference test not likely to accurately classify target condition in Hauser 2003 (CT was appropriately used as the main reference test but if this was not available reference test was "subsequent clinical examination of the patient when fully alert" which may lack rigour)

(c) Unclear blinding of index test when carrying out reference test; long interval between index and reference tests

(d) Unknown interval between index and reference tests

(e) Unclear blinding of index and reference tests; inclusion of only patients diagnosed with X-ray for transverse fracture may have led to bias favouring X-ray sensitivity for other types of fractures

Table 38: Clinical evidence profile: Studies evaluating X-ray in relation to the reference test of MRI for thoracolumbar fractures

Number and name of studies	Population (n)	Risk of bias	Inconsistency	Indirectness	Imprecision	Sensitivity (range)	Specificity (range)	Quality
Diagnostic accuracy of X-ray in relation to the reference test of MRI for thoracolumbar fragility fractures in adults								
1 Ito 2006	People with incident vertebral fragility fractures caused by a weak external force (120)	VS[a]	NA	N	NA	0.55(0.43-0.67)	0.85(0.72-0.93)	LOW

Abbreviations: n, no serious limitations; S, serious limitations; VS, very serious limitations; NA, not applicable

(a) Reference standard could have introduced bias (gold standard of MRI may have made X-rays appear to be more sensitive than they really are, as MRI itself may lack sensitivity in this population); long interval between index and reference tests

Table 39: Clinical evidence profile: Studies evaluating X-ray in relation to the reference test of discharge diagnosis for thoracolumbar fractures

Number and name of studies	Population (n) [in study order]	Risk of bias	Inconsistency	Indirectness	Imprecision	Sensitivity (95% CI) [in study order]	Specificity (95% CI)	Quality
Diagnostic accuracy of CT in relation to the reference test of later outcomes – thoracic fractures								
1 Sheridan 2003	People with thoracolumbar fractures (78)	VS[a]	NA	N	NA	0.58(0.33-0.80)	-	LOW
Diagnostic accuracy of CT in relation to the reference test of later outcomes – lumbar fractures								
1 Sheridan 2003	People with thoracolumbar fractures (78)	VS[a]	NA	N	NA	0.85(0.66-0.96)	-	LOW

Abbreviations: n, no serious limitations; S, serious limitations; VS, very serious limitations; NA, not applicable

(a) Unclear blinding of index test when carrying out reference test, and unclear interval between index and reference tests

Table 40: Clinical evidence profile: Studies evaluating X-ray in relation to the reference test of composite outcomes for thoracolumbar fractures

Number and name of studies	Population (n) [in study order]	Risk of bias	Inconsistency	Indirectness	Imprecision	Sensitivity (95% CI) [in study order]	Specificity (95% CI)	Quality
Diagnostic accuracy X-ray in relation to the reference test of composite outcomes – all thoracolumbar fractures								
2 Wintermark 2003 Berry 2012	People sustaining severe blunt trauma (100) People with blunt trauma (103)	VS[a]	SF	N	NA	0.31 (0.21-0.44) 0.73 (0.52-0.88) Median 0.31 (0.21 to 0.44)	1.0(0.95-1) 1.0 Median: 1 (0.95-1)	VERY LOW
Diagnostic accuracy X-ray in relation to the reference test of composite outcomes – unstable thoracolumbar fractures								
1 Wintermark 2003	People sustaining severe blunt trauma (100)	S[b]	NA	N	NA	0.33 (0.22-0.47)	1.0(no raw data to allow estimation)	MODERATE
Diagnostic accuracy X-ray in relation to the reference test of composite outcomes –thoracolumbar fractures on anterior column								
1 Wintermark 2003	People sustaining severe blunt trauma (100)	S[b]	NA	N	NA	0.74 (no raw data to allow estimation)	-	MODERATE
Diagnostic accuracy X-ray in relation to the reference test of composite outcomes –thoracolumbar fractures on middle column								
1 Wintermark 2003	People sustaining severe blunt trauma (100)	S[b]	NA	N	NA	0.35 (no raw data to allow estimation)	-	MODERATE
Diagnostic accuracy X-ray in relation to the reference test of composite outcomes –thoracolumbar fractures on posterior column								

Number and name of studies	Population (n) [in study order]	Risk of bias	Inconsistency	Indirectness	Imprecision	Sensitivity (95% CI) [in study order]	Specificity (95% CI)	Quality
1 Wintermark 2003	People sustaining severe blunt trauma (100)	S[b]	NA	N	NA	0.40 (no raw data to allow estimation)	-	MODERATE
Diagnostic accuracy X-ray in relation to the reference test of composite outcomes –for transverse and/or spinous fractures of thoracolumbar region								
1 Wintermark 2003	People sustaining severe blunt trauma (100) (100)	S[b]	NA	N	NA	0.09 (no raw data to allow estimation)	-	MODERATE
Diagnostic accuracy X-ray in relation to the reference test of composite outcomes –for thoracic transverse process fractures								
1 Rhea 2001	Multiple trauma patients (125)	VS[c]	NA	N	NA	0.86 (no raw data to allow estimation)	-	LOW
Diagnostic accuracy X-ray in relation to the reference test of composite outcomes –for thoracic burst fractures								
1 Rhea 2001	Multiple trauma patients (125)	VS[c]	NA	N	NA	0.5 (no raw data to allow estimation)	-	LOW
Diagnostic accuracy X-ray in relation to the reference test of composite outcomes –for thoracic compression fractures								
1 Rhea 2001	Multiple trauma patients (125)	VS[c]	NA	N	NA	0 (no raw data to allow estimation)	-	LOW
Diagnostic accuracy X-ray in relation to the reference test of composite outcomes –for thoracic spinous process fractures								
1 Rhea 2001	Multiple trauma patients (125)	VS[c]	NA	N	NA	0 (no raw data to allow estimation)	-	LOW
Diagnostic accuracy X-ray in relation to the reference test of composite outcomes –for lumbar transverse process fractures								
1 Rhea 2001	Multiple trauma patients (125)	VS[c]	NA	N	NA	0.67 (no raw data to allow estimation)	-	LOW
Diagnostic accuracy X-ray in relation to the reference test of composite outcomes –for sacral fractures								
1 Rhea 2001	Multiple trauma patients (125)	VS[c]	NA	N	NA	1 (no raw data to allow estimation)	-	LOW

Number and name of studies	Population (n) [in study order]	Risk of bias	Inconsistency	Indirectness	Imprecision	Sensitivity (95% CI) [in study order]	Specificity (95% CI)	Quality
Diagnostic accuracy X-ray in relation to the reference test of composite outcomes –for lumbar compression fractures								
1 Rhea 2001	Multiple trauma patients (125)	VS[c]	NA	N	NA	0 (no raw data to allow estimation)	-	LOW
Diagnostic accuracy X-ray in relation to the reference test of composite outcomes –for lumbar body/pedicle fracture								
1 Rhea 2001	Multiple trauma patients (125)	VS[c]	NA	N	NA	1 (no raw data to allow estimation)	-	LOW
Diagnostic accuracy X-ray in relation to the reference test of composite outcomes –for lumbar articular process fractures								
1 Rhea 2001	Multiple trauma patients (125)	VS[c]	NA	N	NA	1 (no raw data to allow estimation)	-	LOW
Diagnostic accuracy X-ray in relation to the reference test of composite outcomes –for all thoracic fractures								
2 Rhea 2001 Brown 2005B	Multiple trauma patients (125) People with thoracolumbar fractures (178)	VS[d]	N	N	NA	0.62(0.32-0.86) 0.64 (0.31-0.89) Median 0.62 (0.32 to 0.86)	-	LOW
Diagnostic accuracy X-ray in relation to the reference test of composite outcomes –for all lumbar fractures								

Number and name of studies	Population (n) [in study order]	Risk of bias	Inconsistency	Indirectness	Imprecision	Sensitivity (95% CI) [in study order]	Specificity (95% CI)	Quality
2 Rhea 2001 Rhee 2002 Brown 2005B	Multiple trauma patients (125) Blunt trauma patients (110) People with thoracolumbar fractures (178)	VS[e]	N	N	NA	0.67(0.41-0.87) 0.87(0.8-0.93) 0.69 (0.41-0.89) Median 0.69 (0.41 to 0.89)	-	LOW

Abbreviations: n, no serious limitations; S, serious limitations; VS, very serious limitations; NA, not applicable

(a) For Berry2012, unclear blinding of index test when carrying out reference test; reference test relied on index test results – thus index and reference tests are not independent, reducing validity of diagnostic accuracy measure; unclear duration between index and reference tests. For Wintermark2003, unclear blinding of index test when carrying out reference test, and unclear duration between tests. Thus overall outcome graded as having very serious limitations

(b) Unclear blinding of index test when carrying out reference test

(c) Unclear blinding of index test when carrying out reference test; index test not likely to correctly classify the target condition

(d) Unclear blinding of index test when carrying out reference test; index test not likely to correctly classify the target condition in Rhea2001. Unclear blinding of index test when carrying out reference test, unclear interval between index and reference tests, and reference test not likely to accurately classify target condition in Brown2005B. Overall very serious limitations for outcome

(e) In Rhea2001, unclear blinding of index test when carrying out reference test; index test not likely to correctly classify the target condition. In Rhee2002, unclear reporting of blinding in both index and reference tests and reference test relied on index test results, thus index and reference tests are not independent, reducing validity of diagnostic accuracy measure. Unclear blinding of index test when carrying out reference test, unclear interval between index and reference tests, and reference test not likely to accurately classify target condition in Brown2005B. Overall, very serious limitations for outcomes

(f) Inconsistency between studies in sensitivity

Diagnostic accuracy of CT for thoracolumbar fractures/injuries

Table 41: Clinical evidence profile: Studies evaluating CT in relation to the reference test of discharge diagnosis for thoracolumbar fractures

Number and name of studies	Population (n) [in study order]	Risk of bias	Inconsistency	Indirectness	Imprecision	Sensitivity (95% CI) [in study order]	Specificity (95% CI)	Quality
Diagnostic accuracy of CT in relation to the reference test of later outcomes – thoracic fractures								
1 Sheridan 2003	People with thoracolumbar fractures (78)	VS[a]	NA	N	NA	0.95 (0.74-1)	-	LOW
Diagnostic accuracy of CT in relation to the reference test of later outcomes – lumbar fractures								
1 Sheridan 2003	People with thoracolumbar fractures (78)	VS[a]	NA	N	NA	0.93 (0.76-0.99)	-	LOW

Abbreviations: n, no serious limitations; S, serious limitations; VS, very serious limitations; NA, not applicable

(a) Unclear blinding of index test when carrying out reference test and unclear interval between index and reference tests

Table 42: Clinical evidence profile: Studies evaluating CT in relation to the reference test of composite outcomes for thoracolumbar fractures

Number and name of studies	Population (n) [in study order]	Risk of bias	Inconsistency	Indirectness	Imprecision	Sensitivity (95% CI) [in study order]	Specificity (95% CI) [in study order]	Quality
Diagnostic accuracy CT in relation to the reference test of composite outcomes – all thoracolumbar fractures								
2 Wintermark 2003	People sustaining severe blunt trauma (100)	VS[a]	N	N	NA	0.78 (0.72-0.84)	1.0(0.95-1)	LOW
Berry 2012	People with blunt trauma (103)					1.0 (0.87-1) Median 0.78 (0.72 to 0.84)	0.97 (0.91-1) Median 0.97 (0.91 to 1.0)	
Diagnostic accuracy CT in relation to the reference test of composite outcomes – unstable thoracolumbar fractures								

Number and name of studies	Population (n) [in study order]	Risk of bias	Inconsistency	Indirectness	Imprecision	Sensitivity (95% CI) [in study order]	Specificity (95% CI) [in study order]	Quality
1 Wintermark 2003	People sustaining severe blunt trauma (100)	S[b]	NA	N	NA	0.97 (0.86-0.99)	1.0 (no raw data to allow estimation)	MODERATE
Diagnostic accuracy CT in relation to the reference test of composite outcomes –thoracolumbar fractures on anterior column								
1 Wintermark 2003	People sustaining severe blunt trauma (100)	S[b]	NA	N	NA	0.96 (no raw data to allow estimation)	-	MODERATE
Diagnostic accuracy CT in relation to the reference test of composite outcomes –thoracolumbar fractures on middle column								
1 Wintermark 2003	People sustaining severe blunt trauma (100)	S[b]	NA	N	NA	0.89 (no raw data to allow estimation)	-	MODERATE
Diagnostic accuracy CT in relation to the reference test of composite outcomes –thoracolumbar fractures on posterior column								
1 Wintermark 2003	People sustaining severe blunt trauma (100)	S[b]	NA	N	NA	0.94 (no raw data to allow estimation)	-	MODERATE
Diagnostic accuracy CT in relation to the reference test of composite outcomes –for transverse and/or spinous fractures of thoracolumbar region								
1 Wintermark 2003	People sustaining severe blunt trauma (100)	S[b]	NA	N	NA	0.71 (no raw data to allow estimation)	-	MODERATE
Diagnostic accuracy CT in relation to the reference test of composite outcomes –for thoracic transverse process fractures								
1 Rhea 2001	Multiple trauma patients (125)	VS[c]	NA	N	NA	1.0 (no raw data to allow estimation)	-	LOW
Diagnostic accuracy CT in relation to the reference test of composite outcomes –for thoracic burst fractures								

Number and name of studies	Population (n) [in study order]	Risk of bias	Inconsistency	Indirectness	Imprecision	Sensitivity (95% CI) [in study order]	Specificity (95% CI) [in study order]	Quality
1 Rhea 2001	Multiple trauma patients (125)	VS[c]	NA	N	NA	1.0 (no raw data to allow estimation)	-	LOW
Diagnostic accuracy CT in relation to the reference test of composite outcomes –for thoracic compression fractures								
1 Rhea 2001	Multiple trauma patients (125)	VS[c]	NA	N	NA	1.0 (no raw data to allow estimation)	-	LOW
Diagnostic accuracy CT in relation to the reference test of composite outcomes –for thoracic spinous process fractures								
1 Rhea 2001	Multiple trauma patients (125)	VS[c]	NA	N	NA	1.0 (no raw data to allow estimation)	-	LOW
Diagnostic accuracy CT in relation to the reference test of composite outcomes –for lumbar transverse process fractures								
1 Rhea 2001	Multiple trauma patients (125)	VS[c]	NA	N	NA	1.0 (no raw data to allow estimation)	-	LOW
Diagnostic accuracy CT in relation to the reference test of composite outcomes –for sacral fractures								
1 Rhea 2001	Multiple trauma patients (125)	VS[c]	NA	N	NA	1.0 (no raw data to allow estimation)	-	LOW
Diagnostic accuracy CT in relation to the reference test of composite outcomes –for lumbar compression fractures								
1 Rhea 2001	Multiple trauma patients (125)	VS[c]	NA	N	NA	1.0 (no raw data to allow estimation)	-	LOW
Diagnostic accuracy CT in relation to the reference test of composite outcomes –for lumbar body/pedicle fracture								
1 Rhea 2001	Multiple trauma patients (125)	VS[c]	NA	N	NA	1.0 (no raw data to allow estimation)	-	LOW
Diagnostic accuracy CT in relation to the reference test of composite outcomes –for lumbar articular process fractures								
1 Rhea 2001	Multiple trauma patients (125)	VS[c]	NA	N	NA	0 (no raw data to allow estimation)	-	LOW
Diagnostic accuracy CT in relation to the reference test of composite outcomes –for all thoracic fractures								

Number and name of studies	Population (n) [in study order]	Risk of bias	Inconsistency	Indirectness	Imprecision	Sensitivity (95% CI) [in study order]	Specificity (95% CI) [in study order]	Quality
2 Rhea 2001 Brown 2005B	Multiple trauma patients (125) People with thoracolumbar fractures (178)	VS[d]	N	N	NA	1.0 (0.75-1.0) 0.98 (0.92-1) Median 0.98 (0.92 to 1.0)	-	LOW
Diagnostic accuracy CT in relation to the reference test of composite outcomes –for all lumbar fractures								
2 Rhea 2001 Rhee 2002 Brown 2005B	Multiple trauma patients (125) Blunt trauma patients (110) People with thoracolumbar fractures (178)	VS[e]	N	N	NA	0.94 (0.73-0.99) 0.77 (0.64-0.87) 1.0 (0.97-1) Median 0.77 (0.64 to 0.87)	-	LOW

Abbreviations: n, no serious limitations; S, serious limitations; VS, very serious limitations; NA, not applicable

(a) For Berry2012, unclear blinding of index test when carrying out reference test; reference test relied on index test results – thus index and reference tests are not independent, reducing validity of diagnostic accuracy measure; unclear duration between index and reference tests. For Wintermark2003, unclear blinding of index test when carrying out reference test, and unclear duration between tests. Thus overall outcome graded as having very serious limitations.

(b) Unclear blinding of index test when carrying out reference test

(c) Unclear blinding of index test when carrying out reference test; index test not likely to correctly classify the target condition

(d) Unclear blinding of index test when carrying out reference test; index test not likely to correctly classify the target condition in Rhea2001. Unclear blinding of index test when carrying out reference test, unclear interval between index and reference tests, and reference test not likely to accurately classify target condition in Brown2005B. Overall very serious limitations for outcome.

(e) In Rhea2001, unclear blinding of index test when carrying out reference test; index test not likely to correctly classify the target condition. In Rhee2002, unclear reporting of blinding in both index and reference tests and reference test relied on index test results, thus index and reference tests are not independent, reducing validity of diagnostic accuracy measure.

Unclear blinding of index test when carrying out reference test, unclear interval between index and reference tests, and reference test not likely to accurately classify target condition in Brown2005B. Overall very serious limitations for outcome.

Table 43: Clinical evidence profile: Studies evaluating CT in relation to the reference test of MRI for non-cord soft tissue spinal injuries

Number and name of studies	Population (n) [in study order]	Risk of bias	Inconsistency	Indirectness	Imprecision	Sensitivity (95% CI) [in study order]	Specificity (95% CI)	Quality
Diagnostic accuracy CT in relation to the reference test of MRI for pre-vertebral swelling								
1 Silberstein 1992B	People with trauma (34)	N	NA	N	NA	0.88(0.64-0.99)	0.94(0.71-1)	HIGH
Diagnostic accuracy CT in relation to the reference test of MRI for ligament injury								
2 Silberstein 1992B Tracy 1989	People with trauma (34) People with acute spinal injury (27)	S[a]	N	N	NA	0.27(0.06-0.61) 0(0-0.46) Median 0 (0 to 0.46)	1.0(0.85-1)	MODERATE

Abbreviations: n, no serious limitations; S, serious limitations; VS, very serious limitations; NA, not applicable

(a) No reports of blinding, and up to 5 day interval between different tests in Tracy1989. No flaws in Silberstein1992B, so overall serious limitations for outcome.

Diagnostic accuracy of MRI for thoracolumbar fractures/injuries

Table 44: Clinical evidence profile: Studies evaluating MRI in relation to the reference test of CT for thoracolumbar fractures/injury

Number and name of studies	Population (n) [in study order]	Risk of bias	Inconsistency	Indirectness	Imprecision	Sensitivity (95% CI) [in study order]	Specificity (95% CI)	Quality
Diagnostic accuracy MRI in relation to the reference test of CT for vertebral body fracture								

Number and name of studies	Population (n) [in study order]	Risk of bias	Inconsistency	Indirectness	Imprecision	Sensitivity (95% CI) [in study order]	Specificity (95% CI)	Quality
3 Silberstein 1992B Tracy 1989 Tarr 1987	People with trauma (34) People with acute spinal injury (27) Suspected spinal trauma (14)	VS[a]	N	N	NA	0.91 (0.55-1) 1.0(0.69-1) 1.0(0.77-1) Median 1.0 (0.69 to 1.0)	0.96(0.79-1)	LOW
Diagnostic accuracy MRI in relation to the reference test of CT for posterior element fracture								
3 Silberstein 1992B Tracy 1989 Tarr 1987	People with trauma (34) People with acute spinal injury (27) Suspected spinal trauma (14)	VS[a]	S[b]	N	NA	0.23(0.05-0.54) 0.67(0.3-0.93) 0.57(0.18-0.90) Median 0.57 (0.18 to 0.90)	1.0(0.84-1)	LOW
Diagnostic accuracy MRI in relation to the reference test of CT for subluxation								
1 Silberstein 1992B	People with trauma (34)	N	NA	N	NA	1.0(0.63-1)	1.0(0.87-1)	HIGH

Number and name of studies	Population (n) [in study order]	Risk of bias	Inconsistency	Indirectness	Imprecision	Sensitivity (95% CI) [in study order]	Specificity (95% CI)	Quality
Diagnostic accuracy MRI in relation to the reference test of CT for spondylosis								
1 Silberstein 1992B	People with trauma (34)	N	NA	N	NA	1.0(0.69-1)	1.0 (0.86-1)	HIGH

Abbreviations: *n, no serious limitations; S, serious limitations; VS, very serious limitations; NA, not applicable*

(a) No reports of blinding, and up to 5 day interval between different tests in Tracy1989. No reports of blinding, and up to 2.5 week interval between different tests in Tarr1987. No flaws in Silberstein1992B, so overall very serious limitations for outcome.
(b) Inconsistency between studies for sensitivity.

Table 45: Clinical evidence profile: Studies evaluating MRI in relation to the reference test of surgery for thoracolumbar joint/soft tissue injury

Number and name of studies	Population (n)	Risk of bias	Inconsistency	Indirectness	Imprecision	Sensitivity (95% CI)	Specificity (95% CI)	Quality
Diagnostic accuracy MRI in relation to the reference test of surgery for supraspinous ligament injury								
1 Pizones 2013	People with suspected traumatic thoracolumbar fracture (58)	S[a]	NA	N	NA	0.93 (no raw data to allow estimation)	1 (no raw data to allow estimation)	MODERATE
Diagnostic accuracy MRI in relation to the reference test of surgery for ligamentum flavum injury								
1 Pizones 2013	People with suspected traumatic thoracolumbar fracture (58)	S[a]	NA	N	NA	1 (no raw data to allow estimation)	1 (no raw data to allow estimation)	MODERATE
Diagnostic accuracy MRI in relation to the reference test of surgery for facet capsule injury								
1 Pizones 2013	People with suspected traumatic thoracolumbar fracture (58)	S[a]	NA	N	NA	1 (no raw data to allow estimation)	0.52 (no raw data to allow estimation)	MODERATE
Diagnostic accuracy MRI in relation to the reference test of surgery for interspinous ligament injury								

Number and name of studies	Population (n)	Risk of bias	Inconsistency	Indirectness	Imprecision	Sensitivity (95% CI)	Specificity (95% CI)	Quality
1 Pizones 2013	People with suspected traumatic thoracolumbar fracture (58)	S[a]	NA	N	NA	0.92 (no raw data to allow estimation)	1 (no raw data to allow estimation)	MODERATE

Abbreviations: n, no serious limitations; S, serious limitations; VS, very serious limitations; NA, not applicable

(a) No reporting of time interval between tests

10.3.2 Children

SCI in the cervical region (children)

No articles were found.

SCI in thoracolumbar region (children)

No articles were found.

Isolated spinal column injury in the cervical region (children)

Four articles were found[23,47,61,95]. The outcomes from these studies have been sub-divided into groups evaluating the diagnostic accuracy of:

- X-ray, in relation to
  - the reference test of CT
  - discharge diagnosis
  - composite findings (such as later clinical outcomes/discharge diagnosis, plus other imaging findings)
- CT, in relation to
  - discharge diagnosis
  - composite findings (such as later clinical outcomes/discharge diagnosis, plus other imaging findings)
- MRI, in relation to
  - final clinical diagnosis

Table 46: Summary of studies included in review

Study	Population	Index test(s)	Reference test	Comments
Brockmeyer 2012[23]	Children with suspected cervical spine injury n=24	X-ray OR CT OR MRI	Clinical outcome	Only 1 patient had a diagnosis of cervical instability
Garton 2008[47]	Children with cervical spine injuries n=187	X-ray	Composite tests	Only those with positive gold standard diagnoses included
Henry 2013[61]	Children with trauma n=73	MRI	Clinical outcome	
Rana 2009[95]	Children with trauma n=345	X-ray OR CT	CT OR Further clinical and radiological review	CT used as 'gold standard' for X-ray, but clinical outcome used as gold standard for CT

Quality of evidence

Risk of bias for each outcome was determined by the QUADAS-2 criteria, as shown in Chapter 4. This has informed the risk of bias rating given in the GRADE clinical evidence profile tables (Table 47 to

Table 51). If there were 2 or more major limitations according to the QUADAS criteria, a rating of very serious limitations was given. If there was a single major limitation a rating of serious limitations was given. These ratings contributed to the overall GRADE ratings reported in Table 47 to Table 51.

Diagnostic accuracy of X-ray for cervical fractures/injuries

Table 47: Clinical evidence profile: Studies evaluating X-ray in relation to the reference test of CT for cervical fractures/injuries

Number and name of studies	Population (n) [in study order]	Risk of bias	Inconsistency	Indirectness	Imprecision	Sensitivity (95% CI)	Specificity (95% CI)	Quality
Diagnostic accuracy of X-ray in relation to the reference test of CT for cervical injuries in children								
1 Rana 2009	Paediatric trauma patients (345)	VS[a]	NA	N	NA	0.615(no raw data to allow estimation)	0.016 (no raw data to allow estimation)	LOW

Abbreviations: *n, no serious limitations; S, serious limitations; VS, very serious limitations; NA, not applicable*

(a) Unclear blinding and unclear time between index and reference tests

Table 48: Clinical evidence profile: Studies evaluating X-ray in relation to the reference test of discharge diagnosis for cervical injuries

Number and name of studies	Population (n) [in study order]	Risk of bias	Inconsistency	Indirectness	Imprecision	Sensitivity (95% CI) [in study order]	Specificity (95% CI)	Quality
Diagnostic accuracy of X-ray in relation to the reference test of later outcomes – cervical instability in children								
1 Brockmeyer 2012	Children with suspected traumatic cervical spine injury (24)	S[a]	NA	N	NA	1(0.03-1)	0.96(0.78-1)	MODERATE

Abbreviations: *n, no serious limitations; S, serious limitations; VS, very serious limitations; NA, not applicable*

(a) Unclear blinding

Table 49: Clinical evidence profile: Studies evaluating X-ray in relation to the reference test of composite outcomes for cervical fractures

Number and name of studies	Population (n) [in study order]	Risk of bias	Inconsistency	Indirectness	Imprecision	Sensitivity (95% CI) [in study order]	Specificity (95% CI)	Quality
Diagnostic accuracy X-ray in relation to the reference test of composite outcomes – cervical injuries in children								

Number and name of studies	Population (n) [in study order]	Risk of bias	Inconsistency	Indirectness	Imprecision	Sensitivity (95% CI) [in study order]	Specificity (95% CI)	Quality
1 Garton 2008	Paediatric trauma cases on institutional databases with ICDs consistent with cervical injury (187)	VS[a]	NA	N	NA	0.75 (0.57-0.89)	-	LOW

Abbreviations: *n, no serious limitations; S, serious limitations; VS, very serious limitations; NA, not applicable*

(a) Unclear blinding and unclear time between index and reference tests
(b) Unclear time between index and reference tests
(c) Unclear blinding

Diagnostic accuracy of CT for cervical fractures/injuries

Table 50: Clinical evidence profile: Studies evaluating CT in relation to the reference test of discharge diagnosis for cervical fractures

Number and name of studies	Population (n) [in study order]	Risk of bias	Inconsistency	Indirectness	Imprecision	Sensitivity (95% CI) [in study order]	Specificity (95% CI)	Quality
Diagnostic accuracy of CT in relation to the reference test of later outcomes – cervical injury in children								
1 Rana 2009	Children with trauma identified on a trauma registry 9345)	VS[a]	NA	N	NA	1(no raw data to allow estimation)	0.976(no raw data to allow estimation)	LOW
Diagnostic accuracy of CT in relation to the reference test of later outcomes – cervical instability in children								
1 Brockmeyer 2012	Children with suspected traumatic cervical spine injury (24)	S[b]	NA	N	NA	1(0.03-1)	1(0.85-1)	MODERATE

Abbreviations: *n, no serious limitations; S, serious limitations; VS, very serious limitations; NA, not applicable*

(a) Unclear blinding and unclear time between index and reference tests
(b) Unclear blinding

Diagnostic accuracy of MRI for cervical injuries

Table 51: Clinical evidence profile: Studies evaluating MRI in relation to the reference test of final clinical diagnosis

Number and name of studies	Population (n)	Risk of bias	Inconsistency	Indirectness	Imprecision	Sensitivity (95% CI)	Specificity (95% CI)	Quality
Diagnostic accuracy MRI in relation to the reference test of surgery for cervical instability in children								
2 Henry 2013	Children with suspected cervical injury (73)	VS[a]	VS[b]	N	NA	1(0.03-1)	0.97(0.9-1)	VERY LOW
Brockmeyer 2012	Children with suspected cervical spine injury (24)					0.14(0-0.58) Median 0.14 (0 to 0.58)	1(0.8-1) Median 0.97 (0.9 to 1.0)	

Abbreviations: *n, no serious limitations; S, serious limitations; VS, very serious limitations; NA, not applicable*

(a) Unclear blinding and unclear time between index and reference tests for Henry2013 and unclear blinding for Brockmeyer2012
(b) Extremely serious inconsistency for sensitivity

Narrative summary of findings

MRI was very poor for detecting cervical fractures, and very poor to excellent for detecting cervical instability in children

Isolated spinal column injury in the thoracolumbar region (children)

No evidence was found.

10.4 Economic evidence

Published literature

No relevant economic evaluations were included.

Six economic evaluations relating to this review question were identified but were excluded due to a combination of limited applicability and methodological limitations[13,22,53,54,67,106]. These are summarised in Appendix K, with reasons for exclusion given.

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

New cost-effectiveness analysis

This area was prioritised for new cost-effectiveness analysis.

The GDG identified non-imaging assessment and acute stage imaging for spinal injury as key areas which would benefit from de novo modelling. These questions were looked at in combination to inform components of an overall strategy to clear the spine.

Please see more on this in section 7.4.

10.5 Evidence statements

Clinical

Adults

SCI – cervical/thoracolumbar

CT (reference standard MRI) in adults

Low quality evidence from three diagnostic studies comprising 75 people showed CT has a median sensitivity of 0 (95% CI, 0 to 0.71), and a median specificity of 1 (95% CI, 0.66 to 1.0) in detecting disc herniation when compared with the reference standard of MRI.

High quality evidence from one diagnostic study comprising 34 people showed CT has a sensitivity of 0 (95% CI, 0 to 0.23) and specificity of 1(95% CI, 0.83 to 1) for detecting extra medullary haematoma when compared with the reference standard of MRI.

Low quality diagnostic evidence from two studies comprising 41 people showed CT has a median sensitivity of 0 (95% CI, 0 to 0.71) and a median specificity of 1 (95% CI, 0.72 to 1.0) in detecting epidural haematoma when compared with the reference standard of MRI.

Low quality diagnostic evidence from two studies comprising 41 people showed CT has a median sensitivity of 0 (95% CI, 0 to 0.84) and median specificity of 1.0 (95% CI, 0.69 to 1.0) in detecting spinal cord oedema/haemorrhage or haematoma when compared with the reference standard of MRI.

Low quality diagnostic evidence from one study comprising 27 people showed CT has a sensitivity of 0 (95% CI, 0 to 0.71) and specificity of 1 (95% CI, 0.8 to 1) in detecting transection of spinal cord when compared with the reference standard of MRI.

Low quality diagnostic evidence from two studies comprising 48 people showed CT has a median sensitivity of 0.25 (95% CI, 0 to 0.26) and median specificity of 1 (95% CI, 0.69 to 1.0) in detecting cord compression/cord or thecal sac impingement when compared with the reference standard of MRI.

Spinal column injury - cervical

X-ray (reference standard CT) in adults

Very low quality evidence from four diagnostic studies comprising 1987 people showed X-ray has a median sensitivity of 0.625 (95% CI, 0.35 to 0.85) and median specificity of 0.99 (95% CI, 0.98 to 1.0) for X-ray in detecting cervical fractures when compared with the reference standard of CT.

Low quality diagnostic evidence from one study comprising 442 people showed that X-ray has a sensitivity of 0.72 (95% CI, 0.59 to 0.83) and specificity of 0.94 (95% CI, 0.91 to 0.96) in detecting cervical injuries when compared with the reference standard of CT.

X-ray (reference standard MRI) in adults

Low quality diagnostic evidence from one study comprising 49 people showed X-ray has a sensitivity of 0 (95% CI, 0 to0.37) and specificity of 0.98(95% CI, 0.87 to 1) in detecting cervical ligament injuries when compared with the reference standard of MRI.

X-ray (reference standard discharge diagnosis) in adults

Very low quality evidence from five diagnostic studies comprising 1880 people showed X-ray has a median sensitivity of 0.61 (95% CI, 0.52 to 0.7) and median specificity of 0.97 (95% CI, 0.96 to 0.98) in detecting cervical injuries when compared with the reference standard of discharge diagnosis.

X-ray (reference standard composite outcomes) in adults

Low quality diagnostic evidence from one study comprising 379 people showed X-ray has a sensitivity of 1 (95% CI, 0.54 to 1) and specificity of 0.97 (95% CI, 0.95 to 0.99) in detecting ligamentous cervical injuries when compared with the reference standard of composite outcomes.

Low quality evidence from two diagnostic studies comprising 727 people showed X-ray has a median sensitivity of 0.45 (95% CI, 0.32 to 0.58) and median specificity of 0.97 (95% CI, 0.96 to 0.98) in detecting cervical injuries when compared with the reference standard of composite outcomes.

CT (reference standard discharge diagnosis) in adults

Low quality evidence from two diagnostic studies comprising 995 people showed CT has a median sensitivity of 0.98 (95% CI, 0.91 to 1.0) and a median specificity of 1(95% CI, 0.99 to 1.0) in detecting cervical fractures when compared with the reference standard of discharge diagnosis.

CT (reference standard later outcomes) in adults

Low quality evidence from four diagnostic studies comprising 1205 people showed CT has a median sensitivity of 1 (95% CI, 0.93 to 1.0) and a median specificity of 1.0 (95% CI, 0.99 to 1.0) in detecting cervical injuries when compared with the reference standard of later outcomes.

Low quality diagnostic evidence from one study comprising 824 people showed CT has a sensitivity of 1 (95% CI, 0.98 to 1) and specificity of 1 (95% CI, 0.99 to 1) in detecting cervical injuries when compared with the reference standard of later outcomes.

CT (reference standard composite outcomes) in adults

Low quality diagnostic evidence from one study comprising 379 people showed CT has a sensitivity of 1 (95% CI, 0.54 to 1) and a specificity of 0.97 (95% CI, 0.94 to 0.98) in detecting ligamentous cervical injuries when compared with the reference standard of composite outcomes.

Low quality diagnostic evidence from one study comprising 442 people showed CT has a sensitivity of 0.98(95% CI, 0.9 to 1) and a specificity of 0.99(95% CI, 0.97 to 1) in detecting cervical injuries when compared with the reference standard of composite outcomes.

CT (reference standard MRI) in adults

Low quality diagnostic evidence from one study comprising 97 people showed CT has a sensitivity of 0.94 (95% CI not estimable) and a specificity of 0.88 (95% CI not estimable) in detecting cervical fracture when compared with the reference standard of MRI.

MRI (reference standard CT) in adults

Moderate quality evidence from one diagnostic study comprising 42 people showed MRI has a sensitivity of 0.36 (95% CI, 0.25 to 0.5) and a specificity of 0.98(95% CI, 0.92 to 1) in detecting anterior element cervical fracture when compared with the reference standard of CT.

Moderate quality evidence from one diagnostic study comprising 42 people showed MRI has a sensitivity of 0.12 (95% CI, 0.06 to 0.21) and a specificity of 0.97 (95% CI, 0.89 to 1) in detecting posterior element cervical fracture when compared with the reference standard of CT.

Spinal column injury - thoracolumbar

X-ray (reference standard CT) in adults

Low quality evidence from two diagnostic studies comprising 98 people showed X-ray has a median sensitivity of 0.79 (95% CI, 0.60 to 0.92) and a median specificity of 0.89 (95% CI, 0.71 to 0.98) in detecting thoracolumbar burst fractures when compared with the reference standard of CT.

Low quality evidence from two diagnostic studies comprising 394 people showed X-ray has a median sensitivity of 0.58 (95% CI, 0.41 to 0.75) and a specificity of 0.93 (95% CI, 0.89 to 0.91) in detecting thoracolumbar fractures when compared with the reference standard of CT.

Low quality diagnostic evidence from one study comprising 107 people showed X-ray has a sensitivity of 0.49 (95% CI, 0.37-0.62) and a specificity of 0.55 (95% CI, 0.39-0.70) in detecting thoracic fractures when compared with the reference standard of CT.

Low quality diagnostic evidence from one study comprising 53 people showed X-ray has a sensitivity of 0.82 (95% CI, 0.66 to 0.92) and a specificity of 0.79 (95% CI, 0.49 to 0.95) in detecting unstable lumbar fractures when compared with the reference standard of CT.

Low quality diagnostic evidence from one study comprising 28 people showed X-ray has a sensitivity of 0.75 (95% CI, 0.55 to 0.89) in detecting any lumbar fractures when compared with the reference standard of CT.

X-ray (reference standard MRI) in adults

Low quality diagnostic evidence from one study comprising 120 people showed X-ray has a sensitivity of 0.55 (95% CI, 0.43 to 0.67) and a specificity of 0.85 (95% CI, 0.72 to 0.93) in detecting thoracolumbar fragility fractures when compared with the reference standard of MRI.

X-ray (reference standard discharge diagnosis) in adults

Low quality diagnostic evidence from one study comprising 78 people showed X-ray has a sensitivity of 0.58 (95% CI, 0.33 to 0.80) in detecting thoracic fractures when compared with the reference standard of discharge diagnosis.

Low quality diagnostic evidence from one study comprising 78 people showed X-ray has a sensitivity of 0.85 (95% CI, 0.66 to 0.96) in detecting lumbar fractures when compared with the reference standard of discharge diagnosis.

X-ray (reference standard composite outcomes) in adults

Low quality evidence from two diagnostic studies comprising 203 people showed X-ray has a median sensitivity of 0.31 (95% CI, 0.21 to 0.44) and a median specificity of 1 (95% CI, 0.95 to 1.0) in detecting all thoracolumbar fractures when compared with composite outcomes.

Moderate quality evidence from one diagnostic study comprising 100 people showed X-ray has a sensitivity of 0.33 (95% CI, 0.22 to 0.47) and a specificity of 1 (95% Cis, not estimable) in detecting unstable thoracolumbar fractures when compared with composite outcomes.

Moderate quality evidence from one diagnostic study comprising 100 people showed X-ray has a sensitivity of 0.74 (95% CIs, not estimable) in detecting anterior column thoracolumbar fractures when compared with composite outcomes.

Moderate quality evidence from one diagnostic study comprising 100 people showed X-ray has a sensitivity of 0.35 (95% CIs, not estimable) and 0.40 (95% Cis, not estimable) in detecting middle and posterior column thoracolumbar fractures respectively when compared with composite outcomes.

Moderate quality evidence from one diagnostic study comprising 100 people showed X-ray has a sensitivity of 0.09 (95% CIs, not estimable) in detecting transverse and/or spinous thoracolumbar fractures when compared with composite outcomes.

Low quality diagnostic evidence from one study comprising 125 people showed X-ray has a sensitivity of 0.86 (95% CIs, not estimable) in detecting thoracic transverse process fractures when compared with composite outcomes.

Low quality diagnostic evidence from one study comprising 125 people showed X-ray has a sensitivity of 0.5 (95% CIs, not estimable) in detecting thoracic burst fractures when compared with composite outcomes.

Low quality diagnostic evidence from one study comprising 125 people showed X-ray has a sensitivity of 0.67 (95% CIs not estimable) in detecting lumbar transverse process fractures when compared with composite outcomes.

Low quality diagnostic evidence from one study comprising 125 people showed X-ray has a sensitivity of 0 (95% CIs, not estimable) in detecting both thoracic compression fractures, thoracic spinous process fractures and lumbar compression fractures when compared with composite outcomes.

Low quality diagnostic evidence from one study comprising 125 people showed X-ray has a sensitivity of 1 (95% CIs, not estimable) in detecting both sacral lumbar body/pedicle and lumbar articular process fractures when compared with composite outcomes.

Low quality evidence from two diagnostic studies comprising 303 people showed X-ray has a median sensitivity of 0.62 (95% CI, 0.32 to 0.86) in detecting all thoracic fractures when compared with composite outcomes.

Three low quality diagnostic studies comprising 413 people showed X-ray has a median sensitivity of 0.69 (95% CI, 0.32 to 0.86) in detecting all lumbar fractures when compared with composite outcomes.

CT (reference standard discharge diagnosis) in adults

Low quality diagnostic evidence from one study comprising 78 people showed CT has a sensitivity of 0.95 (95% CI, 0.74 to 1) and 0.93 (95% CI, 0.76 to 0.99) in detecting both thoracic and lumbar fractures respectively when compared with composite outcomes.

CT (reference standard composite outcomes) in adults

Low quality evidence from two diagnostic studies comprising 203 people showed CT has a median sensitivity of 0.89 (95% CI, 0.72 to 0.84) and a median specificity of 0.97 (95% CI, 0.90 to 1.0) in detecting all thoracolumbar fractures when compared with the reference standard of composite outcomes.

Moderate quality evidence from one diagnostic study comprising 100 people showed CT has a sensitivity of 0.97 (95% CI, 0.86 to 0.99) and specificity of 1 (95% CIs, not estimable) in detecting unstable thoracolumbar fractures when compared with the reference standard of composite outcomes.

Moderate quality evidence from one diagnostic study comprising 100 people showed CT has a sensitivity of 0.96 (95% CIs, not estimable), 0.89 (95% CIs, not estimable) and 0.94 (95% CIs, not estimable) in detecting anterior, posterior and middle column thoracolumbar fractures, respectively, when compared with the reference standard of composite outcomes.

Moderate quality evidence from one diagnostic study comprising 100 people showed CT has a sensitivity of 0.71 (95% CIs, not estimable) in detecting transverse and/or spinous fractures of the thoracolumbar region when compared with the reference standard of composite outcomes.

Low quality diagnostic evidence from one study comprising 125 people showed CT has a sensitivity of 1 (95% CIs, not estimable) in detecting thoracic transverse process, burst, compression, and spinous process thoracic fractures, when compared with the reference standard of composite outcomes.

Low quality diagnostic evidence from one study comprising 125 people showed CT has a sensitivity of 1 (95% CI, not estimable) in detecting lumbar transverse process, compression, lumbar body/pedicle fractures, and sacral fractures when compared with the reference standard of composite outcomes.

Low quality diagnostic evidence from one study comprising 125 people showed CT has a sensitivity of 0 (95% CI, not estimable) in detecting lumbar articular process fractures when compared with the reference standard of composite outcomes.

Low quality evidence from two diagnostic studies comprising 303 people showed CT has a median sensitivity of 0.98 (95% CI, 0.92 to 1.0) in detecting all thoracic fractures when compared with the reference standard of composite outcomes. Specificity was not reported.

Low quality evidence from three diagnostic studies comprising 413 people showed CT has a median sensitivity of 0.77 (95% CI, 0.64 to 0.87) in detecting all lumbar fractures when compared with the reference standard of composite outcomes.

CT (reference standard MRI) in adults

High quality evidence from one diagnostic study comprising 34 people showed CT has a sensitivity of 0.88 (95% CI, 0.64 to 0.99) and a specificity of 0.96 (95% CI, 0.79 to 1) in detecting pre-vertebral soft tissue swelling when compared with the reference standard of MRI.

Moderate quality evidence from two diagnostic studies comprising 61 people showed CT has a median sensitivity of 0.00 (95% CI, 0.0 to 0.46) and a median specificity of 1 (95% CI, 0.85 to 1) in detecting ligament injury when compared with the reference standard of MRI.

MRI (reference standard CT) in adults

Low quality diagnostic evidence from three studies comprising 75 people showed MRI has a median sensitivity of 0.69 (95% CI, 0.69 to 1.0) and a median specificity of 0.96 (95% CI, 0.84 to 1.0) in detecting vertebral body fracture when compared with the reference standard of CT.

Low quality diagnostic evidence from three studies comprising 75 people showed MRI has a median sensitivity of 0.57 (95% CI, 0.18 to 0.90) and a median specificity of 1 (95% CI, 0.84 to 1.0) in detecting posterior element fracture when compared with the reference standard of CT.

High quality diagnostic evidence from one study comprising 34 people showed MRI has a sensitivity of 1 (95% CI, 0.63 to 1) and specificity 1 (95% CI, 0.87 to 1) in detecting subluxation when compared with the reference standard of CT.

High quality diagnostic evidence from one study comprising 34 people showed MRI has a sensitivity of 1 (95% CI, 0.69 to 1) and specificity 1 (95% CI, 0.86 to 1) in detecting spondylosis when compared with the reference standard of CT.

MRI (reference standard surgery) in adults

Moderate quality evidence from one diagnostic study comprising 58 people showed MRI has a sensitivity of 0.93 (95% CI, not estimable) and a specificity of 1 (95% CI, not estimable) in detecting supraspinous ligament injury when compared with the reference standard of surgery.

Moderate quality evidence from one diagnostic study comprising 58 people showed MRI has a sensitivity of 1 (95% CI, not estimable) and a specificity of 1 (95% CI, not estimable) in detecting ligamentum flavum injury and interspinous ligament injury when compared with the reference standard of surgery.

Moderate quality evidence from one diagnostic study comprising 58 people showed MRI has a sensitivity of 1 (95% CIs, not estimable) and a specificity of 0.52 (95% CIs, not estimable) in detecting facet capsule injury when compared with the reference standard of surgery.

Children

Spinal column injury – cervical

X-ray (reference standard CT) in children

Low quality diagnostic evidence from one study comprising 345 people showed X-ray has a sensitivity of 0.615 (95% CI, not estimable) and a specificity of 0.016 (95% CI, not estimable) in detecting cervical injury when compared with the reference standard of CT.

X-ray (reference standard discharge diagnosis) in children

Moderate quality evidence from one diagnostic study comprising 24 people showed X-ray has a sensitivity of 1 (95% CI, 0.03 to 1) and a specificity of 0.96 (95% CI, 0.78 to 1) in detecting cervical instability when compared with the reference standard of discharge diagnosis.

X-ray (reference standard composite outcomes) in children

Low quality diagnostic evidence from one study comprising 187 people showed X-ray has a sensitivity of 0.75 (95% CI, 0.57 to 0.89) in detecting cervical injuries when compared with the reference standard of composite outcomes.

CT (reference standard discharge diagnosis) in children

Low quality diagnostic evidence from one study comprising 345 people showed CT has a sensitivity of 1 (95% CIs, not estimable) and a specificity of 0.98 (95% CIs, not estimable) in detecting cervical injury when compared with the reference standard of discharge diagnosis.

Moderate quality evidence from one diagnostic study comprising 24 people showed CT has a sensitivity of 1 (95% CIs, 0.03 to 1 and a specificity of 1 (95% CI, 0.85 to 1) in detecting cervical instability when compared with the reference standard of discharge diagnosis.

MRI (reference standard final clinical diagnosis) in children

Very low quality evidence from two diagnostic studies comprising 97 people showed CT has a median sensitivity of 0.14 (95% CI, 0 to 0.58) and a median specificity of 0.97 (95% CI, 0.9 to 1.0) in detecting cervical instability when compared with the reference standard of final clinical diagnosis.

Economic

No relevant economic evaluations were identified.

An original health economic model found that, for patients with suspected spinal column injury, a CT scan (when indicated by the Canadian C-spine rule [CCR]) was part of the most cost-effective diagnostic pathway to clear the spine. This analysis is directly applicable with potentially serious limitations.

10.6 Recommendations and link to evidence

	Diagnostic imaging **36. Imaging for spinal injury should be performed urgently, and the images should be interpreted immediately by a healthcare professional with training and skills in this area.** **Suspected spinal cord or cervical column injury** **Children** **37. Perform MRI for children (under 16s) if there is a strong suspicion of:** • **cervical spinal cord injury as indicated by the Canadian C-spine rule and by clinical assessment or** • **cervical spinal column injury as indicated by clinical assessment or abnormal neurological signs or symptoms, or both.** **38. Consider plain X-rays in children (under 16s) who do not fulfil the criteria for MRI in recommendation 37 but clinical suspicion remains after repeated clinical assessment.**

39.Discuss the findings of the plain X-rays with a consultant radiologist and perform further imaging if needed.

40.For imaging in children (under 16s) with head injury and suspected cervical spine injury, follow the recommendations in section 1.5 of the NICE guideline on head injury.

Adults

41.Perform CT in adults (16 or over) if:

- **imaging for cervical spine injury is indicated by the Canadian C-Spine rule or**
- **there is a strong suspicion of thoracic or lumbosacral spine injury associated with abnormal neurological signs or symptoms.**

42.If, after CT, there is a neurological abnormality which could be attributable to spinal cord injury, perform MRI.

43. For imaging in adults (16 or over) with head injury and suspected cervical spine injury, follow the recommendations in section 1.5 of the NICE guideline on head injury.

Suspected thoracic or lumbosacral column injury only (children and adults)

Suspected column injury only

44.Perform AP and lateral X-rays as the first-line investigation for people with suspected spinal column injury without abnormal neurological signs or symptoms in the thoracic or lumbosacral regions (T1–L3).

45.Perform CT if the X-ray is abnormal or there are clinical signs or symptoms of a spinal column injury.

46.If a new spinal column fracture is confirmed, image the rest of the spinal column.

Whole-body CT

47.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.

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

49.If a person with suspected spinal column injury has whole-body CT carry out multiplanar reformatting to show all of the thoracic and lumbosacral regions with sagittal and coronal reformats.

	50. 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.
	The recommendations here are supported by the evidence from chapter 11 on radiation and risk and chapter 12 on further imaging. Chapters 11 and 12 should be read in conjunction with this chapter. Refer to Major trauma clinical guideline chapter 11 for the evidence review on Whole Body CT in the trauma patient with multiple injuries.
Relative values of different outcomes	Sensitivity was the most important outcome, as this indicates the false negative rate (1-sensitivity). In the context of column injuries, a false negative (a negative test result when there really is a spinal injury) is potentially dangerous, as failure to pick up a column injury could lead to catastrophic conversion to a SCI. Specificity was of lower importance, as false positive results only present harm to the patient in terms of the (usually) less severe adverse effects of prolonged and unwarranted spinal immobilisation. For cord injuries in conscious people, the risk of false negatives was less of a concern, as the cord injury would normally be evident clinically. However, for unconscious patients, detection of a cord injury might prevent progression from a partial to complete cord injury, and so for this group sensitivity was, again, the most important outcome. Sensitivity and specificity are difficult to interpret, because studies choose different interventions for the gold standard test for comparison and results may be affected by the clinical experience and skill level and training of radiologists
Trade-off between clinical benefits and harms	**Column injuries** The evidence showed that CT has a higher sensitivity than X-ray for detection of bony injuries in both cervical and thoracolumbar spine. CT will therefore lead to less false negatives, and thus, a lower probability of a covert bony injury progressing to a cord injury. However, it may also carry a 100-fold greater radiation risk than X-ray, and thus, may not be appropriate for children or people who have been, or are likely to be, exposed to many scans (see chapter 10 on the risks of radiations risks). Furthermore, despite CT's superiority over X-ray, it should be noted that the false negative rate for CT was still unacceptably high for many column injuries. MRI was found to have comparable sensitivity to CT in the thoracolumbar spine for most column injuries, though this was not supported by the limited evidence for the cervical spine. MRI had particular sensitivity for detecting ligamentous injury, which was deemed by the GDG to be particularly important in children, who are less likely to have bony injuries and more likely to have soft tissue disruption. In addition, its lack of ionising radiation was regarded as a very important advantage over CT, particularly for children. However, its use in children would require sedation or a general anaesthetic, which may involve potential adverse effects. Finally, it was discussed that MRI is not available at all in some centres and not available for 24 hours per day in many others. It was agreed, however, that this should not influence recommendations, as this situation could be rectified if it were cost effective to do so. With CT excluded, there remains a choice between MRI and X-ray. MRI has greater sensitivity than X-ray and in children where there is a strong suspicion of a spinal

	injury, MRI should be performed. A strong suspicion is indicted by obvious neurological signs and symptoms, such as paraesthesia, numbness and motor weakness. In children where there is a lower suspicion of injury and this remains after valid clinical assessment (this will often require a period of observation with repeated clinical assessments) consideration should be given to X-ray initially because of the need for sedation/anaesthesia. The radiation burden of the X-rays was regarded as small, in comparison to those provided by CT. **Cord injuries** Evidence was only found for thoracolumbar cord injuries in adults, and strongly suggested that CT is inappropriate for detection of cord injury, compared with the gold standard of MRI. Although cord injury is normally evident in the conscious patient without the use of imaging, the use of MRI to diagnose a cord injury was regarded as essential for unconscious patients to prevent progression of a partial cord injury to a complete cord injury. It was also regarded as useful to identify the exact site and nature of cord injury in alert neurologically compromised patients.
Economic considerations	No studies that looked at the use of prediction rules and or imaging modalities for the selection and clearance of spinal column injury patients were identified. Six economic evaluations were identified looking at relevant imaging modalities. However, all the studies were excluded due to limited applicability and methodological limitations. An original economic analysis identified the CCR and CT scan strategy to be optimal (in both deterministic and probabilistic analyses) when diagnosing column (bony and ligamentous) injuries. This conclusion was robust to variations in estimates within clinically credible ranges. Sensitivity analysis included evaluation of differing accuracy, long term financial penalty, such as litigation for false negatives, and cord conversion rates following missed injury. CT scanning only in those with a positive X-ray at the assumed prevalence and accuracy rates results in many missed injuries. The analysis has highlighted the inadequacy of X-ray alone or with a decision rule as a clearance tool. The analysis looked at three stage strategies whereby further imaging was conducted. Overall, adding another imaging modality after CT was not cost effective given the low incidence of spinal injury, and in particular ligamentous injury. Only when, in specific scenarios, has an X-ray been used to limit unnecessary radiation risk, was the addition of CT as a third-line imaging strategy potentially cost effective. It was acknowledged that this analysis does not fully account or quantify all of the trade-offs involved in the diagnostic decision on which this analysis is based. No weighting or penalty was given to outcomes such as false positive (although the cost of observation/treatment is taken into account), there are no indeterminate images, patients are cleared or found to have an injury and only spinal column injured patients who are missed (FN) can convert to a cord injury. Patients correctly identified with spinal injury do not convert to cord injuries in the model. The same conversion rate to cord injury is applied to patients with bony column injury or ligamentous column injuries. The analysis also assumed that patients would remain well and experience no deterioration after treatment or imaging. Further limitations regarding the quality of the evidence informing the model are outlined in the below section. A separate subgroup analysis was not conducted for paediatrics. The GDG felt this economic analysis could not be extrapolated to the paediatric population. No evidence was identified for paediatrics and so, it was not possible to determine the appropriateness of model inputs for the paediatric population (in particular, the

	prevalence of spinal column injury and the clinical judgements for further imaging and treatment used in the analysis for adults). The model results may also have limited applicability to young people, dependent on how similar this subgroup is to children or to adults in their baseline epidemiology and risk profile. Sensitivity analysis conducted to explore the potential of radiation risk and variance in incidence of different types of injury (bony or ligamentous) suggested that potentially, use of a decision rule to indicate X-ray to indicate CT (when varying risk of cancer from radiation) or indeed a decision rule to indicate MRI (when prevalence of ligamentous injury is high) may be more cost effective than use of CT alone (again indicated by decision rule) as a primary imaging strategy. In the model, only patients who were found positive on one modality went on to receive the next modality in the sequence. Therefore no indeterminate findings were included in the strategies in the model. Some of the recommendations above recommend further imaging if spinal injury cannot be confidently excluded. Therefore these are in a population not considered in the model; i.e. further imaging of those with a negative result but symptoms remain. It is likely that in this small population of negative CT but of concern (compared to all those positive on a CT) further imaging to definitively rule out spinal cord injury will be cost effective, given the potential costs and consequences of missing an injury. It was accepted that MRI is the gold standard for diagnosing cord injuries. This was therefore not a population that was considered in the model. For children, who were also not included in the model, MRI was felt to be the most appropriate modality. Trauma in children is rarer than in adults, and MRI would only be for those patients indicated by the risk factors of the Canadian c-spine rule. X-ray was not considered an adequate modality for identifying spinal injury in those at high risk, and MRI was chosen because of its sensitivity and specificity, as missing injuries was felt to be a very important factor with large consequences, and also because of the radiation considerations in children. The recommendations made for imaging of suspected spinal injuries are likely to increase the overall use of CT and potentially MRI. Service and capacity implications were discussed by the GDG, particularly access to MRI. The GDG considered that people with suspected spinal injuries are a small population, and the consequences of missing an injury outweigh the additional resources and radiation risk. Patients with a suspected spinal injury should be transported to major trauma centre where these facilities and staff required to interpret them are more accessible. Additional resources such as MRI compatible spinal boards and support staff to sedate children were noted. However it was felt strongly that if an intervention is clinically and cost effective, the ability to recommend this should not be hindered by the cost of implementing the intervention.
Quality of evidence	The quality of evidence for column and cord imaging in adults for both the cervical spine and the thoracic and lumbosacral spine was mostly very low to low, the major limitations being unclear reporting of blinding and the length of time between the index and reference tests. The evidence was felt to be confounded by the age of the studies included in the review. Studies dated over 20 years old would not provide the same sensitivity and specificity of imaging modalities that are used in the present NHS due to advances in volumetric data reconstruction, reformatting technology and image resolution. There was very limited high quality evidence with some moderate evidence, the majority of the moderate evidence was in the imaging of the thoracic and lumbosacral spine.

	The evidence for column and cord imaging of both the cervical spine and the thoracic and lumbosacral spine in children was sparse and was mostly low quality with some moderate evidence in the cervical region of the spinal column. No studies were retrieved for adults or children that looked at ambiguous results as a third possible outcome, alongside the positive and negative findings. None of the studies looked at combinations of imaging (that is, the diagnostic accuracy of X-rays combined with CT scanning). This may have been a more relevant test to have examined. **Spinal column** Although MRI had comparable sensitivity to CT scanning for detecting column injury, this was based on a very limited number of Low quality studies, and goes against the clinical experience of the group who felt that CT scanning would be a more sensitive, and thus, more appropriate imaging modality for bony injuries. **Health economic evidence** The economic analysis is of direct applicability but has potentially serious limitations. In particular, modelling of long-term outcomes was limited by a lack of directly applicable evidence. QALYs were estimated using utilities from proxy conditions and long-term spinal cord injured patients. The adverse events associated with spinal clearance strategies and the decision to remove spinal protective measures was not fully explored in this analysis. Radiation risk associated with imaging modalities are also an important long-term consideration which was explored via sensitivity analysis, but not based on high quality evidence. However, the GDG felt that despite the limitations, the analysis is sufficient for purposes of decision making as it explicitly shows and attempts to quantify the parameters, assumptions and structure underpinning the clinical decision.
Other considerations	The GDG wanted to emphasise the importance of carrying out imaging and obtaining the results as soon as possible. This is vital in guiding the early management of a person with a spinal injury and the impact on later outcomes. It is also important in ruling out a spinal injury and clearing the spine and removing spinal immobilisation devices. The selection of imaging modalities based on age was discussed. Overall, it was agreed that children over the age of 12 years 'fit into an adult pattern', whereas those younger than 12 years require specialist paediatric input. The GDG agreed that the clinical assessment of children should include repeated assessments over time, to ensure consistent clinical findings. It is difficult to assess children and they need to feel safe and secure before a valid assessment of the spine can be done and the decision can be made to image. The exception is the child where there is strong suspicion of a spinal injury and these children should have an immediate MRI. A CT scan or X-ray is not an acceptable first-line investigation for children; the GDG strongly agreed that the MRI is the optimal imaging modality to identify SCI for the reasons detailed in the risks and benefits section. The NICE clinical guideline 176 Head injury: Triage, assessment, investigation and early management of head injury in children, young people and adults, section 1.5 was cross referenced for people with head injury and suspected cervical spine injury. The GDG noted that as part of the acute assessment within the hospital environment clothes, jewellery and metallic artefacts should be removed. Removal in the radiology department prior to imaging is often undertaken with minimal staff and could threaten the immobilisation of a potentially unstable spinal fracture.

11 Radiation risk

11.1 Introduction

Exposure to the ionising (high energy) radiation associated with X-ray and CT scans can have potential health risks, especially for children who are more radiosensitive than adults. Given the widespread use of radio-diagnostic testing, especially in the trauma population, it is important to explore the risks of radiation exposure in people with suspected spinal injuries, and whether the widely accepted clinical usefulness of these imaging technologies is outweighed by the potential damage to living tissue (which can result in mutations, radiation sickness or cancer).

11.2 Review question: For people with clinical signs of spinal injury what are the radiation risks of having a X-ray(s) and/or CT scans?

For full details see review protocol in Appendix C.

Table 52: PICO characteristics of review question

Population	Children, young people and adults undergoing X-ray and/or CT
Prognostic variable/s	• X-ray • CT

Outcomes	Critical
	• Mortality (including all-cause mortality)
	• Genetic mutational risk
	• Non-cancer (cataracts, radiation skin changes)
	• Cancer (lag of ≥10 years)
	  ○ Breast cancer
	  ○ Brain tumours
	  ○ Cancers of the gonads
	  ○ Leukaemia
	  ○ Lymphoma
	  ○ Thyroid cancer
	Confounders
	• Current cancer diagnosis
	• Previous cancer
	• Age

Study design	• Prospective and retrospective cohorts

11.3 Clinical evidence

Three studies were included in this review[78,100,116]. Evidence from these papers is summarised in the clinical evidence profiles below (Table 54, Table 55 and Table 56). See also the study selection flow chart in Appendix D, forest plots in Appendix I, study evidence tables in Appendix G and exclusion list in Appendix J.

The first study[100] included investigated the risk of breast cancer mortality in a cohort of females in the USA with scoliosis exposed to multiple plain film radiographs. Exposure data was collected from medical records and so did not rely on patient recall, and was measured as a continuous variable of absorbed dose (cGy). Results were expressed as either hazard ratios of dichotomous comparisons according to dose category (less than 10, 10-19, 20-29, 30 plus), or as 'excess relative risk per Gy'.

The second study[78] investigated the risk of any malignancy in an Australian Medicare cohort with groups exposed and unexposed to computed tomography. Again, exposure data was collected from medical records and so did not rely on patient recall. However, only Medicare and not private insurers' records were accessed; therefore, measurement of exposure may not have been entirely accurate. The exposure, in this case, was measured as a dichotomous variable 'exposed' versus 'unexposed' and so does not take into account absorbed dose as does the former.

While 2 additional studies published since 2010 were identified that investigated risk of malignancy in cohorts exposed to CT scans[78,90,96], these were excluded from our analysis due to the lag time used being inappropriately short. Another study was identified that investigated eye changes as an outcome relating to radiation exposure[69]. This study, however, included CT scans/X-rays of the head only and did not report a lag time. Additional studies investigating risk of malignancy in cohorts exposed to X-rays were identified in the search which also met all but 1 criterion for inclusion in this review, namely a lag time of 10 years or more[4,56,87].

The third study[116] examined the effects of CT exposure on cataract formation in a large sample of people from 2 longitudinal health insurance databases in Taiwan. This was a retrospective cohort study, and so prone to key confounders not being measured, but in other respects was a well-conducted study.

Table 53: Summary of studies included in the review

Study	Population	Analysis	Prognostic variable(s)	Confounders (list)	Outcomes	Comments
RONCKERS 2010	USA Female scoliosis cohort study n=5573	Cox regression analysis	X-ray exposure	Age at diagnosis, type of curvature, aetiology of curvature, maximum curve magnitude, number of surgeries, number of examinations	Breast cancer mortality	Low risk of bias. Indirect population of patients with curvature of spine.
MATHEWS 2013	Australian Medicare database cohort n=10,939,680	Poisson regression analysis	CT scan exposure	Age, sex, year of birth	All malignancy	High risk of bias. All exposures may not have been captured. Low ratio of events to covariates.
Yuan 2013	Taiwan National health Insurance Research Database	Cox regression analysis	CT exposure (any exposure or number of exposures)	Age, sex, hypertension, DM and history of coronary heart disease	Cataract formation	High risk of bias – retrospective cohort

Table 54: Clinical evidence profile: Outcome – All malignancy

Quality assessment							No. of patients/events		Effect	
No. of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other	No. of events in exposed/ unexposed	Median risk and/or absolute risk difference	Hazard ratios/Odds ratios/AUROC Median [95% CI] Range	Quality
Childhood exposure to CT versus none (10-year lag)										
1	Cohort study	High risk of bias[a]	Not applicable	No serious indirectness	No serious imprecision	None	Events in exposed 3,150/680,211 Events in unexposed 57,524/10,259,469		HR 1.18 (1.11 to 1.25)	MODERATE

(a) The majority of evidence was from studies at high risk of bias.

Table 55: Clinical evidence profile: Outcome – breast cancer mortality

Quality assessment							No. of patients/events		Effect	
No. of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other	No. of events/people (%) with and without risk factor	Median risk in unexposed and/or absolute risk difference	Hazard ratios/Odds ratios	Quality
All age female exposure to 10-19 cGy versus <10 cGy breast dose (10-year lag)										
1	Cohort study	Low risk of bias	Not applicable	Indirect population[a]	Very serious imprecision[b]	None	Events in high dose exposed 23/1239 Events in low dose group 63/3388	63/3388	HR 1.20 (0.70 to 2.06)	VERY LOW
All age female exposure to 20-29 cGy versus <10 cGy breast dose (10 years lag)										

1	Cohort study	Low risk of bias	Not applicable	Indirect population[a]	Serious imprecision[b]	None	Events in exposed 14/540 Events in low dose group 63/3388	63/3388	HR 1.90 (1.00 to 3.61)	LOW
All age female exposure to ≥30 cGy versus <10 cGy breast dose (10 year lag)										
1	Cohort study	Low risk of bias	Not applicable	Indirect population[a]	Serious imprecision[b]	None	Events in exposed 12/345 Events in low dose group 63/3388	63/3388	HR 2.40 (1.20 to 4.80)	LOW
All age female exposure to various X-ray doses. Excess relative risk per Gy										
1	Cohort study	Low risk of bias	Not applicable	Indirect population[a]	Serious imprecision[b]	None	Total events in all dose exposure groups 112/5,513		ERR/Gy 3.90 (1.00 to 9.3)	LOW

(a) Population of women with scoliosis only
(b) Confidence interval crossed 1 MID

Table 56: Clinical evidence profile: Outcome – cataracts

Quality assessment							No. of patients/events		Effect	
No. of studies	**Study design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other**	**No. of events in exposed/ unexposed**	**Median risk and/or absolute risk difference**	**Hazard ratios/Odds ratios/AUROC Median [95% CI] Range**	**Quality**
Exposure to CT versus none										
1	Retrospective Cohort study	High risk of bias[a]	Not applicable	No serious indirectness	Serious imprecision	None	Events in exposed 27/2776 Events in unexposed 201/27761		Adjusted HR: HR: 1.76 (1.18-2.63)	LOW

Quality assessment							No. of patients/events		Effect	
No. of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other	No. of events in exposed/ unexposed	Median risk and/or absolute risk difference	Hazard ratios/Odds ratios/AUROC Median [95% CI] Range	Quality
Exposure to 1-2 CTs versus none										
1	Retrospective Cohort study	High risk of bias[a]	Not applicable	No serious indirectness	Serious imprecision	None	Events in exposed 12/1512 Events in unexposed 201/27761		Adjusted HR: HR: 1.61 (0.9-2.88)	LOW
Exposure to 2-4 CTs versus none										
1	Retrospective Cohort study	High risk of bias[a]	Not applicable	No serious indirectness	Very serious imprecision	None	Events in exposed 6/645 Events in unexposed 201/27761		Adjusted HR: HR: 1.64 (0.73-3.69)	VERY LOW
Exposure to >5 CTs versus none										
1	Retrospective Cohort study	High risk of bias[a]	Not applicable	No serious indirectness	Serious imprecision	None	Events in exposed 9/619 Events in unexposed 201/27761		Adjusted HR for ANY CT exposure: HR: 2.12 (1.09-4.14)	LOW

(a) The majority of evidence was from studies at high risk of bias.

11.4 Economic evidence

Published literature

No relevant economic evaluations were identified.

Two economic evaluations relating to this review question were identified but were excluded due to limited applicability[30,46]. These are summarised in Appendix K with reasons for exclusion given.

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

11.5 Evidence statements

Clinical

Moderate quality evidence from 1 prospective cohort study comprising 10,939,680 participants showed a clinical harm in increased rates of all malignancy related to CT scan exposure in childhood when compared with no exposure , with no serious imprecision.

Very low quality evidence from 1 retrospective cohort study comprising 5,573 participants showed clinical harm in increased rates of breast cancer mortality related to increasing doses of spinal X-ray exposure to women, when compared with lower doses of the same X-rays, with serious to very serious imprecision.

Low to Very low quality evidence from 1 retrospective cohort study comprising 30,337 participants showed clinical harm in increased rates of cataract formation related to increasing doses of head and neck CT exposure to men and women aged 10-50 years, when compared with a zero dose of CT, with very low to low imprecision.

Economic

No relevant economic evaluations were identified.

11.6 Recommendations and link to evidence

Recommendations	**The evidence from this chapter supported the decision making for the imaging recommendations in chapter 10 and the full-body CT scan recommendations in the major trauma clinical guideline.**
Relative values of different outcomes	The following outcomes were critical to decision making: mortality (including all-cause mortality), genetic mutational risk, cancer and non-cancer adverse events, for example, cataracts and radiation skin changes. The GDG identified the following confounders: current cancer diagnosis, previous cancer and age.
Trade-off between clinical benefits and harms	The GDG felt that the evidence concerning malignancy and childhood exposure to diagnostic imaging (in the form of CT scan) showed that radiation had a strong effect on the increased probability of malignancy. One study also showed a clear link between radiation risks and cataract formation, with a doubling of instantaneous risk if a person had received more than 5 CTs. Although the absolute risk difference was not accurately calculable from the adjusted time to event data, it appeared to be less than 1%. In weighing the benefits and harms of the radiation associated with diagnostic

	imaging, the GDG agreed that the increased risk of exposure to children would normally prohibit exposure to CT, and not be outweighed by the need for diagnostic imaging with CT. One exception to this would be the lack of possibility of alternative non-ionising radiation modalities, such as ultrasound or MRI providing sufficient diagnostic information in a timely manner.
Economic considerations	No relevant economic evaluations were found relating to the radiation risk of imaging for spinal injuries. Two papers were excluded; one evaluated patients with Crohn's disease and one compared two different types of X-ray. Although these papers were not used directly, they did, however, make reference to some useful data sources regarding the risk of cancer per unit dose of radiation as well as the cost and QALY loss associated with treatment for various cancers. This data was used to calculate the expected cancer cost and QALY loss per patient for a variety of X-ray and CT examinations (please see appendix M for a summary of these calculations). The GDG were uncertain about the direct relevance of the data as the X-rays and CT scans used were not identical to those used in the spinally injured person. They also thought that the cancer risks presented were higher than expected. The risk of developing cancer from radiation has an impact on the cost effectiveness of the diagnostic imaging modality. The increase in costs due to cancer treatment and the reduction in health-related quality of life both contribute to a lower likelihood that CT scanning is cost-effective. However, this needs to be weighed against the benefit CT brings in diagnosis. A sensitivity analysis in the diagnostic economic model, which explored the potential impact of radiation, suggests that if evidence from the indirect populations described above was applicable, the optimal screening strategy may be to perform CT if indicated by the Canadian C-spine rule (CCR). Alternatively, where there is a strong suspicion of ligamentous injury, it may be preferable to use MRI (rather than CT) as indicated by the CCR. The GDG felt that on the basis of this sensitivity analysis, there may be specific situations whereby, if the clinician and patient feels there is a credible risk of harmful levels of radiation (that is, the patient is young, may be reimaged several times over a lifetime or at low risk of a bony injury), then there may be a case to limit CT usage to only if indicated after all other non-ionising radiation modalities have been tried. In the absence of sufficient quality evidence to parameterise the risk and consequences of radiation in the economic modelling on diagnostic strategies conducted for this guideline, the GDG came to the consensus that the diagnostic benefits in reducing the number of potentially very costly missed fractures by using CT scans outweighed the additional risk of cancer and the potential costs of additional treatment associated with it. They agreed, therefore, in general, that the radiation risk of CT scans was not sufficient enough to affect the recommendation of CT scanning as a cost-effective imaging modality for spinal injuries.
Quality of evidence	**Malignancy evidence** While 8 papers were identified which reported cancer outcomes in cohorts exposed to diagnostic radiation, only two used a lag time between exposure and outcome of ≥10 years and so met criteria for inclusion according to our review protocol. Neither of the included studies were based on our guideline population of

	'people with a suspected traumatic spinal injury'. However, in designing the protocol, the GDG agreed that the population for this review should be extended to include 'children, young people and adults undergoing X-ray or CT' as radiation risk is not affected by the indication for imaging. While both were relatively large cohort studies, there were drawbacks to the evidence provided by each. The first study, investigating the risk of breast cancer mortality according to the dose of radiation exposed to breast tissue in a cohort of females in the USA with scoliosis, clearly is not representative of the overall risk of malignancy in the population. Despite including a large proportion of the Australian population and having good follow-up of outcome, the second study, using linked electronic Australian medicare records fails to record exposure to medical radiation falling outside of the medicare system. The evidence for all malignancy as an outcome was of Moderate quality due to risk of bias from inadequate measurement of exposure in the Australian cohort. Quality for the breast cancer mortality outcome ranged from Low to Very low due to indirectness and degree of imprecision in the effect estimates Despite the quality of evidence being downgraded due to high risk of bias, the GDG felt that this evidence represented the best available evidence for this risk factor. **Cataract evidence** This was a retrospective cohort study, and so prone to key confounders not being measured, but in other respects was a well-conducted study. Adjustments were made in a highly powered multivariable analysis for age, sex, hypertension, diabetes mellitus and history of coronary heart disease.
Other considerations	The GDG also recognised the evidence of association between increased dose exposure and increased risk of cancer mortality. Although this evidence was indirect, being specifically females and the risk of breast cancer, it was felt by the GDG that breast tissue represented a good proxy for other radiation sensitive tissues and the evidence could be extrapolated.

12 Further imaging

12.1 Introduction

Occasionally, imaging results may be inconsistent with a patient's clinical signs and symptoms. For example, a patient may arrive at the emergency department with a clear mechanism for spinal injury, such as a fall from height, and symptoms such as spinal pain made worse by weight bearing and twisting. In such a case, even if initial imaging does not indicate a spinal injury, there is a need for further imaging before removal of spinal protection strategies can be considered. There is currently no nationally agreed strategy of further imaging in such a situation, and this review aims to determine the most clinically and cost effective further imaging approach.

12.2 Review question: For people who have clinical signs of traumatic spinal cord or column injury, but who have normal or indeterminate findings on imaging, what is the most clinically and cost effective further imaging strategy?

For full details see review protocol in Appendix C.

Table 57: PICO characteristics of review question

Population	Children, young people and adults with clinical signs of traumatic spinal injury, but have normal or indeterminate findings on initial imaging
Intervention	• Dynamic fluoroscopy (if X-ray already performed) • CT (if X-ray already performed) • MRI (if X-ray or CT already performed)
Comparison	• CT • MRI • Repeat initial modality with contrast and/or different parameters • Repeat initial modality with different scanning location or body position
Outcomes	Critical: • Mortality at 1, 6 and 12 months • Health-related quality of life • Rates of spinal cord injury (SCI) Important: • Adverse events: effects of radiation, effects of sedation/anaesthetic • Delay in treatment of other injuries whilst re-imaging • Patient-reported outcomes (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	Cross-sectional, retrospective cohort, prospective cohort

12.3 Clinical evidence

No relevant clinical studies were identified.

12.4 Economic evidence

Published literature

No relevant economic evaluations were included.

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

Unit costs

In the absence of recent UK cost-effectiveness analysis, relevant unit costs are provided below to aid consideration of cost effectiveness.

Table 58: Imaging costs

Imaging procedure	Cost	HRG code and description
X-ray 3-plain films	£90	DAPF Direct Access Plain Film Unit cost £30 each
CT	£147	RA14Z Computerised Tomography Scan, more than three areas
CT	£92	RA08A Computerised Tomography Scan, one area, no contrast, 19 years and over
CT	£94	RA08B Computerised Tomography Scan, one area, no contrast, 6 to 18 years
CT	£130	RA08C Computerised Tomography Scan, one area, no contrast, under 5
MRI	£182	RA04Z Magnetic Resonance Imaging Scan, two to three areas, no contrast
MRI	£146	RA01A Magnetic Resonance Imaging Scan, one area, no contrast, 19 years and over
MRI	£153	RA01B Magnetic Resonance Imaging Scan, one area, no contrast, 6 to 18 years
MRI	£187	RA01C Magnetic Resonance Imaging Scan, one area, no contrast, 5 years and under

12.5 Evidence statements

Clinical

No relevant clinical studies were identified.

Economic

No relevant economic evaluations were identified.

12.6 Recommendations and link to evidence

Recommendation	The evidence from this chapter supported the decision making for the imaging recommendations in chapter 10.
Relative values of	The critical outcomes for decision making were mortality up to 1 year, health-related

different outcomes	quality of life and rates of SCI. The important outcomes were: effects of radiation, effects of sedation/anaesthetic, delay in treatment of other injuries whilst re-imaging, pain/discomfort, return to normal activities and psychological wellbeing.
Trade-off between clinical benefits and harms	Initial imaging results may be inconsistent with a patient's clinical signs and symptoms. In such a case, the risk of not pursuing further investigation and removing spinal immobilisation is high and may result in exacerbating or causing an injury. The harms and benefits of the primary imaging modality have been discussed in chapter 10. The value of an imaging modality (for example X-ray) as a screening tool was discussed in detail by the GDG and the risks of using a modality that was less effective and delaying treatment was considered an unacceptable consequence in this population. The early identification and management of a spinal injury can have an enduring impact on both short- and long-term outcome. As a result, the most clinical and cost effective imaging modality has been recommended. To suggest further imaging modality would be of benefit after the optimal modality is nonsensical. The review also aimed to explore the issue of repeated imaging with the same modality, however, no evidence was identified to support any decision making, there are obvious economic implications and the GDG did not want to make a consensus recommendation on this. In the case of a newly diagnosed spinal column fracture, the GDG noted there are benefits to further imaging of the rest of the spine. Column injuries do not always occur in isolation because of the energy required to cause column fractures, and there are often additional fractures. The GDG made a consensus recommendation for this situation.
Economic considerations	No studies that looked at the use of prediction rules and or imaging modalities for the selection and clearance of spinal column injury patients were identified. The original economic analysis described in chapter 7 looked at three-stage strategies whereby further imaging was conducted. Overall, adding another imaging modality after CT was not cost effective given the low incidence of spinal injury, and in particular, ligamentous injury. Only when, in specific scenarios, has an X-ray been used to limit unnecessary radiation risk, was the addition of CT as a third-line imaging strategy potentially cost effective. It was acknowledged that this analysis does not fully account or quantify all of the trade-offs involved in the diagnostic decision on which this analysis is based. No weighting or penalty was given to outcomes, such as false positive (although the cost of observation/treatment is taken into account), there are no indeterminate images, patients are cleared or found to have an injury, only spinal column injured patients who are missed (FN) can convert to a cord injury. Patients correctly identified with spinal injury do not convert to cord injuries in the model. The same conversion rate to cord injury is applied to patients with bony column injury or ligamentous column injuries. The analysis also assumed that patients would remain well and experience no deterioration after treatment or imaging. Further limitations regarding the quality of the evidence informing the model are outlined in the below section. A separate subgroup analysis was not conducted for paediatrics. The GDG felt this economic analysis could not be extrapolated to the paediatric population. No evidence was identified for paediatrics and so, it was not possible to determine the appropriateness of model inputs for the paediatric population (in particular, the prevalence of spinal column injury and the clinical judgements for further imaging and treatment used in the analysis for adults).

	The model results may also have limited applicability to young people, dependent on how similar this subgroup is to children or to adults in their baseline epidemiology and risk profile. In the model, only patients who were found positive on one modality went on to receive the next modality in the sequence. Therefore no indeterminate findings were included in the strategies in the model. Some of the recommendations above recommend further imaging if spinal injury cannot be confidently excluded. Therefore these are in a population not considered in the model; i.e. further imaging of those with a negative result but symptoms remain. It is likely that in this small population of negative CT but of concern (compared to all those positive on a CT) further imaging to definitively rule out spinal cord injury will be cost effective, given the potential costs and consequences of missing an injury.
Quality of evidence	No relevant studies were retrieved for the related further imaging question in either children or adults.
Other considerations	The GDG wanted to emphasise the importance of carrying out imaging and obtaining the results as soon as possible. This is vital in guiding the early management of a person with a spinal injury and the impact on later outcomes. It is also important in ruling out a spinal injury and clearing the spine and removing spinal immobilisation devices.

13 Spinal cord decompression

13.1 Introduction

Cervical spinal cord injuries (SCIs) due to traumatic fractures are associated with persistent neurological deficits. Closed reduction of the cervical spine is a commonly used method for treatment of acute subluxations or dislocations and aims to restore spinal alignment and stability. The procedure is achieved through stepwise skeletal traction and is considered successful when the spinal cord becomes decompressed. However, the treatment is complicated and controversial, and has been associated with a number of adverse events, including cervical disc prolapse and acute deterioration.

Although clinical evidence is weak, early decompression, usually defined as within 24–72 hours of injury, has been hypothesised to be associated with better outcome. There is suggestion that improved neurological outcomes are achieved if decompression is achieved within one hour. While such an early time frame may not be practical in clinical practice, a standard of under 4 hours could have profound effects on long-term quality of life in patients with SCI.

13.2 Review question: What is the clinical and cost-effectiveness of emergency closed reduction of cervical facet joint dislocation of the cervical spine?

For full details see review protocol in Appendix C.

Table 59: PICO characteristics of review question

Population	Children, young people and adults with acute traumatic cervical dislocations
Intervention	Emergency closed reduction (within 4 hours of injury)
Comparison	• Delayed closed reduction (after 4 hours) • No reduction
Outcomes	Critical: • Mortality at 1, 6 and 12 months • Health-related quality of life • Spinal cord neurological function at 1, 6 and 12 months (including American Spinal Injury Association [ASIA] and Frankel) • Adverse effects (deterioration in neurological function, acute cervical disc prolapse) Important: • Patient-reported outcomes (pain/discomfort, return to normal activities, psychological wellbeing)
Study design	RCTs or systematic reviews of RCTs, cohorts and retrospective case series for adverse events

13.3 Clinical evidence

We searched for RCTs, observational cohorts and prospective studies which compared time course for closed reduction of the cervical spine following dislocation. No randomised clinical trials or cohort studies were identified.

Despite identifying 50 studies of potential interest, all were all excluded for final analysis following review. Studies were generally excluded on the basis that they compared open reduction with closed

reduction and did not compare timing of the intervention. Case reports were considered for the adverse effect profile associated with the intervention.

13.4 Economic evidence

Published literature

No relevant economic evaluations were identified.

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

Unit costs

Resources that would be involved in reducing a dislocated cervical spine include: cervical traction and an X-ray. In terms of staff, a senior doctor, such as a consultant, a nurse, a radiographer and a porter are required. An additional resource could be a special bed which is sometimes used.

As reduction of the cervical spine will be done as part of the care and investigations of a suspected spinal injury undertaken in A&E, it could be seen as incorporated under the following Health Resource Group (HRG) code within NHS reference costs[37]:

Table 60: HRG code for reduction of dislocation

HRG code	Code description	National average unit cost
VB04Z	Emergency Medicine, Category 2 Investigation with Category 4 Treatment	£210

This HRG includes 'X-ray plain film PLUS manipulation of dislocation'.

This HRG may be on the conservative side because the HRG cost estimate is an average cost calculated using procedures that are less complex, require less time or require a less senior doctor.

Furthermore, because reducing a dislocated cervical spine is considered to be a specialist procedure, consideration should be given to the costs involved in ensuring sufficient training and/or experience for staff to be able to achieve any beneficial effect suggested by the clinical evidence review.

13.5 Evidence statements

Clinical

No relevant clinical evidence was identified.

Economic

No relevant economic evaluations were identified.

13.6 Recommendations and link to evidence

Recommendations	Research recommendation: What is the clinical and cost effectiveness of emergency reduction of cervical spine dislocations following acute traumatic cervical spinal injury?
Relative values of different outcomes	The principle aim of a closed reduction of the cervical spine dislocation is to prevent or reverse paralysis in order to optimise quality of life. Therefore, health-related quality of life was considered the most critical outcome for decision making. The invasive procedure is at risk of side-effects, including deterioration in neurological

	status and acute disc prolapse, and the GDG believed that understanding these would be critical before any recommendation could be made. Mortality at 1, 6 and 12 months was also considered a critical, although unlikely, consequence of permanent paralysis. Surrogate outcomes regarding spinal cord neurological function were also considered critical but the GDG noted that the impact of these outcomes on daily living was captured by the composite quality of life score. Important outcomes were patient-reported outcomes, such as pain. These were not regarded as critical as they would be unlikely to influence any recommendations in the presence of other outcomes.
Trade-off between clinical benefits and harms	No eligible published studies were found. The GDG discussed a cohort study that showed clinical benefits of closed reduction given at under 4 hours compared with closed reduction after 4 hours, but this was excluded from the review due to a lack of consideration of key confounders. Other ineligible studies that examined the adverse effects of early closed reduction were also discussed, and it was noted that although most studies did not show adverse effects, transient deterioration in neurological function and a prolapsed disc had been observed with early closed reduction. Overall, the GDG felt that they had insufficient evidence to be able to assess the balance of benefits and harms for early closed reduction.
Economic considerations	No economic evidence was identified comparing closed reduction of a dislocation within 4 hours with reduction after 4 hours or no reduction. Reduction of the cervical spine is likely to be included within an A&E code from NHS reference costs. Due to the rarity and complexity of the procedure in comparison to other procedures contained within the same cost code, that is, relocation of dislocations, it is likely the NHS reference cost is conservative. The only clinical evidence discussed compared reduction within 4 hours with reduction after 4 hours. In terms of the difference in resource use between these two comparators, this is likely to be small, such as additional X-rays. However, a larger impact could be from the difference in outcomes between reducing earlier or later, as the clinical review has shown that reducing earlier leads to a clinically important improvement on the Frankel scale. An improvement on the Frankel scale is likely to make a substantial difference to the patient's quality of life as they could be going from no motor or sensory function to some type of function. This improvement could also lead to cost savings, as the lifetime costs of treating a spinal injury vary depending on the completeness of the injury, thus, even a small improvement in the Frankel scale could affect this. Although the resource implications in undertaking the procedure in different timeframes may be small, there could also be potential service delivery implications. For example, it would be necessary to not only have staff available of suitable expertise to do the procedure, but also have staff to diagnose the cervical dislocation and assess the need for the procedure, such as radiologists, within the optimal time frame allotted. With polytrauma patients, other time critical procedures may take priority and undertaking this procedure in the optimal timeframe may not be achieved, and alternative management then may become more cost effective. Assessment of cost effectiveness is further complicated by the lack of evidence on how the procedure compares with a 'do nothing' or 'current care' strategy, which would not involve the use of the specialist bed and expertise. A clinical member

	estimated the cost of the specialist bed to be approximately £20,000-26,000, or the procedure may be done with traction devices routinely available in the major trauma centre. Furthermore, the procedure is likely to be done in the emergency department (ED) resuscitation room, and would require a mobile image intensifier. Cost per patient, however, would depend on the lifetime of the bed and the expected use (given that the bed may also serve as a general ED bed), and a clinical member estimated the annualised cost difference of a specialist bed versus normal bed per patient to be about £400 (based on 2 patients having a reduction annually). The downstream resource implications are also difficult to estimate in relation to a 'do nothing' or 'current management' strategy due to little information on the potential for adverse events of the procedure (in particular, if done by someone inexperienced). As reduction is not commonly practised in the NHS, the cost and service delivery impact of a recommendation in favour of the procedure could be large. Due to the uncertainty regarding the effectiveness of the procedure in the current NHS service context, it was felt further research would be required before a recommendation in favour could be made.
Quality of evidence	No published studies were included.
Other considerations	The GDG agreed that the lack of adequately rigorous evidence precludes any recommendation for use of this highly specialised procedure. Considering the potential clinical benefit of the procedure in the absence of adequate evidence, the GDG felt that a research recommendation would be appropriate. In particular, the GDG felt it was important the research should specify exactly what level of physician should carry out the procedure.

14 Timing of referral to tertiary services

14.1 Introduction

Ideally, when a spinal cord injury (SCI) is diagnosed or suspected in the emergency department (ED) there should be an immediate referral to the nearest on-call spinal surgeon. The location of the on-call spinal surgeon will depend on the destination of the patient. All major trauma centres (MTCs) should have an on-call rota for spinal surgery. In addition, a trauma-related consultant should contact a peer consultant based within the geographic SCI centre (SCIC) linked to the referring hospital in accordance with the NHS National SCI Care Pathway (May 2013). Within the current guidance on managing traumatic SCI (CAG-MTC-SCI 2010) this contact is expected to be made within 4 hours of the diagnosis of SCI.

Referral in this context is for expert guidance on the management of the SCI beyond the initial resuscitation and does not imply the expectation to transfer to a SCIC. The referral is to an NHS specialised service which offers a range of care services, inpatient admission for specialised rehabilitation being one of them. Alternatively, the patient may be assessed by the SCIC as suitable for outpatient management or outreach services.

The chapter assesses whether referral to specialist advice at such an early stage in the management of the patient would be beneficial for the optimal treatment of the patient.

14.2 Review question: Is there a benefit of early liaison and referral (within 4 hours) to spinal cord injury centres compared to delayed liaison?

For full details see review protocols in Appendix C.

Table 61: PICO characteristics of review question

Population	Adults, young people and children with SCI
Intervention	Early liaison/referral with SCIC
Comparison	• Later liaison/referral • No liaison/referral
Outcomes	Critical: • Mortality • Quality of life Important: • Pain levels (immediate, 1 week) • Function and ADL (1 month, 3 months, 1 year, 3 years, 5 years) • Length of SCIC stay • Adverse events after transfer (immediate) • For example altered neurological function • Complications – pressure sores, contractures, stones, urological complications, poor spinal outcome • Duration of admission

14.3 Clinical evidence

No relevant studies were identified that met the eligibility criteria of the protocol. There are no studies in the exclusion list (Appendix K) as the initial sift through the abstracts, performed by 2 blinded reviewers, and did not indicate the need to order full papers.

14.4 Economic evidence

No relevant economic evaluations were identified.

14.5 Evidence statements

Clinical

No relevant clinical studies were identified.

Economic

No relevant economic studies were identified.

14.6 Recommendations and link to evidence

Recommendations	**51. For people in a trauma unit who have a spinal cord injury, the trauma team leader should immediately contact the specialist neurosurgical or spinal surgeon on call in the trauma unit or nearest major trauma centre.** **52. For people in a major trauma centre who have a spinal cord injury, the trauma team leader should immediately contact the specialist neurosurgical or spinal surgeon on call.** **53. For people who have a spinal cord injury, the specialist neurosurgical or spinal surgeon at the major trauma centre or trauma unit should contact the linked spinal cord injury centre consultant within 4 hours of diagnosis to establish a partnership of care.**
Relative values of different outcomes	The critical outcomes to inform decision making for the early liaison and referral of people with SCIs are mortality and health-related quality of life. Mortality rates reflected both the short and long-term impact of receiving suboptimal treatment in the first four hours of having a SCI. Failure to contact a SCIC within the initial acute period and receive specialist spinal input could result in an increased likelihood of associated complications of SCI and consequently an increased risk of mortality. Health-related quality of life at up to three months is a direct measure of the impact of appropriate treatment in the first four hours of having a SCI. Failure to contact a SCIC within the initial acute period and have specialist spinal input could result in an increased likelihood of (associated complications of SCIs) which results in decreased health-related quality. Pain levels were considered an important outcome as pain is often a significant

	problem after spinal injury with a strong short-term effect on quality of life; it may, therefore, be an important outcome if early quality of life data is not available. Measures of function (such as levels of activities of daily living) were also included as important outcomes because early care may have an important effect on eventual functional status. The GDG included length of SCIC stay and duration of admission as an indicator of early optimal treatment, as people receiving optimal treatment are likely to have a shorter length of stay than those who have not. These outcomes are also informative to understand how any resources invested into earlier referral and liaison may be offset. The following associated complications of SCIs were chosen as surrogate outcomes as most likely to influence mortality and health-related quality of life: immediate adverse events (altered neurological function) and long-term adverse events (for example, pressure sores, contractures, urological complications and poor spinal outcome).
Trade-off between clinical benefits and harms	No clinical evidence was identified.
Economic considerations	No economic evidence was identified. The GDG considered the economic implications of early liaison with a SCIC in order to form a consensus recommendation. A patient with suspected SCI will require imaging in the ED before liaison with the SCIC. This means that an early referral would need an available CT scanner and radiographer within 4 hours of arrival at the ED. The GDG discussed the service delivery implications for the receiving centre (that is, 24/7 radiographer cover), and the potential need for increased resource use to meet the timing of an early referral. It was felt that, as only the MTC would liaise with the SCIC, and this type of centre already has round the clock cover, there would not be substantial cost implications. The GDG believed that an early referral could reduce mortality and improve health-related quality of life. They also thought that an early liaison with the SCIC could improve the outcomes of the initial treatment and then reduce the time spent at the SCIC, therefore, reducing the cost of inpatient stay as well as the cost of treating adverse events, such as pressure sores. The GDG came to the consensus that there would be a reduction in costs with earlier liaison due to reduce in-hospital stay and this is likely to outweigh any costs incurred from implementing an early liaison strategy. In addition, an early liaison strategy is thought to improve outcomes for the patient and decrease costs (when compared with the cost of missed or poorly managed cord or column injuries). As such, the GDG agreed that early liaison with the SCIC is likely to be cost-effective and likely to have a cost neutral or cost saving impact
Quality of evidence	No clinical or economic evidence was identified.
Other considerations	These recommendations are consensus, based on the GDG expert opinion. Despite the absence of evidence, the GDG noted the disparity of care across the NHS with respect to referral practices, and felt that it was important to make a recommendation on liaison with a tertiary service and referral to a SCIC in the initial management of people with SCIs.

	The GDG noted that although people with suspected SCIs should only be taken to a MTC and not to a trauma unit (TU) there could be occasions where a person has a SCI confirmed in a TU ED. In this event, the GDG considered it was important to have a recommendation supporting the TU. These are strong recommendations in the context of an absence of evidence, however, the GDG wanted to highlight that this recommendation comes at the beginning of the clinical pathway for the SCI person and the management has not only an immediate, but an enduring impact on a person's health-related quality of life. In the GDG opinion, delayed advice from a specialist neurosurgical/spinal surgeon may result in harm to the acutely spinal cord injured person. Initial management supported by a specialist neurosurgical/spinal surgeon is likely to result in reduced mortality rates and better spinal outcomes. This is further supported by referral to a SCIC by a specialist neurosurgical/spinal surgeon when discussion can start about the most appropriate treatment for the SCI patient and to trigger the local system for outreach support between the SCIC and referring unit. The GDG discussed who should be responsible for contacting specialist advice. The GDG named the trauma team leader as the person responsible for contacting the on-call specialist neurosurgical/spinal surgeon. The GDG recommended contact within 4 hours with the linked SCIC and named the on-call specialist neurosurgical/spinal surgeon as the clinician responsible. The GDG discussed whether it was appropriate and practical for the trauma team leader to contact the SCIC. The GDG considered the trauma team leader was not the most appropriate person to contact the SCIC and the specialist neurosurgical/spinal surgeon is. Trauma team leaders are often the most senior person in an ED with many competing demands. The specialist neurosurgical/spinal surgeon while still busy is best placed to convey the current clinical situation and management as they will be directing the patient's care after the initial contact from the ED. The GDG considered contact within 4 hours as important, underlying the importance of early specialist advice at the beginning of the clinical pathway for the person with SCI. The GDG noted that The British Orthopaedic Association Standard for Trauma 8 "The Management of Traumatic Spinal Cord Injury". Published by The British Association of Spinal Cord Injury Specialists, The British Association of Spine Surgeons, The Society of British Neurological Surgeons and the British Orthopaedic Association, Standard 8 states "Management of the spine must follow the written protocols agreed with the linked Spinal Cord Injury Centre, or alternatively the on call consultant at that centre should be contacted within 4 hours of injury" The GDG discussed at length whether the call should be within 4 hours of diagnosis or injury. They concluded that after diagnosis was a more appropriate point to contact the spinal cord injury centre at this time useful clinical information could be given It is important that the patient is recorded on the National SCI Database as soon as possible. Registration on the National SCI Database ensures that if the patient does not eventually transfer to a tertiary centre they will be registered for NHS SCI Services as well as assisting in NHS data collection and audit. The database also enables the geographic SCIC to manage and track the patient progress remotely and to share that information within the SCI Service network should the patient reside in a different geographic region to the one served by his current SCIC.

15 Referral to a Spinal Cord Injury Centre

15.1 Introduction

Currently, the ultimate destination for the majority of people diagnosed with a new traumatic spinal cord injury (SCI) is to offer admission to 1 of the 8 NHS SCI centres (SCICs).

However, there are concerns over capacity and acceptance criteria for admission into a SCIC. Inpatient capacity of the NHS SCI Service is currently insufficient for need, and whilst in most cases prioritisation is given to cases of traumatic SCI, this service is not exclusive to trauma, and also has a responsibility to provide specialist care for non-traumatic SCI.

Discussion is required about how the SCIC team determine which SCI patients receive which services, and the resourcing strategies or pressures which determine these decisions. This particularly relates to children, older adults, non-UK residents, those without current NHS entitlement beyond emergency care and patients requiring long-term ventilation.

15.2 Review question: What are the clinical factors associated with a positive outcome after transfer to an SCIC for patients with spinal trauma?

For full details see review protocol in Appendix C.

Table 62: PICO characteristics of review question

Population	Adults, young people and children with SCI
Prognostic factors	• Age • Level of injury (C, T, L) • Density of injury (complete/partial)/severity of neurological impairment (American Spinal Injury Association [ASIA]) • Co-existing psychiatric problems • Co-existing head injuries • Co-existing respiratory problems • Co-existing cardiovascular problems • Co-existing non-spinal orthopaedic • Co-existing infection • Co-existing pressure sores • Ventilator dependency • Level of sedation
Outcomes	Critical: • Mortality after transfer (time to event) • Quality of life after transfer (at 1 week, 1 month, 3 months) Important: • Pain levels after transfer (immediate, 1 week) • Function and ADL (1 month, 3 months, 1 year, 3 years, 5 years) • Length of hospital stay
Study design	Study designs: prospective and retrospective cohorts, or systematic reviews of cohorts. (In the event of no other studies consider using case control studies).

15.3 Clinical evidence

No relevant clinical studies were identified.

15.4 Economic evidence

Published literature

No relevant economic evaluations were identified.

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

15.5 Evidence statements

Clinical

No relevant clinical studies were identified.

Economic

No relevant economic evaluations were identified.

15.6 Recommendations and link to evidence

Recommendations	54.All people who have a spinal cord injury should have a lifetime of personalised care that is guided by a spinal cord injury centre.
Relative values of different outcomes	Health-related quality of life and mortality were considered by the GDG to be the most important outcomes to help them determine if there are specific clinical factors that would help identify if there are groups of people with SCI that would benefit most from referral to SCIC and those that can be managed outside a SCIC without disadvantage. Pain levels were considered an important outcome and measures of function, levels of ADL, immediate adverse events (altered neurological function) and long-term adverse events (pressure sores, contractures, bladder and kidney/calculi stones, urological complications, poor spinal outcome) were chosen as surrogate outcomes as most likely to influence mortality and health-related quality of life.
Trade-off between clinical benefits and harms	No clinical evidence was found for this question.
Economic considerations	No economic evidence was retrieved to inform this question. When forming a consensus recommendation the GDG discussed the likelihood that a patient, for example with co-existing respiratory conditions or cardiovascular problems, would clinically benefit more through treatment in a major trauma centre (MTC) than in a specialist centre (due the range of expertise present in the MTC). Furthermore, an MTC may be better placed to initially deal with the patient with multiple injuries. On the other hand, the staff at a MTC were less likely to have expertise in how the spinal injury may impact and be impacted on by comorbidities. The GDG acknowledged that if every spinal injured patient was accepted at the SCIC and transferred, some of these patients may need to be transferred back to the MTC if they cannot be treated appropriately for their other conditions, which will incur additional

	costs. The precise clinical factors which determine the possible net benefit of transfer remains unclear, and as such, cost effectiveness of transfer based on given criteria whilst the patient is in the acute phase also remains unclear. The cost of a specialist spinal injury bed was thought to be higher than that in a MTC; however, in the case of isolated SCI at least, the clinical benefit of the specialist care was likely to justify this additional cost. To provide optimal clinical and cost-effective onward management, the GDG thought that it was important for the SCIC to be involved in a patient's care throughout their lifetime, and to ensure this happened, there should be a defined partnership care, specific to each patient, which is guided by the SCIC. Compared with current practice, it is expected that the recommendations will potentially cost neutral because the GDG has recommended guided care which includes outreach as well as inpatient care and this reflects the cost of current practice.
Quality of evidence	No evidence was identified.
Other considerations	These recommendations are consensus based on the GDG expert opinion. The GDG acknowledged that anyone with a SCI would benefit from direct input and support from a SCIC. The question of how this input is delivered and in the majority of cases where the patient should be located is less clear. As mentioned above, the patient with multiple injuries is usually best managed in a MTC with immediate access to multiple specialists. In light of this, the GDG considered it was important to make a recommendation that a person with a diagnosis of SCI should have a lifetime of personalised care that is guided by a SCIC. This at the least requires the person with SCI to have directed specialist care. This was strongly supported by GDG members working in SCICs. They were keen to ensure that all people with SCI were known to a SCIC and that the centre had active input guiding care.

16 Neuroprotective pharmacological interventions

16.1 Introduction

After an acute spinal cord injury (SCI), several progressive and potentially destructive processes develop within the acutely injured spinal cord. Prevention of movement at the site of the SCI, adequate oxygenation and adequate perfusion are known to be important in minimising the adverse consequences of these secondary events. Neuroprotective pharmacological interventions (such as anti-inflammatories, antioxidants and anti-excitotoxins) have recently become of interest because of benefits reported in animal studies. However, the evidence-base in humans is less well-established. This chapter reviews the evidence for neuroprotective pharmacological interventions.

16.2 Review question: What is the clinical and cost-effectiveness of neuroprotective pharmacological interventions (such as anti-inflammatories, antioxidants and anti-excitotoxins) in people with spinal cord injury during the acute stage?

For full details see review protocol in Appendix C.

Table 63: PICO characteristics of review question

Population	Adults, young people and children with SCI
Intervention/s	• Glucocortorticoids - Methylprednisolone (Medrone, Solu-medrone, Depo-medrone), Dexamethasone • Non-steroidal anti-inflammatories (NSAIDs) - Ibuprofen (Brufen), celecoxib (Celebrex) • Calcium channel blockers - Nimodipine (Nimotop) • Opioid antagonist – Naloxone, thyrotropin releasing hormone (Protirelin) Or a combination of the above interventions
Comparison/s	• Usual care • Each other • Placebo
Outcomes	Critical: • Mortality (at 1, 6 and 12 months) • Health-related quality of life • Spinal cord neurological function (at 1, 6 and 12 months). (including American Spinal Injury Association [ASIA] and Frankel) • Adverse effects (gastrointestinal [GI] bleeding, infection including ventilator associated pneumonia, thrombosis, hyperglycaemia) Important: • Patient-reported outcomes (pain/discomfort, return to normal activities, psychological wellbeing)
Study design	RCTs or a systematic review of RCTs

16.3 Clinical evidence

Summary of included studies

Six RCTs along with 4 additional subsidiary papers were identified for inclusion in this review.[15-21,79,89,93] All of these studies have previously been included in the Cochrane Review by Bracken et al. (2012).[14] The Cochrane review included 2 additional RCTs, which were excluded from our analysis due to indirect populations.

No relevant clinical studies comparing the corticosteroid dexamethasone, or any NSAIDs were identified. All the studies identified had methylprednisolone as one of the comparators.

Four studies compared methylprednisolone with placebo or no treatment. One study had naloxone as a third-arm comparator, and another had 2 additional trial arms comparing nimodipine and a combination of methylprednisolone plus nimodipine.

Two studies compared different doses or regimens of methylprednisolone. One compared a 24-hour regimen with a 48-hour regimen of methylprednisolone (this also had a third trial arm comparing tirilazad mesylate, a drug not licensed in the UK and therefore, not included in our analysis), and the second compared a low dose 10-day regimen with a moderate dose 10-day regimen.

Five of the six studies[15,17,20,79,89] measured the outcome of neurological function using a neurological score developed from the NASCIS studies (NASCIS score). The NASCIS score involves unilaterally (the right side of the body) testing 29 dermatomes and scoring them from 1-3 (absent to normal sensation) giving a sensory score range from 29-87; and testing 14 muscle groups and scoring them from 0-5 (absent to normal motor function), giving a motor score range from 0-70.

One study[93] measured neurological function using the ASIA score. This involves testing 28 dermatomes bilaterally, and scoring them from 0-2 (absent to normal sensation), giving a range from 0-112 for sensory scores; and for motor scores testing 10 myotomes bilaterally, scoring them from 0-5 (absent to normal motor function), giving a range from 0-100.

Due to the non-linear nature of these scales, it was felt inappropriate to pool the data for these different measures.

Outcomes for subgroup analyses of time to treatment are presented only for those studies that pre-specified or stratified this subgrouping and not those that performed a post-hoc analysis.

Although the French RCT Petitjean et al.[91] was excluded from our analysis due to its language of publication, the English translation of this RCT subsequently published by Pointillart et al.[93] was included instead.

Evidence from these are summarised in the clinical GRADE evidence profile in Appendix H. See also the forest plots in Appendix I, study evidence tables in Appendix G, study selection flow chart in Appendix D and exclusion list in Appendix J.

Table 64: Summary of studies included in the review

Study	Intervention/ comparison	Population	Outcomes	Comments
Bracken 1984[15]	Methylprednisolone moderate dose (10 days) versus Methylprednisolone low dose (10 days)	n=330 Age ≥13 years Randomization within 48 hours of injury	• Motor function • Pinprick sensation • Touch sensation • Mortality	Post-hoc subgroup analysis of those treated within 8 hours

Study	Intervention/ comparison	Population	Outcomes	Comments
			• Adverse events	
Bracken 1990[17]	Methylprednisolone high dose (24 hours) versus Naloxone (24 hours) versus placebo	n=487 Age ≥13 years Randomization within 12 hours of injury	• Motor function • Pinprick sensation • Touch sensation • Mortality • Adverse events	Subgroup analyses (treated within 8 hours and completeness of injury) specified but not stratified during randomisation
Bracken 1997[20]	Methylprednisolone high dose (24 hours) versus Methylprednisolone high dose (48 hours)	n=499 Age ≥13 years Randomization within 8 hours of injury	• Motor function • Pinprick sensation • Touch sensation • Mortality • Adverse events	Subgroup analyses (treated between 3-8 hours post injury) specified but not stratified during randomisation
Matsumoto 2001[79]	Methylprednisolone high dose (24 hours) versus placebo	n=46 Age ≥18 years	• Mortality • Adverse events	Treated with gastric protection and empirical antibiotics
Otani 1994[89]	Methylprednisolone high dose (24 hours) versus no treatment	n=117 Age 18-65 years	• Motor function • Mortality • Adverse events	Both groups permitted treatment with other steroids.
Pointillart 2000[93]	Methylprednisolone high dose (24 hours) versus Nimodipine (7 days) versus both treatments versus no treatment	n=106 Age 15-65 years Randomized within 8 hours of injury	• Motor function • Pinprick sensation • Touch sensation • Adverse events	Used ASIA scoring

Table 65: Clinical evidence summary: High-dose methylprednisolone versus placebo/no treatment

Outcome	No. of studies (No. of participants)	Imprecision	GRADE rating	Absolute difference	Control event rate (per 1000)	Control event rate for continuous outcomes
All-cause mortality	3 (n=530)	Very serious	LOW	26 fewer per 1000 (from 43 fewer to 14 more)	57 per 1000	
Motor function at six weeks	2 (n=419)	No serious imprecision	HIGH	MD 1.53 higher (0.53 lower to 3.59 higher)		Change score 7.92
Motor function at six months	2 (n=419)	No serious imprecision	HIGH	MD 0.85 higher (1.79 lower to 3.49 higher)		Change score 13.65
Motor function at one year	1 (n=414)	No serious imprecision	HIGH	MD 0.86 lower (4.62 lower to 2.9 higher)		Change score 13.31
Motor function at six weeks (<8 hours to treatment)	2 (n=249)	Serious	LOW	MD 3.19 higher (0.02 to 6.92 higher)		Change score 7.14
Motor function at six months (<8 hours to treatment)	2 (n=250)	Serious	LOW	MD 4.44 higher (0.96 to 7.93 higher)		Change score 10.83
Motor function at one year (<8 hours to treatment)	1 (n=127)	Serious	LOW	MD 5.2 higher (0.53 lower to 9.87 higher)		Change score 13.41
Motor function at one year: ASIA score	1 (n=50)	Serious	MODERATE	MD 5.7 higher (20.12 lower to 8.72 higher)		Change score 23.7
Pinprick sensation at six weeks	2 (n=414)	No serious imprecision	HIGH	MD 1.55 higher (0.27 lower to 3.36 higher)		Change score 4.98
Pinprick sensation at six months	2 (n=412)	Serious	MODERATE	MD 3.31 higher (1.17 to 5.46 higher)		Change score 6.31
Pinprick sensation at one year	1 (n=284)	No serious imprecision	HIGH	MD 0.18 higher (2.6 lower to 3.05 higher)		Change score 7.6
Pinprick sensation at six weeks (<8 hours to	1 (n=249)	No serious imprecision	MODERATE	MD 1.95 higher (0.41 lower to 4.32 higher)		Change score 5.11

Outcome	No. of studies (No. of participants)	Imprecision	GRADE rating	Absolute difference	Control event rate (per 1000)	Control event rate for continuous outcomes
treatment)						
Pinprick sensation at six months (<8 hours to treatment)	2 (n=250)	Serious	LOW	MD 3.97 higher (1.27 to 6.66 higher)		Change score 6.09
Pinprick sensation at one year (<8 hours to treatment)	2 (n=127)	Serious	LOW	MD 2.41 higher (1.72 lower to 6.54 higher)		Change score 8.36
Pinprick sensation at one year: ASIA score	1 (n=50)	Very serious	LOW	MD 0 higher (20.72 lower to 20.72 higher)		Change score 11.6
Touch sensation at six weeks	2 (n=413)	No serious imprecision	HIGH	MD 1.9 higher (0.04 lower to 3.85 higher)		Change score 4.22
Touch sensation at six months	2 (n=411)	No serious imprecision	MODERATE	MD 3.04 higher (0.84 to 5.24 higher)		Change score 5.73
Touch sensation at one year	1 (n=282)	No serious imprecision	HIGH	MD 0.69 higher (2.21 lower to 3.59 higher)		Change score 6.85
Touch sensation at six weeks (<8 hours to treatment)	2 (n=249)	Serious	LOW	MD 2.55 higher (0.07 to 5.04 higher)		Change score 3.56
Touch sensation at six months (<8 hours to treatment)	2 (n=250)	No serious imprecision	LOW	MD 3.85 higher (1.13 to 6.57 higher)		Change score 4.70
Touch sensation at one year (<8 hours to treatment)	1 (n=127)	Serious	LOW	MD 3.38 higher (0.91 lower to 7.67 higher)		Change score 6.01
Touch sensation at one year: ASIA score	1 (n=50)	Serious	MODERATE	MD 2.9 higher (15.36 lower to 21.16 higher)		Change score 13.3
Adverse effects - Pneumonia at six weeks	1 (n=333)	Very serious	LOW	6 more per 1000 (from 77 fewer to 124 more)	275 per 1000	
Adverse effects -	1 (n=36)	No serious	MODERATE	424 more per 1000 (from 31		

Outcome	No. of studies (No. of participants)	Imprecision	GRADE rating	Absolute difference	Control event rate (per 1000)	Control event rate for continuous outcomes
Hyperglycaemia at six weeks		imprecision		more to 1000 more)	33 per 1000	
Adverse effects - GI haemorrhage at six weeks	3 (n=434)	Serious	MODERATE	28 more per 1000 (from 3 fewer to 109 more)	23 per 1000	
Adverse effects - Pulmonary embolus at six weeks	2 (n=369)	No serious imprecision	HIGH	55 more per 1000 (from 5 more to 227 more)	16 per 1000	
Adverse effects - Wound infection at six weeks	1 (n=333)	Very serious	LOW	34 more per 1000 (from 9 fewer to 150 more)	36 per 1000	
Adverse effects - UTI at six weeks	2 (n=393)	Serious	MODERATE	20 more per 1000 (from 69 fewer to 133 more)	403 per 1000	
Adverse effects - Sepsis at six weeks	3 (n=444)	Very serious	LOW	10 more per 1000 (from 24 fewer to 79 more)	54 per 1000	

Table 66: Clinical evidence summary: Moderate-dose methylprednisolone versus low-dose methylprednisolone

Outcome	No. of studies	Imprecision	GRADE rating	Absolute difference	Control event rate (per 1000)	Control event rate for continuous outcomes
All-cause mortality	1 (n=330)	Serious	MODERATE	36 more per 1000 (from 20 fewer to 147 more)	79	
Motor function at six weeks	1 (n=258)	No serious imprecision	HIGH	MD 0.6 lower (4.44 lower to 3.24 higher)		Change score 8.8
Motor function at six months	1 (n=179)	No serious imprecision	HIGH	MD 0.9 lower (5.38 lower to 3.58 higher)		Change score 14.1
Motor function at one year	1 (n=258)	No serious imprecision	HIGH	MD 0.46 higher (3.11 lower to 4.03 higher)		Change score 11.49
Pinprick sensation at six	1 (n=171)	No serious	HIGH	MD 0.9 higher (3.28 lower to		Change score 6.2

Outcome	No. of studies	Imprecision	GRADE rating	Absolute difference	Control event rate (per 1000)	Control event rate for continuous outcomes
weeks		imprecision		5.08 higher)		
Pinprick sensation at six months	1 (n=223)	No serious imprecision	HIGH	MD 0.5 lower (4.79 lower to 3.79 higher)		Change score 9.9
Pinprick sensation at one year	1 (n=258)	No serious imprecision	HIGH	MD 1.67 lower (4.76 lower to 1.42 higher)		Change score 8.43
Touch sensation at six weeks	1 (n=258)	No serious imprecision	HIGH	SMD 0.4 higher (3.43 lower to 4.23 higher)		Change score 7
Touch sensation at six months	1 (n=171)	No serious imprecision	HIGH	MD 0 higher (4.26 lower to 4.26 higher)		Change score 10.4
Touch sensation at one year	1 (n=221)	No serious imprecision	HIGH	MD 0.25 higher (2.68 lower to 3.18 higher)		Change score 7.31
Adverse effects - Pneumonia at six weeks	1 (n=304)	Very serious	LOW	11 fewer per 1000 (from 78 fewer to 97 more)	190	
Adverse effects - GI haemorrhage at six weeks	1 (n=304)	Very serious	LOW	14 more per 1000 (from 36 fewer to 116 more)	85	
Adverse effects - Pulmonary embolus at six weeks	1 (n=304)	Very serious	LOW	20 more per 1000 (from 12 fewer to 129 more)	26	
Adverse effects - Wound infection at six weeks	1 (n=304)	Serious	MODERATE	67 more per 1000 (from 5 more to 249 more)	26	
Adverse effects - UTI at six weeks	1 (n=304)	Serious	MODERATE	51 more per 1000 (from 48 fewer to 186 more)	301	
Adverse effects - Sepsis at six weeks	1 (n=304)	Very serious	LOW	34 more per 1000 (from 16 fewer to 150 more)	52	

Table 67: Clinical evidence summary: High-dose methylprednisolone 48 hours versus high-dose methylprednisolone 24 hours

Outcome	No. of studies	Imprecision	GRADE rating	Absolute difference	Control event rate (per 1000)	Control event rate for continuous outcomes
All-cause mortality	1 (n=332)	Very serious	LOW	6 more per 1000 (from 29 fewer to 90 more)	54	
Motor function at six weeks (<8 hours to treatment)	1 (n=305)	No serious imprecision	HIGH	MD 2.81 higher (0.62 lower to 6.24 higher)		Change score 9.03
Motor function at six months (<8 hours to treatment)	1 (n=291)	No serious imprecision	HIGH	MD 3.37 higher (0.54 lower to 7.28 higher)		Change score 13.38
Motor function at one year (<8 hours to treatment)	1 (n=286)	No serious imprecision	HIGH	MD 2.35 higher (1.75 lower to 6.45 higher)		Change score 15.44
Pinprick sensation at six weeks (<8 hours to treatment)	1 (n=305)	No serious imprecision	HIGH	MD 1.39 higher (1.55 lower to 4.33 higher)		Change score 7.17
Pinprick sensation at six months (<8 hours to treatment)	1 (n=291)	No serious imprecision	HIGH	MD 0.42 higher (2.57 lower to 3.41 higher)		Change score 8.78
Pinprick sensation at one year (<8 hours to treatment)	1 (n=286)	No serious imprecision	HIGH	MD 0.4 higher (2.7 lower to 3.5 higher)		Change score 10
Touch sensation at six weeks (<8 hours to treatment)	1 (n=305)	No serious imprecision	HIGH	MD 1.72 higher (1.26 lower to 4.7 higher)		Change score 6.92
Touch sensation at six months (<8 hours to treatment)	1 (n=291)	No serious imprecision	HIGH	MD 0.89 higher (2.23 lower to 4.01 higher)		Change score 8.74
Touch sensation at one year (<8 hours to treatment)	1 (n=286)	No serious imprecision	HIGH	MD 1 higher (2.1 lower to 4.1 higher)		Change score 9.6

Outcome	No. of studies	Imprecision	GRADE rating	Absolute difference	Control event rate (per 1000)	Control event rate for continuous outcomes
Adverse effects - Pneumonia at six weeks	1 (n=388)	Very serious	LOW	19 more per 1000 (from 48 fewer to 133 more)	149	
Adverse effects - GI haemorrhage at six weeks	1 (n=388)	Very serious	LOW	-	0	
Adverse effects - Pulmonary embolus at six weeks	1 (n=388)	Very serious	LOW	0 fewer per 1000 (from 11 fewer to 78 more)	13	
Adverse effects - Wound infection at six weeks	1 (n=388)	Very serious	LOW	19 more per 1000 (from 12 fewer to 126 more)	26	
Adverse effects - UTI at six weeks	1 (n=388)	Serious	MODERATE	38 more per 1000 (from 59 fewer to 172 more)	344	
Adverse effects - Sepsis at six weeks	1 (n=388)	Very serious	LOW	26 more per 1000 (from 17 fewer to 134 more)	45	

Table 68: Clinical evidence summary: High-dose methylprednisolone plus nimodipine versus no treatment/placebo

Outcome	No. of studies	Imprecision	GRADE rating	Absolute difference	Control event rate (per 1000)	Control event rate for continuous outcomes
Motor function at one year	1 (n=48)	Serious	LOW	MD 8.1 lower (23.28 lower to 7.08 higher)		Change score 23.7
Pinprick sensation at one year	1 (n=48)	Very serious	VERY LOW	MD 1 lower (21.98 lower to 19.98 higher)		Change score 11.6
Touch sensation at one year	1 (n=48)	Very serious	VERY LOW	MD 1.8 lower (21.04 lower to 17.44 higher)		Change score 13.3

Table 69: Clinical evidence summary: Naloxone versus no treatment/placebo

Outcome	No. of studies	Imprecision	GRADE rating	Absolute difference	Control event rate (per 1000)	Control event rate for continuous outcomes
Adverse effects - Pneumonia at six weeks	1 (n=87)	Serious	MODERATE	54 more per 1000 (from 37 fewer to 182 more)	246	
Adverse effects - GI haemorrhage at six weeks	1 (n=32)	Very serious	LOW	10 fewer per 1000 (from 25 fewer to 50 more)	30	
Adverse effects - Pulmonary embolus at six weeks	1 (n=32)	Serious	MODERATE	40 more per 1000 (from 1 fewer to 229 more)	12	
Adverse effects - Wound infection at six weeks	1 (n=32)	Very serious	LOW	4 fewer per 1000 (from 26 fewer to 68 more)	36	
Adverse effects - UTI at six weeks	1 (n=32)	Serious	MODERATE	32 more per 1000 (from 69 fewer to 161 more)	461	
Adverse effects - Sepsis at six weeks	1 (n=32)	Serious	MODERATE	1 fewer per 1000 (from 38 fewer to 83 more)	66	

Table 70: Clinical evidence summary: Nimodipine versus no treatment/placebo

Outcome	No. of studies	Imprecision	GRADE rating	Absolute difference	Control event rate (per 1000)	Control event rate for continuous outcomes
Motor function at one year	1 (n=47)	Serious	VERY LOW	MD 1.7 lower (15.83 lower to 12.43 higher)		Change score 23.7
Pinprick sensation at one year	1 (n=47)	Serious	VERY LOW	MD 0.4 lower (20.49 lower to 19.69 higher)		Change score 11.6
Touch sensation at one year	1 (n=47)	Serious	VERY LOW	MD 4.2 lower (19.64 lower to 11.24 higher)		Change score 13.3

16.4 Economic evidence

Published literature

No relevant economic evaluations were identified comparing neuroprotective pharmacological interventions with standard care, each other or placebo. There was no excluded evidence.

Unit costs

Table 71: Costs of drugs calculated from the Drug Tariff/BNF

Drug name	Preparation	Unit	Cost/ unit	Milligram/ unit	Cost/ mg	Cost/ tablet
Methylprednisolone	Vials for injection	120 mg/3 ml	£8.96	120mg	£0.07	
Dexamethasone	Vials for injection	(3.3 mg/ml), 2-ml vial	£4.80	6.6mg	£0.73	
Nimodipine	Vial (with polyethylene infusion catheter)	(200 micrograms/ml), 50-ml vial	£13.60	10mg	£1.36	
Naloxone	Disposable syringe	(400 micrograms/ml), 5 ml	£20.40	2mg	£10.20	
Ibuprofen	Tablet	200 mg - 24 tablets	£1.08			£0.05
Celecoxib	Tablet	200 mg - 30 tablets	£21.55			£0.72

(a) The cost of methylprednisolone, ibuprofen, and celecoxib were sourced from the drug tariff (August 2013). Costs for the remaining drugs were sourced from the BNF online as these were not available in the drug tariff.

Table 72: Total cost of administering to spinal injury patient

Drug name	First dose (mg/kg)	No. of times administered	Continuous dose (mg/kg/hour)	Continuous dose duration (hours)	Total mg[a]	Total cost
Methylprednisolone	30	1	5.4	23	11565	**£864**
Dexamathasone	5.6	1	1	23	2145	**£1,560**
Nimodipine	0.015	2	0.03	168	380.25	**£517**
Naloxone	5.4	1	4	23	7305	**£74,511**
			Dose/day	**Tablets/day**	**Duration (days)**	**Total cost**
Ibuprofen			2400 mg	12	3	**£1.62**
Celecoxib			400 mg	2	3	**£4.31**

(a) Based on a person weighing 75 kg
(b) Methylprednisolone and naloxone dosing found from the clinical review. Nimodipine dose was found from the Cochrane review on steroids for acute SCI. Dexamethasone dose was found online. Celecoxib and ibuprofen doses per day were found from the BNF online, duration of NSAIDs was assumed.

Table 73: Estimation of incremental QALY gain required for an intervention to be cost effective at a £20,000 threshold when compared against a zero cost strategy, where only pharmaceutical acquisition cost is accounted for

Intervention	Incremental cost (£)	Minimum incremental QALYs required	Additional life years required at different utility required to make intervention cost effective (where a utility of 1= full health, 0= death)				
			1	0.8	0.6	0.4	0.2
Methylprednisolone	864	0.0432	0.043	0.054	0.072	0.108	0.216
Dexamethasone	1,560	0.078	0.078	0.098	0.130	0.195	0.390
Nimodipine	517	0.02585	0.026	0.032	0.043	0.065	0.129
Naloxone	74,511	3.72555	3.726	4.657	6.209	9.314	18.628
Ibuprofen	2	0.000081	0.000	0.000	0.000	0.000	0.405
Celecoxib	4	0.000216	0.000	0.000	0.000	0.001	1.078

(a) Costs have been rounded to the nearest pound

16.5 Evidence statements

Clinical

Methylprednisolone versus placebo

Mortality

Very low quality evidence from 3 RCTs comprising 530 participants demonstrated that methylprednisolone resulted in a small reduction in mortality when compared with placebo, though the considerable uncertainty in this effect meant that a clear conclusion of benefit or harm could not be determined.

Health-related quality of life

No evidence was found.

Neurological function

Evidence of quality ranging from Low to High from 3 RCTs comprising 469 participants demonstrated that overall, methylprednisolone resulted in some small improvements in motor function, pinprick sensation and touch sensation, though the effects were not a large enough to show a clearly appreciable, clinically important benefit.

Adverse events

Moderate to High quality evidence from 2 RCTs comprising 369 participants demonstrated that methylprednisolone resulted in a clear and clinically important increase in rates of pulmonary embolus and hyperglycaemia compared with placebo. Moderate to High quality evidence from 1 to 3 RCTs with from 323 to 444 participants demonstrated that rates of urinary tract infection (UTI), GI haemorrhage, pneumonia, wound infection and sepsis were not large enough to be clinically appreciable as well as being imprecise estimates.

Methylprednisolone moderate versus low

Mortality

Moderate quality evidence from 1 RCT comprising 330 participants demonstrated that moderate-dose methylprednisolone resulted in a small increase in mortality when compared with low dose, the considerable uncertainty in this effect meant that a clear conclusion of benefit or harm could not be determined.

Health-related quality of life

No evidence was found.

Neurological function

High quality evidence from 1 RCT comprising 258 participants demonstrated that overall, no benefit was found for moderate-dose methylprednisolone in improving motor function, pinprick sensation or touch sensation when compared with low-dose methylprednisolone.

Adverse events

Moderate to Low quality evidence from 1 RCT comprising 304 participants demonstrated that moderate-dose methylprednisolone resulted in a clinically important increase in UTI rates and wound infection compared with low-dose methylprednisolone. The differences in rates of pneumonia, GI haemorrhage, pulmonary embolus and sepsis were not large enough to be clinically appreciable as well as being imprecise estimates.

Methylprednisolone 48 hours versus 24 hours

Mortality

Moderate quality evidence from 1 RCT comprising 332 participants demonstrated that the 48 hour regimen of methylprednisolone resulted in slightly higher mortality than the 24 hour regimen which was felt not to be a clinically important difference, the considerable uncertainty in this effect meant that a clear conclusion of benefit or harm could not be determined.

Health-related quality of life

No evidence was found.

Neurological function

High quality evidence from 1 RCT comprising 35 participants demonstrated overall no benefit for 48-hour regimen methylprednisolone in improving motor function, pinprick sensation or touch sensation when compared with the 24-hour regimen.

Adverse events

Moderate to Low quality evidence from 1 RCT comprising 308 participants demonstrated that the differences between 48-hour regimen methylprednisolone and the 24-hour regimen in rates of pneumonia, GI haemorrhage, pulmonary embolus, wound infection, UTI and sepsis were not large enough to be clinically appreciable as well as being imprecise estimates.

Methylprednisolone plus Nimodipine versus placebo

Mortality

No evidence was found.

Health-related quality of life

No evidence was found.

Neurological function

Low to Very low quality evidence from 1 RCT with 49 participants demonstrated that the combination of methylprednisolone and nimodipine resulted in a small decline in motor function, pinprick sensation or touch sensation when compared with placebo, though these estimates of effect were not large enough to be clinically appreciable as well as being imprecise.

Adverse events

No evidence was found.

Naloxone versus placebo

Mortality

No evidence was found.

Health-related quality of life

No evidence was found.

Neurological function

Insufficient data was reported for this outcome to draw conclusions.

Adverse events

Moderate to Low quality evidence from 1 study with 321 participants demonstrated that naloxone resulted in a clinically important increase in rates of pneumonia compared with placebo while the differences in rates of pulmonary embolus, UTI, sepsis, wound infection and GI haemorrhage were not large enough to be clinically appreciable as well as being imprecise estimates.

Nimodipine versus placebo

Mortality

No evidence was found.

Health-related quality of life

No evidence was found.

Neurological function

Very low quality evidence from 1 RCT with 47 participants demonstrated that nimodipine resulted in a small decline in motor function, pinprick sensation or touch sensation when compared with placebo, though the estimates of effect were not large enough to be clinically appreciable as well as being imprecise.

Adverse events

No evidence was found.

Economic

No relevant economic evaluations were identified.

16.6 Recommendations and link to evidence

Recommendations	**55. The management of a spinal cord injury should be agreed between spinal surgery and spinal cord injury specialists for each person.** **56. Do not use the following medications, aimed at providing neuroprotection and prevention of secondary deterioration, in the acute stage after acute traumatic spinal cord injury:** • **methylprednisolone** • **nimodipine** • **naloxone.**
Relative values of different outcomes	The most critical outcomes to inform decision making for this review were spinal cord neurological function, mortality, health-related quality of life, and the following adverse events; ventilated-associated pneumonia, infection, hyperglycaemia and thrombosis. These specific adverse events were chosen as the most potentially harmful effects of the pharmacological agents investigated. Of these critical outcomes, the GDG agreed that a reduction in mortality rates would be unlikely with these therapies. The purpose of these pharmacological agents is to prevent deterioration or further damage to the spinal cord and therefore, promote recovery in the long term. While it was accepted that these effects may indirectly affect mortality in the long term, this mechanism would have no direct effects on mortality, particularly not in the short term following injury. Neurological function, as the target of neuroprotective pharmacological therapy, was the outcome prioritised for decision making. The GDG acknowledged, however, that the methods of measuring improvements in neurological function (non-linear scores, such as expanded motor and sensory scores) may not always represent clinically significant or functionally important differences and considered this carefully in interpreting the data. Important outcomes were agreed to be patient-reported outcomes, such as pain/discomfort, return to normal activities and psychological wellbeing.
Trade-off between clinical	The GDG discussed the evidence retrieved for methylprednisolone,

benefits and harms	dexamethasone, nimodipine, high-dose naloxone and NSAIDs and discussed whether the associated side effects or harms of each of these drugs outweighed the benefit reported in the evidence. **Methylprednisolone** The GDG agreed that the benefit in improved motor scores suggested by the point estimates could not be taken as representing a meaningful improvement for the patient. This was not due solely to the size of effect estimate but mainly due to the limitations in the neurological scoring system used by the majority of the studies in this review. The weaknesses of the NASCIS scoring system were discussed and the GDG highlighted that the change score does not take account of the baseline score and cannot differentiate between several small improvements spread across the body, or a larger improvement in one area. Similarly, the GDG indicated that there is no way of interpreting whether the improvement gained would be of any use to an individual patient. Considering the lack of clinically significant benefit together with the clinically significant increased risk of adverse events (hyperglycaemia and pulmonary embolus), the GDG felt that the use of high-dose methylprednisolone should not be recommended for neuroprotection in acute SCI. **Nimodipine and naloxone** The GDG considered that given the lack of data for neurological change/improvement for nimodipine and naloxone, alongside some evidence of adverse events, that neither nimodipine nor naloxone could be recommended for use in acute spinal cord injuries for neuroprotection. **Dexamethasone and NSAIDs** No evidence was identified for the use of dexamethasone or NSAIDs for people with acute SCI. On balance of the harms and benefits, the GDG did not support the use of medication aimed at providing neuroprotection in the acute stages of SCI. The lack of evidence and the consideration of adverse effects led the GDG to make a strong do not recommendation for methylprednisolone, nimodipine and naloxone. The GDG noted the absence of evidence for dexamethasone and high dose non-steroidal anti inflammatories and were unable to make a recommendation for not using this medication in this context .On this basis the GDG were keen to make a research recommendation to assess the effectiveness of prophylaxis for neuropathic pain
Economic considerations	No published economic evidence was identified. The GDG were presented with the cost of the interventions prioritised for this review. No clinical benefit was evident from the evidence retrieved, so it was assumed this could also translate to there being no meaningful impact on a person's quality or longevity of life from the interventions. Additionally, the evidence showed there to be some clinical harm arising from the interventions. Thus, as the interventions incur cost, are unlikely to be beneficial and indeed harmful, the group concluded that the interventions (for which evidence was found) are unlikely to be cost effective.
Quality of evidence	The quality of the evidence for neurological outcomes in overall analyses comparing methylprednisolone with placebo/no treatment was High, whereas the quality of the evidence for those subgroups treated within 8 hours (given the risk of bias from subgroup analysis and the uncertainty of the effect

	estimate) ranged from Low to Very low. Although not included in the GRADE rating, the limitations of the neurological rating systems should also be considered. For risk of adverse events the quality of evidence was Moderate to Low. For naloxone, the quality of evidence for adverse event outcomes was Moderate to Low, while for neurological outcomes quality could not be assessed due to incomplete reporting of outcomes (for example, some were simply reported as 'not significant' without any data provided). For nimodipine, no adverse event outcomes were reported and for neurological outcomes the quality was Very low due to inadequate reporting of the outcome measures. No evidence at all was identified for the use of dexamethasone or NSAIDs in acute SCI.
Other considerations	The GDG felt that the most important purpose of medication during the acute stage was for pain relief and the recommendations for the assessment and management of pain is in chapter 14 of the Major Trauma clinical guideline.

17 Neuropathic pain

17.1 Introduction

Spinal cord injury (SCI) has a number of devastating and disabling consequences, with up to 40% of patients developing a chronic neuropathic pain (NP). Most cases of NP begin during the acute rehabilitation stage and can cause further detrimental effects to the patient's quality of life. Pharmaceutical management strategies of NP after symptom onset have had limited success, commonly resulting in a pain reduction of only 20-30%.

Pre-emptive analgesia of the nervous system, in the acute stages of SCI, may provide a greater clinical efficacy as the mechanism driving pain tends to be refractory and its treatment suboptimal following onset. A number of animal studies have demonstrated a reduction in chronic pain with early intervention prior to symptom onset but it is unclear if these findings have translated into humans.

17.2 Review question: What are the optimum strategies given in the acute management stage to prevent later neuropathic pain in people with traumatic spinal cord injury?

For full details see review protocol in Appendix C.

Table 74: PICO characteristics of review question

Population	Children, young people and adults with traumatic SCI
Intervention/s	• Amitriptyline • Trazodone • Duloxetine • Venlafaxine • Lamotrigine • Mexiletine • Carbamazepine • Gabapentin • Pregabalin • Topiramate • Sodium Valproate • Clonidine • Levetiracetam • Ketamine • Alfentanil • Lidocaine
Comparison/s	• No treatment • Placebo • Each other
Outcomes	Critical: • Mortality at 1, 6 and 12 months • NP at 1, 6 and 12 months • Health-related quality of life • Adverse events:

	○ Dizziness and visual disturbance ○ Nausea and vomiting ○ Lethargy Important: • Patient-reported outcomes (pain/discomfort, psychological wellbeing)
Study design	RCTs or systematic reviews of RCTs

17.3 Clinical evidence

One study was included in the review[101]. Evidence from this study is summarised in the clinical evidence summary below (Table 76). See also the study selection flow chart in Appendix D, forest plots in Appendix I, study evidence tables in Appendix G and exclusion list in Appendix J.

The single study identified compared carbamazepine with placebo in patients with acute SCI. The intervention was administered within 2 weeks of the injury in patients who had not yet developed NP symptoms. The intervention was continued for 1 month only, and patients followed until 6 months post injury.

No relevant clinical studies comparing amitriptyline, trazodone, duloxetine, venlafaxine, lamotrigine, mexiletine, gabapentin, pregabalin, topiramate, sodium valproate, clonidine, levetiracetam, ketamine, alfentanil or lidocaine with placebo or no treatment were identified.

Table 75: Summary of studies included in the review

Study	Intervention/ comparison	Population	Outcomes	Comments
Salinas 2012 [101]	Carbamazepine versus placebo	Adults aged >18 years within 2 weeks of traumatic SCI without existing neuropathic pain n=46	• NP (visual analogue scale) • Quality of life (SF-36) • Adverse events ○ Nausea ○ Vomiting • Visual disturbance • Depression (Zung self-rating depression scale)	Academic funding. Low risk of bias.

Table 76: Clinical evidence summary for carbamazepine versus placebo

Outcome	Number of studies	Imprecision	GRADE rating	Absolute difference	Control event rate (per 1000)	Control event rate for continuous outcomes
NP absent or mild (VAS 0-39 mm) – at 1 month	1 (n=46)	Serious	MODERATE	291 more per 1000 (from 19 more to 687 more)	619	
NP absent or mild (VAS 0-39 mm) - at 6 months	1 (n=46)	Serious	MODERATE	118 more per 1000 (from 130 fewer to 501 more)	619	
NP moderate to intense (VAS 40-100 mm) - at 1 month	1 (n=46)	Serious	MODERATE	293 fewer per 1000 (from 15 fewer to 362 fewer)	381	
NP moderate to intense (VAS 40-100 mm) - at 6 months	1 (n=46)	Very serious	LOW	122 fewer per 1000 (from 274 fewer to 248 more)	381	
Quality of life at 6 months – Bodily pain	1 (n=46)	Serious	MODERATE	MD 7.9 higher (9.03 lower to 24.83 higher)		50.8
Quality of life at 6 months - Emotional performance	1 (n=46)	Very serious	LOW	MD 4.1 higher (21.52 lower to 29.72 higher)		36.3
Quality of life at 6 months - Physical performance	1 (n=46)	Very serious	LOW	MD 1.3 higher (12.18 lower to 14.78 higher)		9.5
Quality of life at 6 months - Physical function	1 (n=46)	Serious	MODERATE	MD 7.4 higher (5.47 lower to 20.27 higher)		12.6
Quality of life at 6 months - Social function	1 (n=46)	Very serious	MODERATE	MD 6.4 higher (9.49 lower to 22.29 higher)		45
Quality of life at 6 months - General health state	1 (n=46)	Very serious	LOW	MD 1.8 higher (12.47 lower to 16.07		51.6

Outcome	Number of studies	Imprecision	GRADE rating	Absolute difference	Control event rate (per 1000)	Control event rate for continuous outcomes
				higher)		
Quality of life at 6 months - Mental health	1 (n=46)	Very serious	LOW	MD 1.3 lower (18.18 lower to 15.58 higher)		59.2
Quality of life at 6 months - Vitality	1 (n=46)	Very serious	MODERATE	MD 5 higher (6.89 lower to 16.89 higher)		58.7
Adverse events - Nausea	1 (n=46)	Very serious	LOW	40 more per 1000 (from 39 fewer to 843 more)	48	
Adverse events – Vomiting	1 (n=46)	Very serious	LOW	40 more per 1000 (from 70 fewer to 160 more)	0	
Adverse events - Visual disturbance	1 (n=46)	Very serious	LOW	42 fewer per 1000 (from 48 fewer to 190 more)	48	
Absence of depression at 6 months	1 (n=46)	Serious	MODERATE	183 more per 1000 (from 88 fewer to 705 more)	381	
Mild depression at 6 months	1 (n=46)	Very serious	LOW	154 fewer per 1000 (from 249 fewer to 171 more)	286	
Moderate depression at 6 months	1 (n=46)	Very serious	LOW	13 fewer per 1000 (from 113 fewer to 434 more)	143	
Severe depression at 6 months	1 (n=46)	Very serious	LOW	61 fewer per 1000 (from 158 fewer to 326 more)	190	

17.4 Economic evidence

Published literature

No relevant economic evaluations were identified.

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

Unit costs

For the majority of drugs listed in the protocol, the dose is unknown, either because clinical evidence was not identified to be able to identify the dose, or because the drugs are used for other reasons primarily and thus, the dose for NP may not be the same as for then other uses of the drug.

Prices vary but are generally quite low, the highest priced drug being pregabalin costing £96.60 for 84x50 mg tablets{NHS Business Services Authority, 2014 NHSEDT /id}.

17.5 Evidence statements

Clinical

Moderate quality evidence suggested a clinical benefit for carbamazepine when compared with placebo in improving the rate of absence of NP or presence of mild NP at 1 month but no clinical difference at 6 months (1 study, n=44).

Moderate and Low quality evidence suggested a clinical benefit for carbamazepine when compared with placebo in improving the rate of moderate to severe NP at 1 month and 6 months, respectively (1 study, n=44).

Moderate and Low quality evidence suggested no clinical benefit in carbamazepine when compared with placebo for improving the SF-36 quality of life scores (bodily pain, physical function, social function, vitality, emotional performance, physical performance, general health state and mental health) (1 study, n=44).

Low quality evidence suggested no clinical difference between carbamazepine and placebo in rates of the adverse events nausea, vomiting and visual disturbance (1 study, n=44).

Moderate and Low quality evidence suggested a clinical benefit of carbamazepine when compared with placebo for improving the rate of people free from depression and mild depression (1 study, n=44). Low quality evidence suggested no clinical difference between carbamazepine and placebo in improving rates of moderate or severe depression (1 study, n=44).

Economic

No relevant economic evaluations were identified.

17.6 Recommendations and link to evidence

Recommendations	**57. Do not use medications in the acute stage after traumatic spinal cord injury to prevent neuropathic pain from developing in the chronic stage.**

	See the major trauma recommendations for the assessment and pain relief in the acute setting.
Relative values of different outcomes	The GDG considered mortality, pain, quality of life and the adverse events, dizziness and visual disturbance, nausea and vomiting, and lethargy, to be the most important outcomes to inform decision making for this review. These specific adverse events were chosen as the most common and potentially harmful effects of the pharmacological agents investigated. Of these critical outcomes, the GDG agreed that a reduction in mortality rates would be unlikely with these therapies. The purpose of these pharmacological agents is to relieve pain and this mechanism would have no effects on improving survival, neither is mortality a common associated effect of these agents. Although patient-reported outcomes, such as psychological wellbeing, including depression and anxiety were felt to be important, they were not critical to the decision making. The GDG felt, in the context of NP in spinal injuries, that psychological wellbeing as an individual outcome and not as part of a quality of life measure would not adequately reflect the effects of prevention of NP.
Trade-off between clinical benefits and harms	The GDG felt that the benefits of reduced rates of moderate and severe NP and mild depression could outweigh the low rates of relatively minor (nausea, vomiting and visual disturbance) adverse events reported for carbamazepine. However, the GDG expressed surprise that the only evidence was for carbamazepine, as gabapentin or pregabalin is more commonly the potential treatment choice. The GDG concluded that the limited evidence made it difficult to make a judgement on the relative benefits or harms of the different medications.
Economic considerations	No economic evidence was identified for this question. There is likely to be a difference in resource use in terms of the cost of the medication for prevention of neuropathic pain. The presence of NP will have an impact on the patient's quality of life downstream and potentially affect the capacity for them to undertake their normal activities pain free. Carbamazepine has some benefit in helping with depression, this could contribute to the overall improvement in quality of life as anxiety or depression/mental health are generally captured on health-related quality of life measures. On the other hand, it is also important to consider adverse events from the medications. Although the adverse events were relatively minor and would not have a big impact on resources (for example, vomiting, nausea), these will impact on a patient's quality of life and there may be a point at which a patient feels the risks are outweighing the benefits of taking the intervention. The clinical study identified also reported quality of life data using the SF-36. It was discussed with the GDG whether it would be useful to estimate the cost effectiveness of carbamazepine versus placebo using this data. However the GDG were not very confident about the paper and it was decided that estimating the cost effectiveness using this paper would not add value or help them in making their recommendation. Overall, the GDG agreed that there was positive evidence for carbamazepine,

	with the benefit likely to outweigh the risks. As the intervention is relatively low cost, it is therefore potentially cost effective compared with not taking it. However, as clinical benefit was ascertained using an isolated study, the GDG felt the uncertainty was too great to make a positive recommendation.
Quality of evidence	Only one study investigating the prevention of NP in patients with acute SCI was identified. The comparison was between carbamazepine and placebo; no other studies comparing other preparations were identified. The quality of evidence for outcomes reported in this review ranged from Moderate to Low. Quality was not downgraded due to risk of bias. Having adequate allocation concealment, blinding, low attrition and use of validated outcome measures the risk of bias in the included study was low. Quality was, however, downgraded due to imprecision of the effect estimates. The width of the confidence intervals and thus the uncertainty of the estimate reflects the relatively small number of participants in the study. It was noted by the GDG that the data were from one single study, and that the sample size was so small. The imprecision of the effect estimates was also a significant weakness considered in the discussion. The GDG also discussed concerns that the control group rate of NP, in their experience, was not representative of background rate of NP in SCI patients, suggesting that this may be a specific, narrower population than suggested. The GDG reflected that, should this be the case, the number needed to treat would rise and therefore the balance of harms and benefits may be reversed. Regarding the study design, the GDG felt that in not measuring the initial burden of somatic pain in each group, there may have been hidden significant baseline differences as a source of bias. The GDG were also concerned that the treatment was only continued for 1 month and, while apparent benefits of the treatment were greatest at the 1 month follow-up, this benefit was not maintained at the 6 month follow-up.
Other considerations	These medications have been used for the treatment of NP for some time (see NICE Clinical Guideline 173 Neuropathic pain – pharmacological management: The pharmacological management of neuropathic pain in adults in non-specialist settings). However, their use to prevent NP before it has occurred is an emerging area and there is limited evidence to support a positive recommendation. Given the limitations of the evidence, the GDG were unable to recommend carbamazepine as a preventative treatment and proposed a research recommendation. The GDG emphasised the importance of providing adequate pain relief in the acute stage of injury. See major trauma guideline chapter 14.

18 Information and support

18.1 Introduction

The NICE guideline on 'Patient Experience' (CG138)[82] 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. With respect to the specific context of people with major trauma and their families and carers, there is variation in what information is communicated about their injuries and how this is communicated.

In the hours following a spinal injury, people may be disorientated, distressed and coming to terms with injuries that may include paralysis and loss of sensation that results from damage to the spinal cord. Spinal injury may also be one of the injuries a person has and in these frightening circumstances, it is important that an injured person is given the information they need from the very early stages of assessment and treatment to feel safe and reassured.

Due to the unpredictable nature of a spinal injury during the initial days after the trauma, accurate prognosis is often difficult and cannot be accurately made. However, the patient can still be kept well informed of any procedures, such as the treatment they receive at the scene of the injury or later imaging. Those with injuries to the spinal cord will be referred to a spinal cord injury centre, and the importance of treatment in a dedicated, specialist centre must be made clear as this will frequently involve hospitalisation at a considerable distance from their home.

This chapter describes, through a combination of consensus opinion from the spinal injury GDG and synthesis of findings from qualitative studies from the major trauma guidance chapter 16:

- specific thoughts and feelings of people who have experienced major trauma injuries with special reference to spinal injuries.
- ways in which information and support could best be provided to the population who receive care from major trauma services.

18.2 Review question:

a) What information and support do people with suspected traumatic spinal cord/column injury and their families want in the early stages after trauma before a definitive diagnosis has been made?

b) What information and support do people with a confirmed traumatic spinal cord/column injury and their families want in the early stages after trauma before transfer to specialist care?

For full details see review protocols in Appendix C.

Table 77: Characteristics of review question

Population and setting	People with spinal injuries and/or their families

Objective	To evaluate what kind of information and support that people with spinal injuries and/or their families want
Context	Pre-hospital and acute care for spinal injuries
Review strategy	Meta-synthesis of qualitative research: Thematic analysis - information synthesised into themes and sub-themes. Results presented diagrammatically and as narrative.

The review questions in the major trauma guidance were:

a) What information and support do people with major trauma and their families and carers want in-hospital and on discharge from ED (see major trauma clinical guideline chapter 16)?
b) How should information and support be provided to families and carers (see major trauma service delivery chapter 15)?

18.3 Clinical evidence

No relevant studies were identified that met the eligibility criteria of either spinal injury protocol.

We searched for studies that used either qualitative or quantitative methods to investigate what particular information and support people with suspected or confirmed spinal injuries and their families wanted. While initially identifying 16 studies as possibly relevant for this review, on further assessment, all 16 were excluded. Common reasons for exclusions were: 1) the studies focused on health practitioners' perceptions of what information and support was relevant rather than asking the person with the suspected/confirmed traumatic spinal injury; 2) the studies were guidelines/advice based on anecdotal clinical experience rather than original research; or 3) the study setting was in tertiary care (such as a spinal rehabilitation unit) and outside of the protocol timeframe. See the excluded studies list in Appendix J.

18.4 Economic evidence

Published literature

No relevant economic evaluations were identified.

The economic article selection flow diagram can be seen in Appendix E.

18.5 Evidence statements

Clinical

No relevant clinical studies investigating the information and support needs of people with suspected or confirmed traumatic spinal injuries and their families were identified.

Economic

No relevant economic studies investigating the information and support needs of people with suspected or confirmed traumatic spinal injuries and their families were identified.

18.6 Recommendations and link to evidence

Recommendations	**The NICE guideline on major trauma: service delivery contains recommendations for ambulance and hospital trust boards, senior managers and commissioners on information and support for**

	patients, family members and carers. **Providing support** **58. When communicating with patients, family members and carers:** • **manage expectations and avoid misinformation** • **answer questions and provide information honestly, within the limits of your knowledge** • **do not speculate and avoid being overly optimistic or pessimistic when discussing information on further investigations, diagnosis or prognosis** • **ask if there are any other questions.** **59. The trauma team structure should include a clear point of contact for providing information to the patients, their family members and carers.** **60. Make eye contact and be in the patient's eye line to ensure that you are visible when communicating with this person to avoid them moving their head.** **61. If possible, ask the patient if they want someone (a family member, carer or friend) with them.** **62. If the patient agrees, invite their family member, carer or friend into the resuscitation room. Ensure that they are accompanied by a member of staff and their presence does not affect assessment, diagnosis or treatment.** **Support for children and vulnerable adults** **63. Allocate a dedicated member of staff to contact the next of kin and provide support for unaccompanied children and vulnerable adults.** **64. 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.** **65. For a child or vulnerable adult with spinal injury, enable their family members and carers to remain within eyesight if appropriate.** **66. 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.**

	67. Include siblings of an injured child when offering support to family members and carers. **Providing information** **68. Explain to patients, family members and carers what is wrong, 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** • **information about 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 or psychological effects.** **69. Provide information at each stage of management (including the results of imaging) in face-to-face consultations.** **70. Document all key communications with patients, family members and carers about the management plan.** **Providing information about transfer from an emergency department** **71. 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. Provide information on the linked spinal cord injury centre (in the case of cord injury) or the unit the patient will be transferred to (in the case of column injury or other injuries needing more immediate attention)** • **the name and contact details of the person who was 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. 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. The LETR in this chapter summarises the decision making of the spinal GDG.
Relative values of different outcomes	No evidence was identified for this review. However, the GDG supported the findings of the major trauma review that the information offered to people with major trauma should: • Contain details of their current situation (injuries known or suspected, treatment or procedures that they will receive including possible risks to aid informed decision making). • Be provided on an ongoing basis and be updated regularly as part of an open line of communication between the patient and the staff providing them care. • Contain information about the future clinical course or rehabilitation expectations (expected pain levels and how to manage these, expected improvements in mobility/strength/function). • Contain information on physiotherapy or how to access help. • Be offered in a non-technical and timely manner. • Be offered in both verbal and written formats at specific time-points (verbal in hospital, and later, this should be accompanied with written information to take away with them).

	• The evidence suggested that people who have experienced a major trauma and their families would appreciate having a specific 'go-to' person to provide support and act as a consistent point of contact.
Trade-off between clinical benefits and harms	In the absence of any included published evidence, the GDG used consensus and the evidence from the major trauma reviews to discuss the information and support needs of patients and carers. The GDG used their own professional and personal experiences to inform these recommendations. The GDG wanted to emphasise that for people with spinal injuries it is important to strike a balance between providing reassurance and delivering accurate information. For example, information given should not be overly optimistic, but should be given sensitively with a view to reducing possible distress. The GDG agreed that specific information should be given only when it was possible to give this information with some degree of confidence, but also that the patients and carers should be kept informed about the proposed management that it was not possible to give specific information. The GDG noted that it is important that eye contact is maintained when talking to a person with spinal injuries so that the person is not be encouraged to move their neck and potentially worsen an injury. The GDG thought it is important to acknowledge that the pre-hospital and emergency department (ED) is an extremely difficult environment within which to process information. Therefore, it is important for health practitioners and medical staff to be aware of the way in which they convey information about the patients' injuries and associated medical care including: the content of information (treatment/management plan), the timing of information (ongoing updates) and in appropriate formats (considering developmental, language and cultural barriers). It was also acknowledged that many patients with spinal injuries will have other injuries that will require care from a wide range of specialists. While the patient should be informed of the different aspects of their care, it is important that there is consistency in the information they are receiving. If they have multiple people giving them different information about the management of their injuries this may cause confusion during an already anxious time. To mediate this, the GDG recommended that one specific person should take responsibility for giving the injured person the information they require to feel safe and reassured that the medical treatment they are receiving will deliver the best possible outcomes. When proposing family presence during resuscitation it is important to consider that this can be a very distressing event to witness. Medical staff may be distracted from the resuscitation task if the observing family member(s) experience an intense emotional response. It is possible that during resuscitation patient confidentiality could be threatened. The presence of family member(s) in the resuscitation room may inhibit open and frank discussion about the patient's condition, which in turn may delay decision-making. However, the evidence from the major trauma review suggested that it is common for family members to want to be present during resuscitation, and healthcare professionals should respect the wishes of close relatives. It is possible that seeing what is happening to their loved one is preferable to the anxiety-inducing 'unknown'.

	Updating information The clinical status of a major trauma patient and their management may change rapidly. It is, therefore, important that patients and carers are regularly updated. **Transfer** It is also important to give family members and/or carers information about where the injured person went (in terms of location of hospital) and why (may be a further away location but a better equipped one). The details of the specific person who was responsible for their care or who will be should be provided in conjunction with the name of the trauma coordinator (see service delivery recommendation). Details of the structure and function of the different services that comprise the trauma network should be provided as appropriate. **Children and vulnerable adults** The information and support needs of children and vulnerable people was emphasised by the GDG. Information should be tailored to meet their needs. The presence of parents and carers can provide valuable support to children and vulnerable adults.
Economic considerations	No economic evidence was identified to inform this recommendation. The resource implications of patient information and support strategies will vary depending on the specific strategy. Short-term resource use and costs will be those associated with implementing the strategy, for example, those associated with staff time to give information and support, or the production costs of information leaflets. However, the GDG identified several areas regarding the content (not implementation) of the information as important (that is, ensuring the content is factored around what the patient wants to know, is reflective of the patient's stage in the treatment/diagnostic pathway, is age appropriate and understandable). A change in the content of the information given does not need to come at great expense, whereas changes in method of delivery may incur additional costs. Downstream resource implications will in part depend on how effective the information strategy is in modifying the patient's behaviour in the acute stages, for example, avoiding exacerbating movements and actions caused by inaccurate information. As this may result in a more serious injury with long-term health and cost implications. A key point identified within the GDG discussions was that inappropriate spinal protection and imaging, and delay in clearing the spine of injury appropriately, may alter the patient's perception of his/her condition, that is, more serious than it really was. This may impact on the number of repeat healthcare contacts and more importantly, may lead to anxiety and potentially impact on the patients' and carers' quality of life. Conversely, failure to provide appropriate information and support to patients with an injury can lead to difficulties in engaging with the appropriate treatments, rehabilitation and integration. This impacts on the effectiveness of treatments and may potentially result in delayed improvement in health outcomes and potentially increased costs. Furthermore, information and support should be ongoing throughout these stages as it allows for patients' and carers' expectations to be managed appropriately, thereby avoiding/minimising psychological distress.

	In the absence of available data, the GDG came to a consensus that the potential resources and costs involved in a patient information and support strategy were more than likely to be offset in part or completely by appropriate healthcare engagement. Ensuring the content and delivery is appropriate and effective is likely to reduce downstream costs and bring health benefit and therefore, highly likely to be cost effective. The recommendations were believed to be cost neutral in comparison with current practice
Quality of evidence	No evidence was identified.
Other considerations	The GDG emphasised that giving information and support is a constant process that should be joined up throughout the patient pathway. Appropriate provision of information and support was felt to require training and experience, as well as sensitivity and compassion. The ability to demonstrate empathy and caring was felt to be as important as diagnostic and treatment skills. There was clear recognition of the impact of giving information inappropriately and the impact it can have on the acceptance of a spinal injury and long-term recovery. Early reactions to a traumatic and potentially life changing event can interfere with adaptive coping. This may be particularly pronounced in younger patients. The GDG discussed the lack of literature on how to give information in this context – they noted the literature on breaking bad news in cancer diagnosis, (such as the SPIKE protocol principles) or in the ED to relatives about sudden death, but very little on communication about an unexpected/sudden potentially life changing injury. The GDG discussed the particular difficulties inherent in the special circumstances of an acute trauma situation: • there is little time to prepare for the event • there is likely little or no knowledge of the patients' or any family background information. • there is no previous relationship with the person • shared decision making is probably unrealistic in this situation. The need to recognise the limitations of patient empowerment in an emergency situation was also recognised.

19 Documentation

19.1 Introduction

Accurate documentation is implicit in best clinical practice. Complete documentation should describe the assessment and care provided for the patient and this will facilitate communication between healthcare providers. There are a core set of principles that should be adhered to when documenting the management of a person with trauma injuries and for each specific injury there will be an important subset of information that is required. Specific guidance for the variables to be clinically assessed and documented in the acute stage of spinal injury is likely to aid long-term rehabilitation and improve clinical outcomes in patients with potentially devastating injuries.

Currently within the NHS, there is no standardised national documentation for patients with suspected spinal injury. Regional variation in documentation can cause problems in the transfer of patients (that is, to a major trauma centre or specialist spinal unit) and is further complicated by the multiple assessment tools for spinal injury.

19.2 Review question: What documentation tool should be routinely used to record baseline neurological function in people with spinal injuries?

For full details see review protocols in Appendix C.

Table 78: PICO characteristics of review question

Population	Children, young people and adults experiencing a traumatic spinal injury (including cord, column and penetrating injuries with potential to affect the spine).
Intervention/s	• American Spinal Injury Association (ASIA) • Frankel • Neurological clinical assessment • NASCIS timing of information/support.
Comparison	Standard/usual care
Outcomes	Critical: • Mortality at 1, 6 and 12 months • Health-related quality of life • Spinal cord neurological function at 1, 6 and 12 months (including ASIA and Frankel) Important: • Patient-reported outcomes (pain/discomfort, return to normal activities, psychological wellbeing).

19.3 Clinical evidence

No relevant studies were identified that met the eligibility criteria of either protocol.

We searched for studies investigating the value of documenting tools (ASIA, Frankel, Neurological clinical assessment, NASCIS) for improving patient outcomes in spinal cord injury. Despite identifying 25 studies of potential interest, these were all excluded for final analysis following review. Studies were generally excluded on the basis that they provided a prognostic assessment of the

documentation tools, failing to specifically address the question. Other studies did not present with applicable outcome measures. See exclusion list in Appendix J.

19.4 Economic evidence

No relevant economic evaluations were identified.

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

19.5 Evidence statements

Clinical

No relevant clinical studies were identified.

Economic

No relevant clinical studies were identified.

19.6 Recommendations and link to evidence

Recommendations	**The NICE guideline on major trauma: service delivery contains recommendations for ambulance and hospital trust boards, senior managers and commissioners on documentation within trauma networks.** **Recording information in pre-hospital settings** **72. Record the following in people with suspected spinal injury in pre-hospital settings:** • **<C>ABCDE (catastrophic haemorrhage, airway with in-line spinal immobilisation, breathing, circulation, disability [neurological], exposure and environment)** • **spinal pain** • **motor function, for example hand or foot weakness** • **sensory function, for example altered or absent sensation in the hands or feet** • **priapism in an unconscious or exposed male.** **73. If possible, record information on whether the assessments show that the person's condition is improving or deteriorating.** **74. Record pre-alert information using a structured system and include all of the following:** • **the patient's age and sex** • **time of incident** • **mechanism of injury** • **injuries suspected**

	• **signs, including vital signs and Glasgow Coma Scale** • **treatment so far** • **estimated time of arrival at emergency department** • **special requirements** • **the ambulance call sign, name of the person taking the call and time of call.** **Receiving information in hospital settings** **At the emergency department** **75. A senior nurse or trauma team leader in the emergency department should receive the pre-alert information, and determine the level of trauma team response according to agreed and written local guidelines.** **76. The trauma team leader should be easily identifiable to receive the handover and the trauma team ready to receive the information.** **77. The pre-hospital documentation, including the recorded pre-alert information, should be quickly available to the trauma team and placed in the patient's hospital notes.** **Recording information in hospital settings** **78. Record the items listed in recommendation 72 as a minimum, for the primary survey.** **79. Record the secondary survey results, including a detailed neurological assessment and examination for any spinal pain or spinal tenderness.** **80. If spinal cord injury is suspected in people aged over 4 years, complete an ASIA chart (American Spinal Injury Association) as soon as possible in the emergency department, and record:** • **vital capacity for people over 7 years** • **ability to cough.** **81. One member of the trauma team should be designated to record all trauma team findings and interventions as they occur (take 'contemporaneous notes').** **82. The trauma team leader should be responsible for checking the information recorded to ensure that it is complete.** **Sharing information in hospital settings** **83. 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. **84. Ensure that all patient documentation, including images and reports, goes with the patient when they are transferred to other departments or centres.** **85. Produce a written summary, which gives the diagnosis, management plan and expected outcome and:** • **is aimed at and sent to the patient's GP within 24 hours of admission** • **includes a summary written in plain English that is understandable by patients, family members and carers** • **is readily available in the patient's records.**
	These recommendations were developed and supported by the evidence reviews addressing the scope area 'documentation of clinical assessments and management (including pre-hospital and hospital)' in each of the four clinical guideline: • 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 ,' patient documentation and transfer of information' in the Major trauma services guidance scope area. The chapters on documentation in these guidelines should be read in conjunction with this chapter. **Developing the recommendations** Documentation 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 documenting and communicating the management of a patient with traumatic injuries. 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 documentation recommendations on documenting the secondary survey results and using the ASIA chart. 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. This LETR outlines the decision making of the spinal GDG.
Relative values of different outcomes	The GDG identified mortality up to one year, health-related quality of life and spinal cord neurological function at 1, 6 and 12 months (including ASIA and Frankel) as the critical outcomes for decision making. Mortality was regarded as the most important outcome, as it was believed that the quality of documentation could influence the crucial outcome of mortality. Health-related quality of life was the next most important critical outcome, as this outcome comprehensively captures patient-centred effects. Neurological function was the next most important critical outcome as this captures objective measures of the extent of the neurological injury. The important outcomes were the following patient-reported outcomes: pain/discomfort, return to normal activities, psychological wellbeing.
Trade-off between clinical benefits and harms	No clinical evidence was found to evaluate the trade-off between clinical benefits and harms between different documentation tools. However, the GDG felt that a good documentation tool would have optimal clinical benefit if it prompted documentation of information that could reliably and validly inform appropriate ongoing management. Such information of relevance to both pre-hospital and the emergency department (ED) was deemed to be: • that collected by using the C-ABCDE approach • the existence of spinal pain • the existence of hand and foot weakness • the existence of any sensory deficits • the existence of priapism in an unconscious or exposed person. It was agreed that prompting of recording of imaging and ASIA scores should also be included in the documentation tool. A documentation tool was regarded as having scope for harm if it were either too incomplete or complicated in its data fields, but the GDG agreed that the criteria described above would avoid any such harms.
Economic considerations	No economic evidence was found. It was recognised that documentation requires healthcare resources in terms of staff time to record the information, investment in systems to use, transfer and store the data securely, and to analyse the data to improve care. Furthermore, there may be additional costs if monitoring interventions are undertaken purely for the purpose of documenting change or audit. The GDG did not specify the system in which the information should be documented, rather which aspects of care were most useful and beneficial to document. The consensus of the GDG that any additional costs associated with the recommendation would be minimal to current practice. This coupled with a belief that improved documentation would bring the clinical benefits and improve outcomes; the recommendations are likely to be cost effective when compared with current practice.

Quality of evidence	No relevant clinical or economic studies were identified.
Other considerations	The GDG agreed on the following consensus recommendations on the general principles of documentation for a patient with major trauma injuries: • integrated systems across trauma networks • standardised documentation • minimum data sets • clear line of responsibility for documentation. These recommendations were supported by evidence reviews reported in the major trauma and major trauma services guidance. The GDG also made consensus recommendations that were specific to the patient with spinal injuries; these were documentation on the secondary survey results, using the ASIA chart documenting vital capacity for young people over 7 years and the ability to cough. The GDG considered that measuring vital capacity is a crucial in a person with a spinal injury, respiratory complications are a common cause of mortality in people with acute spinal injury and it is imperative that there is a baseline measurement. The experience of the guideline development group indicated that it is undertaken and is feasible in an ED The GDG considered these recommendations to be crucial to the optimal care of a person with spinal injuries and areas that are currently not assessed or documented. In the pre-hospital setting the GDG agreed that the following brief assessment (motor assessment - hand and foot weakness; sensory assessment - altered or absent in hands and feet and priapism in an unconscious or exposed person) was adequate for the set of baseline neurological observations and that the ASIA tool was too detailed and difficult to apply. Once the patient has arrived in the ED and any life threatening injuries have been identified then the use of the ASIA tool is appropriate. The ASIA tool is currently well-known and understood by healthcare practitioners All these recommendations also facilitate the accurate and complete collection of research and audit data.

20 Access to the skills required for the management of people with spinal injury

20.1 Introduction

Injuries sustained from trauma may be life threatening and could be life changing. Spinal injury in particular is associated with adverse consequences; neurological damage can result in paraplegia, quadriplegia or death. The consequence of poor clinical management from a patient perspective is 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 major trauma and potentially life threatening 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 in the multidisciplinary team required 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 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. Chapter 17 Access to services in the major trauma services guidance summarises the services and skills recommended in each of the guidelines and has an all-encompassing recommendation for the skills required to manage people with trauma.

21 Acronyms and abbreviations

Acronym or abbreviation	Description
ABPI	Ankle brachial pressure index
ADL	Activities of daily living
AIS	Abbreviated Injury Scale
ASIA score	American Spinal Injury Association Impairment score
ATLS	Advanced Trauma Life Support
CI	Confidence interval
CC	Comparative costing
CCA	Cost-consequences analysis
CEA	Cost-effectiveness analysis
CNS	Central nervous system
CT	Computed tomography
CUA	Cost-utility analysis
DASH Score	The Disabilities of the Arm, Shoulder and Hand Score
DVT/PE	Deep vein thrombosis and pulmonary embolism.
eFAST	Extended Focused Assessment with Sonography for Trauma
EMAS	East Midlands Ambulance Service
FAST	Focused assessment with sonography for trauma
GCS	Glasgow coma scale
GOS	Glasgow outcome scale
INR	International normalised ratio
IO	Intraosseous
IR	Interventional radiology
IV	Intravenous
ISS	Injury Severity Score
JRCALC	Joint Royal Colleges Ambulance Liaison Committee
KED	Kendrick Extrication Device
MDCT	Multi-detector computed tomography
MDT	Multidisciplinary team
MRI	Magnetic resonance imaging
MTC	Major Trauma Centre
NEXUS	National Emergency X Radiography Utilization Study
NNT	Number needed to treat
NPV	Negative predictive value
NSAIDS	Non-steroidal anti-inflammatory drugs
ORIF	Open reduction and internal fixation
PACS	Picture Archiving and Communications Systems
PCC	Prothrombin complex concentrate
PPV	Positive predictive value
QALY	Quality-adjusted life year
RCT	Randomised controlled trial

Acronym or abbreviation	Description
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

22 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 and loss of blood. It describes on going bleeding.
Activities of daily living (ADL)	Routine activities carried out for personal hygiene and health (including bathing, dressing, feeding) and for operating a household.
Acute	A stage of injury or stroke starting at the onset of symptoms. The opposite of chronic.
Advanced Trauma Life Support (ATLS)	A training program for medical professionals in the management of acute trauma cases, developed by the American College of Surgeons.
Algorithm (in guidelines)	A flow chart of the clinical decision pathway described in the guideline, where decision points are represented with boxes, linked with arrows.
Allocation concealment	The process used to prevent advance knowledge of group assignment in a RCT. The allocation process should be impervious to any influence by the individual making the allocation, by being administered by someone who is not responsible for recruiting participants.
Ambulation	Walking with braces and/or crutches.
American Spinal Injury Association Impairment (ASIA) Score	A system to describe spinal cord injury and help determine future rehabilitation and recovery needs. It is based on a patient's ability to feel sensation at multiple points on the body and also tests motor function. Ideally, it's first given within 72 hours after the initial injury. Scored from A-E; A means complete injury; E means complete recovery.
Angiography	Radiography of blood or lymph vessels, carried out after introduction of a radiopaque substance.
Angular deformity	Deformity of limbs by angulation at joints or in the bones themselves.
Ankle brachial pressure index (ABPI)	The ratio of the blood pressure in the lower legs to the blood pressure in the arms. It is used for decision-making in leg ulcer assessment.
Antero-lateral	Directed from the front towards the side.
Antero-posterior	Directed from the front towards the back.
Anticoagulation	The process of hindering the clotting of blood.
Antifibrinolytic agent	Pharmacological agents that inhibit the activation of plasminogen to plasmin, prevent the break-up of fibrin and maintain clot stability. They are used to prevent excessive bleeding.
Applicability	The degree to which the results of an observation, study or review are likely to hold true in a particular clinical practice setting.
Arm (of a clinical study)	Sub-section of individuals within a study who receive one particular intervention, for example placebo arm
Arterial injury	An injury following a traumatic injury which results in a laceration, contusion, puncture, or crush injury to an artery.
Arterial shunts	An artificial passageway introduced through a surgical procedure that allows blood to flow from through the arteries.
Aspiration event	The event of food or drink entering the airway.
Association	Statistical relationship between two or more events, characteristics or other

Term	Definition
	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.
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.

Term	Definition
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.
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.

Term	Definition
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. 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

Term	Definition
	treatment effect.
cauda equina syndrome	Cauda equina syndrome is a relatively rare but serious condition that describes extreme pressure and swelling of the nerves at the end of the spinal cord.
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: • 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

Term	Definition
	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.
Detection bias	Bias relating to the way in which data is collected. The most common cause of detection bias results from failure to blind outcome assessors. If outcome assessors know the group allocation of a participant this may influence the way that the measurement is carried out.
Diagnostic RCT	A randomised controlled trial that compares outcomes from groups allocated to two or more different forms of diagnostic assessment. Diagnostic RCTs are a pragmatic way of assessing how well diagnostic tests affect outcome through their ability to determine appropriate management of patients. In contrast to diagnostic accuracy studies, they can encompass issues like the duration or comfort of a test, which may be important considerations in the decision concerning which diagnostic test should be used.
The Disabilities of the Arm, Shoulder and Hand (DASH) Score	A patient reported questionnaire to inform on functional capacity of the arm.
Disability rating index	A patient reported clinical tool for assessing physical disability, mainly intended for clinical settings.
Discounting	Costs and perhaps benefits incurred today have a higher value than costs and benefits occurring in the future. Discounting health benefits reflects individual preference for benefits to be experienced in the present rather than the future. Discounting costs reflects individual preference for costs to be experienced in the future rather than the present.
Discrete Event Simulation	A type of model (also known as time-to-event model) based on patient-level simulation where 'time to event' is the key parameter as opposed to 'probability of event occurring' like in a Markov model.
Dislocation	Displacement of one or more bones at a joint.
Dominance	An intervention is said to be dominated if there is an alternative intervention that is both less costly and more effective.
Drop-out	A participant who withdraws from a trial before the end.
Dynamic fluoroscopy	Imaging technique which uses an X-ray tube and a fluoroscopic screen with an image intensifier to create a real-time image of moving objects.
Economic evaluation	Comparative analysis of alternative health strategies (interventions or programmes) in terms of both their costs and consequences.
Effect (as in effect measure, treatment effect, estimate of effect, effect size)	The observed association between interventions and outcomes or a statistic to summarise the strength of the observed association.
Effectiveness	See 'Clinical effectiveness'.
Efficacy	See 'Clinical efficacy'.

Term	Definition
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.
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

Term	Definition
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.
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

Term	Definition
	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.
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

Term	Definition
	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.
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

Term	Definition
	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	Major trauma is defined a potentially life threatening injury or injuries with the potential to cause the loss of a major limb.
Major Trauma Centre (MTC)	A specialist hospital responsible for the care of major trauma patients across the region. It is a specialist hospital responsible for the care of the most severely injured patients involved in major trauma. It provides 24/7 emergency access to consultant-delivered care for a wide range of specialist clinical services and expertise. It is optimised for the definitive care of injured patients. In particular, it has an active, effective trauma Quality Improvement programme. It also provides a managed transition to rehabilitation and the community. It takes responsibility for the care of all patients with Major Trauma in the area covered by the Network. It also supports the Quality Improvement programmes of other hospitals in its Network. It provides all the major specialist services relevant to the care of major trauma, that is, general, emergency medicine, vascular, orthopaedic, plastic, spinal, maxillofacial, cardiothoracic and neurological surgery and interventional radiology, along with appropriate supporting services, such as critical care. The Royal College of Surgeons cite research advising that such centres should admit a minimum of 250 critically injured patients per year
Major Trauma Network	A collaboration between the providers commissioned to deliver trauma care services in a geographical area. A trauma network includes all providers of trauma care: pre-hospital services, other hospitals receiving acute trauma admissions (Trauma Units), and rehabilitation services. The trauma network has appropriate links to the social care and the voluntary/community sector. While individual units retain responsibility for their clinical governance, members of the Network collaborate in a Quality Improvement programme.
Malunion	Consolidation of a fracture in a position of deformity.
Markov model	A method for estimating long-term costs and effects for recurrent or chronic conditions, based on health states and the probability of transition between them within a given time period (cycle).
Multi-detector computed tomography (MDCT) scan	A form of computed tomography (CT) technology for diagnostic imaging. In MDCT, a two-dimensional array of detector elements replaces the linear array of detector elements used in typical conventional and helical CT scanners. The two-dimensional detector array permits CT scanners to acquire multiple slices or sections simultaneously and greatly increase the speed of CT image acquisition

Term	Definition
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.
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.

Term	Definition
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 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	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.

Term	Definition
Opportunity cost	The loss of other health care programmes displaced by investment in or introduction of another intervention. This may be best measured by the health benefits that could have been achieved had the money been spent on the next best alternative healthcare intervention.
Osteomyelitis	An acute or chronic inflammatory condition affecting bone and its medullary cavity, usually the result of bacterial (occasionally viral) infection of bone.
Ottawa ankle rules	Ottawa ankle rules are a set of guidelines for clinicians to help decide if a patient with foot or ankle pain should be offered X-rays to diagnose a possible bone fracture.
Outcome	Measure of the possible results that may stem from exposure to a preventive or therapeutic intervention. Outcome measures may be intermediate endpoints or they can be final endpoints. See 'Intermediate outcome'.
P-value	The probability that an observed difference could have occurred by chance, assuming that there is in fact no underlying difference between the means of the observations. If the probability is less than 1 in 20, the P value is less than 0.05; a result with a P value of less than 0.05 is conventionally considered to be 'statistically significant'.
Paralysis	Injury or disease to a person's nervous system can affect the ability to move or feel.
Paraplegia	Loss of function and paralysis below the cervical area of the neck; generally, the upper body retains motor and sensory function.
Partial weight bearing	A small amount of weight may be supported by the limb.
Pelvic packing	Pelvic packing is an invasive surgical procedure, used to tamponade sources of pelvic bleeding. Absorbent packs are placed within the preperitoneal and retroperitoneal spaces and must be removed, usually within 48 hours.
Performance bias	Bias resulting from differences in the way different groups are treated, apart from the actual treatment under investigation. This may occur if those caring for participants are not blinded to group allocation. For example, participants in the 'favoured' group may be given better care. Performance bias also relates to participant beliefs about a treatment's efficacy. For example, if a participant knows he/she is in the intervention group then they may experience a placebo effect, which might not be felt by those in a non-treatment group.
Perioperative	The period from admission through surgery until discharge, encompassing the pre-operative and post-operative periods.
Permissive hypotension	The use of restrictive fluid therapy, specifically in the trauma patient, that increases systemic blood pressure without reaching normal blood pressures.
Picture Archiving and Communications Systems (PACS)	PACS enables X-ray and scan images to be stored electronically and viewed on screens.
Pilon	The distal end of the tibia – from the French for a stump, or a pestle. Fractures of the distal tibial metaphysic caused by axial load failure are called "pilon fractures".
Placebo	An inactive and physically identical medication or procedure used as a comparator in controlled clinical trials.
Plantar aspect	Relating to the sole of the foot.
Platelets	Blood cells whose function (along with coagulation factors) is to stop bleeding.
Pneumothorax	A collection of air or gas in the pleural cavity which can cause the lung(s) to

Term	Definition
	collapse.
Polypharmacy	The use or prescription of multiple medications. Polypharmacy is often defined as taking 5 or 10 medications at the same time/
Polytrauma	Patients with associated injury (i.e. two or more severe injuries in at least two areas of the body), or with a multiple injury (i.e. two or more severe injuries in one body area). Also known as multisystem trauma.
Positive predictive value (PPV)	In screening/diagnostic tests: A measure of the usefulness of a screening/diagnostic test. It is the proportion of those with a positive test result who have the disease, and can be interpreted as the probability that a positive test result is correct.
Postoperative	Pertaining to the period after patients leave the operating theatre, following surgery.
Post-test probability	For diagnostic tests. The proportion of patients with that particular test result who have the target disorder
Post-traumatic arthritis	Post-traumatic arthritis is caused by the wearing out of a joint that has had any kind of physical injury. Such injuries can damage the cartilage and/or the bone, changing the mechanics of the joint and making it wear out more 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 amputation	A primary amputation is one that is carried out immediately on admission without any attempt to salvage the limb.
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.

Term	Definition
Publication bias	Also known as reporting bias. A bias caused by only a subset of all the relevant data being available. The publication of research can depend on the nature and direction of the study results. Studies in which an intervention is not found to be effective are sometimes not published. Because of this, systematic reviews that fail to include unpublished studies may overestimate the true effect of an intervention. In addition, a published report might present a biased set of results (e.g. only outcomes or sub-groups where a statistically significant difference was found.
Quadriplegia	Scientifically known as tetraplegia; paralysis affecting all four limbs.
Quality of life	See 'Health-related quality of life'.
Quality-adjusted life year (QALY)	An index of survival that is adjusted to account for the patient's quality of life during this time. QALYs have the advantage of incorporating changes in both quantity (longevity/mortality) and quality (morbidity, psychological, functional, social and other factors) of life. Used to measure benefits in cost-utility analysis. The QALYs gained are the mean QALYs associated with one treatment minus the mean QALYs associated with an alternative treatment.
Randomisation	Allocation of participants in a research study to two or more alternative groups using a chance procedure, such as computer-generated random numbers. This approach is used in an attempt to ensure there is an even distribution of characteristics across groups, which should minimise selection bias.
Randomised controlled trial (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

Term	Definition
	to non-smokers would be calculated by dividing the risk of death in smokers by the risk of death in non-smokers. A RR of 1 would show that the risk of the event is the same for both groups. RR ratio greater than 1 means the risk of the event are greater in the first group. A RR less than 1 means that the risk of the event are less likely in the first group. Sometimes risks can be compared across more than 2 groups – in this case, one of the groups is chosen as the 'reference category', and the RR is calculated for each group compared with the reference category. For example, to compare the risk of dying from lung cancer for non-smokers, occasional smokers and regular smokers, non-smokers could be used as the reference category. RRs would be worked out for occasional smokers compared with non-smokers and for regular smokers compared with non-smokers. See also 'odds ratio'.
Reporting bias	See publication bias.
Rescue board	A robust and light construction board for placing patients on following injury. Rescue boards are particularly useful for water rescues but can be also used on land.
Resource implication	The likely impact in terms of finance, workforce or other NHS resources.
Respiratory compromise	An impairment of normal pulmonary gas exchange. If this leads to an arterial PaO2 of <8Kpa this signals the onset of respiratory failure. Respiratory compromise could be due to respiratory depression (see 'respiratory 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.

Term	Definition
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. Imaging can be undertaken using ultrasound, CT or X-ray.
Selective immobilization	Immobilization following the use of a prediction soon.
Sensitivity	Sensitivity or recall rate is the proportion of true positives which are correctly identified as such. For example in diagnostic testing it is the proportion of true cases that the test detects. See the related term 'Specificity'
Sensitivity analysis	A means of representing uncertainty in the results of economic evaluations. Uncertainty may arise from missing data, imprecise estimates or methodological controversy. Sensitivity analysis also allows for exploring the generalizability of results to other settings. The analysis is repeated using different assumptions to examine the effect on the results. One-way simple sensitivity analysis (univariate analysis): each parameter is varied individually in order to isolate the consequences of each parameter on the results of the study. Multi-way simple sensitivity analysis (scenario analysis): two or more parameters are varied at the same time and the overall effect on the results is evaluated. 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, consequent upon the presence of growth plates and the quality of the bone itself. Immature bone tend 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 in the bones under consideration have closed. 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

Term	Definition
	healing process is complete, and so can be done more quickly, may cross joints, and may not involve such precise reduction.
Softcast	A lightweight splint that is removal and can be applied for immobilisation.
Specificity	The proportion of true negatives that a correctly identified as such. For example in diagnostic testing the specificity is the proportion of non-cases incorrectly diagnosed as cases. See related term 'Sensitivity'. In terms of literature searching a highly specific search is generally narrow and aimed at picking up the key papers in a field and avoiding a wide range of papers.
Spinal Cord Injury (SCI)	An injury to the spinal cord interferes with messages between the brain and the body and results in paralysis and sensory loss below the level of the injury. The location at which the cord is injured and the severity of the injury determines the physical limitations the person will have.
Spinal shock	Often occurring soon after spinal cord injury, this is a loss of reflexes below the level of injury with associated loss of sensorimotor functions. This condition can last for several hours to days after initial injury.
Stakeholder	Those with an interest in the use of the guideline. Stakeholders include manufacturers, sponsors, healthcare professionals, and patient and carer groups.
Subcutaneous	An injection in which a needle is inserted just under the skin.
Supraglottic device	Medical device that when applied facilitates unobstructed access of 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

Term	Definition
	during the operation (for example, emergency surgery for faecal peritonitis), and for traumatic wounds where treatment is delayed, and there is faecal contamination or devitalised tissue present.
Systems model	A problem-oriented representation of a complex system where parts of the system and their interactions that are relevant to the decision problem are explicitly set out.
Systematic review	Research that summarises the evidence on a clearly formulated question according to a pre-defined protocol using systematic and explicit methods to identify, select and appraise relevant studies, and to extract, collate and report their findings. It may or may not use statistical meta-analysis.
Telemedicine	Delivery of health services via remote telecommunications. This includes interactive consultative and diagnostic services.
Tension band	A format for orthopaedic wiring of fracture fragments either alone or with a screw or Kirschner wire to force fragments together in compression.
Tension pneumothorax	A tension pneumothorax occurs when intrapleural air accumulates progressively in and leads to significant impairment of respiration and/or blood circulation. It is a life threatening occurrence requiring rapid recognition and treatment is required if cardiorespiratory arrest is to be avoided.
Test and treat studies	See 'diagnostic RCT'.
Thoracic	Portion of the spinal column in the chest, between the cervical and lumbar areas.
Thoracostomy	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

Term	Definition
	urgency of their symptoms/condition/situation. The aim is to get someone in need to the right place at the right time to see an appropriately skilled person/team.
Ultrasound	Diagnostic ultrasound, also called sonography or diagnostic medical sonography, is an imaging method that uses high-frequency sound waves to produce images of structures within your body.
Univariate	Analysis which separately explores each variable in a data set.
Unrestricted load bearing	Encouraged to use limb as normal.
Unrestricted mobility	Encouraged to use limb as normal.
Unrestricted weight bearing	Encouraged to walk as normal.
Unstable fracture	A fracture with a tendency to displace after reduction.
Utility	A measure of the strength of an individual's preference for a specific health state in relation to alternative health states. The utility scale assigns numerical values on a scale from 0 (death) to 1 (optimal or 'perfect' health). Health states can be considered worse than death and thus have a negative value.
Vacuum mattress	A vacuum mattress is a medical device used for the immobilisation of patients, especially in the case of vertebra, pelvis or limb trauma. The atmospheric pressure enables the mattress to become rigid securing the patient.
Vitamin K antagonist (VKA)	A group of substances that reduce blood clotting by reducing the action of vitamin K.
Whole-Body CT	A scanogram (vertex to toes) followed by a CT scan from vertex to mid-thigh.
Wound photographs	A digital photograph of the wound to kept along kept as documentation with the patients note.
X-ray	A photographic or digital image of the internal composition of something, especially a part of the body, produced by X-rays being passed through it and being absorbed to different degrees by different materials .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

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