National Clinical Guideline Centre

DRAFT FOR CONSULTATION

Spinal injury: assessment and initial management

Spinal injury assessment: assessment and imaging for spinal injury

Clinical guideline <...>

Appendices J - P

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Appendices

Appendix J: Excluded clinical studies

J.1 Protecting the spine

Table 1: Studies excluded from the stabilisation clinical review

Study	Reason for exclusion
Ahn 2011[11]	Review
Anderson 2010 [18]	Not pre-hospital
Baez 2006[31]	Review (looked for RCTs but found none)
Banit 2000[37]	Retrospective chart review
Bernhard 2005[51]	Review
Brouhard 2006[93]	Review
Brown 1998[95]	Study looking at the kappa agreement between EMS and EPs
Champion 2009[105]	Review
Chick 2012[110]	Abstract of chart review
Cohn 1991[115]	Impact of clearance of cervical spine radiographs on patient care
Domeier 1997[151]	Retrospective chart review of pre-hospital clinical findings associated with spinal injury
Domeier 1999[150]	Study to determine whether mechanism of injury affects the ability of clinical criteria to identify patients with spinal injury
Dunn 2004[161]	Description of training program
Fehlings 2001[173]	Review
Flabouris 2001[179]	Retrospective review
Funk 2012[184]	Comparison of risk factors for cervical spine, head, serious and fatal injury in real world rollover crashes
Haan 2009[222]	Study looking at whether rollover is a predictor for trauma centre care
Halpern 2010[233]	Not a pre-hospital protocol
Hasler 2012[245]	Study looking at the accuracy of HEMS at recognising injury
Hauswald 2007[246]	Telephone survey
Helling 2005[251]	Study to determine incidence of occult head and neck injuries
Helling 1999[252]	Study evaluating the pattern and severity of injuries resulting from low falls
Henschke 2009[258]	Study to determine the prevalence of serious pathology in patients presenting to primary care with acute low back pain
Hoffman 2000[263]	Not pre-hospital
Hong 2012[267]	Cross-sectional study (abstract)
Hong 2012[269]	Compliance study
Horn 2004[270]	Study to determine whether cervical abnormalities demonstrated on MRI imaging are predictive of spinal instability
Jaffe 1987[296]	Decision rule to decide who is imaged
Kerr 2005[322]	Before and after study not pre-hospital
Kinkade 2002[329]	Not pre-hospital
Knopp1988 [338]	Study to assess the predictive value of specific mechanisms of injury and

Study	Reason for exclusion
	anatomic injury in detecting critically injured trauma victims
Laham 1994[349]	Retrospective chart review
Leonard 2012[358]	Compared immobilised children with those incorrectly not immobilised
Lustenberger 2011[369]	Retrospective chart review
Markandaya 2012[374]	Review
Meldon 1998[386]	Level of agreement between emergency medical technicians and emergency physicians
Morrison 2012[403]	Abstract of study looking at adherence to protocol
Myers 2009[413]	Retrospective chart review
Ramasamy 2009[474]	Retrospective chart review
Rhee 2006[480]	Retrospective chart review
Rose 2012[487]	In the trauma centre not pre-hospital
Sahni 1997[493]	Simulation to determine the level of agreement between paramedics and physicians on assessment of the C-spine
Stiell 2011[550]	Not pre-hospital
Stiell 2007[549]	Review
Stiell 2003[551]	Comparison of C-spine rule and NEXUS not pre-hospital
Stuke 2011[558]	Review
Tello 2013[564]	Quality assurance study
Touger 2002[575]	Decision rule to decide who is imaged
Vaillancourt2011 [578]	Study design and methodology
Werman 2008[600]	Protocol applied retrospectively

J.2 Spinal injury assessment risk tools

Table 2: Studies excluded from the non-imaging clinical review

Reference	Reason for exclusion
Anderson 2010 [18]	Incorrect study design: meta-analysis including papers on 'clinical assessment'. Refs on specific tools already in file.
Bandiera 2003 [36]	Intervention does not match protocol: ED physicians' unstructured clinical judgement versus CCR
Barrett 2009 [40]	Incorrect study design: discussion points relating to an article on using CCR to exclude injury by paramedics
Blackmore 1999 [58]	Incorrect study design: economic analysis of cervical spine screening with CT
Blackmore 2003 [59]	Incorrect study design: systematic review, appropriate papers already included
Bracken 1978 [84]	Incorrect study design: the study is a classification of the severity of acute spinal cord injury
Brehaut 2010 [88]	No relevant outcomes: measures the acceptability of the rule among clinicians
Browne 2003 [96]	Intervention does not match protocol: no measures of non-imaging strategy
Chaudry 2012 [107]	Abstract only: no data included. Author contacted 19/09/13. 23/09/13 - Article has been provisionally approved, author Majid A. Khan will send through when final approval given.
Clancy 1999 [112]	Incorrect study design: the paper focuses on classifying patients for radiographical clearance of cervical spine

Reference	Reason for exclusion
Como 2009 [118]	Incorrect study design: guidelines based on literature review
Como 2011 [119]	Intervention does not match protocol: comparison of CT clearance as opposed to further MRI
Cook 2011 [121]	Incorrect study design: review article on clinical tests that exhibit the highest utility for the spine
Diliberti 1992 [147]	Incorrect study design: history and current role of radiography in clearing the cervical spine
Domeier 2002 [152]	Setting does not match protocol: pre-hospital selection for immobilisation
Duane 2007 [155]	Intervention does not match protocol: clinical examination not clearly defined
Durham 1995 [162]	No relevant outcomes: do not provide information on diagnostic outcomes and do not provide enough detail to calculate these ourselves
Edwards 2001 [164]	Intervention does not match protocol: poorly defined clinical examination tool was considered for risk association
Evans 2014[168]	Abstract
Fraser 2006 [183]	Intervention does not match protocol: study investigates patterns of cervical spine evaluation practiced in a single community hospital
Gonzalez 1999 [209]	Intervention does not match protocol: no specific clinical assessment tool
Gonzalez 2009 [208]	Intervention does not match protocol: no specific clinical assessment tool
Hadley 2013 [225]	Incorrect study design and population does not match protocol: review of clinical assessment strategies for neurological assessment, functional outcome and pain in those already diagnosed with SCI
Halpern 2010 [233]	Intervention does not match protocol: economic analysis of management strategies for patients in whom clinical evaluation is not possible
Harris 2004 [242]	Incorrect study design: review article on three clearance techniques for the obtunded patient
Hoffman 1998 [264]	No relevant outcomes: methodology of NEXUS study only, no results presented. Captured in Hoffman 2000.
Hong 2014[268]	Intervention does not match protocol
Hsieh [274] 2000	Intervention does not match protocol: inter-rater reliability between nurse and physician cervical spine clearance criteria
Hunter 2014 [280]	Not relevant to protocol
Hussain 2011 [283]	Intervention does not match protocol: no specific clinical assessment tool.
Hutchings 2011 [284]	Incorrect study design: review used for background, reference Viccellio 2001.
Inaba 2011 [286]	Intervention does not match protocol: clinical examination included NEXUS combined with other examination techniques. Not possible to pull out NEXUS only analysis.
Inaba 2011A [287]	Intervention does not match protocol: no specific clinical assessment tool.
Inaba 2015[289]	Intervention does not match protocol; developmental study
Joaquim 2014[303]	Not relevant to protocol
Junkins 2008 [308]	Population does not match protocol: only provided information on those patients with a diagnosed or non-diagnosed T/L fracture, no information provided on true-negatives.
Kaale 2008 [309]	Intervention does not match protocol and no relevant outcomes: clinical examination (passive mobility of soft tissue structures) not well defined. No relation to outcome (sensitivity/specificity).
Kelly 2004 [320]	Comparison does not match protocol: study focuses on the agreement between physicians and nurses on the eligibility for application of the CCR

Reference	Reason for exclusion
Kinkade 2002 [329]	Incorrect study design: study is a short review of Stiell 2001
Knopp 2004[337]	Review. References checked.
Langdon 2010 [352]	Population does not match protocol: evaluation of 2 'clinical signs' to aid diagnosis of osteoporotic vertebral compression fractures
Lee 2003 [357]	Incorrect study design: before and after cervical spine clearance protocol focussing on time to clearance
Liberman 2005 [363]	Intervention does not match protocol: intoxicated patients: clinical examination vs. later imaging or surgical findings (split by C-spine & T/L)
Meek 2007 [382]	Comparison does not match protocol: study focuses on the level of agreement between ED nurses and ED medical staff in the use of NEXUS
Michaleff 2012 [394]	Incorrect study design: meta-analysis, all included references already on file
Moak 2012 [399]	Abstract only: abstract only with no data included. Author contacted 19/09/13 and replied that findings have yet to be written up.
Mohanty 2013[400]	Not relevant to protocol
Morrison 2012 [403]	Intervention does not match protocol: study focuses on ED consultants' compliance with applying NEXUS imaging criteria
Morrison 2013 [404]	Intervention does not match protocol: study focuses on ED consultants' compliance with applying NEXUS imaging criteria
Mower 2004[406]	Correspondence
Mower 2004[405]	Review – references checked
Munera 2012 [410]	Incorrect study design: review used for background
Myers 2000 [412]	Incorrect study design: short clinical update on Hoffman 2000
Neifeld 1988 [417]	Intervention does not match protocol: clinical assessment not defined by NEXUS or C-spine rules
Omorphos 2003 [427]	Intervention does not match protocol: study focuses on establishing if odontoid peg view is useful to exclude cervical spine injury
Osterbauer 1996 [431]	Intervention does not match protocol: study focuses on the use of biomechanical score and ROM, to differentiate injured patients from controls
Pakarinen 2006 [433]	Intervention does not match protocol: investigation into management protocols for Nordic trauma centres who receive infrequent penetrating neck injury patients
Panacek 2001 [434]	Incorrect study design: subset of Hoffman 2000 presenting validity data for separate sections of the NEXUS - does not provide additional info above Hoffman 2000
Paxton 2012 [443]	Incorrect study design: cross-sectional survey reporting incidence of unnecessary C-spine radiography
Puttum 2014[465]	Abstract
Quann 2011 [468]	Incorrect study design: discussion article on different imaging modalities for cervical spine injured patients
Rethnam [478]	Inappropriate outcome data: insufficient information provided to complete 2x2 table and diagnostic accuracy data
Reynolds 2014[479]	Abstract
Roberge 1992 [482]	Intervention does not match protocol: clinical assessment not part of clinical decision rule
Rodriguez 2013 [483]	Population does not match protocol: thoracic injury not inclusive of spinal column injury
Saltzherr 2009 [494]	Incorrect study designs: guidelines based on literature review
Santiago 2006 [500]	Intervention does not match protocol: clinical examination of thoracolumbar

Reference	Reason for exclusion
	spine. Details of examination not clear.
Slack 2004 [533]	Incorrect study design: review used for background, reference Myers 2000.
Smart 2003 [535]	Intervention does not match protocol: clinical assessment not part of clinical decision rule
Stiell 2010 [552]	Intervention does not match protocol: diagnostic accuracy of nurses performing C-spine compared to investigators
Stiell 2011 [550]	Intervention does not match protocol: specificity data and later confirmation information not reported for study of nurse-led C-spine clearance protocol
Stiell 2011 [548]	Commentary on above study
Stroh 2001 [557]	Intervention does not match protocol: looking at clearance protocol for selective immobilisation out-of-hospital rather than clearance in hospital instead of imaging
Vaillancourt 2009 [580]	Setting does not match protocol: Canadian C-spine rule when used by paramedics in the out-of-hospital setting for selective immobilisation
Vaillancourt 2011 [578]	Setting does not match protocol: evaluation of paramedics' use of C-spine rules to make immobilisation decisions. Also paper is only design & methodology, no results presented.
Vaillancourt 2014[579]	Abstract
Vandenberg 2014[585]	Abstract
Venkatesan 2012 [586]	Intervention does not match protocol: study focuses on determining if CT taken for injury to the viscera is of use in detecting spinal fractures

J.3 Immobilising the spine: pre hospital strategies

Table 3: Studies excluded from pre hospital strategies clinical review

Reference	Reason for exclusion
Blaylock 1996 [60]	Product trial of patients anticipated to wear a collar for ten days or more
Haut 2010 [247]	Outcomes associated with immobilised patients
Hogan 1997 [265]	Description of guideline development
Kolb 1999 [339]	Wrong patient population (patients undergoing lumbar puncture)
Peery 2007 [445]	No relevant outcomes: How well straps had been fixed
Powers 2006 [462]	No comparative study, looking at Aspen collar which was in place within 24 hours of injury
Theodore 2013 [567]	Review (all relevant papers included)
Vickery 2001 [587]	Review (all relevant papers included)
Wishlow 2012 [609]	Abstract of paper with no relevant outcomes: time spent on backboard

J.4 Destination (immediate)

J.4.1 Spinal Column

Table 4: Studies excluded from the spinal column destination clinical review

Reference	Reason for exclusion
Demetriades 2005[140]	Spinal cord injury patients
Heinemann 1989[250]	Spinal cord injury patients
Parent 2011[437]	Not all acute trauma patients (relevant studies included)

Reference	Reason for exclusion
Ploumis 2011[458]	Spinal cord injury
Sampalis 1995[496]	Trauma patients not all spinal injury
Spijkers 2010[541]	Trauma patients not all spinal injury

J.4.2 Spinal Cord

Table 5: Studies excluded from the spinal cord destination clinical review

Reference	Reason for exclusion
Heineman [250]n AW, Yarkony 1990 [615]	Outcomes associated with inpatient rehabilitation
Parent 2011[437]	Not all acute trauma patients (relevant studies included)
Ploumis 2011[458]	Outcomes associated with inpatient rehabilitation
Sampalis 1995[496]	Trauma patients not all spinal injury
Spijkers 2010[541]	Trauma patients not all spinal injury

J.5 Diagnostic imaging

Table 6: Studies excluded from the diagnostic imaging clinical review

Reference	Reason for exclusion
Ackland 2006[8]	Review
Andreoli 2005[20]	Not a diagnostic study
Bach 2001[28]	No relevant outcomes
Baker 1999[34]	Unclear gold standard
Barba 2001[39]	Inappropriate outcomes
Barrios 2009[41]	Concerning diagnosis of general thoracic trauma
Barrios 2010[42]	Not concerning spinal injury
Bazzocchi 2013[45]	Index/reference test not as protocol: variant of CT versus CT
Berne 1999 [50]	>50% of participants had a head injury
Betz 1987 [54]	Not a diagnostic accuracy study; cervical spine
Bierry 2014[55]	Aimed at detection of bone marrow oedema
Boese 2013[62]	Systematic review
Cadotte 2011 [98]	Systematic review. Most articles relating to cervical spine
Cain 2010[99]	Review
Chan 2005[106]	Inappropriate outcomes
Chew 2012[109]	Abstract
Como 2011[119]	No relevant outcomes
Como 2007[120]	Population were indeterminate on initial imaging
Dai 2001 [130]	No relevant outcomes
Dare 2002 [131]	Not relevant to this review question
Davis 1995 [137]	Population were indeterminate on initial imaging
Deunk 2007 [142]	Not a diagnostic accuracy study
Duane [156]	No diagnostic accuracy data
Epstein [167]	No relevant outcomes

Reference	Reason for exclusion
Felsberg [175]	Not a diagnostic accuracy study
Fisher 2008 [177]	Insufficient data to calculate diagnostic accuracy
Fisher 2013[178]	Combination of imaging being tested
Frank 2002 [182]	No diagnostic accuracy data
Gale 2005 [188]	>80% with head injury
Ganiyusufoglu 2010[189]	Not traumatic injuries
Gestring 2002 [203]	Used X-rays as the gold standard
Gong 2004 [207]	No gold standard used
Gonzalez 2009[208]	No appropriate outcomes
Green 2004[213]	Not a diagnostic accuracy study
Gross 2010 [218]	Outside scope of question
Hennessy 2010 [256]	X-ray was gold standard
Henry 2013[257]	Abstract
Hernandez 2014[259]	Not all had both index and reference tests
Horn 2004[270]	Insufficient data presented for diagnostic accuracy calculations
Hsu 2003[275]	Not relevant to this review question
Inaba 2006 [288]	Review article; articles searched
Inaoka 2012 [290]	Results do not tally with raw data (but raw data insufficient to allow accurate calculations).
Jelly 2000 [298]	Inappropriate gold standard
Jones 2007 [307]	No relevant outcomes
Kanji 2014 [315]	Systematic review
Keene 1982 [318]	Not a true diagnostic accuracy study – no fixed gold standard
Kirschner 2012 [330]	Review
Lammertse 2007 [350]	Review article
Maeda 2012[371]	No gold standard used
Mascalchi 1993 [375]	Non-diagnostic study; mostly cervical spine
McCracken 2013[377]	Population had negative CT scan of cervical spine
Mehta 2012[384]	Abstract. RCTs already found for this question.
Menaker 2008[389]	Population indeterminate on initial imaging
Menaker 2010[390]	Population indeterminate on initial imaging
Morais 2014[402]	Not a diagnostic study
Nigrovic 2012[422]	Incorrect calculation of sensitivity; no raw data provided on false negatives or false positives
Parashari 2011[436]	Not a diagnostic study
Paszkowska 2010[441]	No relevant outcomes
Petrovic 2013[449]	Index/reference test not as protocol: variant of CT versus CT
Pinheiro 2011[452]	No relevant outcomes
Pizones 2013[454]	No gold standard defined
Platzer 2006A[455]	Unclear gold standard
Platzer 2006[456]	Unclear gold standard
Platzer 2006B[457]	Diagnostic accuracy of an algorithm rather than imaging modalities
Pollack 2001[460]	Inappropriate outcomes

Reference	Reason for exclusion
Ralston 2003[473]	Inappropriate outcomes
Raza 2013 [476]	Concurrent head injury
Rodriguez 2013[484]	Considered a decision instrument not specific imaging
Russin 2013[490]	Systematic review
Sampson 2006[497]	Not relevant to this review question
Samuels 1993[498]	Not relevant to this review question
Sanchez 2005[499]	Diagnostic accuracy of a protocol not a specific imaging modality
Sarani 2007[501]	Population indeterminate on initial imaging
Satahoo2014 [502]	Concurrent head injury
Schoenwaelder 2009[507]	Not relevant to this review question
Sees1998 [515]	Indeterminate population in terms of initial imaging
Sledge 2001[534]	Not a diagnostic accuracy study
Stassen 2006 [545]	Unclear gold standard
Sun 2013 [559]	Not a diagnostic accuracy study
Tan 2014[563]	Concurrent head injury
Theologis 2014 [568]	Not a diagnostic accuracy study
Tissier 2013[570]	Not a diagnostic accuracy study
Tran 2013[576]	Population with negative CT scans
van Vugt 2013[584]	Systematic review
Warner1996 [597]	Insufficient data provided for diagnostic data calculations
Winklhofer 2013[608]	Not a diagnostic accuracy study
Wittenberg 1990[610]	Not a diagnostic accuracy study
Woods 1998[611]	Unclear gold standard
Yamashita 1991[614]	Not a diagnostic accuracy study

J.6 Radiation risk

Table 7: Studies excluded from the radiation risk clinical review

Reference	Reason for exclusion
Abe 2013 [6]	Exposure does not match protocol (occupational exposure)
Almohiy 2014 [16]	Non-SR review – references checked
Anderson 2006 [17]	Outcome does not match protocol (no patient outcomes measured)
Andersson 1993 [19]	Other exclusion criteria as listed in the protocol (year of publication pre 1995)
Andrieu 2006 [21]	Lag time less than minimum in protocol
Angele 2003 [22]	Incorrect study design (laboratory study)
Anon-2013 [4]	Abstract only
Anon-2013a [5]	Incorrect study design (article)
Arbique 2006 [25]	Outcome does not match protocol (no patient outcomes measured)
Bach 2012 [29]	Incorrect study design (narrative review)
Bailey 2010 [33]	Incorrect study design (case-control)
Baker 2006 [35]	Incorrect study design (narrative review)
Bartley 2010 [43]	Incorrect study design (case-control)

Reference	Reason for exclusion
Beentjes 1979 [48]	Incorrect study design (risk modelling)
Behrens 2010 [49]	Incorrect study design (laboratory study)
Bernier 2012 [52]	Outcome does not match protocol (no patient outcomes measured)
Bijwaard 2010 [56]	Incorrect study design (risk modelling)
Bijwaard 2011 [57]	Incorrect study design (risk modelling)
Boice 1977 [67]	Other exclusion criteria as listed in the protocol (year of publication pre 1995)
Boice 1980 [65]	Incorrect study design (article)
Boice 1991 [69]	Other exclusion criteria as listed in the protocol (year of publication pre 1995)
Boice 1991a[68]	Incorrect study design (case-control)
Boice 1992 [66]	Incorrect study design (narrative review)
Boudreau 2009 [72]	Incorrect study design (technology appraisal)
Brambilla 2013 [85]	Incorrect study design (narrative review)
Brenner 2014 [90]	Non-SR review – references checked
Brenner 1999 [89]	Inappropriate comparison (techniques of dosage reduction)
Bross 1979 [92]	Outcome does not match protocol (no patient outcomes measured)
Bunin 1989 [97]	Incorrect study design (case-control)
Calandrino 2013 [100]	Population does not match protocol (pre-existing malignancy)
Chen 2014[108]	Review – references checked
Claus 2012 [113]	Incorrect study design (case-control)
Cook 1974 [122]	Incorrect study design (case-control)
Davis 1987 [136]	Other exclusion criteria as listed in the protocol (year of publication pre 1995)
Davis 1989 [135]	Other exclusion criteria as listed in the protocol (year of publication pre 1995)
Davis 2011 [134]	Incorrect study design (case-control)
Delarue 1975 [139]	Other exclusion criteria as listed in the protocol (year of publication pre 1995)
Dijkstra 2014 [146]	Simulation study
Dirksen 2013 [148]	Incorrect study design (article)
Doida 1971 [149]	Incorrect study design (laboratory study)
Faletra 2010 [171]	Outcome does not match protocol (no patient outcomes measured)
Gelberg 1997 [199]	Incorrect study design (case-control)
Gledo 2012 [204]	Incorrect study design (case-control)
Goel 2009 [205]	Incorrect study design (case-control)
Gofman 1970 [206]	Incorrect study design (article)
Griffey 2009 [215]	Outcome does not match protocol (no patient outcomes measured)
Grudzenski 2009 [219]	Incorrect study design (laboratory study)
Hall 1991 [229]	Incorrect study design (narrative review)
Hallquist 1993 [230]	Incorrect study design (case-control)
Hallquist 1994 [231]	Incorrect study design (case-control)
Hallquist 2001 [232]	Incorrect study design (case-control)
Hammer 2009 [236]	Lag time less than minimum in protocol

Reference	Reason for exclusion
Hammer 2011 [235]	Lag time less than minimum in protocol
Han 2012 [237]	Incorrect study design (case-control)
Hansen 2009 [238]	Incorrect study design (case series)
Hardell 2000 [240]	Incorrect study design (case-control)
Hardell 2001 [239]	Incorrect study design (case-control)
Harlap 2002 [241]	Incorrect study design (case-control)
Harvey 1985 [244]	Incorrect study design (case-control)
Hayes 1979 [249]	Incorrect study design (laboratory study)
Hempelmann 1967 [253]	Exposure does not match protocol (therapeutic exposure)
Henk 1993 [254]	Incorrect study design (case series)
Hennelly 2013 [255]	Incorrect study design (risk modelling)
Hinds 1979 [261]	Incorrect study design (case-control)
Hoffman 1989 [262]	Other exclusion criteria as listed in the protocol (year of publication pre 1995)
Howe 1995 [271]	Exposure does not match protocol (fluoroscopy)
Howe 1996 [272]	Exposure does not match protocol (fluoroscopy)
Hrubec 1989 [273]	Incorrect study design (case-control)
Huang 2010 [276]	Outcome does not match protocol (no patient outcomes measured)
Huda 2011 [277]	Outcome does not match protocol (no patient outcomes measured)
Hung 2013[279]	Exposure does not match protocol (MPS, CA, CV, CTCA and PTCA)
Hurwitz 2007 [282]	Outcome does not match protocol (no patient outcomes measured)
Huvos 1985 [285]	Exposure does not match protocol (therapeutic exposure)
Infanterivard 2000 [291]	Incorrect study design (case-control)
Inskip 1995 [292]	Incorrect study design (case-control)
Jaffurs 2009 [297]	Outcome does not match protocol (no patient outcomes measured)
Jess 2007 [300]	Incorrect study design (case-control)
Jew 2001 [301]	Incorrect study design (case series)
Jimenez 2008 [302]	Outcome does not match protocol (no patient outcomes measured)
Johansson 1995 [304]	Exposure does not match protocol (therapeutic exposure)
John 2007 [305]	Incorrect study design (case-control)
Johnston 1986 [306]	Incorrect study design (case-control)
Kaatsch 1998 [310]	Incorrect study design (case-control)
Kainoawhite 2013 [312]	Abstract only
Karthikesalingam 2009 [316]	Outcome does not match protocol (no patient outcomes measured)
Khan 2010 [325]	Incorrect study design (case-control)
Kim 2009 [327]	Outcome does not match protocol (no patient outcomes measured)
Klein 2000 [334]	Lag time less than minimum in protocol
Kleinerman 2006 [335]	Incorrect study design (narrative review)
Kollarova 2013 [340]	Incorrect study design (case-control)
Krille 2011 [342]	Incorrect study design (study protocol)
Krille 2012 [343]	Incorrect study design (narrative review)
Kubale 2005 [344]	Incorrect study design (case-control)
Laack 2011 [347]	Outcome does not match protocol (no patient outcomes measured)

Reference	Reason for exclusion
Lecarpentier 2011 [353]	Incorrect study design (case-control)
Leung 1983 [359]	Exposure does not match protocol (occupational exposure)
Levy 1996 [360]	Outcome does not match protocol (no patient outcomes measured)
Lin 2013 [364]	Incorrect study design (case-control)
Linet 2009 [365]	Incorrect study design (narrative review)
Little 1999 [366]	Inappropriate comparison (techniques of dosage reduction)
Mayo 2008 [376]	Incorrect study design (article)
McCredie 1994 [378]	Incorrect study design (case-control)
McKinney 1987 [381]	Incorrect study design (case-control)
Meer 2012 [383]	Outcome does not match protocol (no patient outcomes measured)
Meinert 1999 [385]	Incorrect study design (case-control)
Mellemkjaer 2006 [387]	Incorrect study design (case-control)
Memon 2010 [388]	Incorrect study design (case-control)
Meulepas 2014 [391]	Protocol
Meyer 1981 [392]	Other exclusion criteria as listed in the protocol (year of publication pre 1995)
Michaelis 1998 [393]	Incorrect study design (case-control)
Michel 2012 [395]	Outcome does not match protocol (no patient outcomes measured)
Miglioretti 2013 [397]	Outcome does not match protocol (no patient outcomes measured)
Millikan 2005 [398]	Incorrect study design (laboratory study)
Mohner 2010 [401]	Exposure does not match protocol (occupational exposure)
Muchow 2012 [407]	Outcome does not match protocol (no patient outcomes measured)
Muirhead 1991 [409]	Incorrect study design (narrative review)
Myles 2008 [414]	Incorrect study design (case-control)
Naumburg 2001 [416]	Incorrect study design (case-control)
Neta 2013 [418]	Lag time less than minimum in protocol
Neubauer 2012 [419]	Comparison does not match protocol
Neuberger 1991 [420]	Incorrect study design (case-control)
Oppenheim 1974 [428]	Other exclusion criteria as listed in the protocol (year of publication pre 1995)
Ortega Jacome 2010 [430]	Incorrect study design (case series)
Pogoda 2011[459]	Incorrect study design (case-control)
Pearce 2012 [444]	Lag time less than minimum in protocol
Preston-Martin 1989 [463]	Incorrect study design (narrative review)
Rafael 2005 [471]	Incorrect study design (case series)
Rajaraman 2011 [472]	Incorrect study design (case-control)
Ray 2010 [475]	Lag time less than minimum in protocol
Rodvall 1990 [485]	Incorrect study design (case-control)
Ronckers 2008 [486]	Lag time less than minimum in protocol
Ryan 1992 [491]	Incorrect study design (case-control)
Schulze-Rath 2008 [510]	Incorrect study design (narrative review)
Schuz 2001 [511]	Incorrect study design (case-control)
Shiono 1980 [522]	Incorrect study design (case-control)

Reference	Reason for exclusion
Shore 1980 [523]	Exposure does not match protocol (therapeutic exposure)
Shu 1988 [524]	Incorrect study design (case-control)
Shu 1994 [527]	Incorrect study design (case-control)
Shu 1994[525]	Incorrect study design (case-control)
Shu 2002 [526]	Incorrect study design (case-control)
Silverman 1984 [530]	Incorrect study design (article)
Smith-Bindman 2009 [536]	Outcome does not match protocol (no patient outcomes measured)
Smits 2006 [537]	Incorrect study design (article)
Sodickson 2009 [539]	Outcome does not match protocol (no patient outcomes measured)
Sokic 1994 [540]	Incorrect study design (case-control)
Stalberg 2007 [543]	Incorrect study design (case-control)
Stjernfeldt 1992 [554]	Incorrect study design (case-control)
Storm 1986 [556]	Incorrect study design (case-control)
Thelander 1973 [565]	Incorrect study design (narrative review)
Theocharopoulos 2009 [566]	Outcome does not match protocol (no patient outcomes measured)
Thomas 1994 [569]	Incorrect study design (case-control)
Torfs 1996 [573]	Outcome does not match protocol (gastroschisis)
van Duijn 1994 [581]	Incorrect study design (case-control)
Wakabayashi 1994 [588]	Incorrect study design (case-control)
Wakeford 1995 [589]	Incorrect study design (narrative review)
Wakeford 2002 [593]	Incorrect study design (narrative review)
Wakeford 2003 [594]	Incorrect study design (narrative review)
Wakeford 2008 [590]	Incorrect study design (narrative review)
Wakeford 2009 [591]	Exposure does not match protocol (occupational exposure)
Wakeford 2013 [592]	Incorrect study design (narrative review)
Wall 2006 [595]	Incorrect study design (narrative review)
Webster 1981 [598]	Incorrect study design (narrative review)
Webster 1981a [598]	Incorrect study design (narrative review)
Wingren 1997 [607]	Incorrect study design (case-control)
Yuasa 1997 [621]	Incorrect study design (case-control)
Zheng 1996 [625]	Incorrect study design (case-control)
Zheng 2002 [624]	Incorrect study design (case-control)
Zondervan 2013 [626]	Outcome does not match protocol (no patient outcomes measured)

J.7 Further imaging

Table 8: Studies excluded from the further imaging clinical review

Reference	Reason for exclusion
Ackland 2011[7]	No comparator
Adams 2006[9]	No comparator or relevant outcomes
Albrecht 2001[15]	No relevant outcomes
Anglen 2002[23]	Did not address the review question
Barba 2001[39]	No comparator or relevant outcomes

Reference	Reason for exclusion
Baumgarten 1985[44]	No comparator
Boese 2013[63]	No comparator
Borock 1991[70]	No comparator
Brown 2010[94]	No comparator
Dare 2002[131]	No comparator
Davis 1995[137]	No comparator
Davis 1993[138]	No comparator and unrelated to review question
DiGiacomo 2002[145]	No comparator
Dwek 2000[163]	No comparator
Emhoff 2010[165]	No comparator
Gargas 2011[191]	No comparator
Gargas 2013[192]	No comparator
Goodnight 2008[210]	Not relevant to review question
Grabb 1994[211]	No comparator
Hennessy 2010[256]	Not a population with unclear imaging findings
Hogan 2005[266]	No comparator
Ireland 1998[293]	No relevant outcomes
Jelly 2000[298]	No comparator
Kaiser 2012[313]	No comparator
Kasimatis 2008[317]	No comparator
Keiper 1998[319]	No comparator
Khanna 2012[326]	No comparator
Kulaylat 2012[345]	No comparator and not in population with no initial imaging diagnosis
Labattaglia 2007[348]	No comparator
McCulloch 2005[379]	No comparator
Menaker 2008[389]	No comparator
Menaker 2010[390]	No comparator
Muchow 2008[408]	Review
Pollack 2001[460]	No comparator
Ralston 2003[473]	No comparator
Sanchez 2005[499]	No comparator
Sarani 2007[501]	No comparator
Scarrow 1999[506]	No comparator
Schoenwaelder 2009[507]	Comparator was CT of the brain
Schweitzer 2007[513]	No comparator
Shen 2007[520]	No relevant outcomes
Steigelman 2008[546]	No comparator
Stelfox 2007[547]	No comparator
Tomycz 2008[572]	No comparator

J.8 Spinal cord decompression

Table 9: Studies excluded from the dislocation clinical review

Reference	Reason for exclusion
Aguiar1990[10]	Narrative review detailing management of C-spine injuries.
Anon2002[2]	Guideline document. Not appropriate to listed outcome.
Anon2002C[3]	Guideline document. Not appropriate to listed outcome.
Baek2007[30]	Retrospective case series. No robust outcome measure. Not appropriate for protocol outcome.
Berrington1993[53]	Case report. Only 1 patient with no timing data. Not appropriate for analysis.
Bohlman1979[64]	Retrospective cohort study. Comparison between open and closed. No timing of intervention recorded. Not appropriate to protocol outcome.
Cotler1987[123]	Retrospective cohort study. Sets out potential recommendations. Not appropriate to protocol outcome.
Cotler1993[124]	Case Series. Safety analysis of closed reduction. Not appropriate to protocol outcome.
Cowan2008[125]	Case report. Only 1 patient. Not appropriate for analysis.
Cruickshank1989[127]	Letter/position statement. Not appropriate for protocol outcome.
Finch1998[176]	Study does not report outcome (closed reduction before and after 4 hours). Study set up to report difference in open and closed reduction strategies.
Gelb2013[198]	Review article presenting no data specific to outcome.
Grant1999[212]	Retrospective review. Compares complete and incomplete early reduction. No data specific to protocol question. No analysis for appropriate outcome.
Hadley1992[224]	Prospective cohort. Closed versus open reduction without timing information.
Hadley2002[223]	Guideline document. Not appropriate to listed outcome.
Jentzen1987[299]	Case report. Only 1 patient. Not appropriate for analysis.
Kahn1998[311]	Retrospective cohort. Only considers late diagnosis. No comparison data or specific timing info. Not appropriate to protocol outcome.
Key1975[323]	Case series report detailing a method of closed reduction. No comparison and no timing data recorded. Not appropriate to protocol outcome.
Keynan2002[324]	Review article comparing techniques for cervical dislocation. No analysis for appropriate outcome.
Kleyn1984[336]	Prospective case series. No timing of intervention provided. Not appropriate to protocol outcome.
Lee1994[355]	Retrospective cohort study. Comparison between manipulation under anaesthesia and reduction under sedation. No mention of time specific. Not appropriate to protocol outcome.
Lu1998[367]	Case series. Compared unsuccessful traction closure followed by reduction under anaesthesia with no time related data. Outcome inappropriate for protocol.
Ludwig1997[368]	Case report. Only 1 patient looking at adverse event. Not appropriate for analysis.
Mahale1993[372]	Case series. No specific outcome studied, considers complications. Not appropriate for protocol outcome.
Malone2002[373]	Case Series. Reports adverse events following spinal manipulation closure procedure.
Murphy2006[411]	Case series. Indirect population with no dislocation.

Reference	Reason for exclusion
Newton2011[421]	Non-randomised study which is not matched at baseline for confounders (age).
O'Connor2003[424]	Case series looking at traction reduction of the spine. No timing recorded. Not appropriate to protocol outcome.
O'Dowd2010[425]	Review article considering the principles of clinical management for cervical trauma. Not appropriate to protocol outcome.
Obrien1982[423]	Retrospective cohort. Compares open and closed procedures. Specific data regarding time not provided. Not appropriate for protocol outcome.
Oppenheim2005[429]	Case series report. No timing information. No analysis for appropriate outcome.
Osti1989[432]	Retrospective cohort study. Study to look at safety of closed reduction under anaesthesia. No timing recorded. Not appropriate to protocol outcome.
Rabb2007[469]	Retrospective case series. No distinction between subjects who were reduced by closed or open reduction. Not appropriate for protocol outcome.
Radcliff2013[470]	Narrative review. Does not report specific outcomes.
Reindl2006[477]	Inappropriate intervention (open reduction).
Rizzolo1994[481]	Review question. Measures outcome before and post MRI. Not appropriate to listed outcome.
Sabiston1988[492]	Retrospective cohort. Primary outcome is weight applied for traction measure. No timing data reported. Not appropriate for protocol outcome.
Shapiro1993[518]	Retrospective cohort study. Considers if closed reduction is successful or not and subsequent outcome. No time data given for patients. Not appropriate to protocol outcome.
Shapiro1999[517]	Retrospective cohort study. Study compared CT and MR as aids for internal reduction of the C-spine. Not appropriate to study outcome.
Shen 2015[521]	Non-comparative study.
Sribnick 2014[542]	Non-comparative study
Star1990[544]	Retrospective case analysis. Comparison of methods for reduction. Does not consider timing. Not appropriate for protocol outcome.
Torg1991[574]	Case series. Limited timing data for some patients no robust outcome measures. Compares open and closed reduction. Not appropriate for protocol outcome.
Vadera2007[577]	Review article. Guideline recommendation.
Volker1981	Case series. Period to reduction not examined. Compares surgical versus non-surgical. Not appropriate for protocol outcome.
Wilson2011[605]	Indirect population. Surgical reduction.
Wimberley2005[606]	Case report. Only 1 patient looking at adverse event. Not appropriate for analysis.
Xiong1998[613]	Case series. No obvious reporting of timing information. Not appropriate to listed outcome.
Yashon1975[616]	Narrative review. Provides indication for closed reduction but not appropriate for protocol outcome.
Yisheng2007[617]	Prospective cohort. Study considers open reduction. Not appropriate to listed outcome.
Yu2007[620]	Case series considering closed reduction. Timing not documented. Indirect population with no dislocation.

J.9 Timing of referral to tertiary services

Table 10: Studies excluded from the tertiary services clinical review

Reference	Reason for exclusion
Beck 1999[46]	Not multivariate analysis. Outcomes post discharge.
Catz 2002[104]	Outcomes post discharge
Gulati 2011[220]	Descriptive analysis, not multivariate
Kozlowski 2013[341]	Descriptive analysis, not multivariate analysis
Liang 2001[362]	Outcomes post discharge
Beck 1999[46]	Not multivariate analysis. Outcomes post discharge.

J.10 Neuroprotective pharmacological interventions

Table 11: Studies excluded from the medical interventions clinical review

Author	Reason for exclusion
Aito 2002[13]	Narrative Review
Anon-1973[1]	Editorial
Anon-1990	Editorial
Anon-1993[24]	Editorial
Anon-2002	Guideline
Arora 2011[26]	Case series
Bagnall 2003[32]	Health technology assessment – methods not applicable
Baptiste 2007[38]	Narrative Review
Botelho 2009[71]	Review
Bracken 1990[83]	Correspondence
Bracken 1991[74]	Summary of NASCIS II
Bracken 1992[75]	Summary of NASCIS II
Bracken 1993[80]	Narrative on NASCIS II
Bracken 2000[76]	Cochrane Review Superseded by 2012 update
Bracken 2000[79]	Critical appraisal
Bracken 2000[82]	Correspondence
Bracken 2001[77]	Review
Bracken 2002[81]	Subgroup analysis of NASCIS III - outcomes not relevant (prognostic)
Bracken 2012[78]	Cochrane Review – data used
Breslin 2012[91]	Review
Canakci 1997[101]	Not ordered - conference abstract
Coleman 2000[116]	Critical appraisal
Cranston 1973[126]	Correspondence
Ducker 1990[158]	Editorial
Ducker 1990[157]	Editorial
Ducker 1996[159]	Commentary on clinical trial
Dumont 2001[160]	Editorial
Epstein 1980[166]	Retrospective cohort
Faden 1987[169]	Narrative Review

Author	Reason for exclusion
Faden 1996[170]	Narrative Review
Fehlings 2001[173]	Editorial
Fehlings 2005[174]	Narrative Review
Frampton 2006[181]	Questionnaire to determine current practice
Galandiuk 1993[187]	Prospective Cohort
Gardner 1991[190]	Editorial
Geisler 1992[196]	Intervention not relevant
Geisler 1993[197]	Editorial and trial protocol
Geisler 1993[194]	Intervention not relevant
Geisler 1998[195]	Editorial and trial protocol
George 1995[200]	Retrospective cohort
Gerhart 1995[201]	Surveillence data - retrospective cohort study
Gerndt 1997[202]	Prospective cohort with historic control
Greene 1996[214]	Narrative Review
Griffiths 1987[216]	Narrative Review, Systematic Review
Hall 1987[226]	Literature Review
Hall 2004[227]	Narrative Review
Halpern 1991[234]	Guideline
Hawryluk 2008[248]	Narrative Review
Hilton 1992[260]	Guideline
Hugenholtz 2003[278]	Editorial
Hurlbert 2013[281]	Narrative Review
Ito 2009[295]	Retrospective Consecutive Cohort
Kiwerski 1993[332]	Retrospective cohort
Lammertse 2004[351]	Narrative Review
Lee 2007[356]	Retrospective cohort
Levy 1996[360]	Retrospecitve Cohort
Leypold 2007[361]	Retrospective Cohort
Lyons 1990[370]	Correspondence
Mccutcheon 2004[380]	Retrospective cohort
Pandya 2010[435]	Editorial
Petitjean 1995[446]	Not ordered - conference abstract
Petitjean 1998[448]	Not ordered - not in English
Petitjean 1998[447]	Not ordered - not in English
Pettersson 1998[450]	Indirect population - whiplash injuries (Grade II and III) only 22% with neurological symptoms
Pettiford 2012[451]	Systematic Review
Pitts 1995[453]	Intervention not relevant
Qian 2005[467]	Prospective Cohort Study
Savitsky 1996[504]	Editorial
Sayer 2006[505]	Systematic Review of animal models and clinical trials
Schwartz 2010[512]	Economic data and analysis
Senegor 1990[516]	Editorial

Author	Reason for exclusion
Sharma 2012[519]	Narrative Review
Sipski 2006[532]	Editorial
Stifel 1990[553]	Correspondence
Stoica 2009[555]	Narrative Review
Walsh 2010[596]	Narrative Review
Werner 1997[601]	Editorial
Xiong 2011[612]	Retrospective Cohort with indirect population - post surgical decompression.
Yarkony 1990[615]	Correspondence
Yokota 1995[618]	Not ordered - not in English
Young 1994[619]	Narrative Review
Zeidman 1996[622]	Narrative Review
Zhang 2001[623]	Not ordered - not in English

J.11 Neuropathic pain

Table 12: Studies excluded from the neuropathic pain clinical review

Author	Reason for exclusion
Cardenas 2013[102]	Abstract
Forchheimer 2013[180]	Abstract
Guy 2014[221]	Systematic review dealing with management of existing post SCI neuropathic pain rather than prevention
Parsons 2014[439]	Abstract
Parsons 2013[440]	Abstract
Patel 2014[442]	Abstract
Siddall 2006[528]	Purpose of study cure and not prevention.
Snedecor 2013[538]	Systematic review is not relevant to review question or unclear PICO
Wiffen 2011[602]	Systematic review is not relevant to review question or unclear PICO
Wiffen 2011[603]	Systematic review is not relevant to review question or unclear PICO

J.12 Information and support

Table 13: Studies excluded from the information and support clinical review

Reference	Reason for exclusion
Aitken [12]	Population does not match protocol (population included all traumatic injury and results were not sub-grouped by type [for example SCI])
Blumer 1996 [61]	Population does not match protocol (survey conducted with directors of spinal care units to find out informational needs)
Braakman 1976 [73]	Incorrect study design (review paper, does not include qualitative research)
Cassidy 2004 [103]	Incorrect study design (article reports the development of a library resource for SCI patients in rehabilitation)
Davidhizar 2002 [132]	Incorrect study design (article presents issues and strategies for client education following a SCI based on a case-study)
Davidson 2010 [133]	Population does not match protocol (questionnaire given to spinal surgeons to determine variability in information they provide patients)
Dewar 2000 [143]	Population does not match protocol (nurses' experiences of providing

Reference	Reason for exclusion
	information to SCI patients, not asking the patients themselves)
Dewar 2001 [144]	Incorrect study design (review paper, does not include original qualitative research and focuses on the nurses giving bad news, not patients' perspectives)
Dorsey 2005 [153]	Incorrect study design (education plan presented from consensus agreement rather than based on undertaking original qualitative research)
Garrino 2011 [193]	Setting does not match protocol (study conducted in a Spinal Cord Unit [specialist tertiary care])
Kent 1995 [321]	Incorrect study design (article details the nursing response to a case-study patient with multiple injuries including some cervical spine damage)
Kirshblum 2008 [331]	Incorrect study design (discussion guidelines based on health practitioners' consensus rather than based on undertaking original qualitative research)
Klebine 2002 [333]	Incorrect study design (article details "20 free educational Info sheets" on SCI-related topics)
Rundquist 2009 [489]	Population does not match protocol (observational information provided on topics nurses provide education about at the bedside, not patient's perceptions)
Schottler 2010 [508]	Incorrect study design. Four questions asked were not designed to elicit qualitative responses (thoughts/feelings/experiences) but rather were closed questions requiring specific responses. SPSS used to analyse answers (% who answered in particular way).
Swarczinski 1990 [560]	Incorrect study design (checklist offered is based on SCI unit staff consensus not based on qualitative research with SCI patients)

J.13 Documentation

Table 14: Studies excluded from the documentation clinical review

Reference	Reason for exclusion
Wilson 2012 [604]	Systematic review. Prognostic evaluation for predictors of neurological function. Not appropriate to outcome.
Al-Habib 2011A[14]	Systematic review. Considers factors that predict neurological and functional recovery following SCI. Prognostic, not appropriate to outcome.
Bedbrook 1987[47]	Study not specific to protocol. Study provides no appropriate outcomes and is a prognostic review.
Coleman 2004 [117]	Retrospective cohort analysis. Prognostic evaluation of neurological assessment tools. Not appropriate to outcome.
Curt 1997A [128]	Prospective cohort study. Prognostic evaluation of neurological assessment tools. Not appropriate to outcome.
Curt 1998 [129]	Prospective cohort study. Prognostic evaluation of neurological assessment tools. Not appropriate to outcome.
Furlan 2008 [185]	Systematic review. Examines the ability of ASIA to discriminate patients in a longitudinal fashion. Not appropriate to outcome.
Furlan 2011 [186]	Systematic review. Examines the ability of ASIA to discriminate patients in a longitudinal fashion. Not appropriate to outcome.
Hall 1999 [228]	Prospective cohort study. Indirect population. Study measures tools for changes in functional changes in patients during ongoing rehabilitation.
Harrop 2009 [243]	Retrospective cohort review. Study to measure the effectiveness of ASIA to measure changes in neurological status within clinical trials. Inappropriate outcome.

Reference	Reason for exclusion
Ishida 2002 [294]	Small Prospective study. Evaluates the course of neurologic function. Prognostic study. Not appropriate for outcome.
Kirshblum 2008 [331]	Incorrect outcome. Prognostic evaluation of SCI.
Kumar 2011 [346]	Prospective cohort study. Incorrect outcome. Reviews prognostic tool for SCI outcome.
Park 2013 [438]	Prospective cohort study. Incorrect outcome, prognostic study. Evaluates the capability of a diagnostic tool to predict SCI.
Pouw 2011 [461]	Prospective multicentre cohort study. Measures prognostic ability of neurological functional tools. Incorrect outcome.
Putz 2011A[466]	Retrospective cohort analysis. Measures prognostic ability of ASIA assessment tool. Incorrect outcome.
Salvador 2001 [495]	Retrospective study of medical records. Incorrect population. Spinal cord infraction – non-trauma.
Savic 2006 [503]	Prospective experimental analysis. Not applicable to question. Validation study of sensory test for monitoring neurological changes in neurological function.
Schuld 2013 [509]	Prospective longitudinal cohort study. Not appropriate to question.
Scivoletto 2004A [514]	Retrospective cohort analysis. Inappropriate outcome. Measures changes in neurological function following intervention.
Singhal 2008 [531]	Retrospective analysis. Prognostic assessment of neurological tools. Not appropriate for question.
Toh 1998 [571]	Inappropriate to question. Study evaluates and validates scoring system for SCI.
Van Middendorp 2009 [583]	Prospective longitudinal cohort study. Not appropriate to question. Prognostic evaluation.
Van Middendorp 2009A [582]	Prospective longitudinal cohort study. Not appropriate to question. Prognostic evaluation.
Wells 1995 [599]	Comparison of diagnostic tool. No evidence within report can be extracted for appropriate analysis.
Wilson 2012 [604]	Systematic review. Prognostic evaluation for predictors of neurological function. Not appropriate to outcome.

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Appendix K: Excluded economic studies

K.1 Diagnostic imaging

Table 15: Studies excluded from the diagnostic imaging economic review

Reference	Reason for exclusion
Brandt 2004 [86]	This study was assessed as partially applicable with very serious limitations. Set in the USA and is a non-comparative costing study.
Blackmore 1999[58]	This study was assessed as partially applicable with very serious limitations. Set in the USA. The HE subgroup considered the effectiveness estimates to be outdated.
Takami 2014[561]	This study was assessed as not applicable with very serious limitations. Study set in the USA. Effectiveness estimates used not relevant.
Kaneriya1998 [314]	This study was assessed as partially applicable with very serious limitations. Study set in the USA. Costing only study and the effectiveness estimates were not relevant.
Grogan 2005[217]	This study was assessed as partially applicable with very serious limitations. Study set in the USA.
Halpern 2010[233]	This study was assessed as partly applicable with very serious limitations. It is set in the USA. Effectiveness data such as sensitivities and complication rates were considered to be underestimated. The perspective adopted was not that of the NHS and omitted to include cost considerations relevant to the health care provider. Certain key assumptions do not adequately reflect the current UK spinal trauma population. The model structure was considered to have some validity and will be considered to be updated with UK NHS relevant cost and effectiveness data.

K.2 Radiation risk

Table 16: Studies excluded from the radiation risk economic review

Reference	Reason for exclusion
Faria 2013[172]	This study was assessed as partially applicable with very serious limitations. It compared a new type of X-ray to a standard X-ray and the population was patients with orthopaedic conditions.
Cipriano 2012[111]	This study was assessed as partially applicable with very serious limitations. The population of this study was patients with Crohn's disease and the risks of cancer were adjusted to that population. Also the radiation dose differed to that for spinal injury scans.

Appendix L:Cost-effectiveness analysis: Diagnosis of traumatic spinal injury

Introduction

A person with a suspected traumatic spinal injury requires diagnostic assessment to rule out or confirm the injury. A large proportion of patients with a suspected spinal injury will not have sustained an injury that requires management and can be safely discharged. Until the patient is cleared of spinal injury, it is likely that spinal protection may remain and the patient will continue to use health resources unnecessarily. Undertaking a full diagnostic work up using expensive imaging modalities on all people suspected of spinal injury is not likely to be cost effective given that a high proportion of patients may be screened out using clinical assessment alone. Further, strategies involving diagnostic modalities such as x-ray and CT expose a large population to the potential risks of radiation exposure.

On the other hand, if a spinal injury is missed in the diagnostic work up, it can have catastrophic consequences in terms of the patient's health and quality of life, as well as substantial financial cost for the NHS in terms of on-going management and potential litigation.

A careful balance needs to be struck between the health and financial cost of more expensive but potentially accurate diagnostic work ups for all patients, and that of missing an injury. Given the high health and cost impact that could result from recommendations regarding a clearance strategy, the GDG considered this topic area a high priority for economic modelling.

Six economic evaluations were identified looking at relevant imaging modalities for diagnosing spinal injury. [58,86,217,233,314,562] However, all the studies were excluded due to limited applicability and methodological limitations. The head injury guideline model looked specifically at clearing the c-spine in a population of head injured patients, and used a model which in the main was based on expert opinion to estimate the likelihood and consequences of indeterminate findings [415]. The clinical question posed in the spinal injury guideline differs from that in the head injury guideline, as the focus is on the imaging modalities themselves, rather than the decision rules which should be followed given an indeterminate finding.

When looking at the whole spine, further evidence was retrieved on the accuracy of diagnostic modalities in identifying bony versus ligaments injury and suggests varied accuracy of X-ray, CT and MRI for bony and ligamentous spinal column injuries. 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. Overall the clinical evidence on diagnostic imaging was considered to be of generally poor quality, with studies being dated and not reflective of current technological advancements. Further, evidence on potential harm of radiation or complication rates from time spent in spinal protection remains absent.

Treatment pathways following a confirmed spinal injury are specific to type of injury and varied. Treatment of spinal injury is outside of the scope of the guideline and would involve tenuous assumptions to incorporate in an economic model. However, the relative difference in the consequences of diagnostic outcomes is recognised to be large. As such, the final conclusions may be less sensitive to the accuracy of the pay-off related to each diagnostic outcome than if the difference in consequences of diagnostic outcomes were small. Therefore, even without detailed modelling of downstream treatment pathways, the GDG felt that modelling could still be useful in reducing uncertainty.

Given the limitations of the available evidence base and the difficulties in weighing up relative health benefits, harms and costs; the modelling activity was based on ensuring robustness of the assumptions, testing best and worst case estimates, and illustrating the potential economic implications that could arise from recommendations regarding different clearance strategies.

Methods

Model overview

A decision tree model was constructed to understand the economic implications and trade-offs given different assumptions regarding the accuracy of a diagnostic modality.

The model evaluates the clearance strategies available if a person is suspected of column injury, which may be a bony or ligaments injury. There is clinical certainty that the optimal strategy to assess a person with suspected spinal cord injury (that is, presenting with neurological signs) is with an MRI image, and this type of injury was not modelled further. The model is only applicable to adults due to the paucity of applicable evidence for children.

The model synthesizes the prevalence of spinal column injury and type of injury (bony or ligaments) with the accuracy of clinical decision rules and diagnostic imaging techniques. Patients directed to further imaging is dependent on the accuracy of the preceding diagnostic tool used. For example, a clinical decision rule may indicate x-ray for only a proportion of patients. Total diagnostic costs for each strategy are calculated according the proportion of patients who have been imaged.

For each strategy the number of patients correctly provided with treatment (true positives (TP)), provided with unnecessary clinical management (False positives (FP)), correctly and safely discharged (true negatives (TN)), and incorrectly left untreated (false negatives (FN)) is determined. Where injury is missed (FN), there is potential for deterioration and possibly conversion to cord injury. Note that the sensitivity of a test influences the number of true positives and false negatives, and the specificity of a test influences the number of true negatives and false positives identified.

Assigned to each outcome is a pay-off in regards to the patient's expected future health (QALY gain) and initial and on-going treatment costs. Further, an additional cost of litigation due to missed injury is tested in a sensitivity analysis. The evidence on radiation risk in this population is absent; however, a sensitivity analysis tests the potential impact of radiation risk using indirect evidence.

The model estimates the number of people with a particular diagnostic outcome (that is, missed injury), the overall cost of the strategy (in regards to diagnosis and treatment) and the potential QALY gain for a given strategy. From this, the net monetary benefit is calculated for thresholds of £20,000 and £30,000.

L.1.1.1 Comparators

Eighteen clearance strategies were identified. In all strategies, treatment was determined by the indication of the last diagnostic test in the sequence (that is, if positive then treat, if negative then discharge with no further treatment). For example, if a clinical decision rule is used to determine whether imaging is necessary, only under the direction of a clinical decision rule is an image undertaken, otherwise the patient is discharged.

A) Image all people with suspected spinal column injury using one modality:

1. X-ray all (X-ray)
2. CT scan all (CT)
3. MRI all (MRI)

B) Image all people with suspected spinal column injury, and selectively further image based on results of first image:

4. X-ray all, if positive then CT scan(X-ray+CT)
5. CT Scan all, if positive then MRI (CT+MRI)
6. MRI all, if positive then CT Scan(MRI+CT)

C) Selectively image people once based on the results of a clinical decision rule **.**

7. If Canadian C-spine Rule is positive, then X-ray (CCR+X-ray).
8. If Canadian C-spine Rule is positive, then CT scan (CCR+CT)
9. If Canadian C-spine Rule is positive, then MRI (CCR+MRI)
10. If Nexus Rule is positive, then X-ray (NEXUS+X-ray)
11. If Nexus Rule is positive, then CT scan (NEXUS+CT)
12. If Nexus Rule is positive, then MRI (NEXUS+MRI)

D) Selectively image people based on the results of a clinical decision rule **, and further image based on the results of the initial image.**

13. If Canadian C-spine Rule is positive, then X-ray. If X-ray is positive then CT scan (CCR+X-ray+CT)
14. If Canadian C-spine Rule is positive, then CT scan. If CT is positive then MRI (CCR+CT+MRI)
15. If Canadian C-spine Rule is positive, then MRI. If MRI is positive then CT scan (CCR+MRI+CT)
16. If Nexus Rule is positive, then X-ray. If X-ray is positive then CT scan (Nexus+X-ray+CT)
17. If Nexus Rule is positive, then CT scan. If CT is positive then MRI (Nexus+CT+MRI)
18. If Nexus C-spine Rule is positive, then MRI. If MRI is positive then CT scan (Nexus+MRI+CT)

The following 3 strategies were excluded as they would be dominated by the above strategies. This is because the initial image following the clinical decision rule would incur cost but would not influence onward management:

- X-ray all, if positive or negative x-ray then CT ;
- If CCR positive then X-ray, if positive or negative X-ray then CT,
- If Nexus positive then X-ray, if positive or negative X-ray then CT.

These strategies are important to note due their use in current practice. X-ray is a commonly used modality due to its low cost and availability. However, it has recognised limitations as a clearance tool for spinal injuries that is, often poor quality images, inadequate exposure and coverage of relevant areas, and impractical positions required for certain views in an injured patient.

In the above mentioned strategies the effect of the X-ray is nullified with the end action based on the finding of CT regardless of what the x-ray showed, meaning these strategies test the accuracy of the CT scan with the added cost of the X-ray. These strategies would be dominated by strategies which were the same minus the use of x-ray and therefore were excluded from further analysis.

L.1.1.2 Population

The population are adults that arrive at ED with suspected (that is, with and without) spinal column injury and have no other trauma related injuries. The model focuses on diagnosis of spinal column injury; however, it does take into account patients who convert to a cord injury as a result of their column injury when assessing outcomes. This model is not applicable to the paediatric population.

L.1.1.3 Time horizon, perspective and discount rate.

The time horizon was modelled in 3 horizons:

1. The first 4 hours in A&E, and subsequent 5 day initial treatment/deterioration window: this time period was sufficient to capture the diagnostic and treatment costs. It is assumed there are no differences in QALYs at this stage;
2. 10 years: this was deemed a conservative time estimate to realise the impact of a spinal cord injury on a patient's quality of life and on costs to the NHS (sensitivity analysis).
3. A lifetime horizon: this is based on an assumed life expectancy following each diagnostic outcome and subsequent treatment (base case)

The model follows an NHS provider perspective in the base case. A wider societal perspective was considered due to the loss of productivity due to time off work and the potential cost due to spinal injury on public bodies other than the NHS (that is, housing). This perspective is not formally explored in this analysis, however the findings of a sensitivity analysis whereby a high litigation cost is added as a penalty for missed injury are thought indicative of a wider perspective.

The model applies a discount rate of 3.5% in the calculation of QALYs associated with each diagnostic outcome in the base case. The model assumes that the majority of NHS costs occur in the acute period, and these have no discounting applied. The long term NHS costs of care associated with cord injury is discounted at a rate of 3.5%

Approach to modelling

The analysis was undertaken using Microsoft Excel 2010. The model comprises of a series of cohort decision-trees. Figure 1 to Figure 4,show the decision trees of the four types of strategies modelled, where the image could be x-ray, CT or MRI dependent on strategy (TP=True Positive; FN = False Negative; FP= False Positive; TN = True Negative)

Figure 1: Decision tree for when strategy involves imaging all people with suspected spinal column injury using one modality

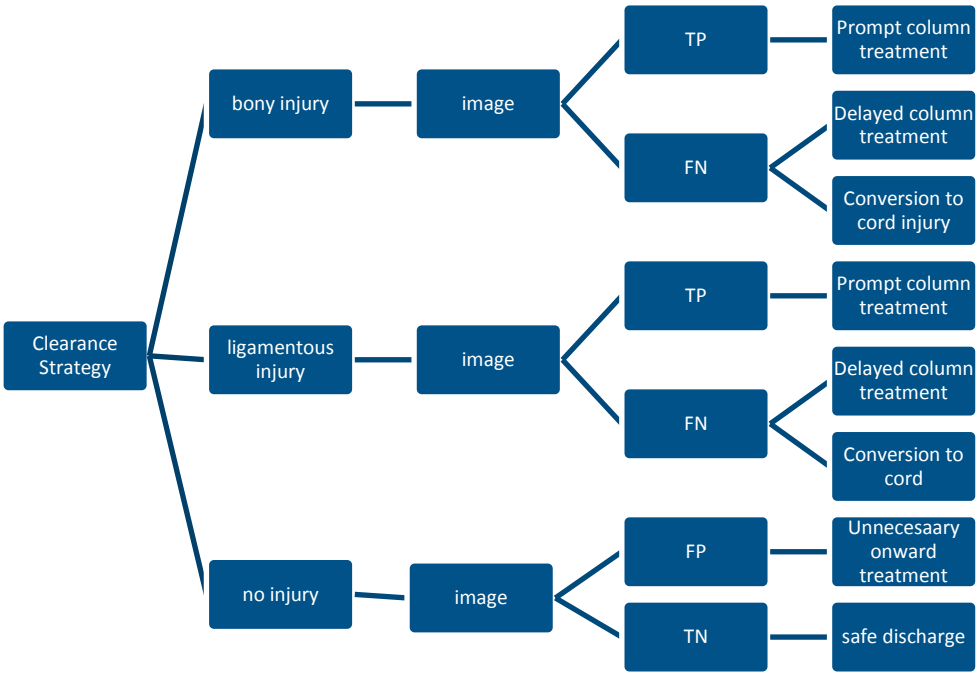


Figure 2: Decision tree for when strategy involves imaging all people with suspected spinal column injury, and selectively further image based on results of first image.

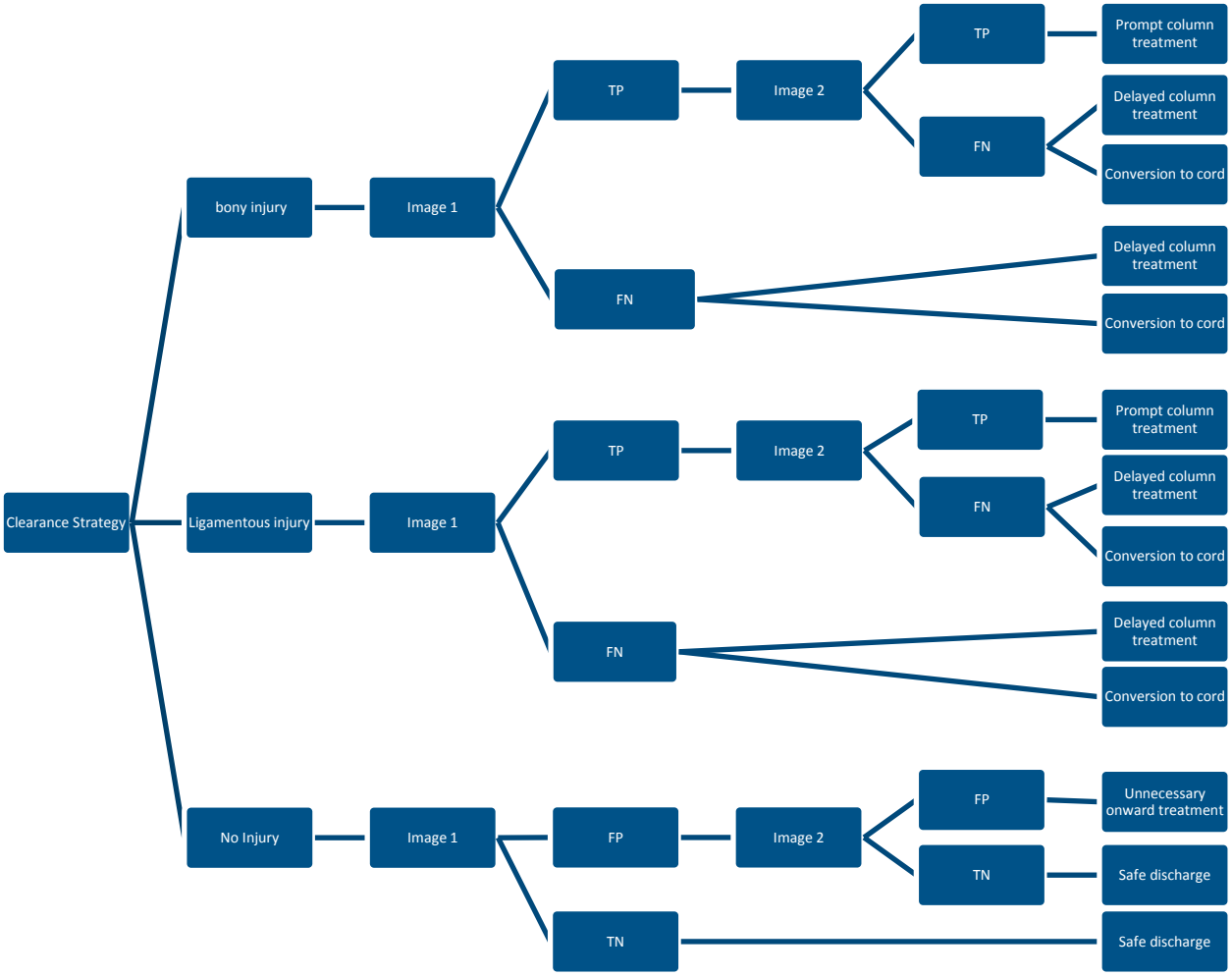


Figure 3: Decision tree for when strategy involves selectively imaging people once based on the results of a clinical decision rule.

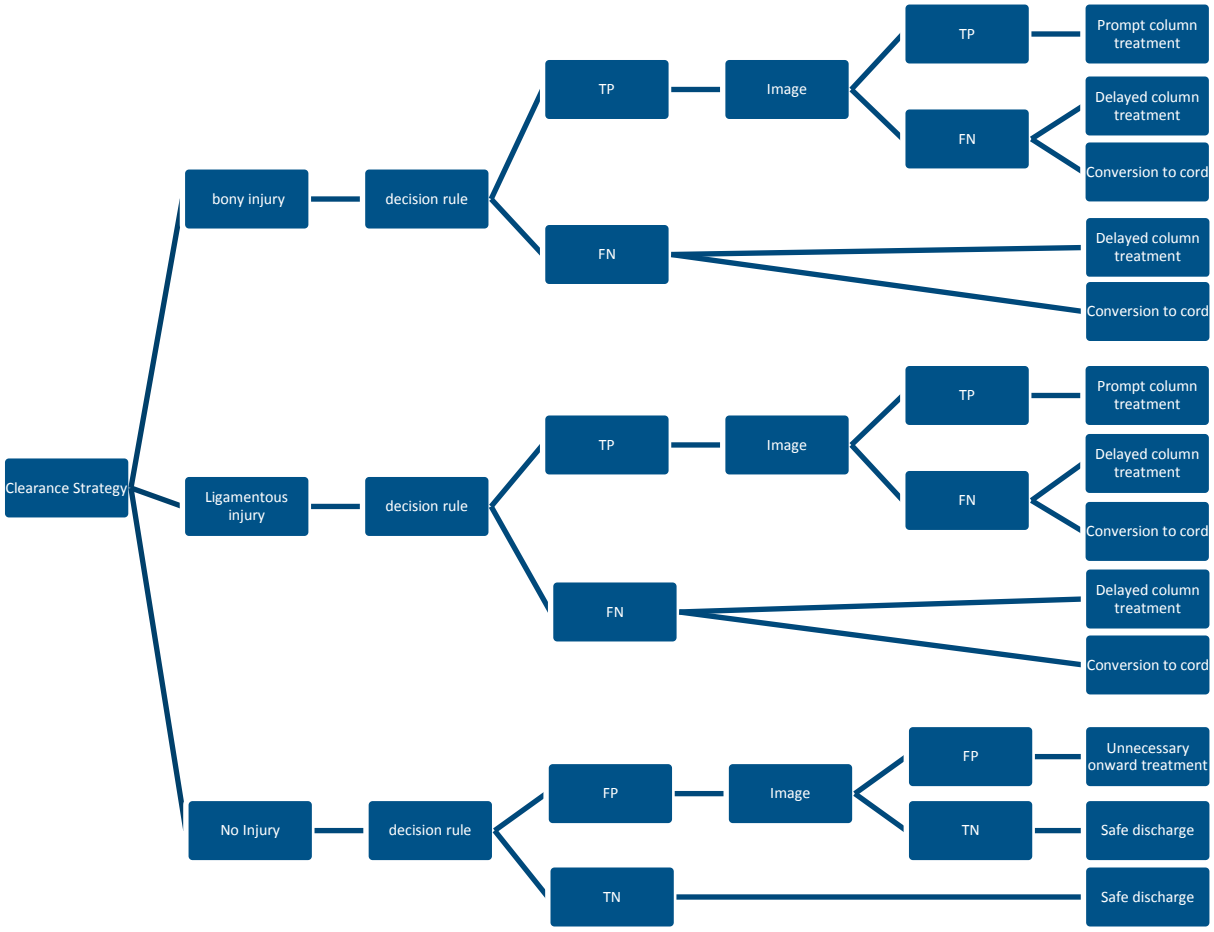
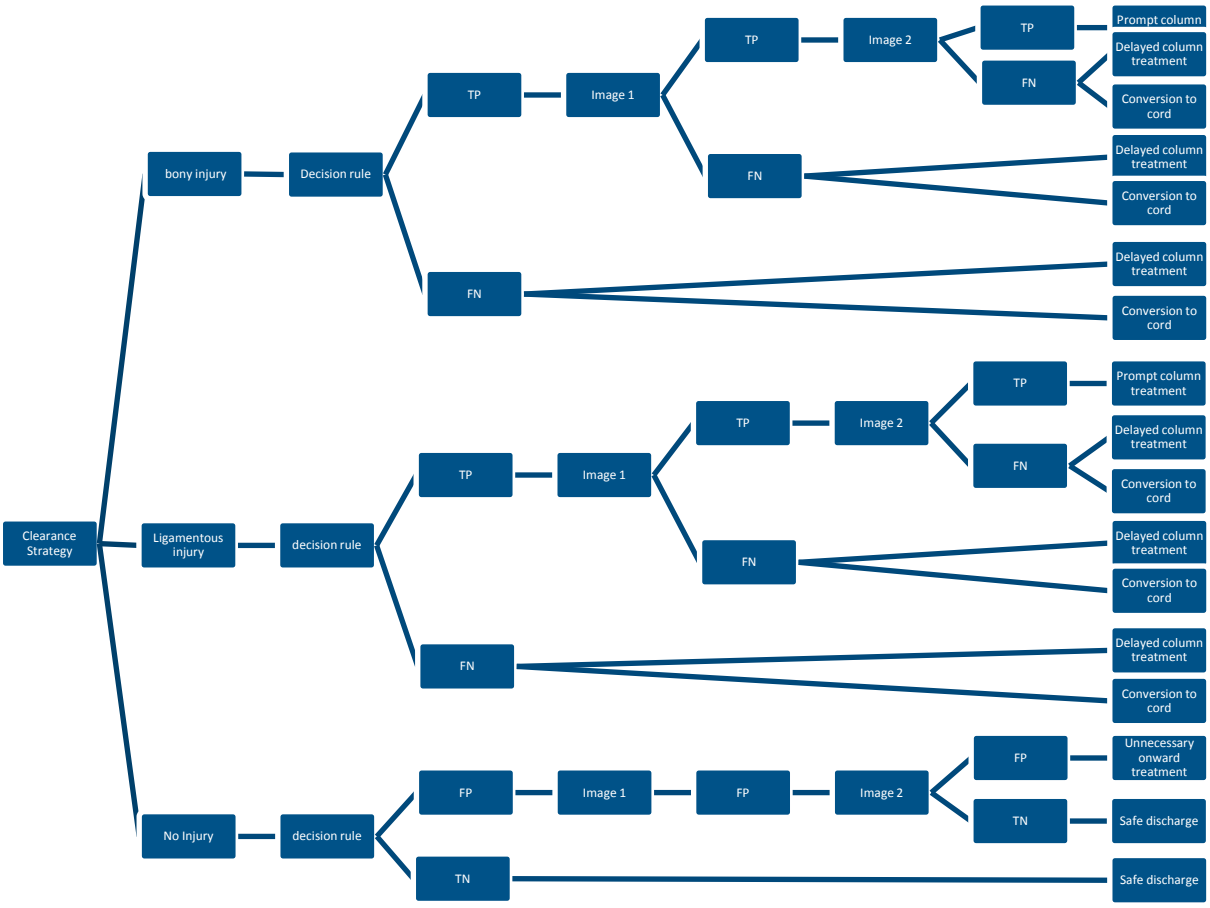


Figure 4: Decision tree for when strategy involves selectively imaging people based on the results of a clinical decision rule, and further image based on the results of the initial image.



L.1.1.4 Diagnostic mark-up

Initial Imaging

The number of patients who received initial imaging (X-ray, CT, or MRI) was different according to the strategy. In blanket strategies, the entire cohort received initial CT / X-ray or MRI imaging. In selective strategies, the number of patients who received an initial imaging was determined by the sensitivity and specificity of the clinical decision rules. No diagnostic imaging is undertaken in patients in whom the clinical decision rule gives a negative result.

Further Imaging

The number of further diagnostic imaging performed is determined by the results from the initial diagnostic imaging technique. Results from a diagnostic imaging technique were categorised as positive (abnormality is present from diagnostic imaging and clinical impression) or negative (diagnostic imaging and clinical impression finds no abnormality). The numbers of positive and negative results were derived from the sensitivity and specificity of diagnostic clearance strategies found in published literature (Table 17).

Patients who did not receive initial imaging and patients with normal (negative) initial imaging results would not be given any further imaging or treatment. Patients with a positive /abnormal initial imaging result could receive further diagnostic imaging. The type of further diagnostic imaging was determined by the strategy.

The cost of diagnostic imaging is the product of the total number of diagnostic images undertaken per strategy and the unit cost of each diagnostic technique.

L.1.1.5 Initial treatment and further management of column injury without cord injury.

The treatment and further management subcategorises patients according to injury characteristics to identify the type of treatment required and apply the correct weighting to costs.

Patients with a spinal column fracture would receive treatment for a fracture. The cost of which was derived from the various categories in the NHS reference costs for 'vertebral column injury' relating to bony and ligamentous injuries. No further treatment costs were assumed if only a column injury was sustained.

L.1.1.6 Missed column injury and conversion to cord injury

A small proportion of people who had undiagnosed spinal column injury at the end of the diagnostic workup will deteriorate and convert to a cord injury. This is assumed to occur within the acute period of 5 days and the probability of conversion is the same regardless of whether the injury was bony or ligamentous in nature. At this point they will return to hospital for acute treatment for a spinal cord injury. After the initial time horizon of 5 days, these patients would also require on-going management and rehabilitation for the remainder of their lifetime.

Those who have missed injury and do not convert to cord injury may still deteriorate slightly and are assumed to return to hospital for treatment, with additional complications resulting on average in another three days length of stay. The model assumes that for people with initially missed injury returning to hospital, another diagnostic workup of these patients is not required on their return, and costs of admission are contained within the treatment cost category for the respective type of injury.

L.1.1.7 Uncertainty

Various deterministic sensitivity analyses were undertaken to test the robustness of model assumptions. In these, one or more inputs were changed and the analysis re-run to evaluate the impact on results and whether conclusions on which intervention should be recommended would change.

L.1.2 Model inputs

L.1.2.1 Summary table of model inputs

Model inputs were based on clinical evidence identified in the systematic review undertaken for the guideline, supplemented by additional data sources as required. Model inputs were validated with clinical members of the GDG. A summary of the model inputs used in the base-case (primary) analysis is provided in the table below. More details about sources, calculations and rationale for selection can be found in the sections following this summary table.

Table 17: Summary of base-case model inputs (¥ = subject to sensitivity analysis)

Input	Data	Source
Epidemiology		
Population size	1000	n/a
Mean age of injury	30	Expert opinion
Prevalence of spinal column injury in A&E population ¥	1%	Expert opinion

Input	Data	Source
Proportion with bony injury	98.5%	Expert opinion
Proportion with ligamentous injury¥	1.5%	Expert opinion
Proportion of missed column Injuries (bony or ligamentous) that convert to cord injury¥	0.5%	Expert opinion
Life expectancy of healthy individual and individual's with previous column injury	80	Informed by ONS, National Life Tables, United Kingdom, 2010-2012 [426]
Life expectancy if cord injury survived	70	Expert opinion supported by Middleton 2012[396]
Performance of decision rule: Canadian C-spine Rule		
sensitivity	100%	Stiell 2003[551]
specificity	45%	Stiell 2003[551]
Performance of decision rule: NEXUS Rule		
sensitivity	99%	Hoffman 2000[263]
specificity	12%	Hoffman 2000[263]
Accuracy of Imaging modality for bony injury¥		
X-ray		
sensitivity	70%	Awan et al.[27]
specificity	84%	Awan et al.[27]
CT scan		
sensitivity	98%	Ptak et al.[464]
specificity	100%	Ptak et al.[464]
MRI		
sensitivity	91%	Silberstein et al.[529]
specificity	96%	Silberstein et al.[529]
Accuracy of Imaging modality for ligamentous injury¥		
X-ray		
sensitivity	0%	Duane et al.[154]
specificity	98%	Duane et al.[154]
CT scan		
sensitivity	27%	Silberstein et al.[529]
specificity	100%	Silberstein et al.[529]
MRI		
sensitivity	93%	Pizones et al.[454]
specificity	100%	Pizones et al.[454]
Cost of Diagnostic Imaging and treatment (£)		
X-ray (2 views)	£59	Calculated from NHS reference cost [141]
CT scan	£92	Calculated from NHS reference cost
MRI	£145	Calculated from NHS reference cost
cost to apply decision rule	£0	Criteria are freely accessible

cost to treat column injury (acute) (True positive)	£2,717	Calculated from NHS reference costs
cost to treat cord injury (acute) (False negative + conversion)	£5,625	Calculated from NHS reference costs
cost to treat missed column injury (acute) (False negative)	£3,561	Calculated from NHS reference costs
cost of treatment after a False positive image (acute)	£281	Calculated from NHS reference costs
cost of living with spinal cord injury¥	£2,500,000	Expert opinion
cost of litigation from missed spinal cord injury ¥	£500,000	Expert opinion
cost of litigation from missed spinal column injury¥	£50,000	Expert opinion
Utility values associated with diagnostic outcome (baseline)		
True Positive	0.77	Cockerill2004. [114]
False Negative-fracture	0.77	Cockerill2004. [114]
False Negative-Cord	0.47	Leduc2002. [354]
False Positive	0.825	KIND 1998. [328]
True Negative	0.825	KIND 1998. [328]
Utility values associated with the long-term health state following a diagnostic outcome		
True Positive (Utility gained 1 year after injury)	0.825	KIND 1998. [328]
False Negative-fracture (Utility gained 2 years after injury)	0.825	KIND 1998[328]
False Negative-Cord¥ (Utility gained 2 years after injury)	0.72	Brasel KJ 1996[87]
False Positive	0.825	KIND 1998. [328]
True Negative	0.825	KIND 1998.[328]

L.1.2.2 Population, prevalence and subgroups

Published evidence sources, including the TARN reports, did not give reliable estimates of prevalence of spinal column injury in our population (that is, within the population presenting at an NHS emergency department (ED). Therefore expert opinion of the GDG was used to provide estimates of prevalence, and the proportion of the spinal injuries which were bony or ligamentous in nature. Of 100,000 trauma patients arriving at A&E, the GDG assumed that 1% of these would have a spinal column injury. The GDG were quite confident that the majority of spinal column injuries were bony in nature. An estimate of 98.5% was used in the model.

L.1.2.3 Effectiveness of intervention: Diagnostic accuracy

The base case analysis accuracy estimates were sourced from specific papers included in the clinical review. There was limited evidence to perform a diagnostic meta-analysis. In order to preserve correlation between sensitivity and specificity, the finding from the best available study was used to parameterise. For this task, each study was assessed taking into account GRADE quality rating (in particular looking at sample size and methodology used), applicability of population/injury type, and credibility to today's technology.

L.1.2.4 Resource use and costs

NHS reference costs[141] were used to identify cost estimates for diagnostic imaging and acute management.

An A&E attendance was considered a prerequisite for every person in the model and would not contribute to incremental cost. This aspect is not included.

Diagnostic Imaging:

The GDG judged that an x-ray investigation would require 2 plain film X-rays, and this was costed using the code DAPF which represents Direct Access Plain Film.

The cost of CT and MRI diagnostic imaging techniques were calculated by taking a weighted average of total activities and cost in outpatient, direct access and other settings. The GDG judged that a CT or MRI scan requires a scan of one to three areas considering patients will need their head and cervical spine and thoracic and or lumbar areas examined. Costs relating to more than three areas or CT with contrast were excluded. HRG codes RA08, RA011, RA014 and RA050 were used to cost CT, and HRG codes RA01 and RA04 were used to cost MRI.

Cost of acute treatment:

Costs for treatment were derived from NHS Reference Costs, HC codes (Spinal Surgery and Disorders Chapter), and represent the weighted average cost inclusive of complications or comorbidities, non-elective short or long stay and long stay excess bed days. Sample size from inspection appeared reasonable.

The cost to treat a spinal column injury (TP) was derived from codes relating to “Vertebral Column Injury without Procedure” (HRG code HC20). The costs relating to extradural spine injury were not included because these injuries are very rare, and the clinical experts felt just the cost of vertebral column injury would adequately capture the costs of treating a spinal column injury.

Some patients with a spinal column injury and in need of treatment are inappropriately discharged and experience deterioration (FN). It is assumed that these patients will again present to the hospital, receive treatment and as a result of the deterioration require a stay of 3 excess bed days. The cost to treat a missed spinal column injury was therefore calculated by adding the cost of 3 excess bed days to the cost of treatment for a spinal column injury. The weighted cost of a single excess bed day was calculated using HRG data for excess bed days specific to vertebral column injury (HRG code HC20).

A proportion of patients will convert to cord injury if their column injury is missed. The acute care costs of cord injury were derived from NHS reference codes HC21 and HC28 which pertain to “Spinal Cord Injury without Procedure” and “Spinal Cord Conditions”

In the case of patients who are diagnosed as having an abnormality when in fact they do not (FP), it was assumed that these patients would require an overnight stay and then be cleared by a more senior member of staff the following day. The cost of this stay was one excess bed day related to “Vertebral Column Injury without Procedure” (HRG code HC20).

A patient who is safely discharged due to no abnormality suspected (TN) does not require treatment and accrues the cost of the relevant imaging modality used (where applicable, as some may be discharged post clinical decision rule without any cost incurred). Note that no cost has been attached to the decision rule in terms of staff time because this will be done during an assessment of a patient that would take place for all patients anyway, regardless of whether a decision rule was used or not. Therefore as patients in all strategies will receive a primary assessment to decide onward management, the cost of employing the decision rule itself is negligible.

Lifetime cost of cord injury:

The lifetime cost to the NHS to treat a cord injury was considered very wide ranging due to the differing types of injuries and the various complications that can occur. The GDG estimated onward care would be in the region of £2,500,000. This parameter was tested in a sensitivity analysis.

Litigation of missed injuries that convert to a cord injury are included in a sensitivity analysis.

To note, no on-going care costs were attributed to spinal column injury. This is under the assumption that predominantly column fractures do not require substantial on-going care and the long term cost to the NHS is minimal. Although potential productivity costs may arise for the patient and society, these remain outside the scope of the perspective of this guideline. However litigation costs are included in a sensitivity analysis as these are felt to be common for missed injuries and capture that the costs mostly involve loss of earnings, rather than costs directly related to the NHS.

L.1.2.5 Quality of life, life expectancy and QALY calculation

A QALY is the product of survival and quality of life (utilities), meaning each year of survival is multiplied by a respective quality of life weighting. Quality of life and life expectancy was assigned to people in the model according to their injury status and whether their treatment was delayed.

Life expectancy

People who had no injury and column injury (which did not convert to cord) were assigned a life expectancy of 80 years (which was supported by data from the ONS life tables 2010-2012)[426]

Expert opinion, supported by findings from Middleton et al. 2012[396], estimated that someone with cord injury could expect to live on average 40 years post injury if the first year was survived and assuming injury occurred at age 30 years. The time horizon of 10 years is given as a sensitivity analysis.

Quality of life

A systematic search, incorporated as part of the literature economic search in the guideline, was undertaken to identify relevant quality of life estimates. No relevant studies were identified that was specific to the population examined. Therefore utilities from identified proxy conditions as used to calculate QALYS. In the base case, it was assumed that no utility loss would be observed due to unnecessary treatment or imaging. The risk of radiation is explored in a sensitivity analysis. A QALY is the product of survival and quality of life (utilities).

People without injury

The full health state utility score used was 0.825. It is the UK population average utility score using EQ5D reported by Kind 1998[328] (recommended for baseline utilities in NICE guidance). It is assumed that these groups remain at the national average for the time horizon.

People with spinal column injury

Adverse events associated with a FN result were a fracture or a conversion to a cord injury. These events were expected to be the key drivers of health effects as well as costs. To model these health implications we searched for comparative utility scores of these adverse events. No data was found in the acute period.

Utility scores for vertebral fractures were reported in Cockerill2004[114]. This study was based on men and women with osteoporosis aged 50 years or older from 12 European centres including the UK.

This was part of the European Vertebral Osteoporosis Study and EQ5D utility data was reported. These utility scores reported for vertebral fractures are applied to patients with a missed vertebral fracture (FN) as well as correctly diagnosed vertebral fracture (TP). However, to differentiate the effect of being correctly diagnosed, it is assumed that those correctly diagnosed (TP) regain full health 1 year after injury, whereas those incorrectly diagnosed (FN) regain full health 2 years after injury.

People with cord injury

Leduc2002[354] reported SF-36 scores from 587 spinal injured patients in the Quebec Paraplegic Association databank. The patient population in this study was 80% male, and the age ranged from 30 to >60 years old. The injury profile of the patients was 67% Paraplegia, 33% Tetraplegia and the score was taken at a minimum of at least 2 years post injury. The SF-36 scores were mapped to EQ-5D scores (please see below for mapping method). A utility score of 0.47 was applied to FN patients who converted to a cord injury post trauma. It was assumed that patients remain at this score for 2 years and then show some improvement. For the long term quality of life once the injury has stabilised, an estimate of 0.72 is applied. This utility score was reported in BRASEL1996[87] in a cost effective analysis on blunt thoracic aortic trauma. The score was based on a visual analogue scale and is a utility score for paraplegia.

Mapping SF-36 to EQ-5D using Rowen et al 2009

To estimate utilities for patients with spinal column and spinal cord injury, the SF-36 data from Leduc [354] was mapped onto the EQ-5D index using a mapping function from Rowen et al 2009[488]. The EQ-5D is the preferred measure of health-related quality of life for NICE, and where this measure is not used, mapped data is considered preferable if an appropriate validated mapping function that provides a reliable prediction exists.

Rowen et al [488] compared five different mapping functions: three different generalised least squares (GLS) models (one linear, one with additional squared terms and one with additional square terms and interaction terms), a Tobit model and a censored least absolute deviations (CLAD) model. The Tobit model was considered as it takes into account the bounded nature of the EQ-5D, which could lead to biases in the GLS models. However, the Tobit model will also produce biased results in the presence of heteroscedasticity and the absence of normality. For this reason, the CLAD model was also considered.

The model chosen to map the data from Leduc and was the GLS model with square terms and interaction terms. This model produced the most accurate prediction of all the models compared in Rowen et al as well as existing mapping functions by Franks et al and Gray et al. This is indicated by a mean absolute error for the full index of 0.127 and a mean squared error for the full index of 0.030. The table 1 shows the mean error, the mean absolute error and the mean squared error for all models by Rowen et al as well as the studies by Franks et al and Gray et al.

The mapping function for the GLS model is given by,

$$\gamma_i = \alpha + \boldsymbol{\beta x_{ij}} + \boldsymbol{\theta r_{ij}} + \boldsymbol{\delta z_{ij}} + \varepsilon_{ij}$$

Where $i = 1, 2 \ldots, n$ represents individual respondents and $j = 1, 2, \ldots, m$ represents the 8 different dimensions of the SF-36. The dependent variable, γ, represents the EQ-5D utility score, $\boldsymbol{x}$ represents the vector of SF-36 dimensions, $\boldsymbol{r}$, represents the vector of squared terms, $\boldsymbol{z}$ represents the vector of interaction terms and ε_{ij} represents the error term. The coefficients $\alpha, \boldsymbol{\beta}, \boldsymbol{\theta}$ and $\boldsymbol{\delta}$, computed by Rowen et al were applied to the data from Leduc and to estimate an EQ-5D utility.

Table 18: Mean error, mean absolute error and mean squared error of mapping models

Full EQ-5D index	GLS 1	GLS 2	GLS 3	Tobit	CLAD	Franks et al	Gray et al
ME	-0.001	0.000	0.000	0.041	-0.031	0.101	0.059
MAE	0.138	0.129	0.127	0.142	0.133	0.178	0.186
MSE	0.033	0.030	0.030	0.033	0.033	0.048	0.076

The coefficients of the mapping function that was used (GLS model with square terms and interaction terms) can be found below in Table 19.

Table 19: Coefficients of mapping function [488]

	Coefficients	Coefficients for dimension squared	Coefficients for interactions
Constant	-0.256	-	-
PF	0.559	-0.227	-
RP	-0.146	0.001	-
BP	0.715	-0.33	-
GH	0.407	0.032	-
VIT	0.017	0.012	-
SF	0.293	-0.163	-
RE	0.067	0.034	-
MH	0.483	-0.242	-
PF x RP	-	-	0.022
PF x BP	-	-	-0.032
PF x GH	-	-	0.073
PF x VIT	-	-	-0.132
PF x SF	-	-	-0.023
PF x RE	-	-	0.047
PF x MH	-	-	-0.014
RP x BP	-	-	0.019
RP x GH	-	-	0.068
RP x VIT	-	-	0.05
RP x SF	-	-	0.067
RP x RE	-	-	-0.012
RP x MH	-	-	0.022
BP x GH	-	-	-0.217
BP x VIT	-	-	-0.002
BP x SF	-	-	0.055
BP x RE	-	-	-0.038
BP x MH	-	-	0.131
GH x VIT	-	-	-0.066
GH x SF	-	-	-0.157
GH x RE	-	-	-0.033

	Coefficients	Coefficients for dimension squared	Coefficients for interactions
GH x MH	-	-	-0.084
VIT x SF	-	-	0.143
VIT x RE	-	-	-0.02
VIT x MH	-	-	0.023
SF x RE	-	-	-0.023
SF x MH	-	-	-0.065
RE x MH	-	-	-0.048

Abbreviations: PF, physical functioning; RP, physical role functioning; BP, bodily pain; GH, general health; VIT, vitality; SF, social role functioning; RE, emotional role functioning; MH, mental health.

L.1.2.6 Discounting

Both long-term cord injury treatment costs and QALYs accrued in the model were discounted to reflect time preference. For example, if a year had passed between one event occurring and the next, the cost and QALY accrued for that one time period would be calculated and the discount function applied would be appropriate to the time which had elapsed since the patient had entered the model and when the update had occurred. Further if a patient experienced a one off cost at a particular time in the model, due to an event or clinical intervention, this cost was discounted using the formula given.

The total discounted QALYs were the sum of the discounted QALYs of each discrete time period. The total discounted costs were the sum of discounted costs accrued over each discrete time period, as well as the sum of discounted one off costs associated with events or interventions.

$$\text{Discounted total} = \frac{\text{Total}}{(1+r)^n}$$

- Where:
- r = discount rate per annum
- n = time (years),

Sensitivity analyses

A number of deterministic sensitivity analyses (DSAs) were undertaken to investigate inputs of particular uncertainty. The majority of parameters were subject to threshold analysis; however the parameters outlined below were of particular interest to test.

L.1.2.7 Prevalence of spinal injury

The prevalence of spinal column injury within the population suspected of injury that present in the NHS ED is unknown. Further, there are particular subgroups where the prevalence is expected to be very low; meaning that positive predictive value of the diagnostic work up will also be very low. This parameter was varied to find the threshold at which the conclusion may change.

L.1.2.8 The accuracy estimates

Examination of the clinical review papers provided a wide range of sensitivities and specificities suitable to use for sensitivity analysis. The base case used the estimates from the sources which were seen as the highest quality of evidence (by developers and Grade). In sensitivity analysis, the highest and lowest retrieved estimates of sensitivity and specificity were used to test robustness of the model. The median accuracy estimates was also tested. Further, estimates used in the Head Injury Guideline were used for information and cross comparison of results.

Table 20: Sensitivity analysis accuracy estimates of the related evidence review {Chapter 10 of full guideline}

Input	Highest estimates	Lowest estimates	Median estimates	HI Injury Model and Halpern 2010[233]
Performance of decision rule: Canadian C-spine Rule				
Sensitivity	100%	100%	100%	100%
Specificity	45%	1%	38%	43%
Performance of decision rule: NEXUS Rule				
Sensitivity	100%	81%	91%	91%
Specificity	46%	12%	24%	37%
Accuracy of Imaging modality for bony injury				
X-ray				
Sensitivity	100%	0%	61%	57%
Specificity	100%	55%	75%	100%
CT scan				
Sensitivity	100%	0%	100%	83%
Specificity	100%	88%	98%	100%
MRI				
Sensitivity	100%	12%	79%	87%
Specificity	100%	96%	99%	100%
Accuracy of Imaging modality for ligamentous injury				
X-ray				
Sensitivity	100%	0%	61%	57%
Specificity	100%	55%	75%	100%
CT scan				
Sensitivity	100%	0%	27%	83%
Specificity	100%	97%	98%	100%
MRI				
Sensitivity	100%	92%	97%	87%
Specificity	100%	52%	100%	100%

The accuracy of the decision rules (CCR and NEXUS) in triaging patients to imaging applies to both bony and ligamentous injuries. The reason being that it is not possible to distinguish between a bony or ligamentous injury at the decision rule stage.

L.1.2.9 The conversion rate to cord injury

The conversion rate from a ligamentous spinal column injury to a cord injury was varied to assess the impact of this estimate on the result. In the base case the conversion rate is the same for both bony and ligamentous injury. Ligamentous injuries are more unstable and this may result in more cord injuries. We did not have the evidence to support this therefore the same conversion rate was assumed for both bony and ligamentous injuries. Due to the QALY loss and high costs of sustaining a cord injury it was important to explore the effect of varying this assumed rate.

L.1.2.10 The utility associated with long term cord injury

Blackmore et al. (1999)[58] reports on a cost effective analysis set in the USA that compared CT scan to X-ray to clear the spine. This analysis uses a utility of 0.516 (as opposed to the base case value of 0.47) for spinal cord injury. This utility was estimated using the Health utilities Index Mark 2 and was

elicited from 3 physiatrists with expertise in care of spinal cord injured patients. A sensitivity analysis was conducted to test the impact of this lower estimated quality of life.

L.1.2.11 On-going treatment costs for cord injury

The lifetime cost to treat a cord injury was considered wide ranging due to the differing types of injuries and the various complications that can occur.

As an additional analysis, a one-off fixed financial penalty was attached to a false negative finding which subsequently caused a cord injury. This may represent a litigation cost or a cost to society. In the first instance a cost of £500,000 was associated to each false negative finding which subsequently caused a cord injury, and in the second a further fixed penalty of £50,000 was also additionally associated with a missed column injury (despite not developing into a cord injury).

To test the impact of both on-going management and litigation costs of cord injury, the onward cost associated with this injury was decreased in increments from £2500000 to £0.

L.1.2.12 Radiation exposure

Faria 2013[172] reports on an economic study comparing a new type of X-ray to a standard X-ray and the population was patients with orthopaedic conditions. This study was assessed as partially applicable with very serious limitations, and was not included within the guideline. However, it provides a reference for the total lifetime risk of cancer, as a function of age at exposure and sex, for various different X-ray examinations and CT scans. These risks are very low. For example, in a population of a million females aged up to 9 years, who receive a thoracic spinal X-ray, it is expected that 65 of them will develop cancer at some point in their life, based on these data. For a CT scan of the chest, this value is expected to be 1100 for the same population.

This paper also presents the costs and loss in QALYs associated with various cancers. The cost of lung cancer treatment, with a diagnosis at the age of 72, is given as £22,712 and the QALY loss as 6.8011. Lung cancer had the highest cost and highest QALY loss of the cancers presented in this study.

If a population approach is taken (whereby the average cost and QALY gain is calculated across a population undertaking a procedure) the expected cost for a 9 year old girl who has a thoracic spinal X-ray and develops cancer is therefore less than £1.48. The expected QALY loss is less than 0.0004.

The expected cost for a 9 year old girl who has a CT scan of the chest is therefore less than £24.98. The expected QALY loss is less than 0.0075.

To assess the potential impact of radiation exposure on the results we use the QALY loss and financial cost above as a penalty for each X-ray or CT undertaken in the model. To reflect time preference we discounted the cost and QALY loss assuming that both occur at 72 years (that is, 42 years post injury). As part of this sensitivity analysis we vary the risk of cancer due to exposure to find the threshold at which the conclusions may change.

L.1.2.13 A scenario to test the strategies for young people, given certain assumptions.

Young adults were thought to be less likely than more skeletally mature adults to fracture their spine, and more likely than mature adults to sustain ligamentous damage (which is more likely to be identified by MRI than CT). Young people also engage in activities whereby, in the absence of major trauma, a bony fracture of the spine is an unlikely outcome (for example, rugby player who has a neck injury during a game is a typical reason to suspect spinal injury in a younger cohort).

There was concern that young people who frequently engage in activities with the potential to injure the spine may have repeated dose of radiation if a recommendation was in favour of CT (which is less likely to detect the most common type of injury within this population). Unfortunately no evidence has stratified by age to inform whether these concerns are valid.

Analyses were undertaken whereby the overall prevalence of spinal column injury and the ratio of ligaments versus bony fracture was examined to explore the threshold at which the conclusions of the analysis would change with and without taking the radiation risk into account.

L.1.2.14 Time horizon

The estimates of survival post injury were uncertain. For this reason we vary the time horizon throughout which survival is assumed. On-going treatment costs were applied on an annual basis.

Outcomes

Estimation of cost effectiveness

The widely used cost-effectiveness metric is the incremental cost-effectiveness ratio (ICER). This is calculated by dividing the difference in costs associated with two alternatives by the difference in QALYs. The decision rule then applied is that if the ICER falls below a given cost per QALY threshold the result is considered to be cost effective. If both costs are lower and QALYs are higher the option is said to dominate and an ICER is not calculated.

$$ICER = \frac{Costs(B) - Costs(A)}{QALYs(B) - QALYs(A)}$$ Where: Costs (X)/QALYs (X) = total costs/QALYs for option X	• Cost-effective if: ICER < Threshold

When there are more than two comparators, as in this analysis, options must be ranked in order of increasing cost then options ruled out by dominance or extended dominance before calculating ICERs excluding these options. An option is said to be dominated, and ruled out, if another intervention is less costly and more effective. An option is said to be extendedly dominated if a combination of two other options would prove to be less costly and more effective.

It is also possible, for a particular cost-effectiveness threshold, to re-express cost-effectiveness results in term of net monetary benefit (NMB). This is calculated by multiplying the total QALYs for a comparator by the threshold cost per QALY value (for example, £20,000) and then subtracting the total costs (formula below). The decision rule then applied is that the comparator with the highest NMB is the most cost-effective option at the specified threshold. That is the option that provides the highest number of QALYs at an acceptable cost.

$$Net\ Benefit(X) = \left(QALYs\ (X) \times \lambda\right) - Costs\ (X)$$ *Where: Costs (X)/QALYs (X) = total costs/QALYs for option X; λ = threshold*	• Cost-effective if: highest net benefit

Both methods of determining cost effectiveness will identify exactly the same optimal strategy. For ease of computation NMB is used in this analysis to identify the optimal strategy.

L.1.2.15 Interpreting Results

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

- The intervention dominated other relevant strategies (that is, it was both less costly in terms of resource use and more clinically effective compared with all the other relevant alternative strategies), or

- The intervention costs less than £20,000 per quality-adjusted life-year (QALY) gained compared with the next best strategy.
- As we have several interventions, we use the NMB to rank the strategies on the basis of their relative cost-effectiveness. The highest NMB identifies the optimal strategy at a willingness to pay of £20,000 per QALY gained.

L.1.3 Model validation

The model was developed in consultation with the GDG; model structure, inputs and results were presented to and discussed with the GDG for clinical validation and interpretation.

The model was systematically checked by the health economist undertaking the analysis; this included inputting null and extreme values and checking that results were plausible given inputs. The model was peer reviewed by a second experienced health economist from the NCGC; this included systematic checking of many of the model calculations.

L.2 Results

L.2.1 Base case

The below table gives the results for the base case analysis. In section L.3 we also give the breakdown of the results for the base case presented by:

1. Number of images taken and cost of imaging strategy,
2. Diagnostic outcome, number expected to convert to cord injury and proportion of correct diagnoses.
3. The expected number of QALYs gained over a lifetime
4. The expected cost of treatment given the proportion of each diagnostic outcome for each strategy
5. The cost of each strategy taking into account diagnostic workup and acute treatment costs.
6. The cost of each strategy taking into account diagnostic workup, acute treatment costs, and on-going care costs for cord injury over a lifetime.
7. The net benefit of each strategy over a lifetime at £20,000 (using results of 3 and 6 above).
8. Expected QALY gain and the cost of each strategy taking into account diagnostic workup, acute treatment costs, and on-going care costs for cord injury over a fixed time horizon of 10 years.
9. Expected lifetime QALY gain and the lifetime cost of each strategy taking into account diagnostic workup, treatment costs, ongoing care costs; as well as, the litigation costs of missed injury.
10. Expected lifetime QALY gain and the lifetime cost of each strategy taking into account diagnostic workup, treatment costs, on-going care costs; as well as, the QALY loss and cost of radiation risk

Each strategy is also ranked from most optimal strategy (1) to least optimal (18) according to a respective outcome. As conclusions did not change when the threshold was increased to £30,000, results are not re-presented here.

Table 21: Summary results for the base case (Results expressed per person, taking a lifetime horizon where management of cord injury is taken into account)

Strategy	Total cost (£) (discounted)	Total QALY gain (discounted)	Net Monetary Benefit (£20K) - discounted	Rank
1. X-ray	160	20.85176	416,875	14
2. CT scan	122	20.85198	416,918	9
3. MRI	190	20.85193	416,849	18
4. X-ray+CT	128	20.85175	416,907	12
5. CT + MRI	130	20.85191	416,908	11
6. MRI + CT	186	20.85191	416,853	17
7. CCR+X-ray	111	20.85176	416,924	5
8. CCR+CT	81	20.85198	416,959	1
9. CCR+MRI	121	20.85193	416,918	8
10. NEXUS+X-ray	147	20.85175	416,888	13
11. NEXUS+CT	112	20.85197	416,928	4
12. NEXUS+MRI	172	20.85193	416,866	16
13. CCR+X-ray+CT	95	20.85175	416,940	3
14. CCR+CT+MRI	89	20.85191	416,949	2
15. CCR+MRI+CT	119	20.85191	416,919	6
16. NEXUS+X-ray+CT	120	20.85174	416,915	10
17. NEXUS+CT+MRI	120	20.85190	416,918	7
18. NEXUS+MRI+CT	169	20.85190	416,869	15

The results demonstrate that the strategy of the Canadian C-spine Rule followed by CT is ranked optimal for each outcome assessed in the base case, including monetary net benefit at £20,000 (which demonstrates its cost-effectiveness in comparison to alternatives). Indeed, this strategy dominated all others being the least costly and most effective over the lifetime horizon used in the base case. To note that the incremental QALY and net monetary benefit gain between strategies is generally small. In the base case, strategies involving x-ray generally ranked poorly despite having the lowest unit cost, having the lowest number of correct diagnoses.

Sensitivity Analysis

The Canadian c-spine rule followed by X-ray remained the most cost effective option for the majority of outcomes, generally regardless of discounting or time horizon. CCR + MRI was the optimal strategy when radiation exposure was taken into account (without discounting).

Please see results tables in section L.3 for results of these scenario analyses.

In addition to each specified analysis (detailed below), we undertook one way sensitivity analysis whereby the value of one parameter was varied whilst keeping the value of all other parameters constant in line with base case values. This found the threshold at which the conclusion (according to discounted net benefit at 20K) may change. In most cases, the threshold at which conclusions changed occurred at a value outside the range that the GDG felt to be plausible. Please see results tables in section L.3 for the full results of the threshold analysis.

L.2.1.1 Prevalence of spinal injury

The threshold analysis demonstrated that if the true prevalence of spinal injury is suspected to be less than 1% of all suspected injuries, then it may be more optimal to undertake CCR+X-ray+CT rather than CCR+CT. If the proportion of bony injuries in this population is less than 38%, and the number of ligamentous injuries is higher than 62%, then it may be preferable to undertake MRI rather than CT following the Canadian C- Spine clinical decision rule.

L.2.1.2 The accuracy estimates

When the lowest accuracy estimates from the clinical review were explored in combination, the nexus rule to indicate CT was found to be the optimal strategy. Using highest accuracy estimates (including that for x-ray) from the clinical review were explored in combination, the nexus rule followed by x-ray was found to be the optimal strategy. When using the median review accuracy estimates, the conclusions remained as per the base case, with CCR+CT being the most optimal strategy. When using estimates from the Halpern 2010 study [233] and head injury model[415] CCR+X-ray was the optimal strategy. A summary of results for the various accuracy analyses conducted are in section L.3.

L.2.1.3 The conversion rate to cord injury

If the probability that a column injury will convert to a cord injury, if a bony injury is missed, is higher than 0.2%, then CCR+CT is optimal instead of CCR+X-ray+CT.

If the probability that a column injury will convert to a cord injury, should ligamentous injury be missed, is higher than 28.4%, then the optimal strategy could be to undertake the c-spine rule to indicate MRI rather than to indicate CT. This threshold is substantially higher than the base case estimate of 1.5% and it is unlikely that conclusions are sensitive to this parameter within plausible ranges.

L.2.1.4 On-going treatment costs for cord injury

The one way deterministic threshold analysis showed that findings were sensitive to the on-going treatment costs of cord injury. The range of lifetime cost which could be associated with cord injury was varied from £0 to £10,000,000 in this analysis. When the on-going treatment costs for cord injury were above £1,000,000, the optimal strategy changed from CCR+X-ray+CT to CCR+CT. Therefore if the base case estimate of £2,500,000 is a significant overestimate, then the optimal strategy would be CCR to indicate x-ray to then indicate CT. It was the opinion of the GDG that this was an important threshold analysis as the base case estimate was particularly conservative as this can vary considerably depending on whether patients are tetraplegics or paraplegics, as the most severe of tetraplegics classify as needing 'continuing care', whereas most paraplegics or tetraplegics are likely to have lifetime care costing less than £1,000,000, if we are referring only to NHS care. However as we are using an average on-going cost, over £1,000,000 is likely to be a plausible estimate.

L.2.1.5 The utility associated with long term cord injury

Using the Canadian C-Spine rule to indicate CT remained the optimal strategy when the lower utility of 0.516 was applied to measure the long term quality of life for a cord injured patient (as cited by Blackmore et al 1999). The one way deterministic threshold analysis indicated that results were not sensitive to this parameter.

L.2.1.6 Radiation exposure

The base case analysis did not take into account radiation exposure in the pay-offs assigned to long term outcomes as no direct data was available to inform this parameter. In an exploratory analysis, a QALY loss and cost for radiation exposure to the chest was incorporated into the payoffs with an expected age of onset of cancer estimated at 72.

When discounting was applied in this exploratory analysis, using the base case estimates, CCR+CT was still the optimal strategy, however changes in several parameters led to the conclusion that CCR+X-ray+CT may be optimal when taking radiation risk and discounting into account. CCR+X-ray+CT became optimal when the radiation risk of CT increased from 0.001150 to 0.00120, when the lifetime cost of cancer increased from £35000 to £35100, and if the QALY loss associated with cancer increased from 7.4 to 7.5. CCR+X-ray+CT was also indicated if the average age of onset of radiation induced cancer decreased below the age of 69 or if the prevalence of spinal column injury was under 0.01.

Removing time preference (that is, discounting) changed the modality of choice after the Canadian c-Spine rule to MRI instead of CT. Without discounting, this finding was sensitive to the proportion of bony versus ligamentous injury within the population as CCR + MRI is optimal if the proportion of spinal injuries which are bony was below 38%. It was also sensitive to the overall prevalence of spinal column injury within the population. If the prevalence increased above 0.08, then the optimal strategy may again be use of the Canadian C-Spine rule to indicate CT.

L.2.1.7 A scenario to test the strategies for young people, given certain assumptions.

Analyses were undertaken whereby the overall prevalence of spinal column injury and the ratio of ligamentous versus bony fracture was examined to explore the threshold at which the conclusions of the analysis would change with and without taking the radiation risk into account.

Regardless of whether radiation risk was taken into account, if the prevalence of column injuries was below 0.01, then the use of the Canadian C-spine rule to indicate x-ray, which in turn would indicate the need for CT could be optimal.

If radiation risk is not taken into account, Canadian C-Spine rule to indicate CT (as opposed to MRI) is optimal so long as at least 39% of column injuries are bony injuries. That is to say even with a proportion of 61% or less ligamentous injury within the tested population, CT is still preferred over MRI.

However if radiation risk is taken into account, Canadian C-Spine rule to indicate CT (as opposed to MRI) is optimal so long as at least 73% of column injuries are bony injuries. That is to say, if you suspect the radiation risk of CT as outlined in this sensitivity analysis and your suspicion is that around a quarter or more of injuries are likely to be ligamentous in your tested population, then MRI would be preferable over CT if imaging is indicated by the decision rule. This shows that when the radiation risk is incorporated, the threshold of the proportion of ligamentous injuries suspected is lower for MRI to be optimal (around 27% or more versus 61% or more – radiation included and no radiation included respectively (both discounted)).

L.2.1.8 Time horizon

The conclusions changed from CCR+X-ray+CT to CCR+CT when the time horizon extended from 3 to 4 years. When using a 10 year time horizon (either discounted or undiscounted), the optimal outcome was CCR+CT.

Findings of the threshold analysis

The below outlines which parameters were sensitive when varied, with all else being held at base-case values. In most cases, the value at which the conclusion changed was deemed outside of the range that the developers deemed reasonable to assume, if all else was held constant. The exception to this was when developers felt most uncertain regarding the potential radiation risk (especially in consideration of young people). The strategy of undertaking CCR+X-ray+CT or CCR+MRI became preferable in many instances when parameters regarding radiation risk and exposure were changed.

All but when the sensitivities of the decision rules were varied, the Canadian C-Spine rule featured in the optimal strategy. Only when costs of implementing the decision rule exceeded £42, did the use of a decision rule not feature as part of an optimal strategy.

Please also refer to Table 33 in section L.3 for full details of the range tested.

In the one way deterministic threshold analysis, conclusions were not sensitive to:

- The discount rate of costs or benefits
- Cohort size
- The sensitivity of the nexus rule
- The specificity of x-ray for bony and sensitivity and specificity of x-ray for ligamentous injuries
- The sensitivity of CT for ligamentous injury
- The sensitivity or specificity of MRI for bony or ligaments injury
- Average life expectancy following no injury and column injury
- The quality of life if no injury was sustained
- The quality of life for cord injury
- The cost of prompt treatment for cord injury
- The average excess bed day cost for cord injury
- Additional litigation costs for missed column and missed cord injuries

However, the conclusion changed when the following parameters and thresholds were varied in a one way deterministic threshold analysis (assessed using discounted lifetime net benefit at £20,000 unless otherwise stated):

Time horizon

- When 'Time horizon in the sensitivity analysis (that is, where lifetime horizon not used)' changed from 3 to 4 years, the optimal strategy changed from strategy '13. CCR+X-ray+CT' to '8. CCR+CT'. Optimality was assessed using the outcome of 'Until time horizon NB (20K) - discounted'.

Epidemiology

- When 'Mean age at injury' changed value from 65 to 70, the optimal strategy changed from strategy '8. CCR+CT' to '13. CCR+X-ray+CT'.
- When 'Prevalence of spinal column injury in presenting ED population' changed value from 0 to 0.01, the optimal strategy changed from strategy '13. CCR+X-ray+CT' to '8. CCR+CT'.
- When 'Proportion of spinal injuries which are bony' changed value from 0.38 to 0.39, the optimal strategy changed from strategy '9. CCR+MRI' to '8. CCR+CT'.

Sensitivities and Specificities

- When 'Nexus Specificity' changed value from 0.45 to 0.46, the optimal strategy changed from strategy '8. CCR+CT' to '11. NEXUS+CT'.

- When 'C-Spine Sensitivity' changed value from 0.65 to 0.66, the optimal strategy changed from strategy '11. NEXUS+CT' to '8. CCR+CT'.
- When 'C-Spine Specificity' changed value from 0.11 to 0.12, the optimal strategy changed from strategy '11. NEXUS+CT' to '8. CCR+CT'.
- When 'X-ray Sensitivity for bony injury' changed value from 0.9 to 1.0, the optimal strategy changed from strategy '8. CCR+CT' to '13. CCR+X-ray+CT'.
- When 'CT Sensitivity for bony injury' changed value from 0.6 to 0.61, the optimal strategy changed from strategy '7. CCR+X-ray' to '8. CCR+CT'
- When 'CT Specificity for bony injury' changed value from 0.85 to 0.86, the optimal strategy changed from strategy '14. CCR+CT+MRI' to '8. CCR+CT'.
- When 'CT Specificity for ligamentous injury' changed value from 0.85 to 0.86, the optimal strategy changed from strategy '14. CCR+CT+MRI' to '8. CCR+CT'.

Probability of conversion

- When 'Probability of conversion if bony injury is missed' changed value from 0 to 0.002, the optimal strategy changed from strategy '13. CCR+X-ray+CT' to '8. CCR+CT'.
- When 'Probability of conversion if ligamentous injury is missed' changed value from 0.282 to 0.284, the optimal strategy changed from strategy '8. CCR+CT' to '9. CCR+MRI'.

Radiation Exposure (optimality assessed using 'Discounted Lifetime NB (20k) taking into account radiation exposure').

- When 'Probability of developing cancer due to X-ray radiation exposure (lifetime)' changed value from 0 to 0.00005, the optimal strategy changed from strategy '13. CCR+X-ray+CT' to '8. CCR+CT'.
- When ' Probability of developing cancer due to CT radiation exposure' changed value from 0.001150 to 0.00120, the optimal strategy changed from strategy '8. CCR+CT' to '13. CCR+X-ray+CT'.
- When 'Cost of cancer' changed value from £35000 to £35100, the optimal strategy changed from strategy '8. CCR+CT' to '13. CCR+X-ray+CT'.
- When 'QALY loss per patient with cancer' changed value from 7.40 to 7.50, the optimal strategy changed from strategy '8. CCR+CT' to '13. CCR+X-ray+CT'.
- When 'Age of diagnosis' changed value from 69 to 70, the optimal strategy changed from strategy '13. CCR+X-ray+CT' to '8. CCR+CT'.

Prevalence of spinal column injury, and proportion of injuries which would be bony or ligamentous when radiation exposure was taken into account

- When discounting was not applied, and When 'Prevalence of spinal column injury in presenting ED population' changed value from 0.07 to 0.08, the optimal strategy changed from strategy '9. CCR+MRI' to '8. CCR+CT'.
- When discounting was not applied, and when 'Proportion of spinal injuries which are bony' changed value from 0.38 to 0.39, the optimal strategy changed from strategy '9. CCR+ MRI' to '8. CCR+CT'.
- When discounting was applied and When 'Prevalence of spinal column injury in presenting ED population' changed value from 0.00 to 0.01, the optimal strategy changed from strategy '13. CCR+X-ray+CT' to '8. CCR+CT'
- When discounting was applied and When 'Proportion of spinal injuries which are bony' changed value from 0.72 to 0.73, the optimal strategy changed from strategy '9. CCR+MRI' to '8. CCR+CT'.

Quality of life and life expectancy estimates

- When 'Quality of life for promptly treated column injury (year 1)' changed value from 0.60 to 0.61, the optimal strategy changed from strategy '13. CCR+X-ray+CT' to '8. CCR+CT'.
- When 'Quality of life for promptly treated column injury (year 2)' changed value from 0.49 to 0.50, the optimal strategy changed from strategy '13. CCR+X-ray+CT' to '8. CCR+CT'.
- When 'Quality of life for promptly treated column injury at end of time horizon' changed value from 0.81 to 0.82, the optimal strategy changed from strategy '13. CCR+X-ray+CT' to '8. CCR+CT'.
- When 'Quality of life for delayed treatment of column injury (year 1)' changed value from 0.8 to 1 the optimal strategy changed from strategy '8. CCR+CT' to '13. CCR+X-ray+CT'.
- When 'Quality of life for delayed treatment of column injury (year 2)' changed value from 0.8 to 1, the optimal strategy changed from strategy '8. CCR+CT' to '13. CCR+X-ray+CT'.
- When 'Quality of life for delayed treatment of column injury at end of time horizon' changed value from 0.83 to 0.84, the optimal strategy changed from strategy '8. CCR+CT' to '13. CCR+X-ray+CT'.
- When 'Average life expectancy if cord injury survived (years)' changed value from 30 to 40, the optimal strategy changed from strategy '13. CCR+X-ray+CT' to '8. CCR+CT'.

Costs

- When 'Cost of decision rules' changed value from 41 to 42, the optimal strategy changed from strategy '8. CCR+CT' to '2. CT scan'.
- When 'Cost of double X-ray' changed value from 25 to 26, the optimal strategy changed from strategy '13. CCR+X-ray+CT' to '8. CCR+CT'.
- When 'Cost of CT' changed value from 249 to 250, the optimal strategy changed from strategy '13. CCR+X-ray+CT' to '7. CCR+X-ray'.
- When 'Cost of MRI' changed value from 72 to 73, the optimal strategy changed from strategy '15. CCR+MRI+CT' to '8. CCR+CT'.
- When 'Average excess bed day for column injury' changed value from 0 to 100, the optimal strategy changed from strategy '7. CCR+X-ray' to '8. CCR+CT'.
- When 'Subtotal of lifetime cost for cord injury' changed value from 0 to 1000000, the optimal strategy changed from strategy '13. CCR+X-ray+CT' to '8. CCR+CT'.

Discussion

L.2.2 Summary of results

Base case analysis identified that the Canadian C-Spine Rule (CCR) + CT scan dominated all other strategies. 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.

Limitations and interpretation

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 the medical professional in deciding on imaging a patient with a suspected spinal injury.

Although CCR featured among the top ranked strategies in the base case, the sensitivity and specificity of the decision rules had 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. It can be concluded that although results support the use of the CCR, in general the use of a decision rule is recommended.

The analysis has highlighted the inadequacy of X-ray alone or with a decision rule as a clearance tool.

It has to be 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 QALY penalty was given to outcomes such as FP (although the cost of observation/treatment is taken into account), there are no indeterminate images, patients are either 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 imaging. No on-going treatment is assumed if a column injury is promptly treated.

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 are also an important long term consideration but only explored as a sensitivity analysis.

The model is also limited by a lack of direct high quality evidence to inform several of its parameters, and makes generalisations regarding the location, type and severity of injury. For example, most diagnostic data applies to the cervical spine, not to the thoracic or lumbar spine. The decision rules evaluated are also for the c-spine. However the clinical experts felt that it is possible that the results of the model could be extrapolated and be applicable to the other parts of the spine.

In the model we did not consider conditional dependence between diagnostic tests. Conditional dependence of test sensitivities occurs when the second test has different sensitivities for individuals with the condition that test positive and for those that test negative on the first test. In the further imaging strategies, only those who are found positive go on to have another type of imaging. This means that the likelihood of picking up an injury from further imaging would be higher than in the initial population imaged (which would contain true and false positives and true and false negatives) because the prevalence has also increased. An important factor in determining conditional dependence is how close to 100% the sensitivity of test B is (in a sequence of test A then B), as all further imaging strategies would end with either CT and MRI which have quite high sensitivity then dependence is likely to have limited impact on the results.

If dependence was included between the risk tools and the imaging modalities (as again only those found positive go on to have imaging), again this is unlikely to have an impact on the results because the sensitivities of the risk scores are high as well as those of the imaging modalities (apart from x-ray which has a lower sensitivity than CT and MRI, but to x-ray only those with a positive risk score - which is highly accurate - would improve the sensitivity of x-ray, however would still be inferior to CT and MRI, thus not changing the conclusions).

The classification of any type of fracture and ligamentous injury under the 'column injury' umbrella captures a range of injury severity and more importantly a range of injuries with different risks of associated cord injury. With respect to the risk of a missed injury converting to a cord injury this will vary hugely depending on the severity of the column injury. A simple spinous process or transverse process fracture would pose little risk of conversion whereas other types of fracture could pose a

greater risk. Similarly whilst both boney and ligamentous injuries are both classified as 'column injury' these may not have the same risk of conversion in the setting of a missed injury.

Similarly there is a range of severity of cord injury from one which could result in a good functional outcome to a complete cord transaction which would have little or no recovery. It would be most unlikely that the latter would be missed (because they would be obvious clinically) and so missed injuries would be on average less severe, and therefore associated with lower resource use and costs than those picked up initially. Assumptions made, for example about the additional costs of treatment (that is, bed days), to treat such injury may overestimate the cost of missed injury. On the other hand, no ongoing treatment costs were applied for missed column injury which may simplify the relationship between unhealed fracture and costs involved in chronic back pain for example. Both assumptions may not hold true, if complicated and complex column injury is more prevalent than the GDG anticipated.

Generalizations and categorizations made within the model were necessary in the absence of granular data to parameterise. Whilst the assumptions made may limit the model, each was tested through sensitivity analysis to determine at which point conclusions may change. Throughout, the model explicitly shows and attempts to quantify the parameters, assumptions, and structure underpinning the clinical decision.

For this reason, whilst recognising the analysis has potentially serious limitations, the analysis is sufficient for purposes of decision making.

L.2.3 Generalizability to other populations/settings

A separate subgroup analysis was not conducted for paediatrics. The GDG felt this economic analysis could not be extrapolated to the paediatric population. The trade-off between the accuracy of diagnosis and the radiation risk associated with a CT scan requires particular discussion. The GDG would consider that a plain film X-ray has lower levels of radiation than a CT scan when writing recommendations for children. Further, no evidence was available to inform the prevalence of spinal column injury in children, and the GDG were wary that the clinical judgements for further imaging and treatment used in the analysis may differ in the paediatric group. It is recognised that certain groups, that is, young people, may have different epidemiology and baseline risks in regard to the type of injury and the likelihood that repeated radiation could occur. Threshold analysis demonstrated that the conclusions may change as to the optimal strategy when likelihood of sustaining an injury is very low or when a ligamentous injury is more likely than a bony injury. Thus, although the GDG considered the results robust for the majority of adults, there may be certain subgroups which benefit from a more tailored approach.

L.2.4 Comparisons with published studies

No studies that looked at the use of clinical decision 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. The economic analysis conducted in the Head Injury guideline (CG176) concluded 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 supports the results presented here.

Conclusion/evidence statement

For patients with suspected spinal column injury the Canadian C-spine rule and CT scan is likely to be a cost effective strategy to clear the spine in the majority of adult population groups. This is based on original economic analysis which is directly applicable but has potentially serious limitations.

Depending on baseline risks, epidemiology and potential radiation risk of the population, a strategy using the Canadian C-spine rule to indicate MRI, or a strategy using Canadian C-spine rule to indicate X-ray to then indicate CT may also be cost effective.

L.2.5 Implications for future research

The modelling of events and costs over a lifetime horizon in this model was limited by assigning simple pay-offs, and which may in turn over or under estimate the long term consequences of employing a given diagnostic strategy. Future research could explore the long term costs and health outcomes to better inform a model with a lifetime horizon. Furthermore, QALYs were estimated using utilities from proxy conditions and long term spinal cord injured patients. Future research could focus on assessing utilities in a trauma patient group. The adverse events associated with spinal clearance strategies, and the decision to remove spinal protective measures, were 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 in this analysis due to a lack of data. Radiation risk associated with imaging modalities is also an important long term consideration, for which we did not have direct data for to inform the model. Children were not assessed in this analysis due to a lack of data. Should clinical studies that look at the accuracy of clinical decision rules and various diagnostic modalities for children be available in the future, this analysis can be modified to provide information on the cost effectiveness of clearance strategies for this subgroup.

L.3 Breakdown of Economic Model Results

Full results of the base case analysis.

Table 22: Breakdown of diagnostic modality use for each clearance strategy (per 1000 people suspected of column injury)

Strategy	X-ray	CT	MRI	Number discharged without any imaging	Total cost of diagnostic imaging (£)	Total cost of diagnostic imaging and cost of radiation exposure (£)	Total cost of diagnostic imaging and cost of radiation exposure (£) -discounted
1. X-ray	1,000			-	£59,205	£60,681	£59,553
2. CT scan		1,000		-	£92,489	£117,472	£98,379
3. MRI			1,000	-	£144,800	£144,800	£144,800
4. X-ray+CT	1,000	182		-	£76,031	£82,052	£77,450
5. CT + MRI		1,000	10	-	£93,892	£118,875	£99,783
6. MRI + CT		49	1,000	-	£149,305	£150,521	£149,591
7. CCR+X-ray	555			446	£32,829	£33,648	£33,022
8. CCR+CT		555		446	£51,285	£65,138	£54,551
9. CCR+MRI			555	446	£80,292	£80,292	£80,292
10. NEXUS+X-ray	881			119	£52,165	£53,466	£52,472
11. NEXUS+CT		881		119	£81,492	£103,504	£86,682
12. NEXUS+MRI			881	119	£127,583	£127,583	£127,583
13. CCR+X-ray+CT	555	103		446	£42,370	£45,766	£43,171
14. CCR+CT+MRI		555	10	446	£52,689	£66,542	£55,955
15. CCR+MRI+CT		31	555	446	£83,148	£83,920	£83,330
16. NEXUS+X-ray+CT	881	161		119	£67,042	£72,362	£68,297
17. NEXUS+CT+MRI		881	10	119	£82,881	£104,894	£88,071
18. NEXUS+MRI+CT		44	881	119	£131,640	£132,736	£131,898

Table 23: Breakdown diagnostic outcome and onward strategy for each clearance strategy (per 1000 people suspected of column injury)

Strategy	Safely discharged (TN)	Prompt treatment (TP)	Delayed treatment - no conversion (FN)	Conversion to cord injury (FN)	Unnecessary management and observation (FP)	Number of correct diagnosis (%)
1. X-ray	815	7	3	0.016	175	82.19%
2. CT scan	990	10	0	0.002	-	99.97%
3. MRI	950	9	1	0.004	40	95.95%
4. X-ray+CT	990	7	3	0.016	-	99.68%
5. CT + MRI	990	9	1	0.006	-	99.88%
6. MRI + CT	990	9	1	0.006	-	99.88%
7. CCR+X-ray	894	7	3	0.016	96	90.06%
8. CCR+CT	990	10	0	0.002	-	99.97%
9. CCR+MRI	968	9	1	0.004	22	97.73%
10. NEXUS+X-ray	836	7	3	0.016	154	84.28%
11. NEXUS+CT	990	10	0	0.002	-	99.96%
12. NEXUS+MRI	955	9	1	0.005	35	96.42%
13. CCR+X-ray+CT	990	7	3	0.016	-	99.68%
14. CCR+CT+MRI	990	9	1	0.006	-	99.88%
15. CCR+MRI+CT	990	9	1	0.006	-	99.88%
16. NEXUS+X-ray+CT	990	7	3	0.017	-	99.67%
17. NEXUS+CT+MRI	990	9	1	0.006	-	99.87%
18. NEXUS+MRI+CT	990	9	1	0.006	-	99.87%

Table 24: Breakdown of QALY gain for each clearance strategy (per 1000 people suspected of column injury)

Strategy	QALY (first year)	Time horizon of 10 years (including on-going cord injury management)	Time horizon of 10 years (including on-going cord injury management) - discounted	QALY (lifetime)	QALY (lifetime) - discounted	QALY (lifetime) with radiation risk taken into account	QALY (lifetime) with radiation risk taken into account - discounted
1. X-ray	824.42	9,073.63	7,924.98	41,249.04	20,851.76	41,248.60	20,851.65
2. CT scan	824.42	9,073.82	7,925.16	41,249.38	20,851.98	41,241.90	20,850.22
3. MRI	824.42	9,073.78	7,925.12	41,249.31	20,851.93	41,249.31	20,851.93
4. X-ray+CT	824.42	9,073.62	7,924.97	41,249.02	20,851.75	41,247.22	20,851.32
5. CT + MRI	824.42	9,073.76	7,925.11	41,249.28	20,851.91	41,241.79	20,850.15
6. MRI + CT	824.42	9,073.76	7,925.11	41,249.28	20,851.91	41,248.91	20,851.83
7. CCR+X-ray	824.42	9,073.63	7,924.98	41,249.04	20,851.76	41,248.80	20,851.70
8. CCR+CT	824.42	9,073.82	7,925.16	41,249.38	20,851.98	41,245.23	20,851.00
9. CCR+MRI	824.42	9,073.78	7,925.12	41,249.31	20,851.93	41,249.31	20,851.93
10. NEXUS+X-ray	824.42	9,073.63	7,924.98	41,249.03	20,851.75	41,248.64	20,851.66
11. NEXUS+CT	824.42	9,073.81	7,925.16	41,249.37	20,851.97	41,242.78	20,850.42
12. NEXUS+MRI	824.42	9,073.77	7,925.12	41,249.30	20,851.93	41,249.30	20,851.93
13. CCR+X-ray+CT	824.42	9,073.62	7,924.97	41,249.02	20,851.75	41,248.01	20,851.51
14. CCR+CT+MRI	824.42	9,073.76	7,925.11	41,249.28	20,851.91	41,245.13	20,850.93
15. CCR+MRI+CT	824.42	9,073.76	7,925.11	41,249.28	20,851.91	41,249.05	20,851.86
16. NEXUS+X-ray+CT	824.42	9,073.62	7,924.97	41,249.02	20,851.74	41,247.42	20,851.37
17. NEXUS+CT+MRI	824.42	9,073.76	7,925.10	41,249.27	20,851.90	41,242.67	20,850.35
18. NEXUS+MRI+CT	824.42	9,073.76	7,925.10	41,249.27	20,851.90	41,248.94	20,851.83

Table 25: Total costs (diagnostics and treatment) for each clearance strategy (per 1000 people suspected of column injury) (£)

Strategy	Diagnosis and initial treatment (no on-going management costs)	Time horizon of 10 years (including costs of on-going cord injury management)	Time horizon of 10 years (including costs of on-going cord injury management) - discounted	Lifetime horizon (including costs of on-going cord injury management)	Lifetime horizon (including costs of on-going cord injury management) - discounted	Lifetime horizon (including costs of on-going cord injury management and radiation exposure)	Lifetime horizon (including costs of on-going cord injury management and radiation exposure) - discounted	Lifetime horizon (including costs of on-going cord injury management) and cord injury litigation	Lifetime horizon (including costs of on-going cord injury management) and litigation for any missed injury
1. X-ray	138,246	147,949	146,598	177,058	159,692	178,534	160,040	184,821	339,294
2. CT scan	119,919	120,877	120,744	123,750	122,036	148,734	127,927	124,517	139,765
3. MRI	183,871	186,674	186,284	195,083	190,066	195,083	190,066	197,326	241,952
4. X-ray+CT	105,969	116,103	114,692	146,505	128,368	152,527	129,787	154,612	315,947
5. CT + MRI	122,067	125,749	125,236	136,793	130,204	161,777	136,095	139,739	198,349
6. MRI + CT	177,479	181,161	180,648	192,206	185,617	193,423	185,904	195,151	253,762
7. CCR+X-ray	89,721	99,424	98,073	128,533	111,167	129,352	111,360	136,296	290,769
8. CCR+CT	78,716	79,673	79,540	82,547	80,833	96,400	84,099	83,313	98,561
9. CCR+MRI	114,351	117,154	116,764	125,564	120,547	125,564	120,547	127,806	172,432
10. NEXUS+X-ray	125,359	135,277	133,896	165,033	147,281	166,334	147,588	172,968	330,872
11. NEXUS+CT	109,005	110,266	110,090	114,048	111,792	136,061	116,982	115,057	135,127
12. NEXUS+MRI	165,396	168,483	168,053	177,746	172,220	177,746	172,220	180,216	229,370
13. CCR+X-ray+CT	72,308	82,442	81,032	112,845	94,707	116,241	95,508	120,952	282,286
14. CCR+CT+MRI	80,863	84,545	84,032	95,590	89,001	109,443	92,267	98,535	157,146
15. CCR+MRI+CT	111,323	115,004	114,492	126,049	119,460	126,821	119,642	128,994	187,605

Strategy	Diagnosis and initial treatment (no on-going management costs)	Time horizon of 10 years (including costs of on-going cord injury management)	Time horizon of 10 years (including costs of on-going cord injury management) - discounted	Lifetime horizon (including costs of on-going cord injury management)	Lifetime horizon (including costs of on-going cord injury management) - discounted	Lifetime horizon (including costs of on-going cord injury management and radiation exposure)	Lifetime horizon (including costs of on-going cord injury management and radiation exposure) - discounted	Lifetime horizon (including costs of on-going cord injury management) and cord injury litigation	Lifetime horizon (including costs of on-going cord injury management) and litigation for any missed injury
16. NEXUS+X-ray+CT	97,038	107,383	105,943	138,419	119,904	143,738	121,158	146,695	311,391
17. NEXUS+CT+MRI	111,132	115,089	114,538	126,961	119,878	148,973	125,068	130,126	193,126
18. NEXUS+MRI+CT	159,890	163,847	163,296	175,719	168,637	176,815	168,895	178,885	241,885

Table 26: Net Monetary Benefit (per person using a threshold of £20,000)

Strategy	First year NB (20K)	Until time horizon NB (20K)	Until time horizon NB (20K) - discounted	Lifetime NB (20K)	Lifetime NB (20K) - discounted	Lifetime NB (20k) taking into account radiation exposure	Lifetime NB (20k) taking into account radiation exposure - discounted	Lifetime NB taking into account litigation for conversion (20K)	Lifetime NB taking into account litigation for conversion (20K) - QALYs discounted	Lifetime NB taking into account litigation for all missed column injuries (20K)	Lifetime NB taking into account litigation for all missed column injuries (20K) - QALYs discounted
1. X-ray	16,350	181,325	158,353	824,804	416,875	824,793	416,873	824,796	416,850	824,642	416,696
2. CT scan	16,368	181,356	158,382	824,864	416,918	824,689	416,876	824,863	416,915	824,848	416,900
3. MRI	16,305	181,289	158,316	824,791	416,849	824,791	416,849	824,789	416,841	824,744	416,797
4. X-ray+CT	16,382	181,356	158,385	824,834	416,907	824,792	416,897	824,826	416,880	824,665	416,719
5. CT + MRI	16,366	181,349	158,377	824,849	416,908	824,674	416,867	824,846	416,898	824,787	416,840
6. MRI + CT	16,311	181,294	158,321	824,793	416,853	824,785	416,851	824,790	416,843	824,732	416,784
7. CCR+X-ray	16,399	181,373	158,402	824,852	416,924	824,847	416,923	824,845	416,899	824,690	416,744
8. CCR+CT	16,410	181,397	158,424	824,905	416,959	824,808	416,936	824,904	416,956	824,889	416,941
9. CCR+MRI	16,374	181,358	158,386	824,861	416,918	824,861	416,918	824,858	416,911	824,814	416,866
10. NEXUS+X-ray	16,363	181,337	158,366	824,816	416,888	824,807	416,886	824,808	416,862	824,650	416,704
11. NEXUS+CT	16,379	181,366	158,393	824,873	416,928	824,720	416,891	824,872	416,924	824,852	416,904
12. NEXUS +MRI	16,323	181,307	158,334	824,808	416,866	824,808	416,866	824,806	416,858	824,757	416,809
13. CCR+X-ray+CT	16,416	181,390	158,418	824,868	416,940	824,844	416,935	824,860	416,914	824,698	416,753
14. CCR+CT +MRI	16,408	181,391	158,418	824,890	416,949	824,793	416,926	824,887	416,940	824,828	416,881
15. CCR+	16,377	181,360	158,388	824,859	416,919	824,854	416,917	824,857	416,909	824,798	416,851

MRI+CT											
16. NEXUS+X-ray+CT	16,391	181,365	158,393	824,842	416,915	824,805	416,906	824,834	416,888	824,669	416,723
17. NEXUS+ CT+MRI	16,377	181,360	158,387	824,858	416,918	824,704	416,882	824,855	416,908	824,792	416,845
18. NEXUS+ MRI+CT	16,328	181,311	158,339	824,810	416,869	824,802	416,868	824,806	416,859	824,743	416,796

Table 27: Rankings (1 = optimal strategy according to outcome)

Strategy	First year NB (20K)	Until time horizon NB (20K)	Until time horizon NB (20K) - discounted	Lifetime NB (20K)	Lifetime NB (20K) - discounted	Lifetime NB (20k) taking into account radiation exposure	Lifetime NB (20k) taking into account radiation exposure - discounted	Lifetime NB taking into account litigation for conversion (20K)	Lifetime NB taking into account litigation for conversion (20K) - QALYs discounted	Lifetime NB taking into account litigation for all missed column injuries (20K)	Lifetime NB taking into account litigation for all missed column injuries (20K) - QALYs discounted
1. X-ray	14	14	14	16	14	10	13	16	16	18	18
2. CT scan	11	11	11	5	9	17	12	4	4	3	3
3. MRI	18	18	18	18	18	13	18	18	18	10	10
4. X-ray+CT	6	10	10	12	12	12	8	12	12	16	16
5. CT + MRI	12	12	12	10	11	18	15	9	10	8	8
6. MRI + CT	17	17	17	17	17	14	17	17	17	12	12
7. CCR+X-ray	4	4	4	9	5	3	4	10	9	14	14
8. CCR+CT	2	1	1	1	1	5	1	1	1	1	1
9. CCR+MRI	10	9	9	6	8	1	5	6	6	5	5
10. NEXUS+ X-ray	13	13	13	13	13	7	10	13	13	17	17
11. NEXUS+ CT	7	5	6	3	4	15	9	3	3	2	2
12. NEXUS+ MRI	16	16	16	15	16	6	16	15	15	9	9
13. CCR+ X-ray+CT	1	3	2	4	3	4	2	5	5	13	13
14. CCR+	3	2	3	2	2	11	3	2	2	4	4

CT+MRI											
15. CCR+ MRI+CT	9	7	7	7	6	2	6	7	7	6	6
16. NEXUS+ X-ray+CT	5	6	5	11	10	8	7	11	11	15	15
17. NEXUS+ CT+MRI	8	8	8	8	7	16	11	8	8	7	7
18. NEXUS+ MRI+CT	15	15	15	14	15	9	14	14	14	11	11

Table 28: Rankings (1 = optimal strategy according to outcome)

Strategy	Proportion of correct diagnoses	Number of cord conversions avoided	Initial cost of diagnosis and initial management	QALY gain over lifetime horizon (1 = highest QALY gain)	Lifetime cost (including cord management, litigation cost excluded)	QALY gain over 10 year time horizon	Cost over 10 year time horizon (including costs of on-going cord injury management)	QALY gain over lifetime horizon, with radiation exposure taken into account (1 = highest QALY gain)	Health risk due to radiation exposure
1. X-ray	18	13	14	13	15	13	14	9	9
2. CT scan	1	1	11	1	5	1	11	17	17
3. MRI	15	4	18	4	18	4	18	1	1
4. X-ray+CT	10	16	6	16	12	16	9	12	12
5. CT + MRI	4	9	12	7	10	7	12	18	17
6. MRI + CT	4	7	17	7	17	7	17	6	7
7. CCR+X-ray	16	13	4	13	9	13	4	7	5
8. CCR+CT	1	1	2	1	1	1	1	13	13
9. CCR+MRI	13	4	10	4	6	4	10	1	1
10. NEXUS+ X-ray	17	15	13	15	13	15	13	8	8
11. NEXUS+ CT	3	3	7	3	4	3	6	15	15
12. NEXUS+ MRI	14	6	16	6	16	6	16	3	1
13. CCR+ X-ray+CT	10	16	1	16	3	16	2	10	10
14. CCR+ CT+MRI	4	9	3	7	2	7	3	14	13
15. CCR+ MRI+CT	4	7	9	7	7	7	7	4	4

Strategy	Proportion of correct diagnoses	Number of cord conversions avoided	Initial cost of diagnosis and initial management	QALY gain over lifetime horizon (1 = highest QALY gain)	Lifetime cost (including cord management, litigation cost excluded)	QALY gain over 10 year time horizon	Cost over 10 year time horizon (including costs of on-going cord injury management)	QALY gain over lifetime horizon, with radiation exposure taken into account (1 = highest QALY gain)	Health risk due to radiation exposure
16. NEXUS+ X-ray+CT	12	18	5	18	11	18	5	11	11
17. NEXUS+ CT+MRI	8	12	8	11	8	11	8	16	15
18. NEXUS+ MRI+CT	8	11	15	11	14	11	15	5	6

Results of the scenario analyses whereby accuracy estimates varied.

Table 29: Results from using the highest reported accuracy estimates

Summary results (per person)				
Strategy	Total cost (£) (discounted)	Total QALY gain (discounted)	Net Monetary Benefit (£20K) - discounted	Rank
1. X-ray	86	20.85201	416,954	9
2. CT scan	120	20.85201	416,920	15
3. MRI	172	20.85201	416,868	17
4. X-ray+CT	87	20.85201	416,953	10
5. CT + MRI	121	20.85201	416,919	16
6. MRI + CT	173	20.85201	416,867	18
7. CCR+X-ray	60	20.85201	416,980	2
8. CCR+CT	78	20.85201	416,962	6
9. CCR+MRI	107	20.85201	416,933	13
10. NEXUS+X-ray	59	20.85201	416,981	1
11. NEXUS+CT	78	20.85201	416,963	5
12. NEXUS+MRI	106	20.85201	416,934	11
13. CCR+X-ray+CT	61	20.85201	416,979	4
14. CCR+CT+MRI	80	20.85201	416,960	8
15. CCR+MRI+CT	108	20.85201	416,932	14
16. NEXUS+X-ray+CT	60	20.85201	416,980	3
17. NEXUS+CT+MRI	79	20.85201	416,961	7
18. NEXUS+MRI+CT	107	20.85201	416,933	12

Table 30: Results from using the lowest reported accuracy estimates

Summary results (per person)				
Strategy	Total cost (£) (discounted)	Total QALY gain (discounted)	Net Monetary Benefit (£20K) - discounted	Rank
1. X-ray	358	20.85121	416,666	16
2. CT scan	238	20.85121	416,786	5
3. MRI	379	20.85131	416,647	18
4. X-ray+CT	256	20.85121	416,768	9
5. CT + MRI	239	20.85121	416,785	7
6. MRI + CT	316	20.85121	416,708	12
7. CCR+X-ray	356	20.85121	416,668	15
8. CCR+CT	237	20.85121	416,787	3
9. CCR+MRI	376	20.85131	416,650	17
10. NEXUS+X-ray	328	20.85121	416,696	13
11. NEXUS+CT	222	20.85121	416,802	1
12. NEXUS+MRI	346	20.85129	416,679	14
13. CCR+X-ray+CT	255	20.85121	416,769	8
14. CCR+CT+MRI	237	20.85121	416,787	4
15. CCR+MRI+CT	314	20.85121	416,710	11
16. NEXUS+X-ray+CT	238	20.85121	416,786	6
17. NEXUS+CT+MRI	223	20.85121	416,802	2
18. NEXUS+MRI+CT	291	20.85121	416,734	10

Table 31: Results from using the median of reported accuracy estimates

Summary results (per person)				
Strategy	Total cost (£) (discounted)	Total QALY gain (discounted)	Net Monetary Benefit (£20K) - discounted	Rank
1. X-ray	238	20.85169	416,795	18
2. CT scan	132	20.85200	416,908	6
3. MRI	191	20.85184	416,846	16
4. X-ray+CT	163	20.85169	416,871	13
5. CT + MRI	144	20.85183	416,893	9
6. MRI + CT	191	20.85183	416,846	15
7. CCR+X-ray	170	20.85169	416,864	14
8. CCR+CT	93	20.85200	416,947	1
9. CCR+MRI	135	20.85184	416,901	7
10. NEXUS+X-ray	199	20.85165	416,834	17
11. NEXUS+CT	114	20.85193	416,925	3
12. NEXUS+MRI	161	20.85178	416,874	11
13. CCR+X-ray+CT	123	20.85169	416,910	4
14. CCR+CT+MRI	107	20.85183	416,930	2
15. CCR+MRI+CT	136	20.85183	416,901	8
16. NEXUS+X-ray+CT	142	20.85165	416,891	10
17. NEXUS+CT+MRI	126	20.85178	416,910	5
18. NEXUS+MRI+CT	161	20.85178	416,874	12

Table 32: Results using estimates taken from the Head Injury Guideline model [415] and Halpern et al (2010) [233]

Summary results (per person)				
Strategy	Total cost (£) (discounted)	Total QALY gain (discounted)	Net Monetary Benefit (£20K) - discounted	Rank
1. X-ray	91	20.85241	416,957	9
2. CT scan	113	20.85252	416,937	13
3. MRI	165	20.85253	416,885	17
4. X-ray+CT	94	20.85238	416,954	10
5. CT + MRI	118	20.85247	416,932	15
6. MRI + CT	170	20.85247	416,879	18
7. CCR+X-ray	65	20.85241	416,983	1
8. CCR+CT	73	20.85252	416,977	4
9. CCR+MRI	103	20.85253	416,948	11
10. NEXUS+X-ray	71	20.85239	416,977	3
11. NEXUS+CT	82	20.85249	416,968	7
12. NEXUS+MRI	114	20.85250	416,936	14
13. CCR+X-ray+CT	68	20.85238	416,979	2
14. CCR+CT+MRI	78	20.85247	416,971	6
15. CCR+MRI+CT	108	20.85247	416,942	12
16. NEXUS+X-ray+CT	74	20.85236	416,974	5
17. NEXUS+CT+MRI	86	20.85245	416,963	8
18. NEXUS+MRI+CT	119	20.85245	416,930	16

Full results of the threshold analysis.

Table 33: Results of the one way deterministic threshold analysis

Parameter name	Outcome on which optimality was assessed	Lower bound of values tested	Upper bound of values tested	Optimal strategy at lower bound	Value at which this strategy was recorded as optimal	Optimal strategy at upper bound	Value at which this strategy was recorded as optimal	Results
Time horizon in sensitivity analysis (i.e. where lifetime horizon not used)	Until time horizon NB (20K) - discounted	1	60	13. CCR+X-ray+CT	3.00	8. CCR+CT	4.00	When 'Time horizon in sensitivity analysis (i.e. where lifetime horizon not used)' changed value from 3 to 4, the optimal strategy changed from strategy '13. CCR+X-ray+CT' to '8. CCR+CT'. Optimality was assessed using the outcome of 'Until time horizon NB (20K) - discounted'.
Discount rate costs	Lifetime NB (20K) - discounted	0	0.05					The conclusions did not change when the parameter 'Discount rate costs' had values between 0 and 0.05. Optimality was assessed using the outcome of 'Lifetime NB (20K) - discounted'.
Discount rate benefits	Lifetime NB (20K) - discounted	0	0.05					The conclusions did not change when the parameter 'Discount rate benefits' had values between 0 and 0.05. Optimality was assessed using the outcome of 'Lifetime NB (20K) - discounted'.
Cohort size	Lifetime NB (20K) - discounted	100	1000					The conclusions did not change when the parameter 'Cohort size' had values between 100 and 1000. Optimality was assessed using the outcome of 'Lifetime NB (20K) - discounted'.
Mean age at injury	Lifetime NB (20K) -	20	70	8. CCR+CT	65.0000	13. CCR+X-ray+CT	70.0000	When 'Mean age at injury' changed value from 65 to 70, the optimal

Parameter name	Outcome on which optimality was assessed	Lower bound of values tested	Upper bound of values tested	Optimal strategy at lower bound	Value at which this strategy was recorded as optimal	Optimal strategy at upper bound	Value at which this strategy was recorded as optimal	Results
	discounted							strategy changed from strategy '8. CCR+CT' to '13. CCR+X-ray+CT'. Optimality was assessed using the outcome of 'Lifetime NB (20K) - discounted'.
Prevalence of spinal column injury in presenting ED population	Lifetime NB (20K) - discounted	0	0.9999	13. CCR+X-ray+CT	0.0000	8. CCR+CT	0.0100	When 'Prevalence of spinal column injury in presenting ED population' changed value from 0 to 0.01, the optimal strategy changed from strategy '13. CCR+X-ray+CT' to '8. CCR+CT'. Optimality was assessed using the outcome of 'Lifetime NB (20K) - discounted'.
Proportion of spinal injuries which are bony	Lifetime NB (20K) - discounted	0	0.99	9. CCR+MRI	0.380	8. CCR+CT	0.390	When 'Proportion of spinal injuries which are bony' changed value from 0.38 to 0.39, the optimal strategy changed from strategy '9. CCR+MRI' to '8. CCR+CT'. Optimality was assessed using the outcome of 'Lifetime NB (20K) - discounted'.
Nexus Sensitivity	Lifetime NB (20K) - discounted	0	1					The conclusions did not change when the parameter 'Nexus Sensitivity' had values between 0 and 1. Optimality was assessed using the outcome of 'Lifetime NB (20K) - discounted'.
Nexus Specificity	Lifetime NB (20K) - discounted	0	1	8. CCR+CT	0.45	11. NEXUS+CT	0.46	When 'Nexus Specificity' changed value from 0.45 to 0.46, the optimal strategy changed from strategy '8. CCR+CT' to '11. NEXUS+CT'. Optimality was

Parameter name	Outcome on which optimality was assessed	Lower bound of values tested	Upper bound of values tested	Optimal strategy at lower bound	Value at which this strategy was recorded as optimal	Optimal strategy at upper bound	Value at which this strategy was recorded as optimal	Results
								assessed using the outcome of 'Lifetime NB (20K) - discounted'.
C-Spine Sensitivity	Lifetime NB (20K) - discounted	0	1	11. NEXUS+CT	0.65	8. CCR+CT	0.66	When 'C-Spine Sensitivity' changed value from 0.65 to 0.66, the optimal strategy changed from strategy '11. NEXUS+CT' to '8. CCR+CT'. Optimality was assessed using the outcome of 'Lifetime NB (20K) - discounted'.
C-Spine Specificity	Lifetime NB (20K) - discounted	0	1	11. NEXUS+CT	0.11	8. CCR+CT	0.12	When 'C-Spine Specificity' changed value from 0.11 to 0.12, the optimal strategy changed from strategy '11. NEXUS+CT' to '8. CCR+CT'. Optimality was assessed using the outcome of 'Lifetime NB (20K) - discounted'.
X-ray Sensitivity for bony injury	Lifetime NB (20K) - discounted	0	1	8. CCR+CT	0.900000	13. CCR+X-ray+CT	1.00000	When 'X-ray Sensitivity for bony injury' changed value from 0.9 to 1, the optimal strategy changed from strategy '8. CCR+CT' to '13. CCR+X-ray+CT'. Optimality was assessed using the outcome of 'Lifetime NB (20K) - discounted'.
X-ray Specificity for bony injury	Lifetime NB (20K) - discounted	0	1					The conclusions did not change when the parameter 'X-ray Specificity for bony injury' had values between 0 and 1. Optimality was assessed using the outcome of 'Lifetime NB (20K) - discounted'.
X-ray Sensitivity for	Lifetime NB (20K) -	0	1					The conclusions did not change when the parameter 'X-ray Sensitivity for

Parameter name	Outcome on which optimality was assessed	Lower bound of values tested	Upper bound of values tested	Optimal strategy at lower bound	Value at which this strategy was recorded as optimal	Optimal strategy at upper bound	Value at which this strategy was recorded as optimal	Results
ligamentous injury	discounted							ligamentis injury' had values between 0 and 1. Optimality was assessed using the outcome of 'Lifetime NB (20K) - discounted'.
X-ray Specificity for ligamentous injury	Lifetime NB (20K) - discounted	0	1					The conclusions did not change when the parameter 'X-ray Specificity for ligamentis injury' had values between 0 and 1. Optimality was assessed using the outcome of 'Lifetime NB (20K) - discounted'.
CT Sensitivity for bony injury	Lifetime NB (20K) - discounted	0	1	7. CCR+X-ray	0.60	8. CCR+CT	0.61	When 'CT Sensitivity for bony injury' changed value from 0.6 to 0.61, the optimal strategy changed from strategy '7. CCR+X-ray' to '8. CCR+CT'. Optimality was assessed using the outcome of 'Lifetime NB (20K) - discounted'.
CT Specificity for bony injury	Lifetime NB (20K) - discounted	0	1	14. CCR+CT+MRI	0.85	8. CCR+CT	0.86	When 'CT Specificity for bony injury' changed value from 0.849999 to 0.859999, the optimal strategy changed from strategy '14. CCR+CT+MRI' to '8. CCR+CT'. Optimality was assessed using the outcome of 'Lifetime NB (20K) - discounted'.
CT Sensitivity for ligamentis injury	Lifetime NB (20K) - discounted	0	1					The conclusions did not change when the parameter 'CT Sensitivity for ligamentis injury' had values between 0 and 1. Optimality was assessed using the outcome of 'Lifetime NB (20K) -

Parameter name	Outcome on which optimality was assessed	Lower bound of values tested	Upper bound of values tested	Optimal strategy at lower bound	Value at which this strategy was recorded as optimal	Optimal strategy at upper bound	Value at which this strategy was recorded as optimal	Results
								discounted'.
CT Specificity for ligamentis injury	Lifetime NB (20K) - discounted	0	1	14. CCR+CT+MRI	0.85	8. CCR+CT	0.86	When 'CT Specificity for ligamentis injury' changed value from 0.849999 to 0.859999, the optimal strategy changed from strategy '14. CCR+CT+MRI' to '8. CCR+CT'. Optimality was assessed using the outcome of 'Lifetime NB (20K) - discounted'.
MRI Sensitivity for bony injury	Lifetime NB (20K) - discounted	0	1					The conclusions did not change when the parameter 'MRI Sensitivity for bony injury' had values between 0 and 1. Optimality was assessed using the outcome of 'Lifetime NB (20K) - discounted'.
MRI Specificity for bony injury	Lifetime NB (20K) - discounted	0	1					The conclusions did not change when the parameter 'MRI Specificity for bony injury' had values between 0 and 1. Optimality was assessed using the outcome of 'Lifetime NB (20K) - discounted'.
MRI Sensitivity for ligamentous injury	Lifetime NB (20K) - discounted	0	1					The conclusions did not change when the parameter 'MRI Sensitivity for ligamentis injury' had values between 0 and 1. Optimality was assessed using the outcome of 'Lifetime NB (20K) - discounted'.
MRI Specificity for ligamentous	Lifetime NB (20K) - discounted	0	1					The conclusions did not change when the parameter 'MRI Specificity for ligamentis injury' had values between 0

Parameter name	Outcome on which optimality was assessed	Lower bound of values tested	Upper bound of values tested	Optimal strategy at lower bound	Value at which this strategy was recorded as optimal	Optimal strategy at upper bound	Value at which this strategy was recorded as optimal	Results
injury								and 1. Optimality was assessed using the outcome of 'Lifetime NB (20K) - discounted'.
Probability of conversion if bony injury is missed	Lifetime NB (20K) - discounted	0	1	13. CCR+X-ray+CT	0.000000	8. CCR+CT	0.00200	When 'Probability of conversion if bony injury is missed' changed value from 0 to 0.002, the optimal strategy changed from strategy '13. CCR+X-ray+CT' to '8. CCR+CT'. Optimality was assessed using the outcome of 'Lifetime NB (20K) - discounted'.
Probability of conversion if ligamentis injury is missed	Lifetime NB (20K) - discounted	0	1	8. CCR+CT	0.282000	9. CCR+MRI	0.28400	When 'Probability of conversion if ligamentis injury is missed' changed value from 0.282 to 0.284, the optimal strategy changed from strategy '8. CCR+CT' to '9. CCR+MRI'. Optimality was assessed using the outcome of 'Lifetime NB (20K) - discounted'.
Average life expectancy if no injury (years)	Lifetime NB (20K) - discounted	30	90					The conclusions did not change when the parameter 'Average life expectancy if no injury (years)' had values between 30 and 90. Optimality was assessed using the outcome of 'Lifetime NB (20K) - discounted'.
Average life expectancy if column injury survived (years)	Lifetime NB (20K) - discounted	30	90					The conclusions did not change when the parameter 'Average life expectancy if column injury survived (years)' had values between 30 and 90. Optimality was assessed using the outcome of 'Lifetime NB (20K) - discounted'.

Parameter name	Outcome on which optimality was assessed	Lower bound of values tested	Upper bound of values tested	Optimal strategy at lower bound	Value at which this strategy was recorded as optimal	Optimal strategy at upper bound	Value at which this strategy was recorded as optimal	Results
Average life expectancy if cord injury survived (years)	Lifetime NB (20K) - discounted	30	80	13. CCR+X-ray+CT	30.000000	8. CCR+CT	40.00000	When 'Average life expectancy if cord injury survived (years)' changed value from 30 to 40, the optimal strategy changed from strategy '13. CCR+X-ray+CT' to '8. CCR+CT'. Optimality was assessed using the outcome of 'Lifetime NB (20K) - discounted'.
Probability of developing cancer due to X-ray radiation exposure (lifetime)	Lifetime NB (20k) taking into account radiation exposure - discounted	0	0.00013	13. CCR+X-ray+CT	0.000000	8. CCR+CT	0.00005	When 'Probability of developing cancer due to X-ray radiation exposure (lifetime)' changed value from 0 to 0.00005, the optimal strategy changed from strategy '13. CCR+X-ray+CT' to '8. CCR+CT'. Optimality was assessed using the outcome of 'Lifetime NB (20k) taking into account radiation exposure - discounted'.
Probability of developing cancer due to CT radiation exposure	Lifetime NB (20k) taking into account radiation exposure - discounted	0	0.0022	8. CCR+CT	0.001150	13. CCR+X-ray+CT	0.00120	When ' Probability of developing cancer due to CT radiation exposure' changed value from 0.00115 to 0.0012, the optimal strategy changed from strategy '8. CCR+CT' to '13. CCR+X-ray+CT'. Optimality was assessed using the outcome of 'Lifetime NB (20k) taking into account radiation exposure - discounted'.
Cost of cancer	Lifetime NB (20k) taking into account radiation exposure -	0	100000	8. CCR+CT	35000.00	13. CCR+X-ray+CT	35100.00	When 'Cost of cancer' changed value from 35000 to 35100, the optimal strategy changed from strategy '8. CCR+CT' to '13. CCR+X-ray+CT'. Optimality was assessed using the

Parameter name	Outcome on which optimality was assessed	Lower bound of values tested	Upper bound of values tested	Optimal strategy at lower bound	Value at which this strategy was recorded as optimal	Optimal strategy at upper bound	Value at which this strategy was recorded as optimal	Results
	discounted							outcome of 'Lifetime NB (20k) taking into account radiation exposure - discounted'.
QALY loss per patient with cancer	Lifetime NB (20k) taking into account radiation exposure - discounted	0	15	8. CCR+CT	7.40	13. CCR+X-ray+CT	7.50	When 'QALY loss per patient with cancer' changed value from 7.399995 to 7.499995, the optimal strategy changed from strategy '8. CCR+CT' to '13. CCR+X-ray+CT'. Optimality was assessed using the outcome of 'Lifetime NB (20k) taking into account radiation exposure - discounted'.
Age of diagnosis	Lifetime NB (20k) taking into account radiation exposure - discounted	60	80	13. CCR+X-ray+CT	69.00	8. CCR+CT	70.00	When 'Age of diagnosis' changed value from 69 to 70, the optimal strategy changed from strategy '13. CCR+X-ray+CT' to '8. CCR+CT'. Optimality was assessed using the outcome of 'Lifetime NB (20k) taking into account radiation exposure - discounted'.
Quality of life for no injury (year 1)	Lifetime NB (20K) - discounted	0	1					The conclusions did not change when the parameter 'Quality of life for no injury (year 1)' had values between 0 and 1. Optimality was assessed using the outcome of 'Lifetime NB (20K) - discounted'.
Quality of life for no injury (year 2)	Lifetime NB (20K) - discounted	0	1					The conclusions did not change when the parameter 'Quality of life for no injury (year 2)' had values between 0 and 1. Optimality was assessed using the outcome of 'Lifetime NB (20K) -

Parameter name	Outcome on which optimality was assessed	Lower bound of values tested	Upper bound of values tested	Optimal strategy at lower bound	Value at which this strategy was recorded as optimal	Optimal strategy at upper bound	Value at which this strategy was recorded as optimal	Results
								discounted'.
Quality of life for no injury at end of time horizon	Lifetime NB (20K) - discounted	0	1					The conclusions did not change when the parameter 'Quality of life for no injury at end of time horizon' had values between 0 and 1. Optimality was assessed using the outcome of 'Lifetime NB (20K) - discounted'.
Quality of life for promptly treated column injury (year 1)	Lifetime NB (20K) - discounted	0	1	13. CCR+X-ray+CT	0.60	8. CCR+CT	0.61	When 'Quality of life for promptly treated column injury (year 1)' changed value from 0.6 to 0.61, the optimal strategy changed from strategy '13. CCR+X-ray+CT' to '8. CCR+CT'. Optimality was assessed using the outcome of 'Lifetime NB (20K) - discounted'.
Quality of life for promptly treated column injury (year 2)	Lifetime NB (20K) - discounted	0	1	13. CCR+X-ray+CT	0.49	8. CCR+CT	0.50	When 'Quality of life for promptly treated column injury (year 2)' changed value from 0.49 to 0.5, the optimal strategy changed from strategy '13. CCR+X-ray+CT' to '8. CCR+CT'. Optimality was assessed using the outcome of 'Lifetime NB (20K) - discounted'.
Quality of life for promptly treated column injury at end of time horizon	Lifetime NB (20K) - discounted	0	1	13. CCR+X-ray+CT	0.81	8. CCR+CT	0.82	When 'Quality of life for promptly treated column injury at end of time horizon' changed value from 0.81 to 0.82, the optimal strategy changed from strategy '13. CCR+X-ray+CT' to '8. CCR+CT'. Optimality was assessed using

Parameter name	Outcome on which optimality was assessed	Lower bound of values tested	Upper bound of values tested	Optimal strategy at lower bound	Value at which this strategy was recorded as optimal	Optimal strategy at upper bound	Value at which this strategy was recorded as optimal	Results
								the outcome of 'Lifetime NB (20K) - discounted'.
Quality of life for cord injury (year 1)	Lifetime NB (20K) - discounted	0	1					The conclusions did not change when the parameter 'Quality of life for cord injury (year 1)' had values between 0 and 1. Optimality was assessed using the outcome of 'Lifetime NB (20K) - discounted'.
Quality of life for cord injury (year 2)	Lifetime NB (20K) - discounted	0	1					The conclusions did not change when the parameter 'Quality of life for cord injury (year 2)' had values between 0 and 1. Optimality was assessed using the outcome of 'Lifetime NB (20K) - discounted'.
Quality of life for cord injury (end of time horizon)	Lifetime NB (20K) - discounted	0	1					The conclusions did not change when the parameter 'Quality of life for cord injury (end of time horizon)' had values between 0 and 1. Optimality was assessed using the outcome of 'Lifetime NB (20K) - discounted'.
Quality of life for delayed treatment of column injury (year 1)	Lifetime NB (20K) - discounted	0	1	8. CCR+CT	0.80	13. CCR+X-ray+CT	1.00	When 'Quality of life for delayed treatment of column injury (year 1)' changed value from 0.8 to 1, the optimal strategy changed from strategy '8. CCR+CT' to '13. CCR+X-ray+CT'. Optimality was assessed using the outcome of 'Lifetime NB (20K) - discounted'.
Quality of life	Lifetime NB	0	1	8. CCR+CT	0.800000	13. CCR+X-	1.00000	When 'Quality of life for delayed

Parameter name	Outcome on which optimality was assessed	Lower bound of values tested	Upper bound of values tested	Optimal strategy at lower bound	Value at which this strategy was recorded as optimal	Optimal strategy at upper bound	Value at which this strategy was recorded as optimal	Results
for delayed treatment of column injury (year 2)	(20K) - discounted					ray+CT		treatment of column injury (year 2)' changed value from 0.8 to 1, the optimal strategy changed from strategy '8. CCR+CT' to '13. CCR+X-ray+CT'. Optimality was assessed using the outcome of 'Lifetime NB (20K) - discounted'.
Quality of life for delayed treatment of column injury at end of time horizon	Lifetime NB (20K) - discounted	0	1	8. CCR+CT	0.83	13. CCR+X-ray+CT	0.84	When 'Quality of life for delayed treatment of column injury at end of time horizon' changed value from 0.83 to 0.839999, the optimal strategy changed from strategy '8. CCR+CT' to '13. CCR+X-ray+CT'. Optimality was assessed using the outcome of 'Lifetime NB (20K) - discounted'.
Cost of decision rules	Lifetime NB (20K) - discounted	0	300	8. CCR+CT	41.00	2. CT scan	42.00	When 'Cost of decision rules' changed value from 41 to 42, the optimal strategy changed from strategy '8. CCR+CT' to '2. CT scan'. Optimality was assessed using the outcome of 'Lifetime NB (20K) - discounted'.
Cost of double x-ray	Lifetime NB (20K) - discounted	0	300	13. CCR+X-ray+CT	25	8. CCR+CT	26	When 'Cost of double X-ray' changed value from 25 to 26, the optimal strategy changed from strategy '13. CCR+X-ray+CT' to '8. CCR+CT'. Optimality was assessed using the outcome of 'Lifetime NB (20K) - discounted'.
Cost of CT	Lifetime NB	0	300	13. CCR+X-	249	7. CCR+X-	250	When 'Cost of CT' changed value from

Parameter name	Outcome on which optimality was assessed	Lower bound of values tested	Upper bound of values tested	Optimal strategy at lower bound	Value at which this strategy was recorded as optimal	Optimal strategy at upper bound	Value at which this strategy was recorded as optimal	Results
	(20K) - discounted			ray+CT		ray		249 to 250, the optimal strategy changed from strategy '13. CCR+X-ray+CT' to '7. CCR+X-ray'. Optimality was assessed using the outcome of 'Lifetime NB (20K) - discounted'.
Cost of MRI	Lifetime NB (20K) - discounted	0	300	15. CCR+MRI+CT	72	8. CCR+CT	73	When 'Cost of MRI' changed value from 72 to 73, the optimal strategy changed from strategy '15. CCR+MRI+CT' to '8. CCR+CT'. Optimality was assessed using the outcome of 'Lifetime NB (20K) - discounted'.
Cost of prompt treatment for cord injury	Lifetime NB (20K) - discounted	0	30000					The conclusions did not change when the parameter 'Cost of prompt treatment for cord injury' had values between 0 and 30000. Optimality was assessed using the outcome of 'Lifetime NB (20K) - discounted'.
Average excess bed day for column injury	Lifetime NB (20K) - discounted	0	1000	7. CCR+X-ray	0.000000	8. CCR+CT	100.00000	When 'Average excess bed day for column injury' changed value from 0 to 100, the optimal strategy changed from strategy '7. CCR+X-ray' to '8. CCR+CT'. Optimality was assessed using the outcome of 'Lifetime NB (20K) - discounted'.
Average excess bed day for cord injury	Lifetime NB (20K) - discounted	0	1000					The conclusions did not change when the parameter 'Average excess bed day for cord injury' had values between 0 and 1000. Optimality was assessed using the outcome of 'Lifetime NB (20K)

Parameter name	Outcome on which optimality was assessed	Lower bound of values tested	Upper bound of values tested	Optimal strategy at lower bound	Value at which this strategy was recorded as optimal	Optimal strategy at upper bound	Value at which this strategy was recorded as optimal	Results
								- discounted'.
Subtotal of lifetime cost for cord injury	Lifetime NB (20K) - discounted	0	10000000	13. CCR+X-ray+CT	0.000000	8. CCR+CT	1000000.00000	When 'Subtotal of lifetime cost for cord injury' changed value from 0 to 1000000, the optimal strategy changed from strategy '13. CCR+X-ray+CT' to '8. CCR+CT'. Optimality was assessed using the outcome of 'Lifetime NB (20K) - discounted'.
Additional litigation cost (one time pay out) for column injury	Lifetime NB taking into account litigation for all missed column injuries (20K) - QALYs discounted	0	10000000					The conclusions did not change when the parameter 'Additional litigation cost (one time pay out) for column injury' had values between 0 and 10000000. Optimality was assessed using the outcome of 'Lifetime NB taking into account litigation for all missed column injuries (20K) - QALYs discounted'.
Additional litigation cost (one time pay out) for cord injury	Lifetime NB taking into account litigation for all missed column injuries (20K) - QALYs discounted	0	10000000					The conclusions did not change when the parameter 'Additional litigation cost (one time pay out) for cord injury' had values between 0 and 10000000. Optimality was assessed using the outcome of 'Lifetime NB taking into account litigation for all missed column injuries (20K) - QALYs discounted'.
Prevalence of spinal column injury in presenting ED population	Lifetime NB (20k) taking into account radiation exposure	0	0.9999	9. CCR+MRI	0.0700	8. CCR+CT	0.0800	When 'Prevalence of spinal column injury in presenting ED population' changed value from 0.07 to 0.08, the optimal strategy changed from strategy '9. CCR+MRI' to '8. CCR+CT'. Optimality

Parameter name	Outcome on which optimality was assessed	Lower bound of values tested	Upper bound of values tested	Optimal strategy at lower bound	Value at which this strategy was recorded as optimal	Optimal strategy at upper bound	Value at which this strategy was recorded as optimal	Results
								was assessed using the outcome of 'Lifetime NB (20k) taking into account radiation exposure'.
Proportion of spinal injuries which are bony	Lifetime NB (20k) taking into account radiation exposure	0	0.99	9. CCR+MRI	0.380	8. CCR+CT	0.390	When 'Proportion of spinal injuries which are bony' changed value from 0.38 to 0.39, the optimal strategy changed from strategy '9. CCR+MRI' to '8. CCR+CT'. Optimality was assessed using the outcome of 'Lifetime NB (20k) taking into account radiation exposure'.
Prevalence of spinal column injury in presenting ED population	Lifetime NB (20k) taking into account radiation exposure - discounted	0	0.9999	13. CCR+X-ray+CT	0.0000	8. CCR+CT	0.0100	When 'Prevalence of spinal column injury in presenting ED population' changed value from 0 to 0.01, the optimal strategy changed from strategy '13. CCR+X-ray+CT' to '8. CCR+CT'. Optimality was assessed using the outcome of 'Lifetime NB (20k) taking into account radiation exposure - discounted'.
Proportion of spinal injuries which are bony	Lifetime NB (20k) taking into account radiation exposure - discounted	0	0.99	9. CCR+MRI	0.720	8. CCR+CT	0.730	When 'Proportion of spinal injuries which are bony' changed value from 0.72 to 0.73, the optimal strategy changed from strategy '9. CCR+MRI' to '8. CCR+CT'. Optimality was assessed using the outcome of 'Lifetime NB (20k) taking into account radiation exposure - discounted'.

Appendix M: TARN Immobilisation costing

Using data from the TARN database, we have costed up the different combinations of spinal protection that were employed for all the patients that were identified in TARN as being immobilised in some form. This has been compared to the costs of using 'full immobilisation' on all these patients identified in TARN that had been potentially suspected of a spinal injury.

Criteria to identify patients immobilised in TARN

All patients in TARN database in 2012 (January –December), excluding:

- Patients from foreign hospitals
- Patients classified as not TARN and
- The second record (receiving hospital after a transfer) from the matched cases.

Patients with spinal injuries were selected using Hasler (2012) criteria, including those who had spinal fractures/dislocations (that is, fractures/dislocations of spinal vertebrae, pedicles, facets, laminae or the odontoid) or spinal cord injuries (that is, cord contusions and lacerations and incomplete and complete spinal cord syndromes). Those injured to the brachial plexus, traumatic disc injuries, fractures of the spinous and transverse processes, spinous ligament, nerve root injuries and strains of the spine were excluded.

Data and costings

In Table 34 are the number of patients identified from TARN who were given multiple protections. There were 11,166 patients in TARN during 2012 for which some form of spinal protection was applied.

Table 34: Number of patients who were given multiple protections

Number of different protections	Number of patients	%	Total number of protections	%
1	5234	46.87%	5234	26.77%
2	3914	35.05%	7828	40.04%
3	1628	14.58%	4884	24.98%
4	346	3.10%	1384	7.08%
5+	44	0.39%	220	1.13%
Total	11,166		19550	

In Table 35 are the device costs for the different devices that could be involved in immobilisation, both the unit costs and on a per patient basis.

Table 35: Device costs

Protection device	Unit cost	Cost per use	Source (a)
Spinal board	£195.00	£0.10	EMAS [(a)]
Spinal protection bed	£25,000.00	£12.50	GDG
Head blocks	£41.99	£0.02	EMAS
Spinal collar	£ 4.80	£4.80	EMAS
Vacuum mattress	£444.95	£0.22	EMAS

Protection device	Unit cost	Cost per use	Source (a)
Sand bags and tape[(b)]	£ -	£ -	EMAS
Scoop stretcher	£295.00	£0.15	EMAS
3-point brace	£161.20	£0.08	Patterson medical

Abbreviations: EMAS, East Midlands Ambulance Service; GDG, Guideline Development Group

(a) EMAS costs from personal contact 08/2013.GDG source from personal contact 08/2013. 3 point brace from supplier website in 08/2013

(b) This is a disused method that now involves manual stabilisation and therefore no cost has been applied

(c) Based on the assumption that each device has a lifetime of 2000 uses

Where full spinal protection/immobilisation is referred to, this includes a scoop stretcher, spinal collar, and head blocks (£4.97 in total). The costs of straps have not been included and are likely to be very small on a per patient basis.

The different combinations of spinal protection that were applied to the 11,166 people identified from TARN can be seen below in Table 36. Using the costs per patient of the different devices shown above, the cost per patient for each combination is reported, as well as the total cost for all those patients immobilised with that combination.

Table 36: Different combinations of spinal protection applied

Combination	n	%	Cost of combination per patient	Total cost
Full spinal protection	1614	14.5%	£4.97	£8,021.58
Spinal Board, Spinal Collar	1438	12.9%	£4.90	£7,046.20
Spinal collar and blocks	1224	11.0%	£4.82	£5,899.68
Spinal Collar	948	8.5%	£4.80	£4,550.40
Spinal Board, Spinal collar and blocks	698	6.3%	£4.92	£3,434.16
Spinal Board	651	5.8%	£0.10	£65.10
Log Roll	504	4.5%	0	£0.00
Log Roll, Spinal Board, Spinal Collar	429	3.8%	£4.90	£2,102.10
Full spinal protection, Log Roll	310	2.8%	£4.97	£1,540.70
Log Roll, Spinal Board, Spinal collar and blocks	295	2.6%	£4.92	£1,451.40
Spinal Collar, Vacu-mattress	216	1.9%	£5.02	£1,084.32
Log Roll, Spinal Collar	214	1.9%	£4.80	£1,027.20
Spinal Board, Spinal Collar, Spinal collar and blocks [(a)]	196	1.8%	£4.92	£964.32
Log Roll, Spinal collar and blocks	172	1.5%	£4.82	£829.04
Vacu-mattress	163	1.5%	£0.22	£35.86
Log Roll, Spinal Board	113	1.0%	£0.10	£11.30
Full spinal protection, Spinal Board, Spinal Collar	112	1.0%	£4.97	£556.64
Spinal Collar, Spinal collar and blocks [(a)]	111	1.0%	£4.82	£535.02
Other with less than 100 events (148 combinations) [(b)]	1758	15.7%	£4.97	£8,737.26
TOTALS	**11166**			**£47,892.28**

(a) The titles of the combination are reported as provided by TARN. Spinal collar has only been included in the cost once.

(b) As the events are not described, the cost of full spinal immobilisation as mentioned above has been used here to be conservative.

Table 37: Total TARN population cost and comparative scenarios

	Total cost	Cost per person
TARN data	£47,892.28	£4.29

	Total cost	Cost per person
Full immobilisation for all	£55,495.02	£4.97
Full immobilisation including vacuum mattress	£57,951.54	£5.19
Full immobilisation including staff time (a)	£71,685.72	£6.42
Full immobilisation including staff time and vacuum mattress	£74,142.24	£6.64

(a) The cost per minute of staff time is calculated from the salary of a paramedic and an emergency care assistant (based on the banding from the NHS agenda for change bands 2013/14) divided by working hours. It is assumed that one paramedic and one emergency care assistant would be present, and immobilisation would take an estimated 4 minutes (GDG opinion. This gives a cost of immobilisation of £1.45

Appendix N: Research recommendations

N.1 Dislocation

Research question: What is the clinical and cost effectiveness of emergency reduction of cervical spinal dislocations following acute traumatic cervical spinal cord injury?**Why this is important:** Half of all traumatic spinal cord injuries involve the cervical spinal cord, and a large proportion of these are caused by cervical spinal dislocation. Cervical spinal cord injury caused by traumatic cervical spinal dislocation produces permanent disability. The greater the permanent neurological impairment the greater the disability. A high level of disability is associated with less independence, fewer opportunities for a full life, reduced prospects for employment and a shorter life expectancy. Any intervention that improves the neurological outcome in this group of people will improve all of these adverse outcomes.

Criteria for selecting high-priority research recommendations:

PICO question	What is the clinical and cost effectiveness of emergency reduction of cervical spinal dislocations following acute traumatic cervical spinal cord injury? (including method of reduction, timing and by whom)
Importance to patients or the population	Patients with permanent cervical spinal cord injury need care and equipment. Their opportunities for employment and engagement in life are reduced. They experience pain and impairment of mobility, bladder, bowel and sexual function. They are at risk of complications of their cervical spinal cord injury. Their life expectancy is reduced. Numerous studies have demonstrated that the less the degree of permanent cervical spinal cord neurological impairment the less the extent of all these adverse features in these patients.
Relevance to NICE guidance	The production of high quality research in this area could inform the clinical practice of major trauma centres in terms of the importance or otherwise of emergency cervical spinal reduction in cases of acute traumatic cervical spinal injury).
Relevance to the NHS	The less the permanent neurological impairment that remains following acute traumatic cervical spinal cord injury the less the impact on the NHS for first-admission care, for readmissions for the treatment of complications and for the provision of continuing health care in the community. The morale of staff is improved when patients are less dependent, less disabled, more engaged in life and achieve more, including returning to work.
National priorities	The National Service Framework (NSF) for Long-Term Conditions Quality Requirement 3 states: “People needing hospital admission for a neurosurgical or neurological emergency are to be assessed and treated in a timely manner by teams with the appropriate neurological and resuscitation skills and facilities”.
Current evidence base	A study of 113 acute traumatic cervical spinal cord rugby injuries showed that cervical spinal reduction within 4 hours of injury was associated with significantly better neurological outcomes than reduction after 4 hours (Newton et al. J. Bone Joint Surg Br 2011; 93-B: 1646-52). This single study is insufficient to draw firm conclusions on the neurological importance or otherwise of reduction of cervical spinal dislocations within 4 hours of acute traumatic cervical spinal cord injury. First the study had high levels of selection bias due to a lack of measures to reduce confounding, such as randomisation or multivariable analysis. Second the neurological assessment tool, the Frankel grade, is crude compared with the more quantitative motor and sensory scores that the modern AIS system allows. Third the implications for current practice of introducing emergency as

	compared with non-emergency cervical spinal reduction within the recently developed England Major Trauma System are unclear.
Equality	This question would address the needs of people with acute traumatic cervical spinal cord injury caused by acute traumatic cervical spinal dislocation.
Study design	The lack of large numbers of patients with this condition means that a multi-centre study will be required. The implication from the Newton study that emergency reduction can have significant neurological benefits precludes the study from being randomised. The centres concerned must have the capability for accurate neurological assessment using the AIS system, for full radiological evaluation of the injured spine and for carrying out cervical spinal reductions, either closed or open or both. All major trauma centres will have these capabilities and so could become part of the study. Only those centres to which acute traumatic spinal cord injured patients are currently taken can be part of this study. A prospective study that includes all acute traumatic cervical spinal cord injured persons in whom an accurate emergency AIS motor and sensory score can be obtained could be included. The study will need to address all plausible confounders and consider them in a multivariable analysis.
Feasibility	The incidence of traumatic cervical spinal injury in England is 350 per annum. A number of years would probably be required to arrive at a conclusion on the benefit or otherwise of emergency cervical spinal reduction in cases of acute traumatic cervical spinal injury. The costs would be those currently incurred in treating acute traumatic cervical spinal cord injured patients. Those contributing centres that chose to include closed reduction as one of their treatment options would have cervical traction equipment and traction application skills as part of their system of care. If they decided in addition to use specialised equipment, such as a specialized bed that has been developed to facilitate emergency closed cervical spinal reduction, then this would be an additional capital cost. This bed could be used for other purposes when not being used for closed reduction, and so would save the cost of a standard bed elsewhere. It would be necessary to ensure that those major trauma centres that chose to have such a bed also had adequate training in its use.
Other comments	All acute traumatic cervical spinal cord injured patients who can be examined satisfactorily using the AIS scale could be included in the study. All major trauma centres are expected to be competent to carry out an AIS assessment in acute spinal patients soon after arrival in the Emergency Department. All traumatic cervical spinal cord injured patients who have a cervical spinal dislocation are currently offered a spinal reduction. The single parameter that this study will assess is whether the timing of the cervical reduction has an impact on long-term neurological outcome.
Importance	• High: the research is essential to inform future updates of key recommendations in the guideline.

N.2 Neuropathic pain relief

Research question: Does early treatment with a centrallyacting analgesic (for example pregabalin) reduce the frequency or severity of neuropathic pain in people with spinal cord injury?

Why this is important: Neuropathic pain occurs in 40% of people with spinal cord injury. It can be severe and disabling, and in people with spinal cord injury it can lead to further impairment of function. Having neuropathic pain can also result in increased care needs and costs of care, and make it difficult to find employment. It also increases the risk of significant depressive illness and suicide. Research is needed to address whether early treatment of spinal cord injury with a centrally acting analgesic such as pregabalin might reduce the frequency or severity of neuropathic pain.

Criteria for selecting high-priority research recommendations:

PICO question	Does early treatment with a centrally-acting analgesic (for example, pregabalin) reduce the frequency and/or severity of neuropathic pain in spinal cord injury patients?
Importance to patients or the population	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 sub-optimal following onset. Research into this area may therefore make a significant difference to the quality of life in people with SCI.
Relevance to NICE guidance	The efficacy of prophylaxis for neuropathic pain was highlighted as a priority by stakeholders during guideline scoping.
Relevance to the NHS	Any reductions in the development of neuropathic pain will reduce the need for potentially costly follow up.
National priorities	None
Current evidence base	One study investigating the prevention of neuropathic pain in patients with acute spinal cord injury has been identified. The comparison was between Carbamazepine and placebo and no other studies comparing other preparations were identified. The study was free from risk of bias, but because of a small sample size there was high imprecision. Hence although point estimates indicated a possible benefit for Carbamazepine there was too much uncertainty about the true direction of effect to allow safe conclusions to be drawn. In addition, the control group rate of neuropathic pain, in their experience, was not representative of background rate of neuropathic pain in spinal cord injury patients, suggesting that this may be a specific, narrower population than suggested. Finally, 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. In summary, because of the limitations of the current evidence base, further research is required in this area, evaluating other commonly used medications such as pregabalin or gabapentin as well as carbamazepine.
Equality	This research would address the needs of a large proportion of people with spinal cord injury
Study design	A randomised controlled trial would be the most rigorous approach. This would be highly feasible, although the need for informed consent would mean that eligibility would be restricted to patients who are fully conscious. Because prophylactic strategies are not currently established there would be few ethical issues in randomising participants to a placebo group, particularly if this research were conducted in settings where prophylaxis is not currently practiced.
Feasibility	This would be a highly feasible study. The current evidence base suggests that a sample size in excess of 100 would be required for sufficient statistical power. This may mean that any study will need to be multi-centre and continue for several years in order to recruit enough participants.
Other comments	None
Importance	• High: Neuropathic pain after spinal cord injury has devastating effects on patients and there is a need to research new methods to prevent it.

N.3 Clinical assessment of the thoracic and lumbar spine

Research question: 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?

Why this is important: Injuries to the thoracic and lumbar spine are associated with significant morbidity and can be associated with relatively minor mechanisms of injury. This is a particular problem in older people where such can have a significant impact on their mobility, functional status and level of independence.

Criteria for selecting high-priority research recommendations:

PICO question	Following injury what is the best method of clinical assessment to to exclude injury to column or cord and thus determine who requires imaging of the thoracic and lumbar spine and who is safe to be discharged without risk of missing significant injury.
Importance to patients or the population	Injuries to the thoracic and lumbar spine are associated with significant morbidity and can be associated with relatively minor mechanisms of injury. This is a particular problem in the elderly where injuries of this sort can have significant impact on patients' mobility, functional status and level of independence. Missed unstable injuries of the spinal column can have catastrophic implications to the patient so any recommended assessment tool must have a very high sensitivity. Currently there is no well documented guidance to support clinicians and improve patient safety. Good clinical evidence in this area to support decision making is likely to be of great assistance to clinicians and patients and is likely to reduce missed diagnosis and the attendant suffering for patients and cost to health systems. There could also be significant reductions of unnecessary imaging with associated reduction of exposure to ionising radiation for patients.
Relevance to NICE guidance	Though good quality clinical evidence exists to support decision making around the need to image the cervical spine there is paucity of evidence that relates to the thoracic and lumbar spine. Answering this clinical question would have an enormous impact on future iterations of the NICE guidance relating to spinal injury.
Relevance to the NHS	The lack of good quality evidence in this area has led to a wide variation in individual practice across clinicians and between hospitals. It also leads to delays in decision making, pressure on experienced staff to manage these cases, costly unnecessary imaging and missed injuries. The NHS including the those working in the area of pre-hospital care would benefit from clear guidance.
National priorities	N/A
Current evidence base	The current evidence base does not offer any standardised method of clinical examination to establish who can be clinically "cleared"; that is, which can show who requires no imaging of the thoracic and lumbar spine and who needs imaging.
Equality	This research is likely to particularly benefit the elderly who are often prone to falls and fractures.
Study design	There are two possible ways to establish the evidence base for decision making in potential thoracic and lumbar spine injuries. 1. Conduct a large scale cohort study, using a logistic regression to elucidate the factors on admission that are associated with the outcome of later clinical findings of a thoracic/lumbar injury. The beta co-efficients in the regression equation would directly inform the weightings in the derived diagnostic algorithm. This diagnostic algorithm would then require external validation in a separate study.

	2. Formulate a diagnostic algorithm from existing evidence and clinical experience and test this in an external validation study. External validation in both methods would involve assessing the diagnostic accuracy of the algorithm (with a set threshold) against a gold standard, which would be later clinical findings, including imaging and surgical findings. The diagnostic accuracy of multiple thresholds of the algorithm would be assessed using ROC curves. The second method should be the first to attempt, as if this is adequately predictive then there is no need to attempt the former method, which will involve two studies and take longer to carry out. The derived algorithm is only likely to apply to patients who are alert and orientated and able to comply with examination and assessment. With this in mind it will not answer the clinical question for all patient groups.
Feasibility	The study design is feasible but would require a large scale, multi-centred study/studies. There are no significant technical issues with conducting research in this area. Though there are no significant technical issues with conducting research in this area ethically there may be concerns about exposure of participants to unnecessary radiation when all patients (including those that in the normal course of events would not be given imaging) are subject to the gold standard test. Given patients the option to decline participation is of course mandatory but this may lead to bias in patient selection. With this in mind using plain x-ray instead of CT may be preferable as it is associated with a lower exposure to radiation.
Other comments	N/A
Importance	This research recommendation is categorised as of high importance to the guideline as the research is essential to inform future updates of key recommendations in the guideline in relation to diagnosis of injuries to the thoracic and lumbar spine.

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Appendix O: NICE Technical team

Name	Role
Sharon Summers-Ma	Guideline Lead
Phil Alderson	Clinical Advisor
Nichole Taske	Clinical Lead
Paul Crossland	Health Economist
Ben Doak	Guideline Commissioning Manager
Thomas Feist	Guideline Coordinator
Annette Mead	Editor

Appendix P: Qualitative study checklist (per theme)

Question	Study 1 (ref id)	Study 2 (ref id)	Study 3 (ref id)	Study 4 (ref id)	Overall limitations per theme
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?					
OVERALL LIMITATIONS per theme **No limitations/ Minor limitations/ Major limitations**					**Major limitations**

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