National Clinical Guideline Centre

DRAFT FOR CONSULTATION

Major trauma: assessment and initial management

Major trauma: assessment and management of major trauma

Clinical guideline <...>

Appendices J-R

August 2015

Draft for consultation

Commissioned by the National Institute for Health and Care Excellence

Royal College of Physicians

The Royal College of Surgeons of England

RCGP Royal College of General Practitioners

Royal College of Nursing

NICE accredited

1

Funding
National Institute for Health and Care Excellence

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J.1.1 Pre-hospital chest imaging

Figure 1: Forest plot for pre-hospital eFAST in detecting pneumothorax only (gold standard=CT, chest radiography and clinical evaluation)

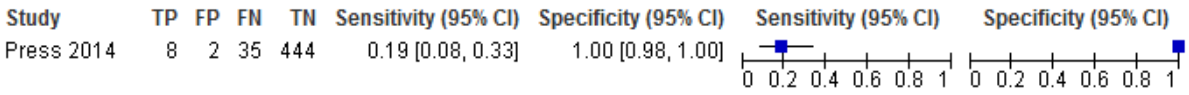
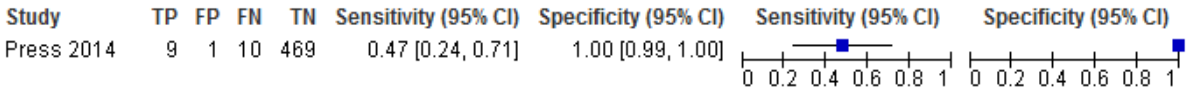


Figure 2: Forest plot for pre-hospital eFAST in detecting pneumothorax requiring intervention [thoracostomy or thoracotomy] (gold standard=CT, chest radiography and clinical evaluation)



J.2 Imaging assessment of chest trauma

Figure 3: Forest plot for hospital eFAST in detecting tension pneumothorax only (gold standard=CT)

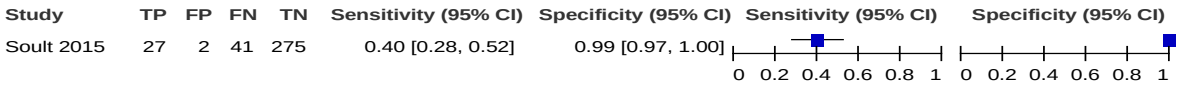


Figure 4: Forest plot for hospital X-ray in detecting tension pneumothorax only (gold standard=CT)

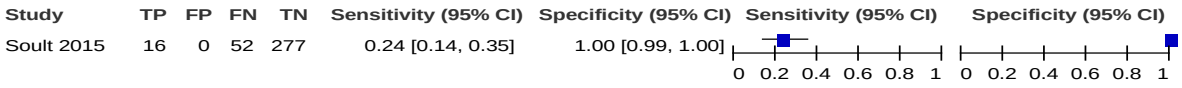


Figure 5: Forest plot for US in detecting pneumothorax (gold standard=CT)

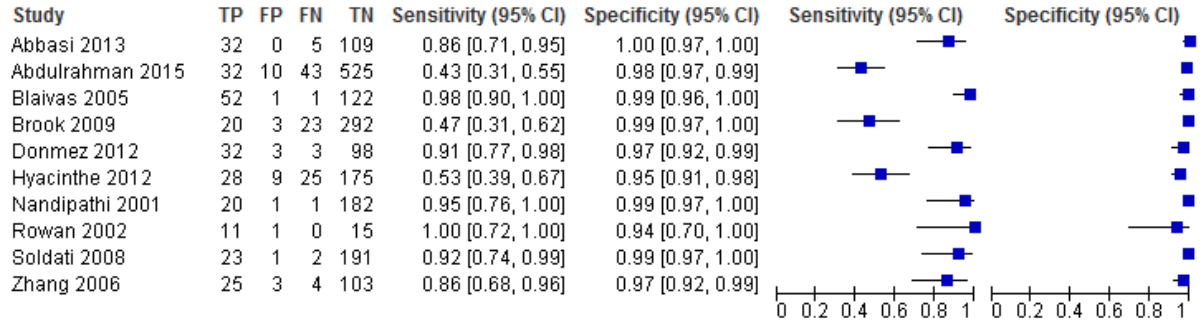


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Figure 6: Forest plot for X-ray in detecting pneumothorax (gold standard=CT)

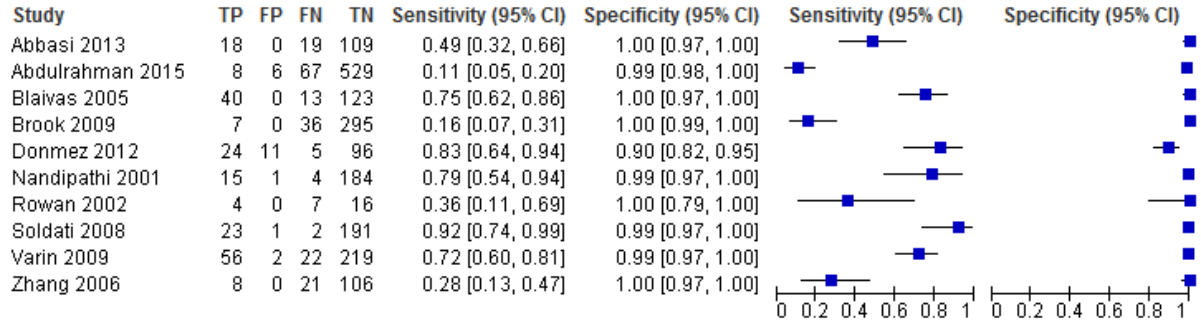

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Figure 7: Forest plot for US in detecting haemothorax (gold standard=CT)

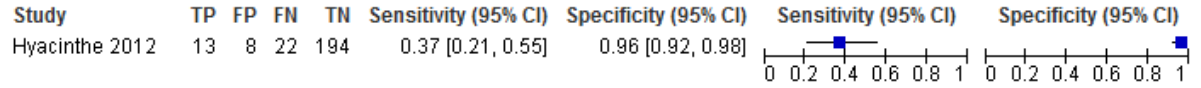

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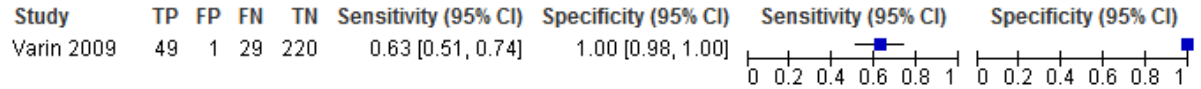
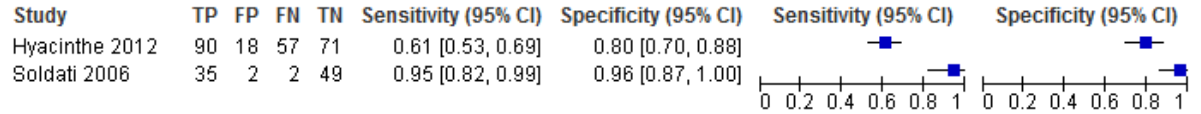
Figure 8: Forest plot for X-ray in detecting haemothorax (gold standard=CT)



Note: Although 5 studies investigated this, only the two below provided sufficient raw data for a forest plot to be produced.

4

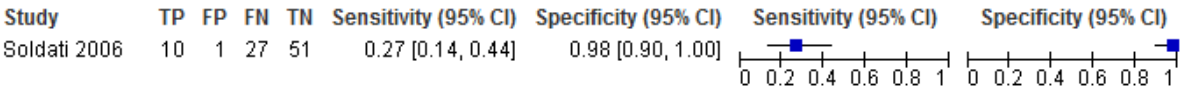
Figure 9: Forest plot for US in detecting pulmonary contusion (gold standard=CT)



Note: Although 3 studies investigated this, only these two studies provided sufficient raw data for a forest plot to be produced.

5

Figure 10: Forest plot for X-ray in detecting pulmonary contusion (gold standard=CT)



Note: Although 3 studies investigated this, only this one study provided sufficient raw data for a forest plot to be produced.

Figure 11: Forest plot for CT in detecting aortic injury (gold standard=aortography)

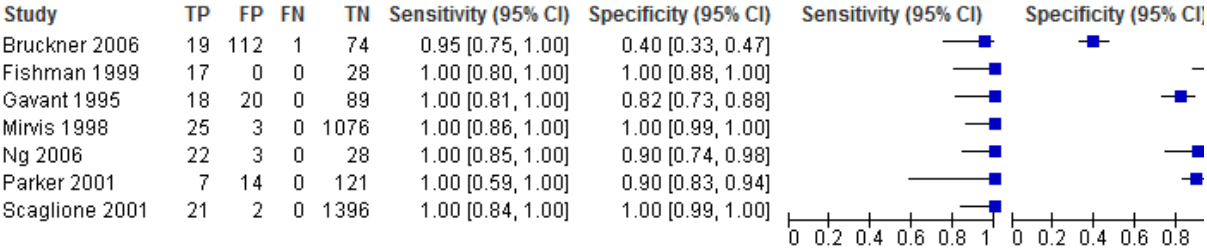
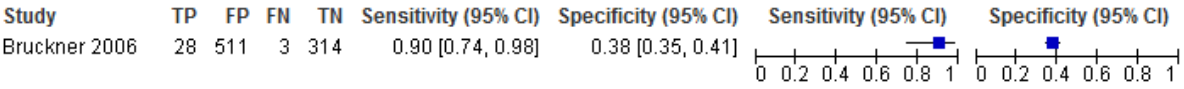


Figure 12: Forest plot for X-ray in detecting aortic injury (gold standard=aortography)



Note: Although 3 studies investigated this, only this one study provided sufficient raw data for a forest plot to be produced.

J.3 Assessment and management of haemorrhage

J.3.1 Pelvic binders

J.3.1.1 Pelvic binders versus no binder

Figure 13: Unadjusted Mortality rate (in-hospital setting)

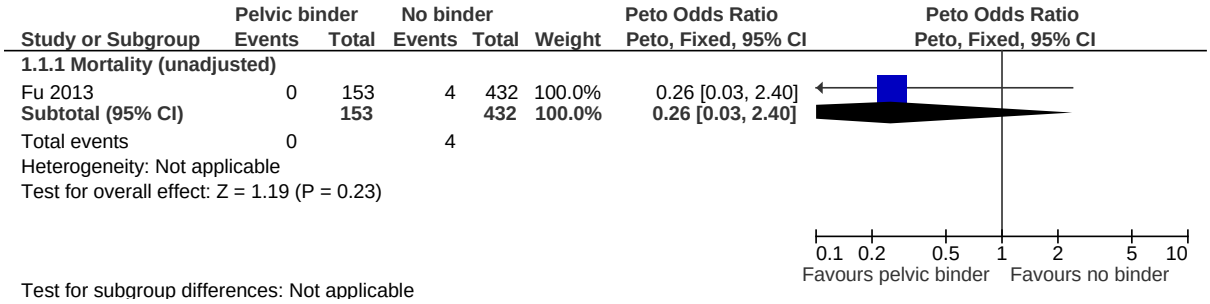


Figure 14: Adjusted Mortality rate (in-hospital setting)

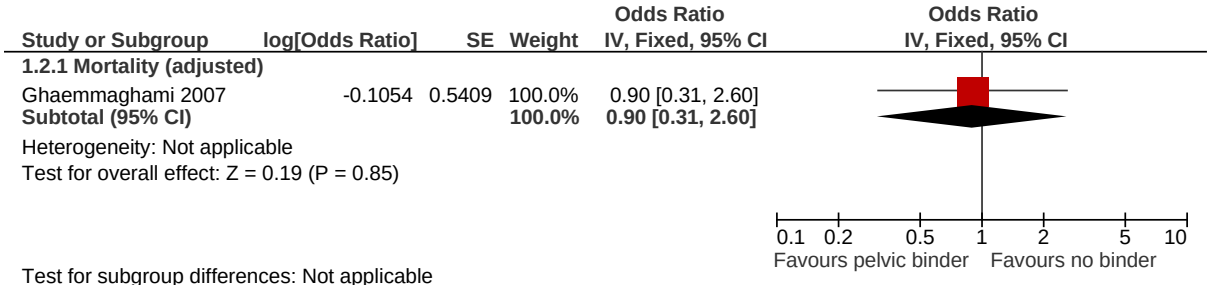


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Figure 15: Volume of blood (pRBC) transfused (pre-hospital and in-hospital setting)

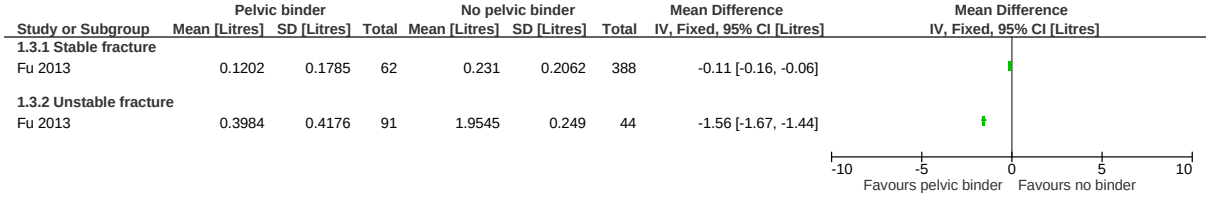

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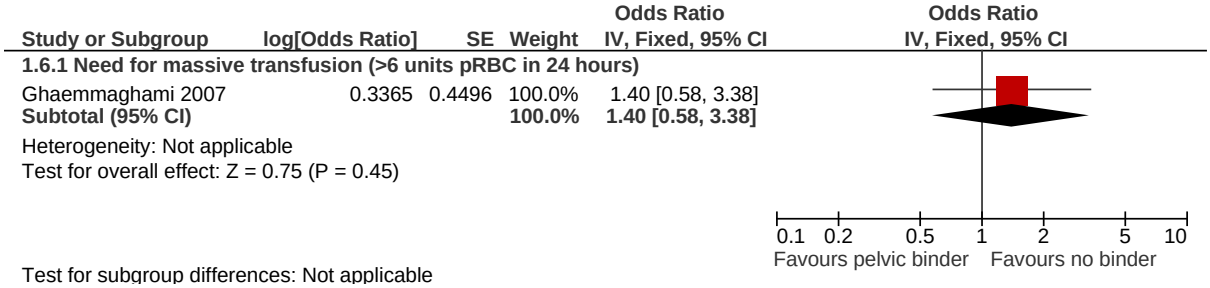
Figure 16: Need for massive transfusion



3 **J.3.2 Haemostatic agents**

4 **J.3.2.1 Tranexamic acid versus standard care**

Figure 17: Mortality

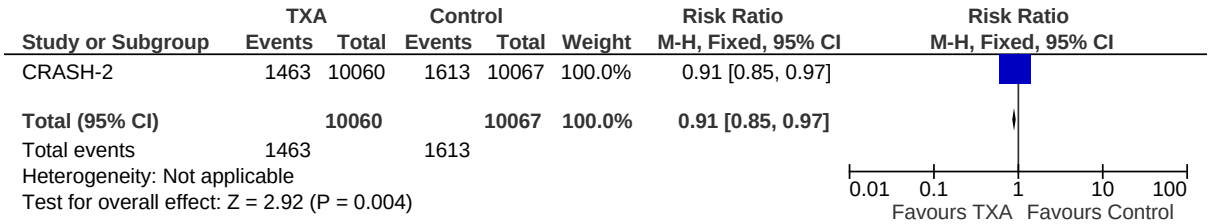


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Figure 18: MI or stroke

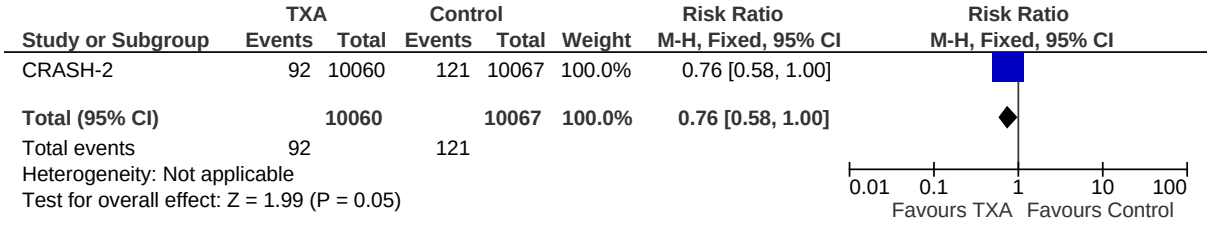

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Figure 19: Pulmonary embolus

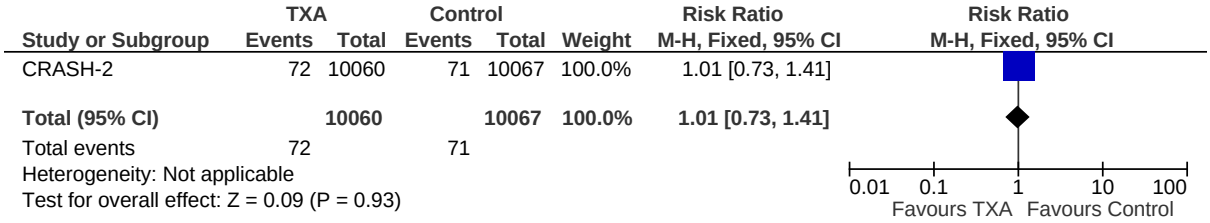

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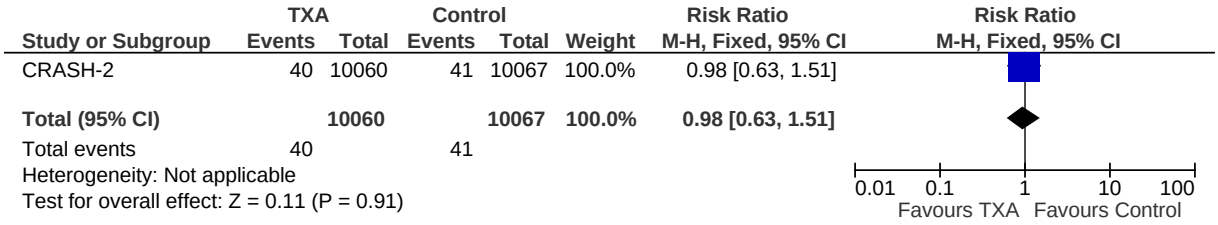
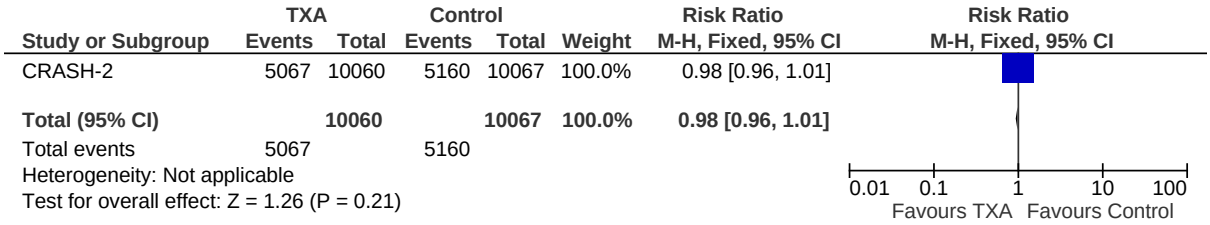
Figure 20: Deep vein thrombosis



3

Figure 21: Blood products transfusion



J.3.2.2 Recombinant factor VIIa versus standard care

Figure 22: Mortality

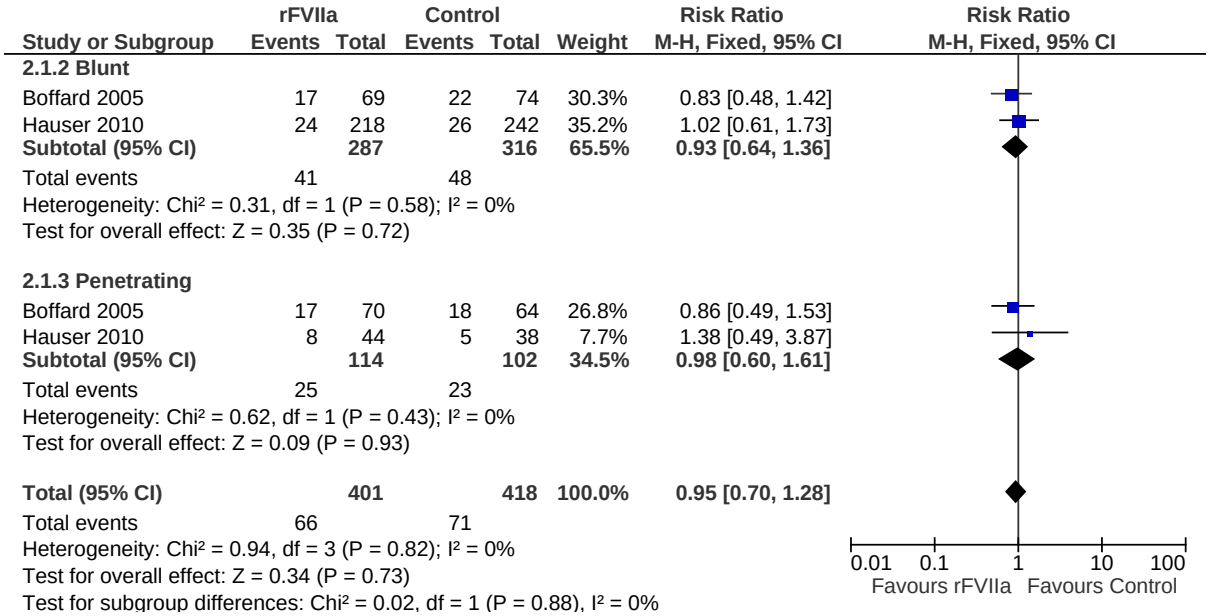


Figure 23: MI or stroke

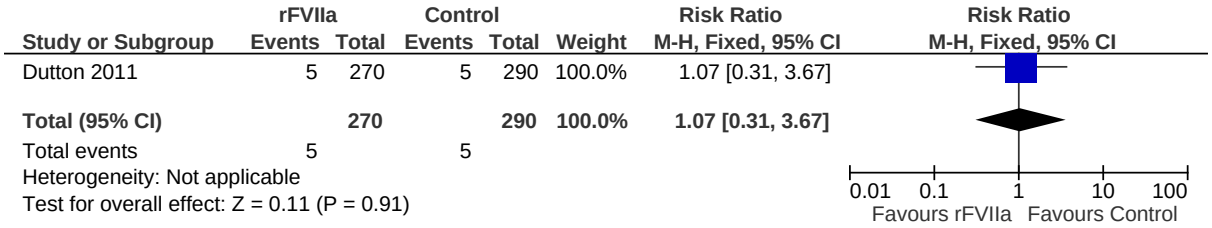


Figure 24: Venous thromboembolic adverse events - Blunt (due to heterogeneity blunt and penetrating are reported separately for this outcome)

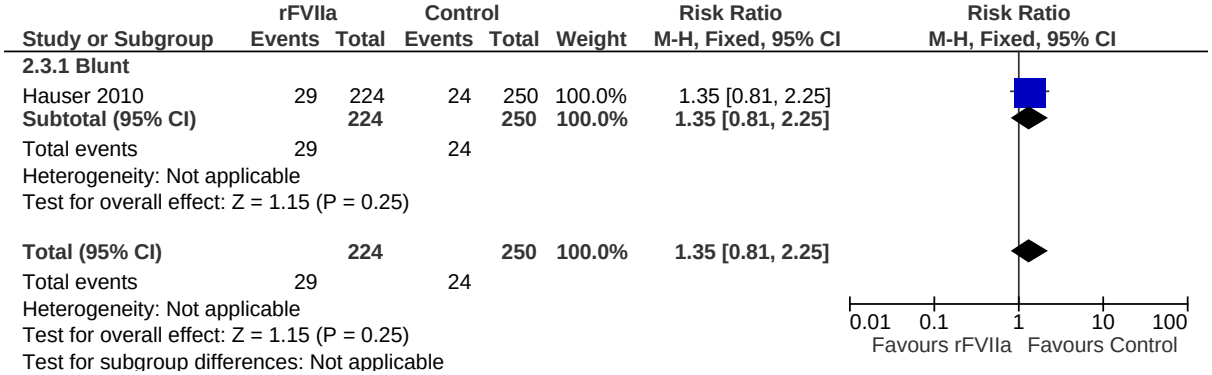
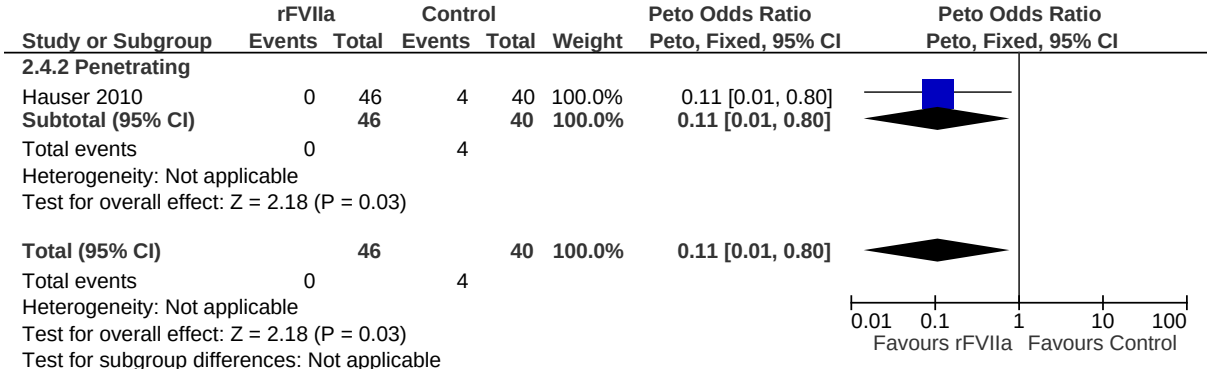


Figure 25: Venous thromboembolic adverse events - Penetrating



1

Figure 26: Pulmonary embolism

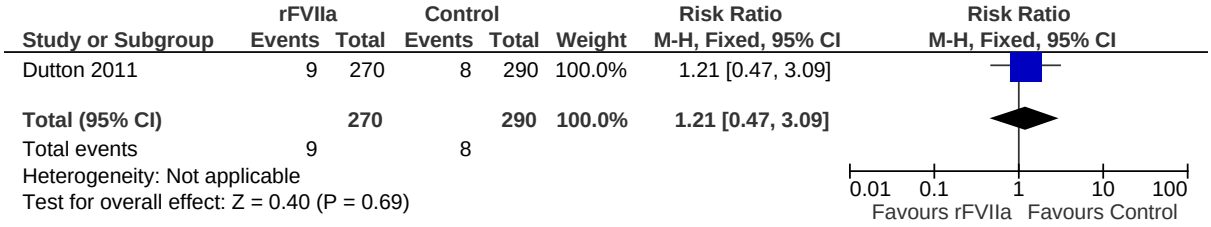


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Figure 27: Thrombotic adverse events

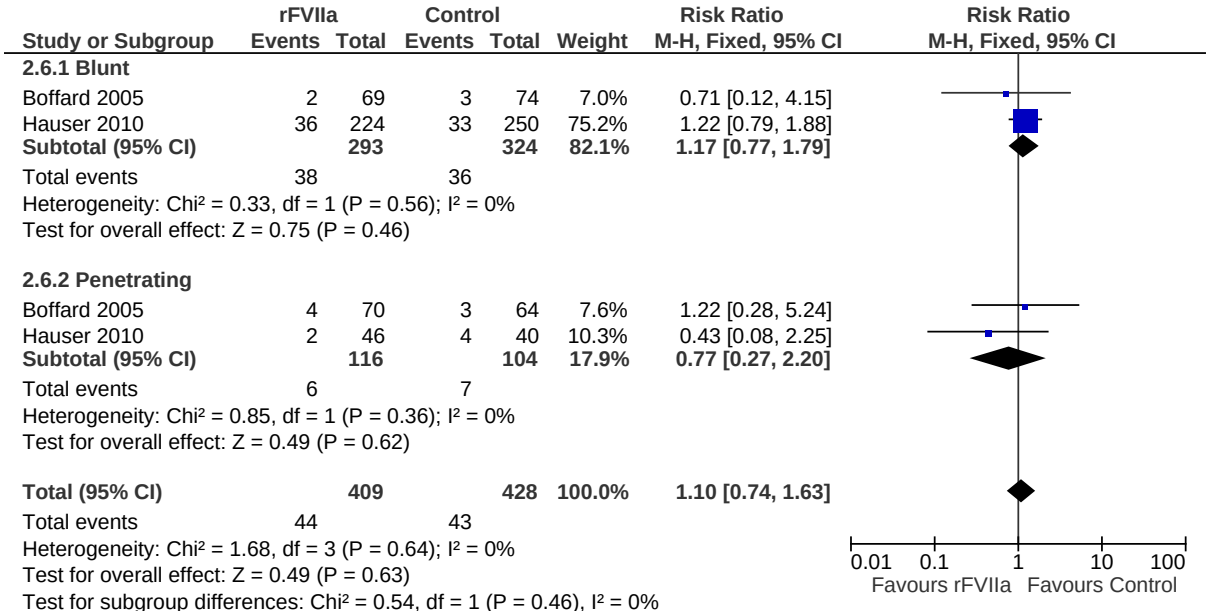

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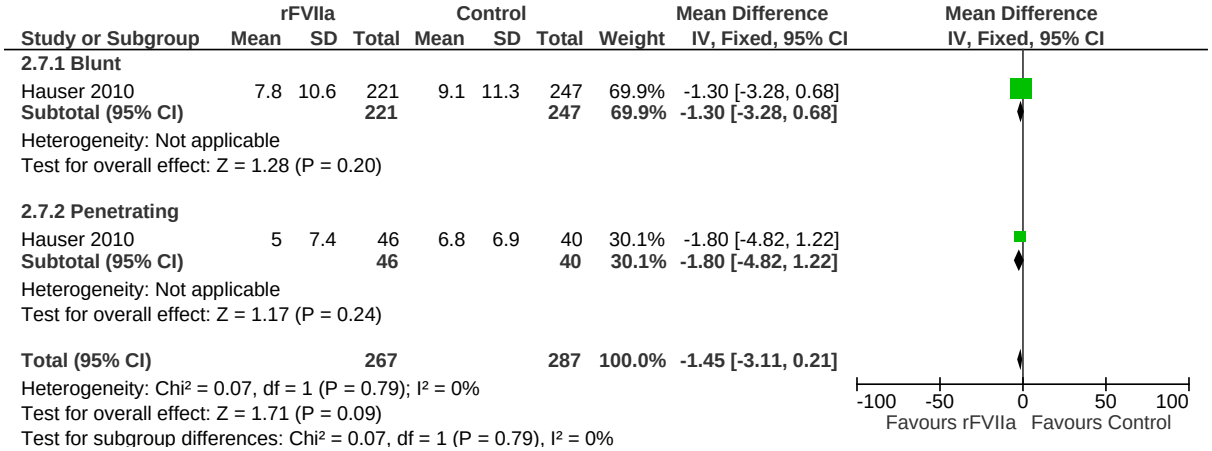
Figure 28: Red blood cells



1

Figure 29: Platelets

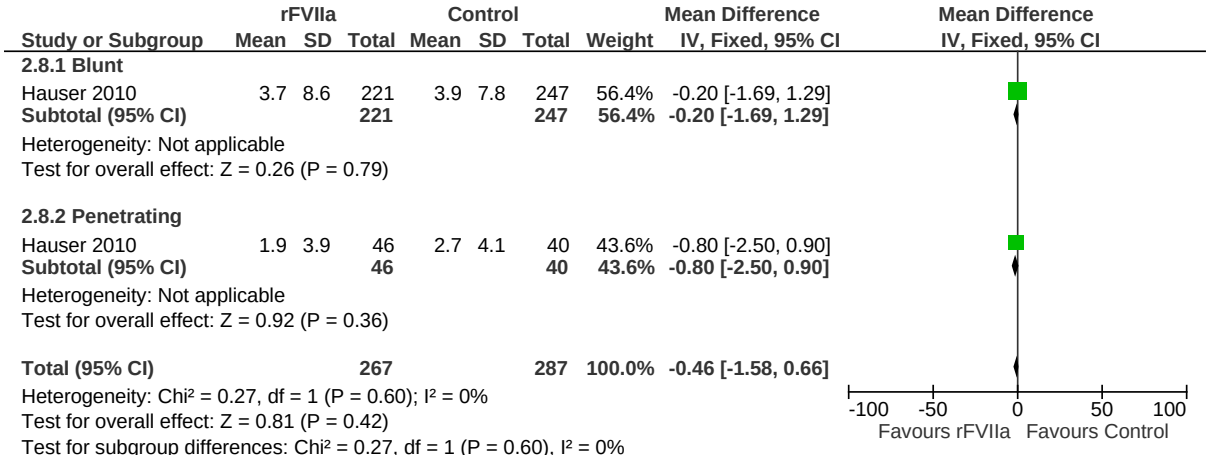


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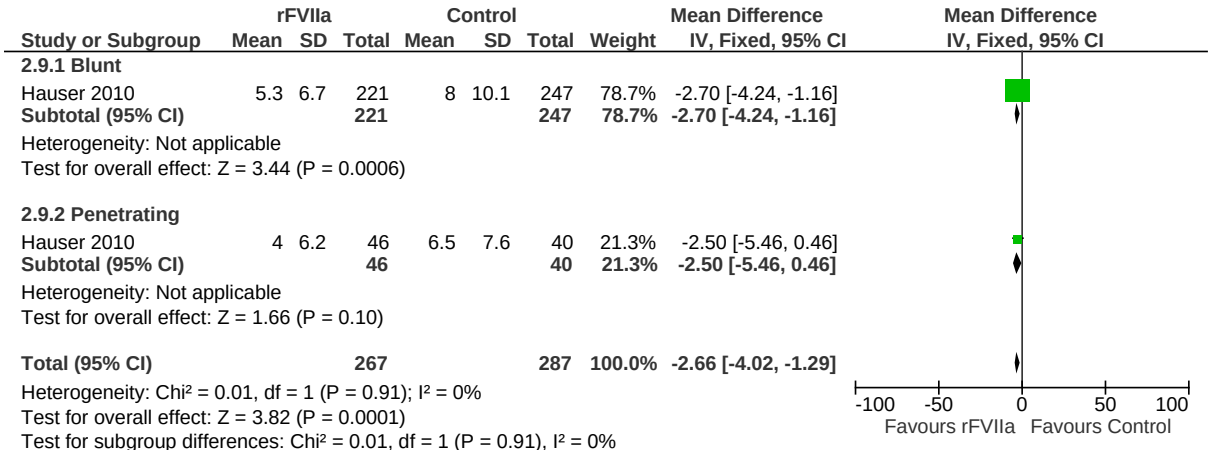
Figure 30: Fresh frozen plasma



3

Figure 31: Cryoprecipitate

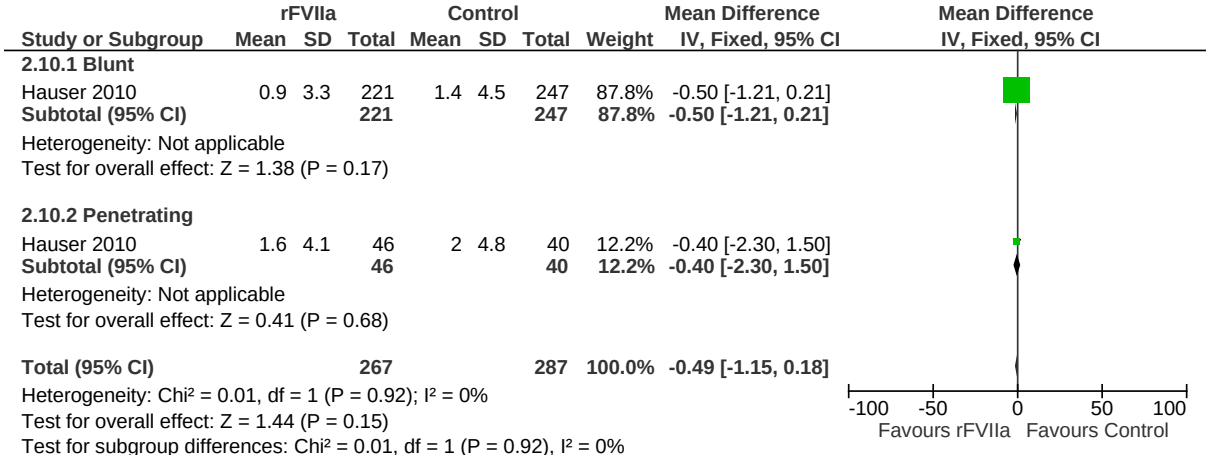
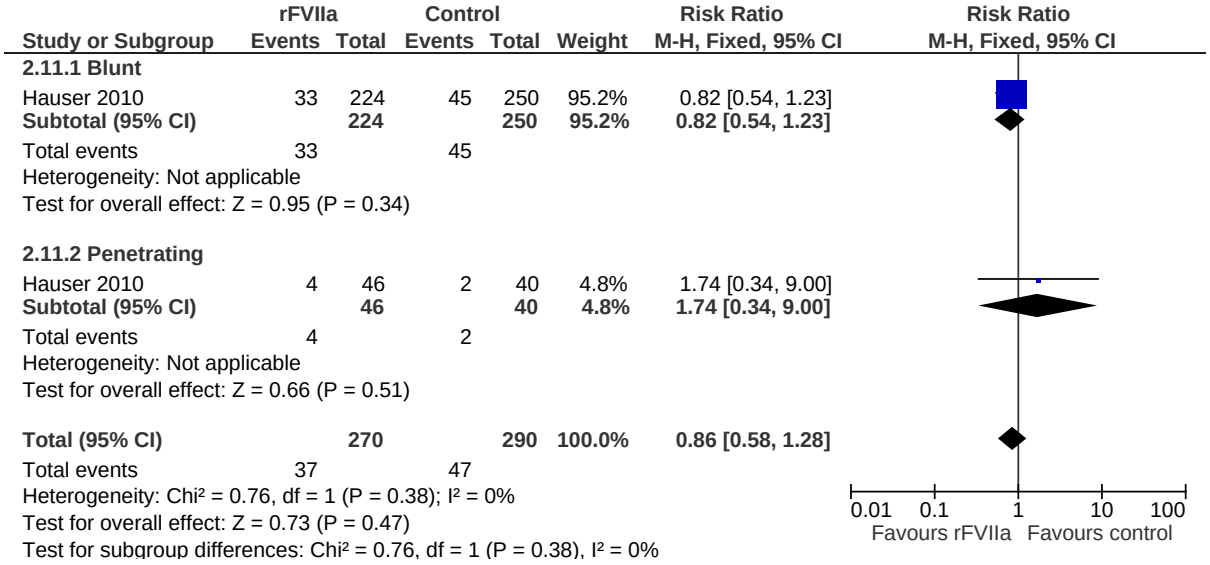


Figure 32: Sepsis



J.3.3 Haemorrhage shock prediction/risk tools

J.3.3.1 ABC

Figure 33: Forest plot of 1 ABC.

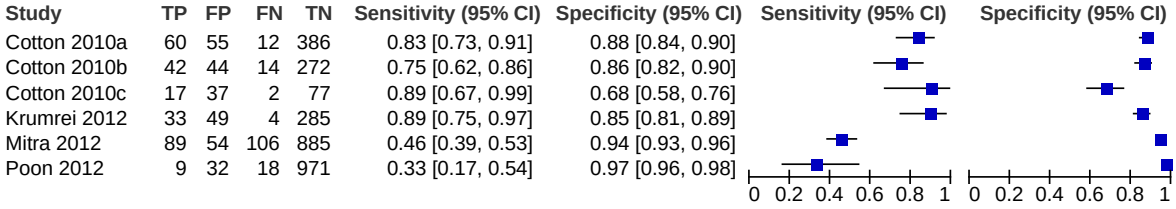
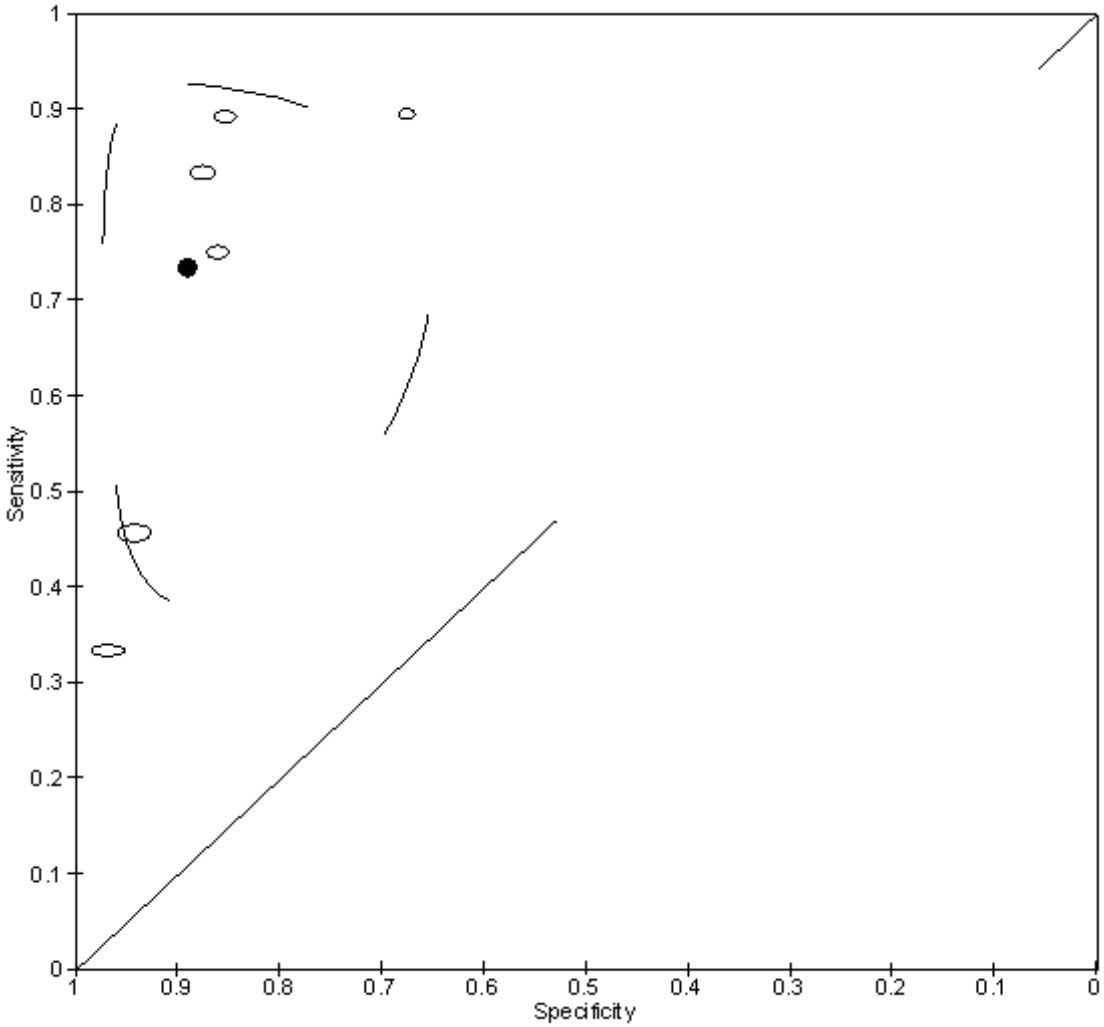
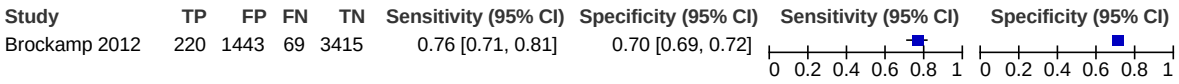


Figure 34: Summary Plot of 1 ABC



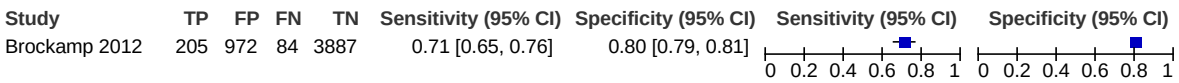
1 **J.3.3.2 ABC threshold 0.5 or more**

Figure 35: ABC threshold 0.5 or more



2 **J.3.3.3 Larson**

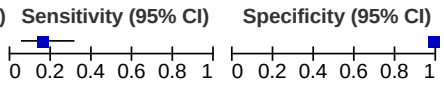
Figure 36: Forest plot of 2 Larson



1 **J.3.3.4 McLaughlin**

Figure 37: Forest plot of 3 McLaughlin

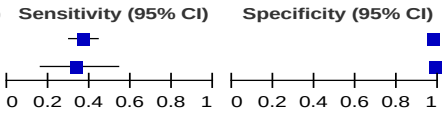
Study	TP	FP	FN	TN	Sensitivity (95% CI)	Specificity (95% CI)
Krumrei 2012	6	6	32	328	0.16 [0.06, 0.31]	0.98 [0.96, 0.99]



2 **J.3.3.5 PWH/Rainer**

Figure 38: Forest plot of 5 PWH'/Rainer

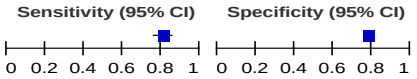
Study	TP	FP	FN	TN	Sensitivity (95% CI)	Specificity (95% CI)
Mitra 2012	72	27	123	912	0.37 [0.30, 0.44]	0.97 [0.96, 0.98]
Poon 2012	9	18	18	985	0.33 [0.17, 0.54]	0.98 [0.97, 0.99]



3 **J.3.3.6 PWH/Rainer threshold 2.5**

Figure 39: PWH/Rainer threshold 2.5

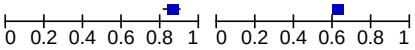
Study	TP	FP	FN	TN	Sensitivity (95% CI)	Specificity (95% CI)
Brockamp 2012	234	1069	55	3789	0.81 [0.76, 0.85]	0.78 [0.77, 0.79]



4 **J.3.3.7 Schreiber**

Figure 40: Forest plot of 6 Schreiber.

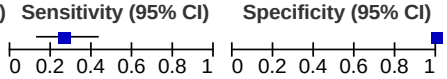
Study	TP	FP	FN	TN	Sensitivity (95% CI)	Specificity (95% CI)
Brockamp 2012	249	1846	41	3012	0.86 [0.81, 0.90]	0.62 [0.61, 0.63]



5 **J.3.3.8 TASH 80% probability of massive transfusion**

Figure 41: Forest plot of 8 TASH 80% probability of MT

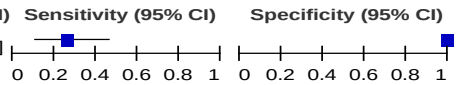
Study	TP	FP	FN	TN	Sensitivity (95% CI)	Specificity (95% CI)
Krumrei 2012	10	1	28	334	0.26 [0.13, 0.43]	1.00 [0.98, 1.00]



6 **J.3.3.9 Modified TASH threshold 16**

Figure 42: Forest plot of 9 Modified TASH threshold 16.

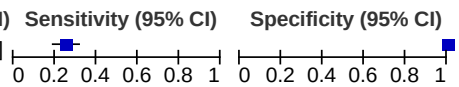
Study	TP	FP	FN	TN	Sensitivity (95% CI)	Specificity (95% CI)
Poon 2012	7	8	20	995	0.26 [0.11, 0.46]	0.99 [0.98, 1.00]



7 **J.3.3.10 Modified TASH threshold 18**

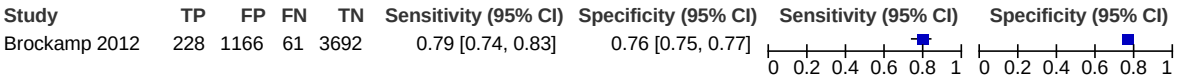
Figure 43: Forest plot of 10 Modified TASH threshold 18.

Study	TP	FP	FN	TN	Sensitivity (95% CI)	Specificity (95% CI)
Mitra 2012	49	2	146	937	0.25 [0.19, 0.32]	1.00 [0.99, 1.00]



J.3.3.11 Vandromme threshold 1.5 or more

Figure 44: Forest plot of 11 Vandromme.

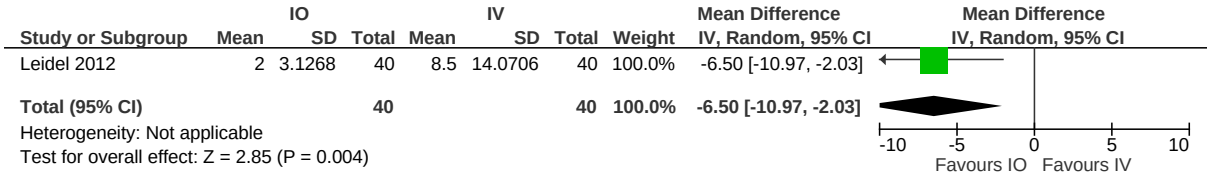


J.3.4 Intraosseous (IO)/intravenous (IV) access

J.3.4.1 IO versus IV

Figure 45: Failed first attempt at access

Figure 46: Time to establish access



J.3.5 Volume resuscitation

J.3.5.1 Permissive hypotension versus resuscitation with normotension as an aim – Pre-hospital

Figure 47: Mortality at 30 days

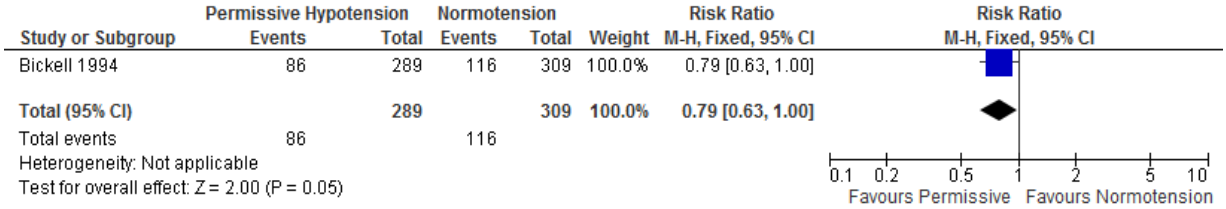


Figure 48: Length of ICU stay

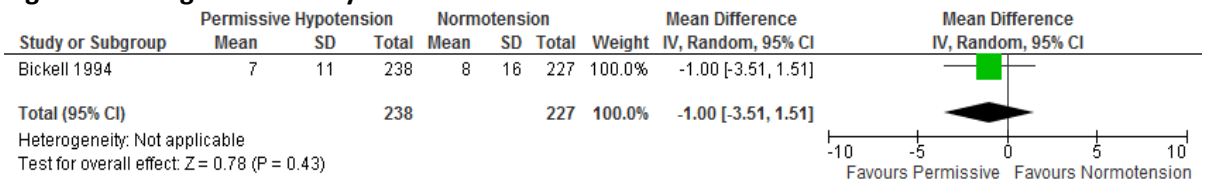
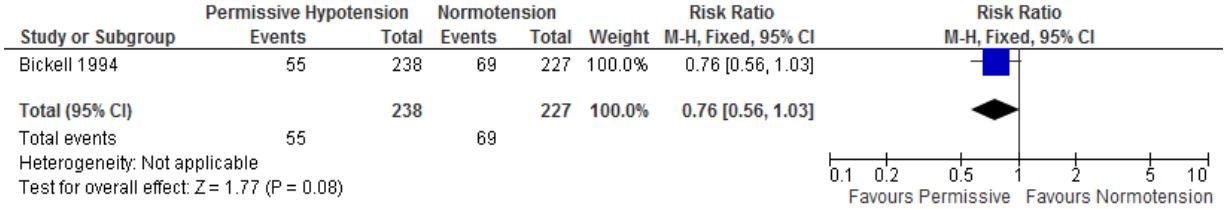


Figure 49: Multi-organ failure



J.3.5.2 Permissive hypotension versus resuscitation with normotension as an aim – In-hospital

Figure 50: Mortality at 24 hours

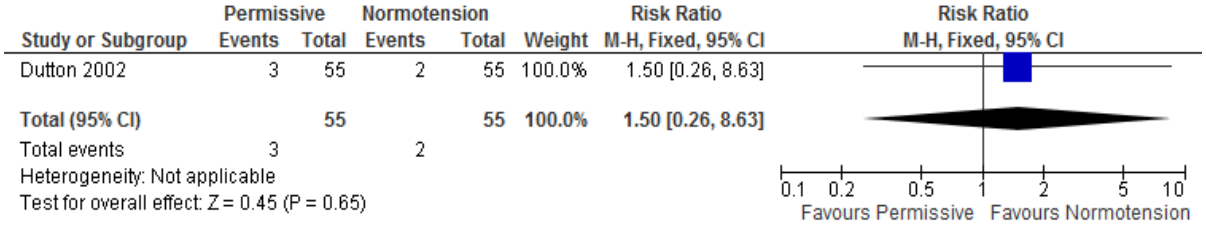


Figure 51: Mortality at 30 days

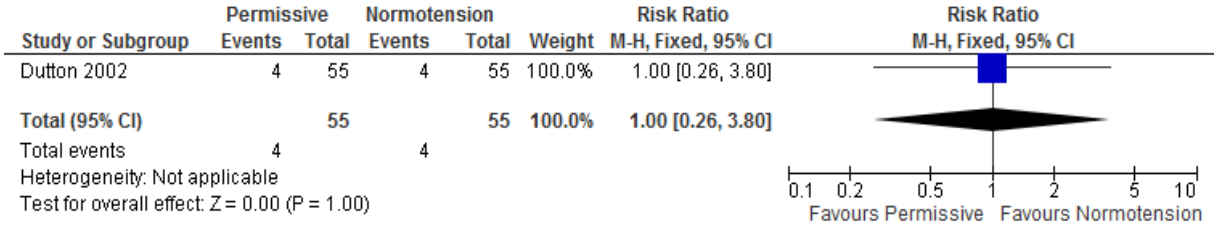
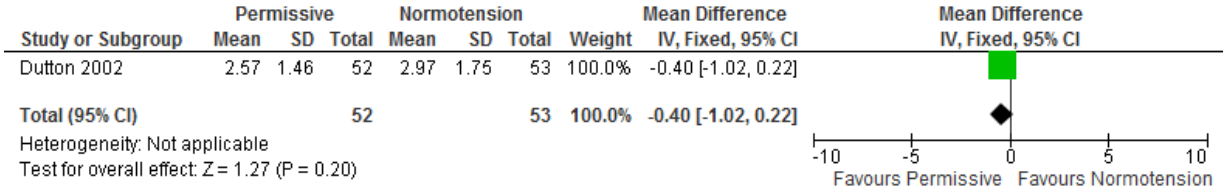


Figure 52: Time to definitive control of haemorrhage



J.3.5.3 Permissive hypotension versus resuscitation with normotension as an aim – In-hospital combined

Figure 53: Mortality at 24 hours

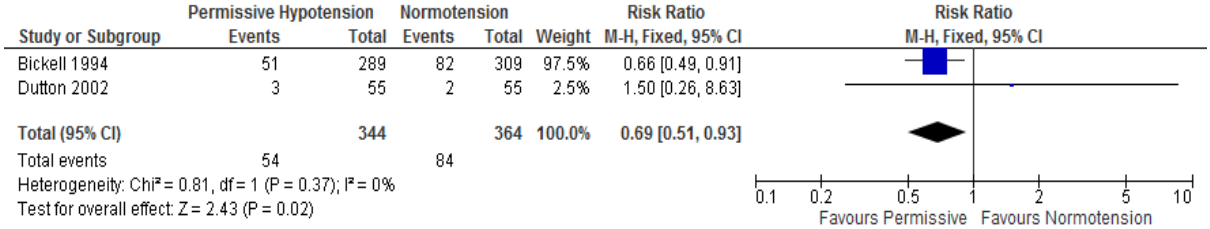
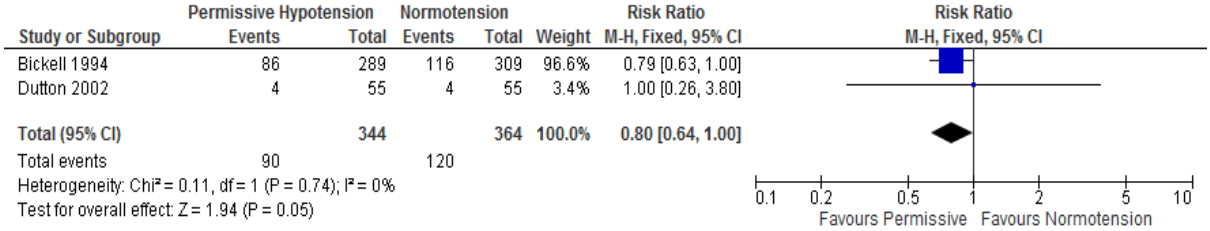


Figure 54: Mortality at 28 days



1

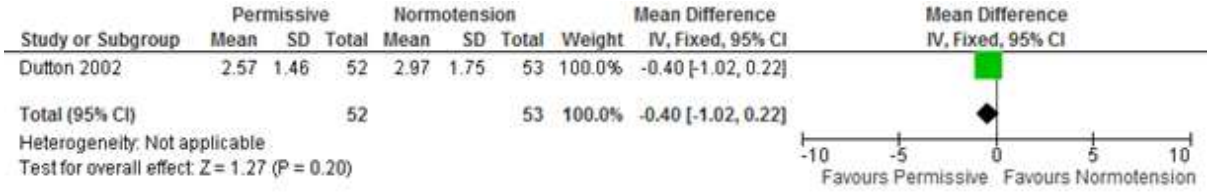
Figure 55: Length of ICU stay

2

Figure 56: Multi-organ failure

3

Figure 57: Time to definitive control of haemorrhage



4 **J.3.5.4 Permissive hypotension versus resuscitation with normotension as an aim – Penetrating trauma**

Figure 58: Mortality at 30 days

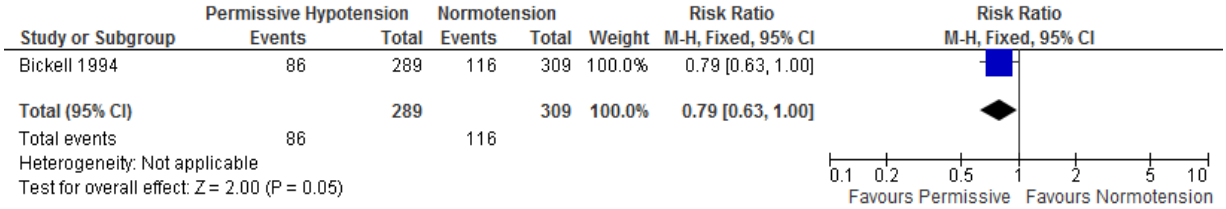


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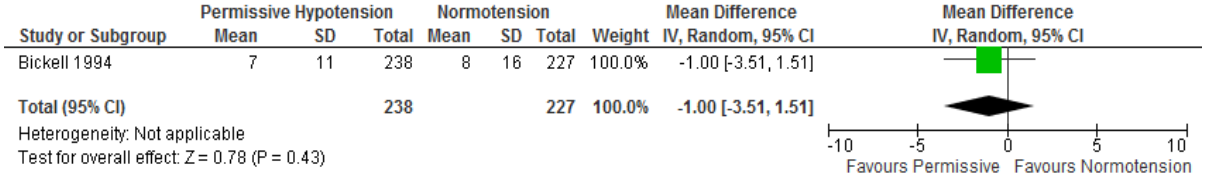
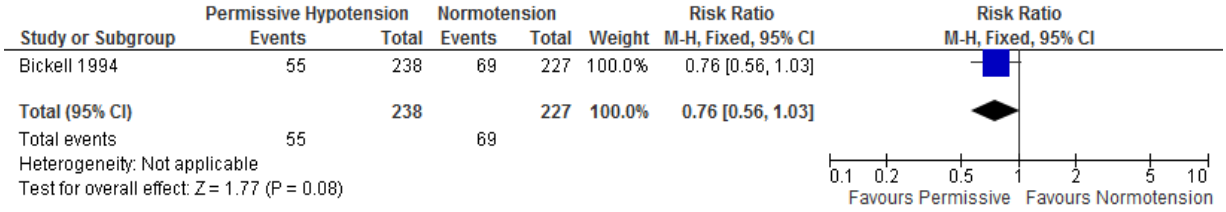
Figure 59: Length of ICU stay



1

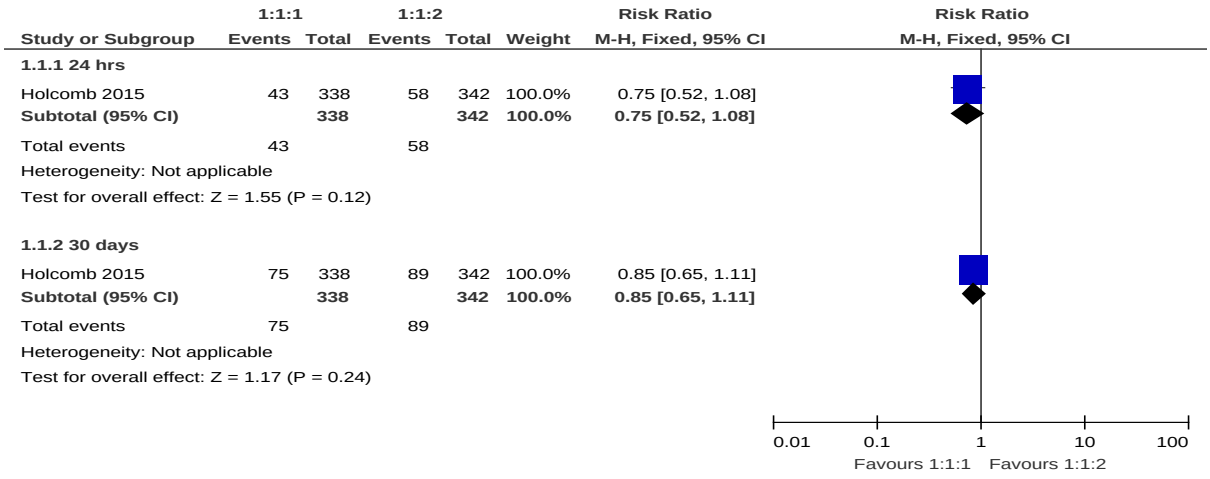
Figure 60: Multi-organ failure



2 **J.3.6 Fluid replacement**

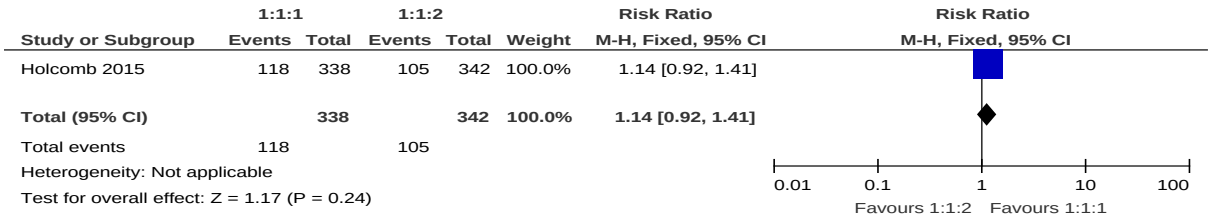
3 **J.3.6.1 Fresh frozen plasma: Platelet:red blood cell**

Figure 61: Mortality



4

Figure 62: Discharged home



5

Figure 63: Transfusion-related metabolic complication

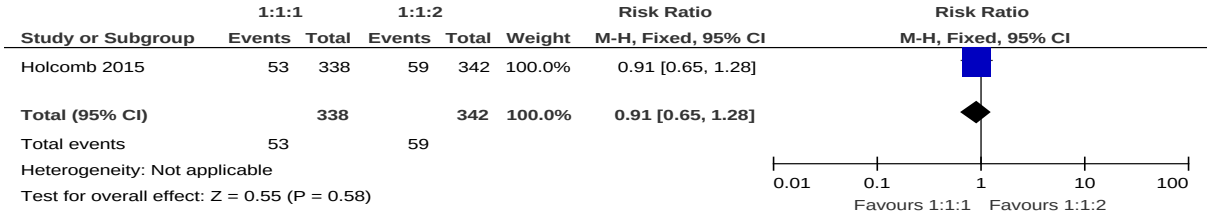


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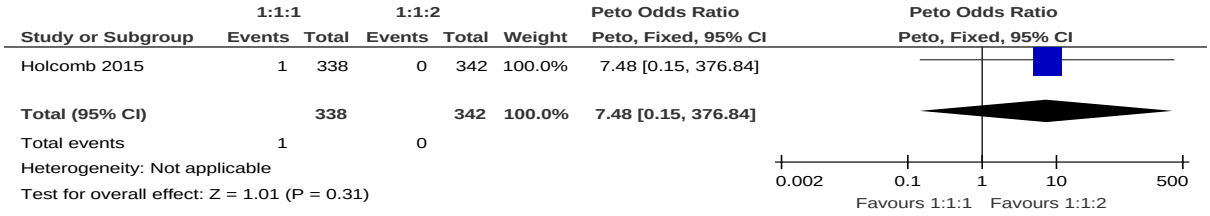
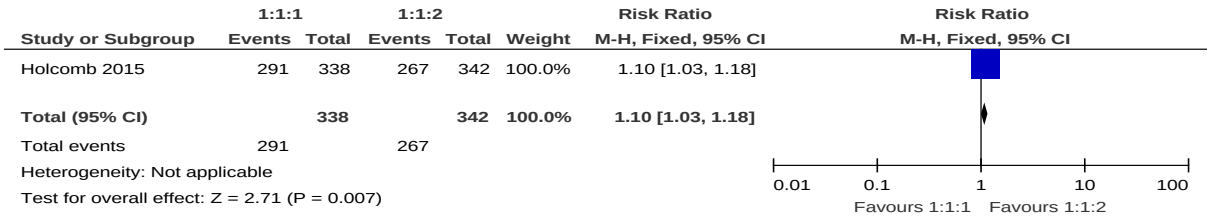
Figure 64: Transfusion-associated circulatory overload



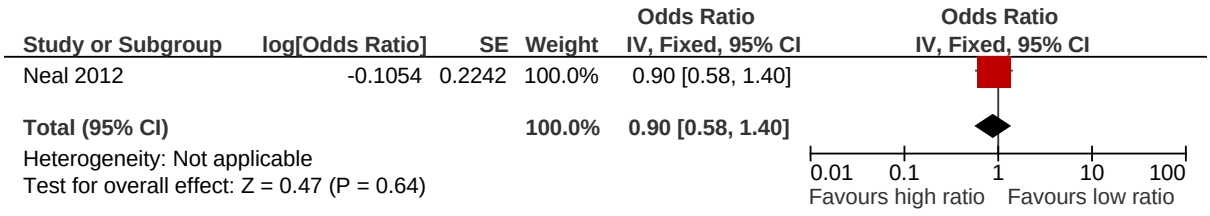
2

Figure 65: Achieved haemostasis



3 **J.3.6.2 Crystalloid: PRBC**

Figure 66: Mortality (in hospital)



4

Figure 67: Nosocomial infection

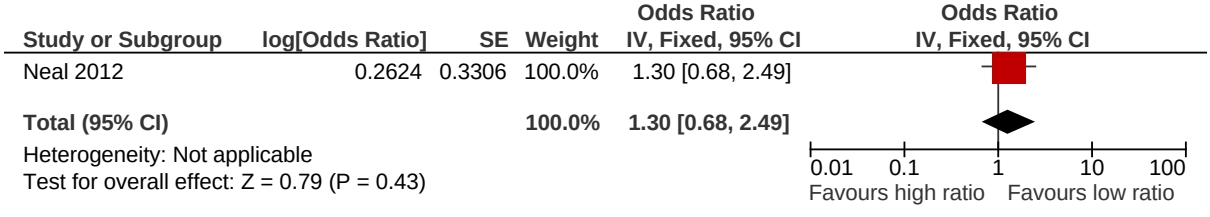


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Figure 68: Multiple organ failure

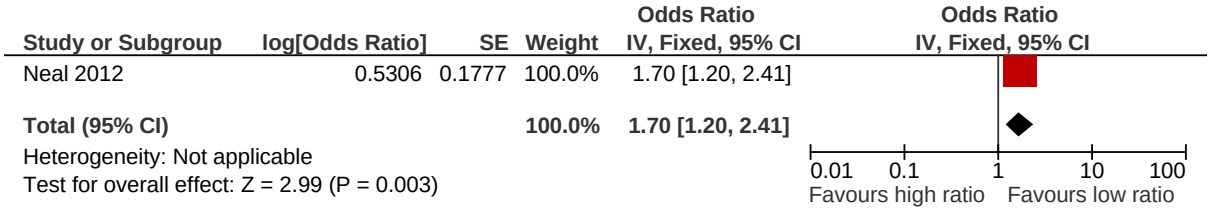

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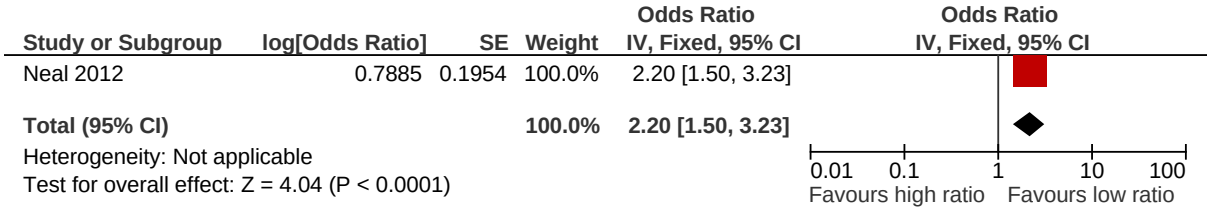
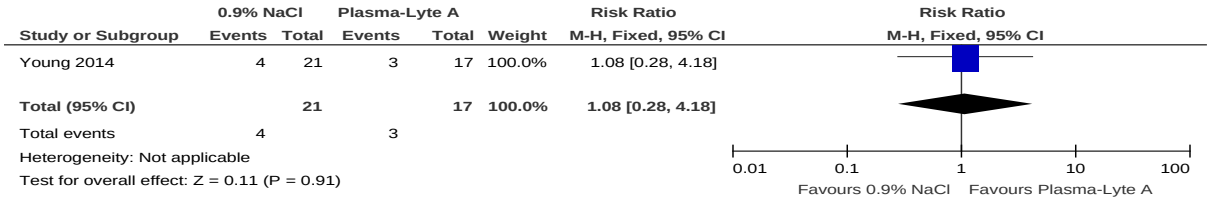
Figure 69: Acute respiratory distress syndrome



2 **J.3.6.3 Crystalloid: crystalloid**

Figure 70: Mortality (in hospital)

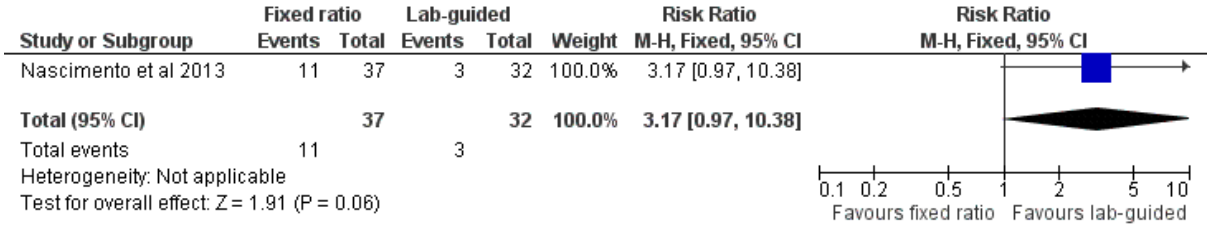


3 # J.4 Control of haemorrhage in hospital

4 ## J.4.1 Haemorrhage protocols

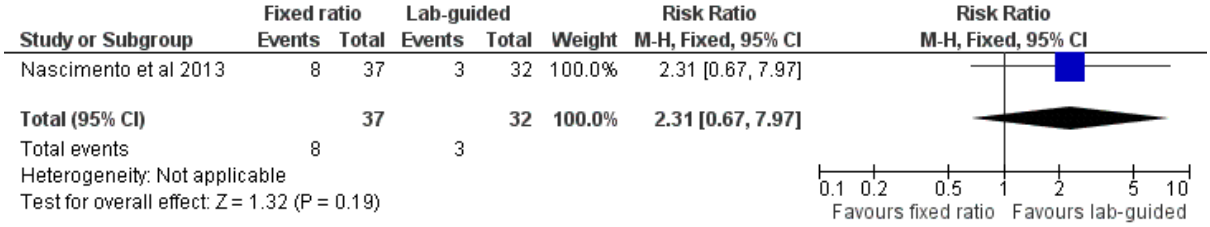
5 ### J.4.1.1 Fixed ratio transfusion protocol versus laboratory-guided transfusion protocol

Figure 71: Mortality (all cause)



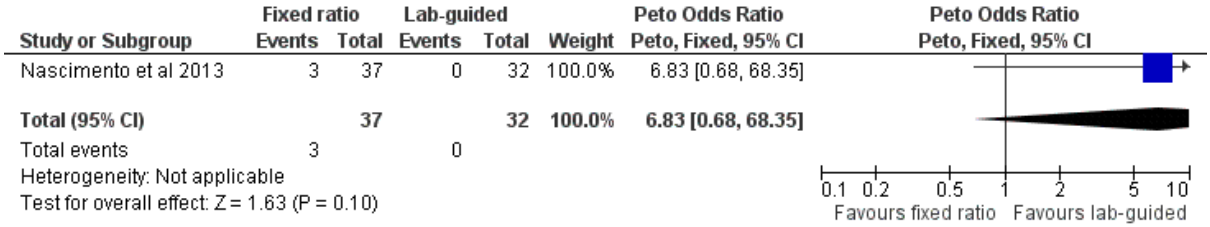
6

Figure 72: Mortality (exsanguination)



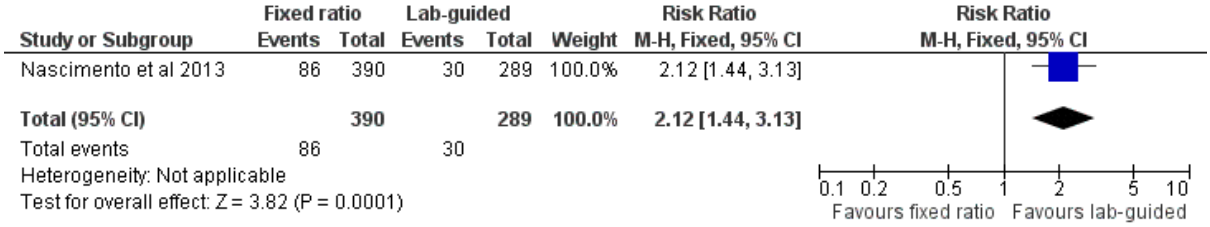
1

Figure 73: Deep vein thrombosis



2

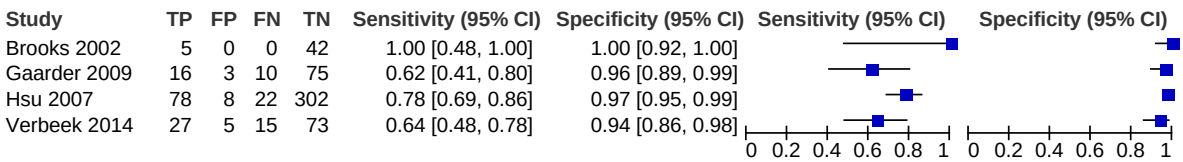
Figure 74: Plasma wasted



3 ## J.4.2 Haemorrhage imaging

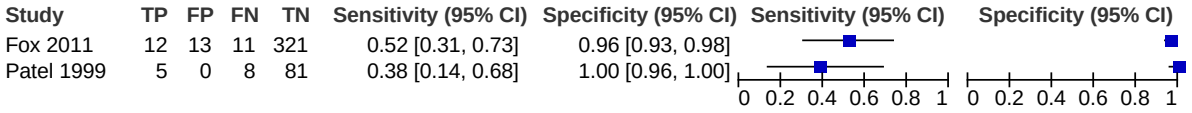
4 ### J.4.2.1 Diagnostic accuracy of FAST and ultrasound imaging for haemorrhage in the adult trauma
5 population

Figure 75: Sensitivity and specificity for FAST imaging for detecting haemoperitoneum/intra-abdominal free fluid (predominately blunt trauma)



J.4.2.2 Diagnostic accuracy of FAST and ultrasound imaging for haemorrhage in the paediatric trauma population

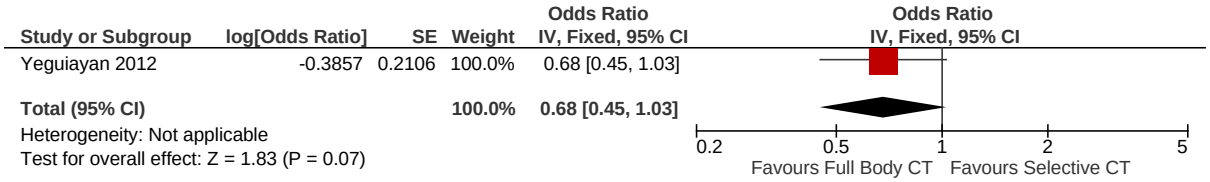
Figure 76: Sensitivity and specificity for FAST imaging for detecting free intraperitoneal fluid (blunt trauma)



J.4.3 Whole-body computed tomography (CT)

J.4.3.1 Whole Body CT (head to pelvis) versus selective Imaging

Figure 77: Mortality at 30 Days



J.4.4 Interventional radiology

J.4.4.1 Blunt aortic injury – Open versus endovascular repair

Figure 78: Mortality (in hospital)

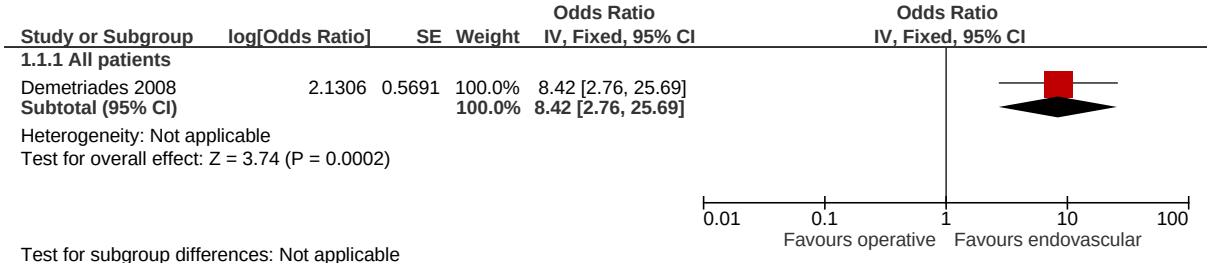


Figure 79: Any systemic complication

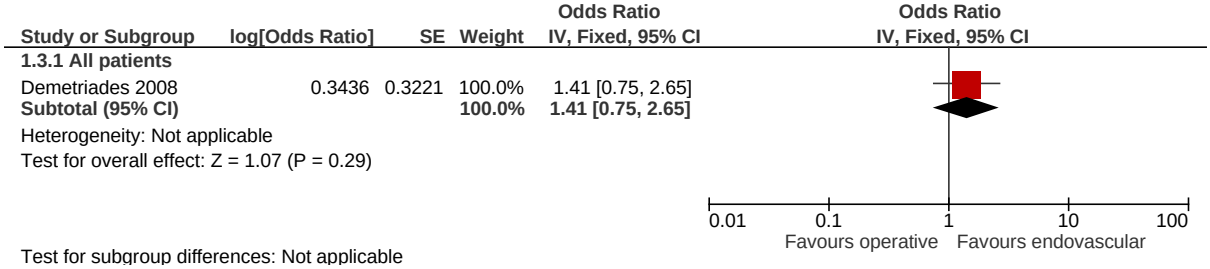
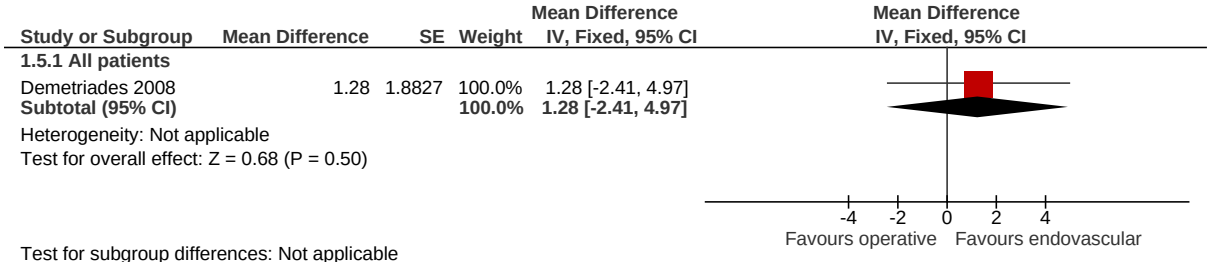
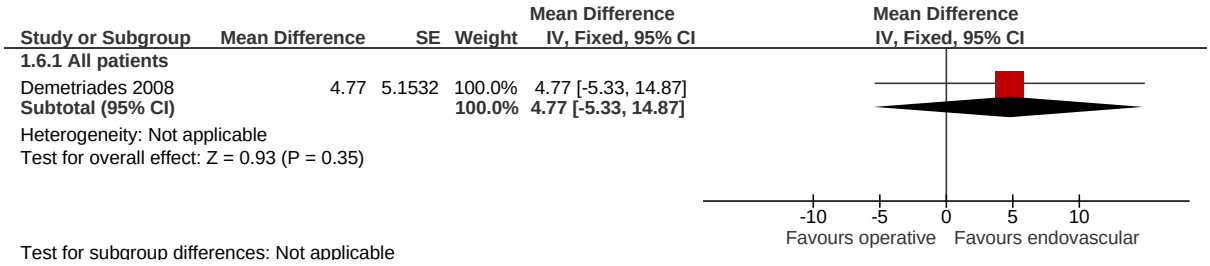


Figure 80: ICU length of stay days



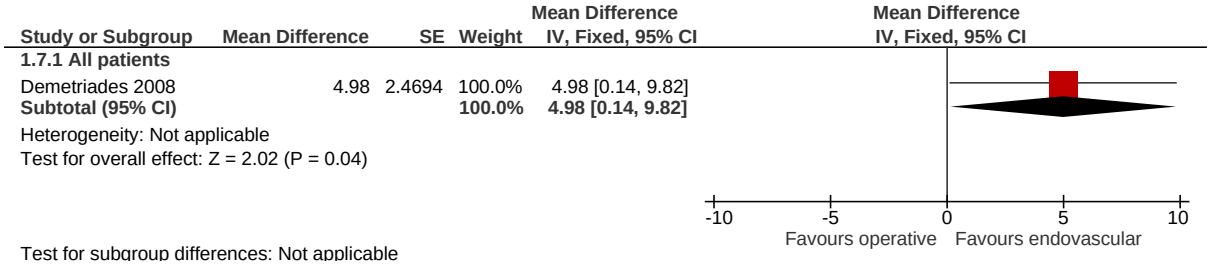
1

Figure 81: Hospital length of stay days



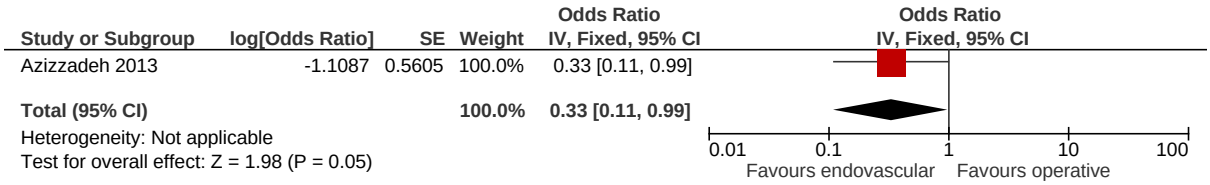
2

Figure 82: Blood units transfused



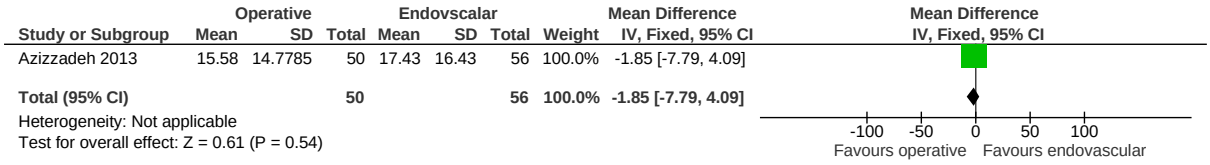
3 **J.4.4.2 Blunt aortic injury – Endovascular repair versus open repair**

Figure 83: Any complication (in hospital mortality)



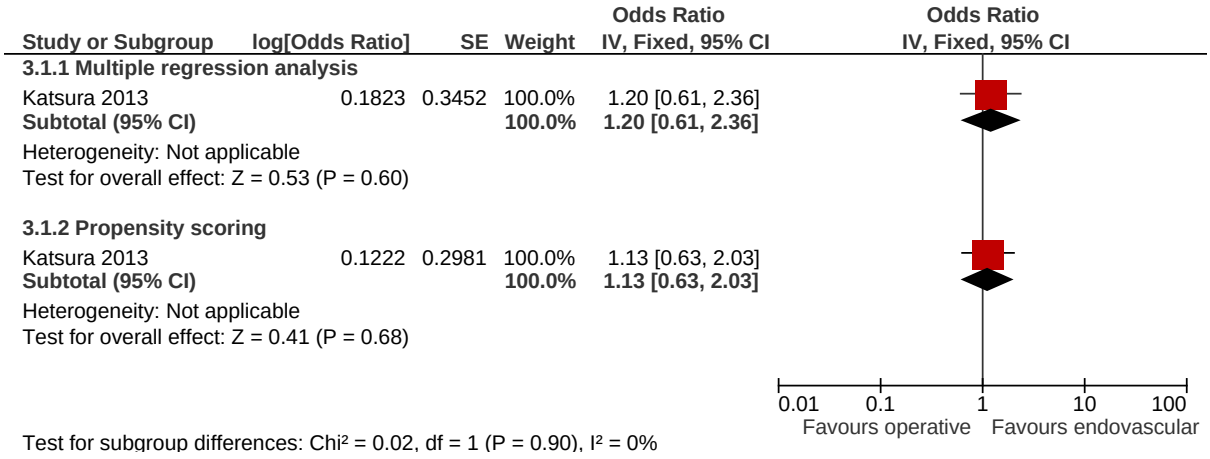
4

Figure 84: ICU length of stay days (adjusted)



J.4.4.3 Blunt pelvic injury

Figure 85: Mortality (in-hospital)

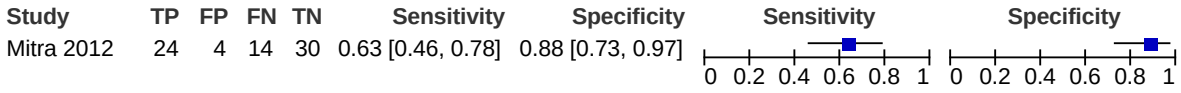


J.5 Monitoring

J.5.1 Coagulation testing

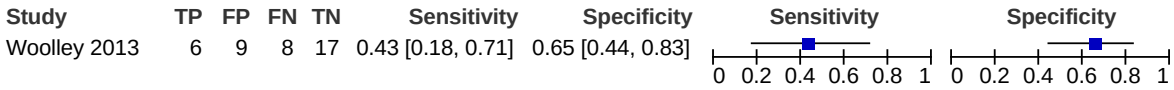
J.5.1.1 CoaguChek

Figure 86: Forest plot for CoaguChek in comparison to reference standard (laboratory PT)



J.5.1.2 ROTEM

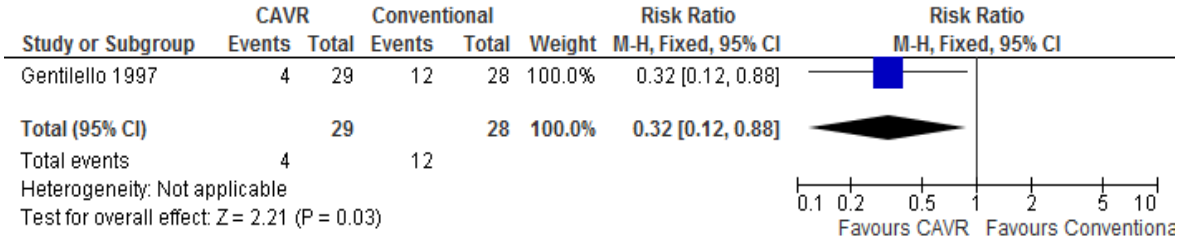
Figure 87: Forest plot for ROTEM in comparison to reference standard (laboratory PT)



J.6 Warming

J.6.1 CAVR plus conventional care versus conventional care

Figure 88: Mortality



J.7 Pain

J.7.1 Pain management

J.7.1.1 Morphine versus ketamine

Figure 3: Pain Levels (Final Score Scale– 0-100

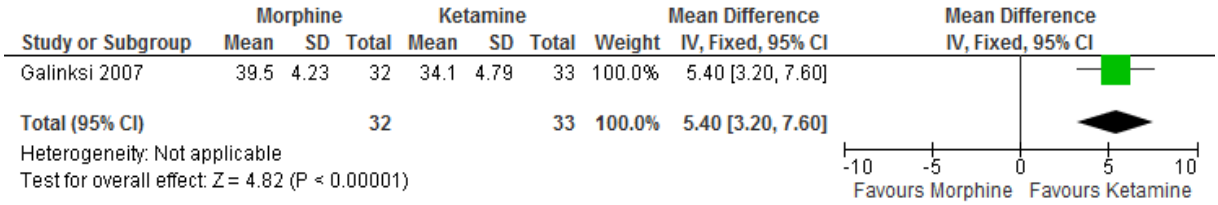


Figure 89: Pain Levels (Change in Pain Score- Scale 0-10)

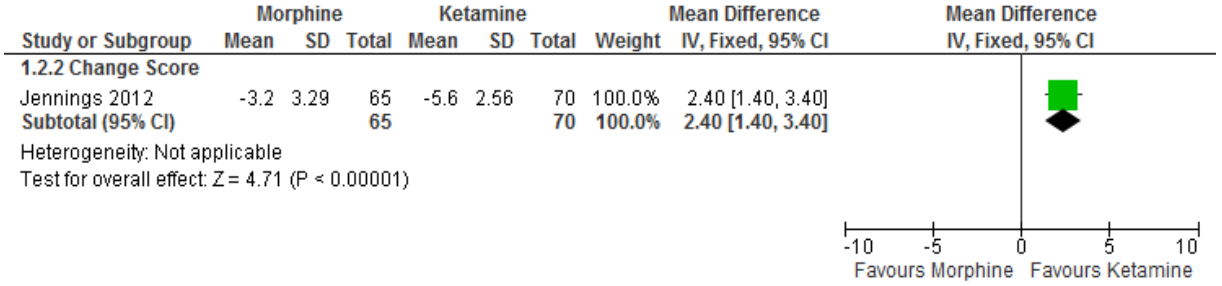


Figure 90: Quality of Life (SF-36)

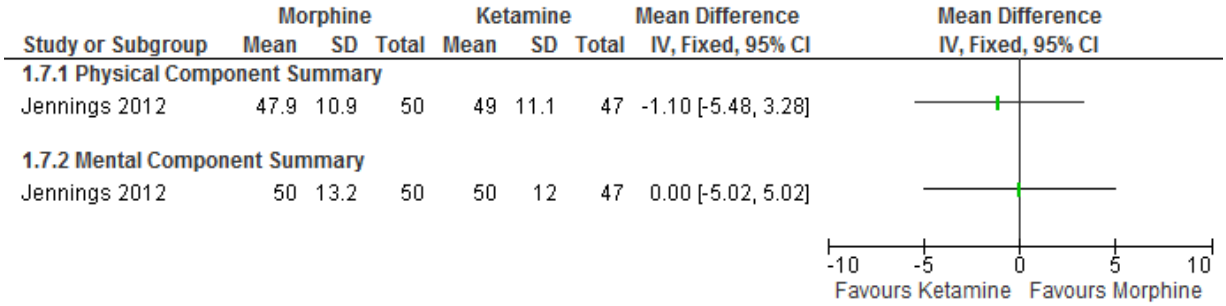


Figure 6: Adverse Effects (Incidence of Nausea)

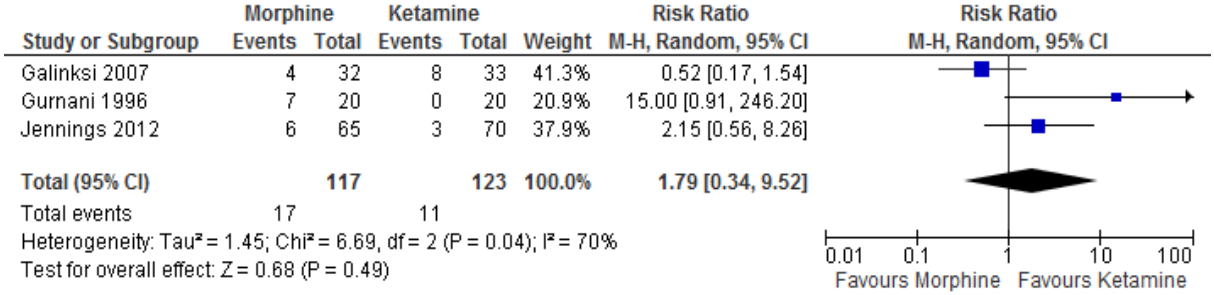
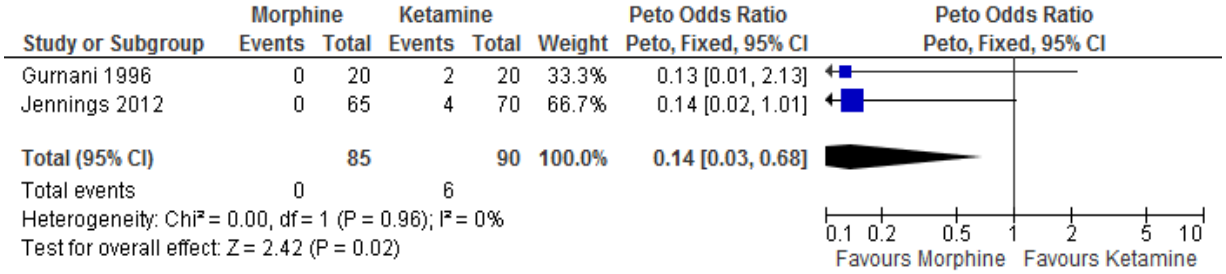
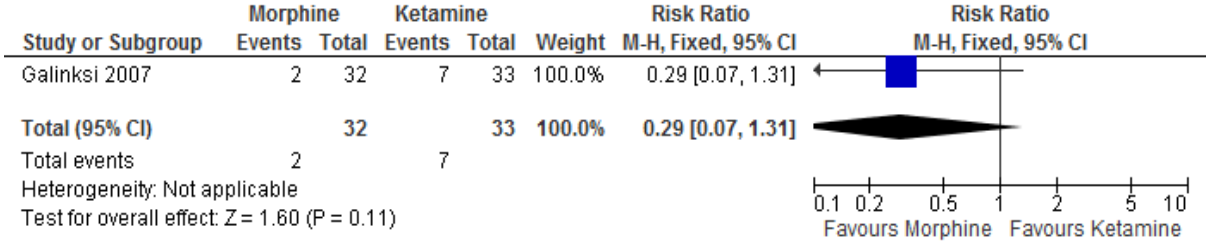


Figure 7: Adverse Effects (Incidence of Hallucinations)



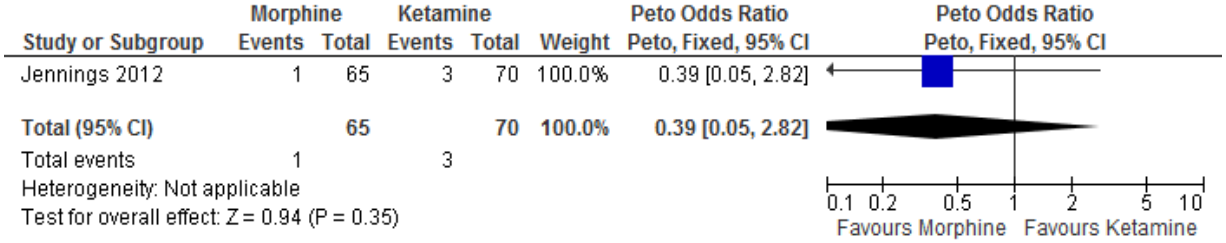
1

Figure 8: Loss of consciousness (Ramsey Score)



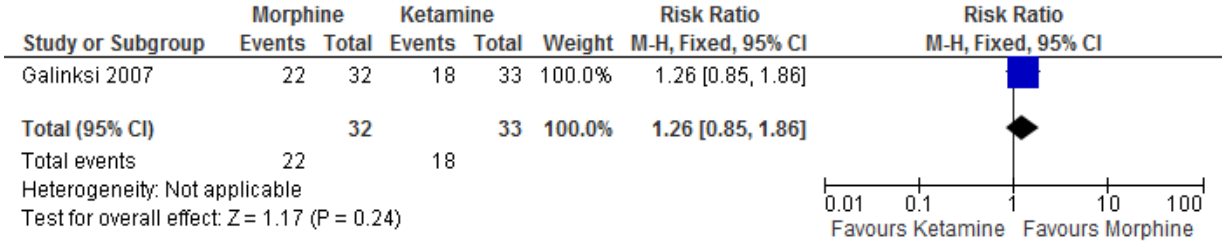
2

Figure 9: Loss of consciousness (Glasgow Coma Score)



3

Figure 10: Patient satisfaction



4 **J.7.1.2 Morphine versus acetaminophen**

Figure 91: Pain Levels (Final Pain Score at 15 minutes – Scale 0-100)

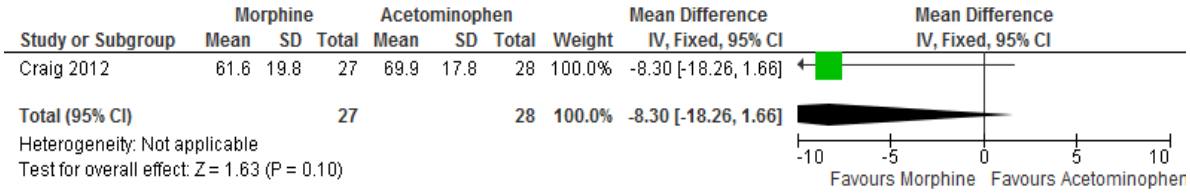


Figure 92: Pain Levels (Final Pain Score at 30 minutes – Scale 0-100)

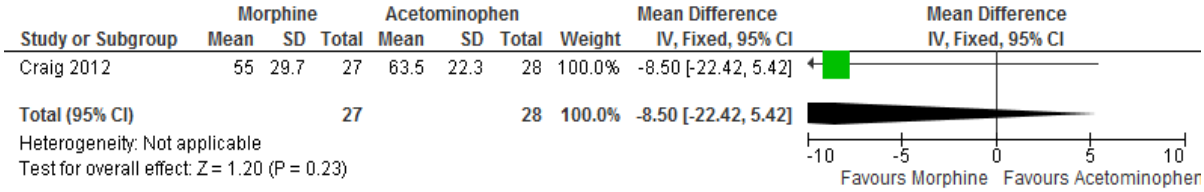


Figure 93: Pain Levels (Final Pain Score at 60 minutes- Scale 0-100)

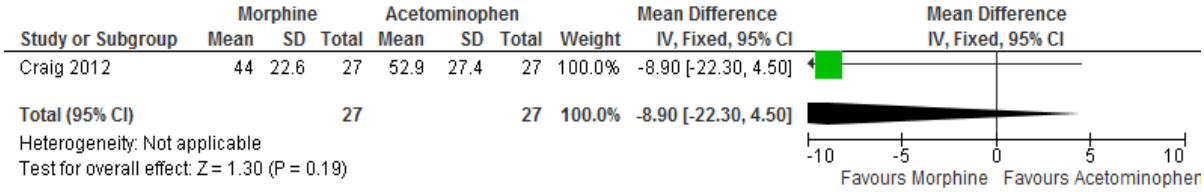


Figure 94: Adverse Events (Incidence of Adverse Events)

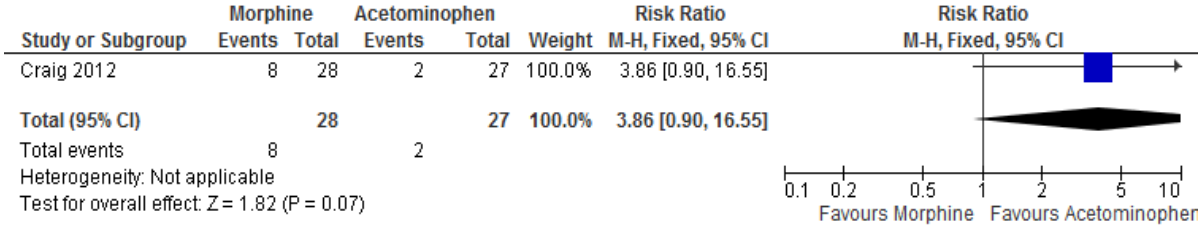
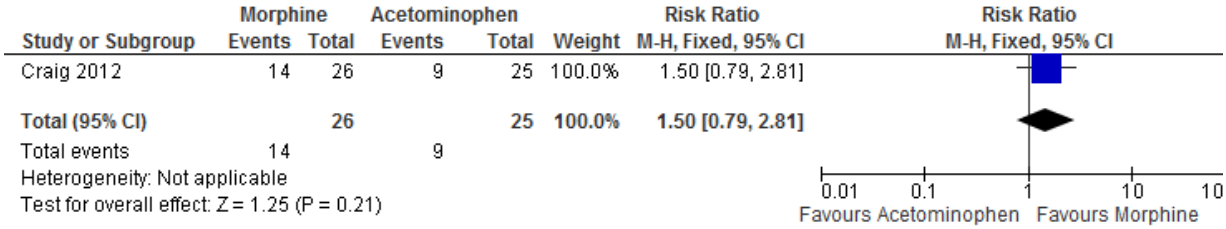


Figure 95: Patient Satisfaction



J.7.1.3 Intermediate dose morphine versus high-dose morphine

Figure 96: Pain Levels (Final Pain Score- Scale 0-10)

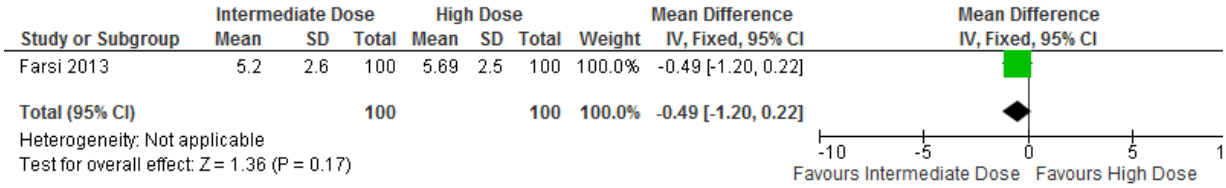
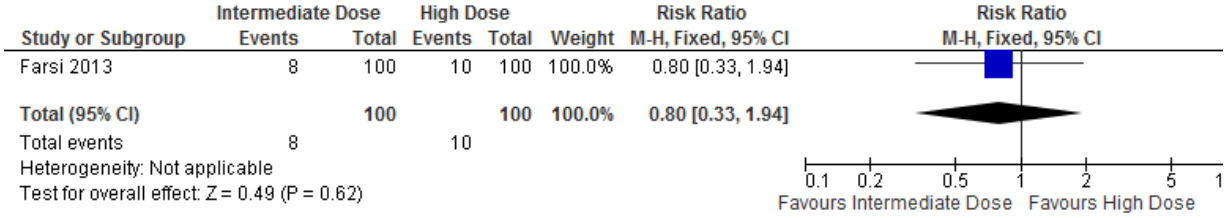
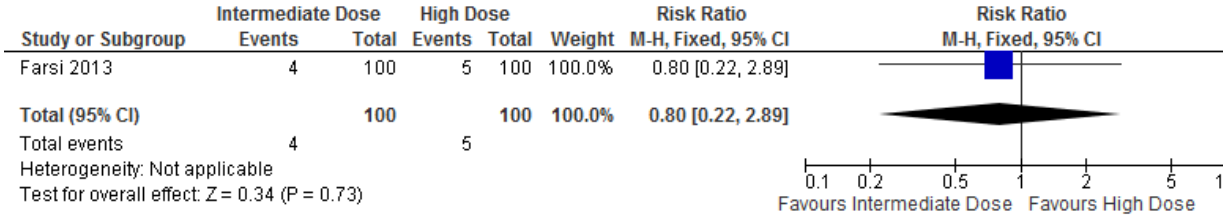


Figure 97: Adverse Effects (Incidence of Nausea)



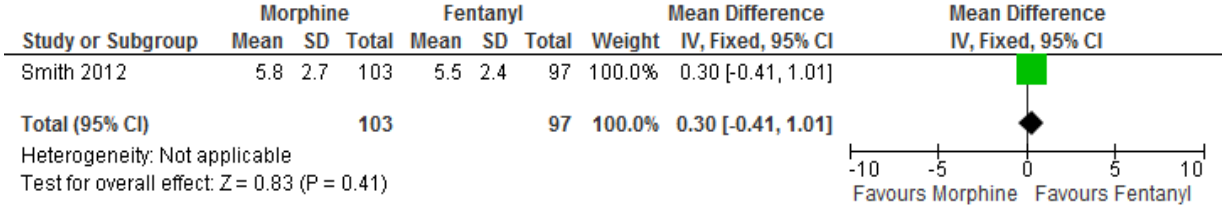
1

Figure 98: Loss of consciousness (Glasgow Coma Score)



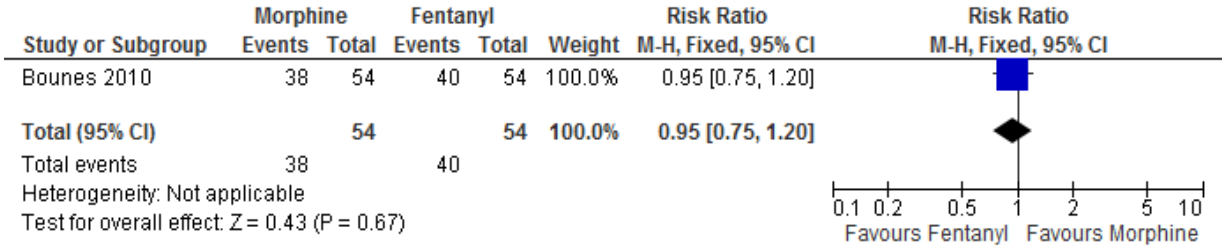
2 **J.7.1.4 Morphine versus fentanyl**

Figure 99: Pain Level (Final Pain Score- Scale 0-10)



3

Figure 100: Pain Level (Change in Pain Score) - Dichotomised



4

Figure 101: Adverse Effect (Incidence of Nausea)

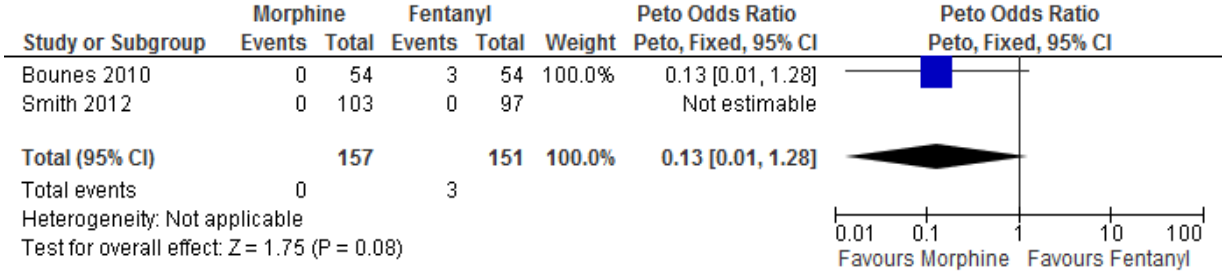


Figure 102: Adverse Effect (Respiratory Depression)

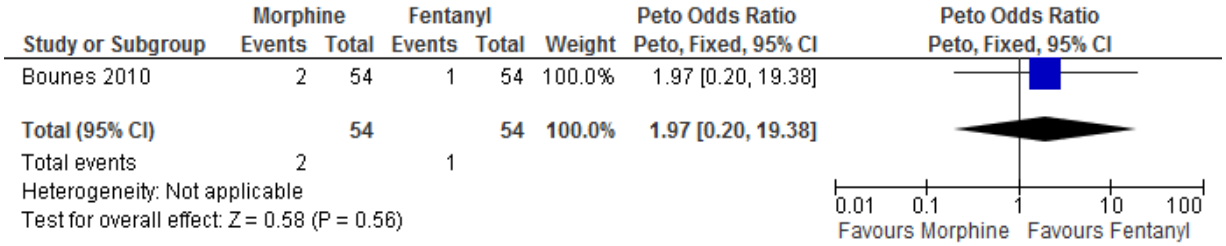
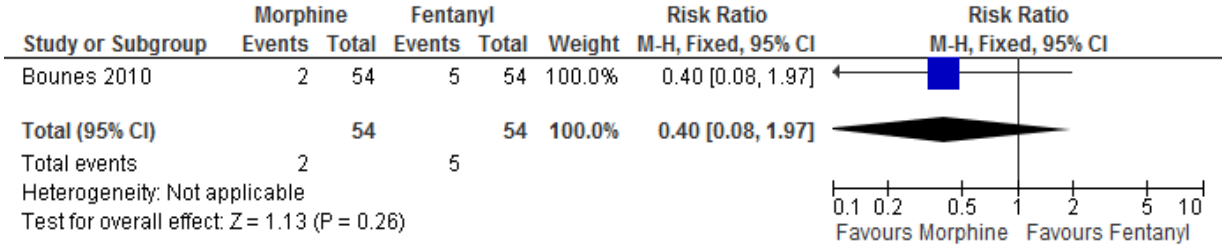
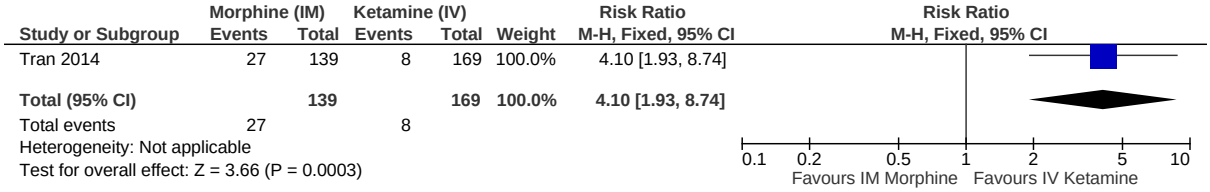


Figure 103: Loss of consciousness (Ramsey Scale)



J.7.1.5 Morphine (intramuscular) versus Ketamine

Figure 104: Adverse Effect (Incidence of Nausea)



J.8 Documentation

J.8.1 Checklist versus no checklist

Figure 105: Mortality

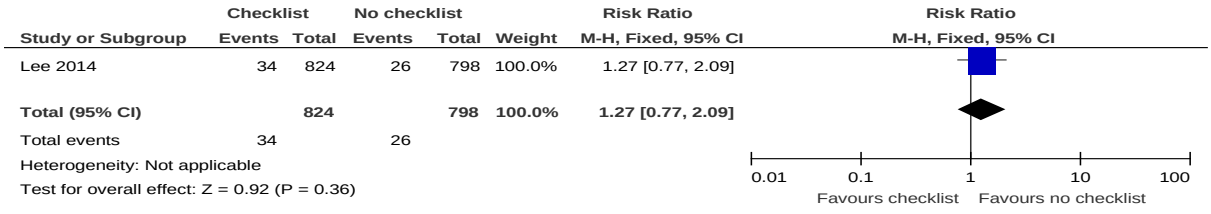
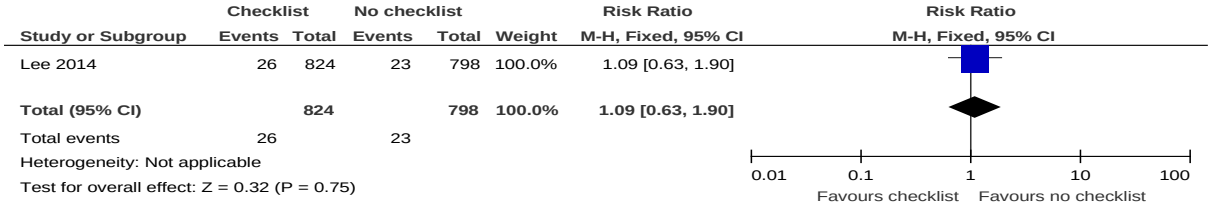
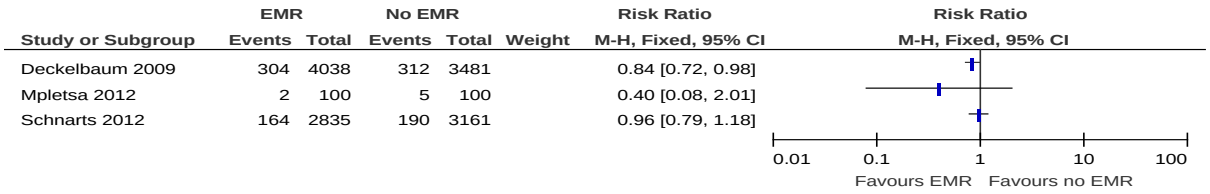


Figure 106: Complications



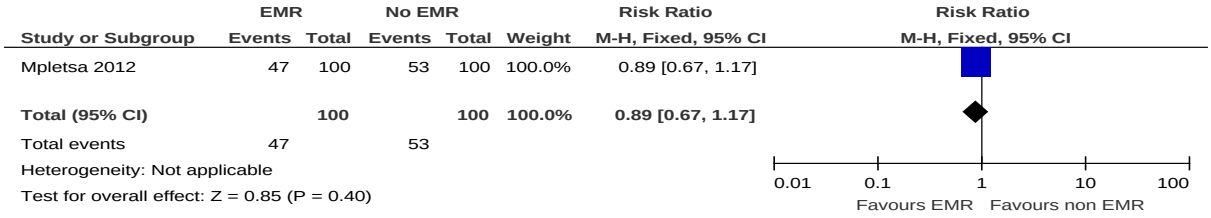
1 **J.8.2 Electronic medical record versus no electronic medical record**

Figure 107: Mortality



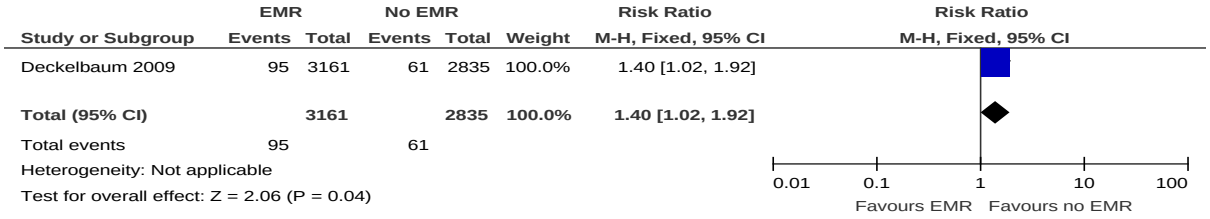
2

Figure 108: Requiring severe surgery



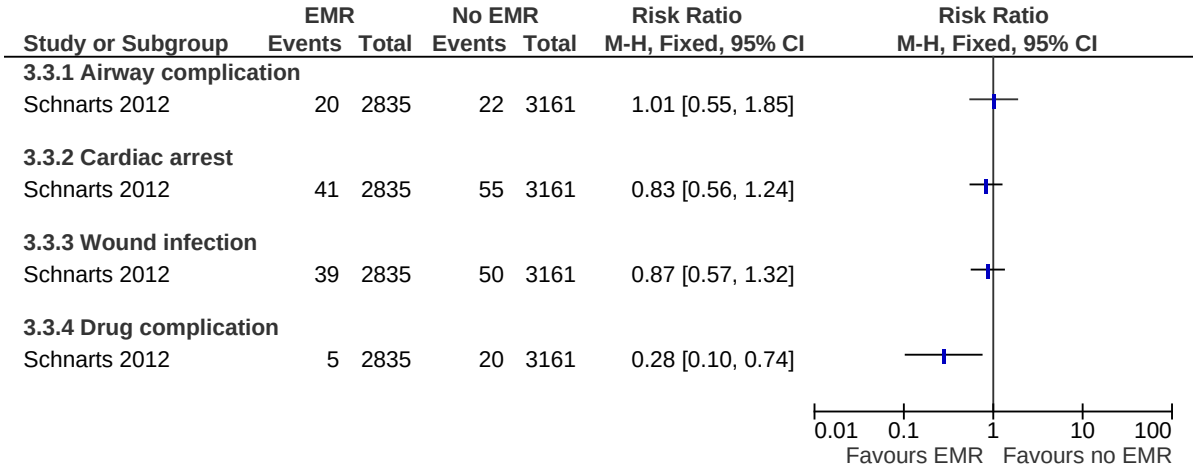
3

Figure 109: Delay in diagnosis



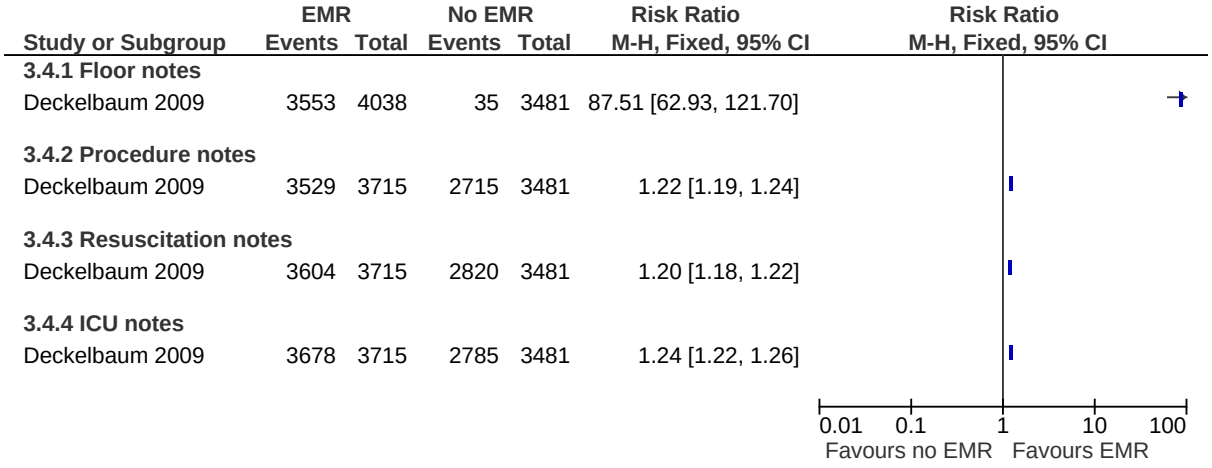
4

Figure 110: Complications



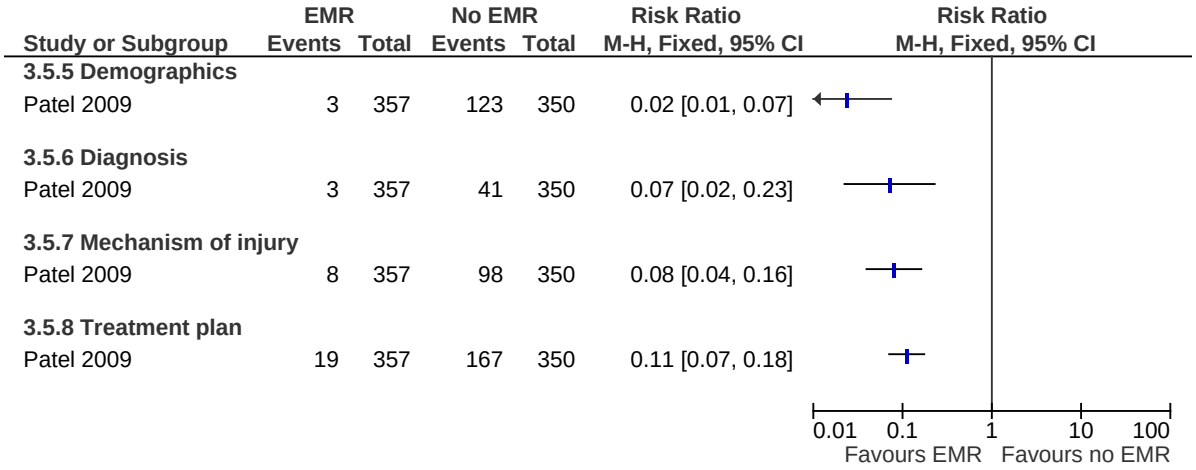
1

Figure 111: Completed data



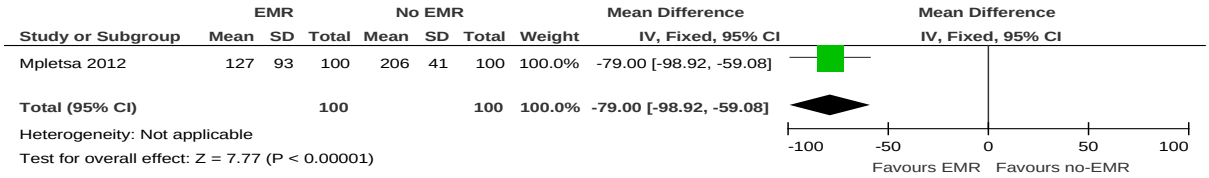
2

Figure 112: Missing data



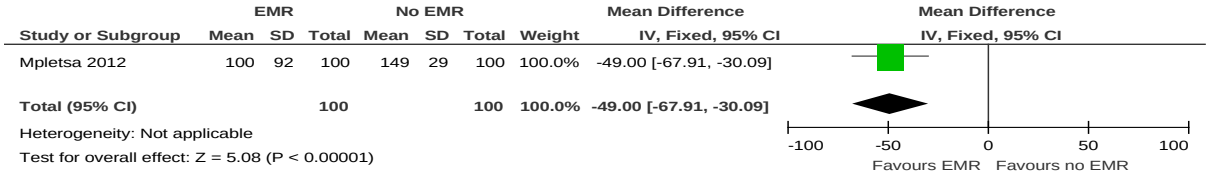
3

Figure 113: Length of stay emergency department (minutes)



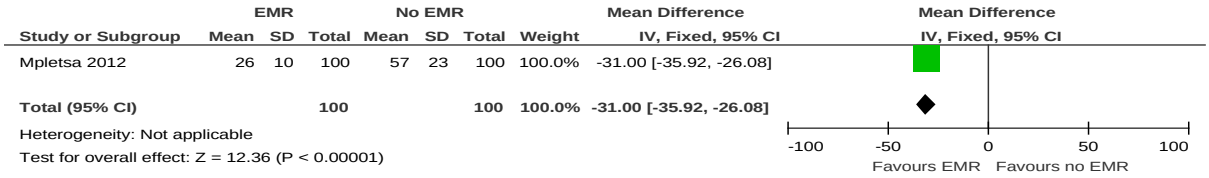
1

Figure 114: Time between admission and completion of care (minutes)



2

Figure 115: Time between completion of care and exit from ED (minutes)



3

4

Appendix K: Excluded clinical studies

K.1 Airway management

Table 1: Studies excluded from the clinical review

Reference	Reason for exclusion
Calkins 2006[101]	Inappropriate comparison
Cudnik 2010[156]	Inappropriate comparison
Davis 2003[163]	Inappropriate comparison
Davis 2010[164]	Inappropriate comparison
Denninghoff 2008[177]	Inappropriate comparison
Evans 2013[220]	Inappropriate comparison
Falcone 1996[226]	Inappropriate comparison
Gerich 1998[260]	Inappropriate comparison
Hubble 2010[317]	Systematic review is not relevant to review question or unclear PICO
Klemen 2006[368]	Cohort study without multivariate analysis
Lecky 2008[412]	Systematic review is not relevant to review question or unclear PICO
Murray 2000[502]	Inappropriate comparison
Rajani 2009[574]	Inappropriate comparison
Sagarin 2002[605]	Incorrect setting: ED
Sobuwa 2013[662]	Cohort study without multivariate analysis
Stockinger 2004[679]	Inappropriate comparison
Von elm 2009[726]	Systematic review: study designs inappropriate

K.2 Assessment and management of chest trauma

K.2.1 Pre-hospital tension pneumothorax

Table 2: Studies excluded from the clinical review

Reference	Reason for exclusion
Barton 1995[45]	Non-randomised study does not account important confounding factors
Coats 1995[143]	Incorrect study design
Davis 2005[165]	Non-randomised study does not account important confounding factors
Deakin 1995[170]	Incorrect study design
Di bartolomeo 2001[184]	Incorrect study design
Massarutti 2006[456]	Incorrect study design
Mistry 2009[485]	Non-randomised study does not account important confounding factors
Waydhas 2007[730]	Systematic review: study designs inappropriate
Wayne 1980[731]	Incorrect study design

K.2.2 Management of open pneumothorax

Table 3: Studies excluded from the clinical review

Reference	Reason for exclusion
Brims 2013[85]	Not review population.
Kotora 2013[380]	Not review population
Massarutti 2006[456]	Incorrect study design.
Tebb 2010[696]	Systematic review is not relevant to review question or unclear PICO.
Waydhas 2007[730]	Systematic review is not relevant to review question or unclear PICO

K.3 In-hospital tension pneumothoraxes

Table 4: Studies excluded from the clinical review

Reference	Reason for exclusion
Chan 2009[120]	Not review population
Contou 2012[148]	Not review population
Di Bartolomeo 2001[184]	Not review population
Fitzgerald 2008[232]	Not review population
Harrison 2014[291]	Study design not relevant to review
Hussain 1999[325]	Not guideline condition.
Kulvatunyou 2011[394]	Not review population
Ramirez 2012[576]	Not review population
Wayne 1980[731]	Incorrect study design

K.4 Imaging assessment of chest trauma

Table 5: Studies excluded from the clinical review

Reference	Reason for exclusion
Alkadhi 2004[8]	Fractures
Alrajab 2013[9]	Review – checked for references
Azizzadeh 2011[34]	Special population where initial angiography was equivocal
Barrios 2009[44]	Not a diagnostic accuracy study
Biquet 1996[65]	Index test of CT was single slice and therefore not applicable to current practice
Boulanger 2001[77]	Abdominal injury
Brar 2010[81]	Not a diagnostic accuracy study
Bridges 1993[84]	Reference test of CT was single slice and therefore not applicable to current practice
Brooks 2004[87]	Reference test of CT was single slice and therefore not applicable to current practice
Cai 2009[100]	Test not on protocol
Chen 2001[122]	Test not on protocol
Cho 2012[130]	Injury not on protocol
Chung 2005[133]	Non-trauma population

Reference	Reason for exclusion
Clontz 2004[140]	Not a diagnostic accuracy study
Collins 2001[147]	Review
Dente 2007[178]	Non-acute stage
Dissanaike 2008[190]	Injury not on protocol
Downing 2001[197]	Diagnostic data could not be extracted due to poor reporting
Dulchavsky 2001[206]	Chest x ray was the gold standard
Durham 1994[208]	Index test of CT was single slice and therefore not applicable to current practice
Dyer 2000[209]	Not all in analysis had gold standard. Assumption made that a negative index test was always a true negative.
Dyer 1999[210]	Index test of CT was single slice and therefore not applicable to current practice
Erhan 2001[218]	Injury not in protocol
Guerrero-Lopez 2000[274]	Not possible to extract diagnostic accuracy data due to poor reporting
Hill 1999[303]	Reference test of CT was single slice and therefore not applicable to current practice
Kirkpatrick 2005[367]	Contains data with Chest X-ray as the gold standard
Kraus 1999[390]	Injury not on protocol
Lai 2012[401]	Non-traumatic injury
Lamb 2007[403]	Not possible to extract diagnostic accuracy data due to poor reporting
Lindner 2013[421]	Test not on protocol
Livingston 2008[425]	No diagnostic accuracy data
Ma 1997[433]	Reference test of CT was single slice and therefore not applicable to current practice
Madayag 1991[437]	Not a diagnostic accuracy study
Magu 2009[443]	No diagnostic data for protocol injuries
Markel 2009[452]	Not possible to extract diagnostic accuracy data due to poor reporting
Maturen 2007[457]	Included abdominal injuries in analyses
McGonigal 1990[465]	Reference standard was unclear
McLean 1991[469]	Index test of CT was single slice and therefore not applicable to current practice
McLellan 1996[470]	No specific analyses for particular injuries
Miller 1989[479]	Index test of CT was single slice and therefore not applicable to current practice
Monti 2009[492]	Animal study
Nagarsheth 2011[505]	Reference test of CT was single slice and therefore not applicable to current practice
Nagy [506]1996	Injury not on protocol
Nchimi 2005[509]	Injury not on protocol
Patel 2003[544]	Injuries not on protocol
Patel 2003[546]	Special population of people with equivocal aortogram
Plurad 2013[557]	Injuries not on protocol
Poole 1993[560]	Not possible to extract diagnostic accuracy data due to poor reporting
Press 2013[566]	Injuries not on protocol
Quinn 2011[570]	Review

Reference	Reason for exclusion
Ramirez 2009[577]	Injury not on protocol
Raptopoulos 1992[581]	Index test of CT was single slice and therefore not applicable to current practice
Rose 2005[594]	Test was abdominal FAST
Rozycki 1998[600]	Injuries not on protocol
Rozycki 1999[601]	Injuries not on protocol
Sisley 1998[650]	Injuries not on protocol
Smith 2010[659]	Mixed abdominal and thoracic trauma with no sub-grouping
Soffer 2004[663]	Mixed abdominal and thoracic trauma with no sub-grouping
Stengel 2012[676]	No discrete injuries covered
Szucs-Farkas 2010[689]	Test not on protocol
Tayal 2004[695]	Injuries not on protocol
Tomiak 1993[703]	Index test of CT was single slice and therefore not applicable to current practice
Traub [707]2007	Not a diagnostic accuracy paper
Uflacker 1999[712]	Not possible to extract diagnostic data due to poor reporting
Velmahos 1999[720]	No diagnostic accuracy data
Wilkerson 2010[739]	Review
Wintermark 2003[741]	Spinal fractures
Xirouchaki 2011 [753]	Non-trauma
Yanchar 2013[755]	No diagnostic accuracy data

K.5 Assessment and management of haemorrhage

K.5.1 Control of external haemorrhage

K.5.1.1 Use of haemostatic dressings

Table 6: Studies excluded from the clinical review

Reference	Reason for exclusion
Cox 2009[154]	Non-randomised study did not account for key confounder: injury severity
Granville-Chapman 2010[267]	Systematic review: study designs inappropriate. Systematic review is not relevant to review question or unclear PICO
Hatamabadi 2015[295]	No outcomes of interest were reported
Ran 2010[579]	Incorrect study design: study design not relevant to review

K.5.1.2 Use of tourniquets in major trauma

Table 7: Studies excluded from the clinical review

Reference	Reason for exclusion
Beekley 2008 [50]	Intervention does not match protocol
Brodie 2007 [86]	Incorrect study design
Clasper 2009 [137]	Intervention does not match protocol
Guo 2011 [275]	Incorrect population

Reference	Reason for exclusion
Kragh 2008 [388]	No relevant outcomes
Kragh 2009 [389]	Intervention does not match protocol
Kragh 2010 [383]	Incorrect study design
Kragh 2011 [385]	Incorrect study design
Kragh 2011A [386]	Incorrect study design
Kragh 2011B [382]	Incorrect study design
Kragh 2011C [387]	Intervention does not match protocol
Kragh 2012 [384]	Incorrect study design
Lakstein 2003 [402]	Incorrect study design
Lee 2007 [413]	Incorrect study design
Mackenzie 2008 [435]	Incorrect study design
Martin-Smith 2013 [455]	Incorrect study design
Niven 2010 [524]	Incorrect study design
Passos 2014 [543]	Incorrect setting
Pollak 1997 [559]	Incorrect setting
Richey 2009 [588]	Incorrect study design
Rush 2012 [604]	Incorrect study design
Smith 2009A [657]	Incorrect setting
Smith 2010 [656]	Incorrect setting
Smith 2010A [658]	Incorrect setting
Spahn 2013 [666]	Incorrect study design
Steinke 2013 [674]	Incorrect study design
Tien 2008 [700]	Incorrect study design

K.5.2 Pelvic binders

Table 8: Studies excluded from the clinical review

Reference	Reason for exclusion
Bonner 2011[74]	Inappropriate comparison
Buckle 1994[94]	Incorrect study design (Article)
Chesser 2012[125]	Incorrect study design (article)
Deangelis 2008[171]	Population does not match protocol (cadaveric study)
Eastridge 2007[213]	Incorrect study design (Article)
Fitzpatrick 2002[233]	Incorrect study design (article)
Ghanayem 1995[262]	Population does not match protocol (cadaveric study)
Krieg 2005[391]	Groups not matched on confounders and no multivariate analysis
Knops 2011[371]	Population does not match protocol (healthy participants)
Nunn 2007[525]	Incorrect study design (case series). Incorrect study design
Pizanis 2013[556]	Population does not match protocol (in-hospital)
Prasarn 2013[565]	Population does not match protocol (cadaveric study)
Spanjersberg 2009[667]	Narrative review (used for reference)
Tan 2010[690]	Setting does not match protocol (in-hospital use rather than pre-hospital use)
Toth 2012[705]	Incorrect study design (audit of current practice)

Reference	Reason for exclusion
Verbeek 2008[721]	Incorrect study design (audit of current practice)

K.5.3 Haemostatic agents

Table 9: Studies excluded from the clinical review

Reference	Reason for exclusion
Auer 1979[30]	Not acute major trauma. Patients had remained comatose for at least seven days
Cap 2011[109]	SR checked for included papers
Crash 2011[155]	Results by time since injury and intervention
Curry 2011[158]	Systematic review checked for included studies
Eckert 2014[214]	Non-RCT
Innerhofer 2013[332]	Cohort studies with groups not matched at baseline for SBP. Propensity analysis performed but groups not matched in GCS
Joseph 2013[346]	Patients with coagulopathy and TBI. Gps not matched on ISS at baseline
Kluger 2007[370]	Post hoc analysis of RCT
Koh 2012[375]	Non-RCT
Kozek-langenecker 2011[381]	SR checked for included studies
McMichan [471]	Unlicensed intervention (Aprotinin)
Mcmullin 2010[472]	Post hoc analysis of RCT looking at prolonged prothrombin time
Narayan [507]	Dose escalation trial with dosing that isn't used in current clinical practice
Nienaber 2011[520]	Fresh frozen plasma versus fibrinogen and/or prothrombin complex concentrates
Nishijima 2009[522]	Systematic review checked for included studies
Olldashi 2011[534]	Pre specified analysis on time to treatment
Rizoli 2006[591]	Sub group analysis of patients with coagulopathy
Roberts 2012[593]	Pre specified analysis on outcomes according to baseline risk of death
Roberts 2013[592]	CRASH-2 results (no additional outcomes from extracted paper)
Ross 2012[596]	Meta-analysis checked for included studies
Simpson[644]	Systematic review crossed checked for relevant studies
Yutthakasemsunt [762]	Patients with traumatic brain injury

K.5.4 Anticoagulation reversal

Table 10: Studies excluded from the clinical review

Reference	Reason for exclusion
Bechtel 2011[48]	Incorrect population: people with intracranial haemorrhage
Joseph 2013[347]	Incorrect population: people with intracranial haemorrhage
Joseph 2014[348]	Incorrect study design: not a RCT
Nishijima 2012[523]	Incorrect population: people with intracranial haemorrhage

K.5.5 Haemorrhage shock prediction/risk tools

Table 11: Studies excluded from the clinical review

Study	Reason for exclusion

Study	Reason for exclusion
Baker[37]	Derivation cohort
Callcut[102]	Study looking at the predictive value of individual massive transfusions triggers rather than a score or tool
Callcut[103]	Derivation cohort
Chen[123]	Abstract – not on a risk prediction tool
DeMuro[176]	Study looking at the prediction of bleeding > 2 packed red blood cells rather than massive transfusion
Gregg[268]	Abstract of scores with full papers already included
Jones[345]	Score to predict transfusion (not massive transfusion).
Jung[350]	Derivation cohort
King[366]	Tool not predicting major haemorrhage
Kuhne[393]	Prediction of transfusion not major haemorrhage
Larson[406]	Derivation cohort
Maegele[439]	Systematic review (included papers cross checked)
Maegele [441]	Internal validation
Mina[480]	Internal validation
Mitra[486]	Prediction of acute traumatic coagulopathy
Ogura 2014[531]	Not an external validation
Ogura[529]	Abstract of derivation cohort
Ogura[530]	Abstract of derivation cohort
Rainer[573]	Derivation cohort
Raux[582]	Target condition not massive transfusion
Ruchholtz[603]	Derivation cohort
Schreiber[620]	Derivation cohort
West[735]	Tested different variables to predict blood requirement and as such represents a derivation data set. No diagnostic accuracy data.
Yucel[761]	Interval validation

K.5.6 IO/IV access

Table 12: Studies excluded from the clinical review

Reference	Reason for exclusion
Anderson 1994[12]	Incorrect study design (non-comparative study)
Baker 2009[38]	Incorrect intervention (training of staff)
Byars 2011[99]	Incorrect study design (non-comparative study)
Cheung 2012[127]	Incorrect study design (survey of clinician beliefs)
Cheung 2013[126]	Incorrect study design (survey of clinician beliefs)
Chiang 2000[128]	Incorrect study design (non-comparative study)
Cooper 2007[150]	Incorrect study design (case series)
Curran 2005[157]	Comparison does not match protocol (comparison of IO devices)
Fenchel 2013[230]	Incorrect study design (non-comparative study)
Findlay 2006[231]	Incorrect study design (laboratory study)
Frascone 2001[242]	Incorrect study design (article)
Frascone 2007[243]	Comparison does not match protocol (comparison of IO devices)

Reference	Reason for exclusion
Gerritse 2009[261]	Incorrect study design (non-comparative study)
Guy 1993[277]	Incorrect study design (non-comparative study)
Hansen 2011[288]	Incorrect study design (non-comparative study)
Harcke 2011[290]	Incorrect study design (laboratory study)
Hartholt 2010[293]	Comparison does not match protocol (comparison of IO devices)
Hunsaker 2013[323]	Guideline
Isayama 2012[333]	Incorrect study design (non-comparative study)
Iserson 1989[334]	Incorrect study design (non-comparative study)
Jaimovich 1991[336]	Incorrect study design (article)
Lamhaut 2010[405]	Incorrect study design (laboratory study)
Leidel 2010[417]	Comparison does not match protocol (comparison of IO devices)
Neal 1994[510]	Incorrect study design (article)
Olaussen 2012[533]	Incorrect study design (literature review)
Parrish 1986[541]	Incorrect study design (article)
Rieger 1994[589]	Incorrect study design (article)
Santos 2013[610]	unavailable
Schwartz 2008[622]	Incorrect study design (non-comparative study)
Shah 2010[629]	Incorrect study design (article)
Smith 2005[655]	Incorrect study design (audit)
Spivey 1987[672]	Incorrect study design (article)
Sunde 2010[685]	Comparison does not match protocol (comparison of IO devices)
Sweeney 2001[688]	Incorrect study design (article)
Torres 2013[704]	Comparison does not match protocol (comparison of IO devices)

K.5.7 Volume resuscitation

Table 13: Studies excluded from the clinical review

Study	Reason for exclusion
Alsawadi 2012[10]	Narrative systematic review.
Bishop 1995[67]	Incorrect interventions. Compares values monitoring techniques following resuscitation.
Dretzke 2006[198]	Narrative review of RCT's and observational studies.
Dunham 1991[207]	Compares a normal resuscitation model with a rapid device.
Kokoska 1998[376]	Incorrect study design. Retrospective review.
Kwan 2001[398]	Previous version of Kwan 2001.
Kwan 2014[399]	Cochrane review with no analyses. Includes non-trauma populations.
Madigan 2008[438]	Incorrect study design. Retrospective chart review
Martin 1992[454]	Preliminary report of Bickell 1994.
Metzger 2011[476]	Animal study.
Morrison [497]	Groups were not matched for ISS score at baseline.
Pearson 2011[550]	Review article for management of shock.
Rossaint 2010[597]	Incorrect study design. Consensus guideline document.
Turner 2000 [710]	Study at very high risk of bias. Study protocol not completed.
Vassar 1993[718]	Incorrect interventions. Study compares fluid regimes given following

Study	Reason for exclusion
	trauma

K.5.8 Fluid replacement

Table 14: Studies excluded from the clinical review

Study	Reason for exclusion
Ball 2013[39]	Cohort study - RCT included
Bhangu 2013[60]	SR checked for included studies
Borgman 2007[76]	Doesn't covary according to age or state if matched at baseline. No adjusted comparison data between cohorts. Crude mortality rates presented for each group.
Borgman 2011[75]	Risk of ratio of blood products based in the TASH score (not recommended in the guideline)
Brakenridge 2011[78]	Study looking at association between early blood product and crystalloid volume resuscitation and the risk of MOD
Brasel 2011[82]	Cohort study - RCT included
Brown 2011[91]	Groups not matched at baseline for age and no adjustment in multivariate analysis
Brown 2013[90]	Low dose vs. high-dose crystalloid
Cotton 2008[152]	Pre vs. post protocol
De biasi 2011[167]	Baseline differences and no multivariate analysis
Del junco 2013[172]	No baseline data presented according to ratios. Adjusted analysis did not include GCS or equivalent or shock
Dirks 2010[189]	Cohort study - RCT included
Duchesne 2010[204]	Damage control laparotomy vs conventional resuscitation
Duchesne 2013[205]	No extractable outcomes
Gonzalez 2007[265]	No relevant outcomes
Halmin 2013[286]	Cohort study - RCT included
Ho 2012[304]	Markov model with no extractable clinical data
Holcomb 2008[310]	Wrong intervention
Holcomb 2011[308]	Wrong intervention
Holcomb 2013[307]	Not massive transfusion
Inaba 2010[329]	Wrong intervention
Kashuk 2008[354]	Excluded patients with co-morbidities
Khan 2011[362]	No comparison of ratios
Kudo 2014[392]	Cohort study – RCT included
Lustenberger 2011[431]	Cohort study - RCT included
Maegele 2008[440]	Cohort study - RCT included
Magnotti 2011[442]	Cohort study - RCT included
Mell 2010[474]	Non-trauma population
Mitra 2010[487]	Cohort study - RCT included
Mitra 2012[488]	Cohort study - RCT included
Peiniger 2011[551]	Cohort study - RCT included
Perkins 2009[553]	Wrong intervention
Rowell 2011[599]	Cohort study - RCT included

Study	Reason for exclusion
Sambasivan 2011[608]	Wrong intervention
Savage 2014[612]	Cohort study – RCT included
Scalea 2008[613]	Cohort study - RCT included
Sharpe 2012[634]	No baseline data or adjustment for head injury
Shaz 2010[635]	No baseline data or adjustment for shock
Snyder 2009[661]	Cohort study - RCT included
Sperry 2008[669]	Cohort study - RCT included
Stinger 2008[678]	Fibrinogen to red cell ratio (fibrinogen derived from multi blood products)
Teixeira 2009[697]	Cohort study - RCT included
Van 2010[716]	No details of baseline variables for high vs low ratio gps
Zink 2009[766]	Same data as used in Holocomb 2008 and Holocomb multivariate analysis

K.6 Control of haemorrhage in hospital

K.6.1 Haemorrhage protocols

Table 15: Studies excluded from the clinical review

Study	Reason for exclusion
Ball 2013[39]	Incorrect study design (cohort study)
Cotton 2009[153]	Incorrect study design (cohort study)
Dirks 2010[189]	Incorrect study design (cohort study)
Duchesne 2008[203]	Incorrect study design (cohort study)
Hallet 2013[285]	Systematic review is not relevant to review question or unclear PICO
Hendrickson 2012[301]	Incorrect study design (cohort study)
Kaur 2011[358]	Systematic review is not relevant to review question or unclear PICO
Khan 2013[363]	Incorrect study design (cohort study)
Kutcher 2013[397]	Incorrect study design (case series)
Mcintyre 2004[467]	Incorrect interventions (liberal versus restrictive allogeneic red blood cell transfusion strategy)
Mcintyre 2006[468]	Incorrect interventions (liberal versus restrictive allogeneic red blood cell transfusion strategy)
Mitra 2013[489]	Systematic review is not relevant to review question or unclear PICO
Morrison 2011[497]	Incorrect interventions (hypotensive versus normotensive resuscitation)
Peiniger 2011[551]	Incorrect study design (case series)
Radwan 2013[572]	Incorrect study design (cohort study)
Rajasekhar 2011[575]	Systematic review is not relevant to review question or unclear PICO
Sisak 2012[649]	Incorrect study design (cohort study)
Tan 2012[691]	Incorrect study design (case series)
Tapia 2013[693]	Incorrect study design (cohort study)
Yin 2014[759]	Incorrect study design (cohort study)

K.6.2 Haemorrhage imaging

Table 16: Studies excluded from the clinical review

Reference	Reason for exclusion
Ahmed 2013[3]	Intervention/comparison does not match protocol
Baron 1993[43]	Intervention/comparison does not match protocol
Brooks 2004[87]	Outcome does not match protocol question
Brown 2005[89]	Intervention/comparison does not match protocol
Catalano 2004[115]	Comparison does not match protocol
Cerva 1996[118]	Intervention/comparison does not match protocol
Demetriades 1995[174]	Intervention/comparison does not match protocol
Dormagen 2010[194]	Intervention/comparison does not match protocol
Eddy 2000a[215]	Intervention/comparison does not match protocol
Friese 2007[247]	Intervention/comparison does not match protocol
Fry 1994[248]	Intervention/comparison does not match protocol
Glaser 1994[264]	Intervention/comparison does not match protocol
Grodzinski 2003[270]	Non-English language publication
Gruessner 1989[272]	Intervention/comparison does not match protocol
Helling 2007[300]	No diagnostic accuracy data and not specifically detecting haemorrhage
Hoffmann 1992 [306]	Intervention/comparison does not match protocol
Holmes 2001[312]	Intervention/comparison does not match protocol
Howes 2012[315]	Incorrect study design
Jehle 1993[341]	Intervention/comparison does not match protocol
Kimura 1991[364]	Intervention/comparison does not match protocol
Knudson 1993[372]	Intervention/comparison does not match protocol
LaSelle 2012[407]	No diagnostic accuracy data and not specifically detecting haemorrhage
Liger 1993[420]	Intervention/comparison does not match protocol
Liu 1993[423]	Intervention/comparison does not match protocol
Lv 2011[432]	Intervention/comparison does not match protocol
Ma 1997[433]	Outcome does not match protocol question
Marnocha 1985[453]	Intervention/comparison does not match protocol
Maturen 2007[457]	Intervention/comparison does not match protocol
Mclellan 1996[470]	Intervention/comparison does not match protocol
Mirvis 1987[483]	Intervention/comparison does not match protocol
Mirvis 1998[484]	Intervention/comparison does not match protocol
Mohseni 2011[490]	Intervention/comparison does not match protocol
Montalvo 1996[491]	Intervention/comparison does not match protocol
Morgan 1992[495]	Intervention/comparison does not match protocol
Mutze 2005[504]	Intervention/comparison does not match protocol
Niola 2011[521]	Intervention/comparison does not match protocol
Ojaghihaghighi 2014[532]	Reference standard of CT was not reported as multidetector or helical
Pereira 2000[552]	Intervention/comparison does not match protocol
Pinto 2010[555]	Intervention/comparison does not match protocol
Poletti 2000[558]	Intervention/comparison does not match protocol
Purvis 2013[568]	Intervention/comparison does not match protocol

Reference	Reason for exclusion
Rabinowitz 2004[571]	Intervention/comparison does not match protocol
Raptopoulos 1992[581]	Intervention/comparison does not match protocol
Renton 2003[585]	Intervention/comparison does not match protocol
Richards 1997[587]	Intervention/comparison does not match protocol
Rozycki 1995[602]	Intervention/comparison does not match protocol
Shackford 1999[626]	Intervention/comparison does not match protocol
Shanmuganathan 1999[632]	Intervention/comparison does not match protocol
Siniluoto 1992[647]	Intervention/comparison does not match protocol
Sivit 1992[652]	Intervention/comparison does not match protocol
Sivit 1994[651]	Intervention/comparison does not match protocol
Smith 2014[660]	Intervention/comparison does not match protocol
Soyuncu 2007[665]	Intervention/comparison does not match protocol
Stephen 1999[677]	Intervention/comparison does not match protocol
Suhail 2010[684]	Intervention/comparison does not match protocol
Sustic 1999[687]	Intervention/comparison does not match protocol
Wintermark 2002[742]	Outcome does not match protocol question
Wu 2011[745]	Intervention/comparison does not match protocol
Yeh 1997[757]	Intervention/comparison does not match protocol
Yeo 1999[758]	Intervention/comparison does not match protocol
Yoshii 1998[760]	Intervention/comparison does not match protocol
Zhou 2012[765]	Intervention/comparison does not match protocol

K.6.3 Whole-body CT

Table 17: Studies excluded from the clinical review

Study	Reason for exclusion
Bardon 2012[41]	Non-comparative study.
Beenen 2014[51]	Study not ordered as Systematic review and more studies available.
Behzadi 2015[52]	Non-major trauma population.
Brun 2014[93]	Non-comparative study.
Caputo 2014[110]	Systematic review: literature search not sufficiently rigorous
Chun 2010[132]	Systematic review: quality assessment is inadequate
Deyle 2009[183]	Comparison does not match protocol (full-body digital x-ray versus standard x-ray)
Dinh 2013[188]	Not applicable to protocol, considers trauma team activation.
Epstein 2009[217]	Not applicable to protocol, Study compares reproducibility of 2 imaging modalities.
Eurin 2012[219]	Non-comparable study.
Exadaktylos 2008[224]	Narrative review.
Fakler 2014[225]	Non-comparative study.
Fanucci 2007[227]	Baseline characteristics not presented.
Foster 2011[236]	Not applicable to predictable, considers addition of whole body to lower body.
Gordic 2015[266]	Not matched for depth of shock, degree of head injury.

Study	Reason for exclusion
Gupta 2011[276]	No data presented for baseline comparison of confounders.
Harcke 2007[289]	Autopsy study
Hartin 2013[294]	Non-comparative, irrelevant outcomes.
Healy 2014[299]	Systematic review: quality assessment is inadequate
Huber-wagner 2009[319]	Not matched for head injury, depth of shock.
Huber-wagner 2013[318]	Not matched for Age, ISS, Head injury.
Hudson 2012[320]	Does not apply to protocol, Study compares the use of a plain radiograph or not, prior to CT.
Hutter 2011[327]	Not matched for ISS, head injury, age, depth of shock.
Kimura 2013[365]	Not matched for age, ISS, depth of shock.
Lee 2014[414]	Cost-analysis. No clinical outcome.
Loewenhardt 2014[426]	Study not applicable to protocol, compares x-ray machines and radiation
Luitse 2009[429]	Incorrect study design (protocol only)
Mahoney 2012[444]	Not matched for ISS, does not report head injury or depth of shock.
Ojaghi haghighi 2014[532]	Study with diagnostic outcomes.
Ong 2015[537]	Not matched for age.
Quick 2013[569]	Does not present with relevant clinical outcomes. Compares in-house radiology protocols.
Saltzherr 2009[606]	Incorrect study design (critical appraisal of cohort study)
Sierink 2012[643]	Study protocol only
Sierink 2012[639]	Incorrect study design, letter to the editor.
Sierink 2012[640]	Systematic review: quality assessment is inadequate
Sierink 2013[642]	Does not report level of shock. Radiation outcomes are not long term.
Sierink 2014[641]	Non-comparative study.
Sierink 2014[638]	Not matched for head injury (GCS) or ISS.
Smith 2012[653]	Report on usage of UK CT scans.
Stengel 2014[675]	Study protocol only.
Surendran 2014[686]	Systematic review: quality assessment is inadequate
Van vugt 2012[715]	Systematic review: literature search not sufficiently rigorous
Weninger 2007[734]	No data reported for baseline shock.
Wurmb 2007[749]	Diagnostic outcomes reported.
Wurmb 2009[748]	Baseline characteristics not presented.
Wurmb 2011[750]	Not matched for ISS.
Yeguiayan 2012[756]	Study reported in French.

K.6.4 Damage control surgery

Table 18: Studies excluded from the clinical review

Reference	Reason for exclusion
Camacho Aguilera 2013[104]	Non-English language
Cirocchi 2013[135]	Review- no useful references yielded
Dubose 2013[201]	Non-comparative study
Higa 2010[302]	Retrospective comparative study, but very large baseline differences between groups in terms of ISS, AIS and TRISS, which were all in favour of definitive surgery. These were so large (ISS in damage control group was

Reference	Reason for exclusion
	double that of the definitive surgery group) that the GDG felt they would have been a major influence on outcomes, rather than the treatments under investigation. Thus the internal validity of the study was felt to be irrevocably compromised. No data on baseline haemodynamics, and no adjustment for baseline haemodynamics.
Huang 2007[316]	No comparison group
Jansen 2009[338]	Review- no useful references yielded
Stahel 2013[673]	Orthopaedic Damage control
Bograd 2013[70]	No adjustment for shock-related baseline variables.
Campion 2013[105]	No data on baseline haemodynamics, and no adjustment for baseline haemodynamics.
Rotondo 1993[598]	No data on baseline haemodynamics, and no adjustment for baseline haemodynamics.

K.6.5 Interventional radiology

Table 19: Studies excluded from the clinical review

Study	Reason for exclusion
Agolini 1997[2]	No baseline data or adjustment
Akowuah 2007[5]	Not Demonstrates baseline comparability or controls for confounders using MVA
Akowuah 2009[4]	SR checked for included studies
Albors 2009[7]	No baseline variables or adjusted results
Andrassy 2006[13]	No baseline comparison between groups
Asaid 2014[21]	No operative repair group
Asano 2011[22]	Not guideline condition
Asensio 2000[23]	Not Demonstrates baseline comparability or controls for confounders using MVA
Asensio 2003[25]	Inappropriate comparison
Asensio 2007[24]	Study is not relevant to review question or unclear PICO
Asmat 2007[27]	Protocol
Augusto negro 2012[31]	Not Demonstrates baseline comparability or controls for confounders using MVA
Azizzadeh 2009[33]	No baseline data or adjustment for shock
Bell 2010[53]	No open repair group
Bessoud 2006[59]	Non-operative versus embolisation
Bhasin 2012[61]	No operative repair group
Broux 2006[88]	Not Demonstrates baseline comparability or controls for confounders using MVA
Bruce 2001[92]	Not Demonstrates baseline comparability or controls for confounders using MVA
Canaud 2011[106]	Only age and ISS in baseline variables, no adjustment
Cannon-2012[108]	No baseline variables or adjustment
Carrick 2010[112]	Not matched on baseline variables or no multivariate analysis
Castelli 2005[114]	Incorrect study design
Clemente 2011[139]	Not Demonstrates baseline comparability or controls for confounders

Study	Reason for exclusion
	using MVA
Cocanour 1998[144]	Not Demonstrates baseline comparability or controls for confounders using MVA
Cook 2006[149]	Not direct comparison between IR and operative repair
Demetriades 1999[173]	Incorrect study design
Demetriades 2009[175]	Early versus delayed endovascular repair
Di eusanio 2013[185]	Delayed management
Dick 2008[186]	Not all trauma patients (no sub group)
Dolin 1992[191]	Incorrect study design
Doss 2003[195]	Not Demonstrates baseline comparability or controls for confounders using MVA. No mention of baseline injury severity, shock or GCS. No multivariate analysis
Du toit 2008[199]	Not Demonstrates baseline comparability or controls for confounders using MVA
Duane 2004[200]	Not Demonstrates baseline comparability or controls for confounders using MVA
Eassa 2010[211]	Not Demonstrates baseline comparability or controls for confounders using MVA
Forlee 2004[235]	Not Demonstrates baseline comparability or controls for confounders using MVA
Gaarder 2006[249]	Incorrect interventions. Comparison of treatment protocols specifying clinical criteria for IR
Gao 2005[253]	Not Demonstrates baseline comparability or controls for confounders using MVA
Gavant 1997[257]	Incorrect study design
Geisbusch 2009[259]	Not matched on head injury/GCS
Gross 2013[271]	No relevant outcomes with multivariate analysis
Haan 2001[279]	Inappropriate comparison
Hagiwara 1997[282]	Not Demonstrates baseline comparability or controls for confounders using MVA
Hauschild 2012[296]	Inappropriate comparison
Hoffer 2008[305]	SR (checked for included studies)
Inchingolo 2014[331]	Not Demonstrates baseline comparability or controls for confounders using MVA
Jeske 2010[344]	Not Demonstrates baseline comparability or controls for confounders using MVA
Karmy-jones 2003[353]	No mention of baseline shock, injury severity, GCS
Kasirajan 2003[356]	Baseline differences in ISS, no adjustment
Klima 2013[369]	Non-RCT (no matched for age 46.1 versus 35.7). No mention of shock
Kokotsakis 2007[377]	No mention of baseline shock or degree of head injury
Kurimoto 2006[395]	Baseline data not comparable or no adjusting for confounders
Kwon 2013[400]	Conference abstract
Lebl 2006[410]	No demographic details at baseline
Letoublon 2011[418]	Incorrect interventions
Li petri 2012[419]	Not Demonstrates baseline comparability or controls for confounders using MVA

Study	Reason for exclusion
Liu 2012[424]	Not Demonstrates baseline comparability or controls for confounders using MVA
Mächler 1999[434]	Aortic valve replacement
Mackenzie 2004[436]	Not Demonstrates baseline comparability or controls for confounders using MVA
Malina 2000[446]	Not guideline condition
Mayglothling 2011[461]	No details of baseline variables or adjusted analysis
Mcphee 2007[473]	No details or adjustment for shock or head injury
Moolman 2012[493]	Not Demonstrates baseline comparability or controls for confounders using MVA
Morishita 2004[496]	Not all trauma patients (no sub group reported)
Moudouni 2001[500]	Inappropriate comparison
Mousa 2010[501]	Adjusted analysis for age only
Mustafa 2010[503]	Not major trauma
Negro 2012[511]	Not Demonstrates baseline comparability or controls for confounders using MVA
Nelson 2013[515]	Non-RCT (no mention of baseline shock or multivariate analysis)
Nicholson 2010[519]	Study is not relevant to review question or unclear PICO
Ott 2004[538]	No baseline data on shock or adjustment
Patel 2009[545]	Not trauma patients
Powers 2013[564]	No details of baseline demographics or multivariate analysis
Rao 1993[580]	Not Demonstrates baseline comparability or controls for confounders using MVA
Richard 2010[586]	Not Demonstrates baseline comparability or controls for confounders using MVA
Saltzherr 2011[607]	Not Demonstrates baseline comparability or controls for confounders using MVA
Sarihan 1998[611]	Not Demonstrates baseline comparability or controls for confounders using MVA
Schuster 2013[621]	Systematic review: study designs inappropriate
Sclafani 1985[623]	Not Demonstrates baseline comparability or controls for confounders using MVA
Shalhub 2011[631]	Not Demonstrates baseline comparability or controls for confounders using MVA
Sincos 2011[645]	Groups not matched on TRISS score Surgery 15.5 endo 31.1
Sinha 2013[646]	Systematic review checked for included studies
Siritongtaworn 2005[648]	Not Demonstrates baseline comparability or controls for confounders using MVA
Trooskin 1993[709]	No baseline reporting or adjustment
Wahl 2002[727]	Not Demonstrates baseline comparability or controls for confounders using MVA
Watson 2013[728]	No baseline reporting of head injury or adjustment
Wei 2008[732]	Not Demonstrates baseline comparability or controls for confounders using MVA
Whigham 2002[736]	Not Demonstrates baseline comparability or controls for confounders using MVA
Worni 2013 [743]	Wrong patient population

Study	Reason for exclusion
Wu 2007[747]	Inappropriate comparison
Wu 2008[746]	Incorrect study design
Xenos 2003[751]	Baseline data not comparable or no adjusting for confounders
Xian-kai 2007[752]	Not Demonstrates baseline comparability or controls for confounders using MVA

K.7 Monitoring

K.7.1 Coagulation testing

Table 20: Studies excluded from the clinical review

Reference	Reason for exclusion
Brazzel 2013[83]	Incorrect study design (non-systematic review)
Celenza 2011[117]	Not trauma population
Choi 2014[131]	Incorrect study design (non-systematic review)
Cotton 2011a[151]	Incorrect index test (not PoC)
Daluz 2013[161]	Incorrect study design (non-systematic review)
Davenport 2009[162]	Conference abstract
Doran 2010[193]	Not diagnostic accuracy
Gryfelt 2013[273]	Conference abstract
Hagemo 2013[281]	Incorrect study design (non-systematic review)
Hanke 2012[287]	Conference abstract
Holcomb 2012[309]	Not diagnostic accuracy
Hunt 2013[324]	Incorrect study design (systematic review protocol)
Jeger 2009[340]	Not diagnostic accuracy
Jeger 2011[339]	Conference abstract
Kashuk 2009[355]	Not diagnostic accuracy
Kaufmann 1997[357]	Not diagnostic accuracy
Keene 2013[360]	Incorrect study design (non-systematic review)
Kutcher 2012[396]	Not diagnostic accuracy
Leeman 2010[415]	Flawed methodology: index test was used to guide treatment and this affected gold standard (future massive transfusion)
Nascimento 2012[508]	Incorrect index test (not PoC)
Nystrup 2011[526]	Flawed methodology: index test was used to guide treatment and this affected gold standard (mortality)
Pezold 2012[554]	Flawed methodology index test was used to guide treatment and this affected gold standard (future massive transfusion)
Ramos 2013[578]	Conference abstract
Raza 2013[583]	Incorrect index test (not PoC)
Reed 2013[584]	Mixed population
Sankarankutty 2012[609]	Systematic review (incorrect PICO)
Schochl 2011[619]	Flawed methodology: index test was used to guide treatment and this affected gold standard (future massive transfusion)
Schochl 2013[618]	Incorrect study design (non-systematic review)
Shah 2011[627]	Conference abstract

Reference	Reason for exclusion
Sorensen 2012[664]	Incorrect study design (non-systematic review)
Subramanian 2014[683]	Incorrect index test (not PoC)
Tanaka 2012[692]	Incorrect study design (non-systematic review)
Tauber 2011[694]	Incorrect index test (not PoC)
Theusinger 2013[698]	Incorrect study design (non-systematic review)

K.7.2 Frequency of blood testing

Table 21: Studies excluded from the clinical review

Study	Reason for exclusion
Asimos 2000[26]	Reports change in management plans as result of point of care testing
Bar-Or 2013[40]	Inappropriate comparison: Study compared outcomes across the staged introduction of a resuscitation protocol using lactate levels to guide treatment for occult hypoperfusion in geriatric patients. A proportion of patients in each group received treatment guided by lactate levels.
Cardenas 2014[111]	No diagnostic accuracy data
Chen 2013[124]	Incorrect setting: pre-hospital
Frederickson 2013[244]	Incorrect interventions: implementation of ED protocols
Louis 2014[428]	Incorrect interventions: fixed or test-guided enoxaparin dosing
Ungerstedt 2003[713]	Incorrect interventions: treatment study investigating antithrombin concentrate

K.7.3 Lactate levels

Table 22: Studies excluded from the clinical review

Reference	Reason for exclusion
Andersen 2013 [11]	Systematic review. Included studies do not match review protocol
Bar-or 2013[40]	Inappropriate comparison: Study compared outcomes across the staged introduction of a resuscitation protocol using lactate levels to guide treatment for occult hypoperfusion in geriatric patients. A proportion of patients in each group received treatment guided by lactate levels.
Blow 1999[69]	Inappropriate comparison: Study compares outcomes of patients who receive lactate-guided treatment for occult hypoperfusion with expected mortality as based on TRISS methodology.
Porter 1998[562]	Systematic review. Included studies do not match review protocol
Wilson 2003[740]	Systematic review. Included studies do not match review protocol

K.8 Warming

Table 23: Studies excluded from the clinical review

Study	Reason for exclusion
Bernardo 1997[57]	No outcomes associated with protocol
Bernardo 2000[58]	Narrative review
Bernardo 2001[56]	No outcomes applicable to protocol
Cohen 2002[145]	No outcomes associated with protocol
Farstad 2001[229]	Incorrect interventions. Compares extracorporeal re-warming protocol in

Study	Reason for exclusion
	severe hypothermia.
Fox 1988[237]	Incorrect interventions. Retrospective case review. No treatment comparison.
Greif 2000[269]	Not guideline condition. Healthy volunteers.
Husum 2002[326]	Population not applicable to question.. No outcomes applicable to protocol.
Karlsen 2013[352]	Study is a survey of available interventions. Does not measure their efficacy based on outcomes.
Kober 2002[374]	Not guideline condition. All patients with minor trauma (small fractures/contusions).
Kornberger 1996[378]	Non-major trauma population. Hypothermia due to severe cold.
Kornberger 1999[379]	Non-major trauma population. Hypothermia due to severe cold.
Leben 1996[409]	Abstract only. Not published as full article.
Lundgren 2011[430]	Outcomes not associated with protocol. Surrogate measures.
Mccall 2008[462]	Not guideline condition
Scheck 2002[615]	Abstract only. Outcomes not applicable to protocol.
Scheck 2003[614]	German Language
Scheck 2004[616]	Outcomes not associated with protocol.
Sharma 2012[633]	Not guideline condition. Abstract only. Perioperative patients.
Spinella 2008[670]	Narrative review
Spinella 2009[671]	Considers addition of warmed blood
Stone 1994[680]	Non-human study
Strasser 2002[681]	Abstract only. Outcomes not applicable to protocol.
Ting 2012[701]	Editorial response
Van der ploeg 2010[714]	Outcomes are not reported per intervention. Population not entirely trauma.
Watts 1999[729]	Outcomes cannot be extracted. Not applicable to protocol. Study not matched for confounders.

K.9 Pain

K.9.1 Pain assessment

Table 24: Studies excluded from the clinical review

Study	Reason for exclusion
Aboud 2003[1]	Not guideline condition. Non-trauma population.
Aragao 2012[16]	Not guideline condition. Patients with Deep infiltrating endometriosis.
Arana 2006[17]	Not guideline condition. Trauma patients excluded from study.
Avluk 2013[32]	Not guideline condition. Non-trauma population - Chronic pain in spinal injury.
Baumann 2007[46]	Study reports the association of pain scales with administration of analgesia. Not specific outcome to protocol.
Baxt 2004[47]	Outcome not appropriate. Correlation between parent and patient-related pain.
Bierner 2012[62]	Validation of tool in alternative language. Non-specific outcome to protocol.

Study	Reason for exclusion
Bierner 2012[63]	Validation of tool in different language. Non-specific outcome to protocol.
Bird 2001[66]	Studies measures clinically significant changes in scale. Non-specific outcome to protocol.
Brand 2010[80]	Review article. Unable to measure outcome.
Brand 2013[79]	Review of literature.
Bulloch 2002[97]	Study assesses changes in paediatric pain scales associated with clinically significant change in pain status. Non-specific outcome to protocol.
Bulloch 2009[96]	Indirectness in population (not all non-trauma). Validation tool for reproducibility of Pain Assessment Tool. Outcome not specified in protocol.
Chan 2007[121]	Not guideline condition. Patients with Carpal Tunnel Syndrome. Indirect Population.
Chisholm 2008[129]	Outcome not applicable. Measures accuracy of pain estimating procedures.
Clay 2012[138]	Not guideline condition. Patients with Chronic Pain following orthopaedic trauma.
De souza 2011[169]	Not guideline condition. Patients with Rheumatoid Arthritis.
Dijkers 2010[187]	Not guideline condition. Chronic pain following spinal cord injury.
Easton 2012[212]	Study measures reproducibility of pain scores. Non-specific outcome to protocol.
En 2009[216]	Patients with chronic non-traumatic neck pain.
Forchheimer 2011[234]	Not guideline condition. Patients with chronic pain following spinal cord injury.
Gallagher 2001[251]	Study measures clinically important difference of a visual analogue scale-related to pain severity. Non-specific outcome to protocol.
Gallagher 2002[250]	Reproducibility and validity study of visual analogue scale. Non-specific outcome to protocol.
Ganty 2009[252]	Not guideline condition. Chronic pain in outpatient setting.
Garra 2011[255]	Study correlated paediatric pain scale and clinical fear scale. Validation study for pain scale. Inappropriate to study outcome.
Garra 2012[254]	Study design incorrect. Correlation of individual pain scales. Non-specific outcome to protocol.
Garra 2013[256]	Unable to obtain paper.
Geers 2011[258]	Study reports the association of pain scales with administration of analgesia. Not specific outcome to protocol. Abstract only.
Hagberg 2005[280]	Not guideline condition. Non-trauma population.
Haley 2012[284]	No relevant outcomes and does not match review question. Abstract only.
Holmes 2010[311]	Not guideline condition. Population was measured for pain 3 months following traumatic incident.
Holtslag 2007[313]	Not Applicable. No tool measuring pain. Non-specific outcome to protocol.
Humphreys 2002[322]	Not guideline condition. Outpatient setting (Chronic Neck Pain)
Iakova 2012[328]	Not guideline condition. Rehabilitation Population. Non-specific outcome to protocol.
Izsak 2008[335]	Pain assessment protocol not specified.
Kelly 1998[361]	Not guideline condition. Study measures clinically relevant change on scale. Non-specific outcome to protocol.

Study	Reason for exclusion
Lamb 2010[404]	Audit of pain management provisions. Outcomes non-specific to protocol.
Maida 2009[445]	Not guideline condition. Patients with advanced Chronic Illness.
Marco 2006[451]	Correlates pain with vital clinical scores (HR, BP). Non-specific outcome to protocol.
Marco 2011[448]	Association of Pain with clinical factors. Non-specific outcome to protocol.
Marco 2012[449]	Association of pain with socio-economic factors. Non-specific outcome to protocol.
May 2011[459]	Study correlates and validates paediatric scales. Inappropriate to study outcome.
Mcconahay 2007[464]	Study outcome measures clinically important differences on a scale. Non-specific outcome to protocol.
Mcconahay 2009[463]	Study evaluates reproducibility of scale. Non-specific outcome to protocol.
Mcgregor 1996[466]	Not guideline condition. Chronic Orofacial Pain.
Miner 2011[481]	Association of pain with stress and anxiety. Non-specific outcome to protocol.
Miner 2012[482]	Study reports the association of pain scales with administration of analgesia. Not specific outcome to protocol. Abstract only.
Nelson 2004[514]	Not guideline condition. Not major trauma.
Nicholas 2008[518]	Not guideline condition. Patients with chronic low back pain.
Olsson 2002[535]	Not guideline condition. Patients with Whiplash
Payen 2001[549]	Validation study of behavioural pain scale in a critically ill sedated population. Non-specific outcome to protocol.
Rose 2013[595]	Study reports the effects of using a observational pain tool on administration of analgesics in a critically ill population. Not specific outcome to protocol.
Scott 2012[624]	Not guideline condition. Osteoarthritis.
Siddall 1999[636]	Not guideline condition. Chronic pain following Spinal Cord Injury.
Siddall 2003[637]	Not guideline condition. Chronic pain following Spinal cord injury.
Todd 1996[702]	Study measures clinically important difference of a visual analogue scale-related to pain severity. Non-specific outcome to protocol.
Tottenham 2011[706]	Validation study determining the relationship between individual pain scales. Non-specific outcome to protocol.
Tristao 2013[708]	Not guideline condition. Non-trauma neonate population.
Vazirani 2012[719]	No relevant outcomes and does not match review question.
Weng 2012[733]	Validation of novel pain assessment tool. Correlation with verbal pain tool. Non-specific outcome to protocol.
Whipple1995[737]	Study measures pain management (that is, time to analgesia) when pain scale is applied. Non-specific to outcome.
Yamamotova 2010[754]	Association of Pain with Biochemical blood measures. Non-specific outcome to protocol.

K.9.2 Pain management

Table 25: Studies excluded from the clinical review

Study	Reason for exclusion

Study	Reason for exclusion
Baharuddin 2014[35]	Incorrect interventions. Study compares intravenous parecoxib with morphine.
Berkenstadt 1999[55]	Incorrect study design. Case series reporting pharmokinetics following opioid administration.
Black karen 2013[68]	Cochrane review for nerve blockade for pain management following femoral fracture.
Bondarsky 2013[72]	Non-major trauma population and incorrect drug administration. Drugs administered orally.
Bonnemaison 1999[73]	Non-English language.
Burge 2013[98]	Not guideline condition. Patient population not defined to include Major trauma.
Candiotti 2010[107]	Incorrect interventions. Study considered different IV doses of acetaminophen. Population incorrect. Inpatient hospital population, typically post-surgery.
Cicala 1990[134]	Study reports Epidural bupivacaine versus Lumbar epidural morphine. Outcomes not to protocol.
Clark 2007[136]	Incorrect interventions. Oral administration of acetaminophen, ibuprofen or codeine. Not specified in protocol.
Curtis 2007[159]	Incorrect study design. Prospective study (non-RCT) reporting on implementation of fentanyl based protocol. No intervention comparison.
De nadal 2000[168]	Head injury.
Devellis 1998[182]	Incorrect study design. Retrospective review of fentanyl analgesia in pre-hospital patients.
Ducasse 2013[202]	Incorrect interventions. Study compares Entonox with medical oxygen. Intervention now specified.
Evans 2005[221]	Study compares method of opioid administration (nurse controlled versus patients controlled).
Farahmand 2012[228]	Population considers the efficacy of pre-administration with naltrexone for reduction in opioid side effects.
Franceschi 2010[238]	Incorrect interventions. Study compares acetaminophen plus codeine with ketorolac.
Franceschi 2013[239]	Review reporting on efficacy and safety of Acetaminophen-codeine combined therapy in non-major trauma populations.
Friday 2009[245]	Non-major trauma population. Acetaminophen and codeine administered orally. Inappropriate intervention.
Gyurove/milanov 2004[278]	Study compares ketamine and midazolam, incorrect intervention comparison. Abstract only.
Hakim 2012[283]	Compares lumbar and thoracic epidural administration of morphine in chest trauma patients. Not appropriate to outcome.
Hoogewijs 2000[314]	Incorrect interventions. Study compares propacetamol, diclofenac, piritramide and tramadol. Interventions not specified in protocol.
Jennings 2011[342]	Systematic review – no outcomes to extract.
Jennings 2014[343]	Same study as Jennings 2012 – Outcomes extracted together.
Kariman 2011[351]	Not guideline condition. Patients with major trauma were excluded from the analysis.
Marco 2005[450]	Incorrect interventions. Study compares oxycodone with hydrocodone, both administered orally.
Moon 1999[494]	Study compares epidural versus parenteral administration of opioids.

Study	Reason for exclusion
Nejati 2011[512]	Study compares ketamine/propofol combination with midazolam/fentanyl. Incorrect interventions.
Nejmi 2010[513]	Non-English language.
Neri 2013[516]	Incorrect interventions. Study compares sublingual ketorolac versus tramadol for pain management.
Oz 2013[539]	Study compares transdermal opioid administration with regional nerve blockade and paracetamol. Outcomes not appropriate. Some population indirectness - not all major trauma.
Paul 2013[548]	Exclude abstract presentation. Full manuscript included.
Paul 2013[547]	Conference abstract. Full study included.
Shaikh 2006[630]	Not guideline condition. Incorrect interventions. Population is made up of trauma and post- operative patients. Trauma population not adequately described. Study outcome compares morphine sparing effects.
Smith 2009[654]	Abstract only. Full paper included in analysis.
Vergnion 2001[722]	Incorrect interventions. Study compares morphine administration with tramadol.

K.10 Documentation

Table 26: Studies excluded from the clinical review

Study	Reason for exclusion
Barnes 2005[42]	No intervention
Bergs 2005[54]	No intervention
Bilyeu 2013[64]	No details of population pre versus post intervention
Budd 2007[95]	No intervention
Carter 2009[113]	No intervention
Catchpole 2013[116]	No intervention
Evans 2010[223]	No intervention
Evans 2010[222]	No intervention
Joseph 2013[349]	No outcomes comparing interventions
Knutsen 2013[373]	No intervention
Laudermilch 2010[408]	No intervention
Leblanc 2014[411]	No comparison data
Lossius 2013[427]	No intervention
May 2008[458]	No intervention
Popernack 2006[561]	No intervention
Porter 2010[563]	No intervention
Sparkes 2009[668]	Abstract
Varelas 2005[717]	Wrong intervention
Zargaran 2014[763]	No outcomes comparing interventions

K.11 Information and support

Table 27: Studies excluded from the review

Reference	Reason for exclusion
Arlidge 2009[19]	Focus does not match protocol
Al-Mutair 2014[6]	Setting does not match protocol
Andreatta 2009[14]	Setting does not match protocol
Andreatta 2010[15]	Setting does not match protocol
Arango-Lasprilla 2010[18]	Population/setting does not match protocol
Armstrong 2002[20]	Population/setting does not match protocol
Atkins 2011[28]	Setting does not match protocol
Au 2010[29]	Incorrect study design
Bailey 2014[36]	Focus does not match protocol
Beckett 2014[49]	Population does not match protocol
Chadwick 2000[119]	Design does not match protocol
Closs 1995[141]	Incorrect study design
Clukey 2009[142]	Incorrect study design
Doohan 2014[192]	Focus does not match protocol
Downey 2010[196]	Design does not match protocol
Franzn 2006[240]	Incorrect study design
Franzn 2008[241]	Incorrect study design
Friedemann-Sanchez 2008[246]	Design does not match protocol
Gholamzadeh 2012[263]	Setting does not match protocol
Harrison 2006[292]	Setting does not match protocol
Hughes 2005[321]	Setting does not match protocol
Hayes 2007[298]	Incorrect study design
Hayes 2009[297]	Incorrect study design
Ince 2010[330]	Incorrect study design
Jamerson 1996[337]	Setting does not match protocol
Keenan 2010[359]	Population and setting do not match protocol
Lefebvre 2012[416]	Setting does not match protocol
Linnarsson 2010[422]	Population/setting does not match protocol
Mangram 2005[447]	Focus does not match protocol
Merrill 2012[475]	Incorrect study design
Mayer 1998[460]	Focus does not match protocol
Meyers 1998[477]	Incorrect study design
Meyers 2004[478]	Population does not match protocol
Morse 2002[498]	Design does not match protocol
Mortelmans 2010[499]	Population does not match protocol
O'Brien 2004 [527]	Focus does not match protocol
O'Connell 2007[528]	Population does not match protocol
Oluwadiya 2010[536]	Incorrect study design
Paiva 2010[540]	Focus does not match protocol
Pasquale 2010[542]	Incorrect study design

Reference	Reason for exclusion
Ringdal 2008[590]	Focus does not match protocol
Schiller 2003[617]	Setting does not match protocol
Scott 2014[625]	Incorrect study design
Thirion 2013[699]	Population does not match protocol
Tutton 2008[711]	Setting does not match protocol
Verhaeghe 2007[724]	Setting does not match protocol
Verhaeghe 2010[725]	Focus does not match protocol
Verhaeghe 2011[723]	Design does not match protocol
Wright 2011[744]	Incorrect study design
Zhang 2013[764]	Population does not match protocol

1

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Appendix L: Excluded economic studies

L.1 Assessment and management of haemorrhage

L.1.1 Haemostatic agents

Table 28: Studies excluded from the economic review

Reference	Reason for exclusion
Koh 2012	This study was assessed as not applicable with very serious limitations. It is a comparative costing based on a retrospective analysis of hospital records in Korea. Very few patients included in the analysis (18 versus 36).

L.1.2 Volume resuscitation

Table 29: Studies excluded from the economic review

Reference	Reason for exclusion
Turner 2000	This study was assessed as partially applicable with very serious limitations. The study was a costing comparison comparing two protocols; one gave all adults fluids pre-hospital, and the other withheld fluids. The resource use was similar between the two groups because of poor compliance to the protocols; therefore it is limited what can be inferred from this study about the cost effectiveness of different amounts of fluids given.

Appendix M: Exploration of modelling the time of imaging in Major Trauma

M.1 Acknowledgment

We would like express our appreciation to TARN for their assistance with this project.

Additionally we would like to thank Robert Grant, senior lecturer in health & social care statistics at Kingston & St George's, formerly medical statistician and senior technical advisor at the National Collaborating Centre for Chronic Conditions (RCP) for his analysis and assistance with the associated report of TARN data

M.2 Introduction

The economic modelling within the Major Trauma guideline focused around the timing of imaging. The purpose of this document is to explain the process and iterations involved in identifying what and how to model in the Major Trauma guideline, which is comprised of complex inter-related interventions for a time critical population.

The document begins with an overall perspective of the questions the guideline was looking to inform, and how the different areas are related. Moving on to how the modelling idea looking at the timing of imaging evolved and took its final form of using regression of TARN data to derive treatment effect. These are broken down into the different iterations that took place in attempting to identify and refine the model.

The methods of this can be found below, along with the reasons as to why, after considerable investment of time and resources, it was decided that TARN was not an appropriate source of data to identify treatment effect, which resulted in no economic modelling for the major trauma guideline.

M.3 Methods

M.3.1 Model overview

The aim of this economic model is to identify the most cost effective imaging strategy and whether early imaging is cost effective in a population of suspected haemorrhage. The model involves comparing various imaging modalities (and sequences) broken down further by timing increments. The outcomes being assessed are mortality, time to discharge from hospital, and time to discharge from ICU.

The data informing the effect of the timing of imaging on outcomes is derived from the TARN audit database, using regression as a primary method, with the results being compared to propensity score matching as a secondary method of audit data analysis. The output of the regression is in the form of predicted time of event.

There were two clinical questions in the guideline that a model on timing of imaging could help answer:

1. **What is the clinical and cost effectiveness of whole body CT imaging in major trauma compared to selective CT imaging?**

Timing is an implicit aspect of this question, as theoretically full body CT could be undertaken immediately with primary assessments being done whilst the patient is in the scanner, whereas comparators such as selective imaging would involve a primary assessment prior to imaging to decide which areas are most likely to be injured. An assumption made from this was that whole body CT imaging would in turn lead to some health benefits from earlier treatment, and the impact that early treatment has dictates when imaging needs to occur. In other words, imaging acts as an enabler to treatment.

2. **What are the most clinically and cost effective imaging strategies for detecting life threatening internal haemorrhage in major trauma patients?**

The model looks at a variety of imaging modalities and sequences of imaging (as well as timing). Therefore the model aims to identify the optimal time of imaging but also to define what that imaging might be. Thus implicitly capturing the trade-off between time and accuracy, as the more definitive modalities (CT) take longer than the less accurate modalities, which is an important trade-off in a time critical situation where the patient is bleeding.

M.3.2 Comparators

It was felt that although CT is considered a gold standard, this does take more time than the other modalities, so accuracy aside, the GDG wanted to look at all the imaging combinations that may be taking place in clinical practice:

- No imaging
- x-ray
- x-ray + FAST
- x-ray + FAST + CT*
- x-ray + CT* + FAST
- x-ray + CT*
- FAST
- FAST + x-ray
- FAST + x-ray + CT*
- FAST + CT* + x-ray
- FAST + CT*
- CT*
- CT* + x-ray
- CT* + x-ray + FAST
- CT* + FAST
- CT* + FAST + x-ray

*CT could be full body or selective and both types may be modelled for the same strategy if data is available.

Measuring time of imaging

These strategies are also divided into time increments of every:

- 15 minutes for the first hour
- Then every 30 minutes until 4 hours

- Then 4 hours or more

It is important to be clear about what time is being taken from the data as the 'time of image', because most strategies are a combination of modalities, and the strategies have to be categorised into timeframes so the regression can be generated.

The time of imaging is taken as the 'time to definitive image'. This has been decided by the GDG as the clinical rationale for the following:

- For strategies containing CT, the definitive image is time to (the first if more than one) CT
- For strategies that do not contain CT, the definitive image is the time of the last modality in the sequence (the first time recorded of the last modality (e.g. for x-ray + FAST this will be the time the FAST was done)

Interactions between the strategies and timings is imperative in the analysis as depending on a particular modalities position in a sequence of modalities, different time intervals will lead to different impacts on outcomes. For example; in a strategy of CT + x-ray + FAST, the time of the first CT would be used as the time of imaging, however this is having a different impact on outcomes compared to a strategy where the first CT came at the end of the sequence, because an implicit assumption that the model structure has not taken into account is that outcomes will also be impacted by timing of treatment, and treatment will be sooner for strategies where the definitive image is at the end of the sequence and thus have a different impact on outcomes compared to a patient waiting for a while for other modalities after CT.

M.3.3 Population

The population of interest is patients with major trauma suspected of bleeding. Although children are also of interest, it was felt that trauma is rarer in children and therefore we were less likely to find enough good quality data in children.

The population will also be sub-grouped by haemodynamically stable and unstable patients, with the aim of making separate recommendations for these groups.

M.3.4 Time horizon, perspective, and discount rates used

The model uses a lifetime horizon. TARN only records data for up to 30 days, so assumptions about survival had to be made beyond this time point.

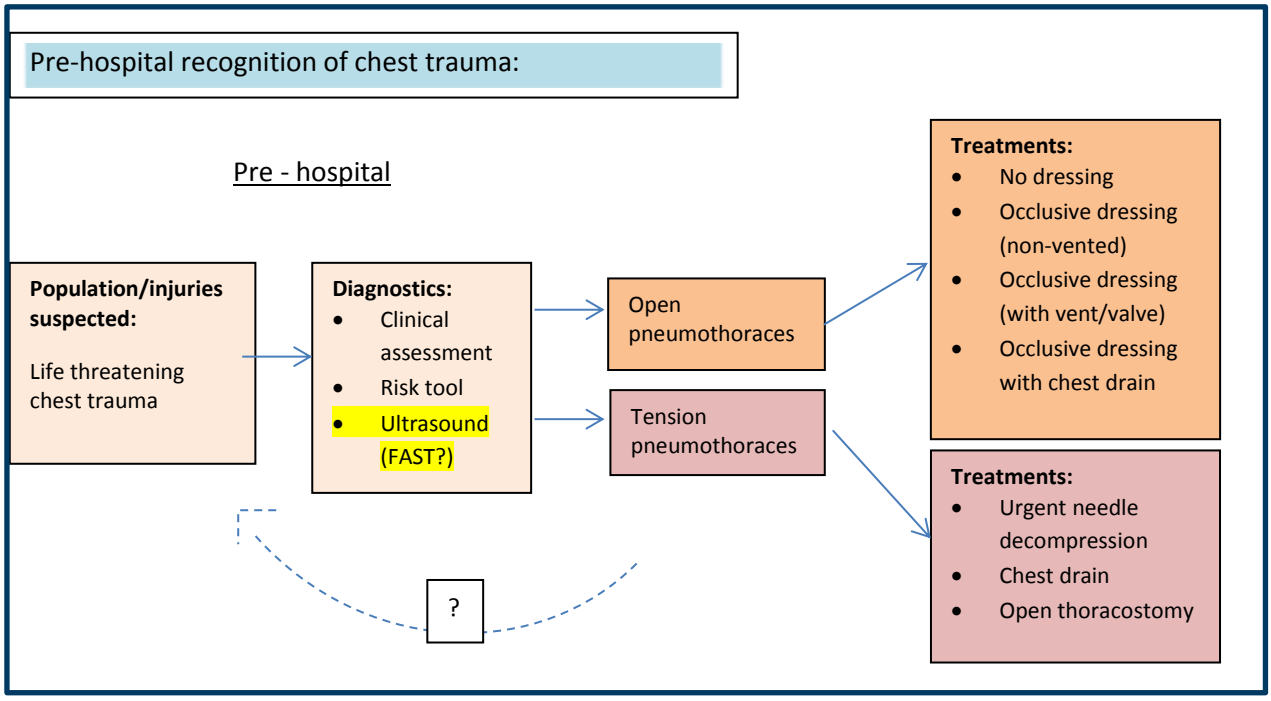
Economic analysis follows the standard assumptions of the NICE reference case including discounting at 3.5% for costs and health effects (with a sensitivity analysis using a discount rate of 3.5% for costs and 1.5% for health benefits), use of an NHS provider perspective and results evaluated by incremental analysis.

M.4 Approach to modelling

M.4.1 Background: Identifying the clinical pathways

Below are diagrams showing how the questions from the guideline fit together, in an attempt to understand; how the parts of the pathway fit together and follow on from each other, where there are overlaps, uncertainties, or complex relationships that may benefit from economic modelling. Where imaging fits into the pathway has been highlighted to show the impact on other parts of the pathway.
These diagrams were put together at the beginning of the guideline development and they do not reflect the final questions in the guideline.

Figure 116: Breathing and ventilation clinical questions



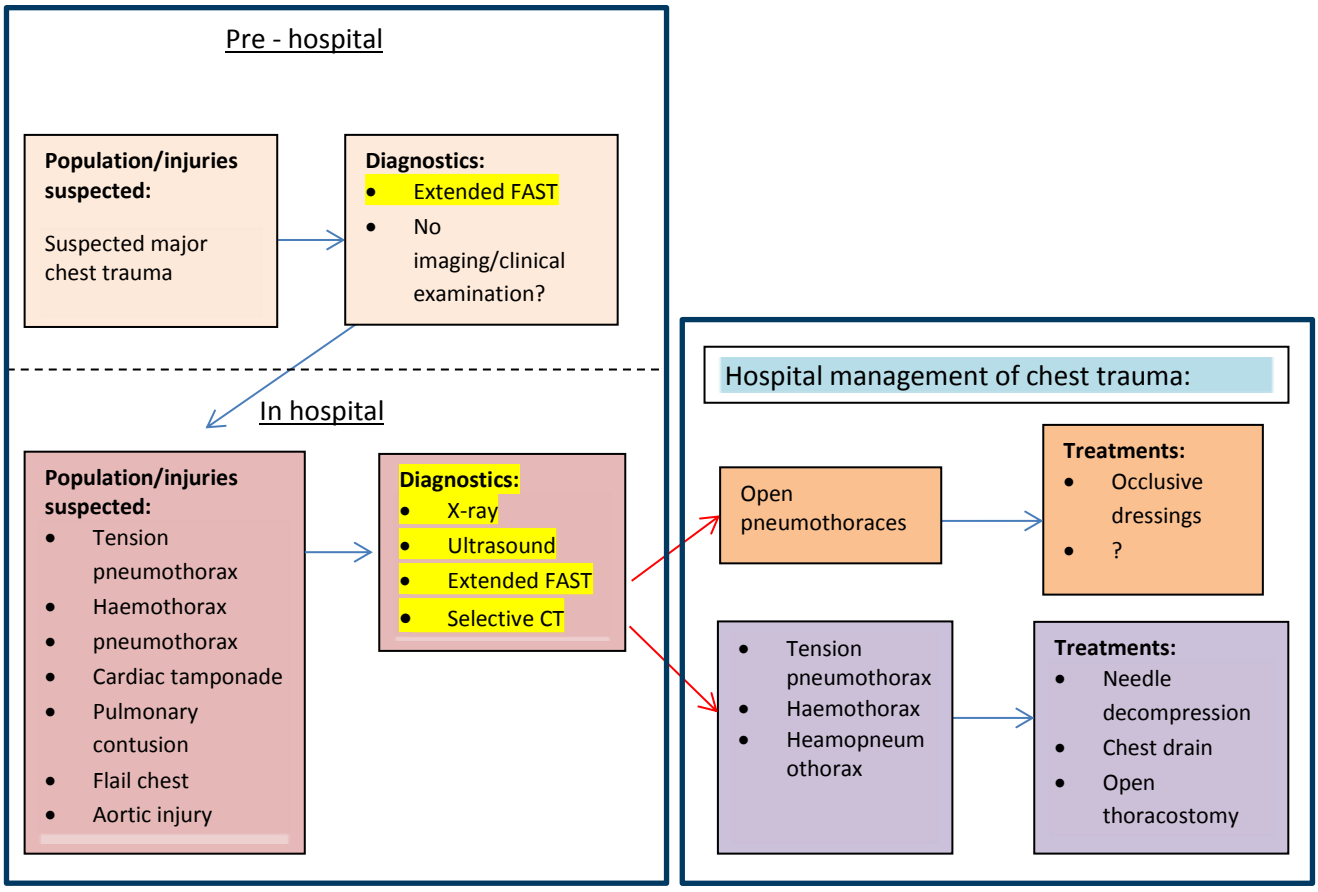
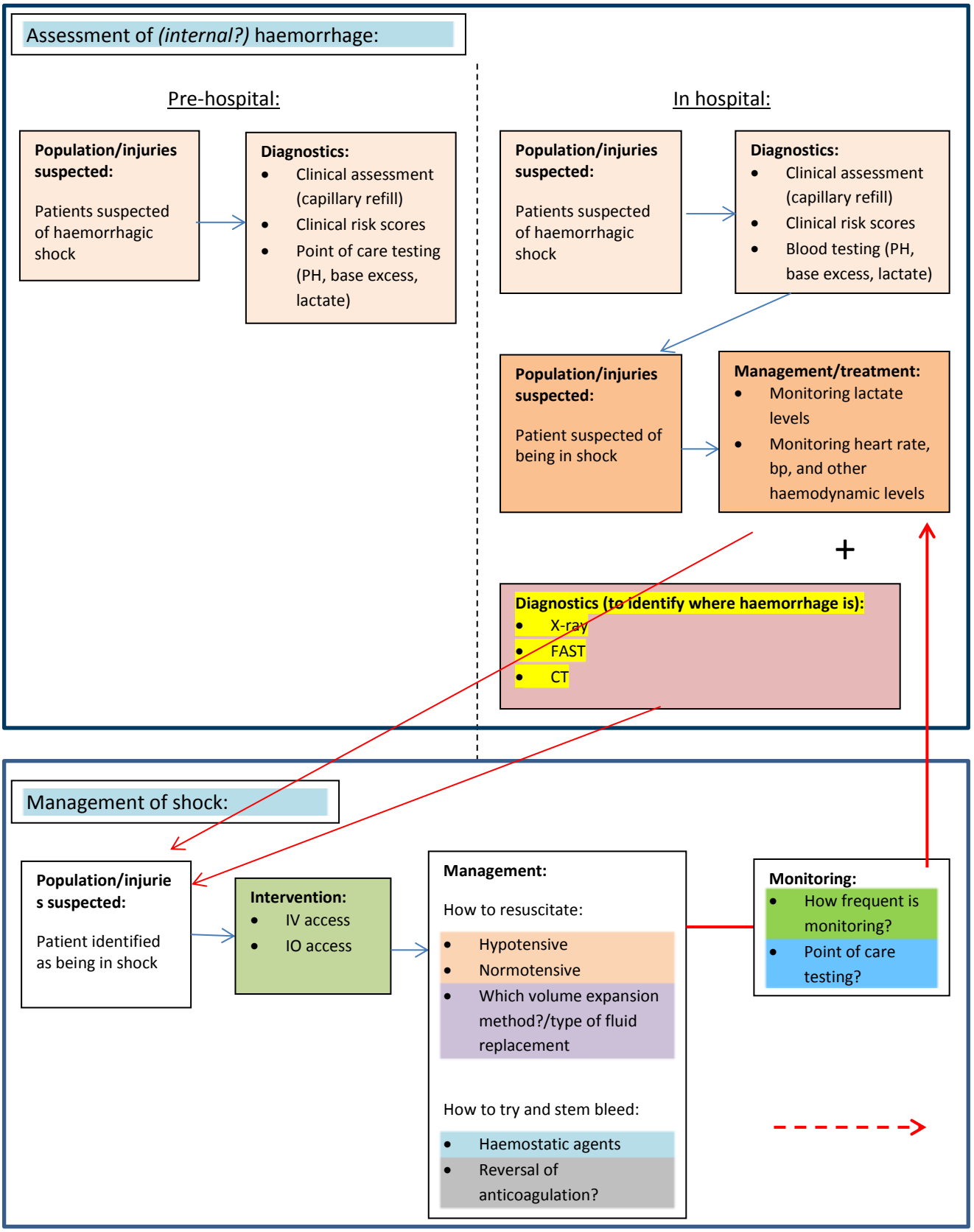
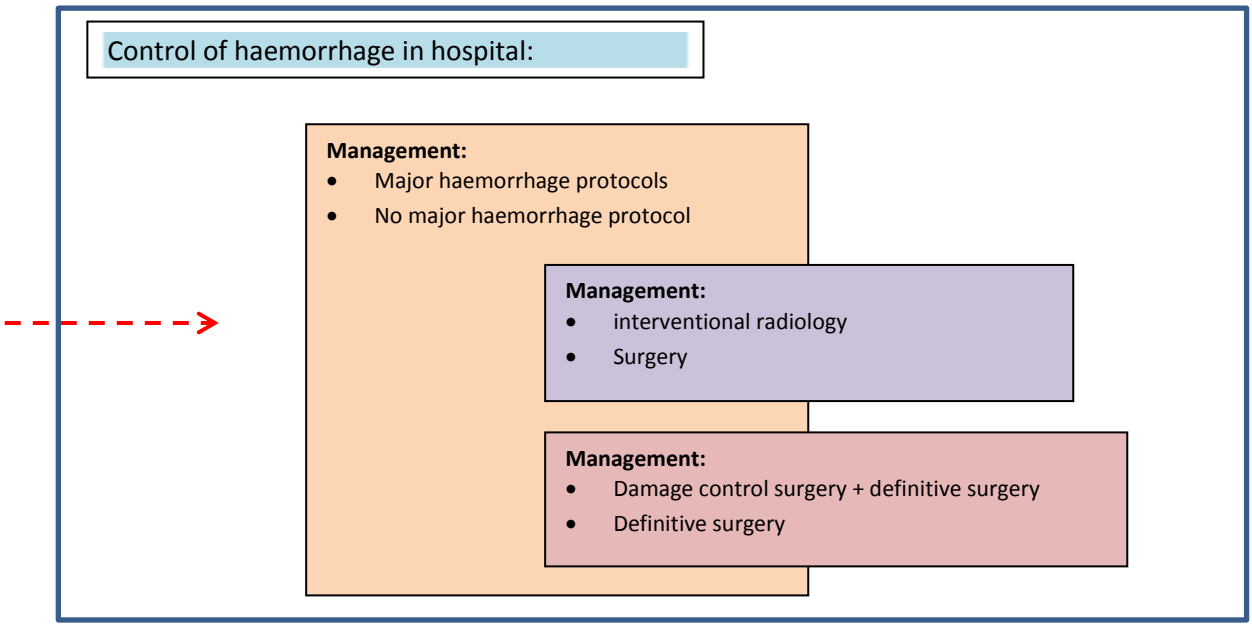


Figure 117: Circulation with haemorrhage control clinical questions





The above displays the pathway for the populations the guideline was focusing on.

Diagnostics are a key part of the pathway for a number of reasons:

- There are multiple populations that would benefit from imaging. Imaging that is used to identify a suspected haemorrhage may also identify a chest injury, and therefore incidental findings from imaging are an important factor driving questions and clinical practice, For example the use of whole body CT, where incidental findings are an important part of the considerations around cost effectiveness because there is benefit in identifying earlier other injuries that benefit from treatment, but this has to be weighed up against the cost of working up clinically irrelevant findings (see more on this in appendix O). Access to imaging (such as more CT scanners available) also benefits other populations not being looked at within this guideline, for example a common indirect population using CT scanners are stroke patients.
- The influence diagnostics have on decision making is important. Particularly for the suspected haemorrhage population – there is a circular decision making process based on observations and monitoring physiological response to fluids and resuscitation (see Figure 117), which impacts when and what type of imaging should take place, and then accompanied with potential imaging, decisions on the patients management will take place. This is a complex and cyclical part of the pathway which warranted more in depth investigation.

M.4.2 Iteration 1: Conceptual mapping

The above pathway diagrams for the guideline provided an overview of the guideline, where imaging fits in, and the complex relationships involved.

In discussion with the GDG, it was highlighted that a recurring theme across many of the questions, and a key outcome, was to reduce the time to definitive haemorrhage control.

Conceptual mapping was one way to approach the problem. This involves diagrammatically representing the relationships between different areas and the interactions between interventions and outcomes (see an example in the methods section of the guideline).

Approaching the model from this perspective led to thinking around this more conceptual approach of tackling the problem, which could incorporate multiple guideline questions in order to capture the competing interactions between the interventions. For example a common outcome across questions is control of haemorrhage, and there are multiple interventions being looked at that might reach this goal.

This was an approach that would be both a useful background exercise and would also have value in an area where there is a lack of evidence to inform a more detailed economic model. Due to the likelihood of difficulty in synthesising the published clinical findings of reviews on different areas of care in a meaningful way (due to heterogeneity in populations, timings etc.) or indeed that published evidence is lacking at critical parts of the pathway, conceptual mapping was proposed to be more beneficial to the GDGs decision making.

M.4.3 Iteration 2: Discrete event simulation

The GDG felt that an important change to current practice would be represented by better access to imaging, not just in major trauma centres but more local hospitals.

As this has large service delivery implications, it was necessary to look at whether early imaging is cost effective, which would then act as an enabler or pre-cursor to any further work on the cost effectiveness of additional imaging facilities which may have been picked up in the service delivery guideline as a potential modelling topic. This narrower focus of the model was the main reason for also reverting back to more of a traditional modelling approach, in order to aim for more definitive outcomes such as cost per QALY which could inform the cost effectiveness of an intervention, rather than the softer approach outlined in the previous section.

No clinical evidence was identified from the clinical reviews from the above questions. Therefore the Trauma Audit Research Network (TARN) was also explored as a source of data (more information can be found on this in appendix N. How this was used was dependent on what treatment effect was needed for the model. Some of the trade-offs identified early on which were considered to be explored as part of the analysis are discussed below.

The trade-offs involved in the decision problem are complicated by a two-step strategy of timely imaging which may result in differential timing of treatment. Another aspect is the involvement of monitoring and resuscitation, which may be treated as a comparator strategy in itself, or used in isolation or alongside radiological findings to assist the clinical decision to treat (definitive treatment such as surgery). Some of the trade-offs identified include:

- Improved accuracy from an imaging modality or strategy which takes more time and is more expensive versus a less accurate but quicker modality or strategy.
- Early/immediate treatment versus delay in treatment following a more definitive diagnosis from monitoring progression and imaging.
- Decision making based on monitoring alone versus decision making including imaging.

Some of these are further refined below with discussion as to how/if the model will evaluate these.

The second and third bullet points above are important points which will be considered separately as to how the model structure could evaluate these:

What treatment effect are we trying to incorporate?

There are several stages to the strategies we are considering. There is a tenuous assumption that earlier imaging automatically leads to earlier definitive treatment. Discussion with GDG members revealed that management decisions for haemorrhage control is not based on radiological findings alone, but also on clinical observational findings or levels of "non-improvement" in the patient's clinical status, despite giving blood/fluid/other (non-definitive) treatments (see Figure 117). We therefore may need to estimate:

1) The impact that monitoring and resuscitation has on timing of imaging
2) The impact that monitoring and resuscitation has on outcomes
3) The impact that timing of imaging has on outcomes
4) The impact that timing of imaging has on time to treatment
5) The impact that definitive treatment has on outcomes

Based on what we want to derive from the audit data, suggestions on structures were made to the GDG explaining the above difficulties:

1. One type of structure would be based on the differential impact on outcomes from different timings of *imaging*, in which case no assumptions are made on differential treatments that might follow on from imaging at different times. Diagnostic accuracy would also not be considered.
   This is the most restrictive model structure because it also assumes no differential resource use between imaging and outcomes for the different strategies, in other words, no difference in resource use after imaging, such as treatment. Therefore it would not be possible to investigate <u>why</u> imaging at different times had an impact on outcomes. Statements would simply be made about how imaging earlier led to certain outcomes. This approach would assume that treatment follows straight on from imaging. It is merely assumed that imaging is an enabler of treatment, and by having this structure we assume policy change in the time to imaging will not impact time between imaging and treatment (which would remain the same as current practice).

2. Another type of structure proposed would be based on the differential impact on outcomes from different timings of *treatment*.
   This would require the GDG to make an assumption about how quickly treatment follows on from imaging.

The GDG preferred option 1 in terms of a structure as they felt that its assumptions would be more plausible than the assumptions in option 2.

What other activities should be included?

The inclusion of other activities into the model was also discussed as the GDG did not want to make a recommendation that would imply that decisions on management should be based solely on imaging results. Other activities play a part in the decision for treatment, in conjunction with imaging results, particularly monitoring of deterioration based on giving blood/fluids and time itself being an important decision/diagnostic tool.

Below is an illustrative diagram (Figure 118) showing the interventions that might be involved (as well as imaging) in treating a suspected haemorrhage patient, and which could be happening simultaneously and all inform the decision on what management the patient needs. If we decided to include the influence of other activities in the model, the model would have had the structure described in Figure 119.

However, given the GDG's preferred approach that we break the TARN data down by timing of imaging and look at the impact on outcomes, without any further exploration of this relationship, the structure is simpler than that shown in Figure 119 (see Figure 120).

It was noted that the TARN data is based on the average patient, and not adjusted for other interventions that would have taken place. Therefore the monitoring activities, and the interventions this would influence, are already taken account of within the effect we will identify from TARN, and including the effect of these activities on baseline risk separately could act as double counting.

Figure 118: Interventions involved in a suspected haemorrhage patient

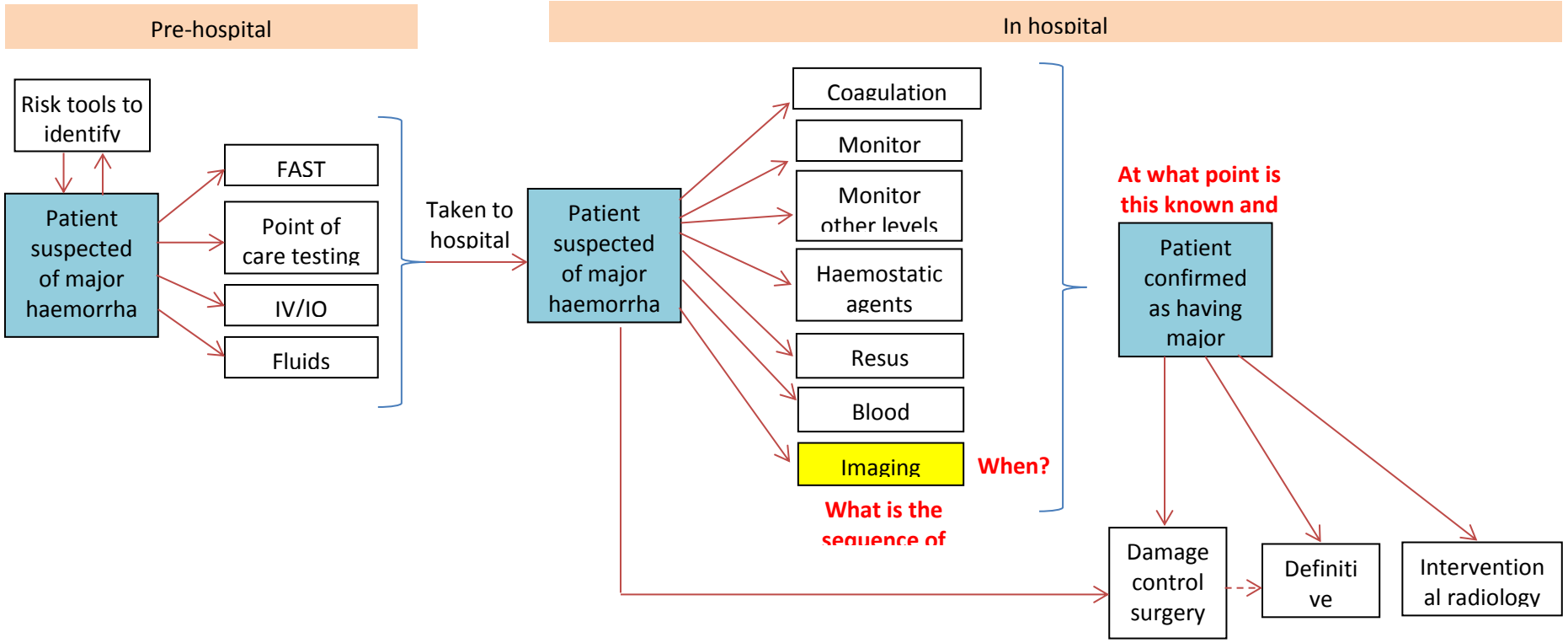
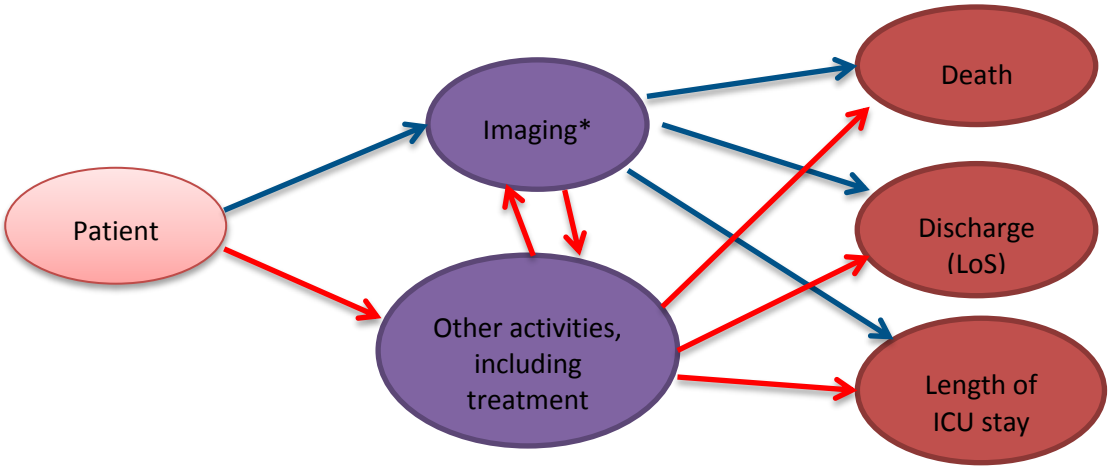


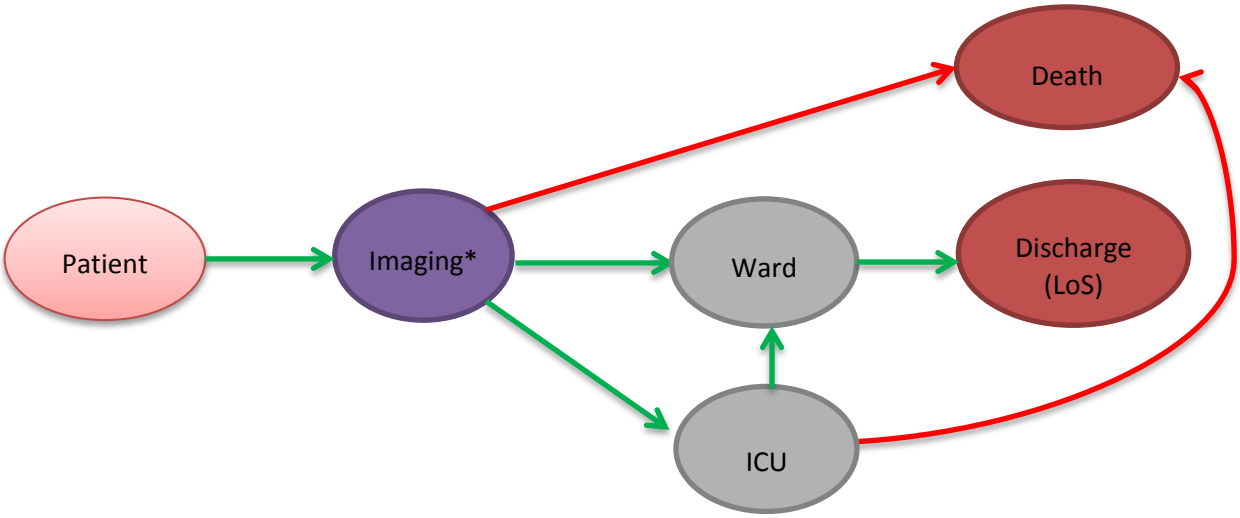
Figure 119: Model structure involving other interventions



*Comparing different strategies and timings including no imaging

As represented in Figure 120, in the final model structure the outcomes identified as being important were death, length of ICU stay, and length of hospital stay.

Figure 120: Final model structure



*Comparing different strategies and timings including no imaging

M.5 Model inputs

M.5.1 Iteration 4: Using TARN to derive treatment effect

M.5.1.1 Aim of statistical model

The aim of the economic model was to identify whether early imaging is cost effective.

This involved comparing various imaging strategies, broken down further by timing increments.

How the statistical analysis of TARN attempted to identify treatment effect needed for the model is further explained below. The outcomes of the statistical model were mortality, time to discharge from hospital, and time to discharge from ICU. The planned approach agreed with NICE was that the statistical method used to analyse the dataset was regression, with the results being compared to propensity score matching.

For more information on the TARN database, and definitions of the statistical methods considered please see appendix N.

The methods of the statistical model outlined are based on the first iteration of the regression that was undertaken. The up to date methods on how the data will be used in the economic model have been described above, and the discrepancies will be highlighted throughout the sections on the statistical analysis. However it was decided by the Statistician (undertaking the analysis and advising the committee) - after an iteration of the statistical analysis, in combination with the Health Economists on the trauma suite - that TARN will not be able to provide reliable effectiveness inputs to the economic models. Please see more on this in the results and discussion sections.

M.5.1.2 Strategies

For the strategies included in the model and identified from TARN please see section M.3.2.

However, in the first iteration of the model, the timings were broken down into every 15 minutes up to 4 hours, and then over 4 hours. Also for the timing of imaging, the time of the first scan is used for all strategies. However the issues identified with this approach are outlined further in section M.5.1.7.

M.5.1.3 Type of analysis of audit data to obtain treatment effect

There are three main methods which are commonly employed to estimate treatment effect from observational data: Use of regression, propensity score matching, and instrumental variables. Discussion of these methods in the context of using TARN to derive treatment effect of delay to intervention is available in appendix N.

Risk stratification was not feasible as a method of analysis to derive treatment effect. A key reason why this method was disregarded was the absence of a validated risk tool despite a comprehensive review of risk tools available. To note, the review on the most accurate risk tool to predict the need for massive transfusion in patients with major trauma was undertaken as part of this guideline. This is what most of the risk scores for trauma predict, as the need for massive transfusion is an intermediate outcome for severity. If patients in TARN were stratified in this way (grouped according to their risk of needing massive transfusion), then the timing of imaging of each risk group would be linked to mortality. Using this method would mean it would be necessary that the predictors within the risk score were included as fields within TARN and this data being recorded.

The Technical Support Unit was consulted in order to gain advice on what statistical method should be used to analyse the TARN data, also considering the constraints of the guideline process. Based on

a previous guideline, it was felt that risk stratification has more limitations than the regression, propensity score matching, or instrumental variables techniques. Thus modelling baseline risk would have been difficult, and therefore the no imaging group acted as baseline in the analysis. More information on the methods explored can be found in appendix N, and the subsequent sections below explains the details on how TARN was used and how the analysis was undertaken.

The methods of propensity score matching and use of instrumental variables were also discounted due to the reasons outlined in appendix N.

It was concluded that regression (accounting in the first instance for the key confounders specified in any related systematic review protocol undertaken for the guideline) should be the primary method of analysis.

M.5.1.4 Variables included in the regression

Dependent variables

The dependent variables for this analysis are:

- Time to death
- Time to ICU discharge
- Time to hospital discharge

Subgrouping the population

The GDG hoped to make separate recommendation for haemodynamically stable and unstable patients, thus subgroups have been included in the analysis from the outset.

This could have been done by stratifying the TARN population and regressing on each population separately, or by including a proxy for stability in the regression itself.

After exploring various options, it was decided to include this as a variable in the regression. This is because keeping the cohort of TARN patients together rather than separating them gives more power to the regression. Both methods are likely to give similar results. The results will then be compared separately for the stable and unstable groups in order to make separate recommendations, as including the variables in the regression still allows the results to be split out because the other coefficients in the regression will change when the stability variable changes, in order to reflect the impact on risk that subgroup (either stable or unstable based on the shock index proxy) had on the regression predictions.

It was decided to use the shock index as a surrogate measure of haemodynamic stability/instability. The shock index is a validated tool and has been used in the literature to predict transfusion requirements of patients who are in shock from major trauma, and has also been found to predict mortality. It is calculated by dividing heart rate by systolic blood pressure. The categorisation of the shock index can vary depending on the literature, however a recently published study (Mutschler 2013), which retrospectively used a large cohort of patients from the German trauma registry, used four groupings of the shock index based on observations from a previous study.

These are; no shock (SI<0.6), mild shock (0.6≤ SI ≤1), moderate shock (1≤ SI ≤1.4), and severe shock (SI ≥1.4). To be in keeping with having two categories, as surrogates for haemodynamic stability and instability, these have been grouped into two categories:

- No/Mild shock, SI < 1 (≈ Haemodynamic stability)
- Moderate/severe shock, SI ≥ 1 (≈ Haemodynamic instability)

Independent variables of principal interest

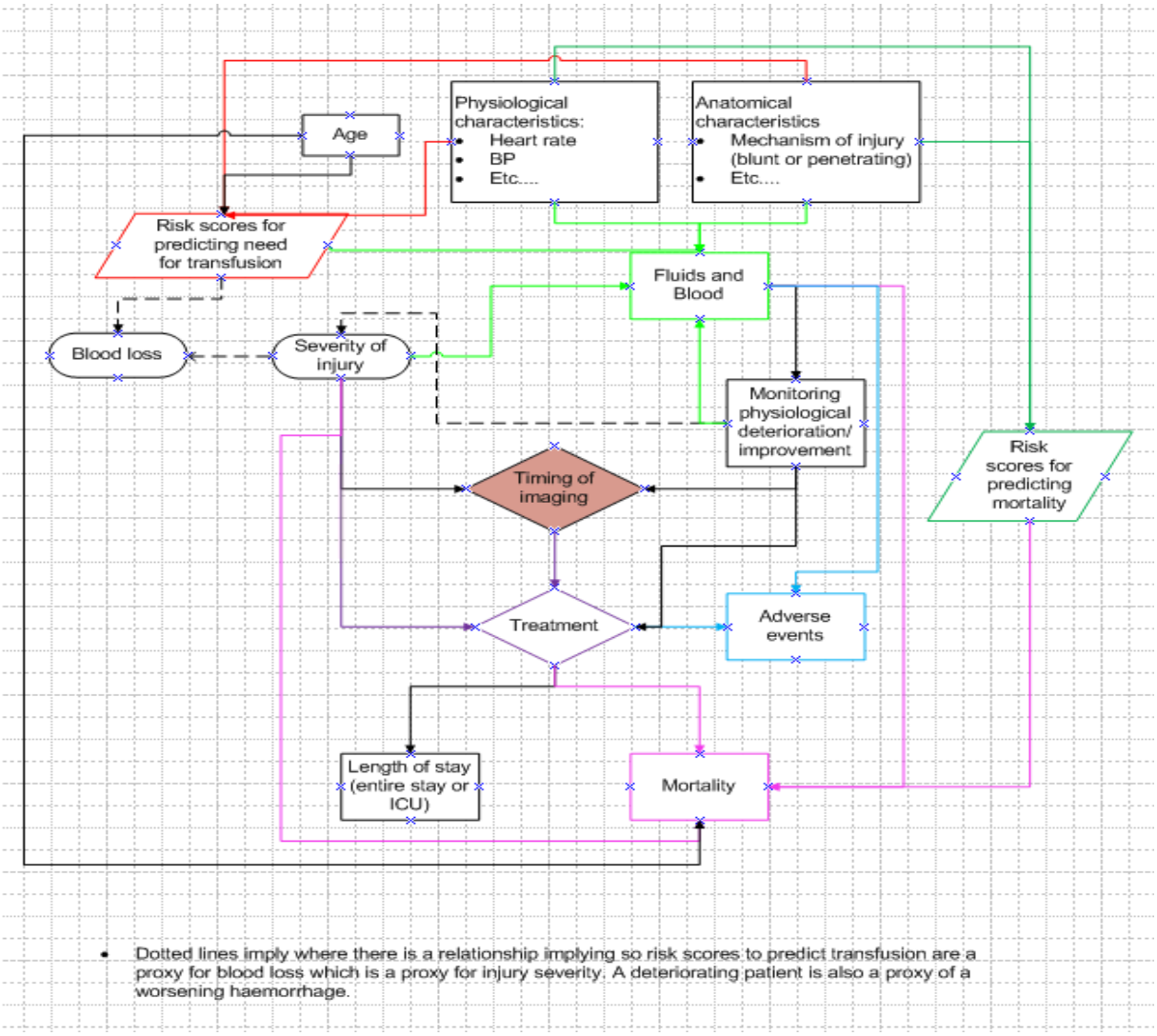
The main independent variables (or predictors) are the strategies (type of imaging, timing in 15 minute intervals, and sequence), as we are trying to find the relationship between the timing of imaging and our outcomes of interest. Sequencing can be represented as a single categorical variable or as the presence and absence of each imaging modality at a given point in time, effectively representing the variation in risks at different points in time for each patient in the TARN database. The latter approach was adopted in our analysis.

Confounders

In observational data, a major problem is confounding. A variable related to both the intervention and the outcome is referred to as a confounder. Broadly speaking, patients who are more severely injured will get more imaging, and sooner, than those who are less severely injured. If only the imaging and the outcomes are considered, this has the paradoxical effect of making imaging appear to be dangerous as the more severely injured get imaging earlier but they are also more likely to die. Other variables contained within TARN were considered as potential measures of this severity, along with co-morbidity, and underlying risks. Any variable that is correlated with presence or timing of imaging, and independently causes a change in the risk of the outcome for that patient, is termed a confounder (See more on this in appendix N).

A mapping exercise, to try and identify what potential confounders might be, is shown below:

Figure 121: Mapping to identify confounders



To be consistent with the clinical review , the variables included in the regression as confounders are at a minimum those which would have been identified within the clinical review studies, had the review dropped down to cohorts. These are:

- Age
- Injury severity (measured by ISS as a continuous outcome)
- Depth of shock ((measured by a systolic blood pressure as a continuous outcome)
- Head injury (measured by AIS head, and also through GCS)

In addition, other confounders included in the analysis that were found to be good predictors of outcome were:

- TARN's own mortality calculator (the PS12). This is a score predicting the probability of survival, also based on a regression of TARN data, and includes the confounders; age, gender, ISS, GCS, and where GCS is not recorded - whether the patient has been intubated is used.

The above and other possible confounders were used and how they fit the data was looked at. This led to a final model including the independent variables reported in Table 30.

Table 30: Confounders included in the regression

Variable name	Description	Measurement
Age	Age in years	Continuous variable
ISS	Injury Severity Score	Continuous variable
SBP	Systolic Blood pressure	Continuous variable
Head	1 if head injury noted in AIS codes	Binary variable
GCS	Glasgow Coma Score; a measure of consciousness and can be used a measure of head injury	Continuous variable
Ps12	The Ps12 composite score	Continuous variable
Arrest	A variable which captures those people who have a SBP of zero	Binary variable
Shock index (over or under 1) [(a)]	This variable represents haemodynamic stability/instability to subgroup the population	Binary variable

(a) The subgrouping of patients was an addition post the first iteration of the statistical analysis (and hence the stopping point of the analysis). Therefore the results in section XX do not include the subgrouping of patients.

More detail on the methods of the regression can be found in section M.5.1.7.

M.5.1.5 Data requested

The model population is comprised of adults suspected of a major haemorrhage. This is defined as adults who have been administered tranexamic acid following injury.

The guideline clinical experts felt that patients administered tranexamic acid are a possible proxy for those with major haemorrhage, as this would be given to patients who were suspected of having a major haemorrhage. This was first recorded in TARN in 2010, meaning 2010 was the cut-off point used for the audit data.

Within the population of all adult trauma patients administered tranexamic acid since 2010, various fields were requested from TARN which would be needed to undertake the analysis. These include fields needed to identify the imaging strategies and the timings they took place relative to the time of injury/admission. Additionally the outcomes we are interested in and the time that these occurred are important, as well as all the confounders that will be included within the regression and propensity score matching. For a full list of the fields requested please see section M.9.

M.5.1.6 Population (inclusions/exclusions)

The dataset based on the population and fields requested resulted in a total number of patients of 6454, and 3884 variables (i.e. fields from the database but some are the same fields with multiple readings or time points).

A breakdown of the population identified from the above criteria is:

Table 31: Number of patients broken down by year of incident

Year	N
2010	23
2011	198
2012	1384
2013	2752
2014	2097

Year	N
Total	**6454**

Cleaning the data

The dataset was studied firstly to improve familiarisation with the variable names and understand the naming and coding of the variables. Then the variables identified as being key for the regression were separated from the original dataset and cleaned by:

- Identifying and correcting or removing typos in dates and times (n=23) and Glasgow Coma Score (n=1) that would affect the analysis.
- Where time of incident was not available but ambulance arrival time was, the average time it took the ambulance to arrive (20 minutes - taken from the difference between the time of the incident and the time of ambulance arrival for patients where both variables had values) was subtracted from the ambulance arrival time.
- Removing records that could not provide a start time (n=638) or end time (n=367) for imaging (94 were missing both so a total of 909 were excluded).
- Removing records without the patient's sex, age, or time of arrival at ED (n=10).

This left a total of 5535 patients' data for analysis.

Baseline characteristics for these patients can be seen below.

Table 32: Baseline characteristics:

	Mean	N	SD	Median	Lower quartile	Upper quartile
Age	43.4	-	20.8	40.8	25.3	57.8
ISS	23.7	-	13.9	22	13	33
SBP	122.8	-	29.2	123	103	140
GCS (a)	12.4	-	4.2	15	11	15
Male	73.1%	4044	-	-	-	-
Minutes from incident to ED	43.4	-	20.8	40.8	25.3	57.8
Hospital length of stay (days)	17.7	-	23.5	10	4	22
CCU length of stay (days)	7.6	-	10.1	4	1	9
Mortality	13.6%	750	-	-	-	-

(a) Not including 69 patients with first SBP recorded as zero.

M.5.1.7 Regression details

Below are the details of how the first iteration of the regression was undertaken.

For outcomes measured as time to an event, survival analysis is broadly the appropriate modelling framework.

The term 'survival analysis' does not mean it is restricted to mortality; we considered length of stay in hospital and length of stay in ICU as well. Survival analysis takes into account the fact that patients are in the TARN database for different lengths of time, and that the event (death, discharge, transfer out of ICU) does not happen to everyone during the period on the database (30 days) – this is called "censoring".

There are different forms of survival analysis, according to the best way of representing the distribution of times-to-event. Another option that avoids making any assumption about the distribution is the Cox regression. These were considered by comparing the theoretical distributions to those of the TARN data, and a log-logistic distribution was found to fit the data quite closely. This led to a regression predicting the median time to death, or discharge from ICU, or discharge from hospital [146]. This is known as an accelerated failure time model because it provides effect sizes in a convenient metric, the time ratio, representing how much an individual's predicted 'survival' until the event of interest is accelerated (which would be a bad outcome in the case of mortality but a good outcome in the case of discharge from hospital or transfer out of CCU) or retarded by the presence of the predictor.

For the mortality outcome, we regarded people in TARN as being at risk of death from the time of the incident onward. Where this time was not recorded, we assumed it occurred 20 minutes prior to the time recorded for ambulance arrival. If neither was present (very rare), we excluded these cases from the analysis; these cases did not appear to be markedly different to the others in terms of baseline characteristics, scanning, and mortality. Outcomes are regarded as only being recorded from arrival at ED, because people who die prior to this are not entered into TARN, making the pre-ED period of time of interest to the study, but what is termed an "immortal period" in retrospective cohort studies: nobody dies by definition, and we must not allow this to distort the statistics. This was included in the specification of the survival analysis. People are followed until the discharge or death date, whichever comes first.

For the length of stay outcomes, we regarded people as being at "risk" of discharge as soon as they arrived at hospital or ICU, and again they are followed until the discharge/transfer occurs or they die.

Rather than regard people as having fixed risk levels that are predetermined by the scans they will have in the future, the model simulates individuals moving from one state to another as they have scans, or primarily from having no imaging (at which point all patients have the same risk) to having imaging. Based on the characteristics of the individual patients, patients are assigned a baseline risk which they continue along until they have imaging, at which point their risk changes (either for the better or worse). So, the episodes of care are divided into the time of the first CT scan, the first FAST and the first X-ray. This allows the risk of death to change as the scans are done. These are included within the regression as binary variables.

Once the accelerated failure time models had been fitted in Stata version 13 software, we obtained a list of regression coefficients (time ratios) linked to each of the predictors (or independent variables). Some of these predictors were of substantive interest (imaging modality and timing, and their interactions) and others were included as confounders. However, there is uncertainty around each of these time ratios, arising from the fact that TARN can be regarded as a sample from the population of all trauma cases. These uncertainties are represented as 'standard errors'.

In this iteration of the regression, the interaction between the timings and strategies is not captured. This means that the risk of CT for example is based on when the first CT happened for all patients, regardless of whether that CT was part of a sequence or alone. Therefore say we are using the regression to predict the time of death for the x-ray + CT strategy, or CT + x-ray strategy, then by deriving the CT variable from everyone who had a CT in any order, these two strategies would have the same predicted risk. E.g. CT within 30 minutes plus the risk of an x-ray. It does not account for the fact that there is an additional delay by having other modalities after the CT which could have an impact on mortality. Therefore grouping together the time to CT, time to FAST, and time to x-ray, and then separately looking at the impact of time will not provide that interaction and differentiate the risk of different strategies.

This problem was identified post this first iteration of the regression and it was planned to be rectified, however it would add further uncertainty to the statistical model because the patients

would have to be split into each of the strategies and then further into timings and analysed separately. The more finely the data is sliced up then the more that uncertainty increases.

Although the model outlined in this appendix did not go ahead, presented in the results section is the first iteration of the regression, which helps to highlight the difficulties identified in using TARN to answer the question posed, and also why the analysis was not continued. Also planned were sub analyses focusing on populations thought more likely to benefit from imaging (such as severe haemorrhage), however as it was decided to not continue with the TARN analysis, these results are also unlikely to be meaningful as they have the additional problem of small population samples to draw inferences from.

M.5.1.8 Format of data for input into economic model

There were various output forms that the data could be used as the treatment effect input in the economic model. This could either be in the form of a regression equation that is used directly in the model, or the predicted times from the regression being an output table used in the model, or predicted hazard ratios of survival time/discharge time (compared to no imaging) being in an output table and feeding into the model. Because of the type of statistical model used, the output decided upon was the regression equation with the coefficients. This means predicted outcome times could be calculated based on the characteristics of the patients and the strategy.

To account for the uncertainty within the regression coefficients (time ratios), a series of 1000 theoretical potential outcomes for each patient, under different imaging modalities and timings were predicted. To do this, we drew 1000 coefficients from the distributions around the software's best estimates, taking the standard errors and their correlations into account. Then, for each patient, these 1000 sets of coefficients are used to calculate the predicted median 'survival' time, under a range of imaging modalities and timings.

M.5.2 Utilities

A systematic search of the quality of life literature was undertaken, and the following 7 papers have been identified as potentially includable.

In the narrative section below the papers have been split into those which report quality of life for our population of haemorrhage, and also those which report a difference in quality of life depending on location being treated (ICU or non ICU) or the length of hospital stay. This differentiation is so that we can link long term outcomes to our short term model outcomes of mortality, length of ICU stay and total hospital length of stay.

Limitations of the studies include mixed populations, utility measures that are not EQ-5D, using the EQ-5D but validated in a non-UK population such as US or country specific. Also some the papers do not report the utilities in tables or the text but in graphical form, making the scores more difficult to interpret.

The studies are also summarised in Table 33.

Haemorrhaging patients

Christensen (2011) reported EQ-5D utilities for a blunt or penetrating trauma population aged 18-70 who had continuing torsos or proximal lower extremity bleeding after receiving 4 units of red blood cells. Quality of life was assessed 3 months after injury for 332 respondents, with an average score of 0.57. ICU stay of more than 3 days was also found to be a predictor of poor quality of life.
This paper has a good size cohort and fits in with our population, however a limitation is that it uses the EQ-5D which has been validated in a US population.

Patients treated according to location/length of stay

Meerding (2004) conducted a survey of patients who attended a Dutch Emergency Department and posted questionnaires which included the EQ-5D. The sample (4639 patients) included both hospitalised and non-hospitalised patients. Quality of life was assessed at 2, 5 and 9 months post injury. As the study population includes hospitalised and non-hospitalised patients, it is quite broad, for example 9.9% had a skull or brain injury, 18.5% had lower extremity fractures, and 6.7% had internal organ injuries. Only 62.6% of patients were hospitalised. The utilities reported broken down by follow up period and hospitalisation of less than/more than 7 days can be seen in the table below. This paper has a large cohort of patients, however the population is quite broad.

Orwelius (2012) includes a population of all adults with trauma who were admitted to the ICU for more than 24 hours and were alive 6 months after discharge from hospital. Quality of life was measured through postal questionnaires of the SF-36 at 6, 12 and 24 months following injury (108 responded at 6 months [these had a mean ISS of 18.8], 85 at 12 months, and 57 at 24 months [mean ISS of 21]). A longer length of stay in ICU or hospital was found to be negatively associated with quality of life in a multivariate regression.
A limitation of this study is that it is using the SF-36 which will have to be mapped onto the EQ-5D, and also the values are not reported in a table but need to be read off a graph.

Toien (2011) compared quality of life in 109 trauma ICU patients (admitted for more than 24 hours) with 139 trauma non-ICU patients. Quality of life was measured using the Norwegian version of the SF-36 at 3 and 12 months.
The SF-36 scores need to be read from graphs and mapped to the EQ-5D, as well as having being validated in a non-UK population.

Stricker (2005) compares patients admitted to a surgical and trauma ICU that had a cumulative length of stay in ICU of more than 7 days with a matched group who had a stay of 7 days or less. Matching criteria was; severity of illness (as measured by the simplified acute physiology score [SAPS] 2 score during the first 24 hours in ICU), and diagnostic group. Not all the patients are trauma patients. The study uses the US version of the SF-36 on a Swiss population and assesses quality of life at approximately 1 year post admission to ICU.
The limitations of this study include that it uses the US version of SF-36, which needs to be mapped to the EQ-5D. Also not all the patients within the sample were trauma patients, some were surgical patients. So assumptions may have to be made about whether these populations are the same.

Timmers (2011) looked at the long term quality of life of patients in a Dutch population after surgical intensive care admission. Patients included were all surviving patients of surgical ICU admission. Out of 575 patients followed up, 194 of these were trauma patients. Within this trauma population, a utility of 0.74 was identified using the UK EQ-5D tariff at a mean follow up of 8.4 years.
Only a proportion of the patients in this study are trauma patients and the utility reported varies depending on the population, with a vascular injury population for example having a utility of 0.65. There may also be some overlap in the populations reported.

Korosec (2006) investigated quality of life following admission into surgical intensive care. A comparison was made between a group of patients with sepsis and a group with trauma. Quality of life was assessed after 2 years following ICU admission using the EQ-5D. Only 39 patients could be followed up and the mean utility was found to be 0.72, however this was not separated for trauma and sepsis patients, but the difference was reported to not be statistically significant. Mortality was also analysed and this showed that sepsis patients have a higher mortality than trauma, thus the two populations are different and this is not only in the short term as cumulative 2 year mortality was also higher in the sepsis group (67%) compared to the trauma group (43%).
The limitation of this study is that the cohort is quite small. It also uses the US tariff of the EQ-5D.

A graphical representation of the utility values identified is shown below. From this we can see that there is perhaps a trend of improvement in the initial 1 to 2 year period following the injury. However the path of stabilisation is unclear as there is a gap of literature between relatively short term and long term quality of life measurements. Additionally one might assume that the papers where the population was solely ICU may have a lower utility than those who were not ICU, however this is not apparent from the graph as the utilities from the Meerding paper for example are lower than some of the ICU papers such as Orwelius. This may be because the populations are mixed in the papers that are not specifically ICU and may still have severely injured patients in their population.

Figure 122: Utility values

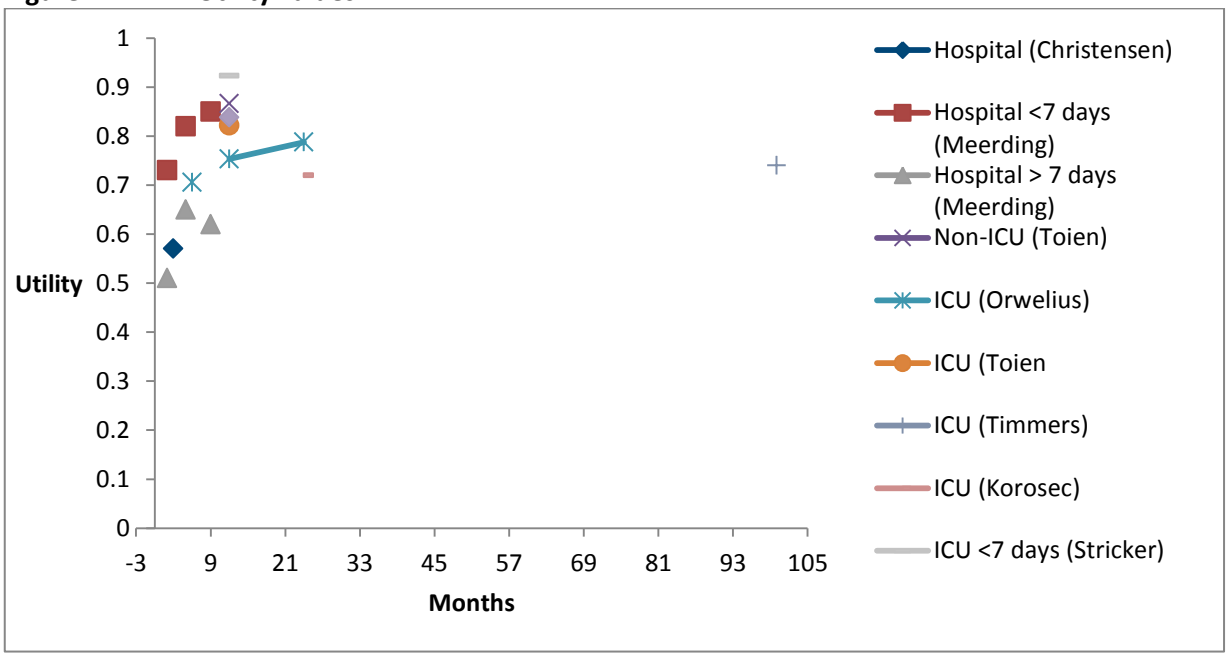


Table 33: Potentially applicable Quality of life studies

Paper	population	detail	utility	Limitations	Assumptions needed for the model
CHRISTENSEN (2011)	Torsos or lower extremity bleeding after receiving 4 units of blood	• 332 patients • 3 months after injury • EQ-5D	Average score of 0.57	• US EQ-5D	
MEERDING (2004)	Patients presenting at ED (separate by age group, and also type of injury, gender, and period of hospitalisation)	• 4639 patients • Measures utility at 2, 5 and 9 months after injury • EQ-5D	Hospitalised <7 days: 2 months = 0.73 5 months = 0.82 9 months = 0.85 Hospitalised >=7 days 2 months = 0.51 5 months = 0.65 9 months = 0.62	• Dutch population • Broad injury severity	This broader population is representative of the haemorrhage population
ORWELIUS (2012)	Trauma patients who were admitted to the ICU for more than 24 hours.	• 57 responders at 24 months • Measured at 6, 12 and 24 months post injury • SF-36	Has to be read from graphs. Regression showed that the length of stay in ICU (more than 58 hours vs 24-57 hours) has a negative relationship with all domains of the SF-36. None were statistically significant.	• SF-36 (Swedish version) • Scores have to be read off graphs	
TOIEN (2011)	Injured patients (all levels of ISS) (103 treated in ICU compared to 139 not treated in ICU)	• 242 patients • 3 and 12 months post injury • SF-36	Reports SF-36 graphically for ICU and non ICU patients at 12 months. Significant difference between ICU and non ICU.	• SF-36 (Norwegian version) • Difficult to read scores off graph	
STRICKER (2005)	Survivors of ICU (only 29 were trauma,	• 75 patients who had been in ICU more than 7 days.	SF-36 scores not separated by the different diagnostics groups (trauma	• SF-36 (US version) • Not all trauma	Trauma and surgical

Paper	population	detail	utility	Limitations	Assumptions needed for the model
	some with and some without cerebral injury)	Matched to a cohort who spent 7 days or less in ICU. Matched by diagnostic group and injury severity. • 12 to 18 months after admission to the ICU • SF-36	or otherwise). Reports individual domain scores for both groups.	patients	populations are similar
TIMMERS 2011	A cohort of patients treated in a surgical ICU. Trauma patients were a subset of the cohort.	• 194 patients were trauma • average of 8.4 years after surgical intensive care admission • EQ-5D	Mean EQ-5D using the UK tariff = 0.74 (compared to population norms).	Some confusion on the methodology as also mentions EQ-6D which hasn't been validated.	
KOROSEC 2006	Two groups of patients admitted to surgical intensive care; sepsis and trauma. The sepsis groups were slightly more severe than the trauma group.	• 39 patients (29 of which were trauma) • Quality of life assessed 2 years post admission • EQ-5D	Mean EQ-5D for the 39 patients = 0.72	• Small cohort • US EQ-5D	Sepsis and trauma populations are similar

Based on the above, it was agreed with the GDG to use:

- Utility of 0.57 at up until 12 months (based on the Christensen study which is the most applicable study to a haemorrhage population)
- Followed by an increase to a conservative utility of 0.75 at 12 months for patients who have been in ICU (Orwelius study), and 0.798 for patients who have not been in ICU (this is taking the Orwelius 12 month ICU utility and adding the difference between ICU and non-ICU utilities from Toien study)
- A 5% increase on the above has been assumed from 12 months onwards (0.791 and 0.838 for ICU and not ICU stay patients respectively).
- The quality of life remains at these values for the rest of the patient's life (i.e. they do not fully recover).

M.5.3 Extrapolating life expectancy

TARN only gives us data for 30 days, and trauma patients are likely to live shorter lives than the normal population. Therefore the UK life expectancy will be taken from life tables from the Office of National Statistics, with a hazard ratio applied reflecting a lower risk of survival over time compared to the general population [567].

M.5.4 Resource use and costs

As the structure of the model only involves imaging and outcomes, there are relatively few costs to be included within the model. The NHS reference costs 2013/14[181] were used to find cost estimates for the imaging strategies. These are detailed below.

Table 34: Imaging costs

Resource	Description	National average unit cost	Lower Quartile Unit Cost	Upper Quartile Unit Cost	NOTES
X-ray	Direct Access Plain Film (DAPF)	**£30**	£24	£33	The number of data submissions for this code was 151, with 5,216,498 units of activity (examinations)
FAST [(a)]	Ultrasound Scan, less than 20 minutes (RA23Z)	**£47**	£34	£57	The number of data submissions for this code was 140, with 1,842,009 units of activity (examinations)
CT selective	Computerised Tomography Scan, one area, no contrast, 19 years and over (RA08A)	**£80**	£62	£97	The number of data submissions for this code was 124, with 90,108 units of activity (examinations)
CT full body	Computerised Tomography Scan, more than three areas (RA14Z)	**£127**	£103	£131	The number of data submissions for this code was 84, with 2,275 units of activity (examinations)

(a) Assumed to be the same as an ultrasound less than 20 minutes.

Below in Table 35 are the resource use costs related to length of stay.

Table 35: Resource use costs

Resource	Description	National average unit cost	Lower Quartile Unit Cost	Upper Quartile Unit Cost	NOTES
ICU stay per day	Weighted average of Adult critical care costs; 0 to 6 organs being supported. From NHS reference costs 2013/14	**£1,229**	£1,039	£1,412	Weighted average of the following currency codes: XC01Z,XC02Z,XC03Z, XC04Z, XC05Z, XC06Z, XC07Z.
Acute trauma bed day		**£350**			Source: Department of Health document on 'improving acute care for trauma patients' (2009).[179]

M.6 Results

Unadjusted statistics showed that FAST and CT patients had worse outcomes than X-ray patients. This is most likely because of their underlying severity, which causes both the outcome and the decision to image. The type of patients having each type of scan can help to suggest the reason for this pattern, for example patients having solely an x-ray or x-ray as part of the strategy suggests that perhaps these patients are not severely bleeding or bleeding at all and other injuries such as fractures may be the more dominant injuries. Whereas FAST - which is used to identify free fluid and blood, and CT - the most accurate modality, are more likely to be used on the suspected bleeding/more severely bleeding patients.

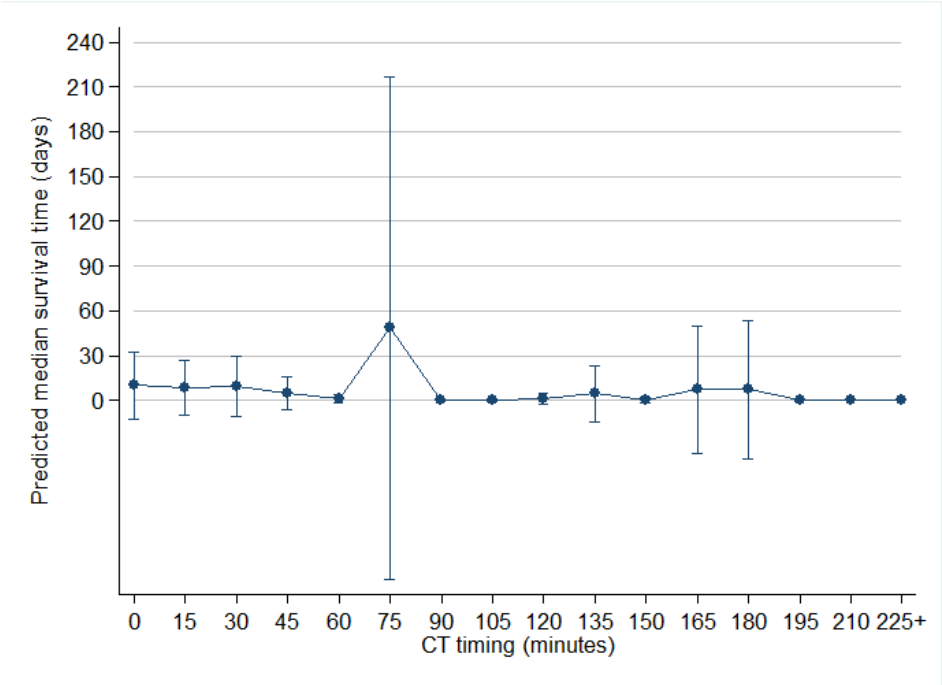
After attempting to adjust for confounding by indication, adjusted results showed similar results to the unadjusted analyses when comparing strategies, and little or no differences between timings, with very wide confidence intervals. Out of the three modalities where timing was investigated, (time to FAST, x-ray, and CT) only CT showed a statistically significant effect of the timing of imaging, and this is discussed further below.

The inclusion of 16 modality strategies with 16 timing periods made conclusions from the model uncertain (this is known as 'degrees of freedom', where many statistical estimates have to be made from the same collection of data). Ideally, the GDG wished to allow the timing effects to differ by strategy and possibly by some of the confounders too (for example haemodynamic stability), taking the number of estimates ('parameters') into the thousands, with attendant impact on the level of uncertainty in the statistical estimates. High uncertainty in the treatment effect will lead to uncertainty within the output of the economic model. As a clear effect could not be identified from the data, it was felt that using this within the model would not lead to meaningful results.

Figure 123 shows the influence of CT timing on survival time, as an example of the adjusted results. The horizontal axis is in intervals of 15 minutes, and the vertical axis is the predicted median survival time in days based on having a CT at different times. The median survival time (i.e. the dots) represents the survival time at the 50% mark for that particular time point, so based on the predicted regression, 50% survived less than this time and 50% survived later than this time. Each person in the dataset has a (log-logistic) distribution of survival times calculated by the model, taking into account their baseline characteristics, and these individual differences are averaged in each timing category of fifteen minutes (this is known as the marginal effect). Around each of the medians (the dots), there is a vertical bar indicating the extent of uncertainty in that estimated value (the 95%

confidence interval). Although the confidence intervals are calculated as symmetric above and below the best estimate, they cannot extend into negative survival times and should be regarded as stopping at zero. The graph shows a flat line with a lot of overlap in the confidence intervals. Although the regression statistics indicate a statistically significant downward slope, we can see from this plot that it is very slight and is swamped by the uncertainty in each of the fifteen-minute intervals, in other words, the uncertainty around the estimates is far greater than any trends. This suggests that no clinically meaningful conclusion could be drawn.

Figure 123: Predicted adjusted median survival time, with 95% confidence intervals, for successive 15-minute times to first CT scan



However, there are other sources of uncertainty too:

- In reality, patients vary above and below the predicted times. Taking 1000 iterations from the sampling error around the predictive outcomes found this additional scatter to be very wide.
- There is a large volume of missing data for blood pressure at the scene. This could be biasing results, but we do not know the extent or direction of it (e.g. if patients in whom blood pressure was not recorded were more likely to die earlier or later), so it forms an additional layer of uncertainty.
- The statistical ran was the first iteration of the analysis, however this needs to be made considerably more complex by accounting for the interaction between modalities and timings in order to ensure that the risk of a strategy captures the time period in which the definitive imaging modality occurred. This would add many more parameters in order to answer all the questions required of the economic model. This will have the effect of slicing up the data more finely and increasing sampling error (reduced degrees of freedom).
- Some of the reverse causality remains evident and statistically significant, such as FAST scans appearing to have higher mortality risk. Propensity score or instrumental variables analysis, alternative analytical approaches, will not help in this situation either, because we do not have any more variables than are already available to us from TARN. The variables that are already contained within TARN are also not ideal predictors of severity to adequately capture this vital confounder (for example measurement of blood pressure at a single time point).

M.7 Discussion

We have explored the feasibility of making evidence based recommendations regarding the timing of imaging through economic modelling. However the evidence base is limited in this area to be able to inform such a model. Limited clinical literature was identified from the clinical review question that indirectly addressed this topic, therefore we had envisioned that we would need to look toward audit data for treatment effect for clinical outcomes.

The goal of analysing the TARN data on patients receiving tranexamic acid was to provide estimates of benefit for different timing and sequences of scans (CT, X-ray, FAST ultrasound). TARN was adopted as a large, up-to-date, British observational dataset, notwithstanding the challenges of secondary analysis in this context.

The exploration of TARN revealed that it is not able to provide reliable effectiveness inputs to the economic models. Despite adjusting for all available confounders within TARN, the most likely reason for the results explained in the results section is residual confounding, i.e. confounding that cannot fully be eliminated through the confounders explored within TARN. Additionally, there is considerable uncertainty about any trends and differences meaning that input into an economic model will not bring additional benefit.

The main rationale behind the decision of abandoning an economic analysis based on TARN is that TARN information is chosen for audit purposes which do not fully capture all features of patients that affect the imaging decision case. This means we cannot fully eliminate confounding by indication (where patients who receive certain interventions quickly are fundamentally different to those who do not, and have worse outcomes that appear incorrectly to be caused by the intervention) or 'residual confounding' as some evidence of this remains even after adjusting statistically for everything we know about the patients that was available in TARN. The decision to image and sequencing of imaging appears to be driven strongly by the severity of injury. The population of the question was quite vague in terms of suspected bleeding, and a lot of the clinical management decisions about the timing of interventions or patient severity are based on clinician judgement/assumptions. In other words, the variables within TARN are not sufficient proxies to be used for the confounders the GDG have identified.

One explanation for the results found may be that there is in fact no relationship between the timing of imaging and outcomes. However there was perceived to be a relationship by the clinical experts, and a large cohort of data was used which would have picked up an effect, and therefore the most plausible explanation for the lack of effect we have seen is that there is too much confounding that we haven't been able to take account of.

It was felt that if the statistical analysis were to continue, with changes made that were discussed after the first iteration (for example incorporating interactions between timings and modality, and splitting by haemodynamically stable and unstable patients), then this would add further layers of complexity to the analysis and 'slice' the population being analysed up into even more segments, which would then reduce the power of the analysis even further. Having already identified that there was not a strong signal of effect, or at least strong enough to warrant further exploration, it was decided that these inputs feeding into an economic model would only lead to uncertain outputs, indicating either no effect, or uncertainty of effect, which would not assist the recommendations being made.

Note that although the type of uncertainty mentioned here can be tested in an economic model using Probabilistic Sensitivity Analysis, it was felt strongly that the uncertainty identified from the statistical analysis would lead to similar uncertainties when fed into the economic model and therefore the results of the model would not lead to, or add strength to, meaningful recommendations.

We considered the option of propensity score or instrumental variables analysis rather than regression. The propensity score approach accounts for the confounders by forming two models: one that predicts the clinical decision to scan, and one that reflects the causes of the outcome. The instrumental variables approach focuses instead on variables that affect the outcome only through their influence on the scanning. A variant of instrumental variables, recently proposed, uses clustering by institution to attempt to capture clinician preferences. After considering these, we felt that no suitable variables were present in TARN that would explain the decisions. Please see appendix N for more detail on other statistical techniques considered for this analysis.

Recommendations were therefore based on consensus and on any clinical evidence identified.

Although audit and other routine data are potentially useful for research, in this case it is the highly demanding question: to understand the reasons for imaging and how it affects outcomes, all other things being equal – that exceeds the information contained in TARN (or any other trauma registry) to inform the guideline.

M.8 Implications for future research

Despite the question regarding the timing of imaging remaining unanswered here, it remains a pertinent issue that continues to drive; improvement in access to imaging services, location of imaging services in a hospital, and ultimately patient outcomes.

With regards to how audit data could further assist in providing treatment effect for economic models, please refer to the question on audit databases in the service delivery guidance.

M.9 Full list of fields requested

- Time (and date) of incident
- Time (and date) of arrival of ambulance on scene /first attendance
- Time (and date) of departure of ambulance from scene
- Time (and date) of arrival at ED/hospital
- Time (and date) of each type of imaging undertaken (x-ray, FAST, CT)
- Time (and date) of admission into ED/hospital/ward
- Time (and date) of arrival into ICU (if applicable)
- Time (and date) of departure from ICU (if applicable)
- Time (and date) of discharge from hospital
- Time (and date) of death
- Key interventions/operations, including:
    - Embolisation
    - Total number of operations
        - Procedure
        - Date and time of each operation
- Was the patient transferred in?
- Date and time of departure (from first hospital)

- Age
- Severity of injury
- Mechanism of injury
- Heart rate

- BP
- Respiratory rate
- Capillary refill
- Breathing status on arrival (aided or unaided)
- Active blood loss
- Base excess
- Lactate
- Interventions such as bloods/fluids
- Cardiac arrest
- State of consciousness
- Co-morbidities (if available)

- pH
- haemoglobin
- INR
- Glasgow Coma Score
- Injury Severity Score
- Intubation
- Gender
- Ps12 score

- Where they go (which MTC/TU)
- Incident post code
- Trapped at scene
- Length of time trapped
- Type of attendant on scene
- Ambulance service
- Patients method of transport
- Trauma team activated?
- Type of attendant in ED
- Grade of attendant in ED
- Is this the trauma team leader?
- Specialty?
- Training

M.9.1 Fields requested but unavailable

- Depth of shock
- Pulse pressure
- Colour
- Use of monitoring, knowledge of deterioration/improvement
- Haematocrit
- Mental state

Appendix N: TARN: Background and statistical techniques considered for analysis

N.1.1 Introduction to TARN

A key source of information considered in the absence of published estimates of clinical effectiveness data was the TARN (Trauma Audit Research Network) database. TARN is a collaboration of hospitals from all over England, Wales, Ireland and other parts of Europe which supports a group of staff on a non-profit making basis; based at the University of Manchester, Hope Hospital, Salford.

The Trauma Network has been operating since 1989 and in 1997 became self-funding. The TARN database is the largest trauma database in Europe with more than 200,000 cases including over 22,000 paediatric patients.

N.1.1.1 Who submits to TARN?

Submission of records to TARN have increased since the database began, submissions are not compulsory (only incentivised) and thus submission of data does tend to be patchy, particularly from Trauma Units (TU).

This is because Major Trauma Centres (MTC's) receive the best practice top-up reimbursement for trauma cases they have submitted to TARN, thus there is a financial incentive for them to report to TARN, meaning submissions from Major Trauma Centres are generally high.

The TARN entry is not complete if it does not have information from roadside/presentation to discharge, so if the patient is transferred to an MTC from a TU or transferred onto a TU, then TARN and the MTC administrative personnel will contact the TU to get that information to ensure the record is complete.

Trauma units are not eligible for the best practice tariff, therefore they have less incentive to report to TARN. It is the patients who only ever went to a TU where data is most likely to be lacking.

The implication of the above is that sample sizes for treatment effect derived from the lower risk population who are more likely to only present to a Trauma Unit will be smaller, and confidence intervals and uncertainty around the true effect size will be greater.

N.1.1.2 What is the population in TARN?

The inclusion criteria for the database is a trauma patient of any age who:

- Is admitted for 72 hours or more, or
- Is admitted to intensive care, or
- Died at the hospital
- Was transferred into the hospital for specialist care
- Was transferred to another hospital for specialist care or for an intensive care bed.

AND

- Whose isolated injuries meet a set of criteria

TARN does not include patients who die on the way to hospital.

N.1.2 Analysis of audit data

N.1.2.1 The need to consider confounding

As audit data is not randomised, it leads to difficulties when attempting to estimate the effect because there is uncertainty as to whether the effect is truly because of the intervention, or because of other factors, known as confounders. A confounder is a characteristic both related to the intervention and to the outcome.

Throughout the NICE trauma suite, an understanding of the impact of undertaking an intervention earlier in the patient pathway is useful to underpin recommendations or parameterise models. A good example of a confounder for an analysis of effect due to early versus late intervention is severity of injury; it is possible that people who are more severely injured would have been imaged and/or respectively treated earlier due to perceived clinical urgency, additionally people who are more severely injured are more likely to die. Without adjustment of the confounder "severity of injury", it is possible that an analysis would find early imaging and treatment leads to worse outcomes. In this case, it would be impossible to know whether the worse outcome was because of the early imaging, or because the groups imaged early were sicker. Therefore any confounders must be adjusted for in order to solely isolate the intervention effect on outcomes.

N.1.2.2 Methods of analysis

Various methods were considered when thinking about how to analyse the audit data. We summarise below the key considerations the developers took into account when selecting a method of analysis.

N.1.2.3 Close risk stratification

Close risk stratification refers to splitting the cohort under analysis into subgroups according to their predicted risk of the outcome concerned. For example, this could be done by subgrouping according to a score calculated with a validated clinical prediction tool. This method in particular is relevant where the tool accounts for key risk factors which clinicians also identify as key confounders in the relationships being explored. The method is relatively quick to apply and would typically be feasible within development times of a guideline. Additionally, recommendations can be tailored to observable risk factors to the clinician. It is important to note however, the most appropriate decision tool for clinical use may not be the most accurate to predict prognosis, progression or deterioration of the patient (i.e. an appropriate tool to recommend may be one which is easy to implement quickly rather than reliant on later test results). Where validated tools exist, they may be based on longer term follow up rather than what is required to understand rate of progression in the acute phase, and their use often implies a linear hazard.

The key disadvantage of this method is that it is reliant on availability of a validated prediction tool for the outcome of interest, and does not offer protection against bias of confounders which are not clinically measurable or observable.

Throughout the suite, this method was disregarded due to absence of validated risk tools.

Below in table is an example of the work that was undertaken in attempting to identify a risk tool for the major trauma model, before this method was disregarded.

Table 36: Risk tools identified to predict massive transfusion

Risk score	Components	Comments

OUTLINED IN PROTOCOL (excluding those that include imaging)		
McLaughlin score	• Heart rate > 105 bpm • Systolic blood pressure < 110 mm Hg • pH < 7.25 • haematocrit < 32% Equation: log (p/[1-p]) = 1.576 + (0.825 x SBP) + (0.826 x HE) + (1.044 x Hct) + (0.462 x pH), where the variables have the value of 0 or 1 based on whether or not the value is classed as predictive	Based on military population, injuries mostly penetrating trauma so less ambiguity as to presence of on-going haemorrhage compared to blunt trauma. Retrospective
Shock Index	HR/systolic BP (0.5-0.7 believed to be normal) The higher the number the higher our suspicion of shock being present	
Shock Classification (part of ATLS protocols	• Heart rate • BP mmHg • Pulse pressure • Resp. rate • Mental state	
OTHERS PICKED UP		
Larson score	• Heart rate • systolic blood pressure • haemoglobin • base deficit	As above (mclaughlin). Uses a variation of the McLaughlin score. Reports the proportion who actually had a transfusion based on how many of the variables in the score were present.
MGAP	• Glasgow Coma Scale (from 3-15 points) • blunt trauma (4 points) • systolic arterial blood pressure (>120 mm Hg: 5 points, 60 to 120 mm Hg: 3 points) • age <60 yrs (5 points)	Originally created as a pre-hospital tool to predict in hospital mortality for trauma patients. (Not specifically those with haemorrhage.) categorises patients into low, medium, and high risk of mortality.
Mina	• mechanism of injury • heart rate • systolic blood pressure • base deficit	There are two parts to the predictive model, so can be expressed as probability of needing a massive transfusion protocol, or can be categorised into discrete categories (very low, low, moderate, and high risk of MTP) based on the intermediate probability values.
Modified Field Triage Score	• GCS (total) • systolic arterial pressure • haemoglobin	
Revised Trauma Score	• GCS • Systolic BP • Respiration rate RTS=0.9368*GCScode+ 0.7326*SBPcode + 0.2908*RRcode	States on trauma.org website that it correlates well to mortality http://www.trauma.org/index.php/main/article/386/ Another document states the primary purpose of this score is to predict mortality.
Schreiber score (derived from	• Haemoglobin • INR	

military)	• penetrating mechanism of injury	
Triage-RTS	• GCS • blood pressure • Respiration	
Vandromme score	• Blood lactate ≥ 5 mmol/l • heart rate > 105 bpm • INR 1.5 • haemoglobin ≤ 11 g/dl • systolic blood pressure < 110 mmHg Threshold ≥ 3	

N.1.2.4 Regression

Regression is a commonly used technique for statistical analysis of observational data. It is likely to be familiar to both developers and the audience of the guideline. Published studies using this technique, although graded as low quality, are commonly accepted to inform NICE guidance so long as limitations are fully explored.

However, regression does not take account of unmeasured or unobservable confounders, and also it tends to work better if the characteristics of people assigned to different treatments are similar. Where regression was considered, the key confounders were those identified on the relevant review protocol so that the quality of the analysis was consistent with that which would have been accepted from the published literature.

Note that the technical summary boxes are taken from another source, with examples adapted for the timing of imaging problem. [166]

Technical summary of regression

Regression can be used to adjust for known confounders by including them as explanatory variables within the regression equation. For example, a regression equation for time to discharge (Td) could take the form;

$$T_d = \beta_0 + \beta_E T_E + \beta_1 x_1 + \beta_2 x_2 + \beta_3 x_3 + \beta_4 x_4 + \cdots \beta_n x_n + \varepsilon_i$$

with β_E being the coefficient associated with the treatment allocation variable, TE, and the other terms ($\beta_i x_i$) being the terms associated with expected confounding variables. In this case the treatment allocation variable, T_E, would be time to imaging and the other explanatory variables, x_i, would be those which influence both time to discharge and time to imaging such as suspected shock.

The β coefficients give the slope of the regression line when varying that particular explanatory variable and holding all others constant and therefore β_E, the coefficient for the treatment variable, gives the treatment effect after adjusting for all the other potential confounding factors included in the regression.

In the above regression equation, the outcome (time to discharge here) is assumed to increase linearly with each explanatory variable (x_i), but this is only one possible functional form for the regression equation. Any of the regression terms could be replaced with other expressions giving a

different functional form (e.g x2, x3, ln(x), 1/x). Interaction terms which allow the effect of a confounding variable to vary according to treatment allocation can also be added by adding terms which are function of both treatment effect and the confounding variable (e.g $T_E x_i$)

Regression can be used to estimate the difference in outcomes, for example time to discharge and time to death, according to treatment allocation. Treatment allocation could be in accordance with the categorisation of the time to imaging or treatment.

In regression it is assumed that the relationship between the outcome and the potential confounders is linear in parameters and that the slope of the regression line does not vary according to treatment allocation.

So in our example, we would have to assume that the impact of severity of injury on length of stay is consistent between patients receiving early intervention (i.e. within 30 minutes) and those receiving later intervention (i.e. within 60 minutes), once other confounding factors which may differ between these groups have been adjusted for. It is possible to extend the statistical model to deal with situations where the slopes are not equal between the groups with different treatment allocations by including interactions between baseline variables and treatment effects. However, if the treatment interacts with any of the baseline measures, and those baseline-by-treatment interactions are not included in the statistical model, then this will result in a biased estimate of the treatment effect.

It is also assumed that there are no unmeasured confounders. The chance of this is increased by including as many potential confounding factors as possible within the regression. Inclusion should be guided by knowledge of previous research in the area and theoretical considerations. Factors thought to influence treatment selection or outcome should not be excluded from the regression because they do not meet traditional tests of statistical significance. Confounding factors measured after treatment allocation may be problematic if these are potentially influenced by the treatment allocation. For example, in this case it would be necessary to consider whether factors such as imaging findings, or the need for particular treatments might be influenced by time to imaging or intervention. When addressing service delivery questions such as this, it is important to consider both patient level and organisational level confounders for inclusion in the regression equation.

Another difficulty with regression is that it works better when the characteristics of those allocated to different treatments are similar in terms of the confounding factors. This is unlikely to be true if those confounding factors are strong predictors of treatment allocation. In our case, this becomes problematic if those patients having early imaging are very different from those having late imaging.

Cox regression models are commonly used to deal with confounding factors when the outcome of interest is the time to an event, in this case either time to discharge or time to death. The proportional hazards assumption for Cox regression requires that the relative hazard associated with a particular treatment or confounding factor is constant over time even if the hazard itself is varying.

N.1.2.5 Propensity score matching

Propensity score matching aims to combine all the characteristics that might be influencing a particular treatment allocation into a score, and patients can then be matched on this score, thereby identifying patients with the same likelihood to receive treatment, but some receive treatment and some do not (or different treatments). More detail can be found below.

The benefit of propensity score matching above the other methods is that it has a very explicit process.

However disadvantages were felt to be; there may be some bias in matching in the same cohort of patients, additionally patients are matched on characteristics (in order to calculate the propensity

score) upon initial presentation, therefore if in fact treatment allocation (or timing to intervention) changes based on anything that happens after this initial presentation (which may be likely given deterioration/ineffective interventions for example) then the method may be limited. As with regression, unobservable confounders and bias may not be addressed by this method. The findings from both regression and propensity score matching are likely to be similar for this reason.[628,682]

Technical summary of propensity score matching

Within an observational dataset, certain factors which predict treatment outcome may be present more commonly in the group of patients who go on to receive one treatment than in the group who go on to receive an alternative treatment. However, an unbiased estimate of the treatment effect may be obtained if two subsets of patients can be identified from the cohort who have different treatment allocations but similar confounding factors. This is what the process of randomisation aims to achieve within a randomised controlled trial, but it can also be achieved by matching patients.

Propensity score matching allows a single score to be used to match patients who received different treatment allocations, but who are similar in other known confounders. The propensity score, PS, is the probability of receiving a particular treatment (e.g. time to imaging, (T_E) given the observed covariates (the confounding factors, x_i).

i.e. PS = Pr (T_E | x_i)

The covariates included in the propensity score should be those thought to predict treatment allocation. Often these are the same covariates as those that you would put in the regression, but this does not need to be case. The propensity score is usually estimated by logistic regression;

$$ln\left(\frac{PS}{1-PS}\right) = \beta_0 + \beta_1 x_1 + \beta_2 x_2 + \cdots + \beta_n x_n$$

Once a propensity score has been defined it provides a single scalar variable which can be used to match patients who received different treatment allocations, so in this case who had a different time to imaging, TE, but had the same propensity score. This generates treatment and control cohorts who are matched on the known confounding factors and the treatment effect can then be estimated within the matched cohort in the same way it would be within a randomised controlled trial.

Treatment effect can then be estimated within the matched cohort in the same way it would be within a randomised controlled trial, as known confounding factors should be balanced between the intervention and control groups.

In our model, the treatment allocation would be the time to intervention and the factors included in the propensity score would be those that clinicians might use to select patients for earlier intervention. Propensity score matching would then allow us to obtain cohorts who were equally likely to receive early intervention based on their clinical need, but who in fact received different levels of intervention delay, thus providing an estimate of the impact of intervention delay that is not confounded by the factors used to determine clinical need which may also predict survival and length of stay.

Propensity score matching requires the groups who received different treatment allocations to have substantial overlap in terms of their propensity scores. If there is poor overlap in propensity scores between the patients receiving different treatments, then this may lead to a substantial number of patients not being matched with an equivalent patient receiving a different treatment. This reduces the generalizability of the relationship estimated from the matched group. One benefit of propensity score matching over regression is that the overlap of the two groups is an explicit outcome of the matching process.

When selecting covariates to include in the propensity score, again, it is generally better to err on the side of including more rather than less potential confounding variables. Omitting important variables can lead to bias in the estimates. However, only variables that are unaffected by the treatment should be included, that is variables that are either fixed over time or measured before the treatment took place. Confounding variables shouldn't be excluded from the propensity scores just because they aren't statistically significant predictors of treatment allocation, but including factors which are not causally associated with the outcome may unnecessarily reduce the statistical power.

Propensity score matching was originally devised to deal with situations where there are two possible treatment allocations. However, it can be extended to more than two groups and to continuous treatments. It may therefore be possible to use propensity score matching with time to intervention treated as a continuous variable. This may be more efficient than treating time as an ordered categorical variable by splitting it up in to a large number of discrete time intervals as this may make it more difficult to specify an appropriate functional form.

N.1.2.6 Instrumental variables

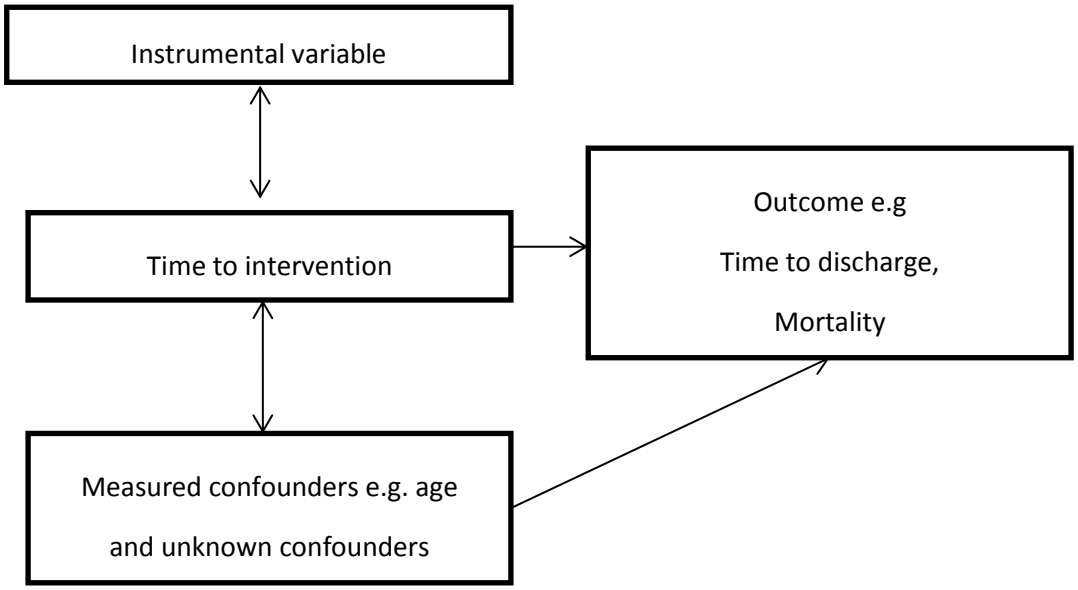
Due to unobservable confounding factors, the use of an instrumental variable to reduce residual bias could be considered a preferred technique. An instrumental variable is that which has a strong correlation with the allocation of an intervention, but has no direct correlation with the outcome of interest. The instrumental variable can only impact the outcome of interest through its relationship with allocation of the intervention.

However, identification of an appropriate instrumental variable can be difficult. Outlined below are the technical details of the method followed by the attempt to identify an appropriate instrumental variable for this analysis.

Technical summary of instrumental variables

An instrumental variable is one which mimics treatment allocation by being a good, but not necessarily perfect, predictor of the treatment received by an individual within the observational dataset. As illustrated in Figure 3, a valid instrumental variable needs to be related to the outcome of interest through its effect on treatment allocation alone and not via any other route. In particular, it cannot be related to any measured or unmeasured confounders which affect both treatment allocation and the treatment outcome.

Figure 124: An illustration of instrumental variable analysis



If these two conditions are met, it is possible to estimate the impact of treatment allocation on outcomes by conducting a 2-stage regression. The first regression assesses the impact of the instrumental variable, Z_i, on treatment allocation, in this case time to imaging, T_E.

$$T_E = \alpha_0 + \alpha_1 Z_i + v_i$$

This is used to give you the predicted value of treatment allocation, $\hat{T}_{E,}$

The second regression assesses the impact of the predicted value of treatment $\hat{T}_{E,}$ on the outcome of interest, in this case time to discharge or death, T_d.

$$T_d = \beta_0 + \beta_1 \hat{T}_E + e_i$$

The main difficulty in using an instrumental variable approach is in identifying an appropriate instrument. A valid instrumental variable is one that is a good predictor of treatment allocation, but which is not related to any known or unknown confounders which affect both treatment allocation and treatment outcomes (see Figure 3).

In the case of the major trauma model, an instrumental variable is required which is a good predictor of time to imaging, but which isn't related to any potential confounding factors that might be related to both time to imaging and the outcome e.g. mortality or time to discharge.

Variables which have been considered as instrumental variables and comments as to why they would be good instrumental variables are considered in the table below.

Within the context of this guideline, no suitable instrumental variable could be identified for bespoke TARN analysis. In part, this was due to the pragmatic constraint of the time allotted to develop the guideline and the time involved in matching datasets to calculate the data such as distance from injury to health provider. For other variables, which in the first instance seemed more feasible to use in analysis, there was no firm consensus that the candidate instrumental variable was truly independent of the effect being measured and indeed not a weak confounder. For example, policy shifts occurred at the same time as advancing technology and practice, the use of different transport confused the relationship between distance and time to health provider, and so on. Further detail

on the variables considered and their limitations in the context of the trauma suite are outlined in the table below.

Table 37: Instrumental variables considered to assist analysis to derive effect of differential timing to intervention.

Potential instrumental variable	Rationale for consideration as a candidate instrumental variable	Limitations and conclusion regarding suitability
Distance from nearest hospital/trauma centre	Those with quicker transfer times are most likely to have the intervention earlier as spent less time getting to the hospital?	Potentially confounded by the triaging by paramedics, as more severe patients go to major trauma centres which may not be the nearest hospital, so maybe travelled further if more severe because want to get them to MTC, and on the other hand maybe travel time was quick if they made a judgement that the person is so severe they are unlikely to live if take 40 minutes to get to trauma centre so took them nearby. Therefore potentially confounded by severity of injury. Depends on geographical location as MTC's may be nearer in some parts of the country. Could potentially find this out from the timings in TARN fields. Would need some work finding out where geographically the nearest hospital was to where the incident took place for each record. This information is not available within TARN. The fact that this instrumental variable may be related to a confounder (severity) means it is not a good instrumental variable.
Location of injury	How close this is to a hospital (MTC or TU?) could predict time to arrival. Therefore those that take longer to arrive take longer to be imaged.	Similar issues to the above. Assuming time to arrival on scene is the starting point of the model, then how close you are to a hospital may not necessarily determine how quickly you get there, as time spent on scene for example which may be related to severity of injury could be impacting this.
Urban vs rural setting	Is there a comparison we could make between locations where access/distance to a major trauma centre is more difficult or non-existent. The rationale being that more immediate access to imaging can be compared to less immediate access (with other patient characteristics and decisions being held constant). As the type of hospital (MTC, TU,	Would have to work out the locations of the hospitals and whether these were rural or urban which may take some time. The numbers of incidents may be small for those parts of the country and therefore have small samples to compare. Rural locations may be served by air ambulance which could have quicker transfer times than vehicles. Especially for longer journeys?

Potential instrumental variable	Rationale for consideration as a candidate instrumental variable	Limitations and conclusion regarding suitability
	general hospital) will have different requirements for access to CT, naturally affecting the time to imaging.	
Pre and post policy changes: - Imaging - MTC/TU system	Have there been any policy changes which would allow us to compare data in TARN before and after these policy changes? For example pre major trauma networks compared to after major trauma networks were introduced may allow a comparison between before the 60 minute CT rule and after the 60 minute CT rule?	TARN pre-dates the major trauma networks going live which was in 2012. However the criteria for the major trauma model population was patients administered tranexamic acid which began being administered in 2010. The number of patients identified from TARN fitting this criteria from 2012-12 was very small. This sample would be too small for comparison.
Anything that impacts clinical decision making (decision to image) E.g. seniority of attending clinician	Higher grade may assess quicker or make decisions quicker and therefore patients imaged quicker	Would be confounded by injury severity (as either more severely injured imaged first to treat quickly, or more severely injured not imaged at all as treated right away).

Appendix O: Research recommendations

O.1 Coagulation testing

Research question: What is the clinical and cost effectiveness of point-of-care coagulation testing using rotational thromboelastrometry (ROTEM) or thromboelstography (TEG) to target treatment, compared with standard laboratory coagulation testing?

Why this is important: More rapid treatment of coagulopathy could reduce mortality from haemorrhage, which is the main cause of death in patients with major trauma. Point-of-care ROTEM and TEG are complex diagnostic tools used to detect coagulopathy. They are used successfully in surgery and intensive care settings. It is thought they might also be effective in targeting treatment for coagulopathy in the resuscitation room.

Point-of-care ROTEM and TEG are faster to perform than standard laboratory tests and enable an earlier transition from an initial fixed-ratio protocol to a protocol guided by laboratory coagulation results. These results can be updated as often as every 15 minutes, which could enable treatment to be adjusted rapidly and targeted effectively. This could result in reduced use of blood products and other treatments for coagulopathy.

Criteria for selecting high priority research recommendations:

PICO question	Population • Children, young people and adults with haemorrhage after experiencing a traumatic incident Intervention • Point of care ROTEM/TEG Comparator • Standard laboratory testing Outcomes • Mortality • Quality of life • Utilisation of blood products • Length of intensive care stay Stratify/subgroup • People on pre-existing anticoagulation therapy Exclusions
Importance to patients or the population	If found to be effective, point of care ROTEM and TEG would lead to improvements in treatment of haemorrhage; the most common cause of mortality in major trauma. Critical gains for patients could be seen in terms of mortality and quality of life.
Relevance to NICE guidance	It would answer the major trauma guideline question around whether point of care testing is clinically effective for guiding transfusion and blood product use.
Relevance to the NHS	Effective use of Point of care ROTEM and TEG is hypothesised to lead to more tailored transfusion and thus potentially reduced use of blood products and other treatments for coagulopathy, and also reduce harms of over transfusion.

	The testing would take place in the resuscitation room by trauma team staff, removing the emphasis for fast turnaround time for clotting screens on the hospital laboratory. There would be costs associated with the purchasing of the technology and training of resuscitation room staff in their use, therefore establishing cost effectiveness of these tests to identify if changes in management offset the capital outlay is important.
National priorities	Department of Health initiative on regional trauma networks.
Current evidence base	The current published evidence base contains diagnostic accuracy studies but no RCTs. The diagnostic accuracy studies did not give sufficient reason to recommend point of care coagulation testing in the trauma setting. However the GDG considered these results to be of limited reliability because the laboratory reference standards against which point of care ROTEM and TEG were evaluated were not directly comparable because they measured different parameters. The GDG agreed that future diagnostic accuracy studies would be similarly flawed and instead a more direct measurement of patient benefit through a RCT was required. Accuracy estimates in isolation were not sufficient to make informed conclusions regarding the clinical benefit which may result from point of care testing and justify the cost in a change of practice. Cost effectiveness of point of care testing in relation to standard care or laboratory testing is unclear, and this topic may benefit from further research given the potentially large capital outweigh in investing in the specialist equipment of the point of care testing machines.
Equality	This research recommendation would potentially benefit children and adults with haemorrhage after a traumatic incident.
Study design	For the reasons highlighted above, an RCT would be the appropriate form of research methodology for this question.
Feasibility	None identified
Importance	This research recommendation is of high importance: the research is essential to inform future updates of key recommendations in the guideline

O.2 Lactate

Research question: Is lactate monitoring in patients with major trauma clinically and cost effective?

Why this is important: In current practice, treatment for hypovolaemic shock is guided by the patient's haemodynamic levels; including heart rate and blood pressure. However, haemodynamic levels such as blood pressure tend to change late and correct early, so may not accurately indicate continuing shock. Research has found a strong correlation between lactate levels and the presence of shock and may therefore be a more responsive indicator of shock that could be used to guide treatment.

Criteria for selecting high priority research recommendations:

PICO question	Population • Children, young people and adults with suspected major trauma

	Intervention: • Treatment guided by the monitoring of lactate levels Comparison: • Treatment for shock not guided by monitoring lactate levels • Treatment for shock guided by monitoring heart rate, blood pressure and other haemodynamic levels Outcome • Mortality at 24 hours, 30 days and 12-months • Health-related quality of life • Length of intensive care stay • Adverse effects: over-transfusion-related morbidity, thromboembolism, transfusion-reactions • Blood product use (red blood cells, platelets, plasma, cryoprecipitate) • Patient reported outcomes (psychological wellbeing) • Time to definitive control of haemorrhage
Importance to patients or the population	Haemorrhage is a major cause of preventable death in patients with major trauma. A significant loss of blood can result in hypovolemic shock, where the heart is unable to circulate enough blood around the body. This can lead to organ failure and death.
Relevance to NICE guidance	The proposed research could potentially support a recommendation in an update of this guideline
Relevance to the NHS	Better targeting of resources in the management of major trauma. If monitoring using lactate can detect haemodynamic status better than traditional measures, this will more appropriately guide the use of blood products and potentially improve patient outcomes. Lactate monitors pre-hospital are not commonly available, therefore both pre-hospital and in hospital there will be costs involved in undertaking the test, however this may be outweighed by the benefit in terms of resource use (such as less wastage of blood products through lactate guided transfusion) and improvement in outcomes. Therefore establishing the clinical and cost effectiveness of lactate monitoring is important.
National priorities	Department of Health initiative on regional trauma networks.
Current evidence base	Currently, there are no published RCT or cohort studies adjusted for key confounders.
Equality	None identified
Study design	A randomised controlled control is the most appropriate study design. Power calculations should be conducted to establish the required sample size of the trial. It is important that the study is adequately powered to detect a clinically important effect size.
Feasibility	The GDG do not foresee any feasibility issues.
Other comments	Economic evaluation assessing the resource use and costs associated with the intervention should be undertaken.
Importance	This research recommendation is of high importance: the research is essential to inform future updates of key recommendations in the guideline

O.3 Pain

Research question: Is morphine clinically and cost effective compared with ketamine for first-line pharmacological pain management (in both pre-hospital and hospital settings) in patients with major trauma?

Why this is important: The use of opioids as first-line analgesics after major trauma is well established but has been associated with negative side effects. Consequently, intravenous ketamine in sub-anaesthetic doses is often used for analgesia in pre-hospital and hospital settings. Some studies have suggested that intravenous morphine in combination with ketamine provides more effective analgesia than morphine alone. However, there is little evidence from well-controlled trials that directly compares the effectiveness and side effects of morphine and ketamine.

Criteria for selecting high priority research recommendations:

PICO question	Population
	• Children, young people and adults who have experienced a traumatic incident.
	Intervention
	• IV Opiates -(for exaple including morphine, fentanyl, alfentanyl)
	Comparator
	• IV Ketamine
	Outcomes
	• Pain levels
	• Health related quality of life
	• Adverse effects:
	  ○ nausea
	  ○ respiratory depression
	  ○ hallucinations
	  ○ Level of consciousness
	• Patient reported outcomes
	
	Stratify/subgroup
	• Pre hospital and hospital
	• Age – Adults and Children
	  ○ Frail and Elderly
	  ○ neonate (<28 days), infant (to 1 year), child (1-15 years), young people(16-17 years
	Exclusions
	• People with a major trauma resulting from burns

Importance to patients or the population	Pain management remains a common complaint from patients following Major Trauma and knowing the safest and most effective analgesic is crucial in the management of patients pain.
Relevance to NICE guidance	Effective analgesia is highlighted as priority in the NICE patient experience guideline, but remains a common complaint in patients following trauma.

	Comparing the most commonly used pharmacological agents used for pain management in major trauma for analgesic and side effects profile will inform on the best drug for pain management in this population.
Relevance to the NHS	There are marginal cost differences between the drugs, but more extensive training on the administration of ketamine may be required. Managing pain is important part of the trauma pathway, but can also have an impact on other injuries through distracting the clinician from the other injuries and delaying their treatment. The adverse event profile of the drugs and the resources involved in treated these also need to be considered. The effectiveness of the drugs in managing pain as well as their adverse event profile should be considered alongside the costs to inform which drug is a cost effective use of NHS resources.
National priorities	Department of Health initiative on regional trauma networks.
Current evidence base	There is a very limited evidence base for this question. A single very low quality study, conducted in a rural setting has directly compared IV Morphine and IV Ketamine in a randomised controlled trial. The study was conducted with low numbers and did not perform a cost effectiveness analysis.
Equality	N/A
Study design	Randomised controlled trial; Cluster or patient.
Feasibility	None identified
Importance	This research recommendation is of high importance: the research is essential for optimum management of pain in severely injured patients and will inform future updates of key recommendations in the major trauma guideline.

O.4 Warming

Research question: Is warming clinically and cost effective in patients with major trauma? If so, which groups of patients will benefit from warming and what is the best method of warming?

Why this is important: After major trauma, patients are often exposed to adverse weather conditions and are at risk of developing hypothermia, which is associated with worse outcomes including higher mortality. However, there is uncertainty about the clinical benefit of warming patients and whether all groups of patients would benefit from warming. In addition, there is a wide range of methods used for warming and little evidence showing their comparative effectiveness, particularly in pre-hospital settings.

Criteria for selecting high priority research recommendations:

PICO question	Population • Children and adults experiencing a traumatic incident Intervention Pre-hospital: External: • Bubble wrap • Foil blankets

- Active heating chemical blankets

Internal:

- Intravenous fluid warmed devices (including IV solutions/blood products)

Emergency department:

Active external rewarming:

- Convection warming units
    - Air convection (Bair hugger/WarmAir)
    - Fluid convection
- Warming mattress (Inditherm warming mattress)
- Radiant warmers/heater

Active internal rewarming:

- Warmed IV solutions
- Ventilation with warmed, humidified air or oxygen

- A combination of the above.

Comparator

- A comparison of the above.
- Standard care (standard blankets)
- No warming

Outcomes

Critical:

- Mortality at 24 hours, 30days/1month, and 12 months
- Health-related quality of life
- Length of intensive care stay
- Adverse effects:
    - skin burns
    - hyperthermia
    - infection
- Neurological outcome

Important:

- Patient-reported outcomes:
    - pain/discomfort
    - return to normal activities, psychological wellbeing

Stratify/subgroup

	Age – Children 0-16 years, Adults (16 and above) Coexisting traumatic brain injury
Importance to patients or the population	Following major trauma, patients are often exposed to extreme conditions which can induce a stress response which may increase the experience of pain and anxiety. It is important to manage these effectively in patients. There is also a subset of patients in which warming may not beneficial and it is critical to identify these patients.
Relevance to NICE guidance	The proposed research could potentially support additional recommendations in an update of this guideline
Relevance to the NHS	Currently warming modalities vary widely and have various expense implications. Effective warming may have reduced severe side effects, reduce length and cost of hospital stays, and improved patient outcomes. However it is important to investigate whether investment in the more expensive modalities provides value for money.
National priorities	Department of Health initiative on regional trauma networks.
Current evidence base	There is no published evidence addressing this question.
Equality	N/A
Study design	Randomised controlled trial; Cluster or patient.
Feasibility	None identified
Importance	This research recommendation is of high importance: the research is essential for optimum management of pain in severely injured patients and will inform future updates of key recommendations in the major trauma guideline.

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Appendix P: Additional cost effectiveness considerations and costing detail

Assessment of cost effectiveness for diagnostic interventions and prognostic tools

The cost effectiveness of a diagnostic modality stems from how accurately it can identify people with the injury and rule out people without the injury, as well as the true prevalence of the condition within the population being imaged. For the major trauma population, who are subject to polytrauma, systemic injury and fast deterioration, cost effectiveness of a diagnostic intervention is also impacted by the trade-off between time efficiency and accuracy of the intervention, as well as the potential for incidental findings. In the absence of economic evidence for a diagnostic review, the GDG were routinely asked to consider the below when assessing cost effectiveness of a diagnostic modality for a particular indication. The same considerations were applied to prognostic reviews on risk tools. Aspects of note are detailed in the respective Evidence and Link to Recommendation section of each review.

Impact of sensitivity, specificity and prevalence on the cost effectiveness of a diagnostic intervention

A modality or risk tool with a low sensitivity will lead to more false negatives (i.e. people missed or incorrectly predicted to have low risk and therefore do not need onward management). This will impact, resource use as well as health outcomes because these people who have been missed could therefore deteriorate, which in turn leads to longer hospital stay or higher mortality. All else being equal and assuming onward management is cost effective, a diagnostic intervention with a higher sensitivity than alternatives will be cost effective.

A modality or risk tool with a low specificity will lead to more false positives (i.e. people incorrectly labelled as having a condition or at high risk needing onward management). This will impact resource use as this leads to unnecessary treatment (which may carry potential harm). All else being equal and assuming onward management is costly and may carry harm, a diagnostic intervention with a higher specificity than alternatives will be cost effective.

Prevalence is important in the consideration of cost effectiveness. If the traumatic injury or condition being investigated is not common within the population suspected of the injury, prevalence of the injury is low. This indicates that a high proportion of people will be investigated, incurring cost, without any benefit. The lower the prevalence of the condition within the population tested the less cost effective the diagnostic intervention will be, regardless of its accuracy.

Incidental findings and cost effectiveness

When employing a diagnostic modality for a particular population group, there is normally “indirect benefit” afforded to other population groups through incidental findings. The incidental findings are of particular relevance for the trauma population for two reasons. Firstly due to the potential for poly-trauma (i.e. chest trauma and major haemorrhage are not mutually exclusive conditions). Secondly, and importantly, one injury may have systemic symptoms, signs and complications (i.e. blood may collect elsewhere to the injury site). Without consideration of potential for incidental findings, the overall benefit from undertaking the diagnostic intervention and therefore cost effectiveness may be underestimated. The sensitivity of the diagnostic intervention to find ANY injury increases as you increase the number and type of injuries that you are trying to identify with one

diagnostic test. Furthermore, predictive power of finding ANY injury increases as the proportion of patients with injury in the pool that you are testing increases. Where appropriate onward management of the type of injury you are assessing is similar, i.e. in systemic injury, cost effectiveness of the diagnostic modality is increased.

On the other hand, if incidental findings are taken into consideration of cost effectiveness, it also needs to be acknowledged that the potential of definitively ruling out ANY injury decreases (that is to say specificity and negative predictive power decreases). If onward management is costly and risky (for example surgery or interventional radiology) then this can decrease the cost effectiveness of the diagnostic intervention.

Radiation risk and cost effectiveness

Please refer to the chapter in Spinal injuries.

A concern raised around imaging is the risk of radiation. This was incorporated in a sensitivity analysis in the Spinal Injuries guideline model. The cost per patient on average is low, and particularly when time preference is taken into account (i.e. discounting of future costs and benefits), the costs and health risks are minimal. None the less, all else being equal, the diagnostic test with least radiation risk will be the most cost effective.

The trade-off between time efficiency and accuracy

Some modalities such as CT may take more time (from time of presentation) to undertake than others, particularly when issues such as scheduling and reporting are taken into account. Clinicians may need time to decide whether they should undertake these modalities only following a primary assessment (whether this is clinical or prior imaging such as x-ray). Thus there is potentially a trade-off between the quicker (and sometimes more readily available modalities) yet less accurate modalities, versus taking a bit more time for a more precise diagnosis. It is assumed that as net benefit increases (due to lack of deterioration), net cost will decrease (i.e. due to reduced length of stay, less complicated and costly treatment).

The service delivery costs of enabling timely diagnostic intervention (such as providing 24/7 CT) were considered outside the remit of this guideline and further considered in Guidance for Trauma Services (CG XXX). Where appropriate this guideline cross references these considerations. The trade-off between time efficiency and accuracy is therefore reflected in determining net clinical benefit, rather than in determination of net cost.

Consideration of overall resource use and costs of a diagnostic strategy

In the absence of economic evidence, the intervention cost of the diagnostic modality, as well the cost associated with each diagnostic outcome (in terms of the indicated onward management), was considered. The total cost of a diagnostic strategy was considered as the sum of the intervention cost and the product of each diagnostic outcome and the respective costs of indicated onward management. Costs of each diagnostic strategy are offset by the net clinical benefit that the strategy brings (i.e. through incidental findings or through time efficient management).

P.1 Imaging costs

Relevant for chest trauma diagnosis, haemorrhage imaging, and whole body CT questions.

Table 38: Imaging costs[180]

Resource	Description	National average unit cost	Lower Quartile Unit Cost	Upper Quartile Unit Cost	NOTES
X-ray	Direct Access Plain Film (DAPF)	£28	£22	£33	The number of data submissions for this code was 153, with 5,254,817 units of activity (examinations)
Ultrasound	Ultrasound Scan, less than 20 minutes (RA23Z)	£59	£69	£69	The number of data submissions for this code was 5, with 1,977 units of activity (examinations)
	Ultrasound Scan, 20 minutes and over (RA24Z)	£40	£36	£36	The number of data submissions for this code was 3, with 13 units of activity (examinations)
CT (selective)	Computerised Tomography Scan, one area, no contrast, 19 years and over (RA08A)	£60	£62	£62	The number of data submissions for this code was 4, with 70 units of activity (examinations)
	Computerised Tomography Scan, one area, with post contrast only, 19 years and over (RA09A)	£71	£71	£71	The number of data submissions for this code was 1, with 10 units of activity (examinations)
	Computerised Tomography Scan, one area, pre and post contrast (RA10Z)	£301	£301	£301	The number of data submissions for this code was 1, with 1 unit of activity (examinations)
	Computerised Tomography Scan, two areas without contrast (RA11Z)	£58	£58	£58	The number of data submissions for this code was 1, with 12 units of activity (examinations)
	Computerised Tomography Scan, two areas with contrast (RA12Z)	£76	£72	£72	The number of data submissions for this code was 2, with 22 units of activity (examinations)
CT (whole body)	Computerised Tomography Scan, more than three areas (RA14Z)	£146	£102	£190	The number of data submissions for this code was 2, with 2 units of activity (examinations)

(a) For ultrasound and CT, the costs are from the 'trauma and orthopaedics' service description.

(b) Note for CT, there is no category under the trauma and orthopaedics service description for below 19 years of age.

(c) The number of data submissions for the activity level recorded for ultrasound more than 20 minutes and CT indicate that the unit cost was likely to be reflective of the costs only incurred by a few providers and not likely to be representative of the national average. This may explain why the ultrasound of more than 20 minutes costs less than the ultrasound of less than 20 minutes.

(d) Note that for some of the modalities the lower and upper quartile costs are the same; however it is reported here as it is reported in NHS reference costs 2012-13.

P.2 Assessment and management of haemorrhage

P.2.1 Control of external haemorrhage

P.2.1.1 Use of haemostatic dressings

None.

P.2.1.2 Use of tourniquets in major trauma

The adverse events from tourniquets could include: amputations, nerve palsies, and renal failure. Although the risk of such events may be small, below is an illustration of the costs involved in treating these adverse events.

P.2.1.2.1 Renal failure

Below are the costs related to an intensive care stay (costs are per day) from NHS reference costs 2012/13 [180]. Assuming that someone with renal failure would need to be kept in intensive care, the costs involved with this could relate to the 'one organ supported' cost.

Table 39: ICU costs per day

Intervention /diagnosis	Reference cost HRG	National average unit cost	Lower quartile unit cost	Upper quartile unit cost	Notes
Adult critical care unit stay	Adult critical care, one organ supported	£852	£681	£981	Data submissions for this code was 152, with 477,039 units of activity

Source: NHS reference costs 2012/13

Additionally, the costs associated with treating renal failure can also be derived from the 'Renal procedures and disorders' sub chapter (LA) of the Healthcare Resource Groups classifications (which NHS reference costs are based on). Although this may not be related to trauma, it is another way in which the costs of treating this particular adverse event can be derived, and will most likely involve the same kind of management.

Table 40: Renal failure HRG costs

Intervention/ diagnosis	Reference cost HRG	National average unit cost	Lower quartile unit cost	Upper quartile unit cost	Average cost of excess bed day	Lower quartile unit cost	Upper quartile unit cost	Weighted national average	Average length of stay	Notes
Acute kidney injury with interventions	Acute kidney injury with interventions, with CC score 0-5 (LA07K)	£3,302	£950	£4,972	NA	NA	NA	NA	11	Data submissions for this code was 3, with 3 units of activity. Setting: non-elective in patient long stay
Acute kidney injury with interventions	Acute kidney injury with interventions, with CC score 6-10 (LA07J)	£2,714	£2,714	£2,714	NA	NA	NA	NA	4	Data submissions for this code were 1, with 1 unit of activity. Setting: non-elective in patient long stay
Acute kidney injury with interventions	Acute kidney injury with interventions, with CC score 11+ (LA07H)	£8,663	£8,663	£8,663	NA	NA	NA	NA	16	Data submissions for this code were 1, with 1 unit of activity. Setting: non-elective in patient long stay
Acute kidney injury with interventions	Weighted for complications and co morbidities for HRG codes: LA07K; LA07J; LA07H; as recorded for non-elective in patient long stay							£4,257	10.60	

(a) No Excess bed day data was available under the service description of 'trauma and orthopaedics' for the above HRG's.
(b) The number of data submissions for the activity level recorded indicated that the unit cost was unlikely to be reflective of the national average given the very few submissions.

P.2.1.2.2 *Amputations*

Amputations may be another adverse event associated with a tourniquet.

Below is an illustration of the costs of treating an upper arm amputation for trauma, and a major knee procedure for trauma.

Table 41: Amputations HRG costs [180]

Intervention/ diagnosis	Reference cost HRG	National average unit cost	Lower quartile unit cost	Upper quartile unit cost	Average cost of excess bed day	Lower quartile unit cost	Upper quartile unit cost	Weighted national average	Average length of stay	Notes
Arm procedures										
Major shoulder and upper arm procedures for trauma (includes OPCS codes; X07.3; X07.8; X07.9)	Major shoulder and upper arm procedures for trauma, without CC (HA61C)	£4,119	£3,419	£4,881	£304	£211	£396	£4,602	3.02	Data submissions for this code were 142, with 1,962 units of activity.
Major shoulder and upper arm procedures for trauma (includes OPCS codes; X07.3; X07.8; X07.9)	Major shoulder and upper arm procedures for trauma, with CC (HA61B)	£6,706	£5,391	£7,649	£314	£178	£399	£6,939	10.10	Data submissions for this code were 137, with 826 units of activity.
Major shoulder and upper arm procedures for trauma (includes OPCS codes: X07.3, X07.8, X07.9)	Weighted for complications and co morbidities for HRG codes: HA61C, HA61B and ; as recorded for Non- Elective Inpatients							£5,295	5.11	
Leg procedures										

Intervention/ diagnosis	Reference cost HRG	National average unit cost	Lower quartile unit cost	Upper quartile unit cost	Average cost of excess bed day	Lower quartile unit cost	Upper quartile unit cost	Weighted national average	Average length of stay	Notes
Major knee procedures for trauma, category 2 (includes OPCS codes: X09.3, X09.4, X09.5)	Major knee procedures for trauma, category 2 without CC (HA21C)	£5,778	£4,582	£6,665	£278	£202	£341	£6,010	6.70	Data submissions for this code were 141, with 1,342 units of activity.
Major knee procedures for trauma, category 2 (includes OPCS codes: X09.3, X09.4, X09.5)	Major knee procedures for trauma, category 2 with CC (HA21B)	£9,491	£6,756	£11,473	£208	£168	£239	£9,852	17.37	Data submissions for this code were 1125, with 417 units of activity.
Major knee procedures for trauma, category 2 (includes OPCS codes: X09.3, X09.4, X09.5)	Weighted for complications and co morbidities for HRG codes: HA21C, HA21B and ; as recorded for Non- Elective Inpatients							£6,921	9.23	

(a) The HRG code was split by age and/or co morbidities and complications. Therefore the unit cost was thought to be reflective of that which would be incurred by the population under consideration.

(b) The average length of stay was thought to be reflective of that which would be incurred by the population under consideration

(c) The number of data submissions for the activity level recorded indicated that the unit cost was likely to be reflective of the national average

It is possible, however, that amputations may be undertaken as part of damage control surgery to control the haemorrhage, or as part of surgery for other major trauma injuries that need an operation, therefore costs may be lower than illustrated here if undertaken on the back of another procedure.

Additional to the actual procedure of amputating the limb, there may also be the need for physiotherapy, as well as the potential use of a prosthetic limb.

The cost of a session of hospital physiotherapy is £32 per hour (PSSRU 2013). The total cost of physiotherapy would depend on the number of sessions.

P.2.1.2.3 Nerve palsies

Treatments for nerve palsies may depend on the extent of the injury.

Generally this would include splints or physiotherapy. On very rare occasions, a nerve transfer operation may be done, although this is usually more appropriate for severed nerves as opposed to crushed nerves (as from a tourniquet).

The cost of a session of hospital physiotherapy is £32 per hour (PSSRU 2013). The total cost of physiotherapy would depend on the number of sessions.

P.2.2 Fluid replacement

Data on the risk of transfusion-related adverse events from the annual SHOT report 2013 [71].

Figure 125: Total issues of blood components in 2013

Number of reports by UK country

	2010		2011		2012		2013	
	Number	%	Number	%	Number	%	Number	%
England	2511	78.5	2749*	80.0	2860*	80.7	2975	83.4
Northern Ireland	154	4.8	150	4.4	156	4.4	129	3.6
Scotland	332	10.4	352	10.2	326	9.2	285	8.0
Wales	203	6.3	184	5.4	203	5.7	179	5.0
United Kingdom	**3200**	100.0	**3435**	100.0	**3545**	100.0	**3568**	100.0

*Includes reports from Ministry of Defence overseas

Table 2.1: Total number of reports to SHOT by UK country 2010-2013

	Red cells	Platelets	FFP	SD-FFP	MB-FFP	Cryo	Totals
NHS Blood & Transplant	1,727,452	268,630	228,826	68,924	11,672	38,894	2,344,398
Northern Ireland Blood Transfusion Service	52,133	8,449	5,212	1,600	414	1,082	68,890
Scottish National Blood Transfusion Service	184,300	25,448	21,458	4,520	1461	3,697	240,884
Welsh Blood Service	79,161	9,613	10,836	4,429	0	284	104,323
Totals	**2,043,046**	**312,140**	**266,332**	**79,473**	**13,547**	**43,957**	**2,758,495**

FFP=fresh frozen plasma; SD=solvent-detergent sterilised; MB=methylene blue-treated; Cryo=cryoprecipitate

Figures contain some transfers between Blood Services, which may lead to inaccuracies in small numbers, such as MB-FFP

Table 2.2: Total issues of blood components from the Blood Services of the UK in calendar year 2013

	2010	2011	2012	2013
England	10.1	10.9	11.7	12.7
Northern Ireland	20.8	21.1	21.3	18.7
Scotland	12.2	14.3	13.2	11.8
Wales	18.1	16.4	18.4	17.2
United Kingdom	**10.9**	**11.6**	**12.3**	**12.9**

Table 2.3: Total number of reports per 10,000 components by UK country 2010-2013

1

Figure 126: Relative risks of major morbidity and mortality per 1,000,000 components issued in 2013

Table 4.1: Relative risks of major morbidity and mortality based on data for 2013 overall and by incident group

Risk of major morbidity and mortality per 1,000,000 components issued in 2013			
Total morbidity			**51.8**
Total mortality			**8.0**
	Mortality	**Major morbidity**	**Total cases**
All errors	2.2	5.1	346.2
Acute transfusion reactions	0.0	27.6	116.0
Haemolytic transfusion reactions	0.4	2.9	17.8
Transfusion-related acute lung injury	0.4	3.3	3.6
Transfusion-associated circulatory overload	4.4	12.3	34.8
Transfusion-associated dyspnoea	0.0	0.4	2.2
Transfusion-associated graft versus host disease	0.0	0.0	0.0
Post-transfusion purpura	0.4	0.0	1.1
Cell salvage	0.0	0.0	4.4
Transfusion-transmitted infection	0.0	0.0	0.0
Unclassifiable complications of transfusion	0.4	0.4	2.2
Paediatric cases	0.7	1.5	37.0

P.3 Control of haemorrhage in hospital

P.3.1 Haemorrhage protocols [180]

Currency Code	Currency Description	Tests	National Average Unit Cost	Lower Quartile Unit Cost	Upper Quartile Unit Cost	Data Submissions	Requests
DAPS03	Integrated Blood Services	24,467,573	£2	£1	£3	20	13,293,585

P.3.2 Haemorrhage imaging

See section P.1 for imaging costs.

Table 42: ICU stay costs [180]

Resource	Description	National average unit cost	Lower Quartile Unit Cost	Upper Quartile Unit Cost	Notes
Critical care day	Adult Critical Care, 6 or more Organs Supported	£1,867	£1,529	£2,116	The number of data submissions for this code was 48, with 6,659 units of activity
	Adult Critical Care, 5 Organs Supported	£1,697	£1,381	£2,002	The number of data submissions for this code was 127, with 37,191 units of activity
	Adult Critical Care, 4 Organs Supported	£1,573	£1,403	£1,779	The number of data submissions for this code was 149, with 143,425 units of activity
	Adult Critical Care, 3 Organs Supported	£1,422	£1,227	£1,614	The number of data submissions for this code was 150, with 289,107 units of activity
	Adult Critical Care, 2 Organs Supported	£1,236	£1,082	£1,416	The number of data submissions for this code was 151, with 337,032 units of activity
	Adult Critical Care, 1 Organ Supported	£852	£681	£981	The number of data submissions for this code was 152, with 477,039 units of activity

Resource	Description	National average unit cost	Lower Quartile Unit Cost	Upper Quartile Unit Cost	Notes
	Adult Critical Care, 0 Organs Supported	£619	£398	£772	The number of data submissions for this code was 126, with 50,028 units of activity

P.3.3 Whole-body CT

See section P.1 for imaging costs.

P.3.4 Interventional radiology[181]

Intervention/ Diagnosis [a]	Reference cost HRG	National average unit cost	Lower Quartile Unit Cost	Upper Quartile Unit Cost	Average cost of excess bed day	Lower Quartile Unit Cost	Upper Quartile Unit Cost	Weighted national average	Weighted average length of stay	NOTES
Embolisation										
Percutaneous Transluminal Embolisation of Blood Vessel	Percutaneous Transluminal Embolisation of Blood Vessel with CC Score 3+ (YR21A); as recorded for Non-Elective Inpatients long stay	£5,465	£2,779	£6,958	£259	£203	£284	£5,987	9.92	The number of data submissions for this code was 92, with 492 units of activity.
Percutaneous Transluminal Embolisation of Blood Vessel	Percutaneous Transluminal Embolisation of Blood Vessel with CC Score 0-2 (YR21B); as recorded for Non-	£3,691	£2,370	£4,335	£329	£225	£391	£4,232	4.41	The number of data submissions for this code was 57, with 130 units of activity.

	Elective Inpatients long stay									
Percutaneous Transluminal Embolisation of Blood Vessel	Weighted for complications and co morbidities for HRG codes: YR21A, YR21B and ; as recorded for Non-Elective Inpatients long stay							£5,620	8.77	
Stent Graft										
Percutaneous Transluminal Angioplasty with Insertion of Stent Graft into Peripheral Blood Vessel	Percutaneous Transluminal Angioplasty with Insertion of Stent Graft into Peripheral Blood Vessel (YR12Z); as recorded for Non-Elective Inpatients	£7,950	£3,671	£13,484	£233	£177	£255	£9,067	6.68	The number of data submissions for this code was 36, with 99 units of activity. [b]

(a) These costs are from NHS reference costs 2013/14. As the HRG groupings for interventional radiology have been expanded in the newer version of NHS reference costs, and these costs were provided by GDG members towards the end of the development phase, after the release of the latest version of NHS reference costs.

(b) The number of data submissions for the activity level recorded for the stent graft procedure was likely to be reflective of the costs only incurred by a few providers and may not be representative of the national average.

P.4 Monitoring

P.4.1 Coagulation testing

P.4.1.1 Point-of-care TEG and ROTEM costs

P.4.1.1.1 Device costs

Taken from the draft version of the NICE diagnostic assessment report on viscoelastic point of care testing.

Table 43: Comparison of costs of ROTEM and TEG based on 2013 costs (from NICE Diagnostic Assessment Report) [738]

Cost component	ROTEM	TEG
4-channel device	£24,950	£20,000
Connectivity kit	£4,078	Included in device cost
Software/Database commander	£2,415	
Printer	£126	
Trolley	£1,015	
Total Device Cost	£32,584	£20,000
Years of use	3	3
Total cost ROTEM and Extras per year	£10,861	£6,667
After care cost per year	£1,750	£2,000
Training cost per year (advanced)	£725	£0
Total cost ROTEM per year	£13,336	£8,677
Number of tests per year with the 4-channel device	500	500
Material cost per test	£26.67	£17.33

Each of the manufacturers quoted a number of extra cost items in addition to the cost of the device itself. Only those extras that were available (and comparable) for the three devices, were included in the acquisition costs in order to maintain consistency. After-care and training costs were also included although the equivalency of these between devices was difficult to assess. As in the Scottish HTA (Craig 2008[a]), we assumed that a machine would be used for three years (the total acquisition cost is then divided by three to obtain the cost per year).

An important variable in the estimation of equipment costs per test is the number of tests per device per year. In the Scottish HTA report, an assumption was made that 200 tests would be done per year. However, experts indicted values much higher, ranging from 600 to 8,000 per year (with the 8,000 performed on an eight channel machine). We have therefore assumed that, on average, 500 tests are performed per centre per year.

a http://www.healthcareimprovementscotland.org/previous_resources/hta_report/thromboelastography.aspx

P.4.1.1.2 Basic test costs

Table 44: Comparison of costs of ROTEM and TEG basic test (trauma patients from the NICE Diagnostic Assessment Report) [738]

Basic Test Cost	
ROTEM intem	£1.13
ROTEM extem	£1.22
ROTEM Fibtem	£2.22
Cup and pin (x3)	£3.15 x 3
Equipment cost[a]	£26.67
Total cost ROTEM test	£40.69
Rapid TEG	£11.25
Pain cup and pin	£5.45
Equipment cost[a]	£17.33
Total cost TEG test	£34.03

(a) From previous table

In line with the study protocol of the ongoing RCT in trauma patients (Moore) we assumed that each patient was tested five times. In addition, we assumed that the acquisition costs would be the same as in the cardiac population as the material costs of the device would be the same and we again assumed that 500 tests would be performed per year.

The only difference in costs in terms of device was for the types of assays used to define a basic test (Table 36). We assumed that trauma patients would not be tested using the heparin assays. Therefore for ROTEM we assumed that a basic test would consist of INTEM, EXTEM and FIBTEM; this was similar to the assays evaluated in the predictive accuracy studies included in the systematic review.

For TEG, we assumed that the regular kaolin test would be replaced by the rapid TEG assay as this was used by almost all the predictive accuracy studies included in the systematic review and is also the assay used in the ongoing RCT.

P.4.1.2 Point of care CoaguChek cost

Table 45: CoaguChek costs

Resource	Cost
Device cost	
CoaguChek device[a]	£1,280.
Years of use	5
No of patients used on over lifetime (assuming 30 patients a day)	54,750[b]
Cost per test	£0.02[c]
Consumables	
Test strips (pack of 48, assuming one per patient)	£2.74
Steret	£0.06

(pack of 50, one per patient)	
Control pack (4 test vials per pack, one pack lasts one month)	£0.02[d]
Total test cost	£2.84

(a) This includes the CoaguChek device with barcode scanner, rechargeable battery pack, base unit, manual & professional lancing system

*(b) 30*365*5 = 54,750*

(c) Cost of device divided by number of people used on over lifetime

*(d) This is used to quality control the results of the device and check for accuracy. Is it performed at predefined criteria? The assumption made here is that the controls are done once per week as part of a quality control procedure. Therefore a pack of 4 vials of fluid will last one month. One month = (30*30) = 900 patients (or tests), £12.30 a pack/900 patients = £0.02 per test*

(e) Cost of device, test strips, and control pack are the list prices from the manufacturer, not including any discounts to providers.

P.5 Information and support

The costs for different bands of NHS staff can be found here. These are the different staff that are likely to be family support workers in the NHS with the cost per hour based on their salary bands [517]. The row at the bottom is taken from the PSSRU document on the unit costs of health and social care [160].

Table 46: Cost per hour by agenda for change band

Staff on Agenda for Change (% allocated as oncosts or overhead which is based on ratios reported by PSSRU [2013])	Band	Hours per annum	Wages	Oncost (24%)	Qualification and ongoing training	Staff (direct) overhead[a]	Non-staff (indirect) overhead[c]	Capital - no equipment	Total	Per hour of working time (non-premium)
Allied professional support worker	2	1606	£15,851	£3,737.00	£0	£3,782	£8,221	£3,159	£34,751	£22
Nurse team manager	7	1569	£35,536	£8,378.00	£10,438	£8,480	£18,431	£2,416	£83,679	£53
Nurse team leader	6	1569	£29,759	£7,016.00	£10,438	£7,101	£15,435	£2,416	£72,165	£46
day ward nurse	5	1569	£24,799	£5,847.00	£10,438	£5,918	£12,862	£1,411	£61,275	£39
Clinical support worker (hospital)	2	1588	£15,851	£3,737.00	£0	£3,782	£8,221	£1,543	£33,135	£21
Staff not on Agenda for Change										
Family support worker [160]		1552	£22,941	£5,408.82	£0	£8,221[b]	£4,536[d]	£1,897	£43,004	£28

(a) 19.31% of wages plus oncosts
(b) 29% of wages plus oncosts
(c) 41.97% of wages plus oncosts
(d) 16% of wages plus oncosts

Appendix Q: NICE technical team

Name	Role
Sharon Summers-Ma	Guideline Lead
Phil Alderson	Clinical Advisor
Nichole Taske	Clinical Lead
Bhash Naidoo	Health Economist
Ben Doak	Guideline Commissioning Manager
Thomas Feist	Guideline Coordinator
Judith McBride	Editor

Appendix R: 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?					

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

1

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