

## **Appendices**

### **Appendix 1          Further details of search strategy**

#### 1. Electronic database search terms

##### Search terms

1. latent cause\*
2. latent error\*
3. latent failure\*
4. latent factor
5. latent factors
6. latent threat\*
7. system factor
8. system factors
9. systems factor
10. systems factors
11. system weakness\*
12. systems weakness\*
13. system error\*
14. systems error\*
15. system failure\*
16. systems failure\*
17. system cause\*
18. systems cause\*
19. potential error\*
20. potential failure\*
21. organi\*ation\* failure\*
22. organi\*ation\* factor
23. organi\*ation\* factors

24. workplace factors
25. contributory factor\*
26. error management
27. system safety
28. systems safety
29. violation
30. active failure
31. unsafe act\*
32. adverse event
33. near miss
34. human error
35. patient safety incident
36. safety
37. (health\* or medic\* or operati\* or hospital or patient)
38. 29 or 30 or 31 or 32 or 33 or 34 or 35 or 36
39. 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26 or 27 or 28
40. 37 and 38 and 39

NB \* refers to truncated term

## 2, Patient safety organisation websites

Websites searched as follows to 20<sup>th</sup> Nov 2010: Agency for Healthcare Research and Quality: [www.ahrq.gov](http://www.ahrq.gov); Australian Patient Safety Foundation: <http://www.apsf.net.au/>; Canadian Patient Safety Institute: <http://www.patientsafetyinstitute.ca/English/Pages/default.aspx>; Danish Society for Patient Safety: <http://www.patientsikkerhed.dk/>; European Union Network for Patient Safety: <http://90plan.ovh.net/~extranet/>; Manchester Patient Safety Network (UK): <http://www.ihs.manchester.ac.uk/ResearchNetworks/patientsafety/>; Lancaster Patient Safety Research Unit (UK): <http://www.lpsru.org.uk/>; Scottish Patient Safety Network (UK): <http://www.spsrn.ac.uk/>; VA National Center for Patient Safety: <http://www.patientsafety.gov/>

### 3. Study databases

Study databases searched were: Action medical register (UK); Australian New Zealand clinical trials registry; Chinese clinical trials registry; German clinical trials registry; ICRCTN international register; Iranian clinical trials registry; Japan clinical trials registry; Medical Research Council (UK); Netherlands trials register;

NIH clinical trials (international); NIH Health Technology Assessment (UK); Pan African clinical trials registry;

Sri Lankan clinical trials registry; US clinical trials registry; Wellcome Trust (UK).

**Appendix Table 1 Summary of data extracted from included studies: incident reporting studies**

Study	Country	Setting	Study method	Study sample	Use of theory	Identification main aim?	Human factors expert?	Patients or staff reporting	Contributory factor list fully developed before data collected?	Method for eliciting contributory factors (if different from study method)	Further details about contributory factor elicitation
Abramson et al (1980) <sup>1</sup>	UK	Intensive care: 16 bed general medical surgical ICU in 560 bed, adult, tertiary referral teaching hospital.	Incident reporting	145 incident reported filed between 1974-1978	None	Secondary aim	No	Staff	Yes	The way in which contributory factors were elicited for inclusion on the incident reporting form was not specified.	N/A
Beckmann & Gillies (2001) <sup>2</sup>	Australia	Intensive care: up to 93 Intensive care units	Incident reporting	143 'reintubation' events taken from data set	None	Primary aim	No	Staff	Yes	Based on previous framework: AIMS-ICU (Beckmann et al 1996)	N/A
Beckmann et al (1996a, 1996b) <sup>3;4</sup>	Australia	Intensive care: 7 intensive care units	Incident Reporting	610 incidents from 536 reports	None	Secondary aim	No	Staff	Yes	Based on previous framework: AIMS-ICU (Beckmann et al 1996)	N/A

Buckley et al (1997) <sup>5</sup>	China (Hong Kong)	Intensive care: 14 bed ICU serving 1430 bed hospital	Incident reporting	281 critical incidents over a 3 year period	Specific: Reason (1990), Eagle, Davies & Reason (1992), Allnutt (1987)	Primary aim	No	Staff	Yes	Based on AIMS framework (Webb et al 1993)	N/A
Busse & Wright (2000) <sup>6</sup> ; Wright et al (1991) <sup>7</sup>	UK	Intensive care	Incident reporting	710 incident reports	Broad: Rasumussen et al 1987– performance shaping factors	Secondary aim	No	Staff	Yes	Uses the Edinburgh Incident Analysis Framework (no further reference)	N/A
Callum et al (2001) <sup>8</sup>	Canada	General Hospital: University affiliated teaching hospital	Incident reporting	819 transfusion incidents reported (Feb 1999-Aug 2000)	None	Secondary aim	No	Staff	No	A. Qualitative: free text coding B. Based on previous framework (Eindhoven Medical Model Classification)	N/A

Chang et al (2008) <sup>9</sup>	USA	General reporting system (nationwide US Vaccine and Drug Safety Reporting System)	Incident reporting	115 events identified involving the 'mix-up of tuberculin purified protein derivatives and vaccines'	None	Primary aim	No	Staff	No	Unclear whether a previous framework was used, or whether the factors were identified from qualitative free text coding of incident reports	N/A
Cote et al (2000) <sup>10</sup>	USA	Anaesthesia: Hospital based paediatric sedation incidents were subset of dataset (non-hospital settings also included)	Incident reporting and Survey	Total of 118 reports of adverse sedation events.	None	Primary aim	No	Staff	No	Qualitative: free text coding of incident reports	95 incidents from total pool retained (where all coders could agree on contributory factors), 43 of these based in hospital
Currie (1989) <sup>11</sup>	Australia	Anaesthesia Two teaching hospitals - wards which used anaesthesia	Incident reporting	167 Anaesthesia reports Jan 1986-June 1988	None	Secondary aim	No	Staff	Yes	Based on previous framework: ACES report (see Currie et al, 1988)	N/A

Currie et al (1988) <sup>12</sup>	Australia	Anaesthesia Two teaching hospitals - wards which used anaesthesia	Incident reporting	88 anaesthesia incidents	None	Secondary aim	No	Staff	Yes	Not specified	N/A
Elnicki & Schmitt (1980) <sup>13</sup>	USA	General hospital: 10 nursing service units in a large Florida Hospital	Incident reporting	432 reported incidents	None	Primary aim	No	Staff	Yes	A. Interviews B. Unsystematic literature review C. Author consensus Were all used to identify <i>measurable</i> factors which could be related to the occurrence of reported incidents on each of the nursing units	Interviews were with 'key hospital personnel'

Frey et al (2000) <sup>14</sup>	Switzerland	Intensive care Multi-disciplinary, neonatal paediatric intensive care unit (ICU) of a non-university, teaching children's hospital	Incident reporting	211 critical incidents over 1 year period (467 child admission)	None	Secondary aim	No	Staff	Yes	Based on previous framework: AIMS-ICU (Beckmann et al 1996)	N/A
Galletly & Mushet (1991) <sup>15</sup>	New Zealand	Anaesthesia	Incident reporting	100 reports over three month period	Broad: 'systems' approach mentioned	Primary aim	No	Staff	No	Unclear but likely to be from free text coding of incident reports	N/A
Graf et al (2005) <sup>16</sup>	Germany	Intensive care Medical Intensive Care Unit in University Hospital	Incident reporting	45 incident report forms	None	Primary aim	No	Staff	Yes	Based on previous framework: Australian Patient Safety Foundation Incident form (no reference given)	N/A



Harding & Petrick (2008) <sup>17</sup>	Canada	Not reported Student nurses (no details of hospitals in which they work)	Incident reporting	77 incident reports	None	Primary aim	No	Staff (student nurses)	No	Qualitative: free text coding of incident reports	N/A
Inoue & Koizumi (2004) <sup>18</sup>	Japan	General Hospital: Tertiary care general hospitals	Incident reporting	300 incident reports randomly sampled from 6 hospitals	None	Secondary aim	No	Staff	Yes	Based on previous framework: EDIT model (see Inoue et al 2002 for an earlier version)	N/A
Kaplan et al (1998) <sup>19</sup>	USA	Transfusion: 2 blood centres and 2 hospital transfusion service	Incident reporting	503 event reports	Specific: Reason (1990) and Rasmussen (1987) mentioned	Secondary aim	No	Staff	Yes	Based on previous framework: Eindhoven Classification (Van Vuuren, 1998)	N/A

Khan & Hoda (2001) <sup>20</sup>	Pakistan	Surgery: Operating room suite in a teaching hospital in Pakistan	Incident reporting	329 reports from Aug 1997-December 1999	Broad: very broad-human/system/design-equipment , attributed to Runciman et al (1993)	Secondary aim	No	Staff	Yes	Based on previous framework: AIMS (Runciman et al, 1993)	N/A
Kusumaphanyo et al (2009) <sup>21</sup> ; Klanarong et al (2005) <sup>22</sup> ; Sintavanuruk et al (2008) <sup>23</sup> Charuluxananan et al (2008) <sup>24</sup>	Thailand	General Hospital: 51 Hospitals across Thailand	Incident reporting	1996 incidents	None	Primary aim	No	Staff	Yes	Based on previous framework: Thai AIMS study (unable to identify reference describing development of the framework)	N/A

Lundy et al (2007) <sup>25</sup>	Republic of Ireland	Transfusion Hospitals with established haemovigilance officer in post	Incident reporting	759 near miss incidents	None	Primary aim	No	Staff	Yes	Based on previous framework: MERS-TM (Battles et al 1998) which used Eindhoven Classification	N/A
Morita (2004) <sup>26</sup>	Japan	General hospital Outpatients from university hospital	Incident reporting	73 potential adverse drug event related to dispensing of wrong drug	None	Secondary aim	No	Staff	Yes	Based on previous framework: Japanese Ministry of Health, Labor and Welfare (2001)	N/A
Nast et al (2005) <sup>27</sup>	USA	Intensive Care: Cardiothoracic intensive care unit & Cardiothoracic post anaesthesia care unit	Incident reporting	163 reports describing 157 events.	None	Primary aim	No	Staff	No	Qualitative: free text coding of incident reports  Based on previous framework: Eindhoven Medical Model Classification	N/A

Needham et al (2004) <sup>28</sup> ; Needham et al (2005) <sup>29</sup> ; Holzmueller et al (2005) <sup>30</sup> ; Sinopoli et al (2007) <sup>31</sup>	USA	Intensive Care: Intensive care units	Incident reporting	In total 1353 incident reports	Broad: Systems approach Reason (2000)	Primary aim	No	Staff	Yes	Based on previous framework: London protocol (Vincent et al, 1998)	N/A
Nuckols et al (2008, 2009) <sup>32,33</sup>	USA	General hospital: Academic referral centre: and a nearby affiliated community hospital in a major metropolitan area in Southern California.	Incident reporting	2228 incident reports for 16575 randomly selected patients	Specific: Reason, 1990	Primary aim	No	Staff	Yes	Literature review (not systematic)	N/A
Short et al (1996) <sup>34</sup>	China (Hong Kong)	General Hospital: Two large public hospitals in Hong Kong	Incident reporting	1037 incidents	Broad: references to latent error in discussion cited to Reason (1990)	Secondary aim	No	Staff	Yes	Based on previous framework: AIMS-ICU (Beckmann et al 1996)	N/A

Skapik et al (2009) <sup>35</sup>	USA	Intensive care: 23 Intensive care units nationwide which treated paediatric patients	Incident reporting	464 paediatric incidents reported from July 1 2002 to June 30 2004	None	Primary aim	Yes	Staff	No	Qualitative: free text coding  This analysis was structured based on a previous framework – the ICUSRS (Wu et al 2002; Holzmueller et al 2005)	N/A
Suresh et al (2004) <sup>36</sup>	USA	Intensive care: Neonatal intensive care units	Incident reporting	Total pool of 1230 reports	Broad: systems approaches to understanding error mentioned in discussion (Reason, 1997, 2000; Vincent 2003, Vincent et al, 1998) cited	Secondary aim	No	Staff	Yes	Way in which possible contributory factors were elicited was not specified	708 incident reports (which used a structured rather than free text format) were used in relation to prevalence contributory factors

Tuttle et al (2004) <sup>37</sup>	USA	General hospital: 750 bed teaching hospital	Incident reporting	2843 safety events	None	Secondary aim	No	Staff	Yes	Based on previous framework: Risk Prevention and Management (RPM) System (Doctor Quality, 2003)	N/A
Williamson et al (1993) <sup>38</sup>	Australia	Anaesthesia	Incident reporting	2000 incident reports	Broad: Reason	Primary aim	No	Staff	Yes	The way in which contributory factors were identified for inclusion in the incident reporting form was not specified	N/A
Wolf et al (2006) <sup>39</sup>	USA	National medication error database	Incident reporting	1305 student made medication errors	None	Primary aim	No	Staff (student nurses)	Yes	Based on previous framework: MEDMARX database (USP dispensing information, 2003)	

**Appendix Table 2 Summary of data extracted from included studies: all other studies**

Study	Country	Setting	Study method	Study sample	Use of theory	Identification main aim?	Human factors expert involved?	Patients or Staff reporting	Contributory factor list fully developed before data collected?	Method for eliciting contributory factors (if different from study method)	Further details about contributory factor elicitation
Ahmad et al (2010) <sup>40</sup>	Ireland	Anaesthesia Patient receiving patient controlled analgesia at Irish Hospital	Observational	27 critical incidents	None	Primary aim	No	Staff	Unclear	The way in which contributory factors were not specified.	N/A
Alfredsdottir et al (2008) <sup>41</sup>	Iceland	Surgery: Operating room department, University Hospital	Interview ( <i>combined interviews and focus groups</i> )	N=8 semi structured interviews N=2 focus groups (4 nurses each)	Explicit: (Reason organisational accident causation model)	Secondary aim	No	Staff	No	Same	N/A
Anoosheh et al (2008) <sup>42</sup>	Iran	General hospital: 3 University Hospitals in Iran	Survey	96 nurses and nursing managers	Specific: systems approach (Reason 2000)	Primary aim	No	Staff	Yes	A. Unsystematic literature review; B. Author opinion	N/A
Barach et al (2008) <sup>43</sup>	USA	Surgery: University Children's hospital	Observational	431 paediatric cardiac operations	Broad: (Reason, Carthey & de Leval,	Secondary aim	No	Staff	No	Same as study method	N/A

Study	Country	Setting	Study method	Study sample	Use of theory	Identification main aim?	Human factors expert involved?	Patients or Staff reporting	Contributory factor list fully developed before data collected?	Method for eliciting contributory factors (if different from study method)	Further details about contributory factor elicitation
					2001)						
Beckmann et al (2003) <sup>44</sup>	Australia	Intensive care: 12 bed intensive care unit	Multiple methods (A. incident reporting and B. case note reviews)	A. 100 facilitated incident monitoring reports, from which 221 incidents were identified. B. 164 patient charts	None	Secondary aim	No	Staff	Yes	Based on previous framework: AIMS-ICU (Beckmann et al 1996)	N/A
Beso et al (2005) <sup>45</sup>	UK	Pharmacy department of 450 bed London teaching hospital	Multiple methods Phase 1: Observation (pharmacists asked to record details of all dispensing errors identified at final check phase for a 2 week period) Phase 2:	130 dispensing errors identified 27 interviews conducted with 16 members of dispensary staff	Explicit: based on Reason's accident causation model (Reason, 1990)	Primary aim	No	Staff (pharmacy staff)	No	Qualitative: interviews; Literature review (not systematic) Based on previous framework: Dean et al (2002)	Only data from 27 interviews used to elicit contributory factors



Study	Country	Setting	Study method	Study sample	Use of theory	Identification main aim?	Human factors expert involved?	Patients or Staff reporting	Contributory factor list fully developed before data collected?	Method for eliciting contributory factors (if different from study method)	Further details about contributory factor elicitation
			Interview								
Blike et al (2005) <sup>46</sup>	USA	General hospital: Dartmouth-Hitchcock Medical Center: 'Tertiary care hospital'	Observational	2 simulations in two different departments (interventional radiology and emergency)	None	Secondary aim	No	N/A	No	In addition to observation used previous framework (London protocol, Vincent et al 2000)	N/A
Catchpole et al (2005, 2006, 2007) <sup>47-49</sup>	UK	Surgery: Paediatric Cardiac Surgery, Children's hospital and elective orthopaedic operations, General Hospital	Observational	24 paediatric operations, 18 orthopaedic operations	Explicit: Systems approach mentioned , specifically , Reason (1990) and Helmreich (2000).	Primary aim	Yes	N/A	No	Same	N/A
Chianca (2006) <sup>50</sup>	Brazil	Anaesthesia Post anaesthesia recovery	Interview	25 'fault' reports elicited via semi-	Specific: Reason (1992, human	Primary aim	No	Nurses	Yes	Qualitative: interviews	Only data from semi-structured interviews

Study	Country	Setting	Study method	Study sample	Use of theory	Identification main aim?	Human factors expert involved?	Patients or Staff reporting	Contributory factor list fully developed before data collected?	Method for eliciting contributory factors (if different from study method)	Further details about contributory factor elicitation
		rooms (PAR) of ten medium and large sized hospitals in Belo Horizonte		structured interviews. 15 'experts' then judged each report according to a set of contributory factors elicited from the interviews	error)						used in elicitation of contributory factors
Christian et al (2006) <sup>51</sup>	USA	Surgery Operating room	Observational	9 surgery cases (colorectal cases involving pelvic dissections and hepatobiliary cases), mean case duration 4 hours 27 minutes (range 2:02-9:33)	None	Primary aim	Yes	N/A	No	N/A	N/A

Study	Country	Setting	Study method	Study sample	Use of theory	Identification main aim?	Human factors expert involved?	Patients or Staff reporting	Contributory factor list fully developed before data collected?	Method for eliciting contributory factors (if different from study method)	Further details about contributory factor elicitation
Coombes et al (2008) <sup>52</sup>	Australia	General Hospital: 700 bed teaching hospital	Interview	14 interviews with interns, reporting 21 prescribing errors	Broad: Reason's chain of errors (Reason 1990)	Primary aim	No	Staff (interns)	No	A. Qualitative: interviews; B. Based on previous framework: London protocol (Vincent et al, 2000)	N/A
Cooper et al (1984) <sup>53</sup>	USA	General Hospital: Four hospitals in Boston Metropolitan area	Interview	1089 incidents (616 from phase 1 interviews, 234 from introductory interviews with trained observers; 239 subsequently reported via telephone by trained observers); from 139 anaesthesiolo	None	Secondary aim	No	Staff	No	N/A	N/A

Study	Country	Setting	Study method	Study sample	Use of theory	Identification main aim?	Human factors expert involved?	Patients or Staff reporting	Contributory factor list fully developed before data collected?	Method for eliciting contributory factors (if different from study method)	Further details about contributory factor elicitation
				gists, residents and nurse anaesthetists							
Cronin(2006) <sup>54</sup>	Canada	General hospital: Winnipeg Regional Health Authority	Multiple methods: Incident reporting; and case studies of specific incidents.	Pilot: 8 incidents, which comprised 38 interviews Roll-out: 30 incidents reviewed	Specific: Reason 1990	Secondary aim	No	Staff	No	A. Interviews from identified incidents B. Based on previous framework (London Protocol, Taylor-Adams & Vincent, 2004)	N/A
Cullen et al (1997) <sup>55</sup>	USA	Surgery and Medicine 11 medical and surgical units in two tertiary care hospitals	Multiple methods Incidents elicited via a variety of methods including A. Interviews –	4,031 patients studied prospectively 266 preventable or potential adverse drug events	Specific: Reason (1990)	Primary aim	No	Staff	Yes	The way in which the contributory factors were identified was not specified.	N/A

Study	Country	Setting	Study method	Study sample	Use of theory	Identification main aim?	Human factors expert involved?	Patients or Staff reporting	Contributory factor list fully developed before data collected?	Method for eliciting contributory factors (if different from study method)	Further details about contributory factor elicitation
			unit personnel asked to report incidents to investigators, investigators also asked staff for further errors B. investigators reviewed charts daily C. Structured interviews with those involved in identified preventable adverse events	identified; 236 structured interviews conducted							
Davis et al (2001, 2003) <sup>56;57</sup>	New Zealand	General Hospital Acute care hospitals with over 100 beds	Case note review	Medical records of 6579 patients; of which adverse events	None	Secondary aim	No	Staff	Unclear	Not specified	N/A

Study	Country	Setting	Study method	Study sample	Use of theory	Identification main aim?	Human factors expert involved?	Patients or Staff reporting	Contributory factor list fully developed before data collected?	Method for eliciting contributory factors (if different from study method)	Further details about contributory factor elicitation
				reported in 339 notes.							
De Leval et al (2000) <sup>58</sup>	UK	Surgery: Neonatal arterial switch operations (21 surgeons from 16 institutions)	Multiple methods Observational Survey	Total of 243 operations Observation: 193 observed, of these 173 thought to be 'sufficiently reliable' Survey: completed at the completion of the operation by the surgeon, first and second assistant, anaesthetist, perfusionist and scrub nurse	None	Primary aim	Yes	Staff	No	In addition to observations, survey was based on previous framework: STAR – Surgical Team Assessment Reward (STAR) questionnaire (no reference for this provided)	N/A
Dean et al (2002) <sup>59</sup>	UK	Pharmacy: Based in pharmacy of	Multiple methods Interview	Only interview data reported in paper: 44	Explicit: Reason's model of	Primary aim	No	Staff (doctors)	No	Qualitative interviews Also based	N/A

Study	Country	Setting	Study method	Study sample	Use of theory	Identification main aim?	Human factors expert involved?	Patients or Staff reporting	Contributory factor list fully developed before data collected?	Method for eliciting contributory factors (if different from study method)	Further details about contributory factor elicitation
		Inpatient hospital	Survey Case note review	interviews regarding prescribing errors (41 doctors)	human error (Reason, 1990)					on previous framework: London protocol, Vincent et al, 2000)	
Dornan et al (2009) <sup>60</sup> , Chapter 4 of final report	UK	General hospital Foundation Year 1 doctors from Nationwide set of medical schools	Interview	N=30 interviews, describing 85 prescribing errors	Explicit: Reason organisational accident model	Primary aim	No	Staff (student doctors)	No	N/A	N/A
Elbardissi et al (2007) <sup>61</sup>	USA	Surgery: Cardiovascular surgery operating room	Survey (administered face to face)	68 staff: 16 cardiac anaesthesiologists; 13 monitor technicians; 11 registered nurses; 10 'CSTs'; 7 perfusionists; 4 residents; 4	Explicit: Reason's model of accident causation	Primary aim	No	Staff	Yes	Based on previous framework: Human Factors Analysis Classification System (Wiegmann & Shappell, 2003)	N/A

Study	Country	Setting	Study method	Study sample	Use of theory	Identification main aim?	Human factors expert involved?	Patients or Staff reporting	Contributory factor list fully developed before data collected?	Method for eliciting contributory factors (if different from study method)	Further details about contributory factor elicitation
				senior cardiac surgeons; 3 'SAs'							
Fabri & Zayas-Castro (2008) <sup>62</sup>	USA	Surgery: Surgical hospital department	Multiple methods used to develop and test a classification of error underlying surgical errors A. Survey B. Incident reporting	Survey: 48 surveys Incident reporting: Data reported on 9830 patients	Broad: Reason (1990)	Secondary aim	No	Staff	Yes	To develop the contributory factor list A. Interviews with experts B. Literature review (not systematic)	A. Faculty members from at least 6 surgical disciplines (general surgery, surgical oncology, paediatric surgery, plastic surgery, vascular surgery, cardiothoracic surgery)
Forster et al (2006) <sup>63</sup>	Canada	Maternity: Labour and delivery unit at tertiary care centre in Eastern	Observational	425 patient encounters identified by trained observer	None	Secondary aim	No	Staff	Yes	A. Literature review (not systematic) B. External expert group	N/A



Study	Country	Setting	Study method	Study sample	Use of theory	Identification main aim?	Human factors expert involved?	Patients or Staff reporting	Contributory factor list fully developed before data collected?	Method for eliciting contributory factors (if different from study method)	Further details about contributory factor elicitation
		Ontario, Canada									
Galvan et al (2005) <sup>64</sup>	USA	Surgery Paediatric Cardiac Surgery	Observational (although paper describes case note review and survey in method, only results from observational element to study are reported here)	22 cardiac surgery cases	Specific: Reason (1990)	Primary aim	No	N/A	No	Same	N/A
Gawande et al (2003) <sup>65</sup>	USA	Surgery Surgeons at three different teaching hospitals	Interview	38 surgeons interviewed	None	Secondary aim	No	Staff (doctors)	Yes	Qualitative: interviews; Based on previous framework: London protocol (Vincent et al, 1998)	N/A
Giraud et al (1993) <sup>66</sup>	France	Intensive care Intensive	Observational	316 iatrogenic complications identified and	None	Primary aim	No	Staff (doctors)	Yes	Based on previous framework	N/A

Study	Country	Setting	Study method	Study sample	Use of theory	Identification main aim?	Human factors expert involved?	Patients or Staff reporting	Contributory factor list fully developed before data collected?	Method for eliciting contributory factors (if different from study method)	Further details about contributory factor elicitation
		care units		coded						(Cooper et al, 1978)	
Graber et al (2005) <sup>67</sup>	USA	General hospital 5 large academic tertiary care medical centres	Multiple methods: Case note review Incident reporting Interviews with staff	100 cases of diagnostic error identified from 3 sources A. Quality assurance activities (57) B. Voluntary reports (33) C. Autopsy discrepancies (10)	None	Primary aim	No	Staff	No	Qualitative interviews Free text coding of reported incidents  Also based on previous framework: root cause checklist developed by VHA (cited references – Johnson, NO YEAR; Henrisen & Kaplan, 2003)	N/A
Hamman et al (2009) <sup>68</sup>	USA	Maternity: Labour and delivery	Observational	4 'in-situ' simulations run and	Broad: latent environme	Primary aim	No	Staff	No	Same	N/A

Study	Country	Setting	Study method	Study sample	Use of theory	Identification main aim?	Human factors expert involved?	Patients or Staff reporting	Contributory factor list fully developed before data collected?	Method for eliciting contributory factors (if different from study method)	Further details about contributory factor elicitation
		ward of midsized Midwestern community hospital.		responses of healthcare team observed. Follow up interviews conducted with 9 staff	nt threats to safety mentioned (Reason, 1997)						
Horwitz et al (2009) <sup>69</sup>	USA	General hospital 944 bed urban academic medical centre with both emergency medicine and internal medicine residency programs	Survey	40 survey responses from medical staff which described adverse event or near miss after emergency department floor transfers	None	Primary aim	No	Staff	No	Qualitative: free text coding of survey responses  Followed by literature review (not systematic)	N/A
Itoh & Andersen (2007) <sup>70</sup>	Japan	General hospital: University hospital in	Survey	Surveys received from: Patients N=920	None	Primary aim	No	Staff and patients	Yes	Based on previous framework: Taken from a	N/A

Study	Country	Setting	Study method	Study sample	Use of theory	Identification main aim?	Human factors expert involved?	Patients or Staff reporting	Contributory factor list fully developed before data collected?	Method for eliciting contributory factors (if different from study method)	Further details about contributory factor elicitation
		Tokyo		Doctors N=164 Nurses N=795						patient questionnaire originally developed for a Danish survey - no reference given	
Kopp et al (2006) <sup>71</sup>	USA	Intensive care Medical/ surgical ICU (16 bed) at a tertiary care academic medical centre	Observation	Thirty-three 12 hour shifts were observed, from these 132 medication errors identified	None	Primary aim	No	Staff	Yes	Based on previous framework: ADE Prevention Study Group (Bates et al, 1995; Leape et al, 1995)	N/A
Leape et al (1995) <sup>72</sup>	USA	General hospital: non obstetric adult patients at two tertiary hospitals, admitted to any of 11	Multiple methods: Case note review Interviews	264 preventable events identified, including 334 errors	Specific: Reason (1990) and others related to systems failures	Primary aim	No	Staff	No	Qualitative interviews External expert group analysed the interviews to determine contributory factor	N/A

Study	Country	Setting	Study method	Study sample	Use of theory	Identification main aim?	Human factors expert involved?	Patients or Staff reporting	Contributory factor list fully developed before data collected?	Method for eliciting contributory factors (if different from study method)	Further details about contributory factor elicitation
		units over a 6 month period									
Lesar et al (1997) <sup>73</sup>	USA	General hospital: 631 bed tertiary care teaching hospital located in North-eastern New York	Case note review (specific review of medication orders)	total of 701 errors selected from larger pool of 2103 confirmed clinically significant medication errors (every third one)	None	Primary aim	No	Staff (pharmacists and physicians)	Yes	Literature review Author opinion	N/A
Meurier et al (1997) <sup>74</sup>	UK	General hospital: District general hospital, and nursing staff attending a day training course	Survey	129	None	Primary aim	No	Staff (nurses)	Yes	Based on previous framework: Medical mistakes questionnaire (Wu et al, 1991)	N/A
Neale et al (2001) <sup>75</sup>	UK	General hospital: General	Case note review	840 cases reviewed, clinical	None	Primary aim	No	Staff	No	Qualitative: free text coding of	N/A

Study	Country	Setting	Study method	Study sample	Use of theory	Identification main aim?	Human factors expert involved?	Patients or Staff reporting	Contributory factor list fully developed before data collected?	Method for eliciting contributory factors (if different from study method)	Further details about contributory factor elicitation
		medicine, general surgery and orthopaedics from two acute hospitals in London area		reviewers wrote brief narratives of the key points of each hospital admission before completing detailed questionnaires. Total of 103 narratives identifying a total of 118 adverse events						narratives	
Parker et al (2010) <sup>76</sup>	Data collected in USA, first author affiliation UKJ	Surgery: Cardiovascular surgery operating room	Observational	Total of 22 operations: 12 were used as calibration to develop a surgical flow disruption tool and 10 were	Explicit: The Tool was developed based on Reason's model of human	Primary aim	Yes	N/A	No	Observation	N/A

Study	Country	Setting	Study method	Study sample	Use of theory	Identification main aim?	Human factors expert involved?	Patients or Staff reporting	Contributory factor list fully developed before data collected?	Method for eliciting contributory factors (if different from study method)	Further details about contributory factor elicitation
				used to validate the tool.	error (1990), and work of Wiegmann and Shappell (2003)						
Pearse et al (2001) <sup>77</sup>	UK	Surgery: Operating suite of a typical acute district general hospital	Observation	159 surgery cases (93% of those operated on in the 30 day study period)	Broad: Reference to Reason's (2000) concept of latent errors	Primary aim	No	Anaesthetists at each operation	Yes	Way in which possible contributory factors were elicited was not specified	N/A
Proctor et al (2003) <sup>78</sup>	Canada	General hospital: Hospital for Sick Children in Toronto	Multiple methods: Case note review Observation (including review of patient charts and attendance at	64 paediatric cases aged 1 month-17 years	None	Primary aim	No	N/A	Yes	Way in which possible contributory factors were elicited was not specified	N/A

Study	Country	Setting	Study method	Study sample	Use of theory	Identification main aim?	Human factors expert involved?	Patients or Staff reporting	Contributory factor list fully developed before data collected?	Method for eliciting contributory factors (if different from study method)	Further details about contributory factor elicitation
			clinical ward rounds with attending surgeons, nurses and house staff)								
Rothschild et al (2005) <sup>79</sup>	USA	Intensive care and coronary care unit of a 720-bed tertiary care academic hospital	Multiple methods: Observation Case note review Incident reporting Pharmacy reports ADE monitoring	120 adverse events identified	None	Secondary aim	No	Staff	Yes	Way in which possible contributory factors were elicited was not specified	N/A
Sanghera et al (2007) <sup>80</sup>	UK	Intensive care 12 bed anaesthetist-led ICU in a 1000-bed UK NHS Trust	Interviews (identified candidates for interview via observation and use of the hospitals incident reporting	13 interviews regarding 12 medication errors	Explicit: Interviews were analysed using Reason's accident causation model	Primary aim	No	Staff	No	Same	N/A



Study	Country	Setting	Study method	Study sample	Use of theory	Identification main aim?	Human factors expert involved?	Patients or Staff reporting	Contributory factor list fully developed before data collected?	Method for eliciting contributory factors (if different from study method)	Further details about contributory factor elicitation
			scheme)		(Reason, 1990)						
Silen-Lipponen et al (2005) <sup>81</sup>	Data collected from Finland, USA, and UK. First author affiliation: Finland	Surgery: Operating room in hospital across Finland, USA and UK	Interview	30 nurses (10 Finnish, 10 British, 10 American)	None	Primary aim	No	Staff	No	Qualitative (interviews)	N/A
Singh et al (2010) <sup>82</sup>	USA	general hospital Paediatricians from 3 tertiary care institutions, and 2 large practice groups (community paediatricians)	Survey	726 completed survey responses	None	Primary aim	No	Staff	Yes	Literature review (not systematic) External expert group	External expert group consisted of experts in patient safety and diagnostic errors, and other paediatricians
Skibinski et al (2007) <sup>83</sup>	USA	Intensive care: General medical and	Multiple methods used to evaluate the effect of a	All patients who were admitted to these units	None	Secondary aim	No	Staff	No	Qualitative: interviews Also based	Interviews only used for elicitation of contributory

Study	Country	Setting	Study method	Study sample	Use of theory	Identification main aim?	Human factors expert involved?	Patients or Staff reporting	Contributory factor list fully developed before data collected?	Method for eliciting contributory factors (if different from study method)	Further details about contributory factor elicitation
		medical intensive care units: Medication focus	technological interview: Interviews Incident reporting Comparing accuracy of medication administration records with orders profiled by pharmacy Audits of practice Observation	who were receiving medications included in the study						on previous framework: Leape et al (1995). Systems analysis of adverse drug events	factors. No details of how many interviews conducted.
Smits et al (2009) <sup>84</sup>	The Netherlands	Emergency department: Emergency departments of 10 hospitals in the Netherlands	Multiple methods: Incident reporting Interview	522 unintended events analysed, staff made reports then were interviewed about causes	Broad: Latent errors mentioned	Primary aim	Yes	Staff	No	Qualitative: interviews  Based on previous framework: Eindhoven Medical Classification (van Vuuren et al, 1997)	N/A

Study	Country	Setting	Study method	Study sample	Use of theory	Identification main aim?	Human factors expert involved?	Patients or Staff reporting	Contributory factor list fully developed before data collected?	Method for eliciting contributory factors (if different from study method)	Further details about contributory factor elicitation
Smits et al (2010) <sup>85</sup>	The Netherlands	General hospital 21 hospitals: 4 University, 6 Tertiary teaching and 11 general hospitals	Case note review	744 adverse events identified through case note review, of which 736 coded for contributory factors	Specific: theoretical framework of Reason mentioned as guiding study (Reason, 1990)	Primary aim	No	N/A	Yes	Based on previous framework: Eindhoven Medical Model Classification (van Vuuren, 1997)	N/A
Sutcliffe et al (2004) <sup>86</sup>	USA	General hospital: 600 bed teaching hospital	Interview	26 residents, age range 25-39 years, mean 29.8 years	Broad: latent flaws referred to, Reason (1997, 2000) referred to	Primary aim	No	Staff (Doctors)	No	Same	N/A
Tang et al (2007) <sup>87</sup>	Taiwan	General hospital Hospital based (no further detail given)	Multiple methods: Survey (with focus group involved in development)	72 nurses responded to survey	None	Primary aim	No	Staff (nurses)	No	A. qualitative focus group B. Literature review (not systematic)	9 registered nurses participated in the focus group
Tissot et al (2003) <sup>88</sup>	France	Geriatric and cardiovascular-thoracic	Observation	During 20 day period, 523 opportunities	None	Primary aim	No	N/A	Yes	The way in which contributory	N/A

Study	Country	Setting	Study method	Study sample	Use of theory	Identification main aim?	Human factors expert involved?	Patients or Staff reporting	Contributory factor list fully developed before data collected?	Method for eliciting contributory factors (if different from study method)	Further details about contributory factor elicitation
		surgery unit units of 1243 bed University Hospital		for error concerning 56 patients and 78 medication administration errors were recorded						factors were elicited for inclusion on the structured observation form was not specified	
Tucker & Spear (2006) <sup>89</sup>	USA	General hospital: total of 21 hospitals	Multiple methods: Observational Interviews Survey	Observation: 11 nurses for complete shifts at 6 hospitals, mean length 9hr 51min; N=6 nurses (same) for interviews N=520 survey responses from staff within 48 units across 21 hospitals	None	Primary aim	No	Staff (nurses)	No	Contributory factors elicited from interview and observational components of study only	N=11 nurses involved in observations
Tucker et al (2008) <sup>90</sup>	USA	General hospital: 20	Multiple methods:	1732 failures collected from	None	Primary aim	No	Staff (staff in hospitals)	No	Same	N/A

Study	Country	Setting	Study method	Study sample	Use of theory	Identification main aim?	Human factors expert involved?	Patients or Staff reporting	Contributory factor list fully developed before data collected?	Method for eliciting contributory factors (if different from study method)	Further details about contributory factor elicitation
		acute care hospitals in the USA	Observation Department 'discussion' groups (called safety communication forums)	173 work areas across 20 hospitals				performed the observation and the discussion groups)			
Valentin et al (2009) <sup>91</sup>	Multinational data collected First author affiliation Austria	Intensive care: 113 intensive care units from 27 countries, focus on parenteral medication errors)	Multiple methods: Observation and survey	861 errors affecting 441 patients	None	Primary aim	No	Staff	Yes	The way in which contributory factors were elicited for inclusion on the incident reporting form was not specified	N/A
Van Beuzekom et al (2007) <sup>92</sup>	The Netherlands	Surgery & Intensive care  Operating rooms of two university	Survey	330 questionnaire responses received	Broad: General failure types and structural systems failures mentioned	Primary aim	No	Staff	Yes	The survey was developed using qualitative interviews and validated by	Development: 8 team members; validated: 10 members of supervising board

Study	Country	Setting	Study method	Study sample	Use of theory	Identification main aim?	Human factors expert involved?	Patients or Staff reporting	Contributory factor list fully developed before data collected?	Method for eliciting contributory factors (if different from study method)	Further details about contributory factor elicitation
		hospitals, and intensive care units of one university hospital and one teaching hospital.			(Reason, 1990)					an external expert group	
Watt et al (2009) <sup>93</sup> , chapter 4	UK	General Hospital Patients and carers recruited from primary and secondary care in large metropolitan area and large rural area	Interview & focus group	30 individual interviews 12 focus group discussions (total of 68 patients)	None	Secondary aim	No	Patients	No	Same	N/A
Wiegmann et al (2007) <sup>94</sup>	USA	Surgery: Cardiac surgical unit	Observation	31 operations, 42 hours of observation; N=341 surgical	Broad: active vs. latent failures	Secondary aim	Yes (observer had 10 hours)	N/A	Yes	Based on previous framework: Human	N/A

Study	Country	Setting	Study method	Study sample	Use of theory	Identification main aim?	Human factors expert involved?	Patients or Staff reporting	Contributory factor list fully developed before data collected?	Method for eliciting contributory factors (if different from study method)	Further details about contributory factor elicitation
				flow disruptions identified and 155 technical operative errors	mentioned . No references given		didactic instruction on human factors, human error and systems safety from a senior human factors scientist – co-author)			Factors analysis classification system (Elbardassi et al, 2001)	
Wong et al (2006) <sup>95</sup>	North America (USA / Canada) First author affiliation Canada	Surgery: Cardiac surgery units in 3 university affiliated teaching hospitals in two countries (USA /	Survey	1627 reports of precursor events gathered from a total of 464 major adult cardiac surgical procedures	Broad: Reason's Swiss cheese model referred to (Reason, 1990)	Primary aim	No	Staff	Yes	The way in which contributory factors were elicited for inclusion in the survey was not specified	N/A

Study	Country	Setting	Study method	Study sample	Use of theory	Identification main aim?	Human factors expert involved?	Patients or Staff reporting	Contributory factor list fully developed before data collected?	Method for eliciting contributory factors (if different from study method)	Further details about contributory factor elicitation
		Canada)									



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