Development of an evidence-based framework of factors contributing to patient safety incidents in hospital settings: a systematic review

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ABSTRACT

Objective: The aim of this systematic review was to develop a 'contributory factors framework' from a synthesis of empirical work which summarises factors contributing to patient safety incidents in hospital settings.

Design: A mixed-methods systematic review of the literature was conducted.

Data sources: Electronic databases (Medline, PsycInfo, ISI Web of knowledge, CINAHL and EMBASE), article reference lists, patient safety websites, registered study databases and author contacts.

Eligibility criteria: Studies were included that reported data from primary research in secondary care aiming to identify the contributory factors to error or threats to patient safety.

Results: 1502 potential articles were identified. 95 papers (representing 83 studies) which met the inclusion criteria were included, and 1676 contributory factors extracted. Initial coding of contributory factors by two independent reviewers resulted in 20 domains (eg, team factors, supervision and leadership). Each contributory factor was then coded by two reviewers to one of these 20 domains. The majority of studies identified active failures (errors and violations) as factors contributing to patient safety incidents. Individual factors, communication, and equipment and supplies were the other most frequently reported factors within the existing evidence base.

Conclusions: This review has culminated in an empirically based framework of the factors contributing to patient safety incidents. This framework has the potential to be applied across hospital settings to improve the identification and prevention of factors that cause harm to patients.

INTRODUCTION

Since the early 1990s high-risk organisations have adopted a systems approach to safety management.[1 2] This approach recognises that the immediate causes of patient safety incidents are errors made by people at the frontline of operations (eg, in the case of medication administration, this is most likely to be a nurse). However, the importance of a systems approach is that it recognises that the organisations within which people work have inherent weaknesses (latent failures) that can arise from decisions made at more senior levels (eg, plans agreed, buildings designed, staffing levels approved, equipment procured) and those external to the organisation (eg, policies imposed, targets set, funding decisions, education provision) and that these failures manifest themselves in local working conditions that promote errors. Thus, a focus on individual responsibility for errors is likely to be ineffective as an incident reduction strategy. Based on this approach it can be argued that there are two main strategies to reduce medical error: reactive and proactive. The first relies on learning from (reacting to) previous incidents to minimise error in the future while the second is concerned with prospectively identifying the latent failures within organisations that represent the preconditions for errors, and addressing these before a serious event occurs. Incident reporting systems, root cause analysis of serious incidents, and case note review are all tools that have the potential to provide data about the prevalence and/or causes of medical errors. However, there is growing frustration with incident reporting systems with low rates of reporting, poorly designed reporting tools and inadequate feedback all being blamed for providing data that have little value in

improving safety.[3 4] Moreover, learning across all of these tools is predicated on the collection of data about the factors contributing to error.[5 6] To date there is no evidence-based and standardised list of contributory factors that can be used as a basis for understanding causation. Without this, reactive systems are unlikely to provide the answers we are looking for.

In other industries such as nuclear power and transport, measurement tools have been developed to assess the extent to which organisational factors (eg, supervision, planning, communication, training, maintenance) represent a failure in the system.[1 7] These tools do not rely on the retrospective analysis of adverse incidents but instead they allow the proactive monitoring of an organisation's safety. However, before such tools can be developed it is necessary to know what represents a latent failure within that particular industry. This systems approach to patient safety is well established in healthcare since the publication of 'to err is human' by the American Institute of Medicine[8] and subsequent policy documents in the UK,[9 10] and a number of frameworks for studying latent failures have been proposed (eg, Eindhoven classification,[11] WHO patient safety classification,[12] the London Protocol,[13] the Veterans Affairs Root Cause Analysis System,[14] the Australian Incident Monitoring System (AIMS)[5]). However, these frameworks are limited by the lack of an empirical basis and a reliance on classifications from non-healthcare settings[15 16] that are very different to the structure and nature of healthcare.

The growing emphasis on systems thinking over the past 20 years in healthcare[17] has meant that there is now a significant body of evidence in the scientific literature (eg, retrospective interview studies, real-time observational studies and aggregated data from incident reporting studies) that can be used as an empirical basis for generating a classification of the contributory factors that impact on healthcare in hospitals. Such a classification could serve to promote more effective organisational learning through the redesign of incident reporting systems and more effective root cause analysis of healthcare incidents. Such a classification system could also inform the development of intervention strategies to improve safety defences or directly address systems failures,[18–22] and to guide the measurement tools used to evaluate policy and service level interventions.[23]

Thus, the aim of this literature review was to produce a framework of contributory factors that contribute to patient safety incidents within hospital settings. As such, it represents the first attempt to summarise the empirical evidence in this area and to use this evidence to develop a clearly defined and hierarchically ordered framework which describes contributory factors from proximal (sharp end) to distal (latent).

A secondary aim was to identify contributory factors that feature most strongly in the literature and which might therefore be appropriate targets for interventions designed to improve patient safety. Finally, we sought to assess the extent to which the contributory factors that were identified most frequently varied as a function of method of elicitation, hospital setting, and whether or not a human factors expert was involved in their identification.

METHODS

Data sources and searches

The Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines were followed in conducting this systematic review. A variety of strategies were used to search the literature to 20 November 2010. Clear identification of studies that identified the contributory factors of active failures was hampered by the lack of consistent terminology used across studies.

First, search terms were developed and electronic database searching was performed across the following databases: Medline, PsycInfo, ISI Web of knowledge, CINAHL and EMBASE. Second, the reference lists of all downloaded articles were manually searched to identify possible relevant papers. Third, a number of patient safety organisation websites were searched to identify other possible published or unpublished reports. Fourth, registered study databases were searched using the terms 'patient safety' to identify any ongoing or finished projects relevant to the current review that may have provided relevant material. A summary of these search strategies can be found in online appendix 1. Finally, key patient safety authors were contacted and asked to provide details of any relevant published or unpublished reports. This search strategy identified a total of 1502 potential articles. Of these, 95 papers (representing 83 studies) met the inclusion criteria and were included in the review (see figure 1). All article titles and abstracts were reviewed for inclusion (by RM). A random sample of 10% of the titles and abstracts were double coded with respect to inclusion or exclusion (by RS). The κ value of 0.73 indicated an acceptable level of agreement. If there was disagreement about inclusion or exclusion, the full text article was obtained and reviewed (by RM and RS) and agreement reached.

Study selection

Studies were included in this review if they reported data from:

(a) Secondary care or hospital environments.

(b) Primary research which either specifically aimed to identify the contributory factors (often referred to as

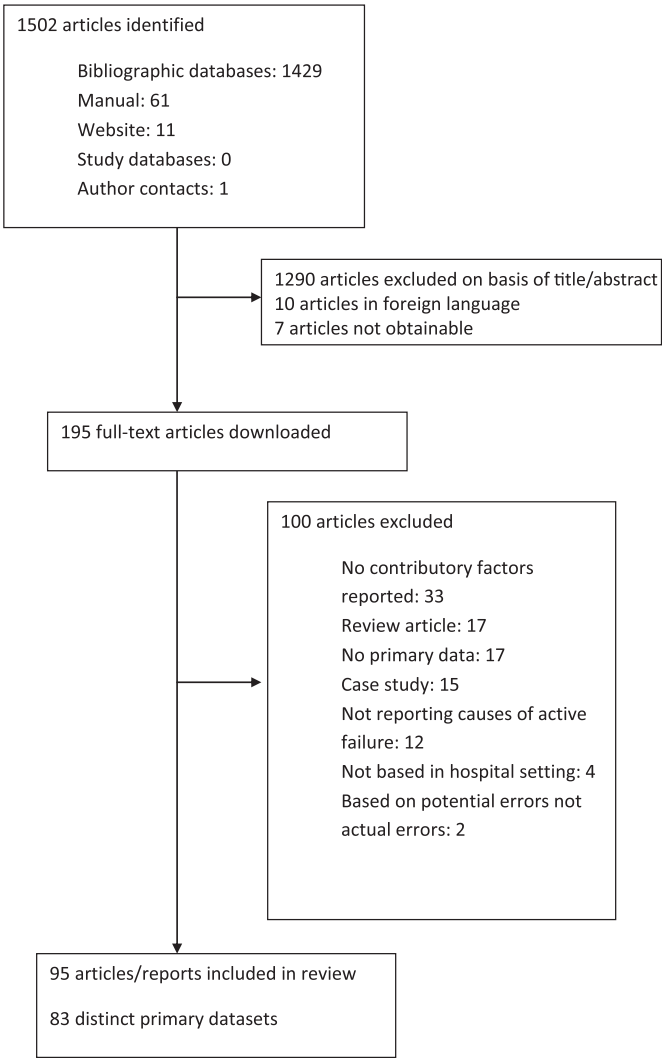


Figure 1 Flow chart of search strategy and included studies.

'causes' within studies) of active failures or threats to patient safety, or reported a clear framework for the categorisation of contributory factors of errors or threats to patient safety in the results section.

Studies were excluded if they reported data from:

(c) Active failures as causes of errors or threats to patient safety rather than underlying latent domains (eg, only specific human 'errors' causing failure of a barcode checking system[24]).

(d) Contributory factors of behaviours or processes that were not active failures (eg, factors affecting the likelihood of staff to report serious medication errors in hospitals [25]).

(e) Case studies reporting contributory factors of a specific adverse event (eg, Chassin and Becher[26]).

(f) Studies that applied proactive risk assessment methods to identify potential failures (eg, failure mode and effects analysis) as these papers focused on exploring potential problems of specific elements of a healthcare system or process.

Data extraction and quality assessment

The study characteristics of 83 datasets were coded. All included articles were blind double coded (by RM and RS) and data were extracted and uploaded onto a Microsoft Access database. Kappas are reported only for dichotomous variables. Articles were coded according to the following characteristics: country of origin; description of setting; study method; study sample; theoretical frameworks informing the research (following the quality coding framework of Sirriyeh *et al*,[27] studies were coded as: explicit use of theory—ie, explicit statement of theoretical framework applied to research; specific use of theory—ie, reference to specific theoretical basis; broad use of theory—ie, reference to broad theoretical basis; or none at all—ie, no theory mentioned); whether identification of contributory factors was a primary or secondary aim of the study (κ=0.66); whether contributory factors were identified by a human factors expert (κ=0.79); and finally, whether patients or staff reported the raw data used to identify contributory factors (κ=1—perfect agreement). Studies varied in the extent to which they used primary data collection methods to elicit contributory factors or whether they used a predefined set of contributory factors, therefore the following additional information was gathered to glean more details about the elicitation of contributory factors: whether the contributory factor list was fully developed before empirical data were collected (yes or no, κ=0.74); the method for eliciting contributory factors (if different from the overall study method); and any further details about the sample used to elicit contributory factors if different or a subset of the overall study sample. Disagreements were discussed and resolved. As we were interested in how contributory factors were identified, regardless of whether this was the primary aim of the study, we did not engage in any further 'quality assessment' coding, as often, very little detail about how contributory factors were identified was reported. All included papers and extracted data can be found in online appendix tables 1 and 2.

All contributory factors reported within the papers were transcribed verbatim onto a Microsoft Excel spreadsheet.

Data synthesis analysis

To develop the contributory factor framework, two of the authors (RL, a human factors expert and RM, a behavioural scientist) first independently grouped all the transcribed verbatim contributory factor items into categories according to their underlying semantic meaning (eg, equipment not working, equipment failure, equipment malfunction would all be grouped as equipment failure). Items could be categorised into more than one category. Second, each author further

grouped these categories into their higher-order domains (eg, equipment failure was grouped with equipment unavailability and insufficient supplies to become 'equipment and supplies)'. At this stage the authors did not explicitly distinguish between latent conditions and local working conditions. Next the two authors met to discuss and agree the number of each of the higher-order domains, and to label and define them (eg, equipment and supplies was defined as 'the availability and functioning of equipment and supplies'). A decision was made to include all factors contributing to patient safety incidents in this framework—both the proximal factors (eg, active failures) and those more distal or external to the organisation (eg, design of equipment and supplies and external policy context). This process resulted in a framework of 20 domains and a definition for each (see figure 2). Finally, the same two authors applied the framework, again independently, to the raw data so as to classify each of the contributory factors based on the framework and to assess agreement. At first, 10% of the factors were coded and at this stage agreement was 55%. Following clarification and modification of definitions (eg, 'human factors design of equipment and supplies' became 'design of equipment and supplies'), the remaining 90% of the contributory factors were coded. Agreement at this second stage was 90%. Disagreements were discussed and resolved through consensus.

To ensure that the framework had relevance and meaning beyond the two authors who developed the initial framework of domains, 10% of the datasets (n=9) and their respective contributory factors were extracted from the database and sent to two academic health professionals (IW, a general practitioner and JW, a hospital physician). Both were provided with instructions, definitions of each of the domains and were asked to code each of the contributory factors using the framework. They were asked to include 'can't code' when they were uncertain of the correct response. Initial agreement between the first two authors and each academic health professional was 62.5% (RL and RM with IW) and 85% (RL and RM with JW). After discussion with the first independent reviewer (IW) and further minor modification of the definitions of domains, agreement rose to 80.1%. Given that agreement with the second reviewer was initially high (85%) further discussion with this reviewer was not deemed necessary.

As noted in the introduction, contributory factors can vary according to their level of proximity to the 'active failure' being accorded to the individual, local working conditions (eg, management of staff and staffing levels) or more latent conditions (eg, design of equipment and supplies). The contributory factors elicited in this review also reflected these distinctions. In a final step, an expert panel of clinicians (n=5), researchers (n=8), managers (n=2) and lay people (n=2) were provided with a list of all contributory factors and definitions and asked to identify the extent to which each factor was removed in time and space from patient safety incidents on a five-point scale from 1 (very close in time and space) to 5 (very distant in time and space). Contributory factors scoring 4 or 5 were deemed to be more 'latent' organisational factors, while those scoring 2 or 3 were deemed to be more related to local working conditions or situational factors. This allowed us to ground the taxonomy in a hierarchical framework, which we have described in figure 2.

RESULTS

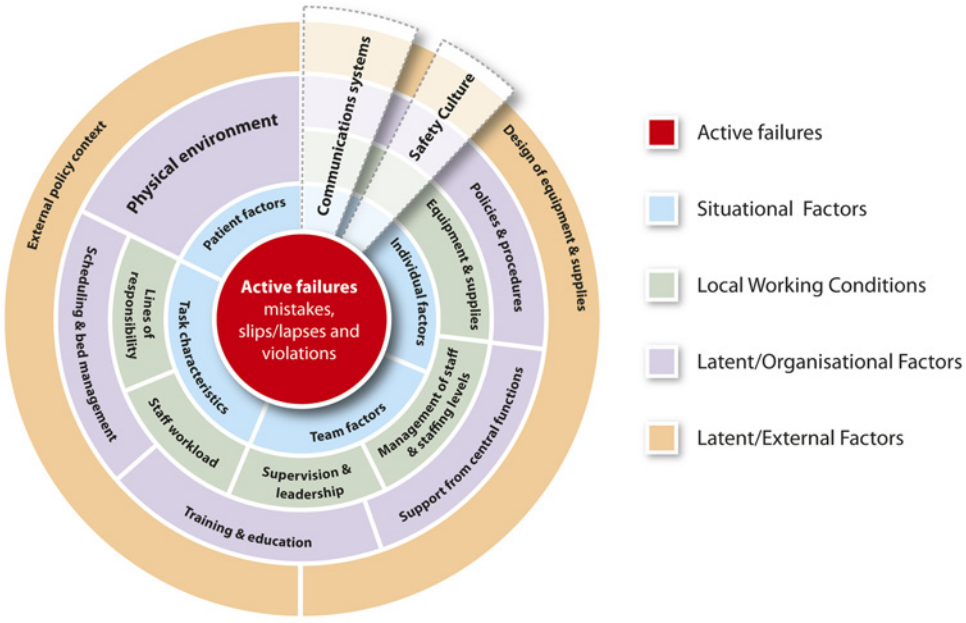
Ninety-five studies fulfilled the inclusion criteria, reporting data from 83 independent datasets.[28–122] A total of 1676 contributory factors were extracted. Studies reported a median of 15 contributory factors each (IQR 8–27). The lowest number of contributory factors extracted from a study was 3[111] and the maximum was 100.[60] All coded information about studies can be found in online appendix tables 1 and 2. For clarity of exposition, individual references are not included next to summaries of study characteristics except to highlight individual studies. Interested readers can find this information in the online appendix tables. A table containing all the extracted contributory factors and their categories is available from the first author on request.

Country of origin

The majority of the studies identified by this review were conducted in the USA (n=34), the UK (n=13), Australia (n=7) and Canada (n=5). One study reported multinational data from 27 countries,[115] one reported data from three countries,[100] and one reported data from the USA and Canada.[121]

Setting

Thirty studies reported data collected from general hospital settings. Other studies focused particularly on intensive care on its own (n=17), in combination with coronary care (n=1) or in combination with medicine and surgery (n=1); surgery settings (n=16, including one in combination with intensive care[116]); anaesthesia (n=7), maternity (n=2), pharmacy (n=2); or transfusion settings (n=2). Other settings included geriatric and cardiovascular wards,[111] and the emergency department.[107] Two studies reported incidents from US general reporting systems (the US Vaccine Adverse Event Reporting System,[45] and the National Medication Error



Factor	Definition
Active failures	Any failure in performance or behaviour (eg, error, mistake, violation) of the person at the 'sharp-end' (the health professional)
Communication systems	Effectiveness of the processes and systems in place for the exchange and sharing of information between staff, patients, groups, departments and services. This includes both written (eg, documentation) and verbal (eg, handover) communication systems
Equipment and supplies	Availability and functioning of equipment and supplies
External policy context	Nationally driven policies / directives that impact on the level and quality of resources available to hospitals
Design of equipment and supplies	The design of equipment and supplies to overcome physical and performance limitations
Individual factors	Characteristics of the person delivering care that may contribute in some way to active failures. Examples of such factors include inexperience, stress, personality, attitudes.
Lines of responsibility	Existence of clear lines of responsibility clarifying accountability of staff members and delineating the job role
Management of staff and staffing levels	The appropriate management and allocation of staff to ensure adequate skill mix and staffing levels for the volume of work
Patient factors	Those features of the patient that make caring for them more difficult and therefore more prone to error. These might include abnormal physiology, language difficulties, personality characteristics (eg, aggressive attitude).
Physical environment	Features of the physical environment that help or hinder safe practice. This refers to the layout of the unit, the fixtures and fittings and the level of noise, lighting, temperature etc.
Policy and procedures	The existence of formal and written guidance for the appropriate conduct of work tasks and processes. This can also include situations where procedures are available but contradictory, incomprehensible or of otherwise poor quality
Safety culture	Organisational values, beliefs, and practices surrounding the management of safety and learning from error
Scheduling and bed management	Adequate scheduling to manage patient throughput minimising delays and excessive workload
Staff workload	Level of activity and pressures on time during a shift
Supervision and leadership	The availability and quality of direct and local supervision and leadership
Support from central functions	Availability and adequacy of central services in support the functioning of wards/ units. This might include support from Information Technology and Human Resources, portering services, estates or clinically related services such as radiology, phlebotomy, pharmacy.
Task characteristics	Factors related to specific patient related tasks which may make individuals vulnerable to error
Team factors	Any factor related to the working of different professionals within a group which they may be able to change to improve patient safety
Training and education	Access to correct, timely and appropriate training both specific (eg, Task related) and general (eg, Organisation related)

Figure 2 The Yorkshire contributory factors framework.

Database[120]). Finally, one study reported data from a cohort of student nurses.[73]

Aim of study (primary/secondary) and theoretical basis

The majority of studies explicitly aimed to identify contributory factors (or more commonly referred to as causes) of errors or active failures (n=55). Over half of the included studies made no reference to a theoretical basis driving the identification of contributory factors (n=48). When theory was explicitly mentioned and related to methodology (n=8), all studies referred to Reason's[123] model of accident causation. Only six studies included explicit human factors expertise in the elicitation of contributory factors.

Description of empirical data collection methods

A third of studies (n=30) reported data collected as part of an incident reporting scheme based within the hospital; see online appendix table 1 for details. Typically these studies reported the frequency with which staff identified contributory factors of a reported incident from a predefined list (eg, Beckmann *et al*[33]) but they also included studies in which free text input from incident reports was analysed qualitatively (eg, Nast *et al*[88]). Other papers reported results from observational studies (n=14), interviews (n=9) and focus groups (n=1), surveys (n=8) or case note reviews (n=4). Seventeen studies reported using multiple methods; see online appendix table 2.

Use of a contributory factors framework

The coders assessed the extent to which studies had generated a deductive predefined list of contributory factors (eg, the London Protocol) which then informed data collection or whether studies used inductive methods to elicit contributory factors from participants. For example, within incident reporting studies, deductive use of lists would take the form of a tick box list given to participants, while within interview studies, a list of closed questions might be used to elicit responses about particular contributory factors. The use of a deductive list in these contexts means that no new contributory factors can be elicited from participants; rather only prevalence with which they are endorsed can be assessed.

In total, 46 studies used a predefined contributory factor list as a basis for data collection. Twenty-six of these were based solely on previous frameworks (eg, 7 studies used a variation of the Australian Incident Monitoring study framework,[5] 3 studies used the Eindhoven classification,[11] 2 studies used the London Protocol,[13] and 14 reported frameworks from miscellaneous previous publications). Seven studies used a combination of literature reviewing and author or other expert opinion to identify the list of contributory factors; one study used previous literature (in addition to pilot work not reported in the paper[93]); and one study only used expert opinion.[116] Twelve studies which used a predefined contributory factors list did not specify how that list was obtained. Two studies were unclear. Of the 34 remaining studies which elicited contributory factors from analysis of primary data, 25 used qualitative methods such as interviews, focus groups or free text coding of incident reports. Eight studies used observational methods, and two used both.

Identification of contributory factors

As described in the Methods section, through the coding of the 1676 contributory factors, a list of 20 contributory factor domains was independently identified by two reviewers (RM and RL) and this list was verified by two further coders (both clinicians, IW and JW). Based on this list we also sought to identify contributory factors that were identified most frequently within the literature. The number of times each of the 20 contributory factors was identified across all of the study settings is shown in table 1 (total column). Across study settings, the five contributory factors identified most frequently were active failures (slips, lapses, mistakes, deviations from policy) (18.2%), individual factors (11%), communication (7.9%), equipment and supplies (6.6%) and management of staff and staffing levels (5.8%). This pattern varied little according to the hospital setting in which the data were collected, with active failures and individual factors consistently being the most frequently identified contributory factors. However, there was some variation. For example, team factors (8.5%) were among the top five contributory factors for surgery, but for no other setting. For anaesthesia, equipment and supplies was the second most cited contributory factor, accounting for 15.2% of the codes. Physical environment was also among the top five factors for anaesthesia. For the general hospital setting, patient factors (7.4%) were among the highest ranked contributory factors but equipment and supplies were not.

Table 2 shows the contributory factors identified by each of the different study methodologies. Studies using incident reporting methodology more commonly identify active failures than interview or observational studies. This is intuitive as generally incident report forms are limiting in terms of the detail of the event which can be recounted and the options for contributory factors available to the reporter. Interview studies appear to more commonly identify individual factors and staff workload as contributory factors. Observation studies tend to identify equipment and supplies marginally more frequently than other methods.

We also investigated variation in the identification of contributory factors as a function of whether or not a human factors expert was involved in the identification. Caution must be exercised due to the low number of studies explicitly utilising a human factors expert in the elicitation of contributory factors. However, there was some evidence that, compared with others, human factors experts tend to identify active failures less frequently (11% vs 19%) and identify more latent contributory factors such as team factors (10% vs 3%) and physical environment (7% vs 3%) more frequently. However, despite some evidence that human factors experts were more likely to identify distal than proximal causes, they were more likely to identify individual factors (eg, fatigue, inexperience, 16%) than others (11%). A similar pattern of findings was apparent when

Table 1 Frequency of identification for contributory factor domains by setting

Domain	Anaesthesia (n=7)		General hospital (n=30)		Intensive care (n=19)		Surgery (n=16)		Other (n=11)		Totals	
	Count	%	Count	%	Count	%	Count	%	Count	%	Count	%
Active failures	17	16.2	79	13.5	112	29.0	51	14.0	46	19.3	305	18.2
Communication systems	2	1.9	47	8.0	35	9.1	33	9.1	15	6.3	132	7.9
Design of equipment and supplies	1	1.0	16	2.7	9	2.3	8	2.2	17	7.1	51	3.0
Equipment and supplies	16	15.2	20	3.4	31	8.0	33	9.1	10	4.2	110	6.6
External policy context		0.0	7	1.2		0.0		0.0	2	0.8	9	0.5
Individual factors	16	15.2	74	12.7	41	10.6	37	10.2	16	6.7	184	11.0
Lines of responsibility		0.0	9	1.5	1	0.3	4	1.1	1	0.4	15	0.9
Management of staff and staffing levels	3	2.9	36	6.2	23	6.0	23	6.3	12	5.0	97	5.8
Patient factors	2	1.9	43	7.4	19	4.9	9	2.5	4	1.7	77	4.6
Physical environment	5	4.8	15	2.6	16	4.1	16	4.4	9	3.8	61	3.6
Policy and procedures		0.0	27	4.6	15	3.9	4	1.1	5	2.1	51	3.0
Safety culture		0.0	10	1.7	4	1.0	4	1.1	8	3.4	26	1.6
Scheduling and bed management		0.0	7	1.2		0.0	9	2.5	2	0.8	18	1.1
Staff workload	1	1.0	23	3.9	9	2.3	5	1.4	7	2.9	45	2.7
Supervision and leadership	4	3.8	17	2.9	7	1.8	8	2.2	4	1.7	40	2.4
Support from central functions	1	1.0	17	2.9	9	2.3	13	3.6	14	5.9	54	3.2
Task characteristics	1	1.0	5	0.9	6	1.6	4	1.1	4	1.7	20	1.2
Team factors	1	1.0	13	2.2	6	1.6	31	8.5	2	0.8	53	3.2
Training and education	1	1.0	19	3.3	8	2.1	3	0.8	8	3.4	39	2.3
Outcome*	7	6.7	9	1.5	1	0.3	27	7.4	13	5.5	57	3.4
Can't code	27	25.7	91	15.6	34	8.8	41	11.3	39	16.4	232	13.8
Grand total	105	100.0	584	100.0	386	100.0	363	100.0	238	100.0	1676	100.0

*Defined as the outcome of a specific action or a behaviour that impacts on the patient. Outcome was not deemed to be a contributory factor because it simply refers to what happens subsequently to the active failure, that is, the outcome for the patient.

Table 2 Frequency of identification for contributory factor domain by method

	Incident reporting (n=30)		Interviews and focus groups (n=10)		Observational (n=14)		Other (n=29)	
Domain	**Count**	**%**	**Count**	**%**	**Count**	**%**	**Count**	**%**
Active failures	149	22.6	22	9.8	24	12.6	110	18.2
Communication systems	38	5.8	12	5.4	16	8.4	66	10.9
Design of equipment and supplies	28	4.3	9	4.0		0.0	14	2.3
Equipment and supplies	55	8.4	4	1.8	20	10.5	31	5.1
External policy context	4	0.6		0.0	1	0.5	4	0.7
Individual factors	68	10.3	54	24.1	12	6.3	50	8.3
Lines of responsibility	2	0.3	4	1.8		0.0	9	1.5
Management of staff and staffing levels	37	5.6	15	6.7	7	3.7	38	6.3
Patient factors	39	5.9	6	2.7	6	3.2	26	4.3
Physical environment	29	4.4	7	3.1	6	3.2	19	3.1
Policy and procedures	16	2.4	5	2.2	4	2.1	26	4.3
Safety culture	9	1.4	5	2.2		0.0	12	2.0
Scheduling and bed management	2	0.3	1	0.4	3	1.6	12	2.0
Staff workload	10	1.5	17	7.6	4	2.1	14	2.3
Supervision and leadership	10	1.5	8	3.6	2	1.1	20	3.3
Support from central functions	23	3.5		0.0	9	4.7	22	3.6
Task characteristics	6	0.9	6	2.7	2	1.1	6	1.0
Team factors	13	2.0	9	4.0	11	5.8	20	3.3
Training and education	17	2.6	2	0.9	5	2.6	15	2.5
Outcome*	9	1.4	1	0.4	25	13.2	22	3.6
Can't code	94	14.3	37	16.5	33	17.4	68	11.3
Grand total	658	100.0	224	100.0	190	100.0	604	100.0

*Defined as the outcome of a specific action or a behaviour that impacts on the patient. Outcome was not deemed to be a contributory factor because it simply refers to what happens subsequently to the active failure, that is, the outcome for the patient.

comparing studies that employed a theoretical framework in developing their contributory factors coding scheme with those that did not.

Figure 2 is a diagrammatic summary of the findings of the review which represents the speculated hierarchical nature of the identified domains. The diagram entitled 'the Yorkshire contributory factors framework' depicts the domains as a series of concentric circles, with active failures at the centre and external policy context as the outer circle. This diagram helps to illustrate the extent to which a domain is proximal to the active failure.

DISCUSSION

As early as 1998, Vincent and colleagues produced a framework for analysing risk and safety in clinical medicine.[124] In this influential article, Vincent refers to Reason's[123] model of organisational safety, making a clear distinction between the active failures (slips, lapses, mistakes and violations) of healthcare professionals and the latent organisational failures that provide the conditions in which active failures occur. The past 20 years has seen a proliferation of research using this framework or similar models to understand the causes of patient safety incidents. However, to date, there has been no systematic review of this research and therefore existing frameworks for risk management have a theoretical, but not an empirical, basis.

In this review we identified 95 studies (83 independent datasets) that reported on primary research work with the aim of identifying the factors that contributed to patient safety incidents. A systematic review and analysis of these studies suggests that, despite the availability of frameworks and models that encourage the elicitation of latent and active failures (eg, the AIMS system[5] asks people to record any physical environment, equipment or work practice or policy issues that contributed to the incident), the overwhelming majority of contributory factors that were identified in this review (irrespective of hospital setting or methodology) were active failures or individual factors. This tendency to focus on the proximal causes of the incident—although slightly less prevalent in our dataset where the reviewer was a human factors expert—was ubiquitous, with approximately 25%

of the contributory factors identified as falling into one of these two domains (active failure or individual factor). In fact, despite claiming to investigate the causes of incidents, some studies did not go much beyond the immediate behaviour, performance or skills of the individual who was 'responsible' for the incident.[73 96 97] Moreover, even when frameworks include systems factors, it is revealing that more attention may be given to the human factors than the systems factors. For example, within AIMS, 33 codes refer to human factors while 21 refer to systems factors. Within the Eindhoven classification (MEDICAL[11]) there are nine codes that refer to human failure but only four referring to technical and five referring to organisational failure. This emphasis on human failure, rather than latent failure, is much less profound in the London Protocol and WHO classifications. However, our review found that, to date, these frameworks have been used less frequently in published empirical work that identifies contributory factors.

Our review has informed the construction of a framework of contributory factors which includes 20 key domains and suggests the extent to which these are proximal or distal (active or latent failures). This pictorial representation is based on previously described accident causation models,[1 17] together with the ratings of our expert group. Thus, it should be noted that while the evidence for the domains reflected within the framework is strong, future research is needed to clarify the exact positioning of the domains within the outer rings and the weighting of each domain (perhaps by varying the size of each segment). Although this framework has a greater number of domains than others (eg, the London Protocol includes just seven domains and the WHO classification specifies five main contributing factors) and therefore might be criticised for being more complex, it captures the full range of contributory factors (across different hospital settings) and gives a greater weighting to systems, rather than human failures. Moreover, some interesting findings have arisen from the work reported here, not least the slight differences in the identification of contributory factors for different settings. The fact that this framework differentiates between surgery, where teamwork was frequently identified, and anaesthesia, where equipment and supply issues were more pronounced, highlights its potential to be generalisable across specialties and error types and yet sufficiently detailed to pick up subtle differences between areas of the hospital to allow the targeting of appropriate interventions. Indeed, this framework has the potential to be used in a number of ways to support improvements to patient safety in practice. It can be used to improve the root cause analysis of serious patient safety incidents. For example, it could be used to analyse patient safety incidents to identify the prevalence of contributory factors and to provide feedback on the quality of existing incident analysis processes. The framework could also be used as a basis for the systematic collection of data about the factors contributing to patient safety incidents through the redesign of local and national reporting systems. The quality of the data elicited through existing reporting systems is often poor[3 4 6] because healthcare professionals who are responsible for reporting errors focus predominantly on the individual and situational factors that are proximal to the error. Without guidance on other factors we may learn little about the organisational interventions that might better support safer practice. The framework may also help clinicians or managers to identify proactively poor safety performance at an organisational level and therefore guide risk management strategies. For example, the framework could be used as the basis for developing a measurement tool for patients to report on the local and organisational factors that impact on their care.

The findings reported here are important but should be treated with caution for two reasons. First, although we identified that active failures, individual factors such as knowledge and experience of the healthcare professionals, communication, and equipment and supplies were the contributory factors most frequently recorded in the literature, this should not be interpreted as reflecting the reality of accident causation. Almost half of the studies included in this review (n=48) did not refer to the use of a theoretical framework to support the identification of contributory factors and only eight made explicit links between theory and the identification of contributory factors. A third of the studies were based on analysing the data from incident reports, data that are often reported to be of poor quality.[125] For example, some studies simply referred to active failures (eg, doctor prescribed the wrong drug dose) to explain another active failure or incident, rather than make any attempt to understand the reasons for this behaviour. Typically, incident reporting frameworks rely on those doing the reporting to select probable causes from a given list. This is problematic because the person completing the report may have very little understanding of the factors, active and latent, that contribute to incidents. In addition, when a tick box of contributory factors is available, this might not represent a complete list of possible contributory factors. Second, most staff are not trained in identification of systems failures and may neglect to look further than the proximal cause of the error (eg, a slip or lapse) when attributing causes to the incident. Together, the lack of a theoretical framework, the paucity of data available in many of the articles about the underlying causes of the incidents, and the

lack of detail about contributory factors also meant that it was impossible to code approximately 15% of the contributory factors. It is also pertinent that only two of the studies reported here involved patients in defining the nature of a patient safety incident or in identifying causes.[77 117] Therefore, it must be acknowledged that this framework does not encompass a patient perspective on the causes of safety incidents. This is certainly a worthy future endeavour.

While the findings about the prevalence of the contributory factors identified within the studies should be treated with caution, the variety of methods and the reach of the research across a range of hospital specialities provide strong grounds for arguing that this work captures the full range of contributory factors. Moreover, the rigorous process employed for coding the contributory factors and developing the classification of these factors means that the resulting framework has a strong evidence base. This is supported by the extent to which our own framework coincides with existing frameworks in this field.[11–14] The framework (see figure 2) explicitly presents contributory factors at a number of different levels (active failures, situational factors, local working conditions, and organisational and external latent factors), which is a welcome addition to the literature. The majority of studies in this review focused on understanding the contributory factors through interviews with frontline staff and their observations and analyses of accidents. These staff may not have a sufficient grasp of the higher-level organisational factors or external policy context that impact on their performance and behaviour. Thus, future research should attempt to further verify the factors in the two outer circles of the framework. Finally, the clear definitions presented within the framework should aid its practical application, and the reliable attribution of contributory factors. In fact, without these definitions the coding task here (see above) was made much more difficult and distinguishing between some domains was problematic (eg, communication and teamwork). Initial pilot work using the framework to categorise contributory factors from 44 serious untoward incident reports within three UK hospital sites has been encouraging, with agreement between two independent assessors at 80%. This compares favourably to published inter-rater reliability of the Eindhoven classification (68%, κ=0.63).[126]

CONCLUSIONS AND POLICY IMPLICATIONS

The poor quality of the current evidence base and the lack of a consistently adopted framework limits the accurate reporting of factors that contribute to error and hence the opportunity to learn from error. We conducted a systematic review of contributory factors identified from a wide range of settings using multiple data collection methods. We then developed an empirically based framework of contributory factors. This framework has the potential to be applied across hospital settings to improve the identification and prevention of factors that cause harm to patients.

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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 20th Nov 2010: Agency for Healthcare Research and Quality: 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/~extranetn/; 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/
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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) [1]	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)[2]	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) [3;4]	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) [5]	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) [6]; Wright et al (1991) [7]	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) [8]	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)[9]	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)[10]	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)[11]	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)[12]	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)[13]	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 *measureable* 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)[14]	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)[15]	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)[16]	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)[17]	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)[18]	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)[19]	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)[20]	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)[21]; Klanarong et al (2005)[22]; Sintavanuruk et al (2008)[23] Charuluxananan et al (2008)[24]	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)[25]	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) [26]	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)[27]	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)[28]; Needham et al (2005)[29]; Holzmueller et al (2005)[30]; Sinopoli et al (2007)[31]	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)[32;33]	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)[34]	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)[35]	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)[36]	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)[37]	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)[38]	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)[39]	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)[40]	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 was not specified.	N/A
Alfredsdottir et al (2008)[41]	Iceland	Surgery: Operating room department, University Hospital	Interview *(combined interviews and focus groups)*	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)[42]	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)[43]	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)[44]	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)[45]	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)[46]	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)[47-49]	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)[50]	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)[51]	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)[52]	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)[53]	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)[54]	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)[55]	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)[56;57]	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)[58]	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)[59]	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)[60], 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)[61]	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)[62]	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)[63]	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)[64]	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)[65]	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)[66]	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)[67]	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)[68]	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)[69]	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)[70]	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)[71]	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)[72]	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)[73]	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)[74]	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)[75]	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)[76]	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)[77]	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)[78]	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)[79]	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)[80]	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)[81]	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)[82]	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)[83]	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)[84]	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)[85]	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)[86]	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)[87]	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)[88]	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)[89]	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)[90]	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 communicatio n forums)	173 work areas across 20 hospitals				performed the observation and the discussion groups)			
Valentin et al (2009)[91]	Multinationa l 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)[92]	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	Developmen t: 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)[93], 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)[94]	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)[95]	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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