Iranian J Publ Health, Vol. 39, No.3, 2010, pp.1-15

Review Article

A Systematic Review of the Extent, Nature and Likely Causes of Preventable Adverse Events Arising From Hospital Care

**A Akbari Sari[1], L Doshmangir[1], T Sheldon[2]*

[1]*Dept. of Health Management and Economics, and Centre of Knowledge Translation and Exchange, Tehran University of Medical Sciences, Iran*
[2]*Dept. of Health Sciences, University of York, UK*

(Received 6 Dec 2009; accepted 15 Jun 2010)

Abstract

Background: Understanding the nature and causes of medical adverse events may help their prevention. This systematic review explores the types, risk factors, and likely causes of preventable adverse events in the hospital sector.
Methods: MEDLINE (1970-2008), EMBASE, CINAHL (1970-2005) and the reference lists were used to identify the studies and a structured narrative method used to synthesise the data.
Results: Operative adverse events were more common but less preventable and diagnostic adverse events less common but more preventable than other adverse events. Preventable adverse events were often associated with more than one contributory factor. The majority of adverse events were linked to individual human error, and a significant proportion of these caused serious patient harm. Equipment failure was involved in a small proportion of adverse events and rarely caused patient harm. The proportion of system failures varied widely ranging from 3% to 85% depending on the data collection and classification methods used.
Conclusion: Operative adverse events are more common but less preventable than diagnostic adverse events. Adverse events are usually associated with more than one contributory factor, the majority are linked to individual human error, and a proportion of these with system failure.

Keywords: *Adverse event, Medical error, Patient safety, Risk management*

Introduction

There are major concerns about the safety of healthcare. Previews studies have suggested that 3 to 17% of hospital admissions lead to adverse events and about 30 to 70% of them are preventable with ordinary standards of care (1-5). These studies have shown that in the USA between 44000 to 98000 people may die each year as the result of adverse events, which makes them the 8th leading cause of death in the USA (6). In addition, adverse events lead to an additional annual cost of around 37 billion dollars in the USA and one to two billion Pounds in the UK (7). Adverse events also result in many intangible costs including pain and discomfort to the patients and their families. This has lead to the establishment of a number of safety initiatives designed to understand the nature and causes of adverse events and to prevent their recurrence. Systematic reviews of the research evidence are the best way of taking stock of the knowledge base (8). Several reviews have investigated the extent, types, risk factors and causes of adverse events (9-12). A wide ranging review to investigate adverse events and the interventions used to prevent them highlighted the need for a systematic review to explore the causes of adverse events in order to provide insights into how such events might be prevented (9). A recent review has summarised the results of eight primary studies (1-3, 13-17) on the extent and nature of hospital adverse events (12). A summary of the studies included in this review are presented in Table 1 (12). These studies have used similar design for identification and measurement of adverse events and their contributory factors (12). The methods they used were a standard

***Corresponding author:** E-mail: akbarisari@tums.ac.ir

retrospective review of medical records conducted in two stages: stage one by trained nurses and stage two by medical doctors. They found that the median overall incidence of in hospital adverse events was 9.2%, with a median percentage of preventability of 43.5% (Table 1), (12). Previous reviews have normally tended to lump all adverse events together, ignoring the fact that adverse events of different severity might have completely different patterns of causes, preventability and outcomes (9-12). In other words, they have not addressed the types of preventable adverse events and the likely causes and factors contributing to preventable adverse events. Therefore, the findings reported by these reviews are not necessarily a reliable summary of preventable adverse events. This paper reports the results of a new systematic review of the types, risk factors and likely causes of preventable adverse events in secondary care.

Materials and Methods

A systematic review of research on the types, nature and likely causes of preventable adverse events was conducted as follows. Any type of empirical study that explicitly investigated the types, risk factors and causes of preventable adverse events in secondary care was considered. Exclusion criteria are presented in Table 2.

Search strategy

MEDLINE, EMBASE, CINAHL and Psych Info, were searched in May 2005 and the MEDLINE search was updated in Nov 2008 using a broad search strategy. A combination of free text terms and MESH terms was used to maximise the sensitivity of the search strategies. Appropriate search strategies were developed for each database with the help of expert librarians.

The databases of theses and dissertations submitted to universities and colleges in the UK including SIGLE (System for Information on Grey Literature in Europe), the ASLIB Index to theses were searched. The World Wide Web address of relevant organizations including Institute of Medicine (IOM), National Patient Safety Foundation (NPSF) and Agency for Healthcare Research and Quality (AHRQ) in the USA; NPSF and the Medicare Advisory Committee in Australia; and National Patient Safety Agency (NPSA) in the UK were also searched. The reference lists of the key reports, dissertations and published papers in this field were searched for additional studies.

Quality assessment

A combination of quality checklists was used to design a list of criteria for appraising the quality of included studies (11-13). Depending on the type of study design, a combination of criteria was used (Table 3). The quality assessment was conducted by one reviewer and checked by a second reviewer. Quality was not an inclusion criterion; however, the results were interpreted with regard to the quality of the included studies, particularly when there was significant heterogeneity in the findings.

Data extraction

A structured form was used to extract data from selected studies. Data were extracted concerning: the study aim; design; setting; participants; methods; quality and reported results. Data were extracted by one reviewer and checked by a second reviewer.

Method of analysis

Because of the wide range of types of design and significant heterogeneity among the studies, it was unsuitable to pool the data, so a structured narrative method was used to summarise the results (8). The summary and interpretation was carried out with regard to the study design, setting and quality. The analysis provided an explanation of the study aim, methods, quality, and results, including the study findings on the types, risk factors and likely causes of preventable adverse events. Any potential heterogeneity was explored by tabulating data. When a significant heterogeneity was found possible, reasons for that were discussed. In addition, a summary result was presented separately for each type of specialty and for each type of method.

Results

After removal of duplicates, 12856 papers were identified from the searches (Fig. 1). The titles and abstracts of these papers were scanned and

11943 papers were deemed not to meet the inclusion criteria. The full text of 913 papers was obtained for further checking against the inclusion criteria after which a further 657 studies were excluded. The remaining 256 studies investigated the types, risk factors and likely causes of adverse events in secondary care. Of these studies, 229 did not explicitly focus on preventable adverse events in secondary care. The remaining 27 papers were included, along with a further 9 papers retrieved as the second reports of original included studies, as these had potential to provide extra information about the original included studies. Therefore, 36 papers from 27 studies are presented in this review. A brief summary of each of the included studies appears in Table 4 (15, 18-44).

The majorities of studies were from the USA and published after 1990. Twenty-one studies analysed preventable adverse events from only one specialty. Eleven were conducted in one or a few hospitals and seven in teaching hospitals only. Twenty-one were retrospective (Table 4).

Study aims were very diverse. Six studies focused on adverse events of any type and the remaining 21 (78%) studies had specific remits such as anaesthesia and ICU, transfusion, surgery, adverse drug events and medication errors, trauma centre, internal medicine, cardiology medicine and obstetrics (Table 4).

Although all these papers explored the types, risk factors or causes of preventable adverse events, this was not necessarily the primary objective. Included studies often addressed rather broader objectives and only subsequently explored the types, risk factors or the likely causes of preventable adverse events. This diversity in study aims resulted in a wide variation of study methods (Table 4). Data on adverse events were generated by case note review in 10 (37%) studies, reporting systems in 12 (44%), questionnaire or interview based survey in 6 (22%) and review of claims reported to the a malpractice insurance company in 2 (7%) studies. Three studies used a combination of two methods; case note review and interview, case note review and reporting system and reporting system and interview (Table 4).

Five of the 10 studies using case note review and one of the three using a questionnaire analysed adverse events of any type from a variety of specialties. The remaining 21 studies, including all the studies which used a reporting system, interview or review of claims, analysed only one type of adverse event (e.g. adverse drug events) or adverse events from one specialty (e.g. ICU), (Table 4).

All the 10 studies using case note review and 3 of the 12 using the reporting system had two stages; estimating the rate of adverse events or preventable adverse events in the first and then the types, risk factors or likely causes of preventable adverse events in the second stage. Studies, which used interview, questionnaire or review of claims, could not of course estimate the rate of adverse events (Table 4).

Quality of included studies

The quality of the studies or their reporting varied widely and was generally poor. Included studies often did not provide adequate information about their methods particularly how causation and preventability were defined, assessed, and used different and poorly defined subjective classifications to analyse adverse events. Use of an established incident analysis technique such as root cause analysis (RCA) or critical incident technique (CIT) for analysing adverse events may increase the level of objectivity and reproducibility (11), but only three included studies used an established technique to analyse adverse events (23, 24, 34), however, they did not explain how they implemented the technique.

Three studies used statistical methods to assess the associations between adverse events and risk factors, which were not necessarily the causes of adverse events. These associations could be influenced by patient case mix and a variety of other factors and need further investigation to demonstrate a causation link (15, 22, 28). For example, adverse events occur more frequent in patients with severe conditions, elderly people and patients who have a longer length of hospital stay (18, 19) and the studies often did not take these factors into account.

Five of the 10 studies, which used case note review, were carried out in a reasonably representative large sample, randomly selected from a

variety of hospitals, and analysed adverse events of any type from a wide range of specialties. Despite some weaknesses, the overall validity and generalisability of these studies is likely to be good (15, 18, 19, 21, 39). The other five studies carried out in one hospital, analysed a relatively small number of preventable adverse events and/or focused only in one specialty or one type of adverse event, so their results may not be representative of adverse events in other hospitals (Table 4).

Studies, which used data from reporting systems, only analysed adverse events from one specialty and did not clearly describe how they defined and assessed the preventability and causality. The adverse events were normally reported by the medical and nursing staff involved in or witnessing the adverse event. Typically, there was a standard form, which required basic clinical details and a brief description of adverse event. The information from this adverse event form was entered into a database and these data were used to classify adverse events and to attribute the preventability and causation link. Little information was given about the level of training in people who reported the adverse events and those who classified them.

All the 6 studies which used interview or questionnaire analysed adverse events from one specialty (Table 4). Two of these did not report the number of preventable adverse events (22, 27). The other 4 studies analysed between 70 and 146 preventable adverse events. Two of these did not report the response rate (29, 39); one reported a response rate of 45% (41) and the other three reported a response rate of between 78% and 85% (22, 25, 27). These studies did not provide a clear description of how the preventability and causality were assessed. Usually the adverse events were analysed according to the judgment of clinicians who were interviewed or completed the questionnaires.

Types of preventable adverse events

Four studies reported the types of preventable adverse events in acute hospitals (Table 5). Three of these studies showed that the majority of adverse events and preventable adverse events were associated with a surgical operation. Operative adverse events accounted for 24%-53% of adverse events and 20%-42% of preventable adverse events. Errors in evaluation and diagnosis and errors in treatment (including drug treatment) were the next most common types of preventable adverse events. Therapeutic adverse events accounted for 15% to 28% of preventable adverse events; and diagnostic adverse events accounted for 9% to 21%. Drug related adverse events were the next most frequent type, accounting for about 10% of preventable adverse events. The most frequent type of preventable adverse drug event was error in dose, followed by error in method of use, inadequate monitoring or follow up, inappropriate drug use and administering a drug to the wrong patient. Preventable adverse drug events were the most common cause of avoidable readmissions to ICU and readmissions due to preventable cardiac arrests. Although the rate of surgical preventable adverse events was highest, surgical adverse events were least likely to be preventable. Seventy five percent to 100% of diagnostic adverse events and 50% to 77% of therapeutic adverse events were preventable, whereas only 17% to 44% of operative adverse events were considered preventable.

Contributing factors

Preventable adverse events were often associated with more than one contributing factor (Table 5-7). The majority were associated with individual error and a large proportion of these caused serious patient harm or death. On the other hand, a small proportion of adverse events were associated with equipment failure which rarely caused serious harm or death. The proportion of system failures contributing to preventable adverse events varied widely, ranging from 3% to 83%. Generally, studies, which used reporting data, interview or questionnaire, reported a higher rate of system failure than studies, which used case, note review (See discussion section).

Type of individual and system errors

Generally technical errors were the most frequent cause of preventable adverse events followed by failure to request or arrange investigation or procedure;

failure to synthesise, decide or act on information and lack of care (Table 7). Inexperience and communication errors were the two most frequent types of system failures (Table 7). This pattern was reported by virtually all the studies which provided relevant data irrespective of the specialty and the methods used.

Table 1: Summary of eight studies included in the vries review (12)

Study	Country	Setting	Data year	Data source	Sample size	Number of AEs	% of AEs	Preventable AEs N(%)
Brennan 1991 (1)	USA	51 hospitals	1984	CNR (R*)	30,121	1133	3.7	657 (58)
O Neil 1993 (14)	USA	1 hospital	1990	CNR (R)	3141	237	6.8	103(43.5)
Wilson 1999 (2)	Australia	28 hospitals	1992	CNR (R)	14,000	2353	16.6	1201 (51)
Thomas 2000 (15)	USA	28 hospitals	1992	CNR (R)	15,000	587	3.2	170 (29)
Vincent 2001(3)	UK	2 hospitals	1998	CNR (R)	1014	110	10.8	57(47.9)
Davis 2003 (16)	New Zealand	13 hospitals	1998	CNR (R)	6,579	850	12.9	513 (60)
Baker 2004 (17)	Canada	20 hospitals	2000	CNR (R)	3745	255	12	106(41.6)
Sari 2006 (13)	UK	1 hospital	2004	CNR (R)	1006	110	8.6	33(31)

*R= retrospective

Table 2: Exclusion criteria

Criteria
Theoretical studies, news, editorials, letters, policy documents and reports
Single case studies
Studies from non-health fields, primary care and nursing homes or studies which did not distinguish between secondary care and other settings
Studies published before 1970
Studies with language other than English, French, German and Farsi
Studies documenting the types, risk factors and likely causes of adverse events regardless of their ultimate outcomes
Studies documenting the types, risk factors and likely causes of adverse events regardless of their preventability

Table 3: Criteria for appraising the quality of included studies (13)

	Criteria
A	**Adequacy of description of study methods**
	Clear explanation of terms and classifications used.
	Adequate explanation of how the incidents were defined identified and analysed.
	Adequate explanation of how causation and preventability was defined and assessed.
B	**Appropriateness of research methods to the study questions**
	Sampling strategy (e.g. type and number of hospitals or specialties).
	Sample size (e.g. number of incidents analysed, interviews or questionnaires).
	Response rate (e.g. for questionnaire or interview based studies).
	Generalisability (e.g. sampling, setting, case mix).
C	**Quality of data collection**
	Source of data (e.g. case note review, reporting system, interview, questionnaire).
	Method of data collection (e.g. structured or unstructured review).
	Validity and reliability of measurement tools (e.g. questionnaires, review forms).
	Who collected the data (profession, experience, training).
	How the criteria of preventability and causation applied (e.g. threshold of causality).
	How many people applied the criteria/how the consensus was made.
	Was the inter-rater reliability checked, level of inter-rater reliability.
D	**Quality of data analysis**
	Time lag between incident and analysis (e.g. recall bias if interviews or questionnaire).
	Incident analysis approach (e.g. use of a standard incident analysis technique).
	Adequate explanation of incidents with regard to: what happened, how and why.
	Covering both individual and system-based factors.
E	**Quality of data presentation**
	Presentation of results and discussion section (e.g. do the data support the results?).
	Adequate explanation of confounding factors (e.g. patient condition, age, case mix).
	Adequate explanation of the possible study weaknesses and limitations.

Table 4: Summary of studies included in the review

Study	Country	Setting/specialty	Focus	Data year	Data source (Prospective or retrospective)	Sample size	Number of AEs/ incidents	Number of preventable AEs (%)
Leape 1991 (18)	USA	51 hospitals	AE	1984	CNR (R)	30,121 admissions	1133	657 (58)
Wilson 1999 (19)	Australia	28 hospitals	AE	1992	CNR (R)	14,000 admissions	2353	1201 (51)
Neale 2001(20)	UK	2 THs	AE	1999-2000	CNR (R)	1,000 admissions	119	57 (48)
Davis 2003 (21)	New Zealand	13 hospitals	AE	1998	CNR (R)	6,579 admissions	850	513 (60)
Thomas 2000 (15)	USA	28 hospitals	AE	1992	CNR (R)	15,000 admissions	587	170 (29)
Baldwin 1998 (22)	UK	Acute hospitals	Mistake	1993-1996	Questionnaire (R)	142 doctors	-	-
Gawande 2003a (23)	USA	Surgery (3 TH)	Errors	2000-2001	Interview & reporting (R)	38 doctors	-	146
JCAHO 2001 (24)	USA	Surgery units	Wrong site surgery	Before 2001	National reporting (R)	-	-	126
Gawande 2003b(25)	USA	Surgery (insurer)	Retained foreign body	1985-2001	Claims notes (R)	-	-	61
Bates 1993 (26)	USA	1 hospital (tertiary)	ADE	-	CNR & reporting (P)	2,967 patient days	73	15 (21)
Cohen 1998 (27)	USA	200 hospitals	Medication error	1994-1995	Questionnaire (R)	156 clinicians	951	-
Bond 2001 (28)	USA	1116 hospitals	Medication error	1992	National reporting (R)	1116 hospitals	430,586	17,338 (4)
Cooper 1984 (29)	USA	4 units of anaesthesia	Incident	Before 1984	Interview (R)	139 interviews	1089	70 (6)
Arbous 2001 (30)	Nether-ands	anaesthesia units	Preventable death	1995-1997	Reporting (P)	869,483 patients	811	119 (15)
Hart 1994 (31)	Australia	1 ICU unit	Incident	1991-1993	Reporting (P)	2153 patients	390	- (106 harms)
Buckley 1997 (32)	Hong Kong	1 ICU (TH)	Incident	-	Reporting (P)	3300 patients	281	- (39 harms)
Darchy 1999 (33)	France	1 ICU (TH)	Iatrogenic disease	1994	CNR (R)	623 patients	68	35 (51)
Bracco 2001 (34)	Switzer-land	1 ICU unit	Incident	1995-1996	Reporting & observation (P)	1024 patients	777	- (241 errors)
Cohen 2002 (35)	UK	Transfusion (199 units)	Error	1996-2001	Reporting (R)	-	699	77 (11)
Murphy 1989 (36)	UK	Transfusion (1 TH)	Cross-match error	1986-1987	Reporting (R)	-	-	5
Honig 1980 (37)	USA	Transfusion (national)	Preventable death	1976-1978	Mandatory reporting (R)	-	70	37 (53)
Sazama 1990 (38)	USA	Transfusion (national)	Preventable death	1976-1985	Mandatory reporting (R)	-	355	256 (72)
Davis 1992 (39)	USA	6 trauma centres	Error	1985-1989	CNR, interview (P)	22,577 patients	-	1,032
Cayten 1991 (40)	USA	8 trauma centres	Preventable death	1987-1989	CNR and autopsy notes (R & P)	13,500 patients	421	50 (12)
Wu 1991 (41)	USA	Internal med (1 TH)	Mistake	1989	Questionnaire (R)	254doctors	114	87 (76)
Bedell 1991 (42)	USA	1 card. unit (TH)	Iatrogenic card. arrest	1981	CNR (R)	203 Patients	28	18 (64)
Ennis 1990 (43)	UK	Obstetrics (insurer)	Serious accident	1982-1989	Claims notes (R)	-	64	-

ADE=adverse drug event , AE= adverse event, CNR= case note review, P=prospective, R=retrospective, TH=teaching hospital

Table 5: Number and percentage of AEs and preventable AEs by types in acute hospitals

Study	**Leape et al 1991 (18)**			**Wilson et al 1995 (2)**			**Vincent et al 2001a (3)**			**Davis et al 2003 (21)**	
Specialties	All SPs except MH			All SPs except MH			GS, OR, GM, OB			All SPs except MH	
Threshold for causation	Likelihood of >50%			Any evidence			Likelihood of >50%			Any evidence	
Threshold for preventability	Likelihood of >50%			Likelihood of >50%			Likelihood of >50%			Likelihood of >50%	
Type of AE	**AE N (%)**	**PAE N (%)**	**% of PAEs**	**AE N (%)**	**PAE N (%)**	**% of PAEs**	**AE N (%)**	**PAE N (%)**	**% of PAEs**	**AE N (%)**	PAE N (%)
Diagnostic	79 (7)	59 (19)	75	314 (13)	254 (21)	81	5 (4)	5 (9)	100	85 (8)	50 (14)
Operative	599(53)	101(32)	17	1159 (49)	509 (42)	44	49 (42)	11 (20)	22.4	258 (24)	99 (29)
Procedural	88 (8)	13 (4)	15	197 (8)	78 (6)	40	5 (4)	4 (8)	80	82 (8)	34 (10)
Therapeutic	62 (6)	47 (15)	77	276 (12)	200 (16)	72	30 (25)	15 (28)	50	89 (8)	49 (15)
Drug related	178(16)	31 (10)	18	249 (11)	107 (9)	43	17 (14)	9 (17)	53	130 (12)	33 (10)
System failure	29 (3)	10 (3)	36	355 (15)	277 (23)	78	-	-	-	254 (24)	157 (47)
Other	98 (9)	51 (16)	52	-	-	-	12 (10)	10 (19)	83	162 (15)	54 (14)
Total	**1133 (100)**	**312 (100)**	**28**	**2353 (108)**	**1200 (117)**	**51**	**119 (100)**	**57 (100)**	**48**	**850 (100)**	**339 (40)**

PAE = preventable adverse event; SPs=specialties. The categories are not all mutually exclusive and so some total % are more than 100

Table 6: Factors contributing to adverse events

Studies used record review	**Method**	**Type of AEs analysed**	**N of AEs preventable**	**% due to individual failures**	**% due to system failures**	**% due to equipment failures**
Leap 1991 (18)	CNR	All types	657	97%	3%	-
Wilson 1999 (19)	CNR	All types	1922	82%	23%*	-
Davis 2003 (21)	CNR	All types	339	93%	47%*	-
Studies used reporting system	Method	Type of AEs analysed	N of AEs preventable	% due to individual failures	% due to system failures	% due to equipment failures
Gawande 2003a (23)	Interview, reporting	Surgical errors	146	86%	83%*	5%
Arbous 2001 (30)	Reporting	Anaesthesia related deaths	119	75%	60%*	0
Sazama 1990 (38)	Reporting	Transfusion deaths	256	100%	In many instances	-
JCAHO 2001 (24)	Reporting	Wrong site surgery	126	-	The majority	-

* The sum of individual and system based errors may be >100% because some adverse events are associated with both types of errors.

Table 7: Distribution of individual and system errors

Studies used case note review	**Leape 1991 (18)**	**Wilson 1999 (19)**
Method	Case note review	Case note review
Type of adverse event	Any type	Any type
Type of errors contributing to AE*	No (%)	No (%)
Total individual errors	1223 (94)	2655 (89)
Technical	559 (43)	1017 (34)
Synthesise, decide or act on information	163 (13)	465 (16)
Failure to request or arrange investigation/ procedure	223 (17)	346 (12)
Lack of care or attention or failure to attend	-	320 (11)
Failure to apply a rule or use of a bad/inadequate rule	-	258 (9)
Practicing outside area of expertise	115 (9)	30 (1)
Violation of policy or protocol	-	140 (5)
Slips or lapses	-	46 (2)
Lack of knowledge	-	33 (1)
Failure of judgement	-	-
Failure of memory	-	-
Failure of vigilance	-	-
Total system failure	82 (6)	332 (11)
Inadequate training, experience or supervision	15 (1.1)	44 (1.5)
Inadequate reporting or communication	11 (0.8)	62 (2.0)
Inadequate or delayed scheduling	10 (0.8)	-
Inadequate monitoring systems	8 (0.7)	-
Fatigue or workload	-	-
Inadequate resource, equipment or staff	13 (1.0)	8 (0.3)
Inadequate function of services	7 (0.6)	16 (0.5)
Defective equipment	8 (0.7)	5 (0.2)
Absence of or failure to use policy, protocol or plan	-	188 (6.3)
Inadequate care	-	-
Organisational factors	-	-
Other	10 (0.8)	9 (0.3)
Total number of errors	1305 (100)	2987 (100)
Studies used reporting system	**Gawande 2003a (23)**	**Arbus 2001 (30)**
Method	Interview reporting	Reporting
Type of adverse event	Surgical	Anaesthesia
Type of errors contributing to AE*	No (%)	No (%)
Total individual errors	169 (40)	334 (77)
Technical	-	-
Synthesise, decide or act on information	-	-
Failure to request or arrange investigation/ procedure	-	-
Lack of care or attention or failure to attend	-	-
Failure to apply a rule or use of a bad/inadequate rule	-	-
Practicing outside area of expertise	-	-
Violation of policy or protocol	-	-
Slips or lapses	-	-
Lack of knowledge	-	-
Failure of judgement	92 (22)	-
Failure of memory	5 (1)	-
Failure of vigilance	72 (17)	-
Total system failure	252 (60)	329 (50)
Inadequate training, experience or supervision	104 (25)	126 (19)
Inadequate reporting or communication	62 (15)	33 (5)
Inadequate or delayed scheduling	-	-
Inadequate monitoring systems	-	-
Fatigue or workload	21 (5)	-
Inadequate resource, equipment or staff	30 (7)	-
Inadequate function of services	-	-
Defective equipment	22 (5)	0 (0)
Absence of or failure to use policy, protocol or plan	2 (0.4)	-
Inadequate care	-	80 (12)
Organisational factors	-	90 (14)
Other	-	11 (3)
Total number of errors	**421 (100)**	**663 (100)**

*AEs may have more than one error, so the number of errors may be more than in Table 3.

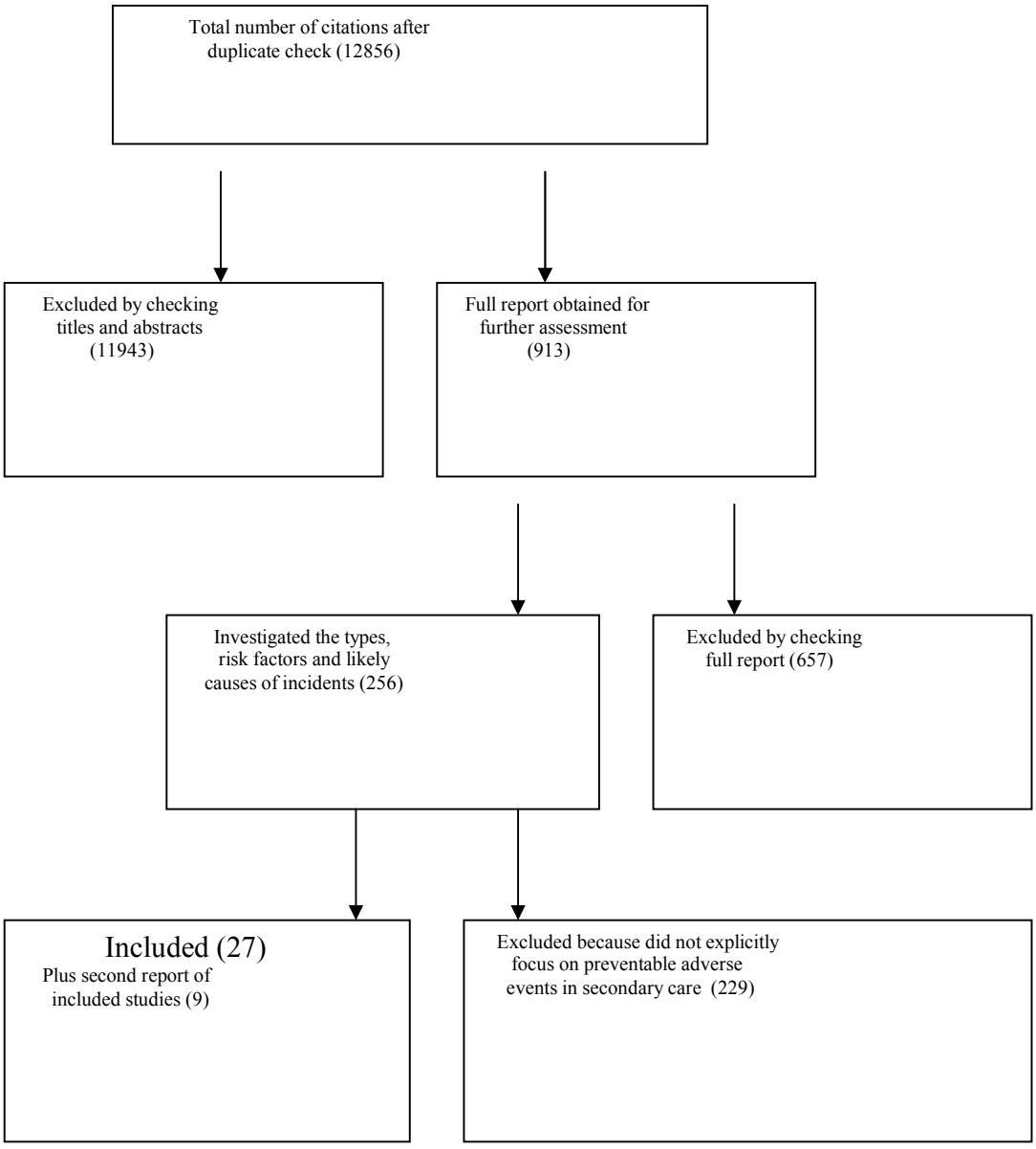

Fig. 1: Number of studies excluded in each stage

Discussion

This review found that operative adverse events were more common but less preventable than other types of adverse events. On the other hand, diagnostic adverse events were less common but more preventable than other types of adverse events. Preventable adverse events are often associated with more than one contributory factor, with the majority associated with individual error and a significant proportion with system failure. While technical errors and cognitive failures were the most common types of error, lack of experience, inadequate supervision of junior staff and problems in communications were the most common types of system error.

Operative adverse events were the most common type of preventable adverse events probably because the majority of admissions in the sampling frame were in surgical wards and subsequently the majority of study samples were se-

lected from these wards (1-3, 21). Although technical error may be the most common cause of preventable operative adverse events, this may not be the most common type of other (such as diagnostic or therapeutic) preventable adverse events. There were no explicit data on the type of individual error for each group of adverse events.

The wide variation in the proportion of system failure reported reflects two factors. Firstly, the majority of preventable adverse events, which were associated with a system failure, were also associated with other factors including individual human error. Even in studies in which a large proportion of adverse events were associated with a system failure, only a small number reported system failure as the main or the sole cause of adverse event (16, 30). Studies which reported a small proportion of adverse events due to a system failure, only noted system failure when it was the main or the sole rather than a contributory cause of adverse events (16, 18, 20, 23, 30).

Secondly, the reported proportion of system failures was strongly related to the methods used. Studies which used case note review to identify and analyze adverse events reported a significantly lower proportion of system failures than studies which used interview, questionnaire or reporting system data (18-20, 23, 24, 30). This is probably because the retrospective case note review often focuses more on the actions of clinicians in the frontline, and less on the actions of other staff or systems with a more supportive role (19). Therefore, some potentially important contextual events might not be recorded in the case notes (19). Hence, retrospective case note review may not provide sufficient information to uncover the underlying causes of adverse events, such as system failures (19).

On the other hand, data collected by the reporting system, interview, or questionnaire may be biased toward the role of system failure and focus less on the role of the individual error (45, 46). Clinicians may report adverse events in a way that shifts the responsibility from the individual and toward system factors. Case note review, therefore, may overestimate the role of individual human factors and underestimate the role of system factors, while reporting systems and interviews or questionnaire-based studies probably do the reverse (13, 47).

Limitations of the included studies

The majority of included studies were conducted in a single specialty in one or a few hospitals. The patient case mix, the type of practice and subsequently the causative pattern of adverse events in these specialties might differ from other specialties, so the results of these studies are not necessarily general sable to the routine practice in secondary care. The majorities of included studies were also small and analyzed a small number of preventable adverse events, probably with too little statistical power to detect significant associations between the categories of preventable adverse events and other factors.

Ten of the 12 included studies, which used case note review or review of litigation notes, were retrospective. This method is dependent on the adequacy of case notes and perception of people who reviewed them (1, 2).

Retrospective case note review may provide inadequate information for uncovering the underlying causes of adverse events (19). The standard of care that forms the basis for any judgment of error is rarely well defined and is open to interpretation (2). The majority of the included studies did not check the inter-rater reliability of clinician's judgement on the preventability of adverse events, but those which did, reported only a moderate or poor reliability (2, 20).

Twelve of the 27 included studies used reporting system data for identifying and analysing adverse events. Studies which used reporting data analysed a range of 5 (36) to 430,000 adverse events (28). The results of these studies might be biased by the significant under-reporting, selective reporting (e.g. of more minor incidents) (47) and incomplete or incorrect reporting (23, 28, 47, 48). The level of under-reporting may be larger when the reporting system operates voluntarily, as it was in all but two (37, 38) of the included studies

which used reporting data. Overall, reporting system data seem to be less reliable than data recorded from case notes.

Six of the 27 included studies used questionnaire or interview, and five of these were retrospective increasing the possibility of recall bias (23, 49, 50). Webb and Davies (51) found that unusual, interesting, and particularly dangerous adverse events are more likely to be reported than minor ones. Minor errors, errors of omission and errors that occurred well before the date of the report are less easily remembered (23). In addition, the information on factors that clinicians think contributed to the adverse events may differ because of inaccurate clinician recall (23). Adverse events detected by reporting systems, interview or questionnaire might be influenced by the perception or characteristics (e.g. personality) of the people who make the report (23).

Two studies used review of claims reported to a malpractice insurance company (25, 43), but since few adverse events result in a claim these studies considered a small number of probably unrepresentative adverse events. Ennis et al found that normally only very serious adverse events were reported to the malpractice insurance companies (43).

The majority of adverse events identified by reporting systems are reported by nurses (50), while most of the adverse events identified by questionnaires or interviews are reported by doctors, as all these studies were carried out among doctors who in many cases were specialists (22, 23, 27, 29, 32, 41). The type of adverse event reported by a doctor might differ from those reported by a nurse. For example, doctors tend to report more serious adverse events (26, 50, 51) and adverse events which are highly preventable (14, 52). Hence, the severity and causative nature of adverse events, which are reported by the interview or questionnaire, may differ from those, which are recorded by reporting systems; and all of these may differ from those identified by record review. Therefore, it is possible that different methods or even similar methods of different quality will produce different patterns. To minimise bias, we considered the results with regard to method and possible reasons for variations in the findings were discussed.

Limitations of the review

Search techniques for identifying non-experimental studies are still developing (8). A broad search approach was used to maximise the number of potentially relevant studies identified, though relevant studies may have been missed. It is also possible that studies with specific designs or findings, for example, studies with interesting, unusual or particular results have been more likely (or possibly less likely) to be published in academic journals. The broad search, which included hand searching of grey literature and contacting relevant individuals and organizations, should have reduced the risk of publication bias.

There was a great deal of heterogeneity in the studies included in this systematic review, so that quantitative meta-analysis was unsuitable. To explore potential heterogeneity resulting from study designs, summary results were presented separately for each specialty and for each method (53). The consistency, or lack thereof, in the results of different types of studies was discussed, as were possible reasons for heterogeneity (54). Studies were not excluded based on their quality, but the quality of included studies was assessed and referred to, in particular when there was significant heterogeneity in the findings.

Gaps in research

This review has shown that a wide range of methods has been used to identify and analyse adverse events, each with some important limitations. The majority of included studies gave an inadequate description of the methods. They used different criteria and measurement tools to identify and analyse adverse events and even the same criteria were applied in different ways. This made comparison between the studies very difficult. We recommend that future research focus on the development and testing of an optimal cost-effective set of standard methods to identify and analyse different types of adverse events and monitor the impact of safety improvement programmes.

Until a more accurate and standard method or combination of methods is developed, it is very important that studies provide sufficient detail about the concepts underlying the terms used and about the way the data have been collected and analysed. In particular, a clear description should be given as to the definition and assessment of the preventability and causation link. This information will improve the accuracy of the comparisons across the studies.

This review showed that the majority of studies in this area have lumped together and analysed adverse events of various types of any severity, regardless of their preventability and ultimate outcomes; ignoring the fact that adverse events of various types and severity might have a different pattern of causes, so future studies should analyse adverse events with regard to their preventability, severity and ultimate outcomes.

In conclusion, although several reviews have examined the types, risk factors and likely causes of adverse events, their potential preventability, and ultimate outcomes have, for the most part, been ignored. This is the first comprehensive review to systematically document and analyse preventable adverse events in secondary care. It provides evidence that operative adverse events are more common but less preventable and diagnostic adverse events less common but more preventable than other adverse events. Preventable adverse events were often associated with more than one contributory factor. The majority were linked to individual human error, and a proportion of these with system failure. This review makes a significant contribution to our understanding of methods of detecting and analysing adverse events particularly in the hospital sector. Improvement programmes should focus more on preventing operative and diagnostic adverse events and on common individual and system errors such as technical errors, supervision of junior staff and communication between all parties in secondary care.

Ethical Considerations

Ethical issues (Including plagiarism, Informed Consent, misconduct, data fabrication and/or falsification, double publication and/or submission, redundancy, etc) have been completely observed by the authors.

Acknowledgements

The authors declare that they have no conflict of interests.

References

1. Brennan T, Leape L, Laird N, Hebert L, Localio A, Lawthers A (1991). Incidence of adverse event and negligence in hospitalized patients Results of the Harvard Medical Practice Study I. *N England J Med*, 324(6): 370-76.
2. Wilson R, Runciman W, Gibberd R, Harrison B, Newby L, Hamilton J (1995). The Quality in Australian Health Care Study. *Med J Aust*, 163: 458-71.
3. Vincent C, Neale G, Woloshynowych M (2001). Adverse events in British hospitals: preliminary retrospective record review. *BMJ*, 322 (7285): 517-19.
4. Sari A, Sheldon T, Cracknell A, Trunbull A (2007). The extent, nature and consequences of adverse events: results of a retrospective case note review in a large NHS hospital. *Qual Saf Health Care*, 16: 434-39.
5. Sari A, Sheldon T, Cracknell A, Trunbull A (2008). Incidence preventability and consequences of adverse events in older people: results of a retrospective case note review. *Jour Age Ageing*, 37: 1-5.
6. Kohn L, Corrigan J, Donaldson M (1999). *To err is human: Building a safer Health system*. National Academy Press, Washington DC.
7. Department of Health (2001). Building a safer NHS for patients. Implementing an organization with a memory. Department of Health, London: The Stationery Office, UK.
8. CRD (2001). *Undertaking Systematic Reviews of Research on Effectiveness*. Centre for Review and Dissemination, UK. Available from: www.york.ac.uk/inst/crd/report4.htm

9. Westwood M, Rodgers M, Sowden A (2001). Patient Safety: A Mapping of the Research Literature. CRD, York, UK. Available from: www.york.ac.uk/inst/crd

10. AHRQ (2001). *Making Healthcare Safer*: A Critical Analysis of Patient Safety Practices. Agency for Healthcare Research and Quality, University of California at San Francisco, Stanford University Evidence-based Practice Center, USA. Available from: www.vipcs.org/resources.htm
11. Woloshynowych M, Rogers S, Taylor-Adams, CV (2005). *The investigation and analysis of critical incidents and adverse events in healthcare*. Health Technology Assessment, 19.
12. Vries Ed, Ramrattan M, Smorenburg S, Gouma D, Boermeester M (2008). The incidence and nature of in-hospital adverse events: a systematic review. *Qual Saf Health Care*, 17:216-23.
13. Sari AB (2006). Study of the scale, nature and causes of adverse events and methods to identify them [PhD thesis]. University of York, UK.
14. O'Neil A, Petersen L, Cook E, Bates D, Lee T, Brennan T (1993). Physician reporting compared with medical-record review to identify adverse medical events. *Ann Intern Med*, 119: 370–76.
15. Thomas E, Orav E, Brennan T (2000). Hospital ownership and preventable adverse events. *Jour Gen Int Med*. 15(4): 211-19.
16. Davis P, Lay Y, R, Briant R, Ali W, Scott A, Schug S (2002). Adverse events in New Zealand public hospitals I: occurrence and impact. *New Zeal Med Jour*, 115(1167): U271.
17. Baker G, Norton P, Flintoft V, Blais R, Brown A, Cox J, et al. (2004). The Canadian Adverse Events Study: the incidence of adverse events among hospital patients in Canada. *CMAJ,* 170(11): 1678-86.
18. Leape L, Brenan T, Laird N, Hebert L, Localio A, Lawthers A (1991). The nature of adverse events in hospitalised patients. *N Engl J Med*, 324: 370-76.
19. Wilson R, Harrison B, Gibberd R, Hamilton J (1999). An analysis of the causes of adverse events from the Quality in Australian Health Care Study. *MJA*, 170: 411-15.
20. Neale G, Woloshynowych M, Vincent C (2001). Exploring the causes of adverse events in NHS hospital practice. *Jour Roy Soc Med*, 94 (7): 322-30.
21. Davis P, LayYee R, Briant R, Ali W, Scott A, Schug S (2003). Adverse events in New Zealand public hospitals II: preventability and clinical context. *New Zeal Med Jour*, 116 (1183): U624.
22. Baldwin P, Dodd M, Wrate R (1998). Junior doctors making mistakes. *Lancet*, 351(9105): 804.
23. Gawande A, Zinner M, Studdert D, Brennan T (2003). Analysis of errors reported by surgeons at three teaching hospitals. *Surgery,* 133(6): 614-21.
24. JCAHO (2001). A follow-up review of wrong site surgery. *Sent Eve Al*, 24: 1-3.
25. Gawande A, Studdert D, Orav E, Brennan T, Zinner M (2003). Risk factors for retained instruments and sponges after surgery. *New Zeal Med Jour*, 348 (3): 229-35.
26. Bates D, Leap L, Petrycki S (1993). Incidence and preventability of adverse drug events in hospitalized adults. *Jour Gen Int Med*, 8 289-94.
27. Cohen M, Proulx S, Crawford S (1998). Survey of hospital systems and common serious medication errors. *Jour Health Risk Man*, 18(1): 16-27.
28. Bond C, Raehl C, Franke T (2001). Medication errors in United States hospitals. *Pharmacotherapy,* 21(9): 1023-36.
29. Cooper J, Newbower R, Kitz R (1984). An analysis of major errors and equipment failures in anesthesia management: Considerations for prevention and detection. *Anesthesiology*, 60(1): 34-42.
30. Arbous M, Grobbee D, van K, JW, de L, JJ, Spoormans H, Touw P, Werner F, Meursing A (2001). Mortality associated with anaesthesia: a qualitative analysis to identify risk factors.

Anaesthesia, 56(12): 1141-53.
31. Hart G, Baldwin I, Gutteridge G, Ford J (1994). Adverse incident reporting in intensive care. *An Int Care,* 22(5): 556-61.
32. Buckley T, Short T, Rowbottom Y, Oh T (1997). Critical incident reporting in the intensive care unit. *Anaesthesia*, 52(5): 403-9.
33. Darchy B, Le M, E, Figueredo B, Bavoux E, Domart Y (1999). Iatrogenic diseases as a reason for admission to the intensive care unit: incidence, causes, and consequences. *Arch Int Med*, 159(1): 71-8.
34. Bracco D, Favre J, Bissonnette B, Wasserfallen J, Revelly J, Ravussin P, Chiolero R (2001). Human errors in a multidisciplinary intensive care unit: a 1-year prospective study. *Int Care Med*, 27(1): 137-45.
35. Cohen H, Love E, Todd A, Jones H, Soldan K, Williamson L (2002). Adverse incidents in blood transfusion: Serious hazards of transfusion (SHOT). *Clinical Risk,* 8(4): 155-8.
36. Murphy W, McClelland D (1989). Deceptively low morbidity from failure to practice safe blood transfusion: an analysis of serious blood transfusion errors. *Vox Sanguinis*, 57(1): 59-62.
37. Honig C, Bove J (1980). Transfusion-associated fatalities: review of Bureau of Biologics reports 1976-1978. *Transfusion,* 20(6): 653-61.
38. Sazama K (1990). Reports of 355 transfusion-associated deaths: 1976 through 1985. *Transfusion*, 30(7): 583-90.
39. Davis J, Hoyt D, McArdle M, Mackersie R, Eastman A, Virgilio R, Cooper G, Hammill F, Lynch F (1992). An analysis of errors causing morbidity and mortality in a trauma system: A guide for quality improvement. *Jour Trau Inj Inf Crit Care*, 32(5): 660-66.
40. Cayten C, Stahl W, Agarwal N, Murphy J (1991). Analyses of preventable deaths by mechanism of injury among 13, 500 trauma admissions. *Ann Sur*, 214(4): 510-21.
41. Wu AW, Folkman S, McPhee S, Lo B (1991). Do House Officers Learn From Their Mistakes? *JAMA,* 256(16): 2089-95.
42. Bedell S, Deitz D, Leeman D, Delbanco T (1991). Incidence and Characteristics of Preventable Iatrogenic Cardiac Arrests. *JAMA,* 21:2815-20.
43. Ennis M, Vincent C (1990). Obstetric accidents: a review of 64 cases. *BMJ*, 300(6736): 1365-7.
44. Cooper JB, Newbower RS, Long CD, McPeek B (2002). Preventable anesthesia mishaps: a study of human factors. *Qual Saf Heal Care*, 277-82.
45. Cooper J, Newbower R, Long C, McPeek B (1978). Preventable anesthesia mishaps: a study of human factors. *Anesthesiology*, 49(6): 399-406.
46. Office NA (2005). *A safer place for patients: Learning to improve patient safety*. National Audit Office, London: The Stationery Office, UK.
47. Sari A, Sheldon T, Cracknell A, Trunbull A (2007). The sensitivity of the routine system for reporting patient safety incidents in an NHS hospital- a retrospective patient case note review. *BMJ*, 334:79-82.
48. Brown C, Patil P, Hofer T, Johal A, Thomson R, Lilford RJ, Nicholl J, Dean BF (2006). *An epistemology of patient safety research*: A framework for study design and interpretation. Patient Safety Research Programme for MRC UK, Dept of Public Health and Epidemiology; The University of Birmingham, UK.
49. Walsh T, Beatty (2002). Human factors error and patient monitoring. *Phy Measur*, 23(3): R111-32.
50. Kingston M, Evans S, Smith B, Berry J (2004). Attitudes of doctors and nurses towards incident reporting: a qualitative analysis. *Med J Aust*, 181(1): 27-8.
51. Webb R, Davies J (1993). Adverse events in anaesthesia: The role of equipment. *Can J An,* 40(10): 911-4.

52. Von Laue N, Schwappach D, Koeck C (2003). The epidemiology of medical errors: a review of the literature. *Wien Klin Woch,* 115(10): 318-25.
53. Egger M, Schneider M, Smith GD (1998). Meta-analysis Spurious precision? Meta-analysis of observational studies. *BMJ*, 316 (7125): 140-44.
54. Glasziou P, Sanders S (2002). Investigating causes of heterogeneity in systematic reviews. *Statis Med*, 21 (11): 1503-11.