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HTA Initiative #17 ● August 2005

Institutional Medical Incident Reporting Systems: A Review

Anita Simon, Robert C. Lee, David L. Cooke, Diane Lorenzetti

25 YEARS OF EXCELLENCE

AHFMR

ALBERTA HERITAGE FOUNDATION FOR MEDICAL RESEARCH

HTA Initiative #17
Institutional Medical Incident Tracking System: A Review

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David L. Cooke, Diane Lorenzetti

Acknowledgements

The Alberta Heritage Foundation for Medical Research is most grateful to the following persons for review and provision of information and comments on the draft report. The views expressed in the final report are those of the authors:

Professor Sir John Lilleyman
National Health Service, London, UK

Dr. Richard Thomson
National Health Service, London, UK

ISBN 1-894927-20-6 (Print)
ISBN 1-894927-21-4 (On-Line)

ISSN: 1706-7855

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Alberta's health technology assessment program has been established under the Health Research Collaboration Agreement between the Alberta Heritage Foundation for Medical Research and Alberta Health and Wellness.

EXECUTIVE SUMMARY

Preventable medical incidents leading to death in hospitals exceed deaths from firearms, motor-vehicle accidents, breast cancer, and acquired immunodeficiency syndrome in the United States, and a similar situation is likely to exist in Canada. Such preventable medical incidents have been estimated to cost between $17 and $29 billion per year in the United States and exact a severe financial burden on all jurisdictions. The term "preventable" is used here in the context of medical incidents and should be interpreted cautiously. It has been used in the medical literature to distinguish such incidents from those that are deemed in retrospect to have been the unavoidable consequences of health care—unanticipated allergic drug reactions, for example.

Incident reporting is one method for preventing adverse events and promoting patient safety through the identification of problems/events that resulted or could have resulted in patient harm. Other methods of incident tracking include reviewing charts or interviewing staff to discover incidents that have occurred but not been reported. Subsequent collection and analysis of the incidents, including their severity, type, frequency, and probable cause, are intended to provide organizations with the necessary information to implement interventions that will limit future recurrence of such events.

A systematic review was conducted to assess the effectiveness of hospital incident reporting systems in improving hospital and clinic performance in terms of patient safety, clinical outcomes, costs, and operations. Specific recommendations were also developed on how to increase the potential value of implemented incident reporting systems in Alberta, Canada, and other publicly funded health care systems.

Major bibliographic databases, including MEDLINE, EMBASE, PsycINFO, and the Cochrane Library; grey literature databases; and the Web sites of major health technology assessment agencies, were searched to identify studies suitable for inclusion in this review. From a screening of 1363 abstracts, 361 studies were selected for full text review. Reference lists of these papers were scanned to identify additional studies. A total of 72 references were deemed relevant, of which 11 were used for the assessment of the effectiveness of incident reporting systems.

The following conclusions and recommendations result from this analysis:

1. Incident reporting can provide valuable qualitative and quantitative data relevant to incidents and adverse events, which in turn can potentially guide organizational and clinical interventions to decrease risks.
2. Despite more than 20 years of research in incident tracking and many countries implementing nationwide reporting systems, studies evaluating the reporting system's effectiveness are limited in number and tend to be qualitative and poorly controlled. This limits the evidence from which conclusions can be drawn.

3. The benefits of incident reporting in a health care environment are not well established. Although the quality improvement model on which incident reporting is founded is logical and has been proven effective in aviation and other non-medical industries, there is only limited scientific evidence of its benefits and effectiveness in a hospital setting.
4. The incident reporting systems reviewed in the literature appear to place more emphasis on reporting than on risk analysis and control. There is clearly a need for a more effective system that not only reports incidents, but also motivates organizational learning and process improvement.
5. The nature of incident reporting, which is subject to hindsight bias, lost information, and contextual clues because of recall, makes it unlikely that robust data will link it directly with improved outcomes unless carefully designed.
6. Incident reporting systems should include near misses; be non-punitive, confidential, or anonymous; involve multidisciplinary teams to investigate and improve care; focus on identifying aspects of the system that contribute to errors rather than blaming individuals; and provide feedback to all interested and involved parties.
7. Studies evaluating the effectiveness, cost, and reliability of incident reporting systems are very limited in number. The studies suggest that incident reporting systems provide a fairly inexpensive although incomplete means for monitoring patient safety and, when combined with systemic interventions, may be effective in reducing preventable incidents.
8. Any use of incident reporting should include pre- and post-test measures of medical error to better determine its effectiveness in enhancing patient care. Confounding factors should be controlled through study design, standardization, and appropriate outcome measures.
9. The use of incident reporting needs to be considered in the context of other standard approaches to promote and implement patient safety practices.
10. Alternative models for risk identification, including process mapping, direct observation, and medical record review, should be compared with incident reporting systems and combined with them to determine the most effective suite of tracking method(s) for monitoring adverse events, incidents, and near misses.
11. To successfully manage and minimize medical risk in institutions, a three-phase approach is required: risk identification, risk analysis, and risk control.
12. Patient safety research must be better designed to incorporate economic approaches, such as cost-benefit analysis, to show where hospitals resources can best be allocated.

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INTRODUCTION

With the exception of anaesthesia mortality, exposure to the health care system is associated with more fatal incidents than the mortality attributable to firearms, motor vehicles, breast cancer, acquired immunodeficiency syndrome, and other hazardous exposures.[1] The Institute of Medicine (IOM) defines an "adverse event" as an event that results in unintended harm to the patient by an act of commission or omission rather than by the underlying disease or condition of the patient.[2] In this report we shall use the general term "incident" to mean any event or condition that causes or has the potential to cause harm. Thus, incidents include adverse events and also include near misses that could have been adverse events were it not for chance. Similarly, an adverse event could result from several incidents that, in isolation, may not have been sufficient to cause harm to the patient.

It has been estimated from major studies of adverse events in US hospitals that 0.2% to 2.0% of hospitalized patients experience a major permanent injury or death as a result of their medical care, not their underlying illnesses.[1] In the Medical Practise Study (MPS), Brennan and colleagues reviewed 30,000 records of patients in acute-care hospitals in New York State in 1984.[3] The investigators found that 3.7% of patients were injured as a result of medical care, rather than as a consequence of the natural history of their disease, and that 13.6% of these adverse events resulted in the patient's death.[4] The Quality in Australian Health Care Study (QAHCS) studied 14,000 admissions from 28 hospitals in New South Wales and South Australia in 1992 and replicated the MPS. In the QAHCS, researchers found that nearly 17% of admitted patients experienced an adverse event and that 51% of these events were preventable.[5] In the MPS and QAHCS studies, the morbidity associated with the adverse events was substantial: 8% of patients were permanently injured and 6.6% died. Thomas and colleagues [6] recently completed another replication of the MPS in which they examined 15,000 records of patients hospitalized in Utah and Colorado in 1992. In this study, 2.9% patients were reported to experience an adverse event, of which 27% to 33% were due to negligent care. Of the adverse events identified in the Utah and Colorado study, 45% resulted from operative procedures and 19% from drug-related incidents.

In a comprehensive review conducted by the IOM, the number of preventable deaths was extrapolated from the rate of deaths from adverse events in the MPS and Colorado–Utah study to the hospitalized patient population in the United States. This report, *To Err Is Human*, estimated that 44,000 to 98,000 deaths occur each year as a result of medical incidents in the United States.[2] If these estimates are accurate, then medical incidents rank as the eighth leading cause of death in the United States.[7]

The IOM report also estimated that preventable health care-related injuries cost from $17 to $29 billion annually, and that half of these costs are direct health care costs in the United States.[2] Medication errors alone were reported to increase in-patient health care

costs by an estimated $4700 per hospital admission, or approximately $2.8 million annually for a 700-bed hospital in the United States.[8, 9] The economic burden of drug-related morbidity and mortality alone is estimated to exceed $100 billion annually in the United States; a major component of these costs is from adverse drug events (ADEs).[10] In Britain, the National Health Service (NHS) report estimated that adverse events total more than £850,000 a year and cost the NHS at least £2 billion a year in additional hospital stays.[10]

Since the publication of the IOM report, adverse events and patient safety have become major concerns of the general public and federal agencies. The growing number of studies and the heightened attention to patient safety has resulted in major policy initiatives in the United States, Australia, and the United Kingdom. Recently, the Canadian Institute for Health Information and the Canadian Institutes of Health Research sponsored a study on adverse events in Canada. A report by Baker and colleagues indicates that the incidence of adverse events in Canada is comparable to that of other countries and estimated to be 7.5%, of which 36.9% are considered preventable. This translates to an estimated annual occurrence of 185,000 adverse events per 2.5 million hospital admissions in Canada, of which close to 70,000 are preventable.[11] There is, accordingly, an urgent need to provide insight into the nature of medical incidents and to develop mechanisms by which these incidents can be reduced systematically on a large scale.

Data on the occurrence, frequency, types, causes, and clinical outcomes of medical incidents are crucial for understanding and ultimately preventing them. The studies of adverse events discussed previously involved *active surveillance* for errors, with comprehensive chart reviews or direct observation by researchers. The cost and labour consumed by these approaches make them impractical outside of the research setting. Furthermore, chart review only detects what has been documented and often does not capture information regarding causes, according to Shojania and colleagues.[7] In addition, chart review does not detect "near misses" or "no harm events", rendering a full picture of incidents impossible. Consequently, over the last few years, health care has turned to incident reporting as an alternative approach for detecting and preventing adverse patient events.[7,12]

Incident reporting represents one of various tracking systems and techniques for collecting data on medical incidents. Other methods for tracking incidents include confidential enquiries, medical audits, retrospective chart review, and litigation databases, to name a few. The major difference between incident reporting and other tracking methods is that incident reporting relies on the acquisition of real-time data from health providers directly involved with the incident.

The goal of incident reporting is to collect qualitative data from front-line health providers regarding deviations from normal practice or undesired clinical outcomes and to provide quantitative "accounting" of such events. Incident reporting systems

may be voluntary or mandatory, include adverse events or near misses, be limited to specific events such as transfusion reactions, or be more comprehensive in nature.

This paper focuses on incident reporting systems relevant to the hospital and efforts to improve patient safety and clinical outcomes. Costs associated with incident reporting systems are included wherever possible. This paper aims to assess the effectiveness of hospital incident reporting systems in improving hospital and clinic performance in terms of patient safety, clinical outcomes, costs, and operations, as supported by literature published between 1994 and 2004. Only research evaluating the effectiveness of actual implemented systems, through pre- and post-implementation comparison of safety parameters, was considered. Theoretical models or planned incident reporting systems are not included in this review. The methodology used in this assessment is outlined in Appendix A.

This work aims to provide institutions such as the Tom Baker Cancer Centre, the Calgary Health Region, and the Health Quality Council of Alberta with information about whether incident reporting is a cost-effective, viable, practical means by which patient safety can be improved, and about the features of successful systems. This report is also relevant to a broader cross-section of Alberta and Canadian health care delivery communities.

DESCRIPTION OF INCIDENT REPORTING

Flanagan first described the critical incident technique in 1954 to examine military aircraft training accidents.[7] Critical incident reporting involves the identification of incidents that could have led or did lead to an undesirable outcome. The reports are provided by personnel directly involved in the process in question at the time of discovery of the event.

In a health care setting, incident reporting may target events in any or all three basic categories:

- Adverse events
- No harm events
- Near misses

An adverse event occurs when a patient suffers injury from medical care rather than from the illness[13] (see Appendix B).

An event without harm is one in which an act of omission or commission may have had the potential for harm but, through luck or robust physiology, had no ill effect on the patient[14] (see Appendix B).

A near miss is an occurrence that could have resulted in an accident, injury, or illness but did not, through chance, skilful management, or timely intervention[15] (see Appendix B).

Established incident reporting systems share the following characteristics in medical and non-medical industries[16]:

- Non-punitive
- Confidential
- Provide feedback to all involved and interested parties
- Emphasize a systems approach to incident analysis rather than a focus on individuals

Incident reporting in medicine takes many forms. Since 1975, the US Food and Drug Administration has mandated the reporting of major blood transfusion reactions that resulted in death or serious injury. Although the critical incident technique found some early applications in medicine, its current use is largely attributed to Cooper's introduction of incident reporting to anaesthesia in 1978, when retrospective interviews were conducted with anaesthesiologists about incidents that occurred while patients were under their care.[17] Recently, near-miss and adverse event reporting systems have proliferated in single-institution settings such as intensive care units (ICUs), in regional settings, and for national surveillance. An example of a national incident reporting

system is the Australian Incident Monitoring Study, under the auspices of the Australian Patient Safety Foundation, where anonymous and voluntary near-miss and adverse event reports are collected for anaesthetists in Australia. Incident reporting in hospitals has a broader focus, capturing errors and departures from expected procedures or outcomes (Table 1).

Table 1: Examples of reported events in hospital incident reporting systems*

Adverse outcomes	Procedural breakdowns	Catastrophic events
Unexpected death or disability	Errors or unexpected complications related to administration of drugs or transfusion	Performance of a procedure on wrong body part (wrong-site surgery)
In-patient falls or "mishaps"	Discharges against medical advice	Performance of procedure on wrong patient
Institutionally acquired burns	Significant delays in diagnosis or diagnostic testing	Infant abduction or discharge to wrong family
Institutionally acquired pressure sores	Breach of confidentiality	Rape of a hospitalized patient

*Source: Shojania et al.[7]

Health care incidents are commonly categorized. Categories help organizations identify how to approach a problem and where the shortcomings of performance may ultimately lie. For example, according to Silver,[18] medical incidents can be classified into one or more of the following eight categories:

1. Injury: known or unknown origin
2. Medication error: in route, dosage, time, quantity, or type
3. Missing person: resulting in a search
4. Criminal act: drug possession, assault, etc.
5. Near death: patient's life in mortal danger
6. Death: expected or unexpected
7. Abuse: inappropriate or unauthorized harm caused by another person that can be physical, psychological, sexual, or restraining in nature
8. Neglect: omission of care as defined by governing policies or guidelines

Each incident category can have many levels of seriousness.[18] For example, a medication error can result in no adverse effect or in death.

There are three levels of incident seriousness according to Silver:

- Non-serious incidents: result in no adverse effect or minor effects to the patient. Incident is not unexpected and incident is usually not reported to governing agencies.
- Serious incident: results in observable adverse effect on patient and usually must be reported to governing agencies.
- Neglect: incident in which some level of neglect is involved, suspected, or has been reported.

Table 2 shows the relationship between incident categories and level of seriousness.

Table 2: Categories of incidents and levels of seriousness*

Category	Non-serious	Serious	Neglect
Injury	Requires first aid or less	Requires medical consult, ER visit, or more†	Omission of care
Medication error	No adverse effect or minor effect	Adverse effect observed	Omission of care
Missing person	Search is initiated	Search initiated after 1 h	Omission of supervision
Near death	Expected	Unexpected	Omission of care
Death	Expected	Unexpected	Omission of care
Abuse	-	-	Negligence
Neglect	-	-	Negligence

*Source: Silver[18]

†ER indicates emergency room.

The Incident Reporting Form

In keeping with the goals of incident reporting to identify problem areas, determine their probable cause, and guide efforts to prevent recurrence, the incident form should include these three essential elements in its design. The form should enable a person who is unfamiliar with the incident to obtain a good sense of what the incident was, why it occurred, and how it could possibly be prevented in the future. For example, Silver recommends that a standard incident form include the following essential elements[18]:

- Description of individual involved: name, gender, age, full diagnosis, and medications
- Date and time the incident was observed or discovered
- Location of incident (bathroom, hallway, ICU)

- Incident category (injury, medication error, etc.)
- Level of seriousness (non-serious, serious, neglect)
- Probable cause or precipitating factors (if known)
- Persons that witnessed the incident (staff, patients, other)
- Short, detailed description of incident
- Intervention provided
- Recommended improvement action to prevent recurrence
- Notifications made (governing agencies, certifying agencies)
- Name and title of report author (optional)

Prevalence and Severity of the Patient Safety Problem

US Studies

The incidence of medical error in the United States has been examined in three large studies, all of which examined medical records retrospectively to measure the prevalence of error (Table 3). The first of these studies was undertaken by the California Medical Association and found a 4.6% incidence of "potentially compensable events" when assessing error in the context of malpractice litigation.[19] A second study, the well-known Harvard Medical Practise Study conducted by Brennan et al.[3] in 1991, analyzed over 30,000 randomly selected charts and found that adverse events occurred in 3.7% of hospitalizations. Of these adverse events, 58% were preventable and attributable to medical error. The frequency of adverse events was confirmed in a third study conducted in Utah and Colorado, where 15,000 acute care patients hospitalized in 1992 in the two states were found to experience between 27% and 33% of adverse events as a result of negligence. Surgery-related adverse events were the most common type, accounting for 45% of the total number of adverse events.[6]

Australian Study

In 1995, Ross Wilson and colleagues published the Quality in Australian Health Care Study (QAHCS) on medical error in Australia and reviewed 14,000 hospital admissions from 28 hospitals. This study reported that 16.6% of admissions were associated with an adverse event and 51% of these events were preventable[5] (Table 3). Preventability of an adverse event was retrospectively assessed in this study as "error in management due to failure to follow accepted practice at an individual or system level", whereby accepted practice was taken to be "current level of expected performance for an average practitioner or system that manages the condition in question".

United Kingdom Studies

The National Health Service (NHS) in Great Britain published a report in 2000 that indicated that at least 400 patients died or were seriously injured from events involving medical devices in 1999 and that nearly 10,000 patients experienced serious adverse reactions to drugs (not all of which were preventable).[19] Since this report, Vincent and colleagues published a pilot study of adverse events in two acute care hospitals in London, using similar methodology to the Australian and US studies (Table 3). Their study found that 10.8% of hospitalized patients experienced an adverse event during their hospital stay and that one-half of these events were preventable.[20]

Canadian Studies

Few studies have been conducted to assess medical error in Canada. A recent study in a Toronto teaching hospital reported that 39% of patients experienced one or more complications during a two-month review period, which amounted to 144 complications in 192 patients, of which 18% were believed to be due to error.[21] Hunter and Bains, in a review of hospital data collected by the Canadian Institute for Health Information, found that 3.3% to 5.0% of Ontario hospital admissions experienced complications between 1992 and 1997.[22] In a more recent study conducted by Baker and colleagues, [11] four hospitals were randomly selected from each of five provinces (British Columbia, Alberta, Ontario, Quebec, and Nova Scotia), and methods similar to the US and Australian studies were used to estimate the incidence of adverse events in Canada (Table 3). The overall incidence rate of adverse events was 7.5%, which suggests that, of almost 2.5 million annual hospital admissions in Canada, about 185,000 are associated with an adverse event, of which 70,000 are considered preventable.[11]

Together, these studies provide clear evidence that adverse events are common occurrences in health care delivery but neglect to take into account that a certain number of errors and adverse events are inevitable in complex health care operations. Although the IOM report was aptly titled *To Err Is Human*, no attempt has been made to define or assess what is an acceptable or unavoidable degree of medical incidents for health care institutions and providers.

Table 3: Studies on the incidence of adverse events and their preventability

Study	Sample	Incidence (%)	Preventability (%) or negligence	Mortality (%)
Brennan et al. 1991[3] (USA)	30,195	3.7	27.6 negligence	13.6
Thomas et al. 2000[6] (USA)	15,000	2.9	Utah 32.3 negligence Colorado 27.4 negligence	6.6
Wilson et al. 1995[5] (Australia)	14,000	16.6	13.0 preventability 51.0 negligence	4.9
Vincent et al. 2001[20] (UK)	1,014	10.8	48.0 preventability	9.0
Wanzel et al. 2000[21] (Canada)	192 (surgery)	39.0	18.0 preventability	1.0
Baker et al. 2004[11] (Canada)	3,745	7.5	36.9 preventability	20.8

Adverse Events and Causal Factors

Data from five prospective studies on adverse events and their causes provide interesting, albeit conflicting, information on areas of concern for hospital patient safety. The wide variation in reporting of incidents may have more to do with reporting incentives and local culture than with the quality of medicine practised at a given institution. These data exemplify the need to use incident reporting as an indicator of problems or progress within an organization rather than as a benchmark across institutions or as an accurate measure of patient care.

In a 1994 University of Iowa study, a research nurse identified 317 adverse events occurring among 35% of patients studied at a 900-bed Iowa City Hospital that included[23] the following:

- Medication-related errors (56%)
- New medical conditions (20%)
- Procedure complications (11%)
- Patient dissatisfaction (5%)
- Equipment-related events (4%)
- Accidents (3%)

A study conducted in the United Kingdom by Andrews and colleagues in 1997 found the following types of incidents [24]:

- Diagnosis (7.5% of all adverse events; 5.2% of serious adverse events)
- Surgery (10.5% of all adverse events; 19.7% of serious)

- Treatment (13.4% of all adverse events; 9.1% of serious)
- Post-operative monitoring (29.3% of all adverse events; 7.1% of serious)
- Medication (9.3% of all adverse events; 5.8% of serious)
- Nutrition (2.3% of all adverse events; 0.4% of serious)
- Anaesthesia (1.3% of all adverse events; 2.4% of serious)
- Complications (19.5% of all adverse events ; 38.1% of serious)
- Other (6.9% of all adverse events; 2.2% of serious)

A US study conducted at a 371-bed Boston-based teaching hospital by Weingart and colleagues reported the following types of incidents among 100 adverse events reported involving 79 patients[25]:

- Diagnosis (26.4%)
- Medication (12.6%)
- Surgery (7.3%)
- Prevention, including inadequate follow-up, monitoring, or supervision (15.4%)
- Clinical services, including laboratory and radiological errors, missed tests (16.3%)
- Support services (9.9%)
- Discharge (9.1%)
- Other events (2.7%)

A large prospective study conducted at the Osaka University Hospital by Takeda et. al.[26] in Japan reported 1550 incidents in eight months from a sample of 10,687 in-patients, with the following classification breakdown:

- Medication (43.2%)
- Lines, tubes, and equipment (19.2%)
- Falls/slips (10.1%)
- Therapeutics and procedures (3.2%)
- Blood transfusion (3.0%)
- Surgery and anaesthesia (2.6%)
- Nutrition (1.8%)
- Lab and radiology services (2.7%)
- Other (10.8%).

An Australian study conducted by Witham and Kendall[27] at a 460-bed teaching hospital reported 158 incidents over a six-month period, of which one-third occurred within 48 hours of hospitalization and one-half were associated with harm or inconvenience to the patients, with the following subgroups:

Delay (42.4%)

- Delay in/wrong treatment (12%)
- Delay in obtaining investigation (12%)
- Delay in interpreting investigation (4.4%)
- Delay in discharge (3.8%)
- Delay in diagnosis (3.8%)
- Delay in assessment (3.2%)
- Delay in ordering tests (1.9%)
- Delay in admission (1.3%)
- Dissatisfaction (2.5%).

Medication (38.5%)

- High international normalized ratio for prothrombin time (9.5%)
- Adverse drug reaction (8.2)
- Missed/late drugs (6.3%)
- Diuretic/angiotensin converting enzyme inhibitor toxicity (1.9%)
- Inadequate anticoagulation (1.3)
- Other (1.2%)

Miscellaneous (26.6%)

- Early unplanned readmission (8.9%)
- Inappropriate care environment (5.1%)
- Lost X-rays (2.5%)
- Refused placement (2.5%)
- Other (7.6%).

These studies clearly support a need to use a standard taxonomy for the classification of incidents and their causality factors to permit comparison of data between institutions and possibly to establish regional or national benchmarks.

The Financial Burden of Adverse Events

The direct cost of preventable adverse events in the US health care system was estimated to be $10.1 billion in 1984 and has likely increased since then.[28] Another study using a representative sample of 28 hospitals in Utah and Colorado suggested that the total health care costs of preventable adverse events from these hospitals could be as high as US $159,245,000, of which 46% was attributed to outpatient medical care.[6] Bates et al.[8] estimated patient care costs of preventable adverse events at more than $4000 per adverse event. Bates indicates that, on average, preventable drug events increased length of hospital stay by 4.6 days and that this could increase health care costs by $2.8 million for a 700-bed hospital.

Malpractice litigation is another source of information regarding additional costs to the health care system as a result of poor safety management. In Canada, it was reported that the average settlement award between 1989 and 1999 in Ontario was Cdn $172,000 and the average across Canada was Cdn $131,000.[29]

To date, only the cost of adverse drug events has been determined in a case-controlled, prospective manner by matching the adverse drug event patient with a control patient, adjusting for confounding factors that affect cost and length of stay, and comparing adjusted costs of the hospital stay.[8,30,31] Senst et al. [30] reported that the average cost per ADE occurring in the hospital was $2162, and ADEs causing admission averaged $6885 for the four US hospitals studied and $7857 for mental health centre patients. The mean length of stay for admissions caused by an ADE ranged from 6.5 to 19.6 days, depending on whether the ADE occurred at the university hospital, community hospital, or mental health centre. Taking incidence into account, Senst and colleagues extrapolated that the total annual projected cost of ADEs will be in excess of $1.7 million dollars for their health care conglomerate, of which preventable ADEs account for $257,000. Classen et al.[31] reported that ADEs increase length of hospital stay by 1.74 days ($p<0.001$) and cost of hospitalization by $2013 ($p<0.001$) when matched to controls. A linear regression analysis for mortality revealed an almost twofold increased risk of death among patient experiencing an ADE (95% confidence interval, 1.54–2.22; $p<0.001$). Bates et al.[8] reported that ADEs increased length of hospital stay by an average of 2.2 days ($p=0.04$) and increased cost of hospitalization by $3244 ($p=0.04$). For preventable ADEs, the increase was 4.6 days in length of stay ($p=0.03$) and $5857 in total cost ($p=0.07$). From these costs, Bates et al. estimated annual costs attributable to all ADEs and preventable ADEs for a 700-bed teaching hospital to be $5.6 million and $2.8 million, respectively.[8] Such costs clearly support the need for most institutions to invest in drug safety programs.

A study conducted by Bothner et al.[32] in Germany revealed that minor peri-operative anaesthesia-related incidents prolonged hospital stay by 6% to 26% when adjusted for severity features such as gender, American Society of Anaesthesiologists (ASA) physical status, type, and duration of surgery. Although cost was not quantified or reported on,

it is reasonable to conclude that minor anaesthesia incidents do increase anaesthesia care utilization and pose a financial and resource burden on hospitals.

The issue of indirect costs has not been studied extensively, but can include lost productivity, lost wages, disability costs, and emotional trauma.[29] A US study reported that lost household wages may average $63,309 and lost household productivity could total $85,828; these losses represent the third-largest cost of medical mishaps.[33]

Indirect costs can be difficult to attach a dollar value to, as individuals and regions vary greatly in socio-economic and cost-of-living indices. However, clearly the burden of adverse events is significant to both health care and social welfare systems when direct and indirect costs are taken into account. The situation in Canada is expected to be similar.

Opportunities for Improvement

Incident reporting aims to improve performance and promote patient safety through the identification of incidents that resulted in, or could have resulted in, patient harm. Subsequent investigation and analysis of the incidents, including their severity, type, frequency, and probable cause, are intended to provide organizations with the necessary information to implement interventions that will limit recurrence of such events and mitigate their impact if they do recur.

Incident reporting is limited in its ability to evaluate the prevalence and severity of medical errors, as it is based on retrospective, potentially biased recall and known to be underreported in magnitude. It is estimated that 50% to 96% of adverse events remain unreported in systems that have incident reporting systems.[34] The American College of Surgeons estimates that incident reports generally capture only 5% to 30% of adverse events, and studies of medical services suggest underreporting is a larger problem, with only 1.5% of all adverse events being reported.[17] It is not known to what extent a "culture of blame" or a general lack of safety management systems contributed to these results.

Active solicitation of physician reporting has been suggested as a way of improving adverse event and near-miss detection rates. Weingart et al.[25] employed direct physician interviews supplemented by e-mail reminders to increase detection of adverse events compared with those captured by the hospital incident reporting system. Of 168 events, only one was reported by both methods. Welsh et al.[35] employed prompting of house officers at morning report to augment hospital incident reporting systems. There was an overlap in only 2.6% of 341 adverse events that occurred during the study. This study questions what causes underreporting and to what extent a culture of blame in the assessment of causality inhibits incident reporting. It is not known why the house officers failed to utilize the hospital's incident reporting system. It appears that incident reporting in itself is not an adequate mechanism for detecting failures in a system. Its function, however, when used to act as a sentinel, is to

alert medical personnel to potential problem areas. When used in this way, the lack of a denominator is not a hindrance, particularly if the reporting is repeated, generating trend data.

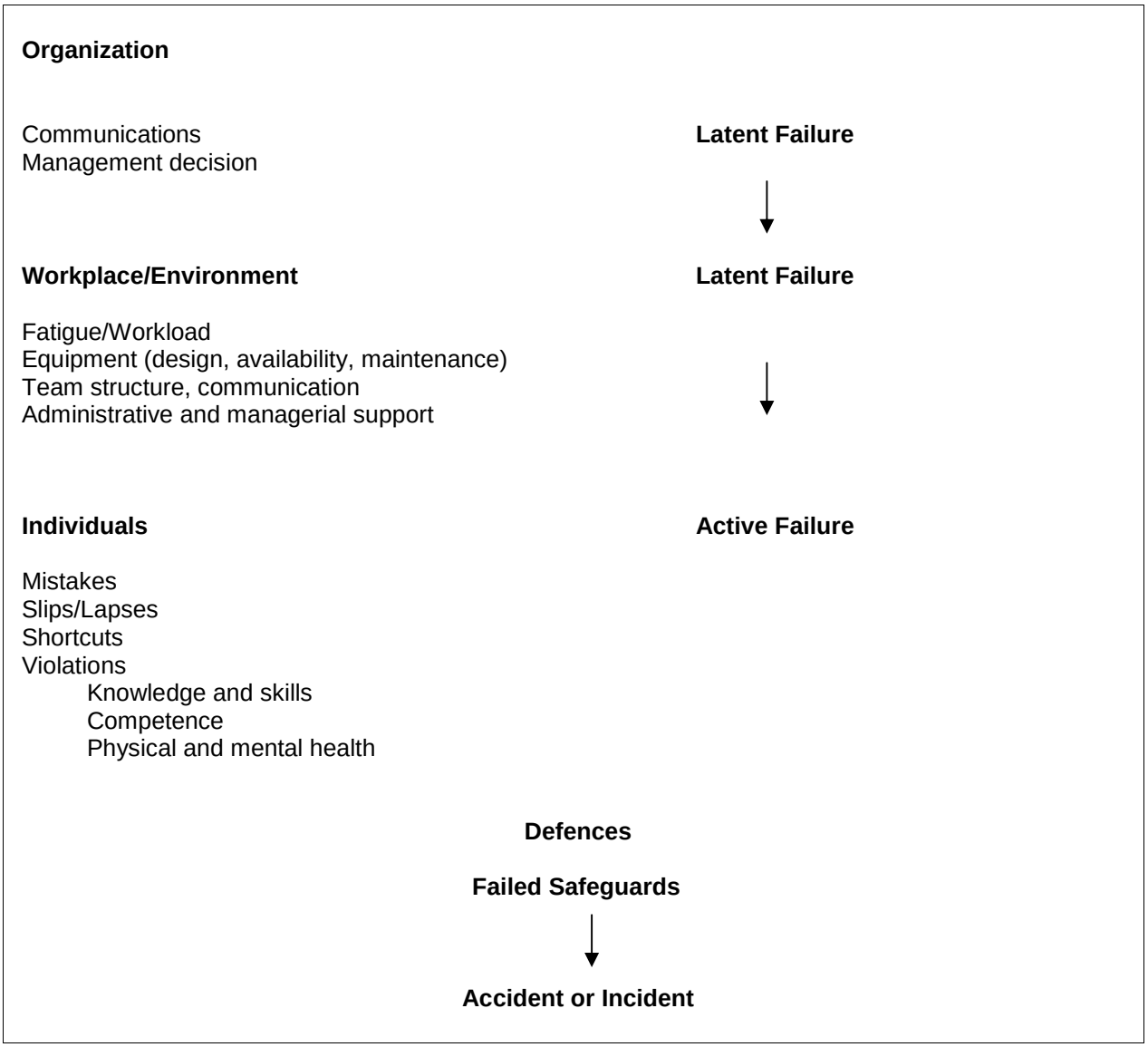
In accordance with recommendations from the Joint Commission on Accreditation of Healthcare Organizations, incident data should be collected for both improvement priorities and continuing measurement. Incident data can help define the nature of problems, guide improvement efforts, and document whether changes made did, in fact, lead to improvement. When analyzed to generate trends and to assess preventability, severity, or causality of all events, incident data can provide the impetus for system change directed at correcting underlying causes rather than symptoms.

According to Crane, it was Reason who first developed the idea that incidents are the result of latent, small failures within a system that combine at some point to cause an accident (see Figure 1)[36]. These failures may originate at the organizational level, with problems in communication or with management decisions, or at the workplace/environmental level, where availability, structure, and competence of resources impact an individual's risk for an accident or incident. As Leape et al. argue, *"Errors are not the disease, they're the symptoms of the disease"*. In many cases, the root problem can be traced to systems of management and operations rather than individual error.[37] Therefore, the main purpose of incident reporting should be to identify root causes of incidents to direct system changes and subsequently measure the effectiveness of system interventions through repeated tracking. By communicating this purpose of the incident reporting process to health care workers, the medical profession can gradually shift the culture from one that focuses on error to one that focuses on system improvement.

Figure 2 illustrates the process by which incident reporting can be integral to the identification and resolution of medical system problems through a multi-stage quality management program. In this organizational model, incident reporting constitutes a key effort to identify events/problems with significant consequences or a high-volume in a health care system and is followed by problem analysis, new process implementation, and subsequent monitoring to evaluate whether system interventions have succeeded in limiting the identified problems .

To encourage participation, reporting systems aimed at identifying health care problems must be user friendly, anonymous, confidential, and non-punitive, and they must provide timely feedback to users.[38] When considering the implementation of an incident reporting system, it is all too easy to develop a simple data collection form that asks questions requiring narrative responses and then to file reports in a drawer or enter them into a spreadsheet. Although this meets the requirement of having a system, it does not provide the necessary means for learning from the incidents and improving health care.

Figure 1: Organizational accident causation model*



Sources: Offredy et al.[39]; Busse and Wright[40]

Factors determining the success and usefulness of incident reporting systems include the culture of an organization, the provision of standardized methodologies, classification systems, the tools for analysis, and the feedback given to the staff. Attention given to these features will lead to staff becoming active participants in the incident reporting system and subsequent process improvement.[14]

Table 4 lists important cultural and organizational aspects of trust that need to be developed or present within an institution before a successful reporting system can be implemented and adhered to by health professionals. A key feature of a successful incident reporting system is to shift from a culture of simply reporting incidents to a

culture of learning from an incident, searching for patterns, and using incident reporting and other surveillance methods to anticipate future risks.[41]

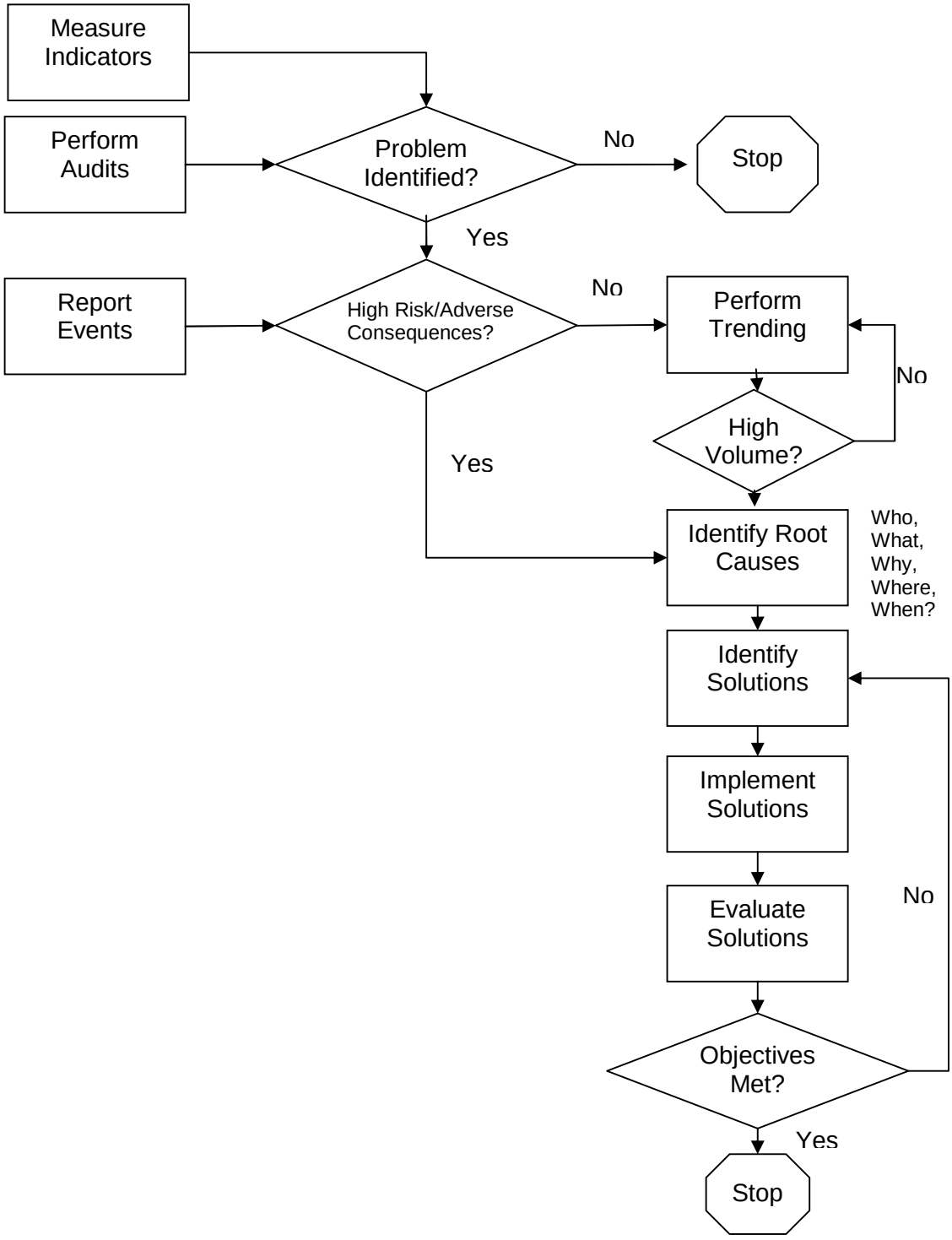
Accidents are inevitable in any complex system. Outside of health care, however, there are organizations that have fewer hazardous events than would be expected, given their high complexity. These organizations, such as nuclear aircraft carriers, nuclear power plants, and air traffic control centres, are referred to as "high reliability organizations".[29] All continuously look into the deeper causes of incidents to build comprehensive safety management systems that are fundamental to the success of their industries. Hospitals and other complex health care operations need to learn from these other industries to develop comprehensive safety management systems, where incident reporting is just one component, such as from those employed by chemical and aviation industries for managing process safety.[42–44]

Table 4: Features of an organization that encourage incident reporting*

Strategies for increasing organizational trust	Description
Less bureaucracy/flat hierarchy	Flatter organizations are better to support open communication between front-line workers and management for open, honest reporting and root cause analysis.
Staff participation in decision making/empowering staff	Giving front-line health providers more participation and discretion on how to do their jobs has been shown to lead to higher levels of commitment and better patient care.
Open communication	Managers should maintain open levels of communication when times are bad as well as good and allow two-way communication as much as possible to reach decisions and implement new processes or policies.
Human resource policies and risk management procedures	Systems of reward, performance appraisal, and incident analysis should be based on evidence and a consistent, just process. Rewards or incentives should be provided for reporting and showing trustworthy behaviour.
Teamwork	Most health care takes place in teams and a lack of effective teamwork has been found to be an important cause of patient errors. Good teams, whose roles are clear, where members feel supported, and where good internal and external dialogue takes place provide better health care.
Leadership ability	An amalgamation of skills and competencies, including being able to influence others, contain anxiety, remedy problems revealed, and deal with cases fairly.
Leadership benevolence	Staff should be given understanding and loyalty and a sense of facing difficult times together. Includes understanding the very real difficulties of clinical care—the stress involved, the lack of resources, and the anxiety about making errors.
Leadership integrity	Managers must keep their word and be honest and consistent in their actions and decisions.

*Source: Firth-Cozens.[45]

Figure 2: Process flow chart for system improvement*



*Adapted from Motcham and Moore as cited in Biddle and Lahaye.[46]

Identifying and Investigating Near Misses

Near-miss events (events without harm) should be included in an incident reporting system, given their similarity to and greater frequency than events with harm. Near-miss events also carry less repercussion to the reporter and may receive more open and honest investigations for effective root cause analysis. As Kaplan stated, "*near miss events allow us to learn why something didn't happen and provide a means to understand human recovery and rescue*". Focusing on recovery and rescue, as well as failure, produces a comprehensive reporting system that includes prevention of error, as well as promotion of quality.[14]

Potential for Harm

Incident reporting and subsequent root cause analysis is a process-improvement approach to patient risk management and follows Reason's and Leape's philosophy that the evaluation and analysis of incident data can provide valuable information to guide system interventions that can prevent incident recurrence.[25] The second approach to prevention focuses on negative patient outcomes (e.g., adverse drug events) rather than on process (e.g., medication near-miss incidents).[7]

The process-improvement angle is thought to be flawed by Classen because it does not distinguish between, for example, medication errors and ADEs.[31] Although dissecting medication errors may improve patient outcomes, only 1% of all medication errors result in ADEs and 50% of ADEs can be prevented.

Reliability of Incident Reporting Systems

Weingart et al.[25] employed direct physician interviews supplemented by e-mail reminders to increase detection of adverse events in a tertiary care hospital. The physicians reported an entirely unique set of adverse events compared with those captured by the hospital incident reporting system. Of 168 events, only one was reported by both methods. Chart review corroborated 73% of the events, but the hospital incident reporting system detected only one event. This research suggested that physicians failed to report events because of their own perceived vulnerability to supervisor's disapproval, fear of developing a bad reputation, or a sense of powerlessness, reinforcing the need to improve existing incident reporting systems.

O'Neil et al.[47] found that although physician reporting identified 89 adverse events compared with the 85 uncovered by retrospective chart review, only 41 of these events related to the same patients. Another study conducted by Stanhope et al.[48] further supports these findings that incident reporting does not accurately quantify the true number of incidents that occur. In this study, incident reporting detected 45 incidents (23%) identified from 500 deliveries in two London obstetric units, and retrospective

chart review detected 107 incidents (55%). However, it should be noted that Stanhope et al.'s findings are based on a small sample size comprising a total of 196 incidents.

In a study conducted by Beckmann et al. in 2003,[49] incident reporting was compared with medical chart review for 176 admissions involving 164 patients. In this study, incident reporting detected 221 incidents from 100 reports, of which 84% were considered preventable, and chart review detected 132 adverse events involving 48% of charts, of which 21% were considered preventable. Incident reporting was thought to provide more contextual information about the incidents and identified a larger number and higher proportion of preventable problems than chart review but fewer problems with infection, pain management, and problems leading to ICU admission.[49]

Flynn and colleagues[50] compared the accuracy and cost of three different methods of medication error detection in a stratified random sample of 36 hospitals in Colorado and Georgia. The study reported that incident reporting detected less than 1% of total errors and 0% of clinically significant errors and had an error rate of 0.04%, and that chart review detected 9% of clinically significant errors and 5% of total errors and had an error rate of 3.0%. Direct observation gave an error rate of 11.7% for the same 2556 doses.[50]

These discrepancies in measures of patient safety between similar tracking systems highlight the fact that the analysis and control of risk should not be solely identified through incident or near-miss reporting, but should take into account a range of internal and external data sources. These sources could include epidemiological data, patient satisfaction surveys, discharge questionnaires, routine audits, complaints, and litigation claims, to name just a few. This inclusion, in turn, would also help control for the fact that incident reporting systems are said to fail in capturing the majority of errors and near misses and capture only 30% of anaesthetic incidents[51] and 6% of ADEs.[52]

INCIDENT REPORTING COSTS AND IMPLEMENTATION

Few estimates of costs for implementing incident or adverse event reporting systems have been reported in the literature. Two studies have been conducted that compare the cost and accuracy of incident reporting with other tracking systems, namely, chart review and direct observation.[47,50] These studies provide important contextual information concerning the value and use of incident reporting systems (Table 5).

One single-centre study at Brigham and Women's Hospital in Boston compared the cost of concurrent incident reporting by electronic mail with retrospective chart review.[47] The comparison showed that concurrent reporting uncovered more preventable adverse events and cost appreciably less than chart review. A total of 3141 admissions were studied for a four-month period between November 1990 and March 1991. Of the adverse events identified by concurrent reporting, 62.5% were preventable, compared with 32% of events identified by chart review. The record-review approach cost a total of $54,462, including $7148 for record retrieval, $14,880 for physician review, $15,133 for data analysis, $14,950 for administration, and $2351 for data entry. The concurrent reporting system cost a total of $15,323, equivalent to less than one-third the cost of retrospective chart review and including $6935 for physician follow-up, $338 for data entry, and $8050 for administration. Both systems differed in the volume, frequency, and type of adverse events detected, reinforcing the need to use more than one tracking method to evaluate medical error. In the study, 133 different events were identified by the two methods, with 44 events being detected by chart review but not by concurrent reporting and 48 events being identified by concurrent reporting but not chart review.

In a stratified random sample of 36 hospitals in Colorado and Georgia, a controlled trial conducted by Flynn et al.[50] compared three different methods of medication error detection for accuracy and cost-effectiveness, namely, chart review, incident reports, and direct observation. The study reported that direct observation was more cost efficient in medication error detection than chart review and paper-based incident reports for the 2556 doses compared. Chart review was reported to be the least costly method of error detection, costing $0.67 per error as compared with $4.36 for incident reporting and $4.82 for direct observation. However, both chart review and incident reporting detected many fewer error rates and were less accurate than observation. Incident reporting detected only less than 1% of total errors and 0% of clinically significant errors and had an error rate of 0.04%, and chart review detected only 9% of clinically significant errors and 5% of total errors and had an error rate of 3.0%. Direct observation gave an error rate of 11.7% for the same 2556 doses.

Three other uncontrolled, non-comparative studies claim that electronic incident reporting systems are more cost-effective than their paper counterparts. However, these claims are largely unsubstantiated because of flawed study design and methodology, such as lack of control for confounding variables and incomplete

sampling information. They are mentioned to provide some basic information on operating time and cost of electronic reporting systems, rather than as indicators of cost-effectiveness.

The first study, conducted at a 323-bed hospital in Seattle, Washington, compared paper-based with Web-based incident reporting. The study suggests that electronic reporting systems reduce data collection and processing time by 71%, from 7 to 2 minutes per report. The electronic system also decreased "incident resolution time" (length of time from filling out a memo to resolution of reported incident) from 53 to 12 days.[53]

The second study, conducted at the Baylor Medical Center in Texas, suggests that Web-based electronic incident reporting systems are more cost-effective than paper-based systems, which require $35,000 annually for data collection, analysis, and management, versus $7000 a year for user fees for the electronic system. These authors claimed that reporting time can be reduced by 25% to 50% and that follow-up and intervention can be more immediate with an electronic system.[54]

The third study, conducted by Mekhjian et al.[55] in 2004 at the Ohio State University Health System, reported that the average time to electronically enter an event was 7 minutes and 40 seconds. This study measured organizational efficiency as follows: the "event open time", which spanned from event entry until an area manager became aware of it, and "manager complete time" from event entry until the area manager completed the incident investigation and information gathering. These indicators of efficiency measured 64.37 hours and 132.1 hours, respectively, and reduced the average hours to open by 44.1% and the hours to complete reporting an event by 71.2%, 30 weeks post-implementation.

Unfortunately, none of these studies provide sampling information or control for confounding variables, nor do they provide a controlled comparison to paper-based or alternative reporting methods. Thus, little can be concluded regarding the validity of their claims with respect to electronic incident reporting systems. They do, however, provide limited information on operating time and cost.

These studies indicate that incident reporting alone provides a fairly cost-effective, although incomplete, means for monitoring patient safety. Multiple, different incident tracking methods are required by institutions to ensure that risk management efforts are based on a comprehensive, accurate portrayal of patient risk.

Table 5: Cost and reliability of incident reporting

Study	Methods	Outcomes	Results	Comments*
O'Neil et al. 1993[47] Retrospective, controlled, cohort study Brigham and Women's Hospital, Boston, MA USA	N=3141 admissions 4-month reporting period (Nov. 1990–Mar 1991) Concurrent, electronic reporting of adverse events vs. retrospective chart review for incident tracking	**Outcomes:** Volume, frequency, and type of adverse events (AEs) and cost of data management and analysis for two different methods of tracking incidents	**Volume AEs:** Treatment group (electronic incident reporting): 89 events (2.8% admissions) vs. Control group (chart review): 85 events for chart review (2.7%) 133 different events by two methods 44 events identified by chart review but not by concurrent reporting 48 events identified by concurrent reporting but not chart review **Preventable AEs:** Concurrent reporting group: 62.5% vs. 32% chart review (p=0.003) Cost: Concurrent reporting: total cost $15,323 vs. chart review $54,462 Including record analysis, physician review, data entry, and administrative costs	Good overall design, fair level of evidence, and large sample size. Patient groups comparable between groups. Reliability of outcome measures questionable and not enhanced by independent assessments of outcomes followed by inter-rater agreement. Does not explain discrepancies in type of event detected by each tracking method. Results suggest both retrospective chart review and concurrent reporting underreport incidents and should not be used as primary patient safety outcomes but rather to direct and monitor progress of organizational efforts to improve quality. Supports need to use more than one tracking method to evaluate medical error.

*Refer to Appendix A for definition of study ratings.

Table 5: Cost and reliability of incident reporting (cont'd)

Study	Methods	Outcomes	Results	Comments*
Flynn et al. 2002[50] Randomized controlled study USA	N=2556 doses; 457 errors **Multi-centre:** 36 hospitals in Colorado and Georgia Compare three different methods of medication error for accuracy and cost-efficiency: chart review vs. direct observation vs. incident reports vs. pharmacist control Study duration: unknown	Number, type medication errors per group (chart review vs. incident reports vs. direct observation) % false positives, % error rate per group Medication error = any discrepancy between prescriber's interpretable medication order and what was administered to patient.	Chart review: Error rate: 3.0% Detected 9% clinically significant errors Detected 5% total errors Missed 96% true errors 0.3% false positives Cost per error: $0.67 Direct observation: Detected 71% clinically significant errors Detected 94% omitted dose Detected 82% wrong dose Detected 17% wrong form Detected 50% extra dose Detected 83% wrong route Detected 100% wrong technique 3.5% false positives 34% missed true errors Cost per error: $4.82 Incident reporting: Error rate: 0.04% 0% clinically significant errors detected Detected <1% total errors Cost per error: $4.36	Very good study design and level of scientific evidence; adequate sample size. Used triangulation and multiple data collection methods to improve study validity. Conducted kappa statistic for inter-rater reliability but did not report or conduct statistical analysis for comparator group outcomes. Concluded direct observation more efficient and accurate than chart review and incident reporting. Low rate of reporting by incident reports conflicts with other studies and may be indicative of a faulty reporting system with no incentives or immunity or a culture not conducive to reporting. Further research warranted to explain extremely low error detection of incident reporting group.

*Refer to Appendix A for definition of study ratings.

EVIDENCE FOR EFFECTIVENESS OF INCIDENT REPORTING SYSTEMS

Incident reporting provides an efficient method of gathering information about problems in a health care system. However, information is only the first stage of any quality assurance program, other stages being incident/problem analysis, formulation of strategies to prevent recurrence of problems, implementation of strategies, and reassessment of the impact of changes made. Past studies have emphasized the value of gathering information but frequently fail to show how it can be used to prevent incident recurrence or evaluate the effectiveness of any approaches taken. In general, published studies of incident reporting do not seek to establish the benefit of incident reporting as a patient safety practice. Their principal goal is to determine if incident reporting captures the relevant events. In fact, no studies have established the value of incident reporting on clinical outcomes such as morbidity and typically use error rate as the main indicator of patient safety.

Appendix C lists retrieved studies that have implemented incident reporting systems but have not conducted post-implementation measures to evaluate the effect of reporting on incidence recurrence. A total of 83 studies were excluded because they only provided qualitative incident information on implemented institutional reporting systems without post-test or follow-up incident measures to assess effectiveness. These studies suffer from the same flaw in that they assume incident data will improve safety performance by directing system or institutional interventions and by impacting health provider knowledge and skills via feedback.

The remainder of this review focuses on studies that have evaluated the effectiveness of incident reporting systems through pre- and post-implementation incident comparison.

Study Designs

Eleven studies assessed the effectiveness of incident reporting through pre- and post-study measures and all of these studies included some form of intervention for error reduction in their study design.[56] Hence, observations reflect the benefit of both incident reporting and the interventions employed because no studies were identified that evaluated the effectiveness of incident reporting alone. Seven of these 11 studies reported on medication errors,[56–62] one on radiograph diagnostic errors,[63] two on adverse events,[64,65] and one on anaesthetic incidents.[66]

Of the 11 studies reviewed, four were observational studies with controls, and seven were observational studies without controls. Of the four controlled observational studies, all were prospective, including two cohort studies.[47,57,63–65] Of the uncontrolled observational studies, five were retrospective[59–62,66] and two prospective.[56,58] Appendix C lists the hierarchy of studies assessed.[47]

Study Outcomes

Reduction of Medical Incidents

Of the 11 studies that measured effectiveness of incident reporting with interventions through pre- and post-test comparisons, seven reported no benefit for incident reporting systems reductions in medication errors or adverse events following the implementation of incident reporting systems,[56–60,64–65] and four cited no benefit for incident reporting systems.[61–63,66] Table 6 provides details on the methods, results, strengths, and weaknesses of these studies.

The overall quality of studies reporting benefits and reduction in adverse events or medication errors following the implementation of a reporting system is notably higher than for those studies that report no improvement. The studies reporting improvement are generally better designed and larger in scale and exhibit some control for confounding factors such as patient characteristics between comparator groups. However, only three[58,64,65] of eight studies reporting a benefit for incident reporting are substantiated with statistical analyses, and the majority do not provide complete reporting of data collection methods. Furthermore, one of these studies combines adverse event data obtained from incident reporting with other tracking techniques, including medical chart review, physician discharge reports, and patient satisfaction surveys, making interpretation of results difficult concerning the effectiveness of incident reporting.[64] Institutional interventions following incident reporting differ substantially between the studies and include education; feedback at variable frequencies with or without additional interventions, including remedial action by managers; work tools/aids; policy and practice changes; or increased supervision.

The largest study supporting the use of incident reporting systems was conducted by Over et al.[65] in a prospective, controlled study that examined 13,277 incident reports and compared adverse event volume and type before and after interventions, comprising weekly incident review and education using 12,594 chart reviews as a control. The study reported a significant decrease in the total number of adverse events in both groups ($p<0.001$), as well as a significant reduction in critical incidents in the incident treatment group ($p<0.003$). The total number of adverse events was reduced by 55% in the incident reporting group and by 56% in the control group that received no educational intervention. The unexpected reduction in total adverse events observed in the control group may be indicative of potential bias in outcome measurements and group selection.

Cimino and colleagues[58] in 2004 conducted a large, prospective, multi-centre, uncontrolled study that assessed number, frequency, severity, and type of medication errors before and after interventions in 21,213 medication orders over a four-month span. The study reported a 32% reduction in orders with errors ($p<0.001$), a 26% reduction in orders with missing information ($p<0.001$), and a 77% reduction in preventable ADEs ($p<0.05$) post-intervention, comprising provider education, dosing

"assists", dosing prompts, and altered floor stocking. Intervention details were not fully described in this study nor were patient groups compared or controlled. Outcome measures were not blinded and independent raters were not used, further biasing potentially confounded results. The short study duration questions whether observed improvements are retained over time.

Wilson et al.[57] conducted a prospective, cohort study that measured adverse events pre- and post-intervention. The study incorporated feedback to providers every three months and changes to policy and practice following incident review. Adverse events were measured one year following implementation of an adverse event incident reporting system. Post-study measures showed reductions in total number of errors (19% decrease), serious errors (50% decrease), and administration errors (54% decrease) but no change in prescription errors. Unfortunately, no statistical analysis was performed to determine whether the reductions were significant, and study methodology was flawed by not assessing comparability between groups or employing blinded or independent raters for outcome measures.

In the Joshi et al. study,[59] medication errors were reduced by 75%, dose errors by 62%, time errors by 87%, patient errors by 94%, and omission by 70% after implementation of an electronic reporting system with ongoing, integrated education and feedback regarding reported incidents. The study also reported a $25,000 to $35,000 annual reduction in cost for data collection, analysis, and management for the electronic system as compared with an earlier paper-based system. However, the study did not report sample size, control for confounding variables, or perform statistical analyses; therefore, the results are largely anecdotal.

In the prospective, uncontrolled study conducted by Farbstein and Clough in 2001,[56] pre- and post-study measures were collected for the following indicators of quality: look-alike/sound-alike medication errors, delayed morning medication, Coumadin administration errors, patient-controlled analgesia (PCA) adverse events, and heparin anticoagulation time. In this study, the intervention succeeded in decreasing look-alike/sound-alike errors, improved heparin time, and reduced PCA adverse events by 80% and Coumadin incidents from three pre-study to two post-study. This study did not report sample size or full outcome data, compare or control patient groups, conduct any statistical analysis, or control for bias in outcome measurements. Interventions and chart review methods were not adequately described and study duration varied across outcomes, making results difficult to interpret and validate.

Ross and colleagues[60] conducted a retrospective, uncontrolled study that looked at incidence and type of medication errors following implementation of a non-punitive error reporting system coupled with undefined systemic interventions. Post-study measures were conducted five years following implementation of the reporting system. Annual dispensing errors were reduced from an average of 9.8 errors per year pre-intervention to 6 errors per year post-intervention. Intravenous drug errors

reduced nominally from 37 to 32 per year, and physician errors were reported to decrease 50% from six per year at the start of the study to three per year at the end of the study. The low incidence of medication errors (0.15%) reported in this study conflicts with other U.S. published studies (e.g., 3.7%–17%) and indicates potential methodological problems with error detection or reporting.

The largest study supporting the use of multiple incident tracking systems with interventions was conducted by Wolff and colleagues in 2001.[64] They assessed adverse event occurrence in 49,834 in-patients and 20,050 emergency patients over a span of eight years and used multiple tracking methods to assess the impact of interventions employed, including education, feedback, changes in administrative and clinical protocols, checklists/aids, increased supervision, and audits on the incidence of adverse events. The study reported a significant reduction in annual in-patient adverse events from 1.35% to 0.74% ($p<0.001$) and a reduction in volume of quarterly emergency adverse events from 3.26% to 0.48% ($p<0.001$). Through a comparison of adverse event detection between incident reports, chart review, practitioner discharge reports, and patient satisfaction surveys, the study also found that incident reporting detected only 16.3% of the total 450 adverse events detected, whereas in-patient and emergency chart reviews detected the majority of adverse events (84%), exemplifying the need to use multiple detection methods for adverse event measures.

The four studies that report no benefit from incident reporting are considerably less controlled and more qualitative in nature. The majority of these studies have inadequate sample sizes, have unclear or poor methodologies, and lack scientific evidence.[61–63,66]

Short et al.[66] performed a retrospective, uncontrolled study that assessed volume, type, and causality factors of anaesthetic incidents annually for five years following the implementation of an incident reporting system. Short and colleagues studied a total of more than 1000 incidents from three hospitals over this time period. Reported incidents varied widely between years within the hospitals studied and did not change or decrease appreciably over time. Total incidents ranged between 34 and 183 per year and human error was identified as a contributing factor in over 75% of the incidents reported. The limited reductions that were observed in incidents were related to design and maintenance of equipment and were corrected by equipment modifications. This study did not report comparability between groups or control for confounding factors, interventions, or data methods. Results may indicate bias in group selection, ineffective interventions, problems with data handling, or increased acceptance and use of reporting over time.

Schneider and Hartwig[62] reviewed 3943 medication errors from a US teaching hospital before and after two interventions were implemented to prevent narcotic incidents and antibiotic medication errors. Medication error type, volume, and severity were measured five to six months following interventions. The authors reported no

appreciable reduction in total error incidence; however, both late antibiotic doses and narcotic incidents showed improvements post-study. Sample size was limited and no statistical analysis was performed. Comparability between groups was not reported and outcome measurements were not controlled to prevent bias, making results questionable.

The remaining studies conducted by Rowe and Koren[61] and Tudor and Finlay[63] report no benefit for incident reporting and provide low levels of scientific evidence, being limited by small sample sizes, inadequate study durations, and lack of statistical analysis and/or control of confounding factors that make interpretation of their significance difficult.

Table 6: Effectiveness of incident reporting

Study	Methods	Outcomes	Results	Comments*
Over et al. 1994[65] Prospective controlled study USA Parkland Memorial Hospital, Dallas, Texas	N>25,000 anaesthesia patients Study duration: 8 mo Treatment group (incident reporting): n=13,277 anaesthesia patients Control group (record review): n=12.594 anaesthesia patients Incident reporting system followed by weekly review and educational intervention.	Monthly comparison of volume, type of adverse events (AEs) between groups	Treatment group: Start study: 13.9% AEs End study: 7.8% AEs Control group: Start study: 3.2% AEs End study: 1.8% AEs Treatment group reported more AEs than control (p<0.001) Significant decrease in total number of AEs in both groups (p<0.001) Significant decrease in number of critical incidents in treatment group (p<0.003)	Good study design, fair level of scientific evidence, adequate sample size. Comparability between groups unknown and raters not blinded or independent, which may confound results. Unexpected results in control group warrants further research and better control of confounding factors, potential bias in outcome measurements, and group selection.
Cimino et al. 2004[58] Prospective, multi-centre, uncontrolled study Nine pediatric intensive care units USA	N=12,026 medication orders baseline N=9,187 post-intervention Medication orders reviewed for prescribing errors and assessed re: error type, cause, and severity Interventions implemented: provider education (47%), dosing “assists” via pre-printed orders, forcing functions or prompts (39%) and floor stocking (13.9%) Study duration: 4 mo: 2 wk pre-study data collection, 3 mo intervention, 2 wk post-study data collection	Number, frequency, type, severity of medication error pre- and post-intervention	Baseline vs. post-intervention medication errors: Orders with errors 11.1% vs. 7.6% post-intervention (p<.001) Incomplete orders 18.7% vs. 13.8% post-intervention (p<.001) Intercepted errors 1.6% vs. 2.0% post-intervention (p<.01) Preventable adverse drug events 0.13% vs. 0.03% post-intervention (p<.05) Total prescribing errors per order 0.22 vs. 0.17 post-intervention (p<.05)	Fair study design, fair level of scientific evidence and good sample size. Comparability between groups not reported or assessed and reliability of outcomes measures somewhat questionable (raters not blinded or independent). Intervention details not described. Post-intervention measurements made 2 wk following interventions. Longer study duration would permit evaluation of whether observed improvements are retained over time.

Table 6: Effectiveness of incident reporting (cont'd)

Study	Methods	Outcomes	Results	Comments*
Wilson et al.1998[57] Prospective, cohort study UK University Hospital of Wales	N=682 admissions, 5315 in-patient days Medication errors evaluated by incident reporting before and after continuous quality improvement approach implemented, comprising error reporting, feedback to providers every 3 mo, and policy and practice changes. Data analysis year 1 vs. year 2. Study duration: 2 y Patient population: pediatric	Volume, type of medication errors compared year 1 vs. year 2. Error rate ratios reported, relative to counts of admissions, in-patient days, and clinical events, and rate ratios assigned confidence intervals using Wilson method.	Medication occurrence ratios Total errors Year 2:Year 1 197:244 (19% reduction) Administration errors 34:76 (55% reduction) Prescription errors 150:152 Serious errors 33:66 (50% reduction) Actual errors 58:59 Frequency not reported. Comparability of patient characteristics between groups unknown and not reported. No direct statistical analysis of volume and frequency of errors reported.	No difference between pre- and post- medication errors, indicating reporting alone does not appear to reduce medication errors in pediatric population. No systemic interventions beyond feedback implemented despite findings that causality factors were systematic in nature. Supports need to couple reporting with systemic interventions to reduce incidence of error. Good sample size, fair study design, but poor level of scientific evidence and reporting. Comparability between groups not reported or assessed; outcome and statistical reporting insufficient.

Table 6: Effectiveness of incident reporting (cont'd)

Study	Methods	Outcomes	Results	Comments*
Joshi et al. 2002 [59] Retrospective uncontrolled study USA Baylor Health Care, Dallas, Texas	Medication errors compared before and after implementation of electronic reporting system. Multi-hospital, 2100 beds Study duration: 8 y (1993–2001) Doctor quality reporting system Incentives (financial and non-financial) provided for reporting incidents Integrated and ongoing education re: reported incidents Individual vs. department or management follows up with incident report to determine causality factors Timely, ongoing feedback to staff and managers on follow-up and aggregate data.	Volume, frequency, type of medication errors Cost for data collection, analysis, and management of error reports	Error rate per total doses dispensed Before electronic reporting system implemented: Wrong medication: 0.00371 Wrong dose: 0.00334 Wrong patient: 0.00138 Wrong time: 0.00143 Omission: 0.00917 After electronic reporting: Wrong medication 0.00091(75.47% reduction) Wrong dose: 0.00127 (61.97% reduction) Wrong patient: 0.00009 (93.48% reduction) Wrong time: 0.00018 (87.41% reduction) Omission: 0.00272 (70.34% reduction) $25,000–$35,000 annual reduction in cost for data collection, analysis, and management 250%–500% increase in error reporting	Authors state Web-based error reporting improves patient safety and outline key strategies for system success. Poor study design and level of scientific evidence. Unclear methodology, no control of confounding variables, unknown sample size, and no statistical analysis performed.

Table 6: Effectiveness of incident reporting (cont'd)

Study	Methods	Outcomes	Results	Comments*
Farbstein and Clough 2001[56] Prospective, uncontrolled study USA: conglomerate of 6 hospitals in eastern Massachusetts	Retrospective chart review for incidents; audit and observation for dispensing of patient information and time to complete morning drug dispensation Post-study outcomes measured at 6 different hospital sites 1–19 mo following interventions designed to improve quality of care indicators.	Pre- and post-study measures made for six indicators of quality of care: 1. Heparin anticoagulation time 2. Look-alike/sound-alike medication errors 3. Patient-controlled analgesia (PCA) adverse events 4. Coumadin administration errors 5. Dispensing patient information on medications 6. Delayed morning medication dispensing	Faster heparin anticoagulation (n=100 pre-study, n=29 post-study): % patients reaching heparin therapeutic range in 1 d doubled, from 16% to 31% 44% patients within therapeutic range in 3 d pre-study; 93% within range in 3 d post-study Fewer look-alike/sound-alike drug medication errors (sample size, outcome data not provided) PCA incidents reduced 80%. Frequency: one incident every 13.8 d pre-study; one incident every 24.4 d post-study (sample size not provided) Coumadin incidents: 3 incidents involving 2 patients pre-study and one incident post-study Nurse review with patient of medications increased from 79% to nearly 100% (sample size not reported) Time to complete morning medications reduced 50%, by 45 min (sample size not provided)	Poor overall design and poor level of evidence. Uncontrolled, unblinded, and non-comparative. Small, uneven, or unreported sample size between groups, unclear methods, and incomplete reporting. Study failed to measure or report confounding variables such as incidence severity, causality factors, or other patient characteristics that could impact outcomes. Interventions and chart review methods not fully detailed and study duration variable across outcomes.

Table 6: Effectiveness of incident reporting (cont'd)

Study	Methods	Outcomes	Results	Comments*
Ross et al. 2000[60] Retrospective, uncontrolled study UK Royal Hospital for Sick Children, Glasgow and tertiary Queen Mother's Maternity Hospital	N=112,536 admissions Non-punitive error reporting system implemented, systemic interventions (mainly educational) and post-intervention measurements on error incidence and type. Multi-centre: 2 sites Study duration: 65 mo/5 y (1994–1999)	Incidence and type of medication errors pre- and post-interventions.	195 medication errors in 5 y (0.15% of admissions). 59% errors occurred on medical ward, 13% surgical wards, 17% in neonatal intensive care, 10% in pediatric intensive care. Nursing staff reported majority (59%) 56% involved IV route administration Physician errors averaged 6 errors/y at start program, 3 errors/y at end study Average of 9.8 dispensing errors/y pre-intervention (change policy, addition of double-check); 6/y post-intervention IV drug errors averaged 37/y pre-intervention (training), 32/yr at end study Error reporting increased from 32.7/y (n=60 errors in 22 mo) to 38/y (n=135 errors in 43 mo) following revision report form to appear less punitive.	Poor study design, insufficient control of confounding variables, no statistical comparison made for post-intervention outcomes. Sample sizes not reported and no statistical analyses performed. Interventions implemented throughout course of study in ad hoc sequence, not fully described or controlled for confounding variables, carry-over effect making interpretation of results difficult. Much lower incidence of medication error than in other published US studies (3.7%–17%).

Table 6: Effectiveness of incident reporting (cont'd)

Study	Methods	Outcomes	Results	Comments*
Wolff et al. 2001[64] Prospective, controlled, open study Australia Wimmera Base Hospital, Horsham, Victoria	N=49,834 in-patients, 20,050 emergency patients Study duration: 8 y (1991–1999) Single site: 6000 in-patients and 9000 emergency on average Detection of adverse events (AEs): multiple methods used: incident reporting system developed by Australian Patient Safety Foundation and chart review, patient satisfaction surveys, and GP discharge reports Interventions to reduce incidence of high-risk and high-volume AEs included education, changes in clinical and administrative protocols, staff discussions, checklists/worksheets/aids for complex procedures, increased supervision of junior staff, regular feedback, focused audits	Frequency, severity of AEs detected by multiple methods AE defined as "an untoward patient event which, under optimal conditions, is not a consequence of patient's disease or treatment"	AE reduction: Annual in-patient AEs decreased 44.9% from 1.35% (69 events) to 0.74% (49 events) ($p<0.001$) Quarterly rate of emergency AEs decreased 85.3% from 3.26% (84 events) to 0.48% (12 events) ($p<0.001$) AE detection: Incident reporting detected 16.3% (66 events) of total 405 reported AEs 61.7% (250 events) detected by emergency medical record review 22% (89 events) detected by in-patient medical record review 4% (16 events) identified by GP discharge reports 4 events identified by patient satisfaction surveys	Good study design and level of scientific evidence, adequate sample size. Use of multiple detection methods increased total number of events identified. Few AEs were identified by more than one detection method. Authors paid specific attention to sample size and study duration and controlled for missing data/underreporting of incidents, unlike other studies, by using multiple detection methods that enhanced study validity. Suggests further research is required to improve methods of detecting AEs to improve efficiency and effectiveness.

Table 6: Effectiveness of incident reporting (cont'd)

Study	Methods	Outcomes	Results	Comments*
Short et al. 1996[66] Retrospective, uncontrolled study Hong Kong	N>1000 incidents Study duration: 5 y Multi-centre: three hospitals with 4000 beds total and a total of 42,000 anaesthetics/y on average Incident reporting system in place for 5 y and incidents evaluated re: type, volume annually for 5 y to determine if incidents reduced by interventions implemented.	Annual volume, type of anaesthetic incidents, and causality factors plus patient clinical outcomes related to incidents (e.g., morbidity, length of hospital stay, death) Incident=any incident that affected, or could have affected, the safety of the patient while under anaesthetic care	Incident frequency, volume, and associated clinical outcomes varied widely between years within each hospital and did not decrease or change significantly over time. Limited reductions in a few incidents mainly related to design and maintenance of equipment and corrected by equipment modifications. Causality analysis showed human error a contributing factor in 75% of incidents on average. Violations identified in 33% incidents on average.	Fair study design, poor level of scientific evidence. Methods, interventions, and statistical analysis not fully reported. Comparability between groups and systemic interventions not reported or fully described, making interpretation of results difficult. Results may indicate ineffective interventions, increased acceptance of reporting over time, or some kind of bias in reporting system or data handling methods.

Table 6: Effectiveness of incident reporting (cont'd)

Study	Methods	Outcomes	Results	Comments*
Schneider and Hartwig 1994[62] Retrospective uncontrolled study USA Ohio State University Medical Centre	N=3943 medication errors Single-site, acute care teaching and research hospital, 963 beds Medication incident reports reviewed and evaluated for severity, type/causality factors. Quality assurance committees review incident data and recommend re: interventions (changes in procedures, policies, etc.) to prevent recurrence. Results of two implemented interventions concerning antibiotic doses and narcotic incidents reported and studied. Interventions for anticoagulant drug errors and transcription errors planned and to be evaluated at a later date. Study duration: 2.5 y (Jan 1990–June 1992)	Medication errors (type, severity, volume, causality) Severity: Level 1: errors that result in no harm Level 2: errors that require additional monitoring Level 3: errors that change vital signs or need for additional lab tests Level 4: errors that require treatment or result in increased length of stay Level 5: errors that require intensive medical care or cause permanent harm to patient Level 6: errors that cause or contribute to death of patient	Incident reporting: 130 incidents/mo reported on average. Medication error reporting rate: 0.03%–0.07% No significant change/reduction in total error incidence during study Decreased late antibiotic doses from 112 incidents/6 mo to 46 incidents/6 mo after intervention Decreased narcotic incidents from 25 incidents/5 mo to 14 incidents/5 mo after intervention Error type: Omission: 34% Unauthorized drug:27% Wrong time:18.5% Wrong dose:11.7% Wrong rate: 6.0% Other: 2.3% Error severity: Level 1: 83% Level 2: 6.7% Level 3: 5.5% Level 4: 4.7% Level 5: 1.3% Level 6: 0%	Fair study design and poor level of scientific evidence. Data predominantly qualitative. No statistical analysis undertaken for pre- vs. post-outcomes and no control for confounding factors (e.g., patient groups not randomized, compared, or described; outcome measures not blinded or independent)

Table 6: Effectiveness of incident reporting (cont'd)

Study	Methods	Outcomes	Results	Comments*
Schneider and Hartwig 1994[62] (cont'd)			Causality factors: Administration: 44% errors Transcription error: 30% medication errors Medication unavailable: 11% errors Communication: 6% errors M.D. order problem: 3.4% errors Dispensing and other: 2.7%, 2.3%	

Table 6: Effectiveness of incident reporting (cont'd)

Study	Methods	Outcomes	Results	Comments*
Rowe and Koren 1997[61] Retrospective uncontrolled study Canada Toronto Hospital for Sick Children	N=503 medication errors Single-site tertiary pediatric hospital Medication incident reports reviewed for actual and potential errors to determine whether drug errors are being reduced, in keeping with organization and program objectives. Completed incident forms forwarded to dept managers for review, follow-up, and remedial action. Medication incidents summarized and reviewed monthly by Pharmacy & Therapeutics Committee as part of hospital's QA program. Study duration: 9 mo (Oct 1994–July 1995)	Medication incidents (actual and potential): frequency, volume Medication incident=when incorrect drug therapy was given to the patient (e.g., wrong dose, omitted dose, or extra dose) Potential incident=when patient did not receive erroneous therapy because the error was intercepted by other staff members	**Incident Reporting:** 73 incidents/mo reported on average. No significant trends or changes in incident volume during course of study. Actual incidents: 64%–84% total incidents reported Majority of incidents reported by nurses: 77% Remedial action reported for errors by nurses and pharmacists: 76% and 87% Remedial action reported for 38% of physician-committed errors 48% of actual error forms signed and reviewed by appropriate responsible physician 40% potential errors signed/reviewed	Poor study design and level of scientific evidence. Unclear methodology, no control of confounding factors, making interpretation of study results difficult. Outcomes and patient groups not characterized or adequately compared. Interventions not standardized or described; error reporting and data collection methods unclear. Results may indicate institutional non-compliance with error reporting or error remediation policies or be indicative of a faulty study design or ineffective QA program. Authors recommend further research and action on how to improve adherence of institutional policies directed toward error detection and remediation.

Table 6: Effectiveness of incident reporting (cont'd)

Study	Methods	Outcomes	Results	Comments*
Tudor and Finlay 2001[63] Prospective, cohort study UK Dept. Radiology, Leicester Royal Infirmary	N=50 radiographs Errors in radiograph reporting assessed before and after educational intervention (comprising reviewing errors). Study duration: 5 mo	Number, frequency, and type of error (perceptual, cognitive or communication, false negative, false positive) in radiograph reporting	Mean accuracy pre-education: 82.2% (range 78%–92%) Mean accuracy post-education 88% (range 76%–96%) No statistical difference pre- or post-education for group as whole. Two radiologists demonstrated statistically significant improvement post-education ($p<0.01$, $p<0.05$), individually	Fair study design, small sample size, poor level of scientific evidence, no statistical analysis. Authors state there was a trend toward improved reporting following error review and recommend follow-up to verify. Used the same set of radiographs pre- and post-feedback using subjects as their own controls. Results could reflect a learned response to the particular series of radiographs rather than improved accuracy.

DISCUSSION

According to the reviewed studies, incident reporting alone does not appear to reduce medical error or improve clinical performance in hospitals. Successful management of medical risk in health care institutions, as in other non-medical systems, requires three phases: risk identification through systems analysis and incident and near-miss reports; risk analysis through root cause analysis or similar methods; and risk control through subsequent system changes and improvements.[70,72] Ideally, the analysis and control of risk is not identified solely through incident or near-miss reporting, but takes into account a range of internal and external data sources, such as public health statistics, analysis of complaints and litigation, regional treatment guidelines, and compliance and patient satisfaction.[70] An effective risk management structure will seamlessly integrate information from multiple sources and through audit, human resource development, and policy or procedural modifications will effect system changes that lead to a reduction of identified risks (Figure 1).

Evidence regarding incidents is an essential precursor to effective action that could prevent recurrence or ameliorate the effects of that incident. However, in health care, *"we have enormous faith that good practice will automatically follow good evidence",* facilitated by education and training.[19] It is unrealistic to assume that information from incident monitoring will impact individual or systematic error in medical institutions that have no mechanism for incorporating this evidence into decision making, yet organizations routinely implement incident reporting systems and collect and analyze incident data without implementing or evaluating interventions to prevent recurrence.

The most important lack in the incident-reporting literature is the absence of consistent post-surveillance measurements of patient safety. Virtually all of the studies utilize different reporting or intervention parameters. Such parameter differences include the following:

1. Electronic versus paper-based reporting
2. Mandatory versus voluntary reporting
3. Incident reporting with or without subsequent root cause analysis
4. Incident reporting with or without interventions
5. Variable interventions (e.g., education, policy changes, staff reorganization, or process change)
6. Provision of incentives for reporting
7. Length of follow-up to accommodate increased reporting as familiarity with the new system occurs
8. Use of surrogate clinical outcomes or objective outcome measures
9. Level of bias in patient selection, comparator groups

From these and other methodological flaws in current research, one cannot conclude that incident reporting by itself actually prevents or reduces medical errors in institutions.

Well-controlled studies are needed to determine whether incident reporting systems with interventions are effective in reducing the incidence of medical adverse events and to define the optimal method of reporting, whether it is mandatory or voluntary, electronic or paper-based. Standard guidelines and protocols are required to help ensure that reporting is both comprehensive and consistent and to assist institutions with systematic data collection and analysis. Ideally, information can be shared across institutions and perhaps lead to national and international benchmarks for reporting.

Four key areas should be targeted to maximize the success of incident reporting systems: integration into existing reporting systems, promoting incident reporting by staff, coding and analysis of event reports, and the use of incident reports to "fix what is broken" or malfunctioning in health care delivery.[38] The ultimate test of a reporting system's usefulness is whether the data gathered are used to improve patient outcomes. As the number of cases reported to any system grows, the effort and cost required to glean lessons from each case and to manage large volume of reports will increase. The large volumes of reports filed with state or federal mandatory incident reporting systems will place increasing demands on data coding, which will limit the ability to provide timely feedback to hospitals and health care providers. Research efforts that focus on developing common taxonomy, analyzing data, and automating coding of text-based incident reports are sorely needed.

To err will always be human, but patient safety systems are needed to put mechanisms in place to predict, prevent, and mitigate human fallibility in health care. Patient safety will require continuous monitoring and identification of potentially error-prone situations and interventions to prevent them. Research on the prevention of adverse events at a system level is urgently needed and will assist hospital managers in their efforts to provide high-quality, safe patient care. It is unclear whether incident reporting is the best mechanism through which patient safety may be monitored. The benefit of incident reporting in promoting patient safety should be further evaluated, given that it is only one of several methods of assessing or addressing medical error (Table 7). Use of incident reporting needs to be considered in the context of other standard approaches to promote and implement safety practices.

BASIC PRINCIPLES OF PATIENT SAFETY PRACTICES

Table 7: Promoting and implementing safety practices*

Frameworks for error reduction	Principles and limitations
Incident reporting	Collects qualitative data from health providers regarding faulty processes or undesired outcomes. May be voluntary or mandatory, include adverse events or near misses, and be limited to specific events or comprehensive. Reporting is ultimately voluntary, even with mandatory systems, and fails to capture majority of errors and near misses due to underreporting. Is not an end in itself and must be coupled with feedback and system improvements to affect patient care.
Risk analysis	Structured approach to analyzing the potential for incidents with tools that systematically examine systems and processes rather than behaviours. Founded in engineering. Includes methods such as failure mode and effects analysis, fault trees, and probabilistic risk analysis.
Root cause analysis (RCA)	Process/method for uncovering less apparent failures of a system or latent errors that contributed to active failures or caused patient harm. Has two distinct stages: assembly of detailed timeline of events leading up to error through chart reviews and interviews, followed by a search for active and latent errors in the system guided by the Reason conceptual framework. Process has some limitations, including problems of hindsight bias, coloring of the analysis by prevailing concerns of the day, medico-legal concerns, and time required to conduct RCA.
Practice guidelines	Systematically developed statements to assist physician and patient decisions about appropriate health care for specific clinical conditions. Among the most widely employed educational techniques for modifying physician behaviour.
Critical pathways	Administrative models that streamline work and production processes to ensure delivery of quality care and decreased occurrence of medical errors. Another commonly used educational method to change provider behaviour.
Clinical decision support systems	Tools to assist clinicians in applying new information to patient care through the analysis of patient-specific variables (e.g., anticoagulation dosing calculators, computer-based differential diagnosis programs).
Accreditation, legislation, market driven, and other approaches	Other less conventional approaches to enhance patient safety through legislation, regulation, or commercial incentives that have potential for widespread implementation and impact.

*Sources: Shojania et al.[7]; University of California at San Francisco Evidence Based Practice Center.[17]

RECOMMENDATIONS FOR FURTHER STUDY

At this time, local, regional, and national reporting systems should be implemented, integrated, and evaluated in terms of effectiveness and cost to ascertain whether incident reporting systems provide a viable means by which medical errors can be reduced and patient safety enhanced. This suggestion is consistent with recommendations made in a report titled *Patient Safety and Healthcare Error in the Canadian Healthcare System* to Health Canada by Baker and Norton.[10]

Health care organizations and funding agencies should be encouraged and supported in efforts to focus on errors, adverse events, and near misses and to link this focus to system change and improvement. The following criteria should be met in an effort to increase the potential value of implemented incident reporting systems and to allow a quantitative assessment of their effectiveness:

- **Study design.** Evidence of efficacy should be obtained through prospective randomized, controlled studies or historically controlled cohort studies (retrospective or prospective), where outcome measures (adverse events, medical errors, and near misses with or without surrogate clinical outcomes) are performed by blinded or independent raters with measured inter-rater reliability.
- **Protocol design and standardization.** Different methods of detecting incidents should be compared against one another to assess the most effective incident tracking system(s) (e.g., morning report, chart audit, electronic vs. paper-based incident reporting, interview, observation). If organizational "interventions" are employed to prevent error recurrence, they should be consistent between tracking groups. If different organizational interventions are to be compared, reporting systems should be constant between interventions. Duration post-intervention should be a minimum of one to two years to bypass the increased reporting that is expected as familiarity and acceptance of the new system is established. The possibility of having multiple post-intervention time points should be considered to accommodate increased reporting expected following implementation of a new reporting system and to control for other unknown time trends in the case mix.
- **Patient selection.** Pre- and post-study groups should be randomly selected or at a minimum compared and described fully to exclude the possibility of time trends in the case mix and to control for confounding factors. Sample size and information needs to be sufficient enough to confirm that patients in two groups are comparable and to permit statistical analysis of outcomes.
- **Outcomes.** Outcomes should be well-defined and clinically meaningful, such as type, frequency, severity, classification of error, or incident per set number of admissions or patients. Relevant clinical outcomes should also be compared or

correlated to incident measures. To avoid outcome bias, several evaluators should independently evaluate incidents, a kappa statistic of inter-rater reliability should be computed, and discussion of all cases should take place until agreement is achieved.

More research is needed to evaluate other frameworks for risk reduction to determine which systems are most effective and feasible to maintain in the long term. System tools and change strategies will play a critical role in securing long-term benefits and compliance of any system employed for risk reduction and will likely become the main thrust of research and activities in the near future.

The following conclusions can be made:

- Despite more than 20 years of research in incident reporting and many countries implementing nation-wide reporting systems, studies evaluating a reporting system's effectiveness are limited in number and tend to be qualitative and poorly controlled. These factors limit the evidence upon which conclusions can be drawn.
- The nature of incident reporting, which is subject to hindsight bias, lost information, and contextual clues as a result of recall, makes it unlikely that robust data will link it directly with improved outcomes unless it is carefully designed.
- Incident reporting systems should include near misses; be non-punitive, confidential, or anonymous; involve multidisciplinary teams to investigate and improve care; focus on identifying aspects of the system that contribute to errors rather than blaming individuals; and provide feedback to all interested and involved parties.
- Studies evaluating the effectiveness, cost, and reliability of incident reporting systems are very limited in number. The studies suggest that incident reporting systems provide a fairly inexpensive although incomplete means for monitoring patient safety and, when combined with systemic interventions, may be effective in reducing preventable adverse events.
- Any use of incident reporting should include pre- and post-test measures of adverse events to better determine its effectiveness in enhancing patient care. Confounding factors should be controlled through study design, standardization, and appropriate outcome measures.
- The use of incident reporting needs to be considered in the context of other standard approaches to promote and implement patient safety practices.
- Alternative models for risk identification, including process mapping, audit and inspections, and medical record review, should be compared with incident

reporting systems and combined with them to determine the most effective suite of tracking method(s) for monitoring adverse events, incidents, and near misses.

- To successfully manage and minimize medical risk in institutions, a three-phase approach is required: risk identification, risk analysis, and risk control.
- Patient safety research must be better designed to incorporate economic approaches such as cost-benefit analysis to show where hospital resources can best be allocated.

APPENDIX A: METHODOLOGY

Incident Reporting Systems Search Strategy

Major electronic bibliographic databases, including MEDLINE, EMBASE, PsycINFO, and the Cochrane CENTRAL Register of Controlled Trials, were searched, as well as the Internet sites of major health technology assessment agencies. Search results were limited to documents published between 1994 and 2004.

Table A.1: Databases and search terms used

Database	Platform or URL	Search terms
MEDLINE Cochrane CENTRAL Register of Controlled Trials	OVID (1966 to October Week 3 2004) OVID (3rd Quarter 2004)	1. adverse event* ADJ5 tracking[Text Words] 2. adverse event* ADJ5 reporting[Text Words] 3. incident* ADJ5 tracking[Text Words] 4. incident* ADJ5 reporting[Text Words] 5. incident* ADJ5 reports[Text Words] 6. medical errors[MeSH Major topic] and (report* or track*)[Text Words] 7. 1 or 2 or 3 or 4 or 5 or 6 8. clinical trial[Publication Type] 9. controlled clinical trial[Publication Type] 10. evaluation studies[Publication Type] 11. meta-analysis[Publication Type] 12. randomized controlled trial[Publication Type] 13. review, academic[Publication Type] 14. clinical trials[MeSH Topic] 15. cost benefit analysis[MeSH Topic] 16. comparative study[MeSH Topic] 17. double blind method[MeSH Topic] 18. evaluation studies[MeSH Topic:not exploded] 19. meta-analysis[MeSH Topic] 20. outcome and process assessment (health care)[MeSH Topic] 21. program evaluation[MeSH Topic: not exploded] 22. prospective studies [MeSH Topic] 23. random allocation[MeSH Topic] 24. randomized controlled trials[MeSH Topic] 25. single blind method[MeSH Topic]

Database	Platform or URL	Search terms
MEDLINE Cochrane CENTRAL Register of Controlled Trials (cont'd)		26. assess or assessing or assessment[Text Words] 26. comparison* or comparing[Text Words] 27. cost effective or cost effectiveness[Text Words] 28. evaluat* or efficacy or effective*[Text Words] 29. improvement* or improving[Text Words] 30. RCT* or random*[Text Words] 31. (single or double or triple or treble) and (blind* or mask*)[Text Words] 32. systematic and (review* OR overview*)[Text Words] 33. 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 or 29 or 30 or 31 or 32 or 33 34. 7 and 34
NHS EED – NHS Economic Evaluation Database HTA Health Technology Assessment Database	University of York CRD http://www.york.ac.uk/inst/crd/crddatabases.htm University of York CRD http://www.york.ac.uk/inst/crd/crddatabases.htm	1. adverse event* and tracking[Text Words] 2. adverse event* and reporting[Text Words] 3. incident* and tracking[Text Words] 4. incident* and reporting[Text Words] 5. incident* and reports[Text Words] 6. medical errors[MeSH topic] and (report* or track*)[Text Words] 7. 1 or 2 or 3 or 4 or 5 or 6
EMBASE	OVID (1980 to 2004 Week 43)	1. adverse event* ADJ5 tracking[Text Words] 2. adverse event* ADJ5 reporting[Text Words] 3. incident* ADJ5 tracking[Text Words] 4. incident* ADJ5 reporting[Text Words] 5. incident* ADJ5 reports[Text Words] 6. medical error[EMBASE Major Topic] and (report* or track*)[Text Words] 7. 1 or 2 or 3 or 4 or 5 or 6 8. clinical trial[EMBASE Topic] 9. cost effectiveness analysis[EMBASE Topic] 10. comparative study[EMBASE Topic] 11. double blind procedure[EMBASE Topic] 12. evaluation[EMBASE Topic] 13. meta analysis[EMBASE Topic] 14. outcome and process assessment (health care)[MeSH Topic] 15. prospective study [EMBASE Topic]

Database	Platform or URL	Search terms
EMBASE (cont'd)		16. randomization[EMBASE Topic] 17. randomized controlled trial[EMBASE Topic] 18. single blind procedure[EMBASE Topic] 19. systematic review[EMBASE Topic] 20. assess or assessing or assessment[Text Words] 21. comparison* or comparing[Text Words] 22. cost effective or cost effectiveness[Text Words] 23. evaluat* or efficacy or effective*[Text Words] 24. improvement* or improving[Text Words] 25. RCT* or random*[Text Words] 26. (single or double or triple or treble) and (blind* or mask*)[Text Words] 27. systematic and (review* OR overview*)[Text Words] 28. 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 29. 7 and 28
CINAHL	OVID (1982 to November Week 1 2004)	1. adverse event* ADJ5 tracking[Text Words] 2. adverse event* ADJ5 reporting[Text Words] 3. incident* ADJ5 tracking[Text Words] 4. incident* ADJ5 reporting[Text Words] 5. incident* ADJ5 reports[Text Words] 6. incident reports[Subject] 7. adverse health care event[Subject] and (report* or track*)[Text Words] 8. 1 or 2 or 3 or 4 or 5 or 6 or 7 9. assess or assessing or assessment[Text Words] 10. comparison* or comparing[Text Words] 11. cost effective or cost effectiveness[Text Words] 12. evaluat* or efficacy or effective*[Text Words] 13. improvement* or improving[Text Words] 14. RCT* or random*[Text Words] 15. (single or double or triple or treble) and (blind* or mask*)[Text Words] 16. systematic and (review* OR overview*)[Text Words] 17. clinical trial or systematic review[Publication Types] 18. clinical trials[Subject] 19. comparative studies[Subject]

Database	Platform or URL	Search terms
CINAHL (cont'd)		20. cost benefit analysis[Subject] 21. evaluation research[Subject] 22. experimental studies[Subject] 23. meta analysis[Subject] 24. outcome assessment[Subject] 25. process assessment (health care) [Subject] 26. program evaluation[Subject] 27. prospective studies[Subject] 28. random assignment[Subject] 29. systematic review[Subject] 30. 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 or 29 31. 8 and 30
Cochrane Database of Systematic Reviews	OVID (3rd Quarter 2004)	1. adverse event* ADJ5 tracking[Text Words] 2. adverse event* ADJ5 reporting[Text Words] 3. incident* ADJ5 tracking[Text Words] 4. incident* ADJ5 reporting[Text Words] 5. incident* ADJ5 reports[Text Words]
PsycINFO	OVID (1872 to October Week 4 2004)	1. adverse event* ADJ5 tracking[Text Words] 2. adverse event* ADJ5 reporting[Text Words] 3. incident* ADJ5 tracking[Text Words] 4. incident* ADJ5 reporting[Text Words] 5. incident* ADJ5 reports[Text Words] 6. errors[Subject] and (report* or track*)[Text Words] 7. 1 or 2 or 3 or 4 or 5 or 6 8. assess or assessing or assessment[Text Words] 9. comparison* or comparing[Text Words] 10. cost effective or cost effectiveness[Text Words] 11. evaluat* or efficacy or effective*[Text Words] 12. improvement* or improving[Text Words] 13. RCT* or random*[Text Words] 14. (single or double or triple or treble) and (blind* or mask*)[Text Words] 15. systematic and (review* OR overview*)[Text Words]

Database	Platform or URL	Search terms
PsycINFO (cont'd)		16. clinical trial or double blind design or meta analysis or program evaluation or prospective study or single blind design [Form/Content Type] 17. costs and cost analysis[Subject] 18. evaluation[Subject] 19. meta analysis[Subject] 20. prospective studies[Subject] 21. 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 22. 7 and 22
ABI Inform Global	ProQuest (1970 to 2004)	1. incident* or adverse event* 2. track* or report* 3. 1 and 2
ECONLIT	EBSCO (1969 to 2004)	4. incident* or adverse event* 5. track* or report* 6. 1 and 2
UK National Coordinating Centre for Health Technology Assessment	http://www.ncchta.org/index.htm	adverse event* track* adverse event* report* incident* track* incident* report*
University of Laval Knowledge Utilization Database	http://kuuc.chair.ulaval.ca/english/index.php	adverse event* track* adverse event* report* incident* track* incident* report*
Canadian Coordinating Office for Health Technology Assessment	http://www.ccohta.ca/	adverse event* track* adverse event* report* incident* track* incident* report*
Health Quality Council of Saskatchewan	http://www.hqc.sk.ca	adverse event* track* adverse event* report* incident* track* incident* report*
BlueCross BlueShield Association	http://www.bluecares.com/healthprofessionals/tec.html	adverse event* track* adverse event* report* incident* track* incident* report*

Database	Platform or URL	Search terms
U.S. Agency for Healthcare Research and Quality	http://www.ahcpr.gov/	adverse event* track* adverse event* report* incident* track* incident* report*
International Network of Agencies for Health Technology Assessment	http://www.inahta.org/inahta_web/index.asp	adverse event* track* adverse event* report* incident* track* incident* report*
NZHTA Clearing House	http://nzhta.chmeds.ac.nz/default.htm	adverse event* track* adverse event* report* incident* track* incident* report*
Australian Safety and Efficacy Register of New Interventional Procedures – Surgical	http://www.surgeons.org/asernip-s/publications.htm	adverse event* track* adverse event* report* incident* track* incident* report*
Institute of Health Economics	http://www.ihe.ca/	adverse event* track* adverse event* report* incident* track* incident* report*

*Denotes truncation of a search term; ADJ# denotes term adjacency.

Results

Total number of abstracts reviewed from search: 1363

Total number of documents retrieved and reviewed: 361

Total number of articles included in report: 72

Limits (where available)

Searches were limited to human; publication dates: 1994 and 2004.

Searches were limited to studies in English.

Reference lists of the selected papers were also reviewed in order to identify additional relevant studies.

Inclusion Criteria

Studies and reviews on institutional incident reporting systems were compiled and reviewed for this report. To assess the effectiveness of implemented institutional

incident reporting systems, only studies with pre- and post-outcomes related to medical errors, adverse events, incidents, or health care cost were included, as indicated below. Eleven studies met the criteria for assessment of effectiveness of institutional reporting systems, as indicated in Table A.2.

Table A.2: Hierarchy of study designs

Level	Study type	Number
1	Randomized controlled trials	0
2	Non-randomized controlled trials—a prospective (preplanned) study, with predetermined eligibility criteria and outcome measures	0
3	Observational studies with controls—includes retrospective, interrupted time series (a change in trend attributable to the intervention), case-control studies, cohort studies with controls, and health services research that includes adjustment for likely confounding factors	4
4	Observational studies without controls (e.g., cohort studies without controls and case series)	7

Jovell and Navarro-Rubio published a classification scheme that comments on quality of evidence and whose assignment to categories is dependent on conditions of scientific rigour. This scheme forms the basis of the classification of studies in Table 5 into the following categories:

Good: Meta-analysis of randomized controlled trials (RCTs) or from large-sample RCTs

Good to Fair: Small-sample RCTs and non-randomized controlled prospective trials

Fair: Non-randomized controlled retrospective trials, cohort studies, and case-control studies

Poor: Non-controlled clinical series and various other approaches

In this review, the following definitions are used:

Efficacy refers to the performance of a technology under "ideal" conditions or conditions of best practice.

Effectiveness refers to the performance of a technology under "routine" conditions, for example, when it has become widely distributed in a health care system.

Appendix C lists studies excluded from this review because of lack of evidence of efficacy or effectiveness. A total of 83 papers were identified that reported incident data (severity, type, volume, and/or causality factors) of implemented institutional incident reporting systems but did not conduct post-test measures of effectiveness and thus did not meet eligibility for the review.

APPENDIX B: DEFINITIONS*

Adverse drug event
An adverse event resulting from a medication error or an unexpected or dangerous reaction to a drug. It is an unwanted effect caused by the administration of a drug. The onset of the adverse reaction may be sudden or may develop over time.

Adverse event
An event causing harm, misadventure, iatrogenic injury, or other wrongful occurrence directly associated with patient care. The event may or may not be preventable, given the current state of medical knowledge and practice, and can be classified by severity (e.g., significant, serious, life-threatening, or fatal).

Contributing factor
An antecedent to an event, effect, result, or outcome that is similar to a cause.

Critical incident
A type of incident that involves the significant loss of limb, function, or life.

Event without harm
An event without harm is one in which an act of omission or commission may have had the potential for harm but, through luck of robust physiology, had no ill effect on the patient.

Incident
An unwanted or unexpected change from normal system behaviour that causes or has a potential to cause an adverse effect to persons or equipment. It includes near misses, events without harm, adverse events, critical incidents, sentinel events, etc.

Incident reporting
A process to document occurrences that are inconsistent with routine hospital operation, policies, or procedures, or with patient care.

Latent condition or latent cause
The structural flaws in a system that contribute to error-producing factors.

Medical error
A type of error that occurs in the context of the provision of health care. There are four types of medical error: diagnostic, treatment, preventative, other.

Medication error
An error in the processing, ordering, delivery, or administration of medication.

Outcome
A product, result, or effect. In health care, outcomes may be measured in a variety of ways and reflect the physical or psychological well-being of the patient and associated costs.

Near miss
An incident that could have resulted in an accident, injury, or illness but did not, through chance, skilful management, or timely intervention.

Risk management
Organizational activities designed to prevent patient injury or moderate financial or organizational losses following an adverse event.

Root cause analysis
A process performed after an adverse event has already occurred to identify basic and contributing causal factors underlying variations in performance associated with near misses, adverse events, and sentinel events. Root cause analysis seeks to find common causes to improve performance.

Sentinel event
Unexpected occurrences involving death or serious physical or psychological injury or risk. Loss of limb or function not previously present requiring continued treatment or lifestyle change.

Source: Arah and Klazinga[73]

APPENDIX C: QUALITATIVE STUDIES OF IMPLEMENTED SYSTEMS

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