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Canadian Patient Safety Institute

ADVERSE EVENT REPORTING AND LEARNING SYSTEMS:

A REVIEW OF THE RELEVANT LITERATURE
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INTRODUCTION

Background

The Canadian Patient Safety Institute (CPSI) determined that a literature review of key published articles in the area of medical error, adverse event and critical incident reporting would be a useful tool to further understanding and insight into reporting systems in health care.

This review draws information from the published literature on adverse event reporting and learning systems in health care and classifies the information according to the following seven themes:

1) Governance and legislative frameworks for national reporting systems
2) Taxonomy, classification, and vocabulary used in data reporting and analysis
3) Technical considerations including reporting system software design and development and user issues
4) Anonymous reporting systems and confidential (but identifiable) reporting systems
5) Reporting by physicians/nurses/allied health professionals as well as patients and family members
6) Financial implications of reporting systems
7) Feedback systems in use to produce safety information from the data and to improve the safety of health systems

Search Methodology

The Librarian/Information Specialist for CPSI completed searches in the electronic health databases Medline, the Cumulative Index for Nursing & Allied Health Literature (CINAHL) and Embase, as well as the multidisciplinary electronic database Web of Science, which searched literature in scientific disciplines other than medicine and health care. The searches were designed to retrieve records that specifically discussed the technology, implementation, learning, or classification of reporting adverse events. The initial search (methodology detailed in the Appendix), identified 220 unique records, which were then limited to 121 resources by CPSI staff. Large scale or very detailed resources considered most relevant to the subject area were included in the 121 selected articles and all works deemed to be irrelevant, editorial, or single case studies were eliminated.

The creation of the literature review included a detailed review of these 121 documents, which were then further reduced to a selection of articles believed to best represent the seven themes described above. Additional publications to include in the review were identified from cross-references in the selected articles and were retrieved. Criteria for excluding articles from the review included the following:

- Not directly relevant to the field of patient safety/adverse event reporting and learning systems.

- Relevant to the field of patient safety/adverse event reporting but did not contain adequate information on any one of the seven themes (above).
- Relevant to the field of patient safety but did not provide an adequate description of adverse event reporting systems.
- Relevant to the field adverse event reporting but did not provide an adequate description of patient safety.

Glossary of Terms

The following terms are used commonly in the description of reporting systems and are defined as follows for the purposes of this literature review (note that all definitions are those of the author unless otherwise stated).

Reporting System – a formal or informal process whereby verbal or written accounts of health care related adverse events are shared with others, either internally within a department/facility/organization or externally with other interested parties. The purpose of a reporting system is often to provide a medium for sharing lessons learned and opportunities for improvement, and to prevent recurrence of similar incidents in the future.

Voluntary Reporting System – a reporting system whereby accounts of health care related adverse events are shared freely and/or spontaneously without compulsion from external authorities.

Mandatory Reporting System – a reporting system whereby accounts of health care related adverse events are compelled by law, policy/regulation, or by any other formal means.

Anonymous Reporting System – a reporting system whereby verbal or written accounts of health care related adverse events are shared without the inclusion of any identifiable details of the patient and/or care providers involved. The information contained in anonymous reporting systems is often less complete than information contained in confidential reporting systems.

Confidential Reporting System – a reporting system whereby accounts of health care related adverse events are shared with the inclusion of identifiable details of the care provider/providers involved to allow for follow-up and/or clarification of the reported incident with the individual who supplied the report. Once it is determined that the details supplied in the report are sufficient and further contact with the reporter is not required, identifying details are stripped from the report. The information contained in confidential reporting systems is often more complete than information contained in anonymous reporting systems.

Adverse Event – the Canadian Patient Safety Dictionary defines adverse event in one of the following three ways: "1. An unexpected and undesired incident directly associated with the care or services provided to the patient; 2. An incident that occurs during the process of providing health care and results in patient injury or death; 3.

An adverse outcome for a patient, including an injury or complication" (Davies et al. 2003). This term is preferred to other commonly used phrases such as "medical error" which can be interpreted to imply blame or fault on the part of the care provider.

Critical Incident – the Canadian Patient Safety Dictionary defines critical incident as the following: "an incident resulting in serious harm (loss of life, limb, or vital organ) to the patient, or the significant risk thereof. Incidents are considered critical when there is an evident need for immediate investigation and response. The investigation is designed to identify contributing factors and the response includes actions to reduce the likelihood of recurrence" (Davies et al. 2003). It is important to note that not all adverse events are critical incidents. Critical incidents are the most serious subset of adverse events.

Revision History

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December 1, 2006: verbal comments provided to author for version 2.0
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1) GOVERNANCE & LEGISLATIVE FRAMEWORKS

Establishing a Need for Adverse Event Reporting and Learning Systems

"*…the value of history lies in the fact that we learn by it from the mistakes of others – learning from our own is a slow process*" (Sykes 1960)

Adverse event reporting and learning systems in health care have the potential to improve safety for all patients through the analysis of reported events, dissemination of recommendations for system improvements, and the local implementation of leading practices. This is achieved while maintaining a system-based emphasis on seeking and understanding the lessons that can be learned. The use of incident reporting in health care can be traced to a landmark 1978 study examining adverse events in the field of anaesthesia (Cooper et al. 1978). Although the impetus for the study was the rising cost of malpractice insurance, the result of the investigation was an improvement in safety practices (Wagner et al. 2005). Since that time, other specialties and sectors of health care have adopted diverse process improvement models, including adverse event reporting and learning systems.

In 1999, the Institute of Medicine challenged the health care system to begin the process of making major reforms in patient safety through the publication of the document *To Err is Human: Building a Safer Health System* (Corrigan et al. 2000). This report recommends the establishment of a U.S. national mandatory reporting system in hospitals, followed by expansion beyond the hospital setting to every site where patients receive care as the next steps toward improving the safety of the health system for all patients.

Although *To Err is Human* was prepared by an American organization, the same guiding principles for the promotion and delivery of safe health care can be applied universally. Studies providing estimates of actual rates of adverse events in health care have been completed in many countries worldwide, including in Canada with *The Canadian Adverse Events Study* (Baker et al. 2004). This study established an estimate of the national rate of adverse events occurring annually in Canada as 7.5% of medical/surgical admissions in acute care hospitals, based on 3,745 chart reviews conducted in five provinces from admissions in the year 2000 (Baker et al. 2004). Approximately thirty-seven percent of these adverse events were deemed to be preventable in nature, which emphasizes that a significant opportunity exists for Canadian health care providers to improve the safety of the care provided to patients on a daily basis (Baker et al. 2004).

Another national initiative to improve patient safety in Canada is the creation of the Canadian Patient Safety Institute (CPSI), an independent not-for-profit organization established in 2004. The mandate of CPSI is to provide national leadership on the improvement of the safety of the health care system for all Canadians through collaboration with health professionals and organizations, patients and members of the public, regulatory

bodies, as well as provincial and national governments (CPSI 2006). Three key areas of focus for CPSI are the following:

1. To promote innovative methods of improving patient safety
2. To empower patients and their families with information and support
3. To establish a funding environment for research/analysis encouraging exploration, exposure, and resolution of patient safety issues (CPSI 2006).

Incentives and Barriers to Reporting: Lessons from Other Industries

Following the release of *To Err is Human*, some organizations have been quick to implement reporting and learning systems for adverse events and critical incidents, while others find the barriers to implementation of a reporting system insurmountable (Beverly 2001). One author (Beverly 2001), who is a nurse, hospital administrator and patient safety advocate in the U.S., identified nine key areas on which to focus efforts when developing and introducing a reporting system:

- Reforming education
- Creating a blame free culture within the organization
- Enhancing communication
- Participating in reporting device design
- Redesigning staffing levels to meet the demands of reporting
- Fostering a continuous learning environment
- Designing reporting systems
- Involving the patient and family in care
- Examining regulatory and legal implications

The Federal Aviation Association in the U.S. has been collecting reports of safety concerns and actual and potential incidents for over 30 years, and manages the reports in a non-punitive culture with an emphasis on system-based learning (FAA 2006). As a result, the aviation industry is often used as an example of implementing a successful reporting scheme to track events and disseminate recommendations for improving the safety of the system as a whole (Billings 1998). A successful system is one in which reports of actual and potential events are submitted, evaluated for safety improvements, and recommendations to improve safety are disseminated to all stakeholders and implemented (Billings 1998). Following the development of the U.S. Aviation Safety Reporting System in 1976, it became clear that in order to achieve success in a reporting system there are two key principles that must be met:

1. There must be a demonstrated, widely agreed-upon and tangible need for more and better information.
2. There must be a highly respected body, independent of the influences of other stakeholders of the system, to conduct the collection and analysis of the data (Billings 1998).

Barach and Small (2000) conducted an in-depth review of 25 non-health care related adverse event reporting systems, including those in the nuclear power, aviation, petrochemical, and aeronautical industries. From the review, they developed a list of the individual, organizational, and societal barriers and incentives to incident reporting; they note that these

are characteristics that can be similarly attributed to the health care industry (Barach and Small 2000).

For an adverse event reporting system to succeed, they established that there must be perceived incentives for professionals to report events voluntarily, completely, confidentially, and objectively, and those incentives must outweigh any perceived barriers (Barach and Small 2000). A useful reporting and learning system is one in which accountability is balanced with transparency and protection for reporters, and the reporting community is actively involved with the oversight of the system as well as support and advocacy (Barach and Small 2000). A successful system must also show a demonstrated ability to prevent, detect, and minimize the effects of undesirable combinations of design, performance, and circumstance that lead to adverse events (Barach and Small 2000).

Table 1. Incentives and Barriers to Implementing Reporting Systems (Barach and Small 2000)

	Individual	**Organizational**	**Societal**
Legal			
Barrier	Fear of reprisals, lack of trust	Fear of litigation, costs, sanctions undermine trust, bad publicity	Legal impediments to peer review, confidentiality, and multi-institutional database
Incentive	Provide confidentiality and immunity	Provide confidentiality and immunity	Ensure accountability, enforce reporting statutes
Cultural (values, attitudes, beliefs)			
Barrier	Dependent on profession, code of silence, fear of colleagues in trouble, skepticism, extra work	Dependent on organization, pathological, bureaucratic, generative cultures, don't want to know	Wide public trend towards disclosure, lack of trust owing to highly publicized medical errors, concerns that professions are too privileged, lack of education about systems effects
Incentive	Professional values, philanthropic, integrity, educational, cathartic	Become a leader in safety and quality, good for business	Enhanced community relations, build trust, improve health care, transparency
Regulatory			
Barrier	Exposure to malpractice, premiums will go up, investigation and potential censure, license suspension and subsequent loss of income	It doesn't apply to us, we do our own internal analysis process, they can't understand our problems anyway	Need more effective regulations, resource intense
Incentive	Prophylactic, follow the rules	Fear of censure	Enhances regulatory trust, more public accountability
Financial			
Barrier	Loss of reputation, loss of job, extra work	Wasted resources, potential loss of revenue, patient care contracts, not cost effective	Cost more tax dollars to enforce, more bureaucracy
Incentive	Safety saves money	Publicity relations, improve reputation of quality and safety	Improves confidence in health care system

National Adverse Event Reporting and Learning Systems

A review of the relevant literature revealed that several countries, including the United States, the United Kingdom, and Japan have published information on national adverse event reporting systems, both mandatory and voluntary in nature, that are in place to improve patient safety. Mandatory and voluntary incident reporting systems have traditionally both played a role in improving system safety, with mandatory systems often designed to track more egregious errors and voluntary systems intended to collect information on less serious errors including potential hazards and near misses (Thompson 2001, Dunn 2003). Both mandatory and voluntary systems have an important role to play in patient safety adverse event reporting and learning systems.

National Reporting in the United Kingdom

The U.K. initiated a national program to improve patient safety in 2000, when the Chief Medical Officer's report *An Organisation with a Memory* was published and drew public attention to the statistic that approximately one in ten patients admitted to a National Health Service (NHS) hospital suffered unintentional harm (Donaldson 2000). The key criticism outlined in the report was that the presence of a culture of blame and the lack of a national system for sharing lessons learned were acting as barriers to the identification and reduction of patient safety incidents (Donaldson 2000). In response to these criticisms, the NHS established the National Patient Safety Agency, which was in turn given the mandate of developing a National Reporting and Learning System (NRLS) (Leigh 2006).

The expectation for incident reporting is built into all organizational clinical governance agreements with NHS facilities (Ashcroft et al. 2005). The NRLS is an Internet-based, anonymous mandatory reporting system used to identify actual and potential adverse events, collect safety information from other existing sources, and develop and distribute solutions and lessons learned based on all information collected (Ashcroft et al. 2005, Leigh 2006).

The vision for the NRLS is to develop a reporting system that becomes an integral aspect of NHS culture with the capacity to:

- Actively identify risk
- Accurately and objectively record and report adverse events
- Analyze events and trends
- Learn from adverse events and disseminate findings
- Implement change to limit future recurrence (Bird 2003).

While the NHS has clearly stated that making the National Health System safer for patients is the cornerstone of clinical governance, a committee reviewing the progress to date has found that insufficient progress has been made towards achieving the goal of improving the safety of the NHS for patients (Leigh 2006). As a result, a number of specific recommendations have been made to improve the efficacy of the NRLS in years to come (Leigh 2006).

National Reporting in the United States of America

In *To Err is Human (2000)*, the Institute of Medicine recommended development of both nationwide mandatory and voluntary incident reporting systems to begin to allow health care providers to identify and learn from adverse events (Corrigan et al. 2000). The Quality of Health Care in America Committee of the Institute of Medicine, the committee responsible for preparing *To Err is Human*, stipulated that American state governments implement mandatory reporting systems that collect standardized information about incidents resulting in death or serious harm (Corrigan et al. 2000). Voluntary reporting systems should also be developed to complement the mandatory systems and focus on collection of information about adverse events causing minimal harm or near misses (Corrigan et al. 2000). Despite this call to action, very few state-wide reporting systems have been developed with the ability to record, track and monitor adverse events and allow organizations to accurately measure their safety environments (Carroll-Solomon and Denny 2005, Joshi et al. 2002).

The U.S. House and Senate passed an Act called the Patient Safety and Quality Improvement Act (Public Law 109-41) in July 2005 (Fong 2005). The bill included the following requirements:

- Create a U.S. national voluntary database of non-identifiable patient safety data to track trends and identify systems-based causes of medical errors resulting in minor injuries or near misses
- Identify patient safety organizations to collect and assess the confidential safety data (including the Agency for Healthcare Quality and Research)
- Make patient safety data privileged to prohibit it from being used against care providers in litigation or administrative proceedings
- Develop standards for communication of health information using information technology (Bleich 2005, Fong 2005, U.S. Department of Health and Human Services 2006).

By September 2005, 25 American states had passed legislation and/or regulations related to the reporting of critical incidents and adverse events occurring in a hospital setting (NASHP 2006). There are 22 U.S. states with mandatory reporting systems actually in place (Bleich 2005). All of these systems are designed to protect collected data, although they are generally established in statute and not in regulation (Bleich 2005). Of these 22 states, seven release incident specific data from their reporting systems, and fourteen release (or plan to release) aggregate reports only, and one is undecided about what information will be shared. Five of the states releasing aggregate data will also include data with individual facilities identified (Bleich 2005).

The requirements for these mandatory reporting systems vary from state to state. Some states only require reporting of incidents causing serious harm to patients, while others mandate the reporting of near misses or incidents that reached the patient but did not cause harm. Some states will release the name or names of practitioners involved, but none of the states release the names of affected patients (Weissman et al. 2005).

Seventeen American statewide public-private partnership patient safety coalitions have been formed, which focus on dissemination of best practices, mandatory and voluntary event reporting, educating policymakers and consumers, developing information technology,

professional accountability, and systems improvement (Bleich 2005). The National Academy for State Health Policy (NASHP) has developed a resource called the Electronic Patient Safety Toolbox for states to provide regulators or policy-makers with common instruments that can be used throughout the development and implementation of new incident reporting systems, or the modification of existing systems (NASHP 2006). Some of the information provided includes tools for collection and analysis of data, as well as the interpretation of data, and appropriate distribution of feedback to maximize system safety improvements.

National Reporting in Japan

Following a highly publicized case in Japan in 1999 where a case of mistaken identity resulted in two patients receiving incorrect heart surgeries, the government mandated a series of requirements for all facilities in the country (Nakajima et al. 2005). All facilities in Japan are now required to have a patient safety policy, collect information related to actual and potential harm, form a committee for the prevention of adverse events, and conduct staff education on patient safety (Nakajima et al. 2005). Tertiary care hospitals are also required to establish a division of patient safety, to employ a full time clinical risk manager, and to open a patient complaint office (Nakajima et al. 2005).

While these requirements are uniformly applied nationwide, it is up to each hospital or facility to develop their own incident reporting process and system. In Japan, the Organization for Pharmaceutical Safety and Research have also created a national voluntary reporting program for medication-related incidents, and the authors of a study on the effects of the voluntary program (Furukawa et al. 2003) indicate that a national mandatory medication incident reporting program will be introduced by April 2004.

Common Themes in Reporting and Learning Systems

Each incident reporting system is unique in its design, maintenance, and operation, however many share common traits in their purpose. These commonalities include maintaining patient and care provider confidentiality as a priority, and focusing on the use of information technologies and deidentified data to recognize problems with the delivery of care and health system rather than to launch reprisals against staff involved with the events (Gillespie 2001).

The success of incident reporting in the aviation industry, including NASA's Aviation Safety Reporting System and the U.K. Confidential Human Factors Incident Reporting Program, has encouraged the development of many similar incident reporting initiatives in the field of health care (Johnson 2003). An aviation-styled incident reporting system moves the focus away from the analysis of low frequency and high consequence events to the analysis of the more frequently occurring near miss events (Johnson 2003). Information about potential events and how to mitigate their occurrence in the future is published frequently in safety alerts, news bulletins, and on Internet websites (Johnson 2003). Many health care reporting systems, however, are still focused on reporting only the critical incidents where harm comes to patients and the great benefit of learning from potential events is lost (Johnson 2003).

There are several characteristics of a successful health care adverse event reporting system, including the following:

- Data are analyzed by independent organizations composed of subject matter and safety experts
- Timely feedback is provided to system users
- Suggests systems-oriented solutions to reported problems
- Participant organizations are responsive to suggested changes
- Non-punitive
- Confidential (Karsh et al. 2006).

Some reporting systems include penalty clauses for failure to comply in the legislative or regulatory requirements for mandatory reporting. The state of Florida, for example, can fine hospitals up to $250,000 for violations of the mandatory reporting system when they fail to report required incidents (Williams et al. 2003). In Japan, hospitals that do not comply with the patient safety infrastructure requirements are penalized by a reduction in government funding of 100 yen (or approximately $1) per patient per day (Nakajima et al. 2005). It is believed that these punitive measures have been somewhat effective at improving compliance with reporting requirements (Williams et al. 2003, Nakajima et al. 2005).

In both mandatory and voluntary systems, timeliness of reporting is very important. Webb and colleagues (1993) examined data reported to the Australian Patient Safety Foundation AIMS system (Australian Incident Monitoring Study), which collects anonymous and voluntarily submitted anaesthesia patient safety data. They determined that the longer the time lapse between when the incident occurred and when the report was filed, the more likely there was a selective loss in report of more minor incidents with less harm or no harm to patients (Webb et al. 1993). This means that there is a correlation between slow reporting timeframes and fewer reports of minor incidents (Webb et al. 1993). It is therefore important that report forms or online systems are immediately available to care providers following adverse events and that the importance of timeliness of report is stressed to frontline staff so that the maximum number of incidents, including those more minor in nature, can be reported (Webb et al. 1993).

The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) is the U.S. body responsible for accreditation of health care facilities. Every JCAHO-accredited facility is required to perform an in depth (root cause analysis) review following a serious care-related event; however, the details of the incident and the outcome of the review are reported to JCAHO on a voluntary basis (Williams et al. 2003). A study of U.S. states with mandatory reporting systems showed that very few incidents reported to the statewide system were also reported to JCAHO (Williams et al. 2003). For example, in 1999 there were 204 events with an outcome of patient death reported to the state mandatory reporting system in Florida, while only 1 comparable event was reported to JCAHO (Williams et al. 2003).

One disincentive to the JCAHO voluntary reporting system may be that information reported to JCAHO is not clearly protected from legal discovery during trial (Williams et al. 2003). Discovery is a pre-trial stage in a lawsuit where each party is able to request documents and other evidence through the use of subpoena, depositions, and requests for production (Williams et al. 2003). Another important point for consideration is that all incident

reporting is essentially voluntary, because regardless of the legislative or regulatory requirements, it is up to the individual care provider or facility to determine whether or not to comply with those requirements and report (Williams et al. 2003).

Charles Billings, former Chief Scientist at NASA Ames Research Center, reminds us to question the purpose for creating a new adverse event reporting system:

> "…there are enough reports of mishaps with potassium chloride, lidocaine, vincristine, and other drugs and devices to have made it very clear that a problem with these exists. The information that these events occur is already present. We may well ask what it is that keeps us from making progress on safety, given that we already know about the existence of these problems. What is added by more formal, elaborate (and expensive) incident reporting?" (Johnson 2003)

Adverse event reporting and learning systems are capable of yielding good insights into local problems and in ideal circumstances can identify regional or national patterns of failure, however, the users of the system need to be receptive of the information as feedback is provided and implement the necessary changes to make the health care system safer for all (Johnson 2003). Without this, reporting systems become merely tools for the collection of statistics (Leigh 2006).

2) TAXONOMY AND CLASSIFICATION SYSTEMS

Reporting adverse events to a national learning system will require a standardized taxonomy for coding and classification of events to ensure the reported data is appropriately categorized and prepared for analysis. Health care adverse event reporting systems differ among organizations and facilities in how they define, count, and track events as well as how information is coded and analyzed, which makes comparisons between systems complicated and sometimes impossible (Loeb and Chang 2003). Inconsistency in the definition, classification, and measurement of adverse events has been shown in the past to hamper the establishment of effective voluntary and mandatory reporting systems (Thompson 2001).

Individuals given the task of developing a new reporting system often find the lack of a standardized taxonomy and clear definition of reportable events to be difficult to overcome (Kivlahan et al. 2002). The more generic and widely accepted definitions of adverse events and/or critical incidents are not specific enough to guide the daily practice of health care workers in deciding when to provide a report (Kivlahan et al. 2002). For a patient safety classification system to be truly effective, the data collected and analyzed must be used to inform the development of strategies for reducing the occurrence of adverse events, or to minimize the harm to patients if they do occur (Loeb and Chang 2003)

When developing the National Reporting and Learning System (NRLS) in the U.K. in 2002, system administrators at the National Patient Safety Agency (NPSA) learned that there was not a single agreed-upon national taxonomy for collecting and organizing patient safety data that covered all care settings in existence in any country (Williams and Osborn 2006). The NPSA reviewed what was available and brought together a team of 300 clinicians and managers to create a new taxonomy suitable for the U.K. context (Williams and Osborn 2006).

Any organization developing an adverse event reporting and learning system might choose to take advantage of a previously existing classification system, such as the World Health Organization International Classification of Diseases codes (ICD), however this has proven complicated because this coding scheme was designed for economic purposes rather than patient safety and it has been difficult to retrofit the ICD coding to suit the purposes of a newly developed incident reporting system (Young 2001).

The World Health Organization (WHO) has recently recognized that the ability to classify, aggregate, and compare patient safety information across differing data collection systems would be of significant benefit to improving patient safety internationally (Lewalle 2006). In order to facilitate these comparisons, an internationally agreed upon classification system for adverse events and near misses needs to be developed. The WHO has initiated the process of development of an international patient safety taxonomy, called the IPSEC (International Patient Safety Event Classification), which will define, harmonize, and group patient safety concepts into an agreed upon classification in such a way as to promote learning and improving patient safety across systems (Lewalle 2006). The IPSEC, currently in the

preliminary stages of development, is intended to be adaptable across cultures and languages and yet consistent throughout the entire spectrum of health care (Lewalle 2006).

Subjectivity in Reporting Systems

System administrators in Missouri deliberately decided to not constrain what patient safety events could be reported with the inclusion of stringent definitions, and instead chose to allow the event reporter to define both the event and harm level, after which the department managers would determine an appropriate level response for the event (Kivlahan et al. 2002). However, the potential workload involved with categorizing these subjective reports would make this style of reporting highly unsuitable for any large scale reporting system (Kivlahan et al. 2002).

Even reporting systems with more complete classification schemes are open to subjectivity in reporting. A medication error reporting system at Johns Hopkins Children's Center in Baltimore found that despite a full complement of descriptive categories of events, almost 60% of the time reporters chose the non-descript "other" category on the reporting tool (Miller et al. 2006). In order to maximize the opportunities for system improvements, it is important to have incidents commonly classified for investigation, analysis and feedback (Lewalle 2006). While an "other" category may be necessary, and indeed desirable, to ensure that all appropriate incidents are reported, it is in the best interests of system administrators that as many incidents as possible are classified into specific categories to allow for improved analysis and detection of potential system improvements.

In the U.K., the requirements for clinical risk management are nationally guided, although the incident reporting systems are locally established (Tighe et al. 2006). Staff members in one emergency department are asked to report on any incident that concerns them or that might endanger a patient (Tighe et al. 2006). A more sophisticated system may include a designated list of incidents that trigger a report, although employees are still able to report on other issues that do not fall into these defined categories (Tighe et al. 2006).

Examples of Classification Models

Eindhoven Classification Model

The Eindhoven Classification Model (Van der Schaaf 1992), was originally developed for the chemical processing industry and has been adapted for use in health care incident reporting frameworks (Battles et al. 1998). The classification model describes adverse events in two distinct categories: those involving latent errors, and those involving active error (Battles et al. 1998). A latent error is one that results from an underlying failure in the system, whereas an active error or human error is one that is precipitated by a human behaviour (Battles et al. 1998).

Table 2. Classification of Latent and Active Errors
(Battles et al. 1998)

Category	Description
Latent errors **Errors that result from underlying system failures**	
Technical Refers to physical items, such as equipment, physical installations, software, materials, labels, and forms	
External	Technical failures beyond the control and responsibility of the investigating organization
Design	Failure due to poor design of equipment, software, labels, or forms
Construction	Correct design was not followed accurately during construction
Materials	Material defects not classified under design or construction
Organizational	
External	Failures at an organizational level beyond the control and responsibility of the investigating organization
Transfer of knowledge	Failures resulting from inadequate measures taken to ensure that situational or domain-specific knowledge or information is transferred to all new or inexperienced staff
Protocols/procedures	Failures related to the quality and availability of the protocols within the department (too complicated, inaccurate, unrealistic, absent, or poorly presented)
Management priorities	Internal management decision in which safety is relegated to an inferior position in the face of conflicting demands or objectives. This is a conflict between production needs and safety (e.g. decision about staffing levels)
Culture	Failures resulting from collective approach to risk and attendant modes of behaviour in the investigating organization
Active errors (human) **Errors or failures resulting from human behaviour**	
External	Human failures originating beyond the control and responsibility of the investigating organization
Knowledge-based behaviours	
Knowledge-based errors	The inability of an individual to apply existing knowledge to a novel situation
Rule-based behaviours	
Qualifications	Incorrect fit between an individual's qualifications, training, or education and a particular task
Coordination	Lack of task coordination within a health care team in an organization
Verification	Failures in the correct and complete assessment of a situation, including relevant conditions of the patient and materials to be used, before starting the intervention
Intervention	Failures that result from faulty task planning (selecting the wrong protocol) and/or execution (selecting the right protocol but carrying it out incorrectly)
Monitoring	Failures during monitoring of process or patient status during or after intervention
Skill-based behaviours	
Slips	Failures in performance of fine motor skills
Tripping	Failures in whole-body movements
Other	
Patient-related factor	Failures related to patient characteristics or conditions that influence treatment and are beyond the control of staff
Unclassifiable	Failures that cannot be classified in any other category

Victoroff Multiaxial Taxonomy

The Victoroff (2006) multiaxial taxonomy of medical errors was used by Fernald and associates (2004) when developing the Applied Strategies for Improving Patient Safety (ASIPS) primary care reporting system. The ASIPS multiaxial classification system consists of five domains and ten axes (Table 3) (Fernald et al. 2004). Each event report must include an applied code for each axis, although multiple codes may be used within any single domain (Fernald et al. 2004). The taxonomy includes a detailed description of the following domains: outcome, course of the event, participants, and event discoverer; a fifth domain, patient information, was collected, however the data is not used for the purposes of analysis (Fernald et al. 2004).

Table 3. ASIPS Multiaxial Taxonomy
(Fernald et al. 2004)

Domain	Axis
Patient information	
Outcome	Harm
	Resultant interventions as result of error
Course of event	Type of event (can never be 'unknown')
	Location
	Intent
	Event process (can never be 'unknown')
	Cause
	System
Participants	Participants
	Contribution
Discovered by	

Other Classification Models

The Joint Commission for the Accreditation of Healthcare Organizations in the U.S. developed a patient safety taxonomy that integrates several existing patient safety event classification systems and is intended to be broadly applicable to any incident resulting from patient care regardless of setting or type of event (Chang et al. 2005). The taxonomy has four root nodes (impact, type of event, causes, and domain) which are broken down into a further 14 secondary classifications that again branch into 140 coded categories with the flexibility to include free-text in addition to the coded responses (Chang et al. 2005).

One example of how many varied classification systems are currently in use can be seen by examining the coding for harm or the level of impact an event has on the patient involved. Carroll-Solomon and Denny (2005) use 11 categories to classify incidents according to the level of impact on patients, while Jones and associates (2004) describe nine categories of harm (Jones et al. 2004), and Fernald and colleagues (2004) use five. The review of relevant literature highlights that a trade-off exists between quality of data and ease of use of the system: to have eleven ways to classifying severity of an incident allows for a more complete understanding of the harm that did or did not occur. The more categories a system contains, however, the more complicated it becomes for users and the more elaborate the requirements are for data analysis.

Table 4. Examples of Severity Categories in Incident Report Systems
(Carroll-Solomon and Denny 2005, Jones et al. 2004, Fernald et al. 2004)

Carroll-Solomon and Denny	Jones et al.	Fernald et al.
Unknown	Circumstances have the capacity to cause error	No known harm (a combination of no reported harm and unknown)
Safety environment	An error occurred, but the error did not reach the patient	Unstable (too early to ascertain harm)
Near miss	An error occurred that reached the patient but did not cause harm	Nonclinical harm
No harm – no increased monitoring	An error occurred that reached the patient and required monitoring to confirm that it resulted in no harm to the patient and/or required intervention to preclude harm	Future risk of clinical harm
No harm – increased monitoring	An error occurred that may have contributed to or resulted in temporary harm to the patient and required intervention	Clinical harm
Temporary harm – no treatment	An error occurred that may have contributed to or resulted in temporary harm to the patient and required initial or prolonged hospitalization	
Temporary harm – minor treatment	An error occurred that may have contributed to or resulted in permanent patient harm	
Temporary harm – major treatment	An error occurred that required intervention necessary to sustain life	
Permanent harm	An error occurred that may have contributed to or resulted in patient death	
Near death		
Death		

Relational Databases

Most large-scale reporting systems use a relational database for the storage of reported information (Johnson 2003). A relational database is one that consists of a collection of relations, or tables, where data is organized into rows and columns of information with the same attributes (Johnson 2003). This type of database is unique in that all data stored within a given column should be in the same domain and consist of the same data type, while neither the rows nor the columns should have an order to them (Johnson 2003).

Relational databases store incident data according to the classification of the incident as entered by the individual who filed the report, however problems will occur when the taxonomy changes (Johnson 2003). Change in taxonomy is seen as inevitable over time as our health systems transform and as the involvement of human factors is altered to represent changing provider roles in health care (Johnson 2003). "The net effect is that, in 10 years time, we may have to go back into our electronic databases and manually reclassify many hundreds of thousands of reports to reflect a revised taxonomy." (Johnson 2003) The effort and necessary expense associated with transforming a dataset in the future as demonstrated by Johnson (2003) highlights the importance of creating as complete a taxonomy as possible from the outset so as to minimize the need for future changes in the short- or medium-term.

3) TECHNICAL / DESIGN CONSIDERATIONS & USER ISSUES

Application and User Interface Design

Developing a new incident reporting system, whether it involves paper or electronic forms, should include extensive consultation with future users to ensure that the design of the system meets the needs and expectations of the users entering reports, as well as the users extracting data from the reporting system for the purposes of improving patient safety. For example, when creating a community pharmacy patient safety reporting initiative in the United Kingdom as part of the National Reporting and Learning System, extensive focus group testing was conducted prior to implementation to determine user preferences as well as comprehensiveness, validity, feasibility and sensitivity of the report form (Ashcroft et al. 2005). In this system, users exhibited a strong preference for report forms and systems that are easy to use, allow for anonymity, and complement existing working practices in the community pharmacy (Ashcroft et al. 2005).

Prior to the creation of a Wisconsin statewide patient safety incident reporting system, Karsh and colleagues (2006) conducted an extensive study exploring barriers and facilitators to the development of the reporting system and created theories of technology acceptance, adoption, and implementation associated with the process. In order to make users of this new incident reporting system comfortable with the process, they determined instructions should be provided that clearly stated the goals, mechanics, limitations and protections of the system (Karsh et al. 2006). Consultation with participants identified a preferred optimal time frame of approximately two minutes to complete a report, and that in no circumstances should it require more than five minutes to file (Karsh et al. 2006).

There were varying opinions on whether reports should be filed immediately following the occurrence of the incident, or whether users should be able to report at any time following the event (Karsh et al. 2006). Participants indicated a preference for a pluralistic system, that is, a system in which there are varying mediums available for reporting, such as electronic, telephone, or paper forms (Karsh et al. 2006). These requirements are suitable to diverse work environments for multiple professions as well as personal comfort level with varying reporting methods. The key component to reporting is that regardless of the mode of report, it be consistently available and provide all individuals within the organization an equal opportunity to report (Karsh et al. 2006).

Paper forms are often not considered ideal choices for reporting incidents based on the following reasons:

- Legibility/interpretation of hand-written comments
- Lost time while forms are passed through appropriate hands/sitting on desks prior to resolution of incident
- Loss of confidentiality if form is seen by others on a desk or in an inbox
- Lack of space to adequately describe event information on one form (Maass and Cortezzo 2000).

For reasons such as these, many patient safety experts consider paper-based reporting systems to be ineffective (Atherton 2002). Staff can be confused about which form to use, how to fill them out, where to send them once completed, and who is responsible for follow up (Atherton 2002). Error is also introduced with the flow of paper from desk to desk, where there exist multiple opportunities for misplacement or misdirection (Atherton 2002). The time required to track incidents and implement system improvements can be reduced by 25-50% when moving from paper reporting to electronic reporting that allows incident reports to be immediately viewed online by managers or other individuals responsible for investigating reports and instituting system-based improvements (Atherton 2002). An electronic reporting system can also ensure the comprehensiveness of data reported by eliminating the need to choose the correct form. As well, all appropriate information fields necessary can be selected automatically and completed with the use of automated prompting for further information given the unique circumstances of each event, as well as directing completed reports to suitable personnel for evaluation of risk and design and implementation of improvement initiatives (Atherton 2002).

Using an electronic incident reporting system has been found to support an organization's ability to have immediate access to descriptive data about adverse events and near misses, and subsequently facilitates the implementation of system improvements and interventions to improve safety overall (Avery et al. 2005). An electronic incident reporting system allows for trending and analysis of data to be performed at the level of the unit, facility, system, or organization, which meets the needs for both process improvement and risk management (Dixon 2002). Electronic forms are considered to be a more secure, confidential, and accurate method of reporting patient safety incidents than the paper forms previously used (Dixon 2002). Developing a new electronic system for the purpose of reporting adverse events can also be seen as an opportunity to do the following:

- Update current data sets and standardize them across the health care system
- Create a risk stratification model with an associated alert mechanism
- Serve as a tool for researching trends and setting benchmarks
- Increase the efficiency, effectiveness, and accuracy of current processes for capturing patient safety data
- Make real-time individual and aggregate data available to facility administration and management
- Comply with external regulatory guidelines and standards (Dixon 2002).

A further six benefits of utilizing an electronic adverse event reporting system have been described as follows:

- Simplifying the reporting process for frontline employees
- Eliminating multiple forms required to report critical incidents
- Increasing the quantity and quality of occurrence reporting data
- Improving response time by linking reports to department leadership and key personnel
- Improving evaluation and follow-up through a structured framework
- Enhancing the quality and safety of patient care and the employee work environment (Avery et al. 2005).

Battles et al. (1998) used a three round Delphi consensus process with a panel of 23 experts in three countries to establish ideal design parameters and functions for a prototype system to capture actual and potential critical incidents in the area of transfusion medicine. The Delphi methodology uses a skilled third-party facilitator who analyzes an expert panel's responses to anonymous questionnaires and uses structured feedback to lead the group through the process of consensus-building (Battles et al. 1998). The expert panel arrived at the following 25 parameters or system characteristics to be included when designing adverse event reporting system software:

Table 5. Ideal Parameters for Reporting System Design
(Battles et al. 1998)

System Characteristics
Overall
Collect and analyze reports of errors and interpret results
Nonreprisal system, no adverse consequences are attributed to the reporter
Report all errors, including no harm and near miss
Solicit input from anyone with firsthand information about an error or event
Solicit input from all those involved in the error or event
System Input
Have the ability to track back from the reported error to the root cause
Identify the specific procedures involved
Indicate whether there was misidentification of patient, or product
Indicate the location of the error in the process
Identify any equipment malfunctions involved in the event or error
Data Collection
Allow further contact with reporters for data clarification while maintaining confidentiality
Make blank report forms available to all who might wish to report errors or events
Emphasize narrative descriptions of events (usefulness of reports resides in the narrative)
Use adaptable, online interactive computer system for easy reporting
Have a trained system operator with knowledge of domain to receive reports
Analytical Process
Look beyond a single error to the entire system
Categorize errors as to where they occurred in the process
Identify links between active human errors and latent system failures
Categorize errors as slips, mistakes, or system design errors
Identify common problems across institutions
Intervention
Find underlying system failures by analysis of all errors
Make recommendations based upon error analysis to appropriate levels of decision makers
Target problem areas prone to error for additional study
Track implemented corrective actions to determine their effectiveness
Develop intervention strategies by multidisciplinary groups

Use of Information Technology

Changes in the availability and the widespread use of new information technologies have the ability to impact an adverse event reporting and learning system. The use of personal digital assistants (PDAs) by physicians at patient bedside has grown in recent years. Pilot studies in the field of anaesthesia medicine explored the use of PDAs for recording cases and complications, and found adoption of this new method of data gathering to be acceptable by the professional community (Bent et al. 2002, Bolsin et al. 2004, Bolsin et al. 2005). A

cancer treatment center in Nashville, Tennessee, has implemented the use of wireless computer technology to allow point-of-care incident reporting as well as to allow the on-demand retrieval of patient support information to permit the team to better care for immediate patient needs at the time of the event (France and Cartwright 2003). While there may be support for using PDAs as one mode of submitting incident reports, the expense associated with providing PDAs to all frontline staff for the purpose of reporting events may be seen as a deterrent to implementation of a broad event reporting and learning system. One option is to design an electronic reporting system with the ability to be accessed from either a PDA or a computer terminal. In this way, multiple front line staff members who do not have PDA technology would be able to use shared access to a computer workstation to utilize the event reporting system.

The Risk Prevention and Management computer system developed by Baylor Health Care in Dallas, Texas includes an interactive education program as a component of the incident reporting software (Joshi et al. 2002). The system also features three reporting modules (anonymous, confidential, and near miss) and a virtual classroom that provides interactive education, as well as links to patient safety educational resources, together with a real-time risk analyzer (Joshi et al. 2002).

Over 300 organizations in the U.S. are using an electronic, Internet-based medication safety event reporting program developed by U.S. Pharmacopeia called Medmarx® (Gillespie 2001). The Medmarx system uses standardized medication error report forms to collect data on actual and potential events, which are then submitted to a national reporting center (U.S. Pharmacopeia 2006). The company then shares information on the quality of health care provided and compliance with technology standards with their member organizations (Gillespie 2001). Access to the Medmarx system is by paid subscription, and permits the sharing of knowledge and experiences among all participating health care facilities and organizations, regardless of connectedness or affiliation (U.S. Pharmacopeia 2006).

Using information technology resources as a method for the collection and transmission of patient safety data highlights the importance of ensuring that data is collected and stored securely. For example, the Medmarx system requires user names and passwords, as well as a unique facility identification code, in order to report an incident. The facility identification code is a random number generated by the Medmarx database and the company responsible for the program, U.S. Pharmacopeia, does not know which facility is assigned each identification number (Gillespie 2001). As well, the Medmarx system uses secure socket layer encryption technology (a security feature using endpoint authentication and cryptography to ensure the privacy of communications over the Internet) to protect the data during transmission to the central database (Gillespie 2001).

Administrators at Dartmouth-Hitchcock Medical Center in New Hampshire created an online Event Reporting Management System (ERMS) that utilizes several nationally-accepted taxonomies for the classification and grouping of each type of event (Avery et al. 2005). The electronic form uses branching logic, where the response to a particular question drives the appearance of the subsequent follow-up questions to be answered while completing the online data entry of information. Once a report is submitted, designated department personnel (such as risk managers or directors of quality and safety) receive immediate email

notification of the occurrence, and the system simultaneously sends email notification to the incident manager responsible for the type of occurrence reported. The incident manager follows up by reviewing the reported event and implementing changes.

The ERMS facilitates analysis of incidents, including graphic displays and comparison of information within the organization (Avery et al. 2005). The system has been credited with the following improvements to patient safety for their organization:

- Simplifying the reporting process for frontline staff
- Eliminating multiple forms used to report adverse events
- Increasing the quality and quantity of occurrence data
- Improving response time by linking reports to department leadership and key personnel
- Improving evaluation and follow-up through a structured framework
- Enhancing the quality and safety of patient care and the employee work environment (Avery et al. 2005).

Common Themes in the Design of Reporting and Learning Systems

Regardless of the specific nature and unique attributes of an adverse event reporting and learning system, there are several categories of pertinent details that should be included in all patient safety databases. When planning for the U.K. National Patient Safety Agency incident reporting system, the minimum data set was determined at the outset to contain the following information:

- What happened (description, severity of actual or potential harm, people and equipment involved)
- Where it happened (location/specialty)
- When it happened (date/time)
- How it happened (immediate causes)
- Why it happened (underlying causes)
- What action taken or proposed (immediate and longer term)
- Impact of event (harm to the organization, patient, other)
- Factors that did, or could have, minimized impact (Lipley 2001)

Other Considerations

When developing an electronic incident reporting tool, one important consideration is whether to allow users to enter free text data (i.e. fields that allow users to describe incidents in their own words) or to allow only structured data (i.e. check boxes or pre-determined selections from a drop down menu). While structured data can be entered more quickly and is easier to analyze, users of one incident reporting database have expressed a preference for a system with free text data fields because it allows them to provide context for the incident and to give a more rich account of what occurred (Holzmueller et al. 2005).

An advantage of the ‘point and click’ nature of a menu-driven electronic incident reporting system is that it provides structure and consistency for the content of reports. The

advantages of these reports versus unstructured or free text reports include a reduction in documentation time, improved quality of the data elements collected, and more efficient methods are available to analyze the data reported so system improvements can be enacted more rapidly (Wagner et al. 2005).

There exists a widespread but mistaken belief that computer-driven incident reporting systems are low cost and simple to operate (Johnson 2003). In fact, there are many complicating factors that need to be considered when developing an electronic incident reporting database and user interface. Johnson (2003) points out that many existing electronic reporting systems are deeply flawed in their design, which severely limits their usability. One example is when a user logs on to the system to report an incident, and the entry screen of the computer program features a logo that is easily visible and widely recognizable (Johnson 2003). The confidentiality of the report is then jeopardized because many health care workers are using shared computer workstations within visibility of coworkers, patients, and family members and it can also serve to discourage reporting altogether (Johnson 2003). User acceptance testing following the initial design phase can identify this type of problem prior to the system being widely implemented (Johnson 2003).

Another complicating flaw in design is the ability of the computer program to recognize the distinct nature of the incidents that will be reported. One system forced the user to identify the day, month, and year of the incident as well as the time the incident occurred. However many adverse events happen over a period of minutes, hours, or days, and may include multiple components, thus making accurate entry of the incident impossible (Johnson 2003). Again, this flawed design could be avoided through user acceptability testing of the system prior to implementation, or by utilizing design staff with a familiarity in the area and the ability to predict this type of problem prior to implementation (Johnson 2003).

When developing an adverse event reporting database it is essential to recruit user interface designers who are able to assist frontline staff through acceptance testing to accurately enter information about complex critical incidents into the database (Johnson 2003). It is also of critical importance to recruit specialists with expertise in the storage and retrieval of large datasets, and to explore alternatives to relational databases such as the use of free text retrieval, which will allow greater flexibility as taxonomies change over time (Johnson 2003).

Users of adverse event reporting systems need to be able to search through existing records in a timely and efficient manner. When software engineers are developing a reporting system, the balance of precision and recall of the system's querying capabilities needs to be appropriate for the specific use of each system (Johnson 2003). For example, a high recall query will return greater volumes of records including a large number that upon examination will be deemed irrelevant. A high precision query will return a small volume of records that are highly appropriate for the user's purposes but other relevant documents may be missed. There are important safety implications to consider for each type of system: a low recall system can defeat the purpose of compiling reports by failing to identify potentially similar incidents, while a low precision system can increase the burden for the user who is required to manually sort the relevant reports from those that are not appropriate (Johnson 2003).

One incident reporting system in a radiology department in France included a management verification step in the report submission process (LeDuff et al. 2005). After a user enters a report, the appropriate manager receives an automatic system-generated email notifying of the incident, and the manager must review the incident and accept it as 'valid' before it is sent to the facility risk manager (LeDuff et al. 2005). This may lead to employees who are intimidated at the prospect of their manager's review of the incident details and choose to not report (LeDuff et al. 2005).

When deidentified information is reported to a national incident reporting system, it is important to make certain that the information is given legal protection (Pace et al. 2003). If legal protection cannot be ensured, then it is important to make certain that the information is not "re-identifiable," that is, that it is not possible to identify an individual incident in a specific facility based on the information provided (Pace et al. 2003). For example, the date and time the incident occurred may allow the linking of an incident report to a known event. In this way, a database created for the purposes of incident reporting will need to meet specific requirements pertaining to date/time relationships, including the ability to link all information pertaining to a single event in a manner that does not identify the time (absolute or relative) the event was reported or the place it occurred without losing any internal event chronology and to manage the data collection without time/date markers (Pace et al. 2003).

While the discussion in this section clearly indicates a trend to move toward the online reporting of patient safety incidents, a recent study of voluntary reporting in a surgical intensive care unit in Missouri found that moving from an online reporting system to a paper form (a brief card with checkboxes and text fields to be completed by hand) increased physician reporting nineteen-fold (Schuerer et al. 2006). In order to encourage participation from all user groups, the forms provided and the technology used must be appropriate and acceptable to the targeted populations. User acceptance testing during pilot phases will help make this determination.

It is important to remember that technology alone can neither guarantee nor drive incident reporting volumes; the computerization of incident reporting systems should instead be seen as a tool to assist in data collection where reporting remains the responsibility of individuals and is dependent on both the culture and values of the organization in which individuals work (Dixon 2002).

4) ANONYMOUS AND CONFIDENTIAL REPORTING SYSTEMS

Ensuring the confidentiality of both the adverse event data and the person who provides the report is of utmost importance when designing reporting and learning systems. The most obvious method of ensuring confidentiality of the reporter is to have incident reports filed anonymously. However, anonymity is not always possible and is also not always the desirable choice in reporting critical incidents because analysts are unable to contact the individual who filed the report if further information or clarification is required (Barach and Small 2000). It has also been suggested that anonymous reports may be less reliable than their confidential counterparts (Barach and Small 2000). Barach and Small suggest that although an anonymous system may be criticized for its lack of accountability and transparency, it may be important to provide anonymity early in the evolution of an adverse event reporting system until trust is developed and frontline staff are able to see practical results and believe they will not be professionally disadvantaged for reporting incidents, at which time confidential reporting can be introduced (Barach and Small 2003).

A demonstration project involving the development of a primary care safety reporting system in Colorado allowed care providers the freedom to choose whether to submit event reports using an anonymous form (which contained no identifying details of the care provider or providers involved, or of the individual who provided the report) or a confidential form (which contained identifying information for the sole purpose of allowing further contact with the reporter if the information provided was incomplete or further clarification of the issue was required) (Fernald et al. 2004). After two years of operation of this dual reporting system, they found that the confidential reporting process was used for reports two-thirds of the time (Fernald et al. 2004). These confidential reports were also significantly more likely to contain codeable data than their anonymous counterparts (Fernald et al. 2004). The level of harm reported did not vary significantly between either the confidential or anonymous system, however clinicians were more likely to use the anonymous system when filing reports and administrative staff were more apt to use the confidential system (Fernald et al. 2004).

The U.S. Agency for Healthcare Research and Quality has funded the development of a voluntary patient safety reporting system and database that captures both anonymous and confidential reports of both actual and potential adverse events and critical incidents in a primary care practices in Colorado (Pace et al. 2003). Incidents can be reported electronically on the Internet, through completion of a paper form, or by an automated telephone hotline; users are given the choice of reporting confidentially (which includes identifiable information such as name and phone number that is held in confidence) or anonymously (Pace et al. 2003).

Some reporting systems utilize confidential reports that are quickly stripped of all identifiable information once the completeness of the data is verified (Pace et al. 2003). These confidential reports have been shown to provide better detail than anonymous reports, however concerns exist about whether the confidentiality of these reports can be maintained should the database be subjected to legal discovery or another security breach (Pace et al.

2003). As well, standard dataset elements such as date, time, or location could allow outside sources to link a reported incident to a specific event (Pace et al. 2003).

Anonymous reports do not allow the opportunity for follow-up questions and as such typically provide less detail than confidential reports. As a result, they do not usually contain sufficient information to understand the root causes of the adverse event (Pace et al. 2003). In the Colorado patient safety reporting system, the confidential report is briefer, and is followed by a telephone interview where the reporter is prompted to answer a series of more specific questions on the incident and further detail is elicited. Users of this system exhibit a preference for the confidential reporting system because of the shorter time required to complete the form, and system administrators prefer the confidential reporting system because of the higher quality data they are able to elicit through the telephone interview (Pace et al. 2003).

If the primary reason for collecting and analyzing reports of adverse events is to develop systems for error reduction or mitigation, then confidential reports have been shown to be the preferable choice when compared to anonymous reports (Pace et al. 2003). This choice is supported by the experience of the U.S. Federal Aviation Administration safety reporting system whose developers felt so strongly that confidential reports provide superior information that their systems will no longer accept anonymous reports (Pace et al. 2003).

If an organizations is shifting from an anonymous system to a confidential adverse event reporting program, studies have shown that any apprehension on the part of care providers can be reduced or alleviated if they can be reassured that organizational processes related to the critical events reported will actually change (Mekhjian et al. 2004). As with all reporting and learning systems, it is extremely important for continued reporting that the safety culture is well established and that individuals who report incidents under a confidential system are not disciplined or in any way professionally disadvantaged for providing their report.

5) REPORTING BY PROFESSIONALS AND/OR PATIENTS

Overcoming Barriers to Reporting by Professionals

Barriers to implementation of effective reporting systems include the need to remove the culture of blame and fear of reprisals, as well as a lack of awareness as to the extent of adverse events and critical incidents and a poor understanding of their causes (Thompson 2001). Finally, we need to design adverse event reporting systems that are also effective learning systems for those who report incidents (Thompson 2001).

Despite legislation, regulations or policies requiring the report of adverse events in a mandatory system, it has been noted that all incident reporting systems are essentially voluntary in that they require the cooperation of care providers to bring the information forward (Billings 1998). Underreporting remains a significant concern for any event reporting system (Billings 1998). In the opinion of the author, underreporting can occur in one of three ways:

1. The care provider is not aware the event occurred.
2. The care provider is aware the incident occurred, but is not aware of requirement to report.
3. The care provider is aware the incident occurred and reporting requirements, but chooses to not report.

A successful adverse event reporting and learning system must be designed in conjunction with appropriate educational programs to encourage care provider awareness of requirements to report. Additionally, the environment surrounding incident reporting should be that of a culture of safety, where reporters are not at risk of professional reprisal for reporting incidents.

In order to overcome existing barriers to incident reporting, it will be necessary to introduce a learning and non-punitive culture of safety; this will be ideally facilitated from the beginning of study in professional schools and graduate training programs and supported on an ongoing basis during professional practice by regulators, consumers, patient advocacy groups, and accreditors (Barach and Small 2000). As well, legal protection for those reporting incidents needs to be continually reinforced, as has been done successfully in Australia and New Zealand where adverse event reporting systems in health care have gained widespread acceptance and credibility (Barach and Small 2000).

A study of a medication event reporting system in Northern Ireland identified that the major factor contributing to low reports of critical incidents was lack of staff awareness of what constituted a reportable incident (Medicines Governance 2003). This was addressed through the introduction of a uniform reporting process, making personal contacts between frontline staff and those responsible for the incident reporting system, publication/distribution of safety memos and a quarterly newsletter, and development of an informational safety website

(Medicines Governance 2003). Following the implementation of these changes, a ninefold increase in reported incidents occurred (Medicines Governance 2003).

Some facilities, for example the Baylor Medical Center at Grapevine, have found success at initiating culture change and encouraging reporting through development and implementation of an incentive program. Individuals and teams that report more adverse events receive free lunches and movie coupons, as well as buttons and other forms of visible recognition for participation in the reporting and improvement process (Atherton 2002). Similar to the Baylor "I Plant Flags" campaign, a community hospital in Geneva, Illinois launched a "LifeSavers" safety program with a highly identifiable visual identity which helped increase the volume of medication event incident reporting in their facility (Force et al. 2006).

While studies show all groups of health care professionals have similar attitudes and beliefs regarding the purpose and importance of adverse event reporting, their response to and compliance with mandatory incident reporting systems in the U.S. is varied (Escoto et al. 2006). One study of physicians and their supporting staff (including nurses and medical assistants) found the following differences in preferences for reporting systems according to professional group:

Table 6. Physician versus Nurse Preferences for Reporting Systems
(adapted from Escoto et al. 2006)

Issue	Physician Preferences	Nurse Preferences
Rules and Regulations	Voluntary system	Mandatory system to ensure participation
Reportable Events	Both adverse event and near-miss reporting	Adverse event reporting only to reduce workload
Reporting Medium	Flexible (paper, phone, electronic) but strong preference for electronic	Flexible (paper, phone, electronic) but less preference for electronic
Duplicate Reporting (e.g. organizational and regional)	Did not view negatively	Viewed negatively because of workload

The implementation and daily operation of incident reporting systems can be complicated by participation bias in the collection of reports from staff (Johnson 2003). Past studies have shown nurses submit the vast majority of reports, and consequently the types of incidents reported, as well as the safety solutions proposed as a result of the reports, are not fully representative of the entire system of health care delivery (Johnson 2003).

An Australian study found that physician and nursing groups are equal in their beliefs that incidents should be reported under the national critical incident reporting system, however nurses are more likely to report incidents than are physicians (Evans et al. 2006). The major barrier to reporting for both groups was a lack of feedback following submission of the report. The time it takes to complete the report, as well as a belief that the incident was too trivial to report were other reasons frequently cited for not reporting events, harm to patients, or near misses (Evans et al. 2006). Senior physicians were less likely to submit reports of

incidents than their more junior counterparts, including interns and residents. The alternative is true for nurses: more senior nurses, including nurse managers and unit supervisors are more likely to submit reports of incidents than their subordinates (Evans et al. 2006). This important discrepancy will need to be addressed by any organization looking to develop and successfully implement an adverse event reporting and learning system.

An opinion poll of Canadian physicians in 2003 found that almost one-half oppose mandatory reporting of drug- and device-related incidents and view it as a burden (Lexchin 2006). This statistic casts doubt as to whether making reporting mandatory as opposed to voluntary will contribute to improved volume and/or quality of reports from physician groups (Lexchin 2006). However, there are several proven methods of encouraging physicians to report incidents: payment, education on the need to report, familiarizing them with the reporting system and its associated forms and guidelines, and providing them with follow-up about reports they have filed (Lexchin 2006).

Some incident reporting programs have tried to encourage participation through monetary incentives to report. A program designed to increase reporting of medication-related adverse events in a Vermont hospital in the early 1990s chose to pay a stipend of $5 to physicians for each incident they reported. All respondents to an informal survey of the program stated that they were initially attracted to the program because there was a stipend offered (Gilroy et al. 1990). The authors note that this is likely not a long-term solution, in part because of limited financial resources and in part because other groups of care providers, including nurses and pharmacists would also expect compensation for their participation in the incident reporting system (Gilroy et al. 1990).

When trying to address incident reporting by the physician and nursing professions, it is important to understand that there are vast differences not only in awareness and use of reporting systems but also in the underlying motivators for reporting (Wild and Bradley 2005). In a survey of conditions influencing decisions to report incident by physicians and nurses in Connecticut, the following differences in response were noted:

Table 7. Conditions Influencing Incident Reporting by Physicians and Nurses (Wild and Bradley 2005)

"I would be more likely to report an error if..."	Residents	Nurses	Significant Difference?
...if it were my own error	54%	91%	yes
...if a resident committed the error	4%	43%	yes
...if a nurse committed the error	38%	42%	no
...if I don't like the person who committed the error	25%	1%	yes
...if the patient was young and healthy	33%	19%	no
...if the patient had an intact mental status	29%	14%	no
...if the error had serious consequences	67%	72%	no

When consulted during the development of a statewide incident reporting system in Wisconsin, participants (including physicians and nurses) indicated that a mandatory reporting system would provide motivation to participate whereas voluntary reports would be a lower priority when considered against other scheduled activities (Karsh et al. 2006).

Participants also identified that voluntary reporting may lead to biased reporting in that only those with a keen interest in change would report (Karsh et al. 2006). There was concern expressed about when it was appropriate to report an incident, and participants felt that clear directives on what constitutes a reportable incident should be an integral part of training and instruction provided (Karsh et al. 2006). A 'laundry list' of specific reportable events may make the reporting process simpler but was thought to be difficult to develop (Karsh et al. 2006).

While many studies emphasize the importance of a culture of safety in eliciting reports of harm or near harm to patients, even employees who work with fear of reprisal or being professionally disadvantaged for the act of reporting have been shown to still actively report incidents in certain areas where there can be no direct action taken personally (Kaplan and Fastman 2003). These reports are most commonly found to involve equipment failures or device malfunctions (Kaplan and Fastman 2003). The next most frequent area for report is incidents that were caused by individuals in another department or area (Kaplan and Fastman 2003).

Including Patients in Reporting and Learning Systems

A survey of a Missouri health care center in 2000 found at least six current and separate data systems existed for reporting adverse events, each with their own paper reports to be completed and each with multiple staff members with roles to play in the review, analysis and intervention following report (Kivlahan et al. 2002). The disparate nature of these systems combined with their inability to be linked lead to confusion, duplication of efforts, and an incomplete understanding of safety issues in place in the facility, and prompted very few system-wide safety improvements to be implemented (Kivlahan et al. 2002). In response, a single new online reporting system was created to replace all previous processes (Kivlahan et al. 2002). Standalone computer terminals were provided throughout the hospital facility for staff, patients, and family or visitors to use to report comments , near misses, adverse events, or critical incidents from any computer in the hospital or from home via the Internet (Kivlahan et al. 2002). Staff members are given the option to report anonymously for near-miss events, although not for actual occurrences (Kivlahan et al. 2002).

Other incident reporting systems have acknowledged the important role patients and their family members can play in the safety improvement process and as such encourage them to identify perceived errors and/or elicit their feedback into incident reporting systems. For example, patients and their family members were found to have identified over 90% of pharmacy related adverse events in a Japanese national voluntary medication error reporting program (Furukawa et al. 2003). A national medical device incident reporting database in the U.K. also allows reports from patients and family members (Jefferys 2005). The responses from patients has been low to date, with only a few patient reports included in the approximately 8,500 total reports received annually (Jefferys 2005).

The Institute of Medicine recommended in *To Err is Human* that patients be involved in their own safety by understanding what medications they are taking and notifying their doctors

about side effects they are experiencing (Bleich 2005). However, the report stopped short of recommending that patients be allowed to submit reports of actual or potential adverse events they become aware of or that they experience directly.

6) FINANCIAL IMPLICATIONS

There are financial resource requirements associated with the development and operation of any adverse event reporting and learning system. Adverse events in health care bring with them associated expenses, not the least of which include increased hospital stays, the need for further interventions or treatments, and litigation costs. To date, very little information has been published about the specific costs associated with the development, implementation, and maintenance of incident reporting databases. The Institute of Medicine estimates that preventable adverse events in the U.S. alone have an associated cost of $17 to 29 billion dollars each year (Bleich 2005).

The National Health Service believes that incident reporting and subsequent system-wide safety improvements can reduce hospital admissions and extended stays and have the potential to save the organization £2 billion each year (Payne 2000), as well as to recover an additional approximately £400 million annually in settled negligence claims (Leigh 2006). The NHS has disclosed the costs associated with development and operation of the NRLS database as an estimated £5 million for the first three years since inception (Williams and Osborn 2006).

Costs associated with ongoing data collection, analysis and management of one online incident reporting system were assessed at $25,000 to $35,000 annually per facility (2002 U.S. dollars), or the equivalent of a 0.5-0.75FTE professional in a mid-sized community hospital (Atherton 2002). These costs do not include the expenses associated with system development and implementation (Atherton 2002). Another similar-sized facility noted that when moving from a paper-based reporting system to an online reporting system, cost savings of data entry personnel time were approximately $30,000 per year per facility (Joshi et al. 2002).

The U.S. Aviation Safety Reporting System has a dedicated team of coders who analyze each incident submitted to the system (Johnson 2003). These coders are trained and monitored to ensure consistency in application of coding to the reported incidents, at a cost of $3 million per year or approximately $100 per reported incident (Johnson 2003). However, a national health care adverse event reporting and learning system would likely not have the financial resources available to have a dedicated team of professionals to code incidents. In the U.K. alone, it would cost an estimated £50 billion to have a similar level of analysis to the adverse events that are believed to occur within the National Health Service each year (Johnson 2003).

Adverse event reporting and learning systems will require a sufficient financial commitment to recruit and retain the necessary expertise to evaluate submitted reports (Billings 1998). In the words of Dr. Billings (1998): “these systems cannot be run with a couple of clerks and a keypunch operator.” Just as the reported events are provided by experts providing direct patient care, there must be equivalent experts responsible for the evaluation of the reports and the determination of lessons learned to be disseminated (Billings 1998).

Studies have suggested that in the long term, a well-targeted safety intervention is likely to be cost effective, meaning that the cost of the system improvements are less than or equal to the potential savings from elimination of future incidents (Webster and Anderson 2002). Even if the improvement is not cost effective, organization administration may consider a net loss as acceptable if a significant reduction in patient harm can be demonstrated (Webster and Anderson 2002).

In the opinion of this author, in order to properly prepare for the financial implications of an adverse event reporting and learning system, the following areas and their associated costs that should be taken into consideration:

- Feasibility testing
- Legal advice
- Computer form design
- Hardware – database storage, data warehouse, backups
- Software – purchase and licensing or develop in-house
- Development of taxonomy/classification system
- User education
- User awareness
- User acceptance testing
- Data coding
- Data analysis
- Feedback reporting
- Promotion of system externally
- Incentive program

In order to develop an appropriate budget, the author recommends that in the early stages of planning an adverse event reporting and learning system that a more complete prediction of associated expenses be developed. As a result of the lack of details available in the published literature, these will most likely need to be obtained through structured interviews or personal communications with developers of similar programs.

7) FEEDBACK SYSTEMS TO IMPROVE SAFETY

> "Learning is more than the analysis of an adverse incident – it is about ensuring there is change based on well-designed action plans. These must be realistic, achievable and sustainable, with all stakeholders involved in their development." (Bird and Milligan 2003)

The key to effectively managing clinical risks and the ultimate purpose of event reporting systems is to learn from investigations into reported events and to share those lessons learned to other facilities and organizations that would be similarly vulnerable to that type of event occurring (Bird and Milligan 2003). One major barrier to incident reporting is perceived futility: users experience frustration when they take the time to complete a incident report and then never know what, if anything, changed as a result of those efforts (Khare et al. 2005). In order in encourage reporting, feedback needs to be frequent and staff involved in an incident should be made aware of any changes made to improve system safety. Improving feedback led to an increase in incident reporting in a community hospital in Illinois (Force et al. 2006).

A review of several studies of incident reporting in intensive care units found that information shared in published journal articles is primarily about the collection and analysis of events, and very little information is included about the implementation of any changes following reporting of the adverse event, and whether patient safety has been improved as the end result (Frey et al. 2002). Similarly, there are very few references in the published literature that address the specific methods for information sharing and safety improvements in multiple organizations once a reported event is determined to have system safety implications.

One of the major challenges when developing an incident reporting system is to find a means of providing users as well as stakeholders with access to meaningful data following reporting. It is important to determine what data sets are appropriate to share, as well as to create user-friendly formats for disseminating the information, targeting the appropriate audience, and establishing the most useful means for disseminating information in order to reach the intended audience (NASHP 2006).

Database users identify a lack of data feedback from the reporting system to be a disincentive to ongoing reporting (NASHP 2006). In this way, the timely dissemination of specific information about progress made and system improvements implemented following the report can act as a motivator and encourage increased participation in an incident reporting system (Karsh et al. 2006). Organizations participating in reporting systems have also suggested they would like to receive feedback in the form of quarterly or yearly summaries that highlight the most frequently reported types of safety events as well as process solutions for addressing certain types of incidents (Karsh et al. 2006).

The National Reporting and Learning System in the U.K. uses information distilled from reports of incidents and near misses to publish regular alerts and bulletins on safety issues through a series of reports called the Patient Safety Observatory (Williams and Osborn 2006). The data can also be used to inform the development of educational curriculum, as well as for performance assessment and standards development, for risk assessments both nationally and locally, and to improve the quality of care provided throughout the National Health Service (Williams and Osborn 2006). Health trusts are required to take action on all patient safety alerts issued by the NRLS, and must certify their compliance with the recommended actions within a predetermined timeframe (Leigh 2006).

A criticism of the NRLS is that although the system receives approximately 60,000 reported incidents each month, a relatively small number of safety alerts have been published to date (Leigh 2006). The committee evaluating the success of the system commented that the Agency responsible for the NRLS: "has yet to demonstrate that it is using this information and knowledge effectively to change health care practices rather than simply collecting statistics" (Leigh 2006). The committee recommended that patient safety feedback reports be produced and distributed to health trusts at least four times per year (Leigh 2006).

"For an organization to adopt event reporting rather than to simply comply with its requirement, there must be timely and effective feedback and demonstrable local usefulness" (Kaplan and Fastman 2003).

The challenge to all organizations implementing an adverse event reporting and learning system is to determine what type of information to disseminate, as well as how frequently and in what format. Keeping frontline care providers engaged in the process and aware of the outcome of investigations and system safety improvements will ultimately encourage continued participation in the event reporting system, driving the chain reaction of awareness of adverse events and their underlying causes to further patient safety initiatives in the future.

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APPENDIX: ELECTRONIC DATABASE SEARCH CRITERIA

Search Results

Database	Initial Search	After De-Dup
Medline	156	140
CINAHL	36	17
Embase	101	49
Web of Science	56	14
Total		**220**

Medline Search

#	Search History	Results
1	adverse drug reaction reporting systems/	2963
2	mandatory reporting/	1141
3	(mandator$ adj3 report$).tw.	449
4	(incident$2 adj4 report$).tw.	1805
5	national$ report$.tw.	250
6	event$ report$.tw.	1500
7	data collection/	51342
8	hospital information systems/	7857
9	information systems/	15832
10	information services/	13558
11	or/1-10	92862
12	exp medical errors/	52202
13	(medica$ adj3 error$).mp.	12314
14	(adverse$ adj3 event$).mp.	30671
15	(adverse$ adj3 effect$).mp.	64439
16	(health care adj3 error$).mp.	124
17	(healthcare adj3 error$).mp.	37
18	(sentinel adj3 event$).mp.	350
19	(diagnos$ adj3 error$).mp.	24899
20	(nurs$ adj3 error$).mp.	210
21	(physician$ adj3 error$).mp.	247
22	(patient care adj3 error$).mp.	43
23	(surg$ adj3 error$).mp.	557
24	near$ miss$2.mp.	596
25	(critical$ adj3 incident$).mp.	891
26	(critical$ adj3 outcome$).mp.	1174
27	(adverse$ adj3 outcome$).mp.	10260
28	(unanticipated adj4 outcome$).mp.	48
29	iatrogenic disease/	9274
30	or/12-29	166832
31	11 and 30	4117
32	limit 31 to english language	3822

33	report$.ti.	255456
34	32 and 33	651
35	classification/	4407
36	classificat$.tw.	
37	taxonom$.tw.	14329
38	computers/	45474
39	comput$.tw.	281541
40	technology/	4774
41	technolog$.tw.	107885
42	implement$.tw.	92559
43	exp systems analysis/	18981
44	data interpretation, statistical/	23610
45	information dissemination/	3378
46	govern$.tw.	56392
47	or/35-46	
48	34 and 47	134

Also considered:

Legal$.tw. -nothing relevant was added. Mostly articles about reporting mental health cases/situations, reporting abuse cases, etc.

Infrastructure$.tw. –nothing relevant was added. (e.g. "Staffing and infrastructure of the recovery room…" and "Clinical research infrastructures and networks in France: report on the French ECRIN workshop"

Cumulative Index for Nursing & Allied Health Literature (CINAHL) Search

#	Search History	Results
1	mandatory reporting/	1652
2	incident reporting/	1037
3	(mandator$ adj3 report$).tw.	136
4	(incident$2 adj4 report$).tw.	545
5	national$ report$.tw.	60
6	event$ report$.tw.	253
7	data collection/	3167
8	exp health information systems/	9108
9	exp information systems/	25470
10	information services/	1892
11	or/1-10	32802
12	medication errors/	3755
13	(medica$ adj3 error$).mp.	4837
14	(adverse$ adj3 event$).mp.	4669
15	(adverse$ adj3 effect$).mp.	4900
16	(health care adj3 error$).mp.	1499
17	(healthcare adj3 error$).mp.	488
18	(sentinel adj3 event$).mp.	342
19	(diagnos$ adj3 error$).mp.	2184
20	(nurs$ adj3 error$).mp.	1862
21	(physician$ adj3 error$).mp.	621
22	(patient care adj3 error$).mp.	999
23	(surg$ adj3 error$).mp.	604
24	near$ miss$2.mp.	137
25	(critical$ adj3 incident$).mp.	874
26	(critical$ adj3 outcome$).mp.	1565
27	(adverse$ adj3 outcome$).mp.	1551
28	(unanticipated adj4 outcome$).mp.	24
29	iatrogenic disease/	526
30	or/12-29	21397
31	11 and 30	1665

32	limit 31 to english language	1644
33	report$.ti.	24428
34	32 and 33	296
35	classification/	671
36	classificat$.tw.	8099
37	taxonom$.tw.	719
38	"computers and computerization"/	3476
39	comput$.tw.	18279
40	exp technology/	8794
41	implement$.tw.	24937
42	exp systems analysis/	725
43	clinical governance/	459
44	govern$.tw.	11454
45	or/35-42	70533
46	34 and 45	45

Embase Search

#	Search History	Results
1	mandatory reporting/	165
2	voluntary reporting/	30
3	(mandator$ adj3 report$).tw.	279
4	(incident$2 adj4 report$).tw.	1291
5	national$ report$.tw.	572
6	event$ report$.tw.	1413
7	information processing/	39409
8	exp information system/	23618
9	information service/	1566
10	or/1-9	64405
11	exp medical error/	18459
12	(medica$ adj3 error$).mp.	5050
13	(therap$ adj3 error$).mp.	462
14	(adverse$ adj3 event$).mp.	30363
15	(adverse$ adj3 effect$).mp.	52371
16	(health care adj3 error$).mp.	123
17	(healthcare adj3 error$).mp.	19
18	(sentinel adj3 event$).mp.	178
19	(diagnos$ adj3 error$).mp.	15806
20	(false$ adj3 result$).mp.	8858
21	(nurs$ adj3 error$).mp.	187
22	(physician$ adj3 error$).mp.	337
23	(patient care adj3 error$).mp.	218
24	(surg$ adj3 error$).mp.	706
25	near$ miss$2.mp.	352
26	(critical$ adj3 incident$).mp.	542
27	(critical$ adj3 outcome$).mp.	1421
28	(adverse$ adj3 outcome$).mp.	9119
29	(unanticipated adj4 outcome$).mp.	23
30	exp iatrogenic disease/	140023
31	or/11-30	241427
32	10 and 31	3814

33	limit 32 to english language	3552
34	report$.ti.	140879
35	33 and 34	449
36	exp classification/	240606
37	classification$.tw.	70183
38	taxonom$.tw.	8419
39	computer/	10637
40	comput$.tw.	193342
41	technolog$.tw.	82116
42	implement$.tw.	67502
43	system analysis/	5346
44	information dissemination/	1636
45	govern$.tw.	38911
46	or/36-45	633133
47	35 and 46	101

Web of Science

#42	56	#34 AND #41
#41	>100,000	#40 OR #39 OR #38 OR #37 OR #36 OR #35
#40	>100,000	TS=govern*
#39	>100,000	TS=implement*
#38	>100,000	TS=technolo*
#37	>100,000	TS=comput*
#36	51,110	TS=taxonom*
#35	>100,000	TS=classificat*
#34	363	#32 AND #33
#33	>100,000	TI="report*"
#32	2,591	#31Language=English
#31	2,668	#13 AND #30
#30	88,603	#29 OR #28 OR #27 OR #26 OR #25 OR #24 OR #23 OR #22 OR #21 OR #20 OR #19 OR #18 OR #17 OR #16 OR #15 OR #14
#29	416	TS="iatrogenic disease*" OR TS="iatrogenic AND disease*"
#28	32	TS="unanticipated outcome*" OR TS="unanticipated AND outcome*"
#27	7,977	TS="adverse* outcome*" OR TS="adverse* AND outcome*"
#26	117	TS="critical* outcome*" OR TS="critical* AND outcome*"
#25	1,121	TS="critical* incident*" OR TS="critical* AND incident*"
#24	6	TS="near* miss*" OR TS="near* AND miss*"
#23	125	TS="surg* error*" OR TS="surg* AND error*"
#22	2	TS="patient care error*" OR TS="patient AND care AND error*"
#21	62	TS="physician* error*" OR TS="physician* AND error*"
#20	23	TS="nurs* error*" OR TS="nurs* AND error*"
#19	969	TS="diagnos* error*" OR TS="diagnos* AND error*"
#18	164	TS="sentinel* event*" OR TS="sentinel* AND event*"

#17	17	TS="health care error*" OR TS="health care AND error*" OR TS="healthcare error*" OR TS="healthcare AND error*"
#16	50,334	TS="adverse* effect*" OR TS="adverse* AND effect*"
#15	28,567	TS="adverse* event*" OR TS="adverse* AND event*"
#14	2,083	TS="medica* error*" OR TS="medica* AND error*"
#13	41,830	#1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9 OR #10 OR #11 OR #12
#12	686	TS="informat* AND service*"
#11	4,619	TS="informat* service*"
#10	4,245	TS="informat* AND system*"
#9	28,536	TS="informat* system*"
#8	1,539	TS="event* AND report*"
#7	1,549	TS="event* report*"
#6	246	TS="national* AND report*"
#5	267	TS="national* report*"
#4	143	TS="incident* AND report*"
#3	642	TS="incident* report*"
#2	56	TS="mandator* AND report*"
#1	234	TS="mandator* report*"

Review of Provincial, Territorial and Federal Legislation and Policy Related to the Reporting and Review of Adverse Events in Healthcare in Canada

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EXECUTIVE SUMMARY

The reporting of patient safety events including Adverse Events, Critical Incidents, Sentinel Events and Near Misses (each such term is hereinafter defined), both within the healthcare organizations that discover them and beyond, is an important means to improve the safety of healthcare systems. Such reporting is consistent with the vision of the National Steering Committee on Patient Safety in their 2002 Report[1] and has been a part of patient safety efforts in the United States, the United Kingdom and elsewhere. However, such reporting raises important issues about protecting the privacy of individuals and creating processes that are consistent with varying legislative and policy requirements that influence the collection, analysis and dissemination of such information.

In this report, we analyze key enablers and barriers for the reporting and review of Incidents (hereinafter defined) on a national scale ("**Pan-Canadian Reporting**"). We report on the following: (a) an analysis of the application of provincial and federal legislation; (b) a review of policies at provincial and regional levels; (c) surveys of healthcare regions, hospitals and other health delivery organizations; and (d) interviews with experts and key stakeholders interested in the reporting of Incidents.

Our review of evidence legislation, general and health-specific privacy laws and related legislation indicates that most jurisdictions provide legislative protections for the privacy of personal health information while enabling a healthcare organization to gather and analyze information to improve quality and safety within such organization. Even so, there remains considerable variation in these approaches. For example, some provinces (Saskatchewan, Manitoba and Quebec) have developed legislation that mandates reporting both within the healthcare institution that discovered the Incident and to the provincial Ministry. Other provinces have not developed mandatory reporting legislation such that reporting of Incidents may only occur at an institutional level, if at all. Moreover, our legislative review also indicates that most jurisdictions prohibit the sharing of patient safety information both within and outside of the province, thereby acting as a barrier to Pan-Canadian Reporting.

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* The authors also wish to thank Dawn Robertson of Fasken Martineau DuMoulin LLP for her work on the legislative research. They also wish to thank Madelyn Law for her assistance in preparing the surveys and the interviews.

[1] National Steering Committee on Patient Safety, "*Building a Safer System: A National Integrated Strategy for Improving Patient Safety in Canadian Health Care*" (September 2002). The Report can be found at http://rcpsc.medical.org/publications/buildingasafersysteme.pdf.

A review of federal, provincial and territorial policies on the reporting of Incidents, along with interviews with key policy makers, indicates that there is a lack of a common approach, shared definitions and other elements needed to collect and compare data on a provincial basis, let alone on a Pan-Canadian basis. In addition, policies in many jurisdictions are underdeveloped in terms of reporting mechanisms, accountability and evaluation criteria and standards.

Our survey of health regions and health delivery organizations reveals a similar pattern of varying policies and incomplete implementation of systems to collect, analyze and learn from Incidents. While some regions and organizations are well advanced in these areas, others are still developing such systems. Based on this information, we interviewed international and national experts on the critical barriers and enablers and potential solutions to advance Pan-Canadian Reporting and sharing of lessons learned.

An effective strategy to improve reporting and learning from Incidents will include both local reporting and analysis, and sharing of lessons learned at a provincial and Pan-Canadian level. Our recommendations urge the development of local capabilities to collect and analyse reports within organizations and regions. Additional funding from the federal government or other sources would help to encourage participation and speed the development of such capabilities.

We also recommend that mechanisms be established to enable the transfer of useful information within each province and beyond. A review of current legislative provisions in most provinces suggests potential barriers to the transfer of such useful information, particularly on a personally identifiable basis. In our view, based on a review of privacy legislation and the privacy provisions of evidence and quality assurance legislation (where applicable), the political capital required to effect the statutory amendments necessary to achieve the Pan-Canadian Reporting of personal health information ("**PHI**") would be immense. We would therefore recommend an alternative approach; modelled on the approach in Alberta, Saskatchewan or Manitoba that would establish a provincial body responsible for reporting in each province (which body could include the Minister, as is the case in Manitoba, or a separate organization, as is the case in the other named provinces). This provincial body could coordinate reporting by healthcare institutions and healthcare professionals in that province in compliance with provincial law. The provincial body would also be responsible for sharing de-identified information with a Pan-Canadian body capable of disseminating information and warnings on a national basis.

In order to obtain useful information, a Pan-Canadian body would work with provincial bodies to develop a framework for the classification of Incidents across the country. By standardizing each province's approach to reporting and to de-identification, Pan-Canadian Reporting can draw from the lessons learned across the country on a consistent basis.

Finally, although we are of the view that federal legislation is not required for the development of Pan-Canadian Reporting and sharing at this point in time, federal legislation could be developed for the purpose of setting out the objectives of the Pan-Canadian model and to provide additional funding to support those objectives. Such legislation would not override provincial legislation but it would likely demonstrate to Canadians the importance of patient safety to the federal government and foster cooperation among the provinces and territories.

DEFINITIONS

In this report the following terms have the meanings set out below:

"**Adverse Events**" are unintended injuries or complications that are caused by healthcare management, rather than the patient's underlying disease and that lead to death or disability or require additional use of hospital or other healthcare organizational resources, such as prolonged hospital stay, additional testing or interventions.

"**Classification System**" is the grouping of information about an event to be deconstructed and translated into a common (coded) language and to create an electronic record that can be compared with other records and analyzed as part of a larger set of data.[2] [3]

"**Critical Incidents**" are incidents resulting in serious harm (loss of life, limb, or vital organ) to the patient/client/resident, or the significant risk thereof, i.e., incidents are considered critical when there is an evident need for immediate investigation and response.

"**Disclosure**" means the communication of information to the patient and open discussion with the patient, by healthcare providers, about an Incident that results in unintended harm to the patient while receiving healthcare and the associated investigation and recommendations for improvement.[4]

"**Government**" means any federal or provincial government or government agency or government funded organization dealing with patient safety.

"**Incidents**" means patient safety events including Adverse Events, Critical Incidents, Sentinel Events and Near Misses; and "**Incident**" means any one of them.

"**including**" means including without limitation and "**includes**" means includes without limitation and neither "**including**" nor "**includes**" shall be construed to limit any general statement which they follow to the specific or similar items or matters immediately following them.

"**Major and Enduring Loss of Function**" is sensory, motor, physiological, or psychological impairment not present at the time services were sought or began. The impairment lasts for a minimum period of two weeks and is not related to an underlying condition.

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[2] WHO, World Alliance for Patient Safety (2005, October) "*Project to Develop the International Patient Safety Event Taxonomy*": Report of the World Alliance for Patient Safety Drafting Group.

[3] Runciman WB, "*Shared Meanings: Preferred Terms and Definitions for Safety and Quality Concepts*". MJA 2006 184;10: S41-S43.

[4] Health Quality Council of Alberta, Disclosure of Harm to Patients and Families Provincial Framework and Australian Council for Safety and Quality in Health Care. "*Open disclosure standard: a national standard for open communication in public and private hospitals, following an adverse event in health care*" (2003). Commonwealth of Australia.

"**Near Misses**" are occurrences that could have caused harm to the patient but ultimately did not as a result of chance or prevention, or mitigation through a planned or unplanned recovery process.

"**RCA**" means root cause analysis of an Incident to determine how the Incident occurred.

"**Reporting/Reported/Report**" means the reporting of an Incident, or the making of a report about an Incident, within the healthcare organization in which the Incident occurred including management, the board and the committee that has as its primary purpose the carrying out of quality assurance activities and to the Government of the province where the Incident occurred.

"**Sentinel Events**" means an unexpected Incident, related to system or process deficiencies and/or human error, which leads to death or Major and Enduring Loss of Function for a recipient of healthcare services.

"**Sharing/Shared/Share**" means the disclosure of an Incident to a person outside of the healthcare organization in which the Incident occurred.

"**Taxonomy**" is a delineation of terms or relationship among terms that provides a structured representation of part of the domain of the knowledge about safety.[5]

INTRODUCTION

We were engaged by the Canadian Patient Safety Institute ("**CPSI**") to conduct a comprehensive review of legislation (Part One) and policy (Part Two) related to the Reporting and review of Incidents in Canadian healthcare, as further described below. Our mandate also included: (a) developing and implementing a survey of health regions and health delivery organizations throughout Canada with respect to their experience with Reporting; and (b) interviewing 15 key informants on this subject (Part Three).

Based on the reviews, surveys and interviews, we were able to identify key barriers and enablers to Reporting. We have developed a set of recommendations for consideration by CPSI when addressing these barriers and promoting Reporting (Part Four).

For clarity, the scope of our work was limited to Reporting. It was not part of our mandate to consider the issue of Disclosure. Accordingly, we have not considered the Draft National Guidelines for the Disclosure of Adverse Events as part of our review. Nonetheless, many institutional policies and academic commentary on Incidents often deal with both Reporting and Disclosure as one topic and may not distinguish between the two. Accordingly, we may at some point throughout this report use the terms "reporting" and "disclosure" interchangeably where it has been done in a particular piece of legislation, policy or by academic commentators and other key stakeholders.

Also, it was not part of our initial mandate to consider the issue of Sharing; however, over the course of the project our mandate was expanded to consider enablers and barriers to Sharing between provinces.

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[5] The Canadian Patient Safety Dictionary (2003).

Our report is divided into four sections. Part One summarizes the findings of our legislative review. Part Two summarizes the findings of our policy review. Part Three summarizes the findings of our surveys and interviews. Collectively, the key findings from these three analyses are used to suggest an integrated series of recommendations for overcoming barriers and promoting Reporting in Part Four.

PART ONE: FINDINGS OF LEGISLATION REVIEW

A. Introduction

Our team reviewed and analyzed relevant federal, provincial and territorial statutes and regulations that relate to Reporting and Sharing and identified seven categories of statutes and regulations[6]. In the discussion and Section B, we summarize the key aspects of each category of legislation. A Legislation Reference Table, found at Appendix 1, identifies the specific statute in each category for each province and territory. In Section C we described legislative enablers and barriers of Reporting and set out in Section D a legislative framework. Collectively, the critical components and levers from lessons learned from jurisdictions have pointed toward the legislative framework, outlined in Section D.

The following qualifications should be noted with respect to the scope of the legislative review. While the legislative review involved a comprehensive examination of the enumerated legislation, we did not review the following: (a) any case law, findings or orders interpreting the legislation that may be available (for example, as may be issued by privacy or information commissioners); (b) other forms of interpretative assistance issued by applicable regulatory authorities, such as guidelines, fact sheets, bulletins, etc; or (c) any documentation relating to the original drafting of legislation (for example, the applicable Hansard records). Similarly, we did not approach any regulatory authorities for their informal views on the intent behind, or their interpretation of, the relevant provisions. Such reviews were beyond the scope of our mandate. However, we would be pleased to conduct this analysis should it be required, perhaps in connection with the work conducted by the panel of experts that we recommend be established.

[6] We also reviewed all current bills in every provincial and territorial legislature and confirmed that no jurisdictions were currently considering bills on Reporting. This was also confirmed in an email from representatives of the governments of Saskatchewan, Manitoba and Nova Scotia.

B. Laws, Inquests and Inquiries, Drug and Medical Device Adverse Event Reporting and Professional Regulation

1. Evidence Laws and Privilege

In nearly all provinces and territories[7], quality assurance records and the proceedings of quality assurance committees are inadmissible as evidence in legal proceedings, and witnesses cannot be questioned in respect of same. The purpose of this "privilege" is to encourage Reporting by healthcare professionals so that Incidents can be investigated and improvements can be made. Generally, this privilege is found in evidence or health services statutes.

It should be noted, however, that this privilege hinges on the definition of "legal proceedings" which varies between jurisdictions. For example, proceedings founded on defamation, civil conspiracy and inducing breach of contract are excluded from this privilege in Saskatchewan and the Yukon, while other jurisdictions exclude discipline proceedings from same[8]. A summary of the relevant provisions across Canada is found at Appendix 2.

It is also important to note that the privilege over quality assurance records does not always protect the information used to create those records. Accordingly, medical charts and information in medical records regarding the provision of health services are admissible as evidence. Similarly, in some jurisdictions, the facts of an Incident, or information or records required by law to be created or maintained by the applicable healthcare entity, whether or not they form part of a medical record, are admissible as evidence.[9]

Beyond the admissibility of evidence, most jurisdictions expressly protect individuals who make disclosures or submissions to a quality assurance committee from any liability that could result from the making of same; however, certain jurisdictions require that such individuals act in good faith in order to be protected from liability.[10] Therefore, by protecting persons who offer information in quality assurance proceedings, the privilege enables Reporting.

2. Privacy Laws

(a) General Privacy Laws

Any Pan-Canadian approach to Reporting and Sharing must address laws that deal with the disclosure of personal information. All provinces and territories have enacted either general privacy statutes or freedom of information type privacy statutes that apply to a public

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[7] The exception appears to be Prince Edward Island as the *Evidence Act* of Prince Edward Island is silent in this regard. See *Evidence Act*, R.S.P.E.I. 1988, c. E-11.

[8] Northwest Territories, Nunavut, British Columbia and Saskatchewan.

[9] In Saskatchewan, Manitoba and Ontario the facts with respect to a quality assurance incident are not privileged.

[10] Determining what constitutes an absence of good faith may be difficult since it speaks to the intent of the submission and the state of mind of the individual. Also, different jurisdictions take slightly different approaches to this qualification (e.g. in the *Evidence Act* (Nova Scotia), the privilege applies if the disclosures or submissions to a hospital committee were not made "with malice"). A review of secondary sources may assist in resolving this ambiguity.

institution's[11] collection, use and disclosure[12] of personal information or information which is about an identifiable individual. These privacy statutes prohibit the disclosure of personal information without the prior consent of the subject individual, unless otherwise required by law.[13] A summary of the relevant disclosure provisions in these provinces is found at Appendix 3. However, it would be a difficult task to obtain consent from each patient or other relevant individual for the purposes of Reporting and Sharing. A more practical approach, to facilitate Reporting and Sharing of information about an Incident, would be pursuant to a permitted exception which avoids the need to obtain consent.

Alternatively, the disclosure of Incident data on a de-identified basis would also enable Reporting and Sharing without contravening general privacy laws, given that, as we have noted above, such laws only apply to personal information or information which is about an identifiable individual. This raises the concern (discussed below) as to what constitutes effective de-identification, such that the Incident data is effectively anonymized but is still useful in respect of Sharing.

(b) Health Information Privacy Laws

In addition to the privacy laws noted above, four provinces have taken the additional step of enacting privacy legislation that is specific to PHI, namely Alberta, Saskatchewan, Manitoba and Ontario. A summary of the relevant disclosure provisions in those provinces is found at Appendix 4. PHI is a subset of personal information, namely information that relates to the health status and the provision of healthcare to an identifiable individual. The PHI statutes govern the collection, use and disclosure of PHI to the exclusion of the more general privacy laws.

Provinces with only general privacy legislation tend to have a unified approach to the disclosure of personal information, whereas provinces with PHI legislation do not. The provisions of PHI legislation (and the various healthcare statutes that relate to quality assurance activities) have a varied approach to disclosure of PHI. In the four provinces noted above, PHI legislation appears to act as both an enabler and a barrier to Reporting and Sharing depending on which entity has custody of the PHI: (a) PHI custodians or trustees; (b) quality assurance committees[14]; (c) third party institutions, including the Government or another regulatory body in the province.

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[11] Hospitals are considered to be public institutions under freedom of information statutes.

[12] As alluded to earlier in this report, it is important to note that in the privacy context, the term "disclosure" refers to the communication of information by a custodian or trustee to another person (i.e. where such person is not considered to be part of the custodian). This should not be confused with the term disclosure in the patient safety context where it is used to denote the communication of information about an Incident to the patient.

[13] In order to properly invoke the "required by law" exception in the context of quality assurance activities, a review of healthcare and related statutes in each jurisdiction would be necessary to determine whether a separate statutory basis requiring such disclosure exists. Such an analysis is beyond the scope of our mandate and has not been addressed in this report.

[14] This refers to committees that have as their primary purpose the carrying out of quality assurance activities. The name of such committees varies between jurisdictions, but for the purpose of this report we refer to them as quality assurance committees.

(i) Custodians or Trustees

PHI legislation enables Reporting to certain persons by allowing custodians or trustees[15] to disclose PHI, without having to obtain the individual's consent, to quality assurance committees for the purpose of reviewing an Incident.

Also in some provinces, such as Alberta and Saskatchewan, the disclosure provisions also act as an enabler to Sharing in that they allow custodians or trustees to disclose PHI to third party organizations with prescribed purposes, without the consent of the individual.[16] These organizations are tasked with coordinating and facilitating quality assurance activities on a province-wide basis. For example, Alberta has made a regulation under the *Regional Health Authorities Act*[17] to form the Health Quality Council of Alberta ("**Alberta Council**"), a province-wide patient safety body.[18] The Alberta Council's mandate is to, in cooperation with health authorities and in accordance with an approved health plan, (a) measure, monitor and assess patient safety and health service quality; (b) identify effective practices and make recommendations for the improvement of patient safety and health service quality; (c) assist in the implementation and evaluation of strategies designed to improve patient safety and health service quality; and (d) survey Albertans on their experience and satisfaction with patient safety and health service quality. The Alberta Council coordinates with the health professions, health authorities, organizations providing health services, academic health centres and others for the purposes of sharing information on patient safety and health service quality issues, identifying and assessing those issues, and developing and recommending effective practices in patient safety and health service quality.

Custodians in Ontario are permitted to disclose PHI to the Ontario Agency for Health Promotion and Protection for the purposes of that agency[19], or at the request of the Minister and subject to certain additional obligations, to a health data institute[20]. We understand however that currently the Agency's mandate does not encompass Reporting but the prospect remains that the Agency's mandate could be amended in order to do so. Moreover, Sharing in Ontario is hampered by the *Quality of Care Information Protection Act*[21], which supersedes Ontario PHI legislation with separate provisions for "quality of

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[15] The definitions of "custodian" and "trustee" vary between jurisdictions, but generally include healthcare institutions and healthcare professionals and related entities that may hold PHI.

[16] Although it does not have PHI-specific legislation, Newfoundland and Labrador has a similar third party organization, the Centre for Health Information. The *Centre for Health Information Act*, S.N.L. 2004, c. C-5.1, section 17.1 (3) ("**CHIA**") amended the *Hospitals Act* to allow hospitals to disclose personal information to the Centre for Health Information in accordance with the CHIA and its regulations. The Centre can make further disclosures of personal information it receives without the consent of applicable individuals (see section 10 of the *Centre for Health Information Regulations*, N.L.R. 57/07).

[17] R.S.A. 2000, c. R-10.

[18] *Health Quality Council of Alberta Regulation*, Alta. Reg. 130/2006.

[19] *Ontario Agency for Health Protection and Promotion Act, 2007*, S.O. 2007, c. 10, Sch. K.

[20] Section 47 of the *Personal Health Information Protection Act, 2004*, S.O. 2004, c. 3, Sch. A. A "health data institute" is an organization that has as its object the performance of data analysis of personal health information, linking the information with other information and de-identifying the information for the Minister.

[21] 2004, S.O. 2004, c. 3, Sch. B.

care information". "Quality of care information" includes any information put before a quality of care committee, whether personal information or other non-personal information. Generally, that Act prohibits the Sharing of "quality of care information" beyond the institution or entity at which the Incident occurred.

In Saskatchewan, the *Health Information Protection Act*[22] and its regulations permit disclosure of PHI to the Health Quality Council (the "**Saskatchewan Council**") without the consent of the subject individual. The Saskatchewan Council may then use the PHI in accordance with the *Health Quality Council Act*,[23] which includes supporting new initiatives and facilitating sharing of best practices among the health regions of Saskatchewan and the Saskatchewan Cancer Agency.[24]

(ii) Quality Assurance Committees

Quality assurance committees receive PHI from custodians or trustees and from other persons as part of an investigation into a particular Incident. Often the ability to disclose PHI to any person other than the institution to which the committee is associated is constrained, whether through PHI legislation or the interaction of other statutes. Therefore PHI legislation acts as a barrier to Sharing Incident data containing PHI with other quality assurance committees within and beyond their respective provinces. Even disclosure of Incident data containing de-identified PHI by a quality assurance committee to another quality assurance committee or other third party in the same jurisdiction and in other jurisdictions is prohibited in most provinces.[25]

(iii) Third Party Organizations

Third party organizations, or the Minister in the case of Manitoba, are tasked with aggregating Incident data in their respective provinces. It is interesting to note that the Alberta Council's authorizing regulations give it the right to have reasonable access, as necessary, to information held by health authorities to carry out its objects noted above. It is unclear, however, whether the Alberta Council would be permitted to share any PHI outside of Alberta; however, such a program would require the approval of the applicable Minister. The Saskatchewan Council is not permitted to disclose PHI as part of its activities. Any Sharing, whether inside or outside of Saskatchewan, would only be permitted on a de-identified basis.

(iv) Variations in Treatment of PHI

While at the outset, there seems to be unity among provinces that have PHI-specific legislation, the potential for disclosure of Incident data that contains PHI to support Pan-Canadian Reporting varies in the jurisdictions:

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[22] *Health Information Protection Act*, S.S. 1999, c. H-0.021.

[23] S.S. 2002, c. H-0.04.

[24] Section 5 of the *Health Information Protection Regulations*, R.R.S. c. H-0.021 Reg. 1.

[25] Alberta seems to be the exception. See footnote 36.

(A) Alberta permits disclosures of PHI to other custodians (i.e. healthcare institutions and practitioners) in Alberta for *internal* "monitoring", "quality improvement" or "evaluation" purposes.[26] What is unclear, however, is the how the word "internal" would operate in this section. For example, in order to effect internal "quality improvement", a hospital may need to share information with other hospitals (effectively for the purposes of benchmarking quality standards). In contrast, internal "monitoring" of a program may not require disclosures to other institutions.

(B) Also, in Alberta, the Alberta Council can receive and have access to PHI held by custodians to carry out its objects related to furthering patient safety as noted above. It is unclear whether the Alberta Council can then disclose information other than on a de-identified basis.

(C) Saskatchewan has similar provisions as Alberta, but appears to permit disclosures to any person in any jurisdiction for the purpose of "evaluating" health services practices in a health services facility (which, like "quality improvement" as set out in (a) above, may or may not require inter-custodian disclosures).[27]

(D) Also, Saskatchewan has a council similar to the Alberta Council, but it is only permitted to disclose de-identified information.[28]

(E) Manitoba permits disclosures of PHI to any person in any jurisdiction if "required" for the purpose of a quality assurance committee or for "risk management assessment".[29]

(F) Ontario only allows disclosures of PHI for the purpose of aggregate analysis to the Ontario Agency for Health Protection and Promotion (the mandate of which we understand does not currently encompass Reporting) or to a health data institute, although "quality of care information" (which could include any information put before a quality assurance committee, whether PHI or non-personal information, other than the facts of the Incident) may not be disclosed beyond the facility or entity at which the Incident occurred pursuant to separate legislation dealing with quality assurance information.[30]

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[26] Section 35(1)(a) with reference to section 27(1)(g) of the *Health Information Act*, R.S.A. 2000, c. H-5.

[27] Section 27(4)(k) of the *Health Information Protection Act*, S.S. 1999, c. H-0.021.

[28] Section 5 of the *Health Information Protection Regulations*, R.R.S. c. H-0.021 Reg. 1.

[29] Section 22(2)(e)(iv) of the *Personal Health Information Act*, C.C.S.M. c. P33.5.

[30] Section 4 of the *Quality of Care Information Protection Act*, 2004, S.O. 2004, c. 3, Sch. B.

In light of the diverse legislative framework across Canada, Pan-Canadian Reporting is severely limited. At best, certain provinces allow Sharing of PHI between individual healthcare institutions (not quality assurance committees of healthcare institutions) and a named third party provincial organization (or the Minister) as noted above. Disclosures beyond such bodies, particularly where the disclosure is to occur to another province or territory is for the most part limited to de-identified information only.

(c) De-identified Information

Generally, de-identified information can be disclosed for any purpose and to any person without the subject individual's consent.[31] "De-identified" commonly means that any information that may be reasonably expected to identify an individual has been removed from the record.[32]

However, even where disclosure of de-identified information is permitted, it is often subject to restrictions. For example, in Alberta, disclosure by the quality assurance committee is barred except for disclosures of *non-identifying* health information to another quality assurance committee, whether in Alberta or in another province or territory.[33] Also, in Ontario, de-identified *factual* information may be disclosed to any person, but quality assurance information, which may include RCA, opinions and the recommendations of a quality assurance committee, can only be Shared with the management of the applicable institution and cannot otherwise be disclosed. As another example, in Saskatchewan, any PHI disclosed to a quality assurance committee by a healthcare institution or a healthcare practitioner cannot thereafter be disclosed by that committee, regardless of whether it has been de-identified.[34]

(d) Findings of Other Reports

In its 2002 report, *Building a Safer System: A National Integrated Strategy for Improving Patient Safety in Canadian Health Care*, the National Steering Committee of Patient Safety recommended that legislation on the privacy and confidentiality of personal information across Canada be standardized in order to facilitate access to Incident data, while respecting the privacy of patients and providers.[35] The Steering Committee envisioned a system whereby patient safety information could be Shared across all jurisdictions.

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[31] In some provinces, quality assurance committees cannot disclose even de-identified information, and Sharing must be by way of the applicable healthcare institution or healthcare provider.

[32] This standard varies between provinces. For example, British Columbia does not include the qualifier "reasonably" and therefore appears to reflect a stricter standard.

[33] Unlike most provinces which tie disclosures to entities existing under the laws of the applicable province, the Alberta PHI Act uses language that does not require the recipient entity to be formed under Alberta law: disclosures may be made to "a committee that has as its primary purpose the carrying out of quality assurance activities within the meaning of section 9 of the *Alberta Evidence Act.* See *Alberta Evidence Act*, R.S.A. 2000, c. A-18, s.9.

[34] Subsection 27(4)(g) of the *Health Information Protection Act*, S.S. 1999, c. H-0.021.

[35] National Steering Committee on Patient Safety, "*Building a Safer System: A National Integrated Strategy for Improving Patient Safety in Canadian Health Care*" (September 2002) at 15.

In a subsequent report, Karen Weisbaum et al.[36] (the "**Weisbaum Report**") concluded that privacy legislation is not - nor will it ever be - standardized.[37] Instead, the authors focused on developing a national harmonized policy for handling Incident data in a privacy protective manner. It is important to note that the Weisbaum Report limited its analysis to medication Incidents and no other type of Incidents. That is the distinguishing feature between the Weisbaum Report and this report.

The Weisbaum Report concluded as follows:

> "… limits on sharing information that stem from privacy rules and other confidentiality provisions are not necessarily applicable to incident data. What counts for determining if sharing is permitted are the characteristics of the data themselves. At least in the case of medication incident data, sharing will be greatly facilitated through harmonization of these characteristics according to an accepted standard or format, and the fact that privacy standards are not harmonized -- or are perceived as not harmonized – will not present a barrier to sharing."[38]

In other words, the authors determined that Incident data need not be identifying data. In their view, nationally accepted categories of de-identified data elements to be included in Reporting (such as those used by the Institute of Safe Medication Practices Canada) would meet privacy requirements and support Sharing about Incidents involving a medication error.

Although we agree that a national consensus on data elements in Reporting and Sharing would be helpful, we are not convinced that nationally accepted categories of data elements for the Reporting and Sharing of all other Incidents (i.e. Incidents not involving medication error) would be sufficient to meet the requirements of privacy laws and support Reporting and Sharing.

First, PHI that is de-identified does not always result in useful information. For example, an individual who has a unique set of characteristics that may make him or her vulnerable to a certain type of Incident would find that the rare combination of characteristics is itself identifiable with that person. If any characteristics were removed in the name of de-identification, this may result in the removal of clinical information that is necessary for effective Reporting.

Second, as noted above, the statute under which personal information is collected can serve to restrict further disclosures, regardless of whether it is de-identified. Some jurisdictions impose a general confidentiality obligation over all information that is collected in the quality assurance process and used by a quality assurance committee. Other jurisdictions expressly restrict

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[36] Karen Weisbaum, Sylvia Hyland and Eleanor Morton, "*Striking a Balance: Facilitating Access to Patient Safety Data While Protecting Privacy Through Creation of a National Harmonized Standard*" (April 2007 Draft) at 2.

[37] It is the view of the authors of this report that standardizing privacy legislation would be difficult. In our view it would not be difficult to standardize privacy legislation from a language point of view; however, it would be difficult to achieve from a political/process point of view.

[38] Karen Weisbaum, Sylvia Hyland and Eleanor Morton, "*Striking a Balance: Facilitating Access to Patient Safety Data While Protecting Privacy Through Creation of a National Harmonized Standard*" (April 2007 Draft) at 3.

disclosures, and the fact that *any* information was collected or otherwise used by a quality assurance committee would serve to limit any subsequent use or disclosure of such information.[39] As a result, de-identification would not facilitate Sharing.

Some jurisdictions have exceptions to the bar against further disclosure of Incident data and information used by quality assurance committees, but they do not seem to be applicable. British Columbia, Northwest Territories and Nunavut permit the disclosure of de-identified information by a quality assurance committee or third party within the province and outside the province only for the purpose of advancing medical research or medical education. Given that quality assurance committees are not engaged in advancing medical research or medical education, *per se*, no disclosure of any information provided to a quality assurance committee in the course of its activities or any resulting findings or conclusions of the committee is permitted. Similarly, most provinces permit disclosure of personal information to prevent harm or injury; however, we have read that exception narrowly, such that a disclosure would be permitted to resolve an immediate harm to a specific individual or group of individuals, and not for broader Reporting in the name of preventing generalized and unspecified harms. While Weisbaum and colleagues argue for a broader interpretation of these harm reduction clauses, it is unclear if such a broad interpretation can be supported. Further consultations with provincial and territorial representatives may be required.

3. Adverse Event/Critical Incident Reporting Laws

Three provinces, Saskatchewan, Manitoba and Quebec, have created statutory adverse event reporting mechanisms. The key provisions of these statutes are summarized in Appendix 5.

Each province defines the Incidents that are to be Reported in a slightly different way, although they all encompass serious Incidents that lead to the actual or potential loss of life, limb or function. Saskatchewan's definition is the most detailed, setting out seven categories of Incidents (surgical, product or device, patient protection, care management, environmental, and criminal).

In each province, the institution is required to notify the responsible Minister of the occurrence of an Incident. Institutions must investigate the event and provide a report to the Minister following the investigation. Few details are provided in the legislation and regulations about what information is to be Reported and what the process is for Reporting. However Saskatchewan has developed detailed guidelines which outline the process.[40] Manitoba and

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[39] Alberta appears to be an outlier on this point, in that quality assurance committees can disclose de-identified health information to other quality care committees within and outside of Alberta. Disclosure by the quality assurance committee is barred except for disclosures of non-identifying health information to another committee that has as its primary purpose the carrying out of quality assurance activities within the meaning of section 9 of the *Alberta Evidence Act*. Had the reference been limited to disclosures to "quality assurance committees" (i.e. a defined term tied to Alberta law), any disclosure would be limited to entities existing under Alberta law (i.e. no disclosures outside of Alberta).

[40] *Saskatchewan Critical Incident Report Guideline, 2004.*

Quebec require that institutions themselves establish written procedures respecting the recording and providing of information about adverse events.[41]

Interestingly, while the Manitoba and Saskatchewan legislation is quite similar in its requirements, Reporting has increased in Saskatchewan but not in Manitoba. The limited impact of the legislative requirements in Manitoba may stem from limitations in resources needed to analyze Incidents and from the limited preparation in terms of education for healthcare organizations about the scope and nature of these requirements. Also, the increase in Reporting in Saskatchewan may also be as a result of the detailed guidelines developed to set out the process.

At present, none of the provinces mandate that the information that is collected by the Minister be made available to the public. Quebec has a provision that would require the Minister to create a register of Incidents for the purpose of monitoring and preventing such occurrence and ensuring control measures are implemented.[42] However, this provision is not yet in force.

All three regimes enable the Reporting and review of Incidents with some restrictions and limitations. The statutes make Reporting mandatory in order to promote patient safety, but place restrictions on Reporting, such as Reporting only de-identified information to Government, in order to protect personal privacy and to encourage health professionals to comply with Reporting requirements.[43]

Finally, by way of comparison, we have included in Appendix 6 Reporting provisions from the laws of California and New York. California's law is substantially similar to the law in Saskatchewan; both are based on the United States National Quality Forum's *Serious Reportable Events in Healthcare: A Consensus Report*. Both states go further than the Canadian jurisdictions in terms of making information available to the public. New York's information is already available to the public through the New York Patient Occurrence Reporting and Tracking System (NYPORTS). Only aggregate information is available to the public; other laws protect the confidentiality of the original source information that is Reported. California's law contemplates going further: it will require information on Reported Incidents to be made available in writing by 2009 and online by 2014, although individually-identifying information will still be protected by other laws.

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[41] Subsection 53.2(1) of *Regional Health Authorities Act*, C.C.S.M. c. R34 and section 235.1 of *An Act respecting Health Services and Social Services*, R.S.Q. c. S-4.2.

[42] Section 431(6.2) of *An Act respecting Health Services and Social Services*, R.S.Q. c. S-4.2.

[43] In Saskatchewan, all notices and reports relating to the critical incident review process must be on a no-names basis (section 10 of the *Critical Incident Regulations*, R.R.S. c. R-8.2 Reg. 3). Manitoba requires that a critical incident review committee must limit the contents of any notices, reports or information disclosed or shared to the minimum amount of personal information that is necessary (section 53.7 of the *Regional Health Authorities Act*, C.C.S.M, c. R.34). Quebec requires that information be Reported in a "non-nominative" form (section 233.1 of *An Act Respecting Health Services and Social Services*, R.S.Q., c. S-4.2).

4. Coroner's Inquests and Public Inquiries

Every province has legislation that governs the investigation of certain fatalities.[44] Under this system, a coroner or medical examiner must investigate deaths that occur in certain circumstances, including:

(a) as a result of suspected misadventure, negligence or accident on the part of others;

(b) where the cause of death is undetermined;

(c) where a stillbirth or neonatal death has occurred where maternal injury has occurred or is suspected either before admission or during delivery;

(d) where the death occurred within 10 days of an operative procedure or under initial induction, anaesthesia or the recovery from anaesthesia from that operative procedure; and

(e) where the death occurred within 24 hours of admission to a hospital.

The coroner or medical examiner shall investigate each death and determine whether or not an inquest must be held. Generally, inquests are open to the public, although a coroner may exclude the public or order that some of the evidence may not be published if certain stringent requirements are met. The findings and any recommendations of the inquest jury are also public. Under the relevant evidence statutes, quality assurance records would be protected by privilege from being accessed by the coroner or revealed in an inquest.

A similar mechanism that could review an Incident that does not result in a death is a public inquiry. The privilege over quality assurance records would also apply in a public inquiry.

The coroner and public inquiry systems enable the review of Incidents, albeit in a limited manner. Only deaths that meet the requirements are reported to the coroner, and the coroner only conducts an inquiry in certain circumstances. Furthermore, there is wide discretion in determining when a public inquiry will be held. Finally, a jury's recommendations are not binding, although the public attention generated by the inquiry may force policy and legislative changes.

It is noteworthy that in two separate coroner's inquests into Incidents in healthcare, the coroner's jury has made recommendations regarding Reporting. In 2004, two coroner's juries in Ontario recommended that hospitals adopt some kind of Reporting scheme. The jury at the inquest into the death of Lana Dale Lewis, who suffered a stroke which was caused by chiropractic neck adjustment, recommended that the Ministry of Health establish an internal database to record cervical manipulations and that a section of the database be used to record the occurrence of Incidents, including stroke, transient ischemic attacks, injury, paralysis and other symptoms.[45]

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[44] We have not prepared an appendix summarizing the relevant provisions of this legislation across Canada given the substantial similarity of the provisions and their limited application to Reporting and review of Incidents.

[45] Ontario, Office of the Chief Coroner, Verdict of Coroner's Jury on Inquest into the Death of Lana Dale Lewis and Recommendations, (Toronto: January 16, 2004) (Presiding Coroner: Dr. B. McLellan).

At the inquest into the death of Marie Tanner, who died as the result of an accidental injection of potassium chloride, the jury recommended that all hospitals adopt a standardized medication safety report program such as the Institute for Safe Medication Practices Canada's "Analyze-err".[46]

5. Drug and Medical Device Adverse Event Reporting

Federal legislation governs Reporting related to drugs and medical devices. These Incidents are fundamentally different from the other Incidents discussed to this point in that device failures or drug effects and interactions, not organizational or administrative failures, cause these Incidents.

Manufacturers are required by law to report certain defined Incidents involving their drugs or devices to the designated branch of Government. These reports must contain a detailed explanation of the Incident and a summary of the actions taken as a result of the manufacturer's investigation. A summary of these provisions is attached at Appendix 7.

Although these schemes make Reporting in certain circumstances mandatory, participation by healthcare professionals is voluntary. This is the major limitation of the schemes: manufacturers and importers can only report the Incidents of which they are aware. Therefore, although the schemes enable Reporting, the efficacy of the schemes is seriously limited.

In her March 2004 report on the regulation of medical devices, Auditor General Shelia Fraser found that "Health Canada has done little work to increase the number and quality of reports received from [healthcare professionals]. As a result, Health Canada is not able to adequately identify adverse events."[47] Furthermore, Ms. Fraser found that Health Canada does not know the extent to which the regulations are being respected. At the time, Health Canada did not engage in any inspection activity at the post-market phase. Health Canada did not know whether manufacturers and importers were "taking appropriate action in response to Incidents or complaints that come to their attention" or "reporting… all serious adverse events that come to their attention."[48] Ms. Fraser noted that Health Canada has completed several studies to assess weaknesses in post-market surveillance and options. However, at the time "Health Canada [acknowledged] that its lower levels of reporting [in comparison to the United States and United Kingdom] are due, in part, to its limited activities in the area of post-market surveillance."[49] Insofar as we are aware, the federal Government has not yet made any changes to the medical device legislation. The Reporting system for drugs suffers from the same limitations as the system for medical devices. Health Canada believes that it receives notice of less than 10% of adverse reactions.[50] In addition, the problems with post-market surveillance that exist with

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[46] Ontario, Office of the Chief Coroner, Verdict of Coroner's Jury on the Inquest into the Death of Marie Tanner, (Peterborough: February 12, 2004) (Presiding Coroner: Dr. J. Cairns).

[47] Office of the Auditor General of Canada, *Report of the Auditor General to the House of Commons, Chapter 2 Health Canada - Regulation of Medical Devices* (March 2004) at 2.87 (http://www.oag-bvg.gc.ca/domino/reports.nsf/html/20040302ce.html).

[48] *Ibid*. at 2.79.

[49] *Ibid*. at 2.89.

[50] Jocelyn Downie et al., *Patient Safety Law: From Silos to Systems, Appendix 2: Country Reports CANADA* (March 31, 2006) at 34.

medical devices also appear to apply to drugs.[51] Nonetheless, we understand that work is currently underway by the federal Government to improve post-market surveillance.

6. Professional Regulation

An Incident that involves the potential misconduct or incompetence of a healthcare professional raises the issues of professional regulation and discipline. The law surrounding professional regulation is large and varied, defined by both jurisdiction and profession. Professional discipline hearings are of very limited use in Reporting. The focus of professional regulation is, of course, the professional, and not more general systemic or department practices that may have contributed to an Incident. Furthermore, regulatory colleges are generally only required to publish very limited information on the facts of an Incident and the result of a hearing. The focus of this report is the review of system performance; therefore, a detailed survey of professional regulation is outside the scope of this report.

One development of note, however, is Ontario's proposed changes to the *Regulated Health Professions Act*. Two of the goals of Bill 171, the *Health Systems Improvement Act, 2007*,[52] are to increase the transparency of health regulatory colleges and facilitate public access to information about the colleges and their members. Proposed changes will mean greater disclosure of regulatory matters on the public register. At present, only the results of discipline and incapacity hearings are available. Bill 171 proposes to make note on the register of referrals from the Inquiries, Complaints and Reports Committee to the Discipline Committee.[53] Furthermore, the register will include a synopsis of the decision in every proceeding and will include notations of reprimands issued to members and, where applicable, a member's resignation and agreement not to practice again in Ontario. Ontario's professional colleges have supported the proposed changes and the increased transparency.

C. Legislative Barriers and Enablers to Reporting and Sharing

Our review of the relevant legislation has identified the following enablers of Reporting and Sharing:

1. The disclosure provisions of the PHI legislation serve as an enabler to Reporting in certain circumstances in that they allow custodians or trustees of PHI to disclose PHI, without the individual's consent, to quality assurance committees for the purpose of reviewing an Incident.

2. Also in some provinces, such as Alberta and Saskatchewan, the disclosure provisions of the PHI legislation also act an enabler to Sharing in that they allow custodians or trustees to disclose PHI to third party organizations to be used for prescribed purposes. Also,

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[51] *Ibid*. at 36-37.

[52] Bill 171, *Health Systems Improvement Act, 2007*, 2nd Sess., 38th Leg., Ontario, 2007. Received Royal Assent on June 4, 2007.

[53] There are a number of gaps in Bill 171. Complaints that are not referred to the Discipline Committee would not be recorded in the register. Furthermore, complaints that are resolved by mediation would also not be recorded. In these circumstances, a member of the public would not know that the regulated healthcare professional had been the subject of the complaint.

although it does not have PHI-specific legislation, Newfoundland and Labrador enacted legislation that created a third party organization to aggregate data from all components of the health and community services system.

3. Provisions in general privacy statutes that allow for the making of regulations respecting the disclosure of personal information to persons or bodies located within or outside the province and the approval of such regulations is an enabler to Sharing.

4. The critical incident reporting legislation in Saskatchewan, Manitoba and Quebec enables Reporting by setting out how certain Incidents are to be investigated and by making the Reporting of such Incidents mandatory.[54]

5. Detailed guidelines to Reporting, like those in Saskatchewan, seem to be an enabler to Reporting.

6. The federal systems for Reporting involving drugs and medical devices provide a mechanism for manufacturers to report problems with respect to same.

7. The privilege over quality assurance information in certain legal proceedings encourages Reporting.

8. Barring of personal liability for any information or disclosure that arises out of a quality assurance committee's activities in all of the larger provinces is an enabler to Reporting given that individuals making submissions or disclosures to a quality assurance committee could not be sued for doing so. The exception to this is where such submissions or disclosures are not made in good faith.[55] Good faith in this context generally means that an individual making a Report does so with an honest belief in what is being Reported and has made such Report without malice or design to gain personally from doing so.

Our review has identified the following barriers to Reporting and Sharing:

9. Incident reports that are outside of the quality assurance process may not be protected by privilege. Since some provinces allow them to be used against a healthcare professional in a discipline hearing[56] or review of hospital privileges[57], healthcare professionals may be inclined to record only limited information in these reports.

10. Provincial privacy and other legislation appears to be a barrier to Sharing given that:

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[54] The federal legislation on drugs and medical devices and the provincial legislation on critical incidents and privacy are all mandatory schemes. From our perspective, these schemes enable reporting; however, we recognize that the mandatory nature of the schemes may influence the behaviour of individual actors and have a counter-productive effect.

[55] Good faith requirement found in British Columbia, Manitoba, Ontario, Nova Scotia, Yukon, Northwest Territories and Nunavut.

[56] Saskatchewan, British Columbia, Northwest Territories and Nunavut.

[57] British Columbia, Northwest Territories and Nunavut.

(a) generally, quality assurance committees are prohibited from disclosing Incident data that contains PHI within and outside of that jurisdiction. Moreover, even disclosure of Incident data containing de-identified PHI by a quality assurance committee to another quality assurance committee or other third party in the same jurisdiction is widely prohibited;

(b) in most jurisdictions that have legislation which addresses quality assurance activities,[58] there are broad confidentiality obligations imposed on quality assurance committees that prohibit the disclosure of quality assurance information, to other persons both within or outside of that jurisdiction; and

(c) in some jurisdictions, third party patient safety organizations are not permitted to disclose Incident data containing PHI inside or outside of those provinces. Therefore, Sharing with a national body to facilitate Pan-Canadian Reporting is prohibited. It could only be done on a de-identified basis.

11. Many of the recording and Reporting responsibilities relating to post-sale of drugs and medical devices fall on the manufacturers and importers, rather than the retailers and hospitals. This information is likely received from retailers and health practitioners who are not mandated to report this information except where they have applied for special approval for a drug or are conducting clinical studies or experimental treatments.

D. Elements of a Legislative Framework for the Jurisdictions

Provincial Legislation

From this analysis, the following considerations are put forward for those provinces and territories that do not have Reporting legislation and are considering developing and tabling such legislation.[59] Accordingly, the following elements should be included in any such legislation:

1. **What is Reported?** The definition of a reportable Incident must be clearly defined so that healthcare professionals and laypersons can easily determine what Incidents must be Reported. For example, Saskatchewan's legislation, particularly the *Saskatchewan Critical Incident Reporting Guideline, 2004*, sets out an expansive definition of "critical incident" and lists over 30 specific Incidents that must be Reported as well as numerous basket clauses to capture other Incidents that lead to death or serious disability.[60]

2. **Who makes a Report?** The group of persons Reporting should be defined. This group may include healthcare professionals, employees of healthcare institutions, students and others. Furthermore, the scheme should provide a mechanism for persons other than

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[58] The exceptions appear to be Alberta and Saskatchewan.

[59] We are not able to say with certainty whether mandatory Reporting increases Reporting. However, it does appear from our understanding of Saskatchewan that legislation coupled with detailed regulations and guidelines has increased Reporting in that province.

[60] These Guidelines are adapted from the U.S. National Quality Forum's *Serious Reportable Events in Healthcare: A Consensus Report* (http://www.qualityforum.org/publications/reports/sre.asp).

those in the defined group (i.e. an individual or the individual's family) to Report a suspected Incident and require an institution to investigate whether an Incident occurred.

3. **How an Incident is Reported?** The legislation must define procedures and timelines for notice and investigation of an Incident and Reporting. The legislation may permit institutions to set these procedures through policy, albeit within certain parameters.

4. **To whom is an Incident Reported?** The legislation should require Reporting by healthcare institutions/healthcare professionals to a quality assurance committee including PHI. The legislation should also require Reporting of Incident data on an unidentified basis to the responsible Ministry or a prescribed third party organization within the province for tracking and analysis purposes.

5. **Confidentiality.** Any published information, including notices and reports, must not include the name of the patient, the name of any healthcare provider, or the name of any other individual who has knowledge of the event. In certain cases of unusual and high profile Incidents where de-identification is insufficient to assure confidentiality, there may be need for further protections in respect of Sharing.

6. **Privilege.** The legislation must explicitly extend this effective "privilege" to all documentation resulting from the quality assurance process including RCA, recommendations, reports and notices.

7. **Non-retaliation.** The legislation must provide that persons who are required to provide information under this process are protected from personal liability, suspension, demotion, harassment and other retaliatory behaviour unless, of course, the person was acting in bad faith.

8. **Expert analysis.** Reports must be classified and critical issues reviewed by experts who have appropriate clinical skills and knowledge of system issues. Such analysis is a critical element in deriving learning from Reporting.

9. **Incidents register.** The Minister or third party organization must maintain a register of Incidents on a de-identified basis for the purpose of aggregating data and Sharing within the province and with a national body that can disseminate warnings across the country. The legislation should encourage the parties involved to develop and use electronic Reporting systems.

10. **Annual review.** Institutions must provide an annual report to the Minister or third party organization that summarizes Reporting and quality improvement recommendations of the previous year. This summary must also include a report on the implementation of quality improvement recommendations of the previous year and an evaluation of the success of those improvements.

Federal Legislation

In our view, federal legislation is not required to enable Reporting. Even so, federal legislation could be developed for the purposes of setting out the objectives of the Pan-Canadian model and

to provide additional funding to support Reporting efforts. Such legislation would not override provincial legislation but could serve to foster cooperation among the provinces and jurisdictions and emphasize the significance of the role of the national body.

PART TWO: FINDINGS OF POLICY REVIEW

A. Introduction

Another key component of this review included conducting a detailed examination of existing provincial, territorial and federal Government policies relating to the Reporting and review of Incidents. This review drew from a representative sampling of policies in place across Canada. 16 separate policies were collected (out of 38 requested). Specifically, the team reviewed these policies to determine their intent and function, whether such policies were compulsory and the manner in which the collected information was used, if at all. Additionally, a number of interviews were conducted to determine the "in the field" perspective and gain an understanding of the practical aspects of the policies in place. From this, enablers and barriers to effective policy were identified and noted. This section outlines the recurring/common themes, general approaches, specific methodologies and weaknesses from the review.

A summary of Reporting policies analyzed is provided in Appendix 8. An outline of the strengths and weaknesses of the policies is provided in Appendix 9. The results of the interviews are set out in Appendix 10.

B. Policy Barriers and Enablers to Adverse Event Reporting

As summarized in Appendix 8, there is a patchwork of policy across Canada in the area of Reporting. In some jurisdictions, policy for Reporting and policy for Disclosure are separate; in other jurisdictions they are combined. In smaller jurisdictions, policy is often created at the provincial level. However for most provinces that are organized regionally, policy is created at the regional level. In Ontario, policy is developed by individual healthcare organizations (e.g., hospitals).

C. Policy Barriers and Enablers to Adverse Event Reporting

Based on our review of the policies obtained and the follow up interviews conducted across jurisdictions, we have identified the following barriers to Reporting:

1. Most policies for Reporting require only voluntary participation. Recently, there has been increased support for mandatory Reporting and the Saskatchewan, Manitoba and Quebec legislation incorporates provisions for mandatory reporting of a defined list of Incidents. Well designed mandatory reporting programmes can promote greater Reporting, but experience in this regard is variable. We understand that although Reporting has increased in Saskatchewan, this is not the case in Manitoba. However, the Manitoba initiative is still in the first year of operation. Also, our interviews with key informants in Manitoba and Saskatchewan suggest that Saskatchewan spent more time informing and preparing its healthcare organizations to respond to the new requirements.

2. All policy reviewed was silent on who (job titles) should participate in Reporting. In some respects this enables all healthcare workers to Report. However, it is a common experience that members of some disciplines are more likely to Report than others. In many settings there is a greater participation of nurses, while members of other health disciplines do not recognize their responsibility to participate in Reporting.

3. Generally, jurisdictional/organizational policy includes clear instruction with regard to whom Reports are submitted and the department or position responsible for collecting those Reports. However, there is a great deal of variance in the methods used to Report ranging from electronic system Reporting to paper generated Reports. The reliance on paper based systems limits participation in Reporting and may slow the analysis and follow up on Reports. Inefficient Reporting systems are likely to reduce the participation of front line staff.

4. The policies reviewed did not include clearly defined accountability or evaluative mechanisms. Although a minority of policies make reference to a quality review process, these are not well formulated in the policy. For most policies, once Reports have been submitted and collected there is little understanding of how they contribute to the improvement process. Policies in general tend to be more robust on the issue of data collection and relatively silent on the issue of quality improvement and evaluation.

5. The absence of common definitions or scope among jurisdictions or healthcare organizations means that information collected across Canada is not comparable. There is no common language or nomenclature used to label Incidents; terminology in use includes: incidents, critical incidents, accidents, adverse events, serious adverse events, sentinel events, hazardous events, close calls and near misses. Thus, there is no ability to compare data from one jurisdiction to another since what is actually being Reported differs along with how each defines these terms. While most jurisdictions Report all Incidents, some policies only include Reporting of 'serious' adverse events. The ability to even recognize an Incident as adverse is among the biggest barriers to Reporting.

Based on our review of the policies obtained and the follow up interviews conducted across jurisdictions, we have identified the following enablers to Reporting:

6. Standardized definitions and a common Classification System for Incidents are seen to be enablers. This is one important area that would be best addressed to ensure consistency both at the provincial level (and possibly a Pan-Canadian level).

7. Development of provincial, regional and organizational policies that enhance the opportunities for all staff to report Incidents.

8. Effective Reporting systems must make it easy and quick for staff to report. Electronic systems (e-systems) may encourage Reporting because they are less time consuming. E-systems also facilitate data analysis, follow up and review, enhancing the value of Reporting systems and encouraging greater participation.

9. Many of those interviewed highlighted the need to build in feedback and follow up mechanisms to those involved in Reporting. Follow up information should be made

available to people who file Reports to avoid the perception that Reporting is not valuable or not used. Presently, most policies remain silent on evaluation of Reporting programs. Such evaluation would highlight ways to improve Reporting and learning and communicate the value of such activities to staff.

10. The presence of legislation that directs Reporting may build support for improved Reporting. In jurisdictions that already have legislation interviewees saw this as an important enabler while those in jurisdictions without legislation saw this as a barrier. Thus Sharing between provinces and more detailed assessment of the experiences of Reporting programs in Canada and elsewhere may clarify the benefits and disadvantages to mandated Reporting.

11. The purpose of Reporting must emphasize improving quality and avoiding future Incidents – not ascribing blame. To support this, Reporting must be confidential and non-punitive. Cultural barriers to Reporting include fear of blame and personal liability. In some areas, Reporting is used for performance management so staff may be reluctant to Report. The extent to which culture can be changed by policy is unclear and since some Incidents are caused by negligence or incompetence there needs to be provisions that allow healthcare organizations to deal with such actions in a distinct manner. However, policy should clearly define different tracks for assessing cases where negligence or incompetence is suspected versus those where individual or system error is suspected. Policies must reinforce that the ultimate goal of Reporting is to improve care and lessen risk and preventable Incidents.

12. Senior management's support of patient safety is important to encouraging Reporting. One way that management can demonstrate its commitment is by providing training programs. Training and education programs on various aspects of Reporting were among the most popular enablers identified. Such programs include information on how to Report, when to Report, how to analyze Reports and what to do with the results.

D. Elements of a Policy Framework

Analysis of the identified barriers and enablers and the existing policies reviewed offers elements of a policy framework for Reporting. As discussed above, current policies contain some of the elements below, but most are incomplete. Consistency in policies across Canada would facilitate use of Shared Incident data. A comprehensive policy framework should include the following elements:

1. Reference to legislation (where applicable). Provincial or regional policies should be based on legislative requirements.

2. Consideration as to whether or not Reporting should be identified as mandatory or voluntary and the range or type of Incidents to be Reported.

3. Scope of policy and responsibilities: does the policy include Disclosure? Who makes a Report? Policy must clearly identify responsibilities for Reporting.

4. Common definitions (which may be linked to legislation) must be included in policy in order to enable comparative Reporting. Common terminology should be used across jurisdictions. In the absence of legislation, policy must set out the terminology as well as characteristics that will be used to define Incidents.

5. Policy must clearly require a proper evaluative framework, Reporting methods and accountability structure which must include a clear Reporting process with an accountability structure; who is responsible for making, collecting and analyzing Reports as well as who is responsible for directing practice changes based on analysis.

6. Policy should specify the goal of establishing accessible electronic Reporting and a reasonable time frame in which systems must be developed to accommodate such Reporting.

7. Policy must encourage a culture of learning and clearly identify the high level goals, principles and commitments that management must make including:

   (a) improving care and lessening risk of preventable Incidents;

   (b) increasing patient safety;

   (c) providing staff training on recognizing Incidents, Reporting, analysis and quality assurance; and

   (d) providing mechanisms and criteria for establishing a separate process for dealing with cases where negligence, incompetence or incapacity is suspected versus those where individual or system error is suspected.

8. Quality assurance and evaluation programs must be mandated in policy and must require member organizations to have such programs for Reporting. Policy must direct that these programs:

   (a) include tracking of Incidents and improvements on outcomes; and

   (b) include feedback to staff based on aggregate data and specific improvements to illustrate status of quality improvement.

PART THREE: FINDINGS OF SURVEYS AND INTERVIEWS

A. Introduction

In addition to reviewing legislation and policy, we designed surveys to identify health region or healthcare organization policy related to the Reporting and review of Incidents. To capture the experiences of these organizations, separate surveys were required: one for health regions and another for individual healthcare organizations in Ontario. The healthcare region survey was also translated into French and mailed to Quebec organizations. The healthcare organization surveys were modified slightly for community and long-term care sectors (see Appendix 11 for the acute care hospital survey exemplar). In addition, interviews with key stakeholders regarding

legislative and policy enablers (see Appendix 12 for interview guide) were conducted. The two data collection methodologies, key findings, including enablers and barriers to Reporting, and recommended changes are described in this section.

B. Survey and Methodology

The surveys were designed to identify organizational policies and practices concerning Reporting and the review of Incidents in Canada.[61] The surveys were mainly comprised of close-ended questions with some open-ended questions. All health regions in provinces and territories were sent the health region survey, while in Ontario a representative sample of hospitals, long-term care facilities and community healthcare agencies were sent their respective survey. The surveys were sent out across Canada in April 2007. Non-responding organizations were contacted by phone or email. However, only one wave of surveys was distributed given the short timelines for this project. Data analysis included descriptive statistics involving frequency mean distribution of the close-ended questions and identification of broad themes from the open-ended questions.

C. Findings of Surveys

This section provides an overview of key findings from the surveys. These key findings are largely consistent with some key points identified from the legislative review (Part One) and policy review, particularly the interviews conducted with "in the field" participants but add some additional issues related to local experience and potential strategies for Pan-Canadian Reporting.

1. **Sample Characteristics**. Overall, 82 surveys from 8 provinces[62] were received from the original 340 that were sent out (response rate of 24%). The final sample included in this analysis was 81 as one survey was incomplete. The sample draws from:

   (a) 37 hospitals;

   (b) 25 health regions;

   (c) 12 from community based organizations; and

   (d) 7 from long-term care organizations.

2. **Implementation of Reporting Systems.** In general the majority of organizations have "fully implemented" systems in place for Adverse Events (N=65) and Sentinel Events (N=66). However, there were lower rates of implemented Near Miss systems in the organizations with 49 systems fully implemented and 16 indicating that their systems are partially implemented.

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[61] Given the move towards broader Reporting systems, the research team also collected information on Sentinel Events.

[62] The hospital, community and long-term care sector samples are from Ontario only, with representation from health regions across Canada with the exception of Quebec and Prince Edward Island.

3. **Type of Reporting Systems.** Of the 77 organizations reporting the use of Adverse Event and Sentinel Event Reporting systems, there are more paper-based systems (N=37, 39 respectively) as compared to electronic systems (N=26 for both). Of the 71 organizations that responded regarding the Near Miss Reporting systems, 32 reported the use of a paper based system and 28 reported using an electronic system. Interestingly, a number of the organizations reported using both systems (N=14 Adverse Events, N=12 Sentinel Events, N=11 Near Miss).

4. **Use of Analytical Approaches to Investigate Events.** The results highlight that organizations in general are either fully implementing analytical approaches or that they are implemented in certain organizations or units in the hospitals. All of the hospitals and health regions did outline that they are at some level implementing these analytical approaches for both Adverse Events and Sentinel Events. Similar to the finding of Reporting systems, fewer hospitals and health regions reported a fully implemented approach to examine Near Miss occurrences (6 hospitals and 4 health regions reported not engaging in examining Near Misses). The long-term care organizations reported lower levels of implementation of analytical approaches for analyzing Adverse Events, Sentinel Events and Near Misses. These responses cannot be used to assess the robustness of the analyses; however, only 43% of responding organizations reported doing more than two RCAs per year, although 60% report doing more than two audits and 74% report doing more than two chart reviews to follow up on safety occurrences. This suggests that most organizations have only limited experience and resources for such work.

5. **Use of Retrospective Tools to Investigate Safety Occurrences.** This section asked participants if they had engaged in various retrospective analytic tools to investigate safety occurrences and, if so, how many were being conducted each year. RCAs are used in the majority of organizations (N=65), with the majority conducting one or two per year (30). Audits are occurring in 59 of the 81 organizations. Chart reviews are the most popular technique being used in all types of organizations (N=67) and at the highest frequency of five or more in most of these organizations (N=48).

6. **Organizational Policies and Practices on Reporting Incidents.** All but two organizations (N=1 hospital; N=1 health region) reported having a Reporting policy in place. Most organizations (N=64) reported that the policy they have in place covers all three patient safety occurrences that were supported by responses to the open-ended question (4b).

7. **Different terminologies**. Different terminologies both (a) within hospital sector (e.g. major vs. minor, good catch, non-employee, unusual occurrence and unusual or unexpected response to standard treatment, not accepted routine operation) and scales (rating from 0-Near Miss to Sentinel Event-4); and (b) across sectors (e.g. unusual occurrence, unexplained injuries in long-term care; client complaints and compliments in community; critical occurrences in health regions).

8. **Policies are under revision and/or development.** A majority of the organizations (N=68) reported that they have a policy in place that requires Disclosure, a finding that

was supported by responses to the open-ended question (4c). Other key themes that emerged included:

(a) Reporting is contingent upon the severity of the occurrence and the perception of the healthcare professional;

(b) in many organizations Reporting policies are under revision and/or development; and

(c) considerable variation exists on what, who and how Reporting occurs, whether it is mandatory, explicitly stated as a policy, and enacted in practice.

9. **Reporting to Board of Directors.** 54 (out of 80) organizations reported having a policy that requires them to Report to the Board of Directors that was supported by responses to the open-ended question (4d). Other key themes that emerged included:

(a) Reporting to the Board of Directors[63] is often not an explicitly stated policy, but is a common practice, ranging from monthly, quarterly, semi-annually, and ad-hoc in frequency (Sentinel Events that involve potential media attention and political implications) and nature of Reporting (trended, aggregate data on Incident, action/plans for improvement, and Sentinel Events); and

(b) variation of what level of the Board of Directors received Reporting ranging from Board of Directors sub-committees (e.g. Quality and Safety Council, Quality Committee, etc.) and by whom (Board of Directors sub-committees to the Board of Directors, CEO to Board of Directors, etc.).

10. **Key themes that emerged from current issues around Reporting.** Key themes (question 4e) included:

(a) revision of policies to align with recent legislative changes (e.g. RHA Act and Evidence Act); accreditation standards (Canadian Council on Health Services Accreditation Required Organizational Practices); and National Disclosure Guidelines (CPSI);

(b) calls for just culture;

(c) broader focus to open Disclosure and Reporting;

(d) need for timely follow up; and

(e) specific sector issues including geographical size and diversity in health regions and amalgamation of CCACs that have different Reporting systems.

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[63] Details on what is Reported to the Board of Directors are not available from the survey.

11. **Frequency of Activities Associated with Reporting and Investigating Patient Safety Occurrences**. Key activities and associated frequencies included:

    (a) Reports to the Board of Directors in the organizations occurred at a majority of the organizations (N=77) with these happening to the greatest extent on a quarterly basis (N=52); and

    (b) the majority of organizations reported that they never include patient safety information when reporting Incidents to the community (N=62).

12. **Staff Education.** The majority of organizations engage in some level of staff education (N=74) occurring on a monthly basis for half of these organizations (N=35) with another 34 organizations reporting either quarterly or annually.

13. **Executive Walk Rounds.** 35 organizations reported not engaging in executive walk rounds in their organizations. For community centres this was not seen as relevant. Of those who did engage in the executive walk rounds the majority were reported in the hospital setting (N=17) and all the long-term care facilities reported engaging in these walk rounds. The timing of these walk rounds varied for all types of organizations.

14. **Review Meetings.** A number of organizations reported engaging in meetings to review Incidents (N=58). Of those that did, the majority did so on a monthly basis (N=28). Collectively, there were 21 participants that reported that they did not hold meetings to review Incidents.

15. **FMEA Analysis.** 51 organizations engaged in Failure Modes Effects Analysis ("**FMEA**") with the majority performing these on an annual basis. 29 of the organizations reported never conducting this type of analysis.

16. **Follow up and Resolution.** More than half of the organizations (N=46) reported that they did not engage in any reports on the follow up and resolution of all alerts and equipment recalls to a third party.

17. **Perception of the Extent to Which the Current Reporting System Captures Incidents**. When asked to respond to how well their current Reporting system captures the numbers of types of Incidents that are occurring in their organizations, most respondents reported frequently (N=40) with 34 reporting within the range of limited extent (N=11) to somewhat (N=23).

18. **Perception of the Extent that the Reporting System and Structures Create Capacity to Analyze and Act.** When asked to report on how well the current system allows for analysis and action based on Reporting, the majority of the respondents perceived this to be somewhat (N=29) or frequently (N=28) occurring.

19. **Reporting to External Agencies.** Participants were asked to outline the various external agencies to which they Report Adverse Events, Sentinel Events and Near Misses. Key findings include:

(a) in relation to Reporting to the Ministry of Health, most health regions (N=20) and all long-term care facilities (N=7) outlined that they made such Reports, whereas the community and hospitals were mixed in their responses. For example, in the hospital sector only 11 (out of 37) engaged in such Reporting;

(b) in relation to Reporting to a regulatory body, the health regions mostly reported that this did not occur (N=20) and the other organizations were mixed between yes and no;

(c) most of the organizations indicated that they did not Report to an external third party body (N= 66/79); and

(d) a majority of the organizations responded that they Report to their insurers (N=55). However, only two of the long-term care organizations reported yes and the others (N=5) indicated that they did not have to Report to their insurers.

20. **Internal and External Enablers.** Respondents were asked to identify both internal (question 8) and external (question 10) enablers that facilitate enactment of policies associated with the Reporting and review of Incidents.

(a) Key internal enablers, organized under structures, processes and culture, included:

(i) structures: education; electronic databases for Reporting and analysis; committees (e.g. Risk Management, Quality Assurance); analytical tools (e.g. FMEA); designated resources (e.g. director level position); and communication strategies;

(ii) processes: organizational policies that include definitions and procedures for Reporting, follow up and review; timely feedback; walk rounds; clear human resources policies around hiring practices and performance management; and

(iii) culture: executive leadership/senior management support; champions at executive and director/management level; just-culture; Board of Director support; front-line staff desire and engagement to provide safe care.

(b) Key external enablers included:

(i) legislation (e.g. *Quality Care Information Protection Act* (Ontario), mandatory reporting in Manitoba and Saskatchewan) and accountability agreements;

(ii) Canadian Council on Health Services Accreditation Required Organizational Practices;

(iii) organizations/networks and associated educational/knowledge management resources (e.g. CPSI, Ontario Hospital Association with

toolkit, hospital report card, Safer Health Care Now, Quality Health Network, Institute of Safe Medication Practices);

(iv) professional/regulatory bodies (e.g. College of Physicians and Surgeons, Canadian Medical Protective Association, College of Nurses of Ontario) and professional expectations;

(v) increased public attention and media; and

(vi) support from insurers (Health Insurance Reciprocal of Canada).

21. **Internal and External Barriers.** Respondents were asked to identify both internal (question 9) and external (question 11) barriers that present challenges to the enactment of policies associated with Reporting and review of Incidents.

(a) Key internal barriers include:

(i) culture of fear, litigation and disciplinary action;

(ii) lack of physician engagement;

(iii) competing priorities within organizations and sectors;

(iv) variation in resources and human resources support;

(v) workload can be a barrier to Reporting, documenting and the audit process;

(vi) lack of awareness/education around the need to Report;

(vii) staffing shortages;

(viii) electronic systems that are not user-friendly;

(ix) funding and financial constraints;

(x) lack of leadership/role modeling; and

(xi) specific sector responses include geographical size and diversity in health regions; mobile, virtual workforce in community; and the Canadian Council on Health Services Accreditation process for the long-term care sector.

(b) Key external barriers include:

(i) culture of fear, litigation and disciplinary action;

(ii) lack of available resources (financial/human). Accountability to external agencies comes at a cost and many organizations do not have the capacity to implement Reporting systems;

(iii) legislation (*Quality Care Information Protection Act* as a double edge sword);

(iv) regulatory bodies (e.g. College of Nurses of Ontario);

(v) public education around safety and Reporting and how organizations will use data to compare;

(vi) lack of standard approach/variation in review approaches and patient safety information; and

(vii) sector specific: reluctance to Share due to managed competition in the community sector and focus on compliance but do not have funding to address issues in long- term care).

22. **Recommended Changes.** As a final question, participants were asked what changes at a practical, policy or legislative level would encourage or facilitate the Reporting and review of Incidents. Key recommended changes included:

(a) province wide mandatory, standardized (with common Taxonomies) Reporting[64] and follow-through aligned with infrastructure (funding and technology);

(b) mandatory, standardized/consistent educational programs for health professional students, practitioners and consumers;

(c) clearer legislation around protection for quality assurance discussions;

(d) agreement support with regulatory bodies (e.g. College of Physicians and Surgeons, Canadian Medical Protective Association);

(e) shift to culture of learning/just culture (from blame);

(f) focus on achieving the Canadian Council on Health Services Accreditation Required Organizational Practices;

(g) resources to implement process changes/quality assurance efforts;

(h) physician engagement through legislation;

(i) research required identifying common high-risk categories and testing of strategies aimed at improving safety; and

[64] Some respondents also identified anonymous reporting.

(j) funding tied to enactment of legislation.

D. Key Informant Interview Methodology

Building on the results from the analysis of legislation and policy and the findings of the survey of health regions and healthcare organizations, interviews were held with key informants across Canada and internationally. These individuals were selected because of their knowledge and experience with Reporting systems or with the Reporting and use of healthcare information more generally. A semi-structured questionnaire was developed to guide the interviews, but the focus of each interview was tailored to the experience and knowledge of each interviewee. Teams of two with one person asking questions and the second taking notes carried out the interviews.

E. Key Findings of Interviews

This section provides highlights of key themes that emerged from the 14 interviews[65] that spanned a broad range of experience and locations represented (five provinces: Ontario, Alberta, Saskatchewan, Nova Scotia and three countries: United States, United Kingdom and Australia).

Several years ago, the United States expert Lucian Leape outlined the goals of Reporting in the following way:

> *"The primary purpose of reporting is to learn from experience. Many other methods are also used to identify threats to safety, but a good internal reporting system ensures that all responsible parties are aware of major hazards. Reporting is also important for monitoring progress in the prevention of errors. Thus, the reporting of close calls, as well as adverse events, is valuable. External reporting allows lessons to be shared so that others can avoid the same mishaps. State-run mandatory reporting systems have an additional purpose: to hold hospitals accountable for safe practices."*[66]

The international experiences with Reporting systems and, in particular, state or national (in addition to organizational) systems, is developing quickly. Even five years ago when Leape outlined the purposes and barriers to Reporting there were few such systems. Leape noted four in the United States, of which only one (the Joint Commission Sentinel Event Reporting System) covered more than medication Incidents. Some United States healthcare systems, notably the Veteran's Health Administration, had created Reporting systems for healthcare organizations in their systems. But lessons learned in these systems were not broadly Shared outside of the systems. The Australian Incident Monitoring System began as an anaesthesiology critical event Reporting system (patterned after similar work in the United States) that then broadened into a system that included a wide range of Incidents. The Australian system and the English system created by the National Patient Safety Agency (NPSA) are now the largest systems reported in the literature. Although a legislative framework for United States systems was created by federal legislation passed in 2005, the regulations supporting such systems have not been enacted. Still,

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[65] Given the short time frames to arrange and carry out interviews it was not possible to interview some individuals identified as key informants.

[66] Lucien Leape, *New England Journal of Medicine*, 2002

many states in the United States have developed Reporting systems and have considerable experience with Reporting issues. The growing experience with Reporting systems has provided information that is relevant to Canadian efforts.

F. Critical issues

Questions for the key informant interviews were based on the issues identified in the initial parts of this report, as well as an examination of key articles and documents. The interviews with key informants thus permitted examination of a number of critical issues and potential approaches to Sharing in Canada. Our review of the interview findings is organized in terms of these critical issues and approaches.

1. **Is there a need to Share Incident information beyond individual organizations?** Most existing Reporting systems exist within individual organizations, health systems or health regions. However, many Incidents are rare events - hence the need to Share such information with other jurisdictions or to a national body that is capable of disseminating such information. However, at the same time, there is a growing recognition that the complexities of a national reporting system have limited their impact. For example, the English National Reporting and Learning System which receives nearly one million reports per year, has been criticized for failing to turn these reports into useful alerts and bulletins and disseminating these in a timely fashion to provider organizations. Many large data collection efforts have allowed considerable leeway in the types of Reports and the types of Reporting systems that have fed information into centralized repositories. As a result, the usefulness of data is often compromised.

2. **What are the Potential Barriers to Sharing Incident Information?** Privacy, evidence and health sector legislation appears to limit the disclosure of personal information, particularly in the context of quality assurance committee proceedings. In addition, the legislation of many provinces prevents data collected in their jurisdiction to be transmitted outside the province, particularly in the manner in which health sector entities are defined.[67] As a result it seems unlikely that it would be possible in the near future to Share information about specific Incidents with quality assurance committees in different provinces. There are concerns in some provinces about the ability to Share information between quality assurance committees, even *within* the province.[68]

3. **Should reporting be mandatory or voluntary?** The issue of mandatory versus voluntary Reporting has been a traditional source of disagreement. On the one hand, some have felt that mandatory Reporting is necessary, particularly in an environment where there is liability for Incidents and organizations and individuals are thus likely to avoid creating risks of legal action. On the other hand, some have claimed that most Reporting is voluntary (even when mandated) since many Incidents are difficult to discover and fear of litigation may be more powerful than concerns about Reporting. At

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[67] For example, a statute may permit the sharing of PHI among "health information custodians"; however, by defining "custodian" as an entity formed pursuant to a specific provincial enactment (e.g. "hospitals formed pursuant to the *Hospitals Act*"), the statute precludes the disclosure of PHI to a hospital in another jurisdiction, formed under the laws of that jurisdiction.

[68] For example, British Columbia, Saskatchewan, Manitoba, Quebec, Northwest Territories and Nunavut.

a national level, the issue of mandatory or voluntary Reporting is complicated by differences in provincial legislation. Some provinces, such as Saskatchewan and Manitoba now have mandatory Reporting for a defined range of Incidents. Others have no formal requirements for such Reporting and rely on voluntary efforts within healthcare organizations. In Saskatchewan and Manitoba the results of mandatory Reporting have differed. Saskatchewan has had more success than Manitoba. This could be due to a number of variables including: (a) differences in resources available; (b) education of staff regarding the scope and nature of the Reporting requirements; and (c) the existence of detailed guidelines in Saskatchewan. However, Manitoba's mandatory Reporting system is new compared to Saskatchewan's system and time could demonstrate an increase in Reporting in Manitoba as well.[69]

4. **What are the information challenges in creating a centralized system?** Several of the key informants described challenges that would need to be addressed in a centralized system. Specifically, there are challenges associated with integration of the existing local IT and communications systems. This would require standardizing the coding and Classification Systems to be used. Another key challenge of a centralized system is to make use of the information that is obtained from regional, provincial and national systems.

5. **What legislative, legal and political issues face the development of a Pan-Canadian system?** According to key informants, the variation between provinces of relevant legislation including privacy legislation, limits the patient safety and quality agendas in healthcare. As noted in the Weisbaum Report, there is little likelihood of standardization of such privacy provisions. From a broader policy standpoint, the variation in expectations by public and healthcare providers of balance between privilege, protection, and transparency to patients and the public at large and the political barriers in Sharing between regions and jurisdictions, present challenges that also need to be addressed in the early stages of development. As one stakeholder stated:

   "a pan Canadian vehicle may be suitable, but politically difficult".

6. **What are possible models to study?** In our interviews we examined the experience of several existing international patient safety Reporting systems. Several of these offer opportunities for further study. These include the Australian Incident Monitoring System which operates in most Australian states and territories, the English National Reporting and Learning System (NRLS), the Pennsylvanian Patient Reporting System (PA-PSRS), the Massachusetts Board of Registration in Medicine's Confidential Reporting System and the National Reporting System for Adverse Events in Denmark.

PART FOUR: RECOMMENDATIONS

Based on our legislative and policy reviews, surveys and interviews, our team has developed the following recommendations with respect to a Pan-Canadian Reporting system:

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[69] As noted above, we are not able to say with certainty whether mandatory Reporting increases Reporting. However, it does appear from our understanding of Saskatchewan that legislation coupled with detailed regulations and guidelines has increased Reporting in that province.

1. Pan-Canadian Reporting Organization. A Pan-Canadian Reporting system should be developed to disseminate Incident data and recommendations on a national basis. We recommend that this be done by a national third party organization whose primary agenda is the promotion of patient safety. Given CPSI's knowledge, expertise and mandate, we are of the view that CPSI should have an integral role in the development and management of this system, and for the purposes of these recommendations, that CPSI act as that national organization.

2. Federal Funding For Patient Safety Programs. In order to achieve a Pan-Canadian Reporting system, Reporting programs and initiatives must be encouraged and stimulated at the jurisdictional and institutional level. Funding programs are needed to, among other things, help local systems that lack technical and human resources to properly run Reporting programs. Given the national scope of the recommended system, such programs should be funded by the federal Government. The federal Government should set aside additional funds for patient safety initiatives. These funds should be delivered through CPSI as the national third party organization referred to above.

3. Funding Allocated by CPSI; Contingent on 'Best Practices'. Funding would be provided by CPSI to jurisdictions implementing Reporting programs that meet certain criteria, which could include, in part, the creation of provincial legislative and policy Reporting frameworks grounded in best practices, as described previously in this report. The jurisdictions would then grant funding to institutions in their respective provinces or territories that implement Reporting programs in accordance with such legislative and policy Reporting frameworks. In our view, assessing eligibility for grant funding at an institutional level would be an arduous task for CPSI. We therefore recommend that it be the task of the province or territory to make such assessments. Reference to province or territory in this regard can either be the Government of each province or territory or a third party organization in each province whose mandate it is to ensure patient safety within such province or territory (e.g. the Alberta Health Quality Council).

4. Collection of Provincial/Territorial Incident Data. To facilitate Pan-Canadian Reporting by a national organization, we recommend that provinces and territories adopt a model similar to Saskatchewan, Alberta or Newfoundland and Labrador, in that a central body in each province or territory collect Incident data from healthcare facilities or entities for the purposes of tracking and analysis. Incident data would be collected and processed at the local or regional level for the purpose of analysis and developing recommendations, and de-identification where necessary. Thereafter, Incident data would be transmitted to a provincial body and aggregated with data from across the province. While the Government in each province could perform this aggregation function, it is likely more efficient and effective to create or designate an arms-length Government funded agency (a "**Provincial Patient Safety Organization**") for this function. The designation or creation of a Provincial Patient Safety Organization in each province and territory could be done in stages, beginning with those jurisdictions that are most amenable. This staged roll-out would also be enhanced by linking the formation of Provincial Patient Safety Organizations with grant funding, pursuant to Recommendation 3 above.

5. Upward Reporting of Provincial/Territorial Incident Data. Each Provincial Patient Safety Organization should be permitted to disclose Incident data on a de-identified basis to a national patient safety organization, such as CPSI, to disseminate information and warnings and provide statistics and other guidance on a national basis. The creation or designation of a Provincial Patient Safety Organization should be done in the context of each jurisdiction's approach to information transfers and privacy. This may require special regulatory provisions or minor statutory amendments in light of each jurisdictions legal framework. Given the necessity for local knowledge and clinical expertise in the formulation of recommendations, we assume that any de-identification would be done at the institutional or regional level.

6. Limit CPSI's Use of Personal Information. In the case of CPSI, any personal information received would need to be collected, used and disclosed in compliance with the privacy laws of its jurisdiction of operation (i.e. Alberta).[70] We recommend that CPSI not receive personal information unless it is necessary for CPSI's purposes. Personal information is subject to statutory restrictions noted above, and its use by CPSI would expose CPSI to the risk that the privacy of individuals may be breached. Even if CPSI determines that it needs personal information in order to effectively analyze Incident data, CPSI would still face barriers to the disclosure of that information on an identifiable basis. Generally, de-identified information, however, can be collected, used and retained without limit, and CPSI could share de-identified information on a national basis. We recommend, however, that CPSI assess whether the benefits would counterbalance the obligations imposed on CPSI in respect of the collection, use and disclosure of personal information. This assessment could be conducted as part of the consultations and the roundtable outlined in Recommendation 9 below.

7. National Guidelines for Reporting. CPSI should also take a leadership role in the development of national guidelines for Reporting (the "**Guidelines**"), which would include common definitions and Taxonomy. Also, CPSI should collaborate with other stakeholders to develop nationally-accepted and consistent definitions, categories for data elements and de-identification standards for all types of Incident Reporting to guide the Provincial Patient Safety Organizations. Such definitions, data elements and de-identification standards should also be consistent with the Guidelines, but would permit each jurisdiction some flexibility in accommodating applicable legal standards in force in that province or territory. Development of these Guidelines and standards could be conducted as part of the consultations and the roundtable outlined in Recommendation 9 below.

8. Demonstration Reporting System. A demonstration project should be conducted for all provinces or territories wishing to implement a provincial Reporting system. This demonstration project would build on the efforts and experiences of Saskatchewan and Manitoba and provide an opportunity for other provinces to learn about the development of Reporting systems and the benefits of same. Such demonstration project could be organized by CPSI with the assistance of representatives from Saskatchewan and Manitoba.

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[70] *Personal Information Protection Act*, S.A. 2003, c. P-6.5.

9. Roundtable Discussion. Given the complexity of the issues, and in order to accurately assess the Recommendations above, we propose that a round-table discussion be held to bring together each province's and territory's position on Reporting. This round-table discussion would involve legal, medical, academic and public sector experts, who would bring together local assessments of applicable legislation, case law and existing practice and discuss common standards and approaches to Reporting, including common Classifications Systems and standards of de-identification of personal information. The roundtable could also consider whether data relating to various types of Incidents (other than medication Incidents) could be non-identifiable and yet still effective. The greater the use of de-identified Incident data, the easier it is to share such data between provinces without contravening provincial privacy legislation. This would require the establishment of categories of data elements to be used for all types of Incidents, similar to that done by the Institute of Safe Medication Practices for medication errors. It is our view that bringing together these experts would be the most efficient and effective way to facilitate what would otherwise be a long and arduous process.

10. Federal Legislation (Optional). Federal legislation could be developed for the purposes of furthering the objectives of a Pan-Canadian Reporting system and to make provision for additional funding to support Reporting and Sharing. Such legislation and funding would encourage provinces and territories to participate because it would yield substantial benefits to those participating jurisdictions.

PART FIVE: CONCLUSION

Our analysis of the key enablers and barriers in legislation, policy and healthcare organizational (or regional) practices associated with Reporting indicates a considerable patchwork of Reporting across Canada. Of immediate urgency is the need for Guidelines and the establishment of a common Taxonomy consistent with the efforts of the World Health Organization.[71]

Closely aligned with the Guidelines and a common Taxonomy is the need for the development of a legislative and policy framework in most of the provinces and territories. However, in order for institutions to comply with such legislative or policy frameworks, an investment in technology and resources will be required. As was noted in our interview process, a lack of available resources was stated to be a barrier to Reporting. The federal Government should earmark funds for the development of Reporting programs in the provinces and territories as a means to incentivize the provinces and territories to undertake this important initiative. CPSI could oversee the allocation of such funds based on a set of specific criteria.

Moving toward an effective Pan-Canadian Reporting system requires establishing effective Reporting systems at both the provincial or territorial level and the national level. Healthcare institutions in each province and territory should be required to disclose de-identified Incident data, RCA and recommendations, to a Provincial Patient Safety Organization funded by the Government of that province. Such data would subsequently be Shared by the Provincial Patient

[71] WHO, World Alliance for Patient Safety (2005, October) "*Project to Develop the International Patient Safety Event Taxonomy*": Report of the World Alliance for Patient Safety Drafting Group.

Safety Organization with a national patient safety body, such as CPSI, for dissemination and warning purposes across Canada.

CPSI is well-positioned for this role and it can obtain assistance from other third parties as necessary by leveraging collaborative partnerships with the federal, provincial or territorial Governments, health professional regulatory bodies, patient safety associations and the national accreditation body.

This strategy will, of course, require a significant investment from the federal Government. This model is currently in place at a provincial level in a few provinces (absent reporting to a national body, of course). We suggest that these models be considered for the remaining provinces and territories. We therefore recommend that a panel comprised of legal, medical, academic and public sector experts from each province collectively determine the feasibility and design of our suggested approach to Pan-Canadian Reporting. This may help speed the development of changes in such provincial legislation as is necessary, even in the absence of mandatory reporting legislation.

At this point we do not think federal legislation is necessary for the development of a Pan-Canadian model of Reporting given the potential constitutional roadblocks surrounding the provincial and federal division of powers. However, the enactment of federal legislation would demonstrate to Canadians the importance of patient safety to the federal Government and emphasize the significant role of CPSI in this regard. It may also foster cooperation among the provinces and territories toward the development of a Pan-Canadian model of Reporting.

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[illegible]	[illegible]	[illegible]	[illegible]	[illegible]

Ministry/Department/Agency	Policy Instrument	Scope of Exemption	Duration of Privilege Period Since Date
[illegible]	[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	[illegible]	[illegible]

Quality Management Site	Quality Management Point	Specification	Employee Average Performance Rating
[illegible]	[illegible]	[illegible]	[illegible]

[illegible]

[illegible]	[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	[illegible]	[illegible]
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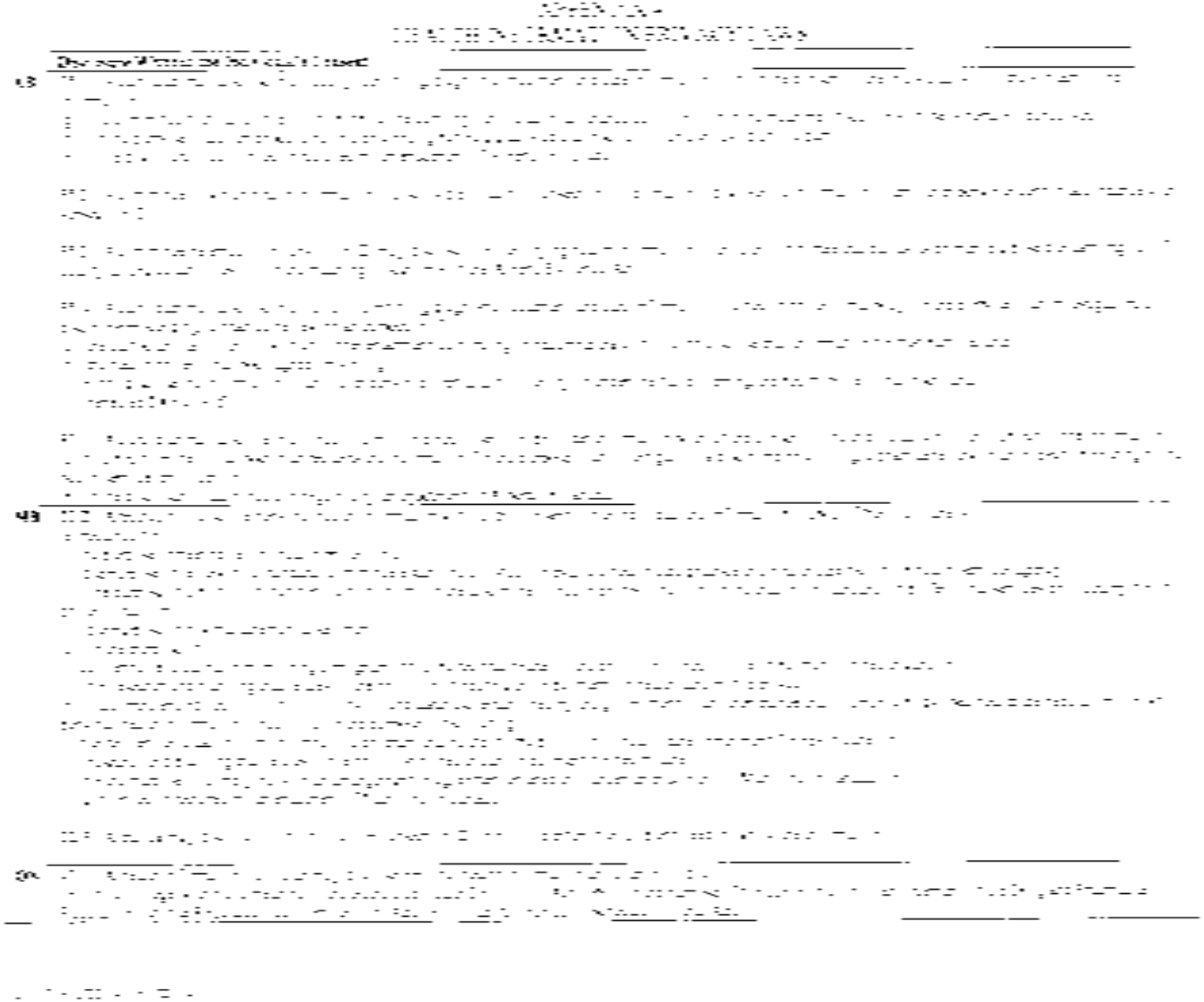

APPENDIX 8

LIST OF POLICIES REVIEWED

INSTITUTE	PROVINCE
Calgary Health Region	Alberta
Vancouver Island Health Authority	British Columbia
Providence Health Centre	British Columbia
Health Canada	
Manitoba Health	Manitoba
Brandon Regional Health Authority Inc.	Manitoba
South Shore Health Authority	Nova Scotia
Hay River Health & Social Service Authority	North West Territory
Ministry of Health and Long-Term Care	Ontario
Sunnybrook Health Sciences Centre	Ontario
Trillium Health Centre	Ontario
University Health Network	Ontario
Department of Health	Prince Edward Island
McGill University Health Centre	Quebec
Shriners Hospital	Quebec
University of Saskatchewan	Saskatchewan

[illegible]

Jurisdiction	Title	Food
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[illegible]	[illegible]	[illegible]

Jurisdiction	Title	Note
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[illegible]	[illegible]	[illegible]

Jurisdiction	Title	Policy
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Jurisprudence	Title	Rule
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Jurisdiction	Title	Policy
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Jurisdiction	Title	Policy
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Jurisdiction	Title	Scope
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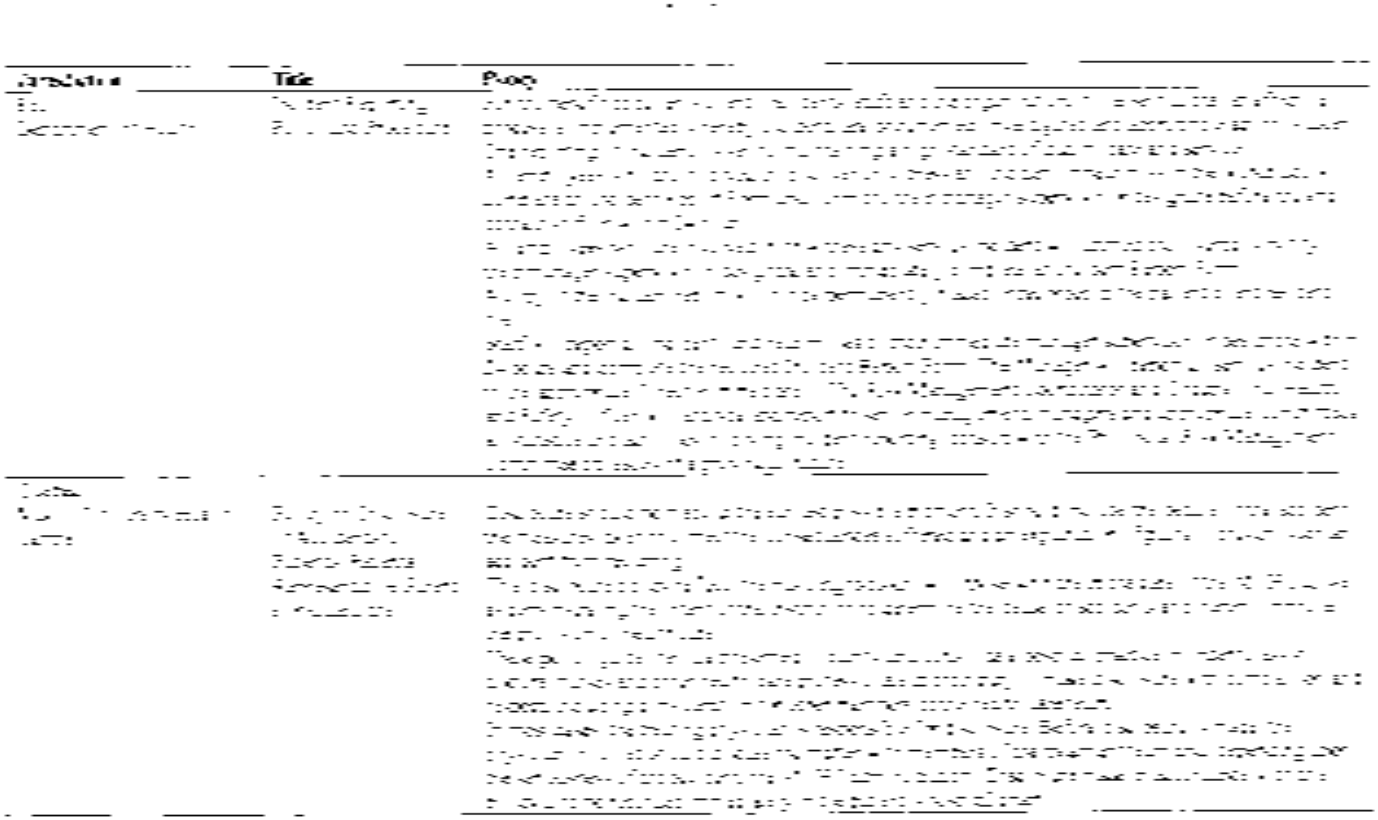

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Jurisdiction	Line	Responsible Party	What is reported	Report Next Is When	Example	Witnesses
[illegible]	[illegible]		[illegible]	[illegible]	[illegible]	[illegible]
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[illegible]

[illegible]

Jurisdiction	Entity	Enablers	Barriers
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[illegible]	[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	[illegible]	[illegible]

[illegible]

Jurisdiction	Entity	Examples	Summary
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[illegible]	[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	[illegible]	[illegible]

Intervention	Safety	Benefits	Barriers
[illegible]	[illegible]	[illegible]	[illegible]
[illegible]		[illegible]	[illegible]

[illegible]	[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	[illegible]	[illegible]

APPENDIX H

Adverse Event, Sentinel Events and Near Miss Reporting Survey
Acute Care Hospitals Version

On behalf of the Canadian Patient Safety Institute, we are reviewing the barriers and enablers to the reporting and review of adverse events, sentinel events and near misses in Canadian hospitals. The following survey has been designed to identify organizational policies and practices concerning the reporting and review of adverse events, sentinel events and near misses reporting in acute care hospitals. This survey asks for information on both internal reporting and review and external reporting to regions or other bodies. This survey is mainly composed of closed-ended questions with some open ended questions. Please note that all information provided in this survey is confidential and the analysis will report only aggregate (that is, group or trend) results.

When you have completed the survey, please return it in the envelope provided addressed to Dr. Ross Baker at the University of Toronto.

Hospital

Hospital Name: _____

Hospital Size - Number of acute care beds _____

Key Contact Name: _____ Phone Number: _____ Email: _____
(To be used if clarification is needed)

Reporting Systems and Analytical Tools

Definitions

Safety Occurrence Taxonomy:

Adverse Events: are unintended injuries or complications that are caused by health care management, rather than the patient's underlying disease and that lead to death or disability or require additional use of hospital resources, such as prolonged hospital stay, additional testing or interventions.

Sentinel Events: An unexpected incident related to system or process deficiencies, which leads to death or major and enduring loss of function for a recipient of health care services.

Near Misses: An event or circumstance, which has the potential to cause serious physical or psychological injury, unexpected death, or significant property damage, but did not actualize due to chance, corrective action, and/or timely intervention.

Reporting System: Organizational routines used to collect information about one or more types of patient safety events. Reporting systems can be paper-based, electronic or a combination of both.

The following questions concern the types of reporting systems for patient safety events (adverse events, sentinel events and near miss occurrences) that exist in your hospital

1. **To what extent has your organization implemented a reporting system for adverse events, sentinel events and near misses and indicate whether system is paper and/or electronic based?**

Reporting System	Please check ✓ your response				Please check ✓ your response	
	Not at all	Partially Implemented (few units)	Majority of Units Implemented	Fully Implemented	Paper Based	Electronic Based
Adverse Event Reporting System						
Sentinel Events Reporting System						
Near Miss Reporting System						

2. **To what extent does your organization use specific analytical approaches (e.g., root cause analysis or quality improvement tools e. g., Flow Diagrams) to investigate reported adverse events, sentinel events, and near miss occurrences? Please check ✓ your response.**

	Not at all	Partially implemented on selected units	Majority of units Implemented	Fully implemented
Adverse Events				
Sentinel Events				
Near Misses				

3. **In the last year, how often has your organization used retrospective analytical approaches for safety occurrences (adverse events, sentinel events, and near misses)? Please check ✓ your response.**

	0	1-2	3- 4	5 or more
Root Cause Analysis				
Audit				
Chart Review				
Other, please specify				

* for those hospitals that circled other, please describe the retrospective analytical approaches you used in the past year

Organizational Policies and Practices

4. a) Does your hospital have a policy on reporting patient safety events?

Please check ✓ your response :: YES :: NO

If yes, please answer the following questions.

b) Does your policy cover all events (adverse events, sentinel events and near misses) or selected events?

Please describe the specific events that your policy covers.

c) Does your policy require disclosure to patients and family members on reported patient safety events?

Please check ✓ your response :: YES :: NO

Please describe.

d) Does your policy require that a summary of patient safety events be reported to the Board of Directors?

Please check ✓ your response :: YES :: NO

Please describe.

e) Are there any current issues around your reporting policy under review in your organization, please describe.

Please append a copy of your policy to your completed survey.

5. In the last year, how often did your hospital participate in the following activities associated with reporting and investigating safety occurrences (adverse events, sentinel events, and near misses)? Please check ✓ your response.

	Never	Daily	Weekly	Monthly	Quarterly	Annually
Included as measures for corporate reporting to the Board.						
Included as measures for reporting to the community.						
Education sessions for staff on safety cultures that include reporting and learning from events and incidents.						
Executive WalkRounds with a formal feedback on actions taken						
Meetings at the unit, division, and portfolio level for the review of safety indicators, and evaluation of planned initiatives						
Failure Mode Effect Analysis						
Reports on the follow up and resolution of all alerts and recalls of equipment to a third party (e.g. ORNT)						
Other, please describe						

6a. To what extent does your current reporting system capture the number and types of patient safety events that you believe to be occurring in your organization. Please circle your response.

1	2	3	4	5
None	Limited Extent	Somewhat	Frequently	Always

6b. To what extent do your current reporting system and structures create a capacity to analyze and act on these patient safety event reports to improve the design and delivery of care? Please circle your response.

1	2	3	4	5
None	Limited Extent	Somewhat	Frequently	Always

7. To what external agencies does your hospital report adverse events, sentinel events and near misses that have taken place in your hospital? (Check all that apply)

- ☐ Ministry of Health
- ☐ Regulatory bodies for health care professionals (e.g. College of Physicians and Surgeons, College of Nurses, College of Pharmacists, etc.)
- ☐ Report to a regional authority
- ☐ Report to other third parties, please specify (e.g. Ombudsmen)
- ☐ Report to insurers (e.g. HIROC, Canadian Medical Practice Association, Canadian Nurse Protective Society, and others)

Other, please describe

Enablers and Barriers for Reporting

For these series of questions, patient safety events refer to adverse events, sentinel events and near misses.

8. In your view, what are the key enablers within your hospital that facilitate enactment of policies associated with reporting and review of patient safety events? Please describe below.

9. In your view, what are the barriers from within your hospital that are challenges to enactment of policies associated with reporting and review of patient safety events? Please describe below.

External

10. In your view, what are the factors outside your hospital that facilitate enactment of policies associated with reporting and review of patient safety events?* Please describe below.

11. In your view, what are the factors outside your hospital that are challenges to the enactment of policies associated with reporting and review of patient safety events?* Please describe below.

12. In your view, what specific changes in practice, policy or legislation would encourage or facilitate the reporting and review of patient safety events? Please describe below.

*Some examples include privilege over quality assurance information, requirements of professional colleges potential lawsuits and provincial privacy legislation.

APPENDIX 12

Interview Questions For CSPI Project on Adverse Event Reporting

Introduction

We are working on behalf of the Canadian Patient Safety Institute to identify and analyze legal and policy barriers and enablers for the reporting and review of adverse events and/or critical incidents on a national scale. As part of this analysis we are conducting key informant interviews with experts in Canada and abroad. We would like to talk with you for 30 minutes about these issues.

Definitions

Patient safety events refer to adverse events which are unintended injuries or complications that are caused by health care management, rather than the patient's underlying disease and that lead to death or disability or require additional use of hospital resources, such as prolonged hospital stay, additional testing or interventions.

Critical incidents are incidents resulting in serious harm (loss of life, limb, or vital organ) to the patient, or the significant risk thereof.

Questions

1. Is there a need for information on patient safety events or critical incidents to be shared more broadly beyond the institutions in which these events are identified?
    a. If so, what types of information?
    b. To whom should this information be reported?
    c. Should this reporting be mandatory or voluntary?

2. Assuming such information can be collected centrally? How should information that is reported be used? Not used? Who should have access to the information?

3. One of the critical issues in reporting is the privileging of information on patient safety events. Are the current protections in your province/state adequate to support reporting or sharing of information on patient safety events?
    a. If not, in your view is it clear what types of legislative or other protections are needed in your province/state?
    b. What is the likelihood that such protection might be established in the near term (i.e., next two to three years)?

4. Will the development of effective privileging to permit information on patient safety events to be used improve care and moderate opposition to mandatory reporting?

5. Do you think that it would be possible to share information on patient safety events across provinces states?
    a. What are the barriers to such sharing?
    b. Could a set of principles be established to harmonize the reporting and sharing of such information?
    c. Would you think this is likely?

6. What are other critical barriers to reporting and sharing of information on patient safety events?
    a. To what extent could these be addressed without new legislation?
    b. What resources are needed to remove these barriers?
    c. Do you think efforts to remove these barriers would be successful?

7. Some have suggested that a good first step would be the creation of a policy framework and best practices on sharing of information. Do you think this would be useful? Is it feasible? Who should take the lead?

8. A commonly stated barrier is the culture of blame that limits reporting. What do you think is needed to address this barrier?