ADVERSE HEALTH EVENT MANAGEMENT

International and Canadian Practices

A Background Document Prepared for the Task Force on Adverse Health Events

Deborah Gregory, Ph.D.
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Executive Summary

Introduction
Studies related to medical error in Canada, Australia, the United Kingdom, and the United States have resulted in growing awareness and heightened concerns related to patient safety within the health system. In response to these concerns, global effort has been placed on patient safety in general, and more specifically, on adverse event management.

Background
The Secretary to Cabinet (Health Issues) in his role as Chair, Task Force on Adverse Health Events, has been mandated by the provincial government of Newfoundland and Labrador to address the following objectives in its terms of reference: (1) to examine and evaluate how the health system identifies, evaluates, responds and communicates with regard to adverse events within the health system; and (2) to examine relevant best practices in other jurisdictions.

Objective
The objective of this paper is to facilitate an understanding of the international, national, provincial and organizational “leading practices” in adverse health event management.

Methods
A scan of existing practices and an extensive review of the literature inform the composition of this paper. In addition, the Task Force sought to learn from the experiences of experts in the field of adverse health event management. Fifteen expert consultations were conducted from five Canadian provinces (Alberta, Manitoba, Saskatchewan, Nova Scotia and Ontario) and four countries (Australia, Ireland, the United Kingdom and the United States). Valuable insight was gleaned from the interview transcripts of these experts who so willingly gave of their time. The dialogue with key informants will comprise a separate but complementary report to the literature review.

Findings
A review of the relevant literature suggests that there are many lessons to be learned from the pioneers (UK, US and Australia) in the field of adverse health event management. In Canada, a tremendous amount of work has been done at the national level and within the provinces and territories. However, in order to learn from adverse health events it is necessary to have in place standard definitions, a standardized adverse health event taxonomy, standardized methods of reporting and timely and appropriate feedback mechanisms to ensure that changes are made to improve patient safety. The Calgary Health Region is considered by many as the country’s most progressive. It can be used as an exemplar of adverse health event management.
Conclusions
In undertaking a review of relevant “leading practices” in other jurisdictions, we were afforded the opportunity to examine and learn about the management of adverse health events from international, national, provincial, regional and organizational perspectives. Clearly, the pioneers in the field of adverse health event management (i.e., the UK, Australia, and the US) have much to offer in the way of lessons learned. The WHO is providing leadership in the area of adverse event reporting, learning systems and the standardization of taxonomy for classifying adverse events.

At a national level, the Canadian Patient Safety Institute (CPSI) has taken a lead role in the development and publication of Canadian Disclosure Guidelines, developing a strategy to create a Pan-Canadian reporting and learning system. It has also developed the Canadian Root Cause Analysis Framework, a quality improvement tool to help individuals and organizations determine all of the contributing factors and root causes that led to an event (e.g., critical incidents and close calls). CPSI is currently engaged with key stakeholders and partners in the development of a Canadian inter-professional, competency-based framework for patient safety.

At the provincial level, a variety of initiatives have been undertaken to address the reporting of “critical incidents” or accidents. A number of these initiatives are tied to legislation and regulations. However, a major limitation is the lack of standardization of definitions and terminology used within and between provinces, within and between regions, and between organizations. It is difficult to say, with any degree of certainty, whether one practice or policy is leading the way in the field of adverse event management, in part, because of the paucity of evaluative outcomes research being conducted in this area.
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Methodology

A scan of existing practices and an extensive review of the literature inform the composition of this paper. In addition, insight has been gleaned from the interview transcripts of 15 national and international expert consultants well versed in the area of adverse health event management. The dialogue with key informants will comprise a separate but complementary report to the literature review.

Findings

Recommendations of the National Steering Committee on Patient Safety

In 2004 the National Steering Committee on Patient Safety produced a report titled *Building a Safer System – A National Integrated Strategy for Improving Patient Safety in Canadian Health Care*. The following recommendations of the report are relevant to an effective response system.
Adopt nonpunitive reporting policies within a quality-improvement framework across the health care system.

Develop a greater focus on improvement through education and remediation, versus blame and punishment, in legal, regulatory and human resource processes.

Review, and where applicable, revise *The Evidence Act* and related legislation within all Canadian jurisdictions to ensure that data and opinions associated with patient safety and quality-improvement discussions, related documentation and reports are protected from disclosure in legal proceedings. The protection would extend to this information whether used internally or shared with others, for the sole purpose of improving safety and quality. Wording within the applicable acts should ensure that all facts relating to an adverse event are recorded on a health record that is accessible to the patient or designated next of kin, and are not considered privileged.

Undertake an analysis of the capabilities and costs of systems for monitoring adverse events, critical incidents and near misses.

Recommend the types of surveillance systems, including relevant patient-safety indicators, to be developed and supported in Canadian health care. The recommendations would be based on the findings of the review proposed in the previous recommendation outlined above.

Publicly report measures of health care quality and safety.

**Recommendations of the Baker and Norton Report**

Baker and Norton\(^{11}\) completed a review of patient safety initiatives elsewhere in the world and provided recommendations for initiatives within Canada. The relevant recommendations for the Task Force are:

Develop better reporting systems:

- New regional and national reporting systems and mechanisms should be pilot tested and evaluated. Key evaluation points must include the linkage of discovered adverse events to improvement efforts. Pilot projects should be undertaken to assess the effectiveness of such efforts. While most work to date has occurred in acute-care facilities, new systems to identify adverse events and errors should be tested at all levels of the system –
acute, chronic and community.

- There should be expanded support for the existing and developing national and provincial Adverse Drug Event (ADE) reporting systems.
- Health care organizations should be strongly encouraged and supported in heightening their focus on errors, adverse events and near misses, and to link this to improvement work and system change.
- Support should be provided to develop curricula and learning experiences in patient safety at all educational levels (undergraduate and postgraduate and continuing professional education).
- Canadian professional colleges and organizations should be encouraged to be active in the areas of disclosure policy and legislation and to lobby for appropriate legislation to enable them to expand their efforts.
- Patient safety programs and initiatives should be integrated into the Canadian Council on Health Services Accreditation standards and other health care accreditation standards.
- Legislation change could enhance the reporting of errors and near misses and should be encouraged and supported.

### Adverse Health Event Management at the National Level

At the national level, a number of organizations are taking lead roles in the optimization of patient safety and adverse health event management, including the Canadian Council on Health Services Accreditation, the Canadian Patient Safety Institute and Health Canada, among others. A brief overview of three organizations and their current and potential future roles is discussed in this section.

#### Health Canada

The Canada Vigilance Program collects data on adverse reactions (AR), defined as harmful and unintended responses to a health product. Guidelines for health professionals and consumers have been created for the voluntary reporting of suspected adverse reactions to health products. Adverse reactions to Canadian marketed health products include prescription, nonprescription, biologic, natural health and radiopharmaceutical products. An adverse reaction may include any undesirable patient effect suspected to be associated with health product use. An unintended effect, health product abuse, overdose, interaction (including drug-drug, and drug-food interactions) and unusual lack of therapeutic efficacy are all considered to be reportable adverse events.
Canadian Council on Health Services Accreditation

The CCHSA (renamed Accreditation Canada in May 2008) is a not-for-profit, independent organization that has provided national and international health and social service organizations with voluntary, external-peer review programs and guidance for over 50 years.

In May 2003, the CCHSA Board approved Phase 1 of its Patient Safety Strategy, which focused on four domains: (1) accreditation program, (2) information, communication and education, (3) research, and (4) partnerships. The accreditation program was enhanced with the development of a list of reportable sentinel events and among other things the implementation of a mandatory reporting policy.12

In October 2004, the CCHSA's Patient Safety Advisory Committee (PSAC) was established to provide direction and advice on the implementation of the Patient Safety Strategy. PSAC consisted of key stakeholders and the CCHSA’s partners in safety, including the Canadian Patient Safety Institute (CPSI), Institute for Safe Medication Practices (ISMP, Canada), Health Care Insurance Reciprocal of Canada (HIROC), Canadian Medical Protective Agency (CMPA) and the Canadian Institute for Health Information (CIHI).

In 2005, CCHSA developed standards promoting adverse event13 and near miss14 reporting- and-learning (the reference guide for sentinel events and near misses is presented in Appendix A).

- An adverse event is “usually negative or unfavourable reactions or results that are unintended, unexpected, or unplanned.”
- A near miss is “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.
- The CCHSA’s sentinel event policy is meant to improve the reporting and sharing of information across organizations. The CCHSA defines a sentinel event as “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. * Major and enduring loss of function refers to sensory, motor, physiological, or psychological impairment not present at the time services were sought or begun. The impairment lasts for a minimum period of two weeks and is not related to an underlying condition.”

In January 2005, the CCHSA’s Patient Safety Goals and Required Organizational Practices (ROP) came into effect. An ROP is defined as “an essential practice that organizations must have in place to enhance patient/client safety and minimize risk.”
Five ROPs are directly related to patient safety culture. More specifically, Canadian health care organizations seeking accreditation are required to:

1. adopt patient safety as a written, strategic priority/goal;

2. provide quarterly reports to the board of directors on patient/client safety, including changes/improvements following incident investigation and follow-up;

3. establish a reporting system for actual and potential adverse events, including appropriate follow-up, in compliance with any applicable legislation and within any protection afforded by legislation;

4. implement a formal (transparent) policy and process of disclosure of adverse events to patients/families, including support mechanisms for patients, family and care/service providers;

5. conduct one patient-safety related prospective analysis per year (e.g., Failure Modes and Effects Analysis) and implement recommended improvements/changes.

In 2007, CCHSA released its Patient Safety Strategy – Phase 2 and vision for 2007-2010. A review of the roles of adverse and sentinel events in the CCHSA accreditation program is currently underway. A provincial and national review of reporting requirements will be part of the process and the roles of adverse and sentinel events in the accreditation process will be clarified further. A major limitation is that accreditation is completely voluntary for Canadian hospitals and long-term care facilities. This may change based on the advice of the Health Council of Canada that all health care facilities be accredited as a condition of funding, and that the findings of the accreditation reports be made public.

**Canadian Patient Safety Institute (CPSI)**

One of the recommendations of the National Steering Committee on Patient Safety report, *Building a Safer System*, was the establishment of the Canadian Patient Safety Institute (CPSI). The CPSI was created to provide leadership and coordination for patient safety and quality improvement across the Canadian health care system. The federal Minister of Health announced the establishment of the CPSI on December 10, 2003. The institute is funded by Health Canada, but has an independent board of directors responsible to its members, including the provincial ministers of health and the public.

In March 2008, CPSI launched *Canadian Disclosure Guidelines* after two years of extensive effort and collaboration by a number of experts from key national organizations representing physicians, nurses, pharmacists, health care providers, patients and others. The Guidelines are intended to assist and support health care providers, inter-professional teams, organizations and regulators in developing and implementing disclosure policies,
practices and training methods across Canada. A summary of the CPSI Disclosure Guidelines is presented in Appendix B.

CPSI is also exploring a pan-Canadian strategy for reporting and learning from adverse events. The CPSI, in collaboration with the Institute for Safer Medication Practices Canada and Saskatchewan Health, also developed the Canadian Root Cause Analysis Framework, a quality improvement tool to help individuals and organizations determine all of the contributing factors and root causes that led to an event (e.g., critical incidents and close calls). Finally, CPSI is engaged with key stakeholders and partners in the development of a Canadian inter-professional competency-based framework for patient safety.

**Reporting and Learning Systems**

The primary purpose of reporting is to learn from experience…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.

Lucian L. Leape, MD

*New Eng J Med, 2002*

Adverse health event reporting and learning systems hold much potential for improving patient safety in general. However, the emphasis must be on lessons learned and sharing of the same, otherwise, the reporting of adverse health events will only result in the collection of interesting statistics.

In 2007 a review of relevant literature on adverse event reporting and learning systems from technology, implementation, learning and classification perspectives was performed. The author classified the review into seven themes: (1) governance and legislative frameworks for national reporting systems (2) taxonomy and classification systems used in data reporting and analysis (3) technical/design considerations and user issues (4) anonymous and confidential reporting systems (5) reporting by professionals and/or patients (6) financial implications, and (7) feedback systems to improve safety. Governance and legislative frameworks must be considered as well as incentives and barriers to implementing reporting systems. An overview of the national reporting systems in the UK, US, and Japan was provided. The author also emphasized the importance of a standardized taxonomy for coding and classification of events such as the WHO International Patient Safety Event Classification (IPSEC) currently being developed. Some of the technical/design considerations and user issues one must take into account include paper-based adverse event reporting systems versus electronic,
use of information technology (e.g., personal digital assistants by physicians at the patient beside), categories of detail that should be included in a patient safety database (e.g., what, where, when, how and why an event happened, what action was taken or proposed, what was the impact of the event (e.g., harm to the patient, organization, etc.), and factor that did, or could have, minimized impact. The choice of anonymous or confidential reporting and learning systems needs careful consideration. Importantly, anonymous reporting does not allow the opportunity for follow-up if questions arise during the course of an investigation, sometimes making it difficult to get at the root cause (s) of the adverse event. The literature review addressed the barriers to reporting by health care professionals, and the differences in physician and nurse preferences for reporting systems. The author suggests that in order to overcome the barriers to reporting, a learning and nonpunitive culture of safety must be promoted, and legal protection provided for those reporting incidents. White states that very little information has been published about the specific costs associated with the development, implementation and maintenance of incident reporting databases. However, the author suggests that to properly prepare for the “financial implications” of an adverse event reporting and learning system, the following areas and their associated costs should be taken into account: feasibility testing, legal advice, computer form design, hardware, software, development of taxonomy/classification systems, user education, user awareness, user acceptance testing, data coding, data analysis, feedback reporting, external promotion of systems and incentive programs. Finally, White highlights the importance of providing frequent “feedback” to staff and notification of any changes made to improve the system.

Leape (2002) suggests that successful health care adverse event reporting systems are exemplified by the following characteristics: (1) nonpunitive (2) confidential (3) independent – data are analyzed by independent organizations (4) expert analysis (5) timely feedback provided to system users (6) systems-oriented solutions to reported problems, and (7) participant organizations are responsive to suggested changes.

In this section of the paper, attention is given to the initiatives that have been undertaken by a number of countries. Although the Task Force is cognizant of the fact that many countries have reporting and learning systems in place (e.g., Japan, Denmark, the Netherlands, the Czech Republic and so on), it will focus only on the World Health Organization and three specific countries (the United States, the United Kingdom and Australia). Finally, several Canadian initiatives, either underway or being considered at a provincial or national level, will be presented.
International Initiatives

World Health Organization

Adverse event and critical incident reporting and learning systems have been developed in several countries and summarized by others. The WHO draft guidelines on adverse event reporting and learning systems were developed in collaboration with Dr. Lucian Leape from Harvard’s School of Public Health. The goal of the development of such guidelines was to help countries develop or improve existing systems. The draft guidelines highlight a number of key characteristics of successful reporting and learning systems: reporting is safe for the individuals who report; reporting leads to a constructive response; expertise and adequate human and financial resources are available to allow for meaningful analysis and learning and the reporting system is capable of disseminating information and recommendations for change.

United States

In 1999, the Institute of Medicine released its landmark report To Err is Human: Building a Safer Health System. One of the report’s recommendations was the establishment of a national mandatory reporting system in hospitals, followed by an expansion to all sites engaged in patient care. As of 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; however, the requirements for these reporting systems vary from state to state. In addition, there is limited evidence of the sharing of information at the national level.

United Kingdom

A landmark report published in 2000, An Organization with a Memory, led to the establishment of the National Patient Safety Agency (NPSA). The NPSA was created to coordinate efforts to report and learn from mistakes and problems that affect patient safety in health care. It is a system for reporting and tracking adverse events and near misses. The NPSA tries to promote an open and fair culture in the NHS, encouraging all health care staff to report incidents without undue fear of personal reprimand. It collects and analyzes information on patient safety incidents from NHS organizations, staff and patients. A core function of the NPSA was the development of the National Reporting and Learning System (NRLS), an anonymous mandatory reporting system that is responsible for collecting reports of patient safety incidents (actual and potential adverse events) from all service settings across England and Wales, and, importantly, learning from such reports. All reporting by individuals is anonymous, but it is mandatory for NHS Trusts to submit any reported
adverse event to the NRLS. The NRLS was launched in February 2004.

An evaluative report reviewing the progress of the NRLS was released by NPSA in February 2008. Over 800 staff participated in the review. A major finding was the insufficient progress in improving patient safety. The staff suggested that the NPSA (1) build on the system currently in place but improve it (2) make the system quicker and easier to use (3) get to the most serious issues quickly (4) streamline routes of reporting, and (5) provide more targeted feedback for organizations and specialties.

**Australia**

The Australian Advanced Incident Monitoring System (AIMS) is a confidential error reporting system. Patient Safety International, a subsidiary of the Australian Patient Safety Foundation, developed the AIMS software tool to consistently capture information on close calls and critical incidents, allowing for in-depth analysis of both types of events. Patient Safety International (PSI) is a leading provider of incident management software to help health care services improve the quality of care by reducing medical errors, waste and harm to patients. The AIMS consists of a confidential incident report form completed at a local level, and an anonymous monitoring system.

The AIMS incident management software is used by over 400 Australian hospitals, as well as at sites in South Africa, New Zealand and the United States. AIMS captures adverse event and near miss information across acute care, community care, disability care, mental health and residential aged care (nursing homes). Unlike other systems, AIMS includes a standardized classification (ontology) that is recognized by the World Health Organization and the US Institute of Medicine. The software is currently in use in over half the Australian public health system and allows a comparison of critical incidents and appropriate interventions to reduce the risk of recurrences among those participating in the surveillance system. A national reporting system, therefore, does not truly exist in Australia.

**Canada**

*Canadian Institute for Health Information*

The Canadian Institute for Health Information (CIHI) collects information on a number of patient safety indicators: (1) obstetrical trauma during childbirth, (2) foreign objects left in after a procedure, (3) post admission pulmonary embolism or deep-vein thrombosis and (4) in-hospital falls and hip fractures. In a 2006 survey of primary care physicians the findings suggested that almost three of five primary care doctors reported that there was no documented process for follow-up and analysis of adverse events.
**Canadian Medication Incident Reporting and Prevention System**

The Canadian Medication Incident Reporting and Prevention System (CMIRPS)\(^3\) is a system that reports, analyses and manages voluntarily reported medication incident data on a national basis. The Canadian Institute for Health Information, Health Canada and the Institute for Safe Medication Practice Canada are collaborating parties of CMIRPS. The CMIRPS coalition is comprised of the Canadian Association of Chain Drug Stores; the Canadian Healthcare Association; the Canadian Institute for Health Information; the Canadian Medical Association; the Canadian Nurses Association; Canadian Pharmacists Association; Canada’s Research Based Pharmaceutical Companies; Canadian Society of Hospital Pharmacists; College of Family Physicians of Canada; Consumers Association of Canada; Health Canada - Marketed Health Products Directorate, Health Products and Foods Branch (Secretariat); Institute for Safe Medication Practices Canada; and The Royal College of Physicians and Surgeons of Canada. CMIRPS promotes an open, “blame-free” system that encourages health care practitioners to voluntarily share their medication incident experiences.

The purposes of the CMIRPS program are to coordinate the capture, analysis and dissemination of information on medication incidents; enhance the safety of the medication-use system for Canadians; and support the effective use of resources through the reduction of potential or actual harm caused by preventable medication incidents.

The goals of the CMIRPS information system are to collect data on medication incidents; facilitate the implementation of reporting of medication incidents; facilitate the development and dissemination of timely, targeted information designed to reduce the risk of medication incidents facilitate the development and dissemination of information on best practices in safe medication use systems.

The CMIRPS collects reports on potential and actual incidents related to any medication and occurring at any stage of the medication-use system: prescribing, order communication, product labeling and packaging, compounding, dispensing, distribution, administration, monitoring, documentation or use. Incident reports can be submitted by health care professionals, institutions such as hospitals, and from patients themselves. Medication incidents may involve improperly prescribed medication, improper administration or incorrect dosage or protocol.
The Canadian Patient Safety Institute is currently engaged in a process to establish the Canadian Adverse Event Reporting and Learning System (CAERLS), one of its strategic business plan goals. As an initial step, a review of leading national and international practices was conducted in the reporting of adverse events, medical error and critical incident reporting, and related improvement mechanisms designed to facilitate knowledge transfer, learning and, ultimately, to improve patient safety.

A comprehensive review of the published literature on adverse event reporting and learning systems in healthcare for the Canadian Patient Safety Institute encompassed an examination of governance and legislative frameworks; taxonomy and classification systems; technical/design considerations and user issues; anonymous and confidential reporting systems; reporting by professionals and/or patients; financial implications; and, feedback systems to improve safety.

In 2007, CPSI commissioned a separate review focusing on provincial, territorial and federal legislation and policy related to the reporting and review of adverse events in healthcare in Canada. As part of the review, the authors addressed key enablers and barriers for the reporting and review of incidents on a national scale. The authors (1) analyzed the application of provincial and federal legislation, (2) reviewed policies at provincial and regional levels, (3) conducted surveys of healthcare regions, hospitals and other health delivery organizations, and (4) interviewed experts and key stakeholders interested in the reporting of incidents. The report’s findings indicated that while some provinces have enacted legislation for the mandatory reporting of adverse health events, the reporting of adverse events remains at the institutional level in many other provinces. Importantly, the prohibition of the sharing of patient safety information, both within and outside of the province, would act as a significant barrier to the creation of a national reporting system. Other factors that would prove to be challenging include “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” (page 2).

The authors recommend the development of local capabilities to collect and analyze reports within organizations and regions. They suggest the establishment of a provincial body (e.g., Minister or other separate body) responsible for reporting in each province. The provincial body would be responsible for coordination of the reporting by institutions and professionals in healthcare in compliance with legislation within that province. De-identified information would be shared by the provincial body with a national body (i.e., a pan-Canadian body) that had the capacity to disseminate information and warnings on a national basis. Finally, in order to learn from lessons across the country, a framework for the classification of incidents on a pan-Canadian level would be required.

The collaborating organizations of CMIRPS (Health Canada, Canadian Institute for Health Information, and the Institute for Safe Medication Practices) are exploring the possible integration of CAERLS and CMIRPS.
**Regional and Provincial Initiatives**

Several initiatives are currently underway in a number of regional health authorities/health care organizations including the British Columbia Incident Reporting Information System (IRIS) Project; Regional Occurrence System Enhanced (ROSE) Project, Eastern Health, Newfoundland and Labrador; and Patient Safety Reporting System (PSRS), Capital Health (Halifax), Nova Scotia.

**Incident Reporting Information System (IRIS) project**

The IRIS project\textsuperscript{42} is an initiative of the British Columbia Patient Safety Task Force. It is a collaborative effort of all six BC Health Authorities and the Health Protection Program. The project is funded by Canada Health Infoway, British Columbia Ministry of Health and the Health Authorities. The project will consist of four stages: (1) feasibility study 2003/04 (2) package selection, 2005/06 (3) pilot implementation, and (4) provincial rollout 2007-2010. The exercise will cover all facilities in the community. The objective of the project is to enable the identification, management, analysis, learning and sharing lessons acquired. DATIX\textsuperscript{43} software, a web-based incident, complaints and claims reporting tool, will be used in all regions of the province. Anyone with access to an organization’s intranet will be able to report incidents directly into the DATIXWeb software using easy-to-use web pages. Managers receive an automatic email with details of incidents. They can complete the details of the investigation through the web and also run analyses incidents. DATIX uses a standard coding system for clinical and nonclinical adverse events and near misses. The Calgary Health Region is also a client of DATIX and will be implementing the reporting tool across its region in the near future.\textsuperscript{44}

**Regional Occurrence System Enhanced (ROSE) Project**

The Regional Occurrence System Enhanced (ROSE) Project\textsuperscript{45} proposed by Eastern Health will entail the development and implementation of an electronic occurrence reporting system (OCR) across the continuum of patient care encompassed by the Eastern Health Regional Authority in Newfoundland and Labrador. The project will consist of three stages: (1) requirements finalization and implementation planning (2) staged implementation and testing, and (3) benefits determination/evaluation. The project has five broad objectives (1) to enhance the development of a patient safety culture through intense education and ongoing support initiatives (2) to improve the efficiency and effectiveness of the occurrence reporting system(3) to improve communications related to occurrence reporting and implementation of action plans (4) to support related quality, research and evaluation activities (5) to explore opportunities for collaboration throughout development, implementation, evaluation, and knowledge transfer.\textsuperscript{46}
Patient Safety Reporting System (PSRS)

Findings from two patient safety culture surveys conducted in 2003 and 2005 at Capital Health (Halifax) suggested that staff believed that they “… would probably be treated in a negative way for reporting or discussing errors or serious occurrences” by 45.4% in 2003 and 50.4% (p=0.03) in 2005. Capital Health recently developed and launched an in-house incident reporting system. The Patient Safety Reporting System (PSRS), an intranet-based online reporting and data retrieval system created on a network platform provided by CCD Systems, was implemented at three pilot sites in June 2007, and in 2008 the system was expanded across the region. The program allows computerized reporting of patient safety issues from a network-ready computer. Report completion and delivery occurs immediately after the clinical staff or physician completes the report online, thereby eliminating the handling of paper forms and time-intensive data entry. The system will, upon completion of the event entry, send an email notification to the responsible clinical leaders and/or physician, allowing them to review and follow-up their reports immediately and enhance system accountability. Past practice included Risk Management assigning a severity rating to the event; however, with the new system the individual entering the event is able to assign the severity or patient impact to the actual event or near miss. Confidentiality of the new reporting system is anticipated to increase staff/physician confidence in the reporting system.47

Summary

Learning is more than the analysis of an adverse incident – it is about ensuring there is a change based on well-designed action plans. These must be realistic, achievable and sustainable, with all stakeholders involved in their development.48

Adverse health reporting and learning systems have been developed and implemented in a number of countries. Canadian organizations and institutions that have adopted or are engaged in the development of reporting and learning aspects of adverse health care management should remain cognizant about the challenges experienced by other countries and organizations (e.g., National Patient Safety Agency –UK – National Reporting and Learning System). More specifically, an evaluation observation coming out of the UK in relation to the NRLS suggests that

despite the high volume of incident reports collected by the NPSA … there are too few examples where these have resulted in actionable learning for local NHS organizations. The National Reporting and Learning System (NRLS) is not yet delivering high-quality, routinely available information on patterns, trends, and underlying causes of harm to patients (p.6). 49

Provincial reporting and learning initiatives are slowly beginning to emerge. Each province and territory has established individual policies and guidelines for reporting
adverse health events. Furthermore, in many areas policies and guidelines vary between jurisdictions and or regional health authorities and or organizations. Finally, the focus of adverse health event reporting has been on the acute-care setting (i.e., institutions). Gaps in patient safety and adverse health event reporting have been identified in long-term care and home care. The Health Council of Canada’s 2007 Annual Report stressed the importance of implementing standardized, systematic reporting of adverse health events across the continuum of health care (i.e., acute care, long-term care, and community). The Council cautioned that without such an approach jurisdictions would be “unable to collect and monitor information, understand the extent of the errors, and share learning and knowledge” (page 47).

It is important to remain focused on the purposes of establishing national reporting and learning systems: to collect information, disseminate lessons learned and transfer the knowledge and learning to all health system stakeholders. Lessons learned from pioneers (the US, the UK, and Australia) in the field of adverse health event management will be very helpful in the planning and implementation of a pan-Canadian reporting and learning system.

**Provincial Legislation – Quality of Care Committees**

Legislative and regulatory frameworks focused on quality of health care services exist in all Canadian provinces and territories. A detailed listing is provided in Appendix C. Details associated with various pieces of legislation specific to the Newfoundland and Labrador setting are presented and discussed elsewhere in this report.

Information related to quality of care committees is protected by legislation. The intent of the legislation is to protect and prevent the information from being used in subsequent legal or disciplinary proceedings, thereby encouraging full participation of health care providers in quality improvement. Quality improvement programs in hospitals/institutions often use quality of care committees to analyze clinical outcomes, adverse events and close calls. Recommendations arising from the analyses are used to help correct any system failures that are identified. Some jurisdictions explicitly prohibit the sharing of any findings, conclusions or recommendations of a quality improvement committee to persons other than in management responsible for their implementation.

**Provincial Incident Reporting and Investigation Legislation**

Three provinces (Saskatchewan, Manitoba and Quebec) have legislation that requires the reporting of various types of incidents that occur in health care facilities (hospitals, long-term care, child care, personal care homes). Saskatchewan and Manitoba, in particular, have moved from a voluntary reporting of adverse events to a more comprehensive...
legislated process, including mandatory reporting and shared learning, in an effort to reduce the potential of critical incident reoccurrence. As of July 1st, 2008, Ontario will become the most recent province to amend legislation, thereby mandating the disclosure of critical incidents to patients.

CPSI engaged a group to conduct a review of provincial, territorial and federal legislation and policy related to the reporting and review of adverse events in health care in Canada. A legislation reference table is presented in Appendix C. The review identified only three provinces that address adverse events/critical incidents in their legislation. The key provisions of the statutes summarized by Baker, Grosso, Heinz et al are included in Appendix D.

In this section of the paper, an overview of established provincial incident reporting, the investigation legislation of three provinces (Saskatchewan, Manitoba and Quebec) and new legislation in Ontario as of July 1st, 2008 are discussed.

**Saskatchewan**

In 2002, Saskatchewan became the first Canadian province to enact legislation requiring mandatory reporting of adverse events to the provincial Department of Health.

On September 15, 2004, the government of Saskatchewan passed legislation requiring the reporting and investigation of occurrences of critical incidents in health care. The aim of such legislation is reporting for learning to enhance patient safety. A critical incident is defined as:

A serious adverse health event including, but not limited to, the actual or potential loss of life, limb or function related to a health service provided by, or a program operated by, a regional health authority (RHA) or a health care organization (HCO).

Saskatchewan’s Personal Care Homes Regulations (R.R.S. 2000, c. P.-6.01, Reg 2 amended by Saskatchewan Regulations 69/2002 and 89/2003), mandate reporting of “serious incidents.” This includes “any occurrence, accident or injury that is potentially life threatening” as well as “any harm or suspected harm suffered by a resident as a result of unlawful conduct, improper treatment or care, harassment or neglect on the part of any person” (s.13 (1)). Licensees must notify the “resident’s supporter,” their physician, the department responsible and the regional health authority. They are also obligated to provide a written report to the government department responsible, outlining a number of things including “any actions taken…to solve the problems…and to prevent recurrences of the serious incident” (s.13(2)(b)).

The Saskatchewan Critical Incident Reporting Guidelines lists the critical incidents
that must be reported to the Department of Health. Since 2004, notification of “critical incidents” must be made by health care organizations to their regional health authorities. This guideline was adapted from the US National Quality Forum, *Serious Reportable Events in Health Care: A Consensus Report* published in 2002.57 It is the responsibility of the authority to directly notify the minister. Investigations and written reports are to follow (*Act to Amend the Regional Services Act*, (2004); *Critical Incident Reporting Guideline and Saskatchewan Critical Incident Regulations*). Details of the report must include a description of the circumstances surrounding the incident, the identification of potential contributing factors that upon modification could prevent a reoccurrence of the event, actions taken and future plans of action the organization or authority might identify as a result of the critical incident investigation. The names of patients, health care providers or any other individuals with knowledge of the critical incident are protected by a confidentiality provision in the legislation, and therefore cannot be named in any report arising from the investigation of the critical incident.

**Manitoba**

In 2005, the Manitoba government passed legislation to amend the *Regional Health Authorities Act* and the *Manitoba Evidence Act*.58 The amendments contained mandatory critical incident reporting requirements. A critical incident is defined as:

Unintended event that occurs when health services are provided to an individual and result in a consequence to him/her that (a) is serious and undesired, such as death, disability, injury or harm, unplanned admission to hospital or unusual extension of hospital stay, and (b) does not result from the individual’s underlying health condition or from risk inherent in providing the health service.59

Manitoba does not have a “common list” or guideline of reportable critical incidents similar to the one used in Saskatchewan. However, once identified, the channel for reporting a critical incident is similar to that of Saskatchewan, the health care organization would report the event to the regional authority, which in turn would report the incident directly to the Minister of Health. If a critical incident occurs, the regional health authority, health corporation or health care organization must ensure (1) that appropriate steps are taken to fully inform the individual, as soon as possible, about the facts of what actually occurred with respect to the critical incident (2) its consequences for the individual as they become known, and (3) the actions taken and to be taken to address the consequences of the critical incident, including any health services, care or treatment that are advisable. A complete record must be made about the critical incident, which must address the preceding points. The individual who experienced the critical incident may examine the report and receive a copy, free of charge.
Quebec

The government of Quebec amended legislation in an effort to mandate when and what a patient should be told after an accident or incident occurs in institutions. The amended legislation ensures a specific right to be informed of an accident. An “accident” is defined as “an action or situation where a risk event occurs which has or could have consequences for the state of health or welfare of the user, a personal member, a professional involved or a third person”. An “incident” is defined as “an action or situation that does not have consequences for the state of the health or welfare of a user, a personal member, a professional involved or a third person, but the outcome of which is unusual and could have had consequences under different circumstances”.

Health care facilities’ obligations concerning disclosure of accidents, declaration of accidents and incidents, allowance of support for patients, their families and health care workers involved in the accident, creation of a risk- and-quality management committee, accreditation on patient safety, quality and risk management and the development of a local registry are addressed in Bill 113. The Bill also makes provision for a province-wide registry of incidents and accidents.

Ontario

In February 2003, the Council of the College of Physicians and Surgeons of Ontario approved a policy that mandates disclosure of a critical incident. The disclosure of a critical incident in Ontario was addressed at a provincial level in July 2008, with a new regulation that amends Regulation 965 under the Public Hospitals Act. The amendment mandates the disclosure of a critical incident to a patient.

A critical incident is defined as

any unintended event that occurs when a patient receives treatment in the hospital, (a) that results in death, or serious disability, injury or harm to the patient, and (b) does not result primarily from the patient’s underlying medical condition or from a known risk inherent in providing the treatment.

Hospitals are expected to adopt and implement the regulation; however, they may also retain or develop expanded disclosure policies that exceed (but do not contravene) the requirements of the Act. The boards are responsible for ensuring that hospital administrators establish a system for ensuring the disclosure of every critical incident. Policies and procedures for staff reporting will be based on what is most appropriate for their particular facility.
Summary

The definition of reportable incidents varies between the three provinces that have legislated adverse event reporting requirements. The most inclusive definition is in the Saskatchewan Critical Incident Report Guideline. In each of the provinces, the minister must be notified of a critical incident occurrence, and a report must follow. While detailed reporting guidelines are available in Saskatchewan, institutions in Quebec are responsible for developing written recording and provision of information procedures as they relate to adverse event occurrences. Manitoba and Saskatchewan have very similar requirements when it comes to reporting critical incidents; however, Manitoba does not have a detailed reporting guideline process such as the one used in Saskatchewan. In Ontario, the boards will be responsible for ensuring that hospital administrators establish a system for ensuring the disclosure of every critical incident. The policies and procedures for staff reporting will be facility-specific.

Disclosure

A number of comprehensive overviews of open disclosure are available in the literature (Canadian Patient Safety Institute, 2006; Australian Commission on Safety and Quality in Health Care, 2008). Open disclosure policies have been developed and implemented in a number of countries over the last five years:

- **Australia** - Open Disclosure Standard: A National Standard for Open Communication in Public and Private Hospitals, Following an Adverse Event in Health Care (2003);
- **UK** - Being Open -Communicating Patient Safety Incidents with Patients and Carers: NHS (2005);

Most recently, CPSI launched the Canadian Disclosure Guidelines (CPSI, 2008). The guidelines are based on a national and international environmental scan and review of the literature. The purpose of the guidelines is to provide support for the development and implementation of policies, procedures and training methods (e.g., Canadian root cause analysis) as they relate to adverse health events disclosure processes to health care providers, interdisciplinary teams, organizations and regulators. The approach to the disclosure process in these guidelines is purported to occur in two stages: (1) initial disclosure and (2) post analysis disclosure. During the initial disclosure, consideration should be given to the following: (a) participants in the disclosure discussions (b) when disclosure should take place (c) the setting and location of the disclosure (d) what to disclose, and (e) how will disclosure occur. During the initial disclosure, the guidelines suggest providing facts, explaining the care plan, avoiding speculation, expressing regret, outlining expectations, arranging follow-up, identifying a contact and documenting.
During the second phase of disclosure, further facts and any actions taken are provided to the patient/family with an appropriate expression of regret. The information is documented. The Task Force will not be duplicating the extensive efforts of CPSI on identifying an appropriate disclosure process; rather, the Task Force will review the applicability of the CPSI Disclosure Guidelines to the Newfoundland and Labrador setting.

Additionally, the Newfoundland and Labrador Commission of Inquiry on Hormone Receptor Testing in Breast Cancer has a policy focus and includes a review of both the policy and legal issues raised in its Terms of Reference. The Commission engaged six experts to prepare disclosure obligation papers to assist the Commission with its policy development role. The papers are available at http://www.cihrt.nl.ca/partIIoftheinquiry.html. The papers focused on the following topics:

1. Legal and Ethical Obligations of Public Health Authorities and Government (Dickens, G.);
2. Examining Disclosure Options: Procedures for Disclosing Adverse Events: A Literature Review (Espin, S.);
3. Disclosing Unanticipated Outcomes to Patients: International Trends and Norms (Gallagher, T.H.);
4. Disclosure: Ethical and Policy Considerations (Hébert, P.C.); and
5. The Legal Duty of Physicians to Disclose Medical Errors (Robertson, G.B.).

Adverse Health Event Management – Policies of Select Canadian Organizations

As part of the work of the Task Force, we identified and examined a number of policies related to the management of adverse health events at the organizational, regional, provincial and federal levels. A complete listing of the policies reviewed is presented in Appendix E. The Task Force has decided to focus on three regional policies only in this section. The policies are presented in Appendix F.

Alberta

Calgary Health Region

The Calgary health region is considered by many to be the country’s most progressive. A quality improvement framework - with patient safety as a focal point - and a supporting program were developed after the region’s first full accreditation in 1999. A number of regional safety policies exist between the region/providers and patients (i.e., disclosure of harm policy), between providers and the region (reporting hazards, close calls and harm policy), between the region and its providers (i.e., just and trusting culture policy) and
between the region and its principal health care partners/stakeholders (i.e., informing). Detailed procedure manuals complement each of the regional policies. Reporting focuses on all types of incidents (i.e., harm, close calls and hazards) and is done on a voluntary basis to the Calgary Health Region. Sharing of information for the purpose of learning and making system improvements within the region and in other health care organizations is fostered.

One of the guidelines used in the region focuses on the “Immediate and Continuing Management of Serious (Potential) Adverse Events.” The purpose of the guideline is “to outline the immediate and continuing roles and responsibilities of senior administrators or medical leaders in the Calgary Health Region when potentially serious adverse events have or may have occurred” (page 4). The guideline is used as a framework to assist senior administrators/medical leaders in decision-making, planning and taking actions. The initial and critical steps in the immediate management can be captured in the acronym RESPOND. The RESPOND checklist addresses the following steps:

- **R** esuscitate/react – to the patient’s immediate needs
- **E** nvironment – ensure that it is safe for patients and providers
- **S** ecure equipment – for examination and evaluation
- **P** rotect other patients – that they cannot be immediately harmed
- **O** ffer support - to the patients/families and health care providers involved
- **N** otify – appropriate clinicians/administrators and complete a Safety Learning Report
- **D** isclosure – acknowledge the adverse event

Actions associated with RESPOND are outlined in the procedure manual.

Once the immediate management of the potentially serious adverse event has been addressed, a senior administrator/medial leader is accountable for the continued management of the event (i.e., patient/family, health care provider(s) involved, region). A second checklist focuses on advocacy, communication and evaluation (ACE) and actions that may or may not be taken.

- **A** dvocate – and continue to support the patient/family and health care provider(s) involved:
  - Assigning a patient advocate, providing ongoing support for the patient/family and health care providers are key actions.

- **C** ommunicate – important information to the patient/family, health care providers and/or other stakeholders:
  - Disclosing to the patient/family, completing a safety learning report (required in the event of a patient suffering fatal or severe harm, but also strongly encouraged when a patient has suffered from moderate or minimal harm or experienced a close call), and informing principal partners and stakeholders.
Evaluate – the potentially serious adverse event so that the Region can learn and make improvements, where appropriate, for the safety of the next patient.

- Key actions include:
  - Conducting a safety analysis (if there is reason to suggest that system contributing factors may be associated with the potentially adverse event or risk thereof (close call)). The Safety Analysis does not review or assess the performance of individuals, and would not be conducted by persons who have administrative responsibilities for the area and health care providers involved.
  - And/or an administrative review (when there is evidence or probable reason to suggest that individual contributing factors may be associated with the potentially adverse event or risk thereof (close call)). An administrative review is conducted by individuals with administrative responsibilities for the actions of the individuals involved. The reviews are not conducted under the direction of the clinical safety committee; therefore, Section 9 of the Alberta Evidence Act does not apply to these documents. The provincial privacy legislation does not permit the release of the outcome of the administrative reviews.

A summary of three presentations by Dr. Ward Flemons, VP Health Outcomes that focus on the operational response to an adverse event, acting on the management of an adverse event and embracing a culture of safety are presented in an accompanying document – Provincial Forum on Adverse Health Events – Summary Proceedings.

Manitoba

Winnipeg Regional Health Authority

The Winnipeg Regional Health Authority (WRHA) Patient Safety team\textsuperscript{75} develops and supports programs and initiatives with the goal of reducing unnecessary patient injuries and deaths in the region. The regional team is led by Dr. Rob Robson, Chief Patient Safety Officer and Harvard-trained health care mediator. A comprehensive strategy to improve the region’s capacity to effectively manage and learn from adverse events – or what the region refers to as Critical Clinical Occurrences (e.g., medication errors, misdiagnosis, equipment failures and so on) – was implemented by the authority. The Regional Integrated Patient Safety Strategy has four focal points: (1) promoting culture change with the aim of moving from a culture of blame, fear and retribution to a safety culture that encourages openly discussing adverse events, asking questions and making improvements (2) directly involving patients by way of a Patient Safety Advisory Council (3) learning from clinical practice (e.g., Critical Clinical Occurrence), and (4) promoting change in care delivery with the aim of enhancing acceptable standards of care.

The WRHA has two regional policies available on its website that apply to all WRHA governed sites and facilities (including hospitals and personal care homes), and are
specifically related to reporting, investigating, disclosing and learning from critical incidents. The policies, Critical Incident Management and Learning and Disclosure of Information Related to Care and Treatment, were adopted by the WRHA in 2007. The Disclosure of Information Policy mandates the disclosure of pertinent clinical information, not only following critical incidents but in other patient-centered care circumstances. The Reporting of critical incidents or provisional critical incidents within the regional authority for any individual including employees and medical staff is mandatory. Provincial legislation dealing with critical incident reporting provides protection from litigation for the work of committees created to investigate such incidents. It is also mandatory for the regional authority to report critical incidents to the Ministry initially (i.e., after the event has been confirmed as a critical incident), to submit a status report on the critical incident within 30 days to Manitoba Health, and to submit a copy of the final report within 90 calendar days of the critical incident or upon completion of a critical incident review.

In 2008, Dr. Robson and Elaine Pelletier, a patient safety process analyst for the region, published an article in *Health Care Quarterly* that focused on the factors that led the WRHA to develop a process to identify cases involving patient harm following critical incidents in the health care system. The coauthors described the main steps that would lead to early compensation discussions with patients in cases when preventable contributing factors were under the control of WRHA.

**Saskatchewan**

**Saskatoon Health Region**

All critical incidents are reported through a region-wide reporting process in compliance with Section 58 of the Regional Health Services Act and its corresponding regulations - The Regional Health Services Critical Incident Regulations – and the Accountability Agreement with Regional Health Authorities and Saskatchewan Health.

Critical incident is defined according to the legislation and regulations. The Saskatchewan Critical Incident Reporting Guideline (2004) is adapted from the 2002 *National Quality Forum Serious Reportable Events in Health Care: A Consensus Report*. The guideline provides a list of reportable events including surgical events (e.g., surgery performed on a wrong body part, on the wrong patient), patient death or disability associated with product or device events (e.g., contaminated drugs, devices or biologics), patient protection events (e.g., an infant discharged to the wrong person), care management events (e.g., patient death or disability associated with hemolytic reaction due to the administration of ABO-incompatible blood or blood products), environmental events (e.g., patient death associated with a fall while being cared for by an RHA or Health Care Organization), and criminal events (e.g., sexual assault of a patient that occurs on the grounds owned or
controlled by an RHA or HCO).

The Saskatoon Health Region Critical Incident Reporting Policy was revised in September 2007. Critical incidents must be reported immediately to the Director of Risk Management or designate. During the weekend or night shift, the most senior administrator on call is contacted through the Switchboard or the appropriate on-call process. The administrator then notifies the Director of Risk Management and appropriate senior managers. The event is entered into the Safety Reporting System (computer-based) or a confidential Safety Report is completed by staff member, physician, volunteer or student of the service/dept/area who was involved in, witness to, or became aware of the critical incident. This must happen within 24 hours of the critical incident occurring or when the incident is recognized as a critical incident and be in accordance with the procedures outlined in the Safety Reporting Policy (#7311-50-006).

When the Safety Report form is completed, it must be submitted to Risk Management within 48 hours of the critical incident. Other reporting forms or documentation that may have been completed (i.e., a medication error report) must accompany the confidential Safety Report. When the Safety Reporting System (computer-based) is used, automatic notification of the appropriate individuals will occur. Safety Reports are not part of the health record. The original report is filed in Risk Management. A factual note of the event and the patient assessment must be documented in the patient’s/resident’s chart.

Risk Management notifies the appropriate senior management that a critical incident has occurred. Risk Management, according to the legislation, shall notify the Minister of Health of a critical incident within three business days following the incident or the date the regional health authority becomes aware of it. Notification to the Minister of Health by Risk Management shall include de-identified, factual information about the critical incident.

Saskatoon Health Region shall investigate the critical incident through a nonpunitive, multidisciplinary review (Appendix B – Multidisciplinary Case Review). The investigation includes:

- the circumstances leading up to and culminating in the critical incident;
- any current practice, procedure or factor involved in the health service that contributed to the critical incident;
- actions considered, developed or required as follow-up to the critical incident; and
- implementation of any recommendations resulting from the critical incident review.

Risk Management, according to the legislation, will provide a written report of de-identified factual information including actions taken, planned and the quality improvements the RHA will be implementing as a result of the critical incident review.
The report must be submitted within 60 days of the RHA becoming aware of the critical incident.

Appropriate senior managers within SHR will receive a copy of the written report of de-identified factual information including the actions taken, planned and any quality improvements that will be implemented as a result of the critical incident multidisciplinary case review. Feedback/direction will be provided to appropriate stakeholders to implement quality improvements as required.

The region and its affiliates also have a Disclosure of Adverse/Unanticipated Events Policy that became effective in October 2007. The policy addresses multijurisdictional disclosure and multiperson disclosure. Further details are provided in Appendix F.

**Apology Legislation in Canada**

Apology legislation may be divided into three categories:

1. Expressions of sympathy, regret or benevolence;
2. Limited apology legislation; and
3. Comprehensive apology legislation.79

Derwin elaborates on the differences among the three categories. The first type of legislation makes expressions of sympathy, regret or benevolence inadmissible in court actions. A number of American states have passed laws protecting “expressions of sympathy, regret or benevolence”. According to Derwin, such laws are not true apology laws and serve a very limited purpose.80 As many as 36 states have adopted “apology laws”, thereby providing legal protection related to disclosure; however, the degree of protection varies.81 The second category of legislation protects apologies, but is limited in scope. Limited apology legislation may exclude apologies offered in certain types of actions, such as sexual assault lawsuits, tobacco litigation or intentional torts. The third type of apology legislation is comprehensive, protecting all forms of apologies, including apologies which admit liability. The Apology Act of Manitoba82, the Uniform Apology Act83, Apology Act, S.B.C. 2006, Chap. 19 (British Columbia)84 and the Evidence Act, S.S. 2006, c. E-11.2, Section 23.1(1) (Saskatchewan)85 are all forms of comprehensive apology legislation. Health Care providers’ fears that information, opinion or speculation offered during the course of an investigation would be used against them in a medical malpractice lawsuit, inhibited reporting in the past. The intent of the legislation was to provide the protection to do so without fear of reprisal. It was felt that the legislation provided by the Apology Act would encourage health care professionals and institutions to apologize for their errors without that apology being admissible as evidence of fault.
On May 18, 2006 British Columbia became the first province to enact apology legislation. This was followed by Saskatchewan in 2006 and Manitoba in 2007. In 2006, the British Columbia Ministry of Attorney General carried out a review of the academic literature, and focused on factors in favour and against apology legislation. These factors are listed below.

**Factors in favour of apology legislation include:**

a. To avoid litigation and encourage the early and cost-effective resolution of disputes;

b. To encourage natural, open and direct dialogue between people after injuries; and
c. To encourage people to engage in the moral and humane act of apologizing after they have injured another; and to take responsibility for their actions.

**Negative factors include:**

a. Public confidence in the courts could be adversely affected if a person who has admitted liability in an apology is not found liable;

b. Insincere and strategic apologies could be encouraged; and
c. Apologies encouraged by such legislation might create an emotional vulnerability in some plaintiffs who may accept settlements that are inappropriately low.

In the British Columbia and Manitoba Apology Acts, apology is defined as

an expression of sympathy or regret, a statement that one is sorry or any other words or actions indicating contrition or commiseration, whether or not the words or actions admit or imply an admission of fault in connection with the matter to which the words or actions relate.

The Yukon Legislative Assembly is also considering an apology act. As was the case for the Manitoba Apology Bill, Bill 103 is modeled after the British Columbia legislation. The apology for an adverse event is inadmissible in court for the purpose of proving liability in British Columbia, Manitoba, and Saskatchewan. The legislation in British Columbia, Manitoba and the Yukon addresses the issue of insurance in the following manner:

an apology does not, despite any wording to the contrary, in a contract of insurance, and despite any other enactment, void, impair or otherwise affect insurance coverage that is available, or that would, but for the apology, be available to the person in connection with that matter.

Ontario was the fourth and most recent province to consider an Apology Act. In April, 2008, A Private Members Bill (Bill 59) entitled the Apology Act, 2008, was tabled by Sault Ste. Marie Liberal MPP David Orazietti. The intent of the Act is to allow an individual to express an apology in connection with any civil matter, without that apology
being considered an implied or expressed admission of fault or liability, or admissible as such in any court of law. It is anticipated that by removing the threat of litigation from an apology, more open communications in the health care environment will occur. The Ontario Medical Association and the Canadian Medical Protective Association welcomed the introduction and passing of Bill 59.92

The Uniform Law Conference of Canada was held in Prince Edward Island in 2007. The Conference, founded in 1918, harmonizes the laws of the provinces and territories, and also where appropriate, federal laws. At the 2007 Conference, recommendations on the Uniform Apology Act were adopted. The Act provides that an apology is not admissible in civil proceedings for the purpose of proving liability and that an apology is not an admission of liability. The conference suggested that: “As an alternative to a separate statute, a jurisdiction may wish to enact the provisions of the Uniform Apology Act as an amendment to its Evidence Act.” 93

A section common to all existing and draft apology legislation in Canada provides that an apology will not disentitle a person to insurance coverage, even if their policy or provincial legislation stipulates otherwise. Another similarity is the use of the term “person”. Person, under provincial interpretation legislation, is defined as a person or corporation.

The existing and draft apology legislation in Canada is generally consistent, although there are some minor differences in wording. Some legislation for example uses the term “notwithstanding,” while other legislation uses the term “despite.” Saskatchewan’s legislation refers to an event or occurrence, while the remaining legislation uses the term “matter.”

Another distinction arises the Manitoba legislation and the draft Yukon legislation, neither of which include a clause that precludes an apology from being considered an acknowledgement of a claim for purpose of their respective limitations legislation.

The Canadian Patient Safety Institute supported the enactment of the Ontario Apology Act and is advocating that apology legislation be adopted by all Canadian provinces and territories.

Conclusions

In undertaking a review of relevant “leading practices” in other jurisdictions, we were afforded the opportunity to examine and learn about the management of adverse health events from international, national, provincial, regional and organizational perspectives. Clearly, the pioneers in the field of adverse health event management (i.e., the UK, Australia, and the US) have much to offer in the way of lessons learned. The WHO is
providing leadership in the area of adverse event reporting and learning systems and the standardization of taxonomy for classifying adverse events.

At a national level, the Canadian Patient Safety Institute (CPSI) has taken a lead role in the development and publication of Canadian Disclosure Guidelines and developing a strategy to create a pan-Canadian reporting and learning system. It has also developed the Canadian Root Cause Analysis Framework, a quality improvement tool to help individuals and organizations determine all of the contributing factors and root causes that led to an event (i.e., critical incidents and close calls). CPSI is currently engaged with key stakeholders and partners in the development of a Canadian interprofessional competency-based framework for patient safety.

At the provincial level, a variety of initiatives have been undertaken to address the reporting of “critical incidents” or accidents. A number of these initiatives are tied to legislation and regulations. However, a major limitation is the lack of standardization of definitions and terminology used within and between provinces, within and between regions, and between organizations. It is difficult to say, with any degree of certainty, whether one practice or policy is leading the way in the field of adverse event management; this in part, because of the paucity of evaluative outcomes research being conducted in this area.
Appendix A  Canadian Council on Health Services Accreditation

In January 2005, the CCHSA’s Patient Safety Goals and Required Organizational Practices (ROP) came into effect. An ROP is defined as “an essential practice that organizations must have in place to enhance patient/client safety and minimize risk”. These goals and required organizational practices are meant to be widely applicable (i.e., acute care, long-term care, community settings). Five ROPs are directly related to patient safety culture. CCHSA conducts an evaluation of implementation and evidence of compliance of the ROPs as part of the accreditation process. Information is provided by the participating organization to surveyors to test for compliance and evidence that must be in place for each practice. Surveyors are provided with suggested methods (e.g., team interviews, staff interviews, documentation review, and so on) to assess compliance. The test for compliance and the required evidence are highlighted below. Methods for surveyors are not addressed in this report.

The ROP for Patient Safety Area are as follows:

1. to adopt patient safety as a written, strategic priority/goal;

Tests for compliance
Is patient/client safety written as a strategic priority/goal?
Are resources allocated to support the organization’s implementation of the patient safety strategic priority/goal?

Required evidence
Documentation to ensure that patient/client safety is a written, strategic priority/goal, e.g. review strategic plan, annual report, and/or list of organizational goals.

2. to provide quarterly reports to the Board of directors on patient/client safety, including changes/improvements following incident investigation and follow-up;

Tests for compliance
Is there written evidence of patient/client safety-related quality reports provided to the Board?
Do the quarterly reports demonstrate activities and accomplishments that support the strategic priority/goal?
Is there evidence of the Board’s involvement in supporting activities identified in the quarterly reports?

Required evidence
Review self-assessment info for L&P 5.4. {Board receiving useful, timely, and accurate information so that it can identify issues, address concerns, and make informed decisions}
Documentation re: quarterly reporting to the board.

3. to establish a reporting system for actual and potential adverse events, including
appropriate follow-up, in compliance with any applicable legislation and within any protection afforded by legislation;

**Tests for compliance**

Is there a reporting policy and process for actual and potential adverse events?
Are improvements made following incident investigation and follow-up?

**Required evidence**

Reporting policy and process in place and used.

4. to implement a formal (transparent) policy and process of disclosure of adverse events to patients/families, including support mechanisms for patients, family, and care/service providers;

**Tests for compliance**

Is there a policy and process for disclosure, including support mechanisms for patients, family, and care/service providers?

**Required evidence**

Policy and process for disclosure is implemented.

5. to conduct one patient-safety related prospective analysis per year (e.g., Failure Modes and Effects Analysis) and implement recommended improvements/changes.

**Tests for compliance**

Has at least one prospective analysis been completed within the past year?
Documented evidence of at least one prospective analysis completed in the past year.

**Required evidence**

Evidence of improvements/changes.

Non-compliance with any one ROP results in a conditional award. Organizations have six months to follow-up by putting the appropriate processes and systems in place to meet the requirements of the ROP. The organization is required to demonstrate compliance through a report or focused visit within six months. Four categories are used to assess compliance with ROPs: (1) not in place (2) in development (3) fully implemented, and (4) a leading practice.
Appendix B  Canadian Patient Safety Institute Disclosure Guidelines

Released in March 2008, the Canadian Patient Safety Institute disclosure guidelines are the product of a national working group. They were designed for an audience of health care providers, organizations, ministries and regulatory and professional bodies, to support and encourage the development or enhancement of disclosure guidelines in each such organization, and recognizing that the CPSI guidelines would be adapted as appropriate in each setting.

Principles of the CPSI guidelines: 1) patient centred health care; 2) patient autonomy; 3) safe health care; 4) leadership support; 5) disclosure is the right thing to do; 6) honesty and transparency.

In some cases a patient may be defined as the substitute decision maker. All aspects of disclosure must be governed by applicable privacy laws and policies.

CPSI recognizes the importance of disclosure as a basis for respecting patient rights, as the basis for ethical professional behaviour, to ensure trust and confidence in providers and health care institutions and to reduce legal liability. It points out that the CCHSA requires accredited health care organizations to adopt a transparent and formal disclosure policy what includes supports for patients, family and care or service providers.

The term “error” is not used in the guidelines because it suggests negligent action that can be attributed to specific people. Often, disclosure needs to happen before complete assessments of causation have been completed, so it may be too early to call the cause an error. Usually adverse events are the product of system factors or the interplay of events. Avoiding the term “error” allows for a more supportive environment for disclosure and learning from adverse events.

Creating a culture of patient safety includes ensuring that there is a channel for the reporting of adverse events, whether inside or outside the organization. A safety culture recognizes that systems failure is often the main cause of an adverse event. The lessons learned from an AE are used to repair system components so that the adverse event can be prevented in the future.

Patients should be supported by providing them with timely access to further health care, including clinical investigations, treatments and transfers; designating a staff person to provide emotional and practical support; facilitating support from family, friends, etc; and assisting patients to access other professional support, such as social workers, counselors and community services.
Providers also need training in how to properly undertake disclosure; they also need support when adverse events occur and disclosure becomes necessary. Guidance and instruction on how to effectively communicate and respond to unintended patient outcomes should be integrated into undergraduate and graduate curricula for all health care providers.

The first priority after an adverse event is to attend to the patient, deal with any emergency, and ensure the prevention and mitigation of harm.

The disclosure process may consist of more than one conversation with the patient; it may be a dialogue over time. The initial disclosure should occur as soon as possible after an event; this is principally the obligation of the provider, but sometimes the organizational leadership or management may provide advice or assistance. The discussion will generally focus on the medical condition, further investigations and treatments, and associated risks. At this stage, even if an adverse event is recognized, it is unlikely that all the contributors may be known. The facts that are known should be communicated and, if appropriate, a commitment made to learn more. If the plan for further investigation is known, it should be communicated. Also appropriate is an expression of regret, avoidance of blame and speculation, and the provision of emotional and practical support.

The second stage is post analysis disclosure. Additional facts and the reasons for the events, if known, may be discussed. The involvement of leadership/management is likely to be more significant at this stage in determining what is disclosed. Leadership/management and providers must consider not only “the information needs of the patient, but also any restrictions or requirements on information exchange that might arise from the application of national or provincial legislation, regulations or local institutional/hospital by-laws and policies. The advice of legal counsel may be required.” Patients may be told of what improvements have been made, and as appropriate further expression of regret, an apology or an acceptance of responsibility may be included.

When an investigation is conducted by a legally protected quality of care or similar committee, it is important to be aware of how the law around this process will impact information exchange. Providers and patients should be aware of the limitations in discussing some of the investigative information.

An organizational policy for disclosure may be flexible in order to recognize the different levels of harm and the varying levels of administrative response and communication support. The organization should support the patient-provider relationship by implementing an organized and practical disclosure process. Disclosures should be appropriately documented according to established policy.

Close calls need only be disclosed depending on their circumstance, although each event has its own unique issues and sense of whether the event could happen again. In general,
if an event did not reach the patient, there may be no requirement to disclose. But if the event reached the patient, and there is potential for harm, the event should be disclosed. Even if it reached the patient but there is no potential for harm, the event generally should be disclosed. Depending on the circumstances, a consultation with an ethics committee may be advisable.

Regarding multiple-patient disclosure, disclosure should be one patient at a time, and in-person, if possible. If not, it should be done by registered letter or by telephone with opportunity for follow-up. “In addition, disclosure should be timed, if possible, to occur with all patients involved at approximately the same time and, if possible, prior to any informing process, especially media coverage, being considered.”

Where more than one RHA is involved, the RHA involved in the actual adverse event should if possible lead the disclosure process. Ideally, representatives from both jurisdictions should participate. Effective communication and consultation regarding the facts should occur first. The matters should be addressed on a case-by-case basis.
## Appendix C  Legislation Reference Table

### Legislation Reference Table

<table>
<thead>
<tr>
<th>Province</th>
<th>Evidence</th>
<th>Health Information Privacy/Freedom of Information and General Privacy</th>
<th>Adverse Event/Critical Incident</th>
</tr>
</thead>
<tbody>
<tr>
<td>BC</td>
<td>Evidence Act, R.S.B.C, c. 124.</td>
<td>Freedom of Information and Protection of Privacy Act, R.S.B.C. 1996, c. 165.</td>
<td>N/A</td>
</tr>
<tr>
<td>NS</td>
<td>Evidence Act, R.N.S. 1989, a 154.</td>
<td>Freedom of Information and Protection of Privacy Act, S.N.S. 1993, c. 5.</td>
<td>N/A</td>
</tr>
<tr>
<td>YT</td>
<td>Evidence Act, R.S.Y. 2002, c. 78.</td>
<td>Access to Information and Protection o Privacy Act, R.S.Y. 2002, C.1.</td>
<td>N/A</td>
</tr>
</tbody>
</table>

¹ All statutes also as enacted for Nunavut, pursuant to the Nunavut Act, S.C. 1993, c.28.
### Appendix D  Adverse Event/Critical Incident Reporting Laws

#### Table 1: A Review of provincial, territorial and federal legislation and policy related to the reporting and review of adverse events in health care in Canada: Appendix 5, Adverse Event/Critical Incident Reporting Laws.  

<table>
<thead>
<tr>
<th>What is reported?</th>
<th>How is the event reported?</th>
<th>To whom is the event reported?</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>MB</strong> 53.1 “Critical Incident” means an unintended event that occurs when health services are provided to an individual that results in a consequence to him or her that (a) is serious and undesired, such as death, disability, injury or harm, unplanned admission to hospital or unusual extension of hospital stay, and (b) does not result from the individual’s underlying health condition or from a risk inherent in providing the health services. (&lt;&lt;incident critique&gt;&gt;) “Critical Incident Review Committee” means a committee of one or more individuals established under subsection 53.3 (1) or 53.4 (1). (&lt;&lt;comité d’examen des incidents critiques&gt;&gt;)</td>
<td>53.2 (2) If a critical incident occurs when a regional health authority, health corporation or prescribed health care organization is providing health services to an individual, the authority, corporation or organization must ensure that (a) appropriate steps are taken to fully inform the individual, as soon as possible, about (i) the facts of what actually occurred with respect to the critical incident (ii) its consequences for the individual as they become known, and (iii) the actions taken and to be taken to address the consequences of the critical incident, including any health services, care or treatment that are advisable; (b) a complete record is promptly made about the critical incident, which includes (i) the facts of what actually occurred with respect to the critical incident (ii) its consequences for the individual as they become known, and (iii) the actions taken and to be taken to address the consequences of the critical incident, including any health services, care or treatment that are advisable; (c) the record described in clause (b) is available to be examined and copied by the individual at no cost.</td>
<td>53.3 (1) Except as provided in subsection (6), if a critical incident occurs when health services are provided to an individual by a health corporation or a prescribed health care organization, the corporation or organization must promptly (a) notify the regional health authority for the health region in which the critical incident took place about the critical incident, in accordance with the guidelines established by the regional health authority, to investigate and report respecting the critical incident. 53.3 (2) Promptly upon being notified about a critical incident under subsection (1), the regional health authority must notify the minister about the critical incident. 53.3 (3) A critical incident review committee established under subsection (1) must, in accordance with the health corporation’s or prescribed health care organization’s directions, (a) investigate the critical incident and, during the investigation, provide information and reports to the corporation or organization as requested; and (b) upon completing the investigation, report its findings and recommendations to the corporation or organization in writing. 53.3 (4) In accordance with guidelines established by the regional health authority, the health corporation or prescribed health care organization must provide information and reports to the authority about the critical incident and the critical incident review committee’s investigation, including a written report upon completion of the investigation. 53.3 (5) The regional health authority must provide information and reports to the minister about the critical incident and the critical incident review committee’s investigation, including a written report upon completion of the investigation.</td>
</tr>
<tr>
<td>What is reported?</td>
<td>How is the event reported?</td>
<td>To whom is the event reported?</td>
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<tr>
<td><strong>QC</strong> 8. “Accident” means an action or situation where a risk event occurs which has or could have consequences for the state of health or welfare of the user, a personal member, a professional involved or a third person.</td>
<td>8. The user is also entitled to be informed, as soon as possible, of any accident having occurred during the provision of services that has actual or potential consequences for the user’s state of health or welfare, and of measures taken to correct the consequences suffered, if any, or to prevent such an accident from recurring.</td>
<td>223.1 Any employee of an institution, any person practising in a centre operated by an institution, any person undergoing training in such a centre or any person who, under a service contract, provides services to users on behalf of an institution must, as soon as possible after becoming aware of any incident or accident, report it to the executive director. Such incidents or accidents shall be reported in the form provided for such purposes, which shall be filed in the user’s record.</td>
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<tr>
<td>183.1 The organization plan of an institution must also provide for the creation of a risk management committee. The number and members of that committee and the rules governing its functioning shall be determined by by-law of the board of directors of the institution. The composition of the committee shall ensure a balanced representation of the employees of the institution, of users, of the persons practising in a centre operated by the institution and, if applicable, of the persons who, under a service contract, provide services to users on behalf of the institution. The executive director or the person the executive director designates shall be ex officio a member of the committee.</td>
<td>183.2 The functions of the committee include seeking, developing and promoting ways to 1) identify and analyze the risk of incidents or accidents in order to ensure the safety of users and, in particular in the case of nosocomial infections, prevent such risks and reduce their recurrence; 2) make sure that support is provided to the victim and the close relatives of the victim; and 3) establish a monitoring system including the creation of a local register of incidents and accidents for the purpose of analyzing the causes of incidents and accidents, and recommend to the board of directors of the institution measures to prevent such incidents and accidents from recurring and any appropriate control measures.</td>
<td>235.1 The board of directors of an institution shall, by by-law, establish rules to be followed on the occurrence of an accident, so that all the necessary information is disclosed to the user, to the representative of an incapable user of full age or, in the event of the user’s death, to the persons referred to in the first paragraph of section 23.</td>
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<tr>
<td>183.2 “Incident” means an action or situation that does not have consequences for the state of health or welfare of a user, a personal member, a professional involved or a third person, but the outcome of which is unusual and could have had consequences under different circumstances.</td>
<td>257. Every institution must transmit an annual report of its activities, including activities related to risk and quality management, to the agency and to the minister within three months after the end of its fiscal year. The report must be filed in the form determined by the minister and must contain any information required by him and by the agency.</td>
<td>431. With a view to improving the health and well-being of the general public, the minister shall determine priorities, objectives and orientations in the field of health and social services and see to their implementation. He shall in particular…</td>
</tr>
<tr>
<td>278. Every institution must transmit an annual report of its activities, including activities related to risk and quality management, to the agency and to the minister within three months after the end of its fiscal year. The report must be filed in the form determined by the minister and must contain any information required by him and by the agency.</td>
<td>6.2) from the content of the local registers referred to in section 183.2, establish and maintain a national register of incidents and accidents having occurred during the provision of health services and social services for the purpose of monitoring and analyzing the causes of incidents and accidents, ensuring that measures are taken to prevent such incidents and accidents from recurring and ensuring that control measures are implemented, where appropriate … [6.2 is not yet in force].</td>
<td></td>
</tr>
<tr>
<td>SK</td>
<td><strong>What is reported?</strong></td>
<td><strong>How is the event reported?</strong></td>
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</table>
| 58(1) In this section: **(a)** “critical incident” means an incident that:  
(i) arises as a result of the provisions of a health service by a regional health authority, a health care organization or the cancer agency; and  
(ii) is listed or described as a critical incident in the Saskatchewan Critical Incident Reporting Guideline, 2004 published by the department, as amended from time to time, or any subsequent edition of the Saskatchewan Critical Incident Reporting Guideline; | **58(2) A regional health authority shall, in accordance with the regulations:**  
(a) give notice to the minister of the occurrence of any critical incident that arises as a result of a health service provided by the regional health authority; and  
(b) investigate any critical incident mentioned in clause (a) and provide a written report to the minister with respect to that critical incident and investigation. | **From the Critical Incident Regulations:**  
8(1) A regional health authority shall investigate any critical incident described in subsection 4(1) and prepare a written report with respect to each critical incident described in subsection 4(1) and prepare a written report with respect to each critical incident that it investigates. |
| **Reference should be made to the Saskatchewan Critical Incident Reporting Guideline, 2004 for a list of critical incidents that must be reported to Saskatchewan Health.** | **Similar provisions require reporting by health care organizations (58(3)) and the cancer agency (58(4.1)).** | **8(2) A written report required by subsection (1) must include:**  
(a) a description of the circumstances leading up to and culminating in the critical incident;  
(b) a statement identifying any current practice, procedure or factor involved in the provision of the health service or the operation of the program that:  
(i) contributed to the occurrence of the critical incident; and  
(ii) if corrected or modified, may prevent the occurrence of a similar critical incident in the future;  
(c) a description of the actions taken and the actions intended to be taken by the regional health authority as a result of the investigation; and  
(d) any recommendations arising from the investigation. |
| **4(1) A regional health authority shall, in accordance with sections 6 and 7, give notice to the minister of any critical incident that occurs:**  
(a) in a facility that the regional health authority operates; or  
(b) in relation to a health service that the regional health authority provides or a program that the regional health authority operates. | **4(2) Notice pursuant to subsection (1) must be given within three business days, or as soon as possible thereafter, after the day on which:**  
(a) the critical incident occurs; or  
(b) the regional health authority becomes aware of the critical incident. | **8(3) The regional health authority shall submit the written report to the minister immediately on completion of the report.** |
| **Similar provisions set out notice to be provided by health care organizations (5(1) and (2)).** | **6 For the purposes of sections 4 and 5, notice may be given:**  
(a) orally by telephone or in person; or  
(b) in writing, including transmission by facsimile or electronic mail. | **8(4) If an investigation and a written report required by subsection (1) cannot be completed and the report submitted to the minister within 60 days after the day on which, the regional health authority became aware of the critical incident, the regional health authority shall advise the minister of the delay, the reason for the delay and the anticipated date of completion of the report, which is to be not later than 180 days after the day on which the regional health authority became aware of the critical incident.** |
| **7 Subject to section 10, notice required by section 4 and 5 must include:**  
(a) a summary of the facts that led to the critical incident;  
(b) a summary of the health status of the person to whom the critical incident relates;  
(i) before the critical incident; and  
(ii) after the critical incident;  
(c) the actions that the regional health authority or health care organization, as the case may be, has taken or will be taking to investigate the critical incident; and  
(d) a statement as to whether the critical incident has been reported to any organization that is not part of the regional health authority or health care organization, as may be the case, and the names of those organizations, if any. | **Similar provisions set out how a critical incident must be reported by a health care organization (9(1)-(4)).** | | 227 |
Ontario

Note: In February 2003, the Council of the College of Physicians and Surgeons of Ontario (CPSO) approved a policy that mandates disclosure of a critical incident, and the Canadian Medical Protective Association (CMPA) encourages appropriate disclosure of harm.

Subsection 1 (1) of Regulation 965 of the Revised Regulations of Ontario, 1990 is amended by adding the following definition:

“critical incident” means any unintended event that occurs when a patient receives treatment in the hospital, (a) that results in death, or serious disability, injury or harm to the patient, and (b) does not result primarily from the patient’s underlying medical condition or from a known risk inherent in providing the treatment; (“incident critique”)

Section 2 of the Regulation is amended by adding the following subsections:

The board shall ensure that the administrator establishes a system for ensuring the disclosure of every critical incident, as soon as is practicable after the critical incident occurs, (a) to the affected patient; (b) if the affected patient is incapable, to a person lawfully authorized to make treatment decisions on behalf of the patient; or (c) if the affected patient has died, (i) to the patient’s estate trustee, or to the person who has assumed responsibility for the administration of the patient’s estate if the estate does not have an estate trustee, or (ii) to a person who was lawfully authorized to make treatment decisions on behalf of the patient immediately prior to the patient’s death, or who would have been so authorized if the patient had been incapable.

(5) The disclosure referred to in subsection (4) shall include, (a) the material facts of what occurred with respect to the critical incident; (b) the consequences for the patient of the critical incident, as they become known; and (c) the actions taken and recommended to be taken to address the consequences to the patient of the critical incident, including any health care or treatment that is advisable.

(6) Subject to the Quality of Care Information Protection Act, 2004, the board shall ensure that the administrator establishes a system for ensuring that at an appropriate time following a disclosure of a critical incident under subsection (4), there be a disclosure to the person referred to in clauses (a) to (c) of subsection (4) of the systemic steps, if any, that the hospital is taking or has taken in order to avoid or reduce the risk of further similar critical incidents, and that the content and date of this further disclosure be recorded.

Disclosure of Critical Incidents

A new regulation comes into effect in July 2008 that amends Regulation 965 under the Public Hospitals Act in order to mandate the disclosure of a critical incident to a patient.

Hospitals will be expected to adopt and implement the regulation, however, they may also retain or develop expanded disclosure policies that exceed (but do not contravene) the requirements of the Act. The amendments place responsibility on hospital administrators to set up a system for ensuring the disclosure of critical incidents; therefore, it will be their task to designate staff duties around reporting, and to establish internal protocols based on what is most appropriate for their particular facility.
**Appendix E  List of RHAs/ HCO Policies Reviewed**

<table>
<thead>
<tr>
<th>Institute</th>
<th>Province*</th>
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<tbody>
<tr>
<td>Calgary Health Region</td>
<td>Alberta</td>
</tr>
<tr>
<td>Alberta Health Quality Council</td>
<td>Alberta</td>
</tr>
<tr>
<td>Saskatoon Health Region</td>
<td>Saskatchewan</td>
</tr>
<tr>
<td>Winnipeg Regional Health Authority</td>
<td>Manitoba</td>
</tr>
<tr>
<td>Sunnybrook Health Sciences Centre</td>
<td>Ontario</td>
</tr>
<tr>
<td>McGill University Health Centre</td>
<td>Quebec</td>
</tr>
<tr>
<td>Capital Health Halifax</td>
<td>Nova Scotia</td>
</tr>
<tr>
<td>Health Canada</td>
<td>Federal Agency</td>
</tr>
</tbody>
</table>

*Policies of the four Regional Health Authorities of Newfoundland and Labrador are reviewed in greater detail in another section of this report.*
## Appendix F  Select RHAs/ HCO Policies

<table>
<thead>
<tr>
<th>Jurisdiction</th>
<th>Policy Title</th>
<th>Policy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alberta Calgary Health Region</td>
<td>Reporting Harm, Close Calls and Hazards Reference Number 1626</td>
<td>The Region requires its health care providers to report all situations where patients have suffered fatal or severe harm. The Region strongly encourages its health care providers to report all situations where patients have suffered moderate or minimal harm or experienced a close call. The Region strongly encourages its health care providers to report all hazards. The Region encourages its patients, families, volunteers and visitors to report all situations where patients have suffered harm or experienced close calls and any hazards that could lead to patient harm. The Region is committed to reviewing all reported hazards and all situations where patients have suffered harm or experienced close calls. This policy applies to all Calgary Health Region health care providers working, training or volunteering in Region facilities or services. Health care providers will complete a Safety Learning Report to report hazards and situations where patients have suffered harm or experienced close calls. The Region has a responsibility to learn from hazards and situations where patients have suffered harm or experienced close calls so that improvements can be made to the safety of patient care.</td>
</tr>
<tr>
<td></td>
<td>Effective Date: 2006/10/18</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Next review: 2008/10/18</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Definitions</td>
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<tr>
<td></td>
<td><strong>CLOSE CALL</strong> means a situation where a patient was nearly harmed, but for one or more reasons, the patient was “saved” from harm.</td>
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<td></td>
<td><strong>HARM</strong> means an unexpected or normally avoidable outcome that negatively affects a patient’s health and/or quality of life, and occurs or has occurred during the course of receiving health care or services from the Region (modified from the Ontario College of Physician and Surgeons, Disclosure of Harm Policy, Feb. 2003).</td>
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<tr>
<td></td>
<td><strong>Severe harm</strong> - a patient suffers complete loss of limb or organ function or requires intervention to sustain life.</td>
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<td></td>
<td><strong>Moderate harm</strong> - a patient suffers partial loss of limb or organ function.</td>
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<tr>
<td></td>
<td><strong>Minimal harm</strong> - a patient suffers harm that is less extensive and does not involve loss of limb or organ function.</td>
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<td></td>
<td><strong>No apparent harm</strong> – at the time of the event or reporting of the event, the patient does not appear to suffer any harm, but could do so in the future.</td>
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</table>

**Note:** The policies and procedures are separate documents within the region. The following procedures are available:

1. Immediate & Continuing Management of Serious (Potential) Adverse Events
2. Conducting an Administrative Review
3. Conducting a Safety Analysis
4. Disclosing Harm to Patients
5. Informing Principal Health Partners & Stakeholders – Safety Hazards, Failures, Fixes
The Region is committed to open and honest discussions with patients/families when patients have suffered harm. The Region defines this communication process with patients/families as disclosure. The Region is also committed, when it is appropriate, to disclosure when a patient has experienced a close call. In these situations, disclosure is discretionary and based on serving the greatest good for the patient.

This policy applies to all Calgary Health Region health care providers working, training or volunteering in Region facilities or services.

The disclosure process includes:
- Acknowledging harm to the patient/family;
- Providing an apology for harm; and
- Discussing factual information with the patient/family about how harm occurred and recommendations that have been made to improve the system.

During the disclosure process, the Region will provide/facilitate care and support for the patients/families and health care providers involved – including treatment, counseling, debriefing, and other forms of assistance that may be appropriate.

In most cases, the health care provider most responsible for the patient’s care will disclose to the patient/family. In some circumstances, as dictated by the severity of the harm, the patient’s current health and the health of the health care provider(s) involved, disclosure may also involve a Region administrator and/or a medical leader.

The Region recognizes the importance of disclosure in maintaining and rebuilding trust between patients/families, the Region and its health care providers when patients have suffered harm or experienced close calls.

The Region recognizes that the disclosure process must be respectful of the situation, support the needs of patients/families and the health care providers involved, and adhere to appropriate legislation.
The Region is committed to promoting a just and trusting culture of safety in which its health care providers can readily report harm, close calls and hazards so that the Region can learn and work to improve the safety of patient care.

When health care providers have been involved in situations where there has been failure in the provision of care to a patient, the Region commits to: providing appropriate care and support to the patients/families and health care providers involved; evaluating all systemic factors that may have contributed to failure; and following established fair procedures for evaluating the actions and behaviors of health care providers.

This policy applies to all Calgary Health Region administrators and medical leaders.

Region administrators and medical leaders will use a framework and follow procedures that are just and fair when conducting administrative reviews to evaluate health care providers’ actions and behaviors. The framework (See Note 1 in References) includes three types of actions and behaviors and the Region’s responses to them: Note 1: Based on the work of Dr. Jan Davies (U of C, Faculty of Medicine, Dept. of Anaesthesia) and the work of James Reason (University of Manchester, UK).

ERRORS – when there has been failure in the provision of care to a patient, and the health care provider did not deviate from established policies, procedures, standards or guidelines, then the health care provider will not be disciplined by the Region.

NON-COMPLIANCE – when there has been failure in the provision of care to a patient, and the health care provider deviated from established policies, procedures, standards or guidelines, then the Region will commit to evaluate:

- the appropriateness of its policies, procedures, standards or guidelines; and of the circumstances that led to the non-compliant action(s), before determining an appropriate course of action.

INTENTION TO HARM – when there has been failure in the provision of care to a patient, and the health care provider intended to cause harm, then the Region will seek disciplinary action and criminal investigations may result. (These situations are extremely rare.)
Informing Principal Health Partners & Stakeholders – Safety Hazards, Failures, Fixes
Reference Number 1629
Effective Date: 2006/10/18
Next review: 2008/10/18

The Region is committed to communicating open, honest and timely information to its principal health partners and stakeholders about safety hazards, failures and fixes. The Region defines this process as informing.

The Region informs its principal health partners and stakeholders about safety hazards, failures and fixes to:
- communicate important changes in risks to patients’ well-being from known hazards;
- maintain trust through transparent communication in situations where failures have affected or have the potential to affect confidence in the care and services provided by the Region;
- foster a culture of sharing information about patient safety which will lead to further system improvements.

This policy applies to senior management of the Calgary Health Region.
The Region’s principal health partners have a right to know about any substantial changes in risks to their well-being from safety hazards that are known to the Region. The Region’s stakeholders have a right to know about any changes in risks to their well-being from safety hazards that are known to the Region. The Region’s stakeholders also have a right to know what recommendations have been made to improve patient care.

The Region has a duty to maintain the confidence of its principal health partners in the care and services that it provides.

The framework is a consensus document by the Health Quality Network which is a HQCA collaborative consisting of health authorities, the Ministry, the AMA, College of Pharmacists, the College of Physicians and Surgeons, College and Association of registered nurses, and the federation of regulated health professions. The document states that with this framework Albertans will know that guidelines for disclosure are understood and accepted by all health authorities and professional bodies.

The framework is a guideline to enable health authorities and professional bodies to develop and adjust their own specific policies and procedures in a manner which is consistent with the provincial framework. (There does not appear to be any legislative backing for this framework, just a voluntary consensus that it represents good policy.)

The framework will be supported on an ongoing basis with disclosure education programs, and dissemination of communication materials for patients, families and health care providers.

The document recognizes in several places that disclosure must be accompanied by such things as information on what happened, the causes, and what will be done to ensure the same thing does not happen again. However, it does not address the systems necessary to ensure that good information is available to support those aspects of disclosure. Unless there is a reporting system and an assessment system, there will be only partial information on which to base a disclosure. The quality of the other parts of the system are essential if successful disclosure is to take place.
When should disclosure occur? Disclosure should occur when a patient experiences harm while receiving health care [Harm is defined as “an unexpected or normally avoidable outcome that negatively affects the patient’s health and or quality of life, which occurs or occurred in the course of health care treatment and is not due directly to the patient’s illness.”]; when an adverse event occurs and there is no apparent harm to the patient but the potential for harm remains; when an adverse event was narrowly avoided prior to harm occurring to the patient (in this circumstance disclosure is discretionary and needs to be determined on a case by case basis by the health care team – as to whether disclosure is in the best interests of the patient – though no criteria are provided). Disclosure should take place as soon as possible, at most within one or two days following the discovery of harm.

The framework provides guidance for the kind of setting for meetings (private), who should be present (2-3 people ideally including the direct provider), and suggests that the Health Boards of Alberta, CMPA and other respective insurers “should be informed and consulted as appropriate prior to the disclosure meeting.” The framework does not say why the insurer should be consulted.

What should be disclosed? At all disclosure meetings “information shared should be factual and agreed upon through a process of consensus by the health care team prior to initiating the disclosure process.” (This implies that all members of the team have a veto. This does not appear to support true disclosure if one member of the team does not agree. Some guidance needs to be provided.) Information should be related to the event and not about any individuals – the facts should be related to the patient’s diagnostic, treatment and care information (what happened, the sequence of events, diagnostic test results, consequences of the harm, changes to treatment plan and any other relevant factual information).

In regard to QACs which are covered by the Evidence Act, the framework says that all facts should be disclosed to a patient and family. Only facts should be shared. “All other information collected during an investigation and Quality Assurance Committee records must remain confidential and protected.” Persons who carry out the QA process investigation must not be included on the disclosure team. The lead person on the investigation is responsible for communicating the facts to an “appropriate individual or department within the health authority administration for approval.” These individuals will be responsible for determining how the facts will be shared with the patient and family. “Only new facts that would have otherwise been on the patient’s chart, as well as actions being taken to try to prevent a similar event from happening again, should be shared.” (This process may prevent a full explanation of the causes of an event, especially if the causes reveal information about an individual health care provider or requires assumptions to be made that fall short of facts.)

The Alberta framework includes an extensive explanation of the details of disclosure – the meeting, who should disclose, to whom, the type of documentation, the conversation, how to disclose and providing emotional support.
Multi-jurisdictional disclosure arises when a patient is transferred from one health authority to another, or from a private setting to a public setting. In certain situations the event in an originating setting may not be identified until later. In situations where disagreement occurs, it is anticipated that the organization discovering the harm and the entity where the event occurred will agree how, when and who will disclose to the patient. Where immediate disclosure is not crucial, efforts should be made to contact the originating jurisdiction to inform them of the situation and the planned process for disclosure. If possible, representatives from both jurisdictions should be involved. With the adoption of the provincial framework it is anticipated that the disclosure process will be consistent between jurisdictions and disagreements will be rare. If there is still disagreement, the HQC will be available to mediate the resolution of issues in a confidential and anonymous manner. Multi-patient disclosure should not occur in a group setting; steps should be taken to ensure that all patients are contacted prior to a release to the media; patients can be contacted by registered mail or telephone or a face-to-face meeting, and opportunities should always be made for a face-to-face meetings.

The Alberta document also includes a glossary, an overview of relevant legislation, and samples of communications materials prepared for distribution to people in the health system.

| Saskatchewan Saskatoon Health Region | Critical Incident Reporting  
Date Effective: September 2004  
Date Revised: September 2007  
Note: The critical incident policy is currently under revision now that the province has gone through a period of three years of legislated reporting. | All critical incidents will be reported through a region-wide reporting process in compliance with Section 58 of the Regional Health Services Act and its corresponding regulations – The Regional Health Services Critical Incident Regulations – and the Accountability Agreement with Regional Health Authorities and Saskatchewan Health. Critical Incident is defined according to the legislation and regulations:  

**Critical Incident** means a serious adverse health event including, but not limited to, the actual or potential loss of life, limb or function related to a health care service provided by, or being provided by, a regional health authority or health care organization (see Appendix A Saskatchewan Critical Incident Reporting Guideline for examples of serious reportable events).  

Critical incidents must be reported immediately to the Director of Risk Management or designate. During the weekend or night shift, the most senior administrator on call is contacted through switchboard or the appropriate on-call process and the administrator will notify the Director of Risk Management and appropriate senior managers – refer to on-call process for your area.  

The event is entered into the Safety Reporting System (computer-based) or a confidential Safety Report is completed by a staff member, physician, volunteer or student of the service/dept/area who were involved in, witness to or become aware of the critical incident within 24 hours of the critical incident occurring or when the incident is recognized as a critical incident and according to the procedure outlined in Safety Reporting Policy (#7311-50-006). Time frame is important to overall reporting, however, it should not discourage critical incidents being reported at any time. |
When the Safety Report form is completed, it must be submitted to Risk Management within 48 hours of the critical incident occurring. Other reporting forms or documentation that may have been completed (i.e., a medication error report) must accompany the confidential Safety Report when submitted. When the Safety Reporting System (computer-based) is used, automatic notification to the appropriate individuals will occur.

Immediate identification of any medication, medication container, supplies or equipment that may have contributed to the occurrence must occur. Packaging and all components of the equipment should be saved. Quarantine the objects after labelling "DO NOT USE" (immediately contact Clinical Engineering if biomedical equipment is involved). Photographs may be necessary for documentation.

Safety Reports are NOT part of the health record. The original report is filed in Risk Management. A factual note of the event and the patient assessment MUST be documented in the patient’s/resident’s chart.

Risk Management will notify appropriate senior management that a critical incident has occurred. Risk Management, according to the legislation, shall notify the Minister of Health of a critical incident within three business days following the incident occurrence or the date the regional health authority becomes aware of the incident.

Notification to the Minister of Health by Risk Management shall include de-identified, factual information about the critical incident.

SHR shall investigate the critical incident through a nonpunitive, multidisciplinary review (Appendix B – Multidisciplinary Case Review) including:

- the circumstances leading up to and culminating in the critical incident;
- any current practice, procedure or factor involved in providing the health service that contributed to the occurrence of the critical incident;
- actions considered, developed or required as follow-up to the critical incident; and
- implementation of any recommendations resulting from the critical incident review.

Risk Management, according to the legislation, will provide a written report of de-identified factual information, including actions taken, planned and quality improvements the RHA will be implementing as a result of the critical incident review, within 60 days of the RHA becoming aware of the critical incident.

Appropriate senior managers within SHR will receive a copy of the written report of de-identified factual information, including actions taken, planned and any quality improvements that will be implemented as a result of the critical incident multidisciplinary case review. Feedback/direction will be provided to appropriate stakeholders to implement quality improvements as required.
The Saskatoon Health Region and affiliates believes that patients/clients/residents and their families are entitled to information about the outcomes of tests, treatment and care. In some cases, poor outcomes are a result of an adverse event (AE). The Saskatoon Health Region and affiliates are committed to respecting the rights of patients/clients/residents and their families to be informed about such events.

Disclosure of adverse/unanticipated events to patients/clients/residents and their families is an integral part of Saskatoon Health Region’s patient/client/resident safety initiative; it ensures open, honest and constant communication to allow for increased trust and satisfaction between patients/clients/residents and the health care team; a joint responsibility of the Saskatoon Health Region organization and the clinical person(s) involved; a professional responsibility of all care providers.

**Effective communication is at the heart of safe and effective health care**

Discussions with the patient/client/resident or family may be warranted if there is a change in the treatment plan or unanticipated event or outcome of which the patient/client/resident or family may not otherwise be aware.

Critical incidents must be reported to Risk Management immediately.

Communication of an adverse/unanticipated event must occur when harm has come to the patient/client/resident.

Consultation should occur with care providers and Risk Management in cases of a near miss or harm never reaching the patient/client/resident to determine if discussion with the patient/client/resident or family is warranted.

Communication of an adverse/unanticipated event should occur as soon as possible subsequent to a triggering event. Ideally, they should occur within 24-48 hours of the health care team becoming aware of the event.

The patient/client/resident or family will be the recipients of the adverse/unanticipated event information. Communication of an adverse/unanticipated event will ideally be provided by a team. The team will likely include the most responsible physician (at the time of the event), a representative for the region (a manager/director for the area) and in some cases, depending on the severity of harm and circumstances, a representative from Risk Management. Lead for the discussions should rest with those who have the most knowledge of the event.

All members of the health care team involved should be aware that communication with the patient/client/resident or family has occurred.

Other support resources such as the client representative or social worker (with appropriate permission) may be included in the discussion to assist patients/clients/residents and families by providing support during and subsequent to the discussion.

The discussion should take place in a private, quiet location.
Factual information should be provided professionally, compassionately, truthfully and with the absence of blaming statements. Opinions should not be discussed. Disclosure of the circumstances should not be delayed because all facts are not known. The recipient of the information should be made aware that all facts may not yet be known, and a follow-up discussion should be planned to disclose new facts.

An offer of apology or an expression of regret can be offered and is not an admission of guilt.

Pertinent health record documentation will be available for the discussion, and patients/clients/residents and families will be provided with information about how to access their health information.

The initiator of the discussion must document the content of the meeting in the patient's/client's/resident’s health record including date and time of meeting; participants – (including names and relationship to the patient/client/resident), and factual account of the information shared.

Meeting notes are to be taken and kept on file by the manager/director involved.

The review process that will be conducted should be provided to the patient/client/resident and family. In most cases involving a critical incident, a multidisciplinary review will occur. Quality improvement recommendations from the review can be shared with the patient/client/resident and family if so desired.

The occurrence of an AE can have significant emotional and psychological impact on the involved providers' care for the patient/client/resident. Support for the providers involved in an adverse/unanticipated event will be provided/facilitated by the Saskatoon Health Region. Supports such as the Employee Family Assistance Program (EFAP), Risk Management or Social Work can be offered.

Multi-jurisdictional disclosure:

There may be disclosures that extend beyond jurisdictional borders, such as a patient receives care and harm occurs as a result of the care in the originating jurisdiction, but is not disclosed and/or unknown prior to the transfer to another jurisdiction.

Effective communication and cooperation between jurisdictions is key. Ideally, all jurisdictions should be a part of the disclosure. The lead for the system review will typically fall within the responsibility of the jurisdiction in which the event occurred.

Multi-person disclosure:

There may be disclosures that involve more than one patient/resident/client. Initial contact may include a registered letter, telephone call, or an invitation to an in-person meeting. Appropriate clinicians should be involved and/or advised of the disclosure.

Adverse/unanticipated event is defined as an undesired and unplanned occurrence directly associated with the care or services provided to a patient/client in the health care system”. The occurrence may result from “commission or omission (e.g., administration of the wrong medication) and can include problems in practice, products, procedures and systems.” CCHSA 2003
Policy: Physician Disclosure of Adverse Events and Errors that Occur in the Course of Patient Care.

College of Physicians and Surgeons of Saskatchewan, 2002 and Professional Codes of Ethics (Health Care Professionals of Saskatchewan)

“Critical Incident” means a serious adverse health event including, but not limited to, the actual or potential loss of life, limb or function related to a health care service provided by, or being provided by, a regional health authority or health care organization. SHR’s Critical Incident Reporting Policy 7311-50-008.

Multidisciplinary Case Review: A coordinated approach to managing risk.

Risk Management or the administrator on call will discuss the circumstances with appropriate senior management, including Chief of Staff (if appropriate) and appropriate vice president or other senior management if deemed appropriate. At the direction of senior management, an Ad Hoc Multidisciplinary Review Team may be appointed. The facilitator will be a member of the Department of Risk Management.

The membership of the review team will include:
- The attending physician (if involvement in the event),
- The department manager(s), director(s), general manager(s) and/or department head of the department(s) involved,
- Selected staff who provided care, (e.g. nursing staff, residents, JURSIs) and,
- other consultants at the discretion of the team.

Mandate of the multidisciplinary review team:
- Risk Management or designate will be responsible for gathering all of the relevant information.
- To meet with 14 days of the occurrence.
- To review the health record, related documentation surrounding the occurrence, and any relevant policies, procedures and/or protocols.
- To interview individuals who may provide additional relevant facts or pertinent background information
- To summarize their findings in a report to the Senior Management sponsors within 21 days of the occurrence.
- The report will concisely describe the circumstances that are believed to have led to the actual or potential adverse outcome and the recommended measures to prevent a similar occurrence (if in fact there are any).

Documentation is to be concise and focused on the facts of the topic. No copies are distributed of any reports prepared for this process. All documents are clearly marked, “PRIVILEGED AND CONFIDENTIAL – FOR MEDICAL QUALITY IMPROVEMENT PURPOSES.” If email is used, messages begin with the note, “Confidential – for Medical Quality Improvement Purposes” and should be discarded as soon as possible.

Reporting outside of this internal review process should only be done on the advice of Risk Management and/or legal counsel for the Region.
Critical Incident is defined as an unintended event that occurs when health services are provided to an individual and result in a consequence to him/her that (a) is serious and undesired, such as death, disability, injury or harm, unplanned admission to hospital or unusual extension of hospital stay, and (b) does not result from the individual’s underlying health condition or from risk inherent in providing the health service.

“Provisional Critical Incident” is an event that may meet the above criteria but has not yet been designated a CI. Legal privilege as described in The Regional Health Authorities Amendment and Manitoba Evidence Amendment Act does not begin until a “Provisional Critical Incident” is designated as a Critical Incident by the facility/program/setting. Therefore, any information collected prior to designating this event is not legally privileged.

Any individual, including employees and medical staff, who becomes aware of a CI shall promptly report it in the manner designated by the WRHA Chief Patient Safety Officer in accordance with The Regional Health Authorities Amendment and Manitoba Evidence Act.

3.2 With the goal of encouraging a culture of reporting, the WRHA shall support individuals who report a CI in good faith.

3.3 The WRHA shall ensure all CIs are appropriately investigated (including debriefing of appropriate staff, patients and family whenever possible) in order to promote system-wide learning through the appointment of Critical Incident Review Committees (CIRC), as described in The Regional Health Authorities Amendment and Manitoba Evidence Amendment Act, and as detailed in section 4.0 below.

3.4 In the spirit of establishing a just and fair learning culture, the WRHA shall not discipline any staff member involved in events leading to a CI and shall treat the event as a learning opportunity, except as outlined in sections 3.5.

3.5 When a staff member or medical staff has demonstrated disregard for patient safety or has acted in breach of any policies or obligations, WRHA reserves the right to address such instances in an appropriate manner in accordance with applicable policies or processes, collective agreements or medical staff by-laws even when such a staff member or medical staff is involved in a CI.

3.6 The WRHA shall evaluate the implemented recommendations arising from CI reviews. Lessons learned shall be shared with all appropriate individuals and organizations, as detailed in section 4.0 below.

3.7 Disclosure of the CI shall occur in accordance with the WRHA Policy # 10.50.030 – Disclosure of Critical Incidents and as described in The Regional Health Authorities Amendment and Manitoba Evidence Amendment Act.
3.8 No record or information, including an opinion or advice, prepared solely for the use of a CIRC, or collected, compiled or prepared by a CIRC for the sole purpose of carrying out its duties, may be produced in any legal proceeding.

3.9 No witness in a legal proceeding may be asked or permitted to answer any question or make any statement about a CIRC proceeding.

Any individual who observes or has knowledge of a Critical Incident (CI) or a Provisional CI shall:

4.1.1 ensure that the patient(s) and personnel are safeguarded,
4.1.2 identify and secure any pertinent equipment/supplies. Determine if the room or scene needs to be secured, e.g. in the case of a suicide, homicide, suspicious death.
4.1.3 report the CI/Provisional CI by calling the WRHA Critical Incident Reporting Line, 24 hours a day, 7 days a week. (Note: Patient Safety are no longer accepting the paper report form). Callers who choose to, may report anonymously. (Note: reported events accepted by the WRHA Critical Incident Reporting Line will be classified as Provisional CIs until designated as a Critical Incident by the involved facility/program/setting.)
4.1.4 at the caller’s discretion, notify his/her manager/supervisor to provide assistance/support. Employees are encouraged to provide the information to their manager/supervisor, following usual lines of reporting.

4.2 the information collected from the CI Reporting Line at the Provincial Health Contact Centre will be sent to the WRHA Patient Safety CI database application.

4.3 A Provisional CI notification email (containing de-identified information) will automatically be sent from the database application to identified recipients at the involved facility, WRHA Programs, WRHA Patient Safety, and Manitoba Health. (Note: Information in the notification email is not legally privileged.)

4.4 During regular working hours (08:00-17:00), a facility/program/setting representative (as identified by the facility/program/setting) shall:
4.4.1 determine whether or not the reported event meets the defined CI criteria. If assistance is needed with this step, contact the WRHA Patient Safety Team.
4.4.2 if the event is designated as a CI, ensure that:
   4.4.2.1 appropriate disclosure to the patient/family member(s) has occurred.
   4.4.2.2 an individual has been designated to provide ongoing contact and support for the patient and family members as appropriate.
   4.4.2.3 there is appropriate ongoing support for staff member(s) and physician(s) involved.
   4.4.2.4 any student/trainee contacts his/her supervisor for support.
   4.4.2.5 the site insurer is notified when appropriate.
4.4.3 ensure that a Critical Incident Review Committee (CIRC) is named to investigate the CI (see Appendix). Collaborate as needed with the WRHA Patient Safety Team to determine the level and membership of the CIRC.
By the end of the next business day, advise the WRHA Patient Safety Team in writing (preferably by email) whether or not the reported event has been designated a Critical Incident. If the event has been designated as a CI, indicate that a CIRC has been established and provide the names and titles of the CIRC members. (Note: Legal privilege begins once the event has been designated as a CI by the facility/program/setting/WRHA Patient Safety.)

Within 28 calendar days of the CI, send a status report to the WRHA Patient Safety Team (preferably via email) which is marked “Privileged under Section 9 of the Manitoba Evidence Act” and contains the following information:

1. Date of the CI, any changes in the condition of the patient, indication that a review has been completed or is in progress, review findings and recommendations (if the review has been completed) and the steps taken to inform the patient/family of the unfolding consequences to the patient’s health.

Within 88 calendar days of the CI, send a copy of the CIRC’s written final report to the WRHA Patient Safety Team (preferably via email). The report must be marked “Privileged under Section 9 of the Manitoba Evidence Act” and contain the findings, recommendations and follow-up action plan.

During regular working hours (08:00-17:00), the WRHA Patient Safety Team shall:
1. Verify as needed, in collaboration with the Patient Safety representative from the facility/program/setting (as designated by the facility/program/setting), whether or not a Provisional CI meets the defined CI criteria.
2. Collaborate as needed with the facility/program/setting to determine the level and membership of the Critical Incident Review Committee (CIRC).
3. Participate in and/or chair CIRCs as required.
4. As appropriate, ensure that an appropriate person provides ongoing follow-up and support for the patient/family members.
5. Ensure that Manitoba Health has received initial notification of the CI.

Within 30 calendar days of the CI, ensure that Manitoba Health receives a copy of the status report that includes: the date and time of the CI, further details, condition of the patient, steps taken to inform the patient/family of the unfolding consequences to the patient’s health, confirmation of establishment of a CIRC, indication that a review has been completed or is in progress and review findings and recommendations (if the review has been completed).

Within 90 calendar days of the CI or upon completion of the CI Review, ensure that Manitoba Health receives a copy of the written final report. The report must be marked “Privileged under Section 9 of the Manitoba Evidence Act” and contain the findings, recommendations and follow-up action plan.

Courier the final CIRC Report to the Chief Operating Officer (COO)/Chief Executive Officer (CEO) of the involved facility/setting or, in the case of Community CIs, to the VP of Community Health Services, when CI reviews are led by a member of the WRHA Patient Safety Team.
4.6 Once the Provisional CI has been reported to the WRHA Critical Incident Reporting line, after hours (between 17:00 and 08:00), or on a weekend or statutory holiday:
4.6.1 A designated representative from the facility/program-setting (as designated by the facility/program/setting) if aware of the Provisional CI, shall notify the WRHA administrator on call by paging her/him. The notification should include the name and contact information of the person reporting, time and date of the Provisional CI, a brief description of the facts, and the patient’s condition.
4.6.2 The WRHA administrator on call if aware of the Provisional CI, shall notify Manitoba Health by calling the after-hours cellular phone. The notification should include the name and contact information of the person reporting, time and date of the Provisional CI, a brief description of the facts, and the patient’s condition.

CRITICAL INCIDENT REVIEW COMMITTEES

As soon as possible after an event is confirmed as a CI, a CIRC should be appointed by the site or setting where the CI occurred. In order to be a member of a CIRC, an individual must have completed one of the workshops required by the WRHA Patient Safety Team. The WRHA Patient Safety Team maintains a list of such individuals.

Certain individuals must be excluded from the CIRC, specifically anyone who:
• Has a conflict of interest in the CIRC; e.g., manager of the involved unit;
• Was or is directly involved in providing care to the patient;
• Has a potential future role in disciplinary matters arising from that CI or the program or site involved; e.g., Manager/Program Director/Medical Director; as outlined in 3.5;
• Is the ongoing patient/family support person.

The appropriate size and type of CIRC will depend on the CI. There are a number of possibilities:
1) Site based single person CIRC
   - the most common and efficient type of CIRC;
2) Site based CIRC made up of two or more persons
   - appropriate if the case is complex or involves more than one program within a site;
3) Regional CIRC made up of one or more persons
   - appropriate if the case involves more than one facility, more than one program within the region or if the issues are highly “visible”;
4) External CIRC
   - appropriate if a consultant outside the WRHA is required.

In all cases a CIRC will:
1) Reconstruct the sequence of events:
   • Debrief (hear the story of) involved staff;
   • Debrief (hear the story of) involved patient and family;
   • Gather records
2) Meet with persons who are sources of applicable information;
3) Consult with program team regarding recommendations;
4) Prepare the final report.
5) Ensure that all CIRC documents are marked “Privileged under Section 9 of the Manitoba Evidence Act” and stored in a confidential file in a locked office.

As needed a CIRC will:
1) Seek expert opinions;
2) Obtain standards and protocols from external sources;
3) Seek information from non-WRHA sources (e.g., family physician, paramedics, pharmacy, literature, etc.);
4) Convene a meeting of clinical experts to assist the CIRC to formulate recommendations.

Special situations for a CIRC:
1) If there are serious concerns about the competence or performance of a provider, a CIRC may and should contact the appropriate Facility Senior Management member or the Site Executive Director/Community Area Director directly.
2) If a CIRC member has a mandatory reporting duty to a licensing body, the CIRC should make the disclosure preferentially through the appropriate Facility Senior Management member or the Site Executive Director/Community Area Director.
3) If there are serious concerns about possible criminal activity, a CIRC may involve police, preferentially by notifying the appropriate Facility Senior Management member or Site Executive Director/Community Area Director.
4) In addition, there may be parallel investigations underway, e.g., police investigations, administrative reviews.

The CIRC will send a copy of the final report only to the facility Chief Operating Officer/Chief Executive Officer and the WRHA Patient Safety Officer who will forward a copy of the final report to the Minister of Health (Manitoba Health). The exception is that, upon request, a copy of the final report may also be sent to the office of the Continuing Medical Examiner and, in some cases, the Protection of Persons in Care Office.

The WRHA Chief Patient Safety Officer or designate will provide patients/families, facilities, and others with a de-identified abstracted summary of the event, findings and recommendations.


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<th><strong>Disclosure of Information Related to Care and Treatment</strong></th>
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<td><strong>Regional Policy</strong></td>
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“Critical Incident” (CI) is an unintended event that occurs when health services are provided to an individual and result in a consequence to him or her that:

- a) is serious and undesired, such as death, disability, injury or harm, unplanned admission to hospital, or unusual extension of hospital stay; and
- b) does not result from the individual’s underlying health condition or from a risk inherent in providing the health services.

“Disclosure” is a process that includes sharing pertinent information with the patient and/or substitute decision-maker about the care provided, as well as responding to questions. The process may involve a number of encounters over time as more information is learned about a particular situation.

The sharing of pertinent information about care and treatment provided to patients by staff/medical staff will be integrated into the routine processes of providing services. The sharing of information will occur in a timely manner by means of discussions and conversations as well as by providing access to current treatment records, upon request.

With respect to events and situations that fulfill the criteria to be considered a critical incident (refer to policy 10.50.040) all employees and members of medical staff involved in disclosure discussions which will take place with the patient and/or substitute decision-makers, will include the following:

- The facts of what actually happened;
- The consequences for the patient and the steps to be taken to address those consequences;
- A regret that the event occurred and resulted in harm to the patient; and
- The availability of copies of the health record.

The sharing of pertinent information will be provided by the most appropriate person(s) after discussion with the supervisor/manager of the clinical area. Questions to be considered will include:

- Who has the appropriate knowledge of the event details?
- Who is comfortable sharing the information?
- Who has developed a trust relationship with the patient/family?

Guidelines For Disclosure in the case of Critical Incidents:

1. What events or situations ought to be disclosed?
   Refer to the definition of critical incident as outlined in the Critical Incident Management and Learning policy (10.50.040).

2. To whom should the disclosure be made?
   Disclosure should be made directly to the patient and/or his/her substitute decision-maker. If the patient lacks the capacity to understand the information, disclosure should be made available to a person authorized by the regulations to receive information and records on the individual’s behalf (see 2.2).

3. When should disclosure take place?
   The initial disclosure of the Critical Incident should take place as soon as is practically possible after it has occurred or has been identified.
4. Who ought to disclose details to clients and/or family?
Disclosure may best be accomplished by a team of care providers and requires coordinated planning prior to the disclosure. In most, the attending or most responsible physician(s) should be included in the group making the disclosure. Those involved in disclosure discussion, should be knowledgeable about the details of the event as well as comfortable undertaking such discussions. Advice and assistance will be available through the regional WRHA Patient Safety Team.

5. What ought to be disclosed?
This is defined in both the legislation and the Critical Incident Management and Learning policy (10.50.040). In addition to a description of the facts of what actually occurred, the consequences for the individual and the steps that will be taken to address those consequences, it is appropriate to include the following:

- An expression of regret that the Critical Incident occurred and caused harm to the client.
- An offer to provide copies of the documentation in the health record, as described in the legislation and policy regarding Critical Incidents.

These considerations will apply equally to those events that do not meet the criteria to be considered a CI, as well as those events that are considered a CI. In most cases, the most responsible staff members, likely the physician(s) if available, will participate in discussions involving disclosure of critical incidents. Where possible, an offer of a second opinion, the involvement of outside assistance, or the transfer of care to another provider or facility.

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**Ontario Sunnybrook Health Sciences Centre**

*Accountability for Patient Safety*  
*Note: This policy is cited in the following article*


It is a strategic goal of Sunnybrook Health Sciences Centre to be the safest hospital in Canada. To create a culture that will support the goal, Sunnybrook has adopted, the following principles about patient safety that will guide Sunnybrook employees, physicians, students, volunteers and agents of the hospital [theses categories of individuals will be referred to collectively as “staff” through this policy]:

1. The organization and each individual staff member share the accountability for ensuring the safest possible patient care and service.
2. Staff reports of errors, near misses and adverse events are a critical component of patient safety and must be reported diligently and without fear of reprisal by all staff.
3. The majority of errors, near misses and adverse events involve competent and caring staff interacting with complex systems. Sunnybrook responds to reports of errors, near misses, and adverse events by carefully examining and improving the systems of care.
4. Sunnybrook needs and values the participation of staff and professionals in the investigation of the system of care, and in creating and testing improvements.
5. Sunnybrook has a responsibility to address the actions of individuals when their actions fail to meet professional, patient care and/or services standards. These situations include intentional acts meant to harm or deceive; physical or mental impairment of staff; substance abuse by staff; staff incompetence. If it becomes clear that a staff member cannot practice in a reliably safe manner, in spite of education and counseling, this situation will be treated as a staff competency issue in accordance with professional standards and Human Resource principles.
Ontario Sunnybrook Health Sciences Centre

Disclosure of Adverse Medical Events and Unanticipated Outcomes of Care

It is Sunnybrook & women’s policy, in keeping with our mission, vision, values and philosophy of care, to ensure that patients and/or their substitute decision-maker, and/or their family are properly informed about their health care. This includes an obligation on the part of all physicians and health care practitioners to inform patients about significant adverse medical events and unanticipated negative outcomes of care that may affect their well-being.

DEFINITIONS:
Adverse Medical Events (significant):
Adverse medical events are negative patient outcomes that can occur as the result of health care treatment and not due to the patient’s illness. They are often unanticipated and unexpected outcomes of health care that do, or have the potential to, negatively impact a patient’s health and quality of life. They include complications and side effects of treatment as well as errors in the performance of medical duties. Adverse medical events are not necessarily markers of substandard care.

Non-Significant Events:
Non-significant medical events are minor incidents that do not have a negative impact on patient outcomes, now or in the foreseeable future. No extra procedures affecting the patient are required to prevent negative patient outcomes. These events are not significant from the patient’s perspective and disclosure to the patient and/or substitute decision-maker or family is discretionary.

Disclosure Process
Disclosure of significant adverse medical events is required as part of the general professional duty to inform patients about events that have affected or may affect their health in the future. It is the timely and open response to such difficult incidents by trusted and responsible medical personnel that can prevent dissatisfaction with care and improve the quality of care provided to patients in the future. Health care practitioners are encouraged to seek out the available hospital resources to help them inform patients about an adverse medical event. [See Appendix I: Frequently Asked Questions (FAQ’s), which offers guidelines for disclosure and resources to enable practitioners to be open with patients about difficult incidents]

APPENDIX I
Frequently Asked Questions (FAQs)
About Disclosing Adverse Medical Events & Unanticipated Outcomes of Care

1. What events ought to be disclosed?
   * Incidents causing patients harm or, in some cases, having the potential to do so, or
   * Incidents requiring additional non-trivial interventions to prevent Harm.

Examples:
This might include events such as an unexpected admission to intensive care due to a drug reaction, a prolonged hospital stay on account of complications arising from treatment, or an intraoperative event, such as rupturing an organ or major blood vessel, that requires unexpected and significant interventions to correct.
2. To whom should disclosure be made?
   * Disclosure of the event should be made to the patient, or in certain circumstances, the patient’s substitute decision-maker and/or family.
   
   * ii. If the patient is deemed incapable of understanding a discussion of this nature, then in accordance with the Health Care Consent Act (1996), the patient’s substitute decision-maker should be informed.

   When should disclosure take place?
   * Disclosure of the event should take place as soon as practically possible after it has occurred or has been identified.
   
   * Disclosure to the patient should occur when the patient’s condition is stable and/or the patient is able to comprehend the information. Disclosure to the patient’s substitute decision-maker may occur prior to this and will depend on the severity of the event.

4. Who ought to disclose events to patients?
   * If the event is most associated with physician staff, the patient’s attending physician, whether or not this physician was involved in the event, would usually initiate the discussion with the patient. There may be situations where another staff physician would take the lead, for example where the event occurred in one of the diagnostic units.
   
   * If the event is most associated with non-physician staff employees of the hospital, such as nursing or other health care professionals, the manager or director of the area would usually initiate the disclosure in consultation with the Director of Quality and Risk Management or delegate. The patient’s attending physician will always be informed of the event and will be given the option of being part of the discussion with the patient.

5. Are there events where disclosure is not required?
   * Disclosure of non-significant events (ones that do not harm a patient), should be a matter for clinical judgement by the skilled practitioner. Such incidents do not require disclosure to the patient because they do not affect the patient’s well-being. Disclosure is a matter of “proportionality”: the greater the harm or risk of harm caused by an event, the greater is the duty of the health practitioner to disclose this event to the patient and/or to the patient’s substitute decision-maker.

Examples:
A minor delay in giving a patient a medication may be an unwanted event, but if there was no harm to the patient as a result, disclosure would not be required. The disclosure of certain intraoperative events, such as bleeding or hypotension that are promptly treated with no consequence to the patient, would also be discretionary.
6. What mechanism will be in place to help with disclosure?
* During business hours, staff involved in an event who are employees of the hospital will immediately contact the Director of Quality and Risk Management or delegate to review an adverse event. The role of Quality and Risk Management is to facilitate the staff’s discussion about the event and to help plan the conversation with the patient or substitute.
* After hours, the manager or Administrator-on-Call is contacted immediately.
* The Director of Quality and Risk Management or delegate is available upon request to support physicians in the disclosure of adverse events.

7. What are the beneficial consequences of disclosure?
* Patients will receive prompt and thorough interventions for any harm suffered or anticipated.
* Patients and/or their families will have their concerns and fears openly addressed and respected.
* Patients will receive important information about their care in a timely manner.
* Errors and adverse events, while unwanted, are opportunities for practitioners and institutions to learn how to improve the quality of care and patient safety.

8. What is the difference between an error and an adverse event?
* Errors and adverse events overlap but are also different.
* Adverse events and errors are alike in that they are unwanted and often unanticipated events or processes of care. They occur to even the most careful practitioner and are not markers of negligent care.
* Some adverse events are unexpected, such as an allergic reaction to a first-time treatment with penicillin.
* An error is sometimes considered to be a “preventable adverse event,” such as prescribing penicillin to a patient with a history of penicillin allergy. It is unlikely, however, that all errors are “preventable.”
* What may seem like an “error” after the fact may simply be due to differences in professional judgement. Professional judgement tolerates a wide variety of approaches to patient situations. Less than optimal patient outcomes and even adverse outcomes may be due to legitimate differences in approach rather than any “error” per se.
* Adverse events are “adverse” because they cause, or threaten some harm to patients. Not all errors are harmful to patients if caught in time, such as a pharmacist, who, noting the patient has a penicillin allergy, alerts the prescribing doctor. Such “harmless” errors are “near misses” that should not require disclosure to the patient.

9. What actions are recommended for staff to take when a significant event occurs or is identified? These actions apply to those most immediately responsible for the care of the patient.
* The event should be documented in the patient’s chart in an objective, factual and narrative way. This should be done as soon as possible after the event has occurred or has been recognized.
* Staff who are employees of the hospital will involve their manager and the Director of Quality and Risk Management or delegate immediately. Quality and Risk Management is available upon request to support physicians with disclosure on request.
* Disclosure of the event to the patient, substitute decision-maker, and / or family should take place in a timely way. The adverse outcome may be obvious; what may require special attention is disclosure of the circumstances leading up to / surrounding the event. [See #2, “When Should Disclosure Take Place?”; #6, “What Mechanism Will Be in Place to Help with Disclosure?”; #7, “What are the Beneficial Consequences of Disclosure?”]
<table>
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<th>10. What Hospital actions will be taken when a significant event occurs or is identified?</th>
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<td>* The hospital encourages reporting of adverse events and errors and will support staff in this initiative. Patient safety is the primary concern of the organization, not disciplining the individuals involved in events. The hospital will focus on correcting the factors that allow events to occur and work with staff affected to prevent the recurrence of such events. * Secondary records made about the event, e.g., incident reports, interview notes, will be factual and objective. They will be stored in a secure area and will be destroyed in keeping with Retention Guidelines. Summary reports used for quality improvement or to meet the requirements of Sunnybrook’s Accountability System. Secondary records will not contain information that would identify the patient or staff.</td>
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<th>11. What are the recommendations for disclosure?</th>
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<td>* The attending physician or manager (see #4 above) should meet with the patient / substitute decision maker as promptly as other duties permit and as appropriate given the patient’s clinical condition. The assumption is that most patients / families would want to know what has happened. However, patients have the right to decline disclosure. If in doubt, ask before you tell. Waivers of information should be recorded in the patient’s chart. * Disclosure is a process. Practitioners should avoid speculation, focus on what is known about the event at the time of the discussion, and answer questions from the patient or substitute decision-maker to the best of their ability. Unanswered questions ought to be noted, and prompt and thorough responses sought. * Avoid attributing blame to specific individuals or simple explanations as to “cause”. Most serious events have multiple contributing factors that may not always be apparent at the time of the first meeting with the patient/family. * A timely and empathic expression of sorrow or regret and condolences may well be appropriate and should not be construed or taken to be an admission of liability or fault. (“This must be very difficult for you. I wish things had turned out differently.”) Doing so soon after an adverse outcome can help promote confidence in hospital staff and prevent unnecessary feelings of distrust.</td>
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* Discuss the event with members of the patient's care team and, where appropriate, the manager or department/division head.
The MUHC is committed to taking positive steps to reduce and prevent errors in order to improve patient care. If a sentinel event has occurred, the MUHC is committed to understanding the processes, attitudes and behavior that underlie the event, and making changes in the systems and processes, as well as attitudes and behavior, to reduce the probability of their reoccurrence.

This policy is based on the belief that, in order to improve performance, organizations need to conduct credible investigations of sentinel events. The objective is not to assign blame but to improve patient care by understanding the processes that led to a mishap.

**Sentinel Event**
A sentinel event is an unexpected occurrence involving death or serious physical or psychological injury, or risk thereof. Serious injury specifically includes loss of limb or function. The phrase, “or risk thereof” includes any process variation for which a recurrence would carry a significant chance of a serious adverse outcome. Such events are called “sentinel” because they signal the need for immediate investigation and response.

**Policy**
When a member of the MUHC community becomes aware that a potential sentinel event has occurred at the MUHC, he/she must notify the appropriate individuals within the organization. The facts will be reviewed to determine whether the event should be treated as a sentinel event. Once it is deemed to have been a sentinel event, an investigation will be undertaken to understand the causes that underlie the event and to make changes in the organization’s systems and processes as well as attitudes and behaviors to reduce the probability of such an event in the future. The investigation is designed to identify the contributing factors, and the response includes actions to reduce the likelihood of recurrence.

Criteria for selecting sentinel events is based on the CCHSA event types (surgical events or invasive procedures, device or product events, patient protection events, environmental events, care management events and criminal events).

## Nova Scotia Capital District Health Authority (Halifax)

### Patient Safety Reporting – Event Category and Types

The Capital Health Patient Safety Reporting System uses an event category and type listing as a guideline for the reporting of an adverse event across the region. There are 11 categories as listed below. Examples are provided for each category.

1. **Diagnostic procedure** – results reporting issue, missing specimen, specimen collection issue and so on.
2. **Medication related** – medicine incidents related to professional practice, drug products, procedures and systems. May include prescribing, order communication, product labeling/packaging/nomenclature, compounding, dispensing, distribution, administration, education, monitoring and use.
3. **Medication Administration-related** – adverse drug reaction, extra dose, incorrect (wrong) patient, incorrect (wrong) rate, and so on.
4. **Medication Order-related** – illegible order, incorrect order, incorrect (wrong) patient chart, known allergy, and so on.
5. **Medication Dispensing-related** – expired drug, incorrect (wrong) drug dispensed, incorrect patient, and so on.
6. **Patient/Client Behavior** – accidental injury, left against medical advice, refusal of treatment, self-inflicted injury, suicide, sexual assault, and so on.
7. **Patient Identification and Documentation** – misfiled reports/records, missing record, patient armband/identification, and so on.
8. **Patient-related equipment** – equipment failure, equipment misuse, inappropriate for the task, and so on.
9. **Privacy issues** – conversations overheard, records unsecured, released patient information/hospital documents without consent, release of patient information/hospital documents to the wrong party, and so on.
10. **Falls**

   A fall is defined as a sudden, uncontrolled, unintentional, downward displacement of the body to the ground or other object, excluding falls resulting from violent blows, other purposeful actions, strokes, fainting, and/or seizures.

   A near-fall is a sudden loss of balance that does not result in a fall or other injury. This can include a person who slips, stumbles, or trips but is able to regain control prior to falling.

   An unwitnessed fall occurs when a patient is found on the floor and neither the patient nor anyone else knows how he or she got there.


11. **Therapeutic Procedures** – blood type issue, delay in patient management, infection control issue, patient identification issue, procedure delayed, procedure cancelled, surgical count issue, retaining foreign body, and so on.
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<th>Patient Safety Impact Classification</th>
<th>Capital Health utilizes a Patient Safety Impact Classification System consisting of eight levels of harm as described below.</th>
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<tr>
<td><strong>Level 1 - No Harm / Detectable Harm</strong></td>
<td>There was no injury or no harmful effect to the patient and no potential risk identified. NEAR MISS</td>
</tr>
<tr>
<td><strong>Level 2 – Minimal Temporary Harm</strong></td>
<td>Requires little or no intervention.</td>
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<tr>
<td><strong>Level 3 – Minimal Permanent Harm</strong></td>
<td>Requires initial but not prolonged intervention.</td>
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<tr>
<td><strong>Level 4 – Moderate Temporary Harm</strong></td>
<td>Requires initial but not prolonged hospitalization.</td>
</tr>
<tr>
<td><strong>Level 5 – Moderate Permanent Harm</strong></td>
<td>Requires intensive but not prolonged hospitalization.</td>
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<tr>
<td><strong>Level 6 – Severe Temporary Harm</strong></td>
<td>Requires intervention necessary to sustain life but may also require prolonged hospitalization.</td>
</tr>
<tr>
<td><strong>Level 7 – Severe Permanent Harm</strong></td>
<td>Requires intervention necessary to sustain life and prolonged hospitalization, long-term care or hospice.</td>
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<tr>
<td><strong>Level 8 – Death</strong></td>
<td>Drastic outcome as a result of an event.</td>
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Guide to Disclosure:
Clinician-Patient Interviews
1. Choose appropriate physical setting.
2. Involve the care team.
3. Listen & deal with emotions.
4. Factual explanation.
5. Communicate a strategy.
Closure and follow-up.

Definition of adverse event: an unexpected and undesired incident directly associated with the care provided to the patient, or the environment in which care was provided, which does, or can be reasonably expected to, harm the patient (negatively affect the patient’s physical and/or psychological health and/or quality of life).
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<th>Nova Scotia Health (provincial policy)</th>
<th>Disclosure of Adverse Events Policy</th>
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<tr>
<td>All designated organizations providing health care in Nova Scotia that receive public funds, are required to have a process in place to promptly inform clients of pertinent facts associated with adverse events. This process requires maintaining a written policy that outlines the associated responsibilities, procedures and support. The provincial policy on health care disclosure of adverse events aims to assist organizations to provide an environment where clients receive the information they need to understand what happened and to make informed decisions about their care and create an environment where clients, care providers and managers all feel supported when adverse events occur.</td>
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<td>This policy applies to the Nova Scotia Department of Health (DoH) and to Nova Scotia organizations receiving public funds to provide health care, such as district health authorities, the IWK Health Centre, and N.S. DoH contractors providing emergency health services.</td>
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<tr>
<td><strong>Adverse Event</strong>—an unexpected and undesired incident directly associated with the care or services provided to the client or the environment in which the care is provided.</td>
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<td><strong>Near Miss</strong>—an event or circumstance which has not affected the client nor caused harm but the potential for harm exists. This near miss “almost happened” but may not have reached the client due to chance, corrective action, and/or timely intervention.</td>
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<td>The policy outlines the conditions that require disclosure. At minimum, the facts of the event and its impact on the client and on the care must be disclosed when an adverse event occurs during the process of providing health care and results in client injury, death or negatively impacts health (real or perceived).</td>
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<tr>
<td>A sample organizational ethics decision-making framework for disclosure of significant adverse events is provided as a guideline for the health regions.</td>
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| Health Canada | Canadian Adverse Drug Reaction Monitoring Program | Adverse reactions (ARs) to Canadian marketed health products, including prescription, non-prescription, biologic (including fractionated blood products, as well as therapeutic and diagnostic vaccines), natural health and radiopharmaceutical products are collected by the Canada Vigilance Program. An adverse reaction (AR) is a harmful and unintended response to a health product. This includes any undesirable patient effect suspected to be associated with health product use. Unintended effect, health product abuse, overdose, interaction (including drug-drug, and drug-food interactions) and unusual lack of therapeutic efficacy are all considered to be reportable ARs.

To report a suspected AR for health products—[pharmaceuticals, biologics (including fractionated blood products, as well as therapeutic and diagnostic vaccines), natural health products or radiopharmaceuticals] marketed in Canada, health professionals or consumers (preferably in conjunction with their health professional, so that information about medical history can be included in order to make the reports more complete and scientifically valid) should complete a copy of the Canada Vigilance Reporting Form Report of Suspected Adverse Reaction Due to Health Products Marketed in Canada (HC/SC 4016): This form may be obtained from the Internet at: http://www.hc-sc.gc.ca/dhp-mps/medeff/reportdeclaration/ ar-ei_form_e.html, from your Canada Vigilance Regional Office, and is also available in the appendices of the Compendium of Pharmaceuticals and Specialities.

To report an Adverse Event Following an Immunization (AEFI) for a vaccine used in the prevention of infectious diseases, the same criteria as stated in these guidelines are used. Health professionals should complete a copy of an Adverse Event Following Immunization Reporting Form. This form is available on the internet at http://www.phac-aspc.gc.ca/im/aefi-form_e.html or in the appendices of the CPS. Forms also exist as customized provincial/territorial adverse event forms which can be obtained either from local public health departments or from the provincial/territorial health authorities.

Any information related to the identity of the patient and/or the reporter of the AR will be protected as per the Privacy Act. |
Sources cited in this Table:

**Calgary Health Region, Alberta**
- Reporting Harm, Close Calls and Hazards. Reference Number 1626
- Disclosing Harm to Patients. Reference Number 1627
- Just and Trusting Culture. Reference Number 1628
- Informing Principal Health Partners & Stakeholders – Safety Hazards, Failures, Fixes. Reference Number 1629

**Alberta Health Quality Council, Alberta**

**Saskatoon Health Region, Saskatchewan**
- Saskatoon Health Region Critical Incident Reporting Policy. (2007).
- Saskatoon Health Region Multidisciplinary Care Review: A coordinated approach to managing risk (September, 2004).

**Winnipeg Regional Health Authority, Manitoba**

**Sunnybrook Health Sciences Centre, Ontario**

**McGill University Health Centre, Quebec**

**Capital Health Halifax, Nova Scotia**
- Capital Regional Health (Halifax) Patient Safety Reporting System – Event
Category and Types. (Version 2007/05/30).

**Health Canada, Federal Agency**

References


36 *Canadian Medication Incident Reporting and Prevention System (CMIRPS)*. http://www.ismp-canada.org/cmirps.htm


60 An Act to amend the act respecting health services and social services as regards to the safe provision of health and social services, RSQ 2002, Bill 113, c 71. Retrieved June 4, 2008 from http://www2.publicationsduquebec.gouv.qc.ca/dynamicSearch/telecharge.php?type=5&file=2002C71A.PDF


