Appendix B:

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

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Executive Summary

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

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

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

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

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

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

We also recommend that mechanisms be established to enable the transfer of useful information within each province and beyond. A review of current legislative provisions in most provinces suggests potential barriers to the transfer of such useful information, particularly on a personally identifiable basis. In our view, based on a review of privacy legislation and the privacy provisions of evidence and quality assurance legislation (where applicable), the political capital required to effect the statutory amendments necessary to achieve the Pan-Canadian Reporting of personal

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

health information ("**PHI**") would be immense. We would therefore recommend an alternative approach; modelled on the approach in Alberta, Saskatchewan or Manitoba that would establish a provincial body responsible for reporting in each province (which body could include the Minister, as is the case in Manitoba, or a separate organization, as is the case in the other named provinces). This provincial body could coordinate reporting by healthcare institutions and healthcare professionals in that province in compliance with provincial law. The provincial body would also be responsible for sharing de-identified information with a Pan-Canadian body capable of disseminating information and warnings on a national basis.

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

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

Definitions

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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5 The Canadian Patient Safety Dictionary (2003).

Introduction

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

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

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

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

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

PART I: Findings of Legislation Review

A. Introduction

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

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

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

1. Evidence Laws and Privilege

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

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

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

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

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

8 Northwest Territories, Nunavut, British Columbia and Saskatchewan.

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

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

2. Privacy Laws

a. General Privacy Laws

Any Pan-Canadian approach to Reporting and Sharing must address laws that deal with the disclosure of personal information. All provinces and territories have enacted either general privacy statutes or freedom of information type privacy statutes that apply to a public institution's[11] collection, use and disclosure[12] of personal information or information which is about an identifiable individual. These privacy statutes prohibit the disclosure of personal information without the prior consent of the subject individual, unless otherwise required by law.[13] A summary of the relevant disclosure provisions in these provinces is found at Appendix 3. However, it would be a difficult task to obtain consent from each patient or other relevant individual for the purposes of Reporting and Sharing. A more practical approach, to facilitate Reporting and Sharing of information about an Incident, would be pursuant to a permitted exception which avoids the need to obtain consent.

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

b. Health Information Privacy Laws

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

Provinces with only general privacy legislation tend to have a unified approach to the disclosure of personal information, whereas provinces with PHI legislation do not. The provisions of PHI legislation (and the various healthcare statutes that relate to quality assurance activities) have a varied approach to disclosure of PHI. In the four provinces noted above, PHI legislation appears to act as both an enabler and a barrier to Reporting and Sharing

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

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

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

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

depending on which entity has custody of the PHI: (a) PHI custodians or trustees; (b) quality assurance committees[14]; (c) third party institutions, including the Government or another regulatory body in the province.

i. Custodians or Trustees

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

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

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

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

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

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

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

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

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

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

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

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

ii. Quality Assurance Committees

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

iii. Third Party Organizations

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

iv. Variations in Treatment of PHI

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

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

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

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

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22 *Health Information Protection Act*, S.S. 1999, c. H-0.021.
23 S.S. 2002, c. H-0.04.
24 Section 5 of the *Health Information Protection Regulations*, R.R.S. c. H-0.021 Reg. 1.
25 Alberta seems to be the exception. See footnote 36.
26 Section 35(1)(a) with reference to section 27(1)(g) of the *Health Information Act*, R.S.A. 2000, c. H-5.
27 Section 27(4)(k) of the *Health Information Protection Act*, S.S. 1999, c. H-0.021.

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

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

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

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

c. De-identified Information

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

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

d. Findings of Other Reports

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

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28 Section 5 of the *Health Information Protection Regulations*, R.R.S. c. H-0.021 Reg. 1.
29 Section 22(2)(e)(iv) of the *Personal Health Information Act*, C.C.S.M. c. P33.5.
30 Section 4 of the *Quality of Care Information Protection Act*, 2004, S.O. 2004, c. 3, Sch. B.
31 In some provinces, quality assurance committees cannot disclose even de-identified information, and Sharing must be by way of the applicable healthcare institution or healthcare provider.
32 This standard varies between provinces. For example, British Columbia does not include the qualifier "reasonably" and therefore appears to reflect a stricter standard.
33 Unlike most provinces which tie disclosures to entities existing under the laws of the applicable province, the Alberta PHI Act uses language that does not require the recipient entity to be formed under Alberta law: disclosures may be made to "a committee that has as its primary purpose the carrying out of quality assurance activities within the meaning of section 9 of the *Alberta Evidence Act.* See *Alberta Evidence Act*, R.S.A. 2000, c. A-18, s.9.
34 Subsection 27(4)(g) of the *Health Information Protection Act,* S.S. 1999, c. H-0.021.
35 National Steering Committee on Patient Safety, "*Building a Safer System: A National Integrated Strategy for Improving Patient Safety in Canadian Health Care*" (September 2002) at 15.

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

The Weisbaum Report concluded as follows:

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

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

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

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

Second, as noted above, the statute under which personal information is collected can serve to restrict further disclosures, regardless of whether it is de-identified. Some jurisdictions impose a general confidentiality obligation over all information that is collected in the quality assurance process and used by a quality assurance committee. Other jurisdictions expressly restrict disclosures, and the fact that *any* information was collected or otherwise used by a quality assurance committee would serve to limit any subsequent use or disclosure of such information.[39] As a result, de-identification would not facilitate Sharing.

Some jurisdictions have exceptions to the bar against further disclosure of Incident data and information used by quality assurance committees, but they do not seem to be applicable. British Columbia, Northwest Territories and Nunavut permit the disclosure of de-identified information by a quality assurance committee or third party within

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

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

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

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

the province and outside the province only for the purpose of advancing medical research or medical education. Given that quality assurance committees are not engaged in advancing medical research or medical education, *per se*, no disclosure of any information provided to a quality assurance committee in the course of its activities or any resulting findings or conclusions of the committee is permitted. Similarly, most provinces permit disclosure of personal information to prevent harm or injury; however, we have read that exception narrowly, such that a disclosure would be permitted to resolve an immediate harm to a specific individual or group of individuals, and not for broader Reporting in the name of preventing generalized and unspecified harms. While Weisbaum and colleagues argue for a broader interpretation of these harm reduction clauses, it is unclear if such a broad interpretation can be supported. Further consultations with provincial and territorial representatives may be required.

3. Adverse Event/Critical Incident Reporting Laws

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

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

In each province, the institution is required to notify the responsible Minister of the occurrence of an Incident. Institutions must investigate the event and provide a report to the Minister following the investigation. Few details are provided in the legislation and regulations about what information is to be Reported and what the process is for Reporting. However Saskatchewan has developed detailed guidelines which outline the process.[40] Manitoba and Quebec require that institutions themselves establish written procedures respecting the recording and providing of information about adverse events.[41]

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

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

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

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40 *Saskatchewan Critical Incident Report Guideline, 2004.*

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

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

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

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

4. Coroner's Inquests and Public Inquiries

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

1. as a result of suspected misadventure, negligence or accident on the part of others;
2. where the cause of death is undetermined;
3. where a stillbirth or neonatal death has occurred where maternal injury has occurred or is suspected either before admission or during delivery;
4. where the death occurred within 10 days of an operative procedure or under initial induction, anaesthesia or the recovery from anaesthesia from that operative procedure; and
5. where the death occurred within 24 hours of admission to a hospital.

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

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

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

It is noteworthy that in two separate coroner's inquests into Incidents in healthcare, the coroner's jury has made recommendations regarding Reporting. In 2004, two coroner's juries in Ontario recommended that hospitals adopt some kind of Reporting scheme. The jury at the inquest into the death of Lana Dale Lewis, who suffered a stroke which was caused by chiropractic neck adjustment, recommended that the Ministry of Health establish an internal database to record cervical manipulations and that a section of the database be used to record the occurrence of Incidents, including stroke, transient ischemic attacks, injury, paralysis and other symptoms.[45] At the inquest into the death of Marie Tanner, who died as the result of an accidental injection of potassium chloride, the jury recommended that all hospitals adopt a standardized medication safety report program such as the Institute for Safe Medication Practices Canada's "Analyze-err".[46]

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

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

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

5. Drug and Medical Device Adverse Event Reporting

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

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

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

In her March 2004 report on the regulation of medical devices, Auditor General Shelia Fraser found that "Health Canada has done little work to increase the number and quality of reports received from [healthcare professionals]. As a result, Health Canada is not able to adequately identify adverse events."[47] Furthermore, Ms. Fraser found that Health Canada does not know the extent to which the regulations are being respected. At the time, Health Canada did not engage in any inspection activity at the post-market phase. Health Canada did not know whether manufacturers and importers were "taking appropriate action in response to Incidents or complaints that come to their attention" or "reporting... all serious adverse events that come to their attention."[48] Ms. Fraser noted that Health Canada has completed several studies to assess weaknesses in post-market surveillance and options. However, at the time "Health Canada [acknowledged] that its lower levels of reporting [in comparison to the United States and United Kingdom] are due, in part, to its limited activities in the area of post-market surveillance."[49] Insofar as we are aware, the federal Government has not yet made any changes to the medical device legislation. The Reporting system for drugs suffers from the same limitations as the system for medical devices. Health Canada believes that it receives notice of less than 10% of adverse reactions.[50] In addition, the problems with post-market surveillance that exist with medical devices also appear to apply to drugs.[51] Nonetheless, we understand that work is currently underway by the federal Government to improve post-market surveillance.

6. Professional Regulation

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

One development of note, however, is Ontario's proposed changes to the *Regulated Health Professions Act*. Two of the goals of Bill 171, the *Health Systems Improvement Act, 2007*,[52] are to increase the transparency of health regulatory colleges and facilitate public access to information about the colleges and their members. Proposed

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

48 *Ibid*. at 2.79.

49 *Ibid*. at 2.89.

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

51 *Ibid*. at 36-37.

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

changes will mean greater disclosure of regulatory matters on the public register. At present, only the results of discipline and incapacity hearings are available. Bill 171 proposes to make note on the register of referrals from the Inquiries, Complaints and Reports Committee to the Discipline Committee.[53] Furthermore, the register will include a synopsis of the decision in every proceeding and will include notations of reprimands issued to members and, where applicable, a member's resignation and agreement not to practice again in Ontario. Ontario's professional colleges have supported the proposed changes and the increased transparency.

C. Legislative Barriers and Enablers to Reporting and Sharing

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

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

2. Also in some provinces, such as Alberta and Saskatchewan, the disclosure provisions of the PHI legislation also act an enabler to Sharing in that they allow custodians or trustees to disclose PHI to third party organizations to be used for prescribed purposes. Also, although it does not have PHI-specific legislation, Newfoundland and Labrador enacted legislation that created a third party organization to aggregate data from all components of the health and community services system.

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

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

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

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

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

8. Barring of personal liability for any information or disclosure that arises out of a quality assurance committee's activities in all of the larger provinces is an enabler to Reporting given that individuals making submissions or disclosures to a quality assurance committee could not be sued for doing so. The exception to this is where such submissions or disclosures are not made in good faith.[55] Good faith in this context generally means that an individual making a Report does

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

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

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

so with an honest belief in what is being Reported and has made such Report without malice or design to gain personally from doing so.

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

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

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

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

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

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

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

D. Elements of a Legislative Framework for the Jurisdictions

Provincial Legislation

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

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

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56 Saskatchewan, British Columbia, Northwest Territories and Nunavut.
57 British Columbia, Northwest Territories and Nunavut.
58 The exceptions appear to be Alberta and Saskatchewan.
59 We are not able to say with certainty whether mandatory Reporting increases Reporting. However, it does appear from our understanding of Saskatchewan that legislation coupled with detailed regulations and guidelines has increased Reporting in that province.
60 These Guidelines are adapted from the U.S. National Quality Forum's *Serious Reportable Events in Healthcare: A Consensus Report* (http://www.qualityforum.org/publications/reports/sre.asp).

2. **Who makes a Report?** The group of persons Reporting should be defined. This group may include healthcare professionals, employees of healthcare institutions, students and others. Furthermore, the scheme should provide a mechanism for persons other than those in the defined group (i.e. an individual or the individual's family) to Report a suspected Incident and require an institution to investigate whether an Incident occurred.

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

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

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

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

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

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

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

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

Federal Legislation

In our view, federal legislation is not required to enable Reporting. Even so, federal legislation could be developed for the purposes of setting out the objectives of the Pan-Canadian model and to provide additional funding to support Reporting efforts. Such legislation would not override provincial legislation but could serve to foster cooperation among the provinces and jurisdictions and emphasize the significance of the role of the national body.

Part II: Findings of Policy Review

A. Introduction

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

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

B. Policy Barriers and Enablers to Adverse Event Reporting

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

C. Policy Barriers and Enablers to Adverse Event Reporting

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

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

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

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

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

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

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

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

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

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

4. Many of those interviewed highlighted the need to build in feedback and follow up mechanisms to those involved in Reporting. Follow up information should be made available to people who file Reports to avoid the perception that Reporting is not valuable or not used. Presently, most policies remain silent on evaluation of Reporting programs. Such evaluation would highlight ways to improve Reporting and learning and communicate the value of such activities to staff.

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

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

7. Senior management's support of patient safety is important to encouraging Reporting. One way that management can demonstrate its commitment is by providing training programs. Training

APPENDIX B: LEGISLATION REVIEW

and education programs on various aspects of Reporting were among the most popular enablers identified. Such programs include information on how to Report, when to Report, how to analyze Reports and what to do with the results.

D. Elements of a Policy Framework

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

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

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

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

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

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

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

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

    a. improving care and lessening risk of preventable Incidents;

    b. increasing patient safety;

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

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

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

    a. include tracking of Incidents and improvements on outcomes; and

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

B20

APPENDIX B: LEGISLATION REVIEW

PART III: Findings of Surveys and Interviews

A. Introduction

In addition to reviewing legislation and policy, we designed surveys to identify health region or healthcare organization policy related to the Reporting and review of Incidents. To capture the experiences of these organizations, separate surveys were required: one for health regions and another for individual healthcare organizations in Ontario. The healthcare region survey was also translated into French and mailed to Quebec organizations. The healthcare organization surveys were modified slightly for community and long-term care sectors (see Appendix 11 for the acute care hospital survey exemplar). In addition, interviews with key stakeholders regarding legislative and policy enablers (see Appendix 12 for interview guide) were conducted. The two data collection methodologies, key findings, including enablers and barriers to Reporting, and recommended changes are described in this section.

B. Survey and Methodology

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

C. Findings of Surveys

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

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

    a. 37 hospitals;

    b. 25 health regions;

    c. 12 from community based organizations; and

    d. 7 from long-term care organizations.

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

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

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

B21

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

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

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

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

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

8. **Policies are under revision and/or development.** A majority of the organizations (N=68) reported that they have a policy in place that requires Disclosure, a finding that was supported by responses to the open-ended question (4c). Other key themes that emerged included:

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

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

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

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

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

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

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

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

    b. calls for just culture;

    c. broader focus to open Disclosure and Reporting;

    d. need for timely follow up; and

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

    b. Key external enablers included:

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

ii. Canadian Council on Health Services Accreditation Required Organizational Practices;

iii. organizations/networks and associated educational/knowledge management resources (e.g. CPSI, Ontario Hospital Association with toolkit, hospital report card, Safer Health Care Now, Quality Health Network, Institute of Safe Medication Practices);

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

v. increased public attention and media; and

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

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

a. Key internal barriers include:

i. culture of fear, litigation and disciplinary action;

ii. lack of physician engagement;

iii. competing priorities within organizations and sectors;

iv. variation in resources and human resources support;

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

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

vii. staffing shortages;

viii. electronic systems that are not user-friendly;

ix. funding and financial constraints;

x. lack of leadership/role modeling; and

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

b. Key external barriers include:

i. culture of fear, litigation and disciplinary action;

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

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

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

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

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

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

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

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

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

c. clearer legislation around protection for quality assurance discussions;

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

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

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

g. resources to implement process changes/quality assurance efforts;

h. physician engagement through legislation;

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

j. funding tied to enactment of legislation.

D. Key Informant Interview Methodology

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

E. Key Findings of Interviews

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

64 Some respondents also identified anonymous reporting.

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

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

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

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

F. Critical issues

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

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

2. **What are the Potential Barriers to Sharing Incident Information?** Privacy, evidence and health sector legislation appears to limit the disclosure of personal information, particularly in the context of quality assurance committee proceedings. In addition, the legislation of many provinces prevents data collected in their jurisdiction to be transmitted outside the

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

province, particularly in the manner in which health sector entities are defined.[67] As a result it seems unlikely that it would be possible in the near future to Share information about specific Incidents with quality assurance committees in different provinces. There are concerns in some provinces about the ability to Share information between quality assurance committees, even *within* the province.[68]

3. **Should reporting be mandatory or voluntary?** The issue of mandatory versus voluntary Reporting has been a traditional source of disagreement. On the one hand, some have felt that mandatory Reporting is necessary, particularly in an environment where there is liability for Incidents and organizations and individuals are thus likely to avoid creating risks of legal action. On the other hand, some have claimed that most Reporting is voluntary (even when mandated) since many Incidents are difficult to discover and fear of litigation may be more powerful than concerns about Reporting. At a national level, the issue of mandatory or voluntary Reporting is complicated by differences in provincial legislation. Some provinces, such as Saskatchewan and Manitoba now have mandatory Reporting for a defined range of Incidents. Others have no formal requirements for such Reporting and rely on voluntary efforts within healthcare organizations. In Saskatchewan and Manitoba the results of mandatory Reporting have differed. Saskatchewan has had more success than Manitoba. This could be due to a number of variables including: (a) differences in resources available; (b) education of staff regarding the scope and nature of the Reporting requirements; and (c) the existence of detailed guidelines in Saskatchewan. However, Manitoba's mandatory Reporting system is new compared to Saskatchewan's system and time could demonstrate an increase in Reporting in Manitoba as well.[69]

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

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

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

6. **What are possible models to study?** In our interviews we examined the experience of several existing international patient safety Reporting systems. Several of these offer opportunities for further study. These include the Australian Incident Monitoring System which operates in most Australian states and territories, the English National Reporting and Learning System

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

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

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

(NRLS), the Pennsylvanian Patient Reporting System (PA-PSRS), the Massachusetts Board of Registration in Medicine's Confidential Reporting System and the National Reporting System for Adverse Events in Denmark.

PART IV: Recommendations

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

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

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

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

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

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

knowledge and clinical expertise in the formulation of recommendations, we assume that any de-identification would be done at the institutional or regional level.

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

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

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

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

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

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

PART V: Conclusion

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

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

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

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

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

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

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

APPENDIX 1
Legislation Reference Table

	Evidence	Health Information Privacy/Freedom of Information and General Privacy	Adverse Event/Critical Incident	Coroner or Fatality Inquiry/Public Inquiry
AB	*Alberta Evidence Act*, R.S.A. 2000, c. A-18.	*Health Information Act*, R.S.A. 2000, c. H-5. *Freedom of Information and Protection of Privacy Act*, R.S.A. 2000, c. F-25.	N/A	*Fatality Inquiry Act*, R.S.A. 2000, c. F-9. *Public Inquiries Act*, R.S.A. 2000, c. P-39.
BC	*Evidence Act*, R.S.B.C., c. 124.	*Freedom of Information and Protection of Privacy Act*, R.S.B.C. 1996, c. 165.	N/A	*Coroners Act*, R.S.B.C. 1996, c. 72. Bill 6, *Public Inquiry Act*, 3rd Sess., 38th Parl., 2007.
MB	*The Manitoba Evidence Act*, C.C.S.M c. E150.	*The Personal Health Information Act*, C.C.S.M. c. P33.5. *Freedom of Information and Protection of Privacy Act*, C.C.S.M. c. F175.	*The Regional Health Authorities Act*, C.C.S.M, c. R.34. *Critical Incidents Regulation*, Man. Reg. 211/2006.	*The Fatality Inquiries Act*, C.C.S.M. c. F52. *The Manitoba Evidence Act*, C.C.S.M c. E150.
NB	*Evidence Act*, R.S.N.B. 1973, c. E-11.	*Protection of Personal Information Act*, S.N.B. 1998, c. P-19.1.	N/A	*Coroners Act*, R.S.N.B. 1973, c. 23. *Inquiries Act*, R.S.N.B. 1973, c. I-11.
NL	*Evidence Act*, R.S.N.L. 1990, c. E-16.	*Access to Information and Protection of Privacy Act*, S.N.L. 2002, c. A-1.1.	N/A	*Fatalities Investigations Act*, S.N. L. 1995, c. F-6.1. *Public Inquiries Act*, 2006, S.N.L. 2006, c. P-38.1.
NT[1]	*Evidence Act*, R.S.N.W.T. 1988, c. E-8.	*Access to Information and Protection of Privacy Act*, S.N.W.T.. 1994, c. 20.	N/A	*Fatal Accidents Act*, R.S.N.W.T. 1988, c. F-3. *Public Inquiries Act*, R.S.N.W.T. 1988, c. P-14.
NS	*Evidence Act*, R.N.S. 1989, c. 154.	*Freedom of Information and Protection of Privacy Act*, S.N.S. 1993, c. 5.	N/A	*Fatality Investigations Act*, S.N.S. 2001, c. 31. *Public Inquiries Act*, R.S.N.S. 1989, c. 372.
ON	*Quality of Care Information Protection Act*, S.O. 2004, c. 3, Sch. B.	*Personal Health Information Protection Act, 2004*, S.O. 2004, C. 3, Sch. A. *Quality of Care Information Protection Act, 2004*, S.O. 2004, c. 3, Sch. B *Freedom of Information and Protection of Privacy Act*, R.S.O. 1990, c. F.31.	N/A	*Coroners Act*, R.S.O. 1990, c. 37. *Public Inquiries Act*, R.S.O. 1990, c. P-41.
PE	*Health Services Act*, R.S.P.E.I. 1988, c. H-1.5.	*Freedom of Information and Protection of Privacy Act*, R.S.P.E.I. 1988, c. F-15.01.	N/A	*Coroners Act*, R.S.P.E.I 1988, c. 25. Public Inquiries Act, R.S.P.E.I 1988, c. P-31.
QC	*An Act Respecting Health Services and Social Services*, R.S.Q., c. S-4.2.	*An Act Respecting Access to Documents Held by Public Bodies and the Protection of Personal Information*, R.S.Q., c. A-2.1.	*An Act Respecting Health Services and Social Services*, R.S.Q., c. S-4.2.	*An Act Respecting the Determination of the Causes and Circumstances of Death*, R.S.Q., c. R-0.2. *An Act Respecting Public Inquiry Commissions*, R.S.Q., c. C-37.
SK	*The Evidence Act*, S.S. 2006, c. E-11.2.	*The Health Information Protection Act*, S.S. 1999, c H-0.021. *Freedom of Information and Protection of Privacy Act*, S.S. 1990-91, c. F-22.01	*The Regional Health Services Act*, S.S. 2002, C. R-8.2. *The Critical Incident Regulations*, R.R.S. 2000, c. R-8.2, Reg 3.	*The Coroners Act, 1999*, S.S. 1999, c. 38.01. *Public Inquiries Act*, R.S.S. 1978, c. P-38.
YT	*Evidence Act*, R.S.Y. 2002, c. 78.	*Access to Information and Protection of Privacy Act*, R.S.Y. 2002, c. 1.	N/A	*Coroners Act*, R.S.Y. 2002, c. 44. *Public Inquiries Act*, R.S.Y. 2002, c. 177.

1 All statutes also as enacted for Nunavut, pursuant to the *Nunavut Act*, S.C. 1993, c. 28.

Federal legislation: *Food and Drug Regulations*, C.R.C., c. 870, Part C.
Medical Devices Regulations, S.O.R./98-292.

APPENDIX 2
Evidence Laws and Privilege

	Quality assurance committee	**Quality assurance record**	**Scope of the protection**	**Exceptions to Privilege/Permitted Disclosure**
AB	9(1)(b) "quality assurance committee" means a committee, commission, council or other body that has as its primary purpose the carrying out of quality assurance activities and that is (i) appointed by (A) a regional health authority, (B) the Alberta Cancer Board, (C) the Alberta Mental Health Board, (D) the board of an approved hospital under the Hospitals Act, or (E) the operator of a nursing home, (ii) established by or under another enactment of Alberta, or (iii) designated by an order of the Minister of Health and Wellness as a quality assurance committee for the purposes of this section, but does not include a committee whose purpose, under legislation governing a profession or occupation, is to review the practice of or to deal with complaints respecting the conduct of a person practising a profession or occupation;	9(1)(c) "quality assurance record" means a record of information in any form that is created or received by or for a quality assurance committee in the course of or for the purpose of its carrying out quality assurance activities, and includes books, documents, maps, drawings, photographs, letters, vouchers and papers and any other information that is written, photographed, recorded or stored in any manner, but does not include software or any mechanism that produces records.	9(2) A witness in an action, whether a party to it or not, (a) is not liable to be asked, and shall not be permitted to answer, any question as to any proceedings before a quality assurance committee, and (b) is not liable to be asked to produce and shall not be permitted to produce any quality assurance record in that person's or the committee's possession or under that person's or the committee's control. 9(5) Neither (a) the disclosure of any information or of any document or anything contained in a document, or the submission of any report, statement, memorandum or recommendation, to a quality assurance committee for the purpose of its quality assurance activities, nor (b) the disclosure of any information, or of any document or anything contained in a document, that arises out of the quality assurance activities of a quality assurance committee, creates any liability on the part of the person making the disclosure or submission.	9(3) Subsection (2) does not apply to original medical and hospital records pertaining to a patient.

	Quality assurance committee	Quality assurance record	Scope of the protection	Exceptions to Privilege/Permitted Disclosure
BC	51(1) “committee” means any of the following: (a) a medical staff committee within the meaning of section 41 of the Hospital Act; (b) a committee established or approved by the board of management of a hospital, that includes health care professionals employed by or practising in that hospital, and that for the purpose of improving medical or hospital care or practice in the hospital (i) carries out or is charged with the function of studying, investigating or evaluating the hospital practice of or hospital care provided by health care professionals in the hospital, or (ii) studies, investigates or carries on medical research or a program; (c) a group of persons who carry out medical research and are designated by the minister by regulation; (d) a group of persons who carry out investigations of medical practice in hospitals and who are designated by the minister by regulation;	on by a committee, if the record (i) was compiled or made by the witness for the purpose of producing or submitting it to a committee, (ii) was submitted to or compiled or made for the committee at the direction or request of a committee, (iii) consists of a transcript of proceedings before a committee, or (iv) consists of a report or summary, whether interim or final, of the findings of a committee.	51(2) A witness in a legal proceeding, whether a party to it or not, (a) must not be asked nor be permitted to answer, in the course of the legal proceeding, a question concerning a proceeding before a committee, and (b) must not be asked to produce nor be permitted to produce, in the course of the legal proceeding, a record that was used in the course of or arose out of the study, investigation, evaluation or program carried on by a committee, if the record (i) was compiled or made by the witness for the purpose of producing or submitting it to a committee, (ii) was submitted to or compiled or made for the committee at the direction or request of a committee, (iii) consists of a transcript of proceedings before a committee, or (iv) consists of a report or summary, whether interim or final, of the findings of a committee.	51(3) Subsection (2) does not apply to original or copies of original medical or hospital records concerning a patient. 51(5) A committee or any person on a committee must not disclose or publish information or a record provided to the committee within the scope of this section or any resulting findings or conclusion of the committee except (a) to a board of management, (b) in circumstances the committee considers appropriate, to an organization of health care professionals, or (c) by making a disclosure or publication (i) for the purpose of advancing medical research or medical education, and (ii) in a manner that precludes the identification in any manner of the persons whose condition or treatment has been studied, evaluated or investigated.
			51(4) A person who discloses information or submits a record to a committee for the purpose of the information or record being used in a course of study, an investigation, evaluation or program of that committee is not liable for the disclosure or submission if the disclosure or submission is made in good faith	51(6) A board of management or any member of a board of management must not disclose or publish information or a record submitted to it by a committee except in accordance with subsection (5) (c). 51(7) Subsections (5) and (6) apply despite any provision of the Freedom of Information and Protection of Privacy Act other than section 44 (2) and (3) of that Act.

	Quality assurance committee	Quality assurance record	Scope of the protection	Exceptions to Privilege/Permitted Disclosure
MB	9(1) “committee” means (a) a critical incident review committee established under Part 4.1 of The Regional Health Authorities Act; (b) a standards committee appointed under section 24 of The Hospitals Act; (c) a medical staff committee established for the purpose of studying or evaluating medical practice in a hospital; (d) a research committee of a hospital; and (e) a medical research committee designated in a regulation made by the Minister of Health for the purpose of sections 9 and 10. (« comité »)	9(1) “record” means a record of information in any form, and includes any information that is written, photographed, recorded or stored in any manner, on any storage medium or by any means, including by graphic, electronic or mechanical means.	9(2) Subject to subsection (4), a witness in a legal proceeding, whether a party to it or not, (a) is not liable to be asked and is not permitted to answer any question or to make any statement with respect to a committee proceeding; and (b) is not liable to be asked to produce, and is not permitted to produce, (i) any record or information - including, without limitation, an opinion or advice - that is prepared solely for the use of, or collected, compiled or prepared by, a committee for the purpose of carrying out its duties, (ii) any record or information - including, without limitation, an opinion or advice - that is used solely in the course of, or arising out of, a committee proceeding, or (iii) a notice, report or other record or information respecting a critical incident that is required to be provided by a health corporation, prescribed health care organization or regional health authority under section 53.3 or 53.4 of The Regional Health Authorities Act (patient safety). 9(3) Subject to subsection (4), a record and information referred to in clause (2)(b) are not admissible as evidence in a legal proceeding. 10(1) The disclosure of (a) a record or information to a committee for use in committee proceedings; or (b) a record or information that arises out of committee proceedings; does not raise or create any liability on the part of the person making the disclosure, unless the person was acting in bad faith.	9(4) The privileges in subsections (2) and (3) do not apply (a) to information in a record created or maintained for the purpose of providing health services, including health care or treatment, to an individual; (b) to the facts of what actually occurred with respect to a critical incident that are contained in a record, unless those facts are also fully recorded in a record described in clause (a), or another record, that is available to the individual affected by the critical incident; or (c) to information in a record required by law to be created or maintained by the owner, operator or person in charge of a facility or by a health care provider.

	Quality assurance committee	Quality assurance record	Scope of the protection	Exceptions to Privilege/Permitted Disclosure
NB	"Committee" not specifically defined 43.3(1) "regional health authority" means a regional health authority as defined in the Regional Health Authorities Act; 43.3(4) A committee referred to in subsection (2) does not include a medical advisory committee exercising its functions respecting surgical and other privileges of the medical staff.	See scope of protection in s. 43.3(2): (b)…any document made by or for a regional health authority or a committee established by the regional health authority, prepared for the purpose of being used in the course of, or arising out of, any study, research or program the dominant purpose of which is medical education or improvement in medical or hospital care or practice, and (c)…any written or verbal opinion that (i) is provided to a regional health authority or to a committee referred to in this subsection when it is investigating an occurrence, and (ii) is an opinion as to the standard of the medical or hospital care or practice that was provided by any person in the circumstances under investigation.	43.3(2) A witness, whether a party to a legal proceeding or not, is excused from (a) providing any information as to any proceeding before a committee established by a regional health authority to conduct any study, research or program for the purpose of medical education or improvement in medical or hospital care or practice, (b) producing any document made by or for a regional health authority or a committee established by the regional health authority, prepared for the purpose of being used in the course of, or arising out of, any study, research or program the dominant purpose of which is medical education or improvement in medical or hospital care or practice, and (c) disclosing any written or verbal opinion that (i) is provided to a regional health authority or to a committee referred to in this subsection when it is investigating an occurrence, and (ii) is an opinion as to the standard of the medical or hospital care or practice that was provided by any person in the circumstances under investigation.	43.3(3) Subsection (2) does not apply to (a) records maintained by regional health authorities as required by the Hospital Act or the Regional Health Authorities Act or the regulations under those Acts, or (b) medical records maintained by attending physicians pertaining to a patient.
NL	8.1(2) This section applies to the following committees: (a) the Provincial Perinatal Committee, (b) a quality assurance committee of a member, as defined under the Hospital and Nursing Home Association Act , and (c) a peer review committee of a member, as defined under the Hospital and Nursing Home Association Act.	See scope of protection in s. 8.1(3): No report, statement, evaluation, recommendation, memorandum, document or information, of, or made by, for or to, a committee to which this section applies…	8.1(3) No report, statement, evaluation, recommendation, memorandum, document or information, of, or made by, for or to, a committee to which this section applies shall be disclosed in or in connection with a legal proceeding. 8.1(4) Where a person appears as a witness in a legal proceeding, that person shall not be asked and shall not (a) answer a question in connection with proceedings of a committee set out in subsection (2); or (b) produce a report, evaluation, statement, memorandum, recommendation, document or information of, or made by, for or to, a committee to which this section applies.	8.1(5) Subsections (3) and (4) do not apply to original medical or hospital records pertaining to a person.

	Quality assurance committee	Quality assurance record	Scope of the protection	Exceptions to Privilege/Permitted Disclosure
NT	13 “committee” means (a) a committee that is established or designated by the Minister responsible for the Medical Profession Act or a Board of Management and, for the purpose of improving medical or hospital care or medical practice in a hospital, (i) carries out or is responsible for studying, investigating or evaluating the hospital practice or hospital care provided by health care professionals in the hospital, or (ii) studies, investigates or carries on medical research or a program, and (b) a subcommittee of a committee referred to in paragraph (a); (comité)	See scope of protection in s. 14(1): a document made by a committee that was prepared exclusively for the purpose of being used in the course of, or arising out of, any study, investigation, medical research or program, the dominant purpose of which is to improve medical or hospital care or medical practice in a hospital	14. (1) A witness in legal proceedings, whether a party to them or not, (a) shall not be asked nor be permitted to answer, in the course of legal proceedings, a question as to a proceeding before a committee; and (b) shall not be asked to produce nor be permitted to produce, in the course of legal proceedings, a document made by a committee that was prepared exclusively for the purpose of being used in the course of, or arising out of, any study, investigation, medical research or program, the dominant purpose of which is to improve medical or hospital care or medical practice in a hospital. 15. (1) No action or other proceeding for damages lies against a person who, in good faith, discloses information or submits a record to a committee for the purpose of the information or record being used in the course of research or a study, investigation, evaluation or program carried out by the committee.	14 (2) Paragraph (1)(b) does not apply to records maintained by hospitals or medical records pertaining to a patient. 15(2) No committee and no person on a committee shall disclose or publish a record of the committee or information submitted to or compiled for the committee, except (a) to the Minister, in the case of a committee established or designated by the Minister responsible for the Medical Profession Act; (b) to the Board of Management, in the case of a committee established or designated by a Board of Management; (c) to a professional association, in the discretion of the committee; or (d) for the purpose of advancing medical. 15(3) Where a committee discloses or publishes a record of the committee or information submitted to or compiled for the committee, the committee shall ensure that the manner of disclosure or publication does not permit the identification, in any manner, of the person whose condition or treatment has been studied, evaluated or investigated. 15(4) No person who receives information from a committee or a record of a committee under subsection (2) shall publish or disclose the information or the record except for the purpose of advancing medical research or medical education and the disclosure or publication must be in accordance with subsection (3).

	Quality assurance committee	Quality assurance record	Scope of the protection	Exceptions to Privilege/Permitted Disclosure
NS	See scope of protection in s 60(2): (a) a research committee of a hospital; (b) a hospital committee established for the purpose of studying or evaluating medical or hospital care or practice in a hospital; or (c) a research committee recognized by the Minister of Health and Fitness and approved for the purpose of this Section	See scope of protection in s. 60(2): any report, statement, memorandum, recommendation, document or information of, or made by …[see committee definition]… and that is used in the course of, or arising out of, any study, research or program carried on by a hospital or any such committee for the purpose of education or improvement in medical or hospital care or practice.	60(2) A witness in any legal proceeding, whether a party thereto or not, is excused from answering any question as to any proceedings before, or producing any report, statement, memorandum, recommendation, document or information of, or made by (a) a research committee of a hospital; (b) a hospital committee established for the purpose of studying or evaluating medical or hospital care or practice in a hospital; or (c) a research committee recognized by the Minister of Health and Fitness and approved for the purpose of this Section, and that is used in the course of, or arising out of, any study, research or program carried on by a hospital or any such committee for the purpose of education or improvement in medical or hospital care or practice. 61 Neither (a) the disclosure of any information or of any document or anything therein, or the submission of any report, statement, memorandum or recommendation, to any committee referred to in subsection (2) of Section 60, for the purpose of its being used in the course of any study, research or program carried on by a hospital or any such committee for the purpose of education or improvement in medical or hospital care or practice; nor (b) the disclosure of any information, or of any document or anything therein, that arises out of any such study, research or program, raises or creates any liability on the part of the person making the disclosure or submission unless such disclosure or submission is made with malice.	60(3) Subsection (2) does not apply to original medical and hospital records pertaining to a patient.

	Quality assurance committee	Quality assurance record	Scope of the protection	Exceptions to Privilege/Permitted Disclosure
ON	“quality of care committee” means a body of one or more individuals, (a) that is established, appointed or approved, (i) by a health facility, (ii) by an entity that is prescribed by the regulations and that provides health care, or (iii) by an entity that is prescribed by the regulations and that carries on activities for the purpose of improving or maintaining the quality of care provided by a health facility, a health care provider or a class of health facility or health care provider, (b) that meets the prescribed criteria, if any, and (c) whose functions are to carry on activities for the purpose of studying, assessing or evaluating the provision of health care with a view to improving or maintaining the quality of the health care or the level of skill, knowledge and competence of the persons who provide the health care; (“comité de la qualité des soins”)	“quality of care information” means information that, (a) is collected by or prepared for a quality of care committee for the sole or primary purpose of assisting the committee in carrying out its functions, or (b) relates solely or primarily to any activity that a quality of care committee carries on as part of its functions, but does not include, (c) information contained in a record that is maintained for the purpose of providing health care to an individual, (d) information contained in a record that is required by law to be created or to be maintained, (e) facts contained in a record of an incident involving the provision of health care to an individual, except if the facts involving the incident are also fully recorded in a record mentioned in clause (c) relating to the individual, or (f) information that a regulation specifies is not quality of care information and that a quality of care committee receives after the day on which that regulation is made; (“renseignements sur la qualité des soins”)	5(1) No person shall ask a witness and no court or other body holding a proceeding shall permit or require a witness in the proceeding to disclose quality of care information. 5(2) Quality of care information is not admissible in evidence in a proceeding.	No exceptions. 4(3) Despite subsection (1) and the Personal Health Information Protection Act, 2004, a quality of care committee may disclose quality of care information to, (a) the management of the health facility or entity mentioned in subclause (a) (ii) of the definition of “quality of care committee” in section 1 that established, appointed or approved the committee if the committee considers it appropriate to do so for the purpose of improving or maintaining the quality of health care provided in or by the facility or entity; or (b) the management of a health facility or health care provider, where an entity mentioned in subclause (a) (iii) of the definition of “quality of care committee” in section 1 carries on activities for the purpose of improving or maintaining the quality of health care provided by the facility, the provider or a class including the facility or the provider, if the committee considers it appropriate to do so for the purpose of improving or maintaining the quality of health care provided in or by the facility, provider or class. 4(4) Despite subsection (1) and the Personal Health Information Protection Act, 2004, a person may disclose quality of care information if the disclosure is necessary for the purposes of eliminating or reducing a significant risk of serious bodily harm to a person or group of persons. 4(5) A person to whom information is disclosed under subsection (3), (4) or (6) shall not use the information except for the purposes for which the information was disclosed to the person. 4(6) A member of the management of a health facility or entity described in subsection (3) to whom quality of care information is disclosed under that subsection may disclose the information to an agent or employee of the facility or entity if the disclosure is necessary for the purposes of improving or maintaining the quality of health care provided in or by the facility or entity. 4(7) A person to whom information is disclosed under subsection (3), (4) or (6) shall not disclose the information except if subsection (4) or (6) permits the disclosure.

	Quality assurance committee	Quality assurance record	Scope of the protection	Exceptions to Privilege/Permitted Disclosure
PE	"Committee" not specifically defined	See scope of protection, s. 4(2): … incident reports, working papers, drafts or reports of a committee respecting an internal investigation… 4(1)(b) "internal investigation" means an investigation by a committee within a facility, community hospital or provincial hospital respecting specific incidents at the facility or hospital;	4(2) No employee or member shall be compellable (a) to produce incident reports, working papers, drafts or reports of a committee respecting an internal investigation; or (b) to disclose communications made to or by an employee or member in connection with an internal investigation, in any matter, or in any action for negligence, malpractice or breach of contract commenced against a community hospital authority, an employee or agent, administrator or member of the board of a community hospital authority, the Minister, an employee or agent of the Department or a person licensed under the Medical Act	None.
QC	183.1. The organization plan of an institution must also provide for the creation of a risk management committee. The number of 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.	No specific definition See scope of protection s. 183.3	183.3. The answers given by a person in the course of risk management activities, including any information or document supplied in good faith by the person in response to a request of a risk manager or a risk management committee may not be used or be admitted as evidence against the person or against any other person in a judicial proceeding or a proceeding before a person or body exercising adjudicative functions. 183.4. Notwithstanding the Act respecting Access to documents held by public bodies and the Protection of personal information (chapter A-2.1), the records and minutes of a risk management committee are confidential. 183.3 Nothing contained in a risk management record, including the conclusions with reasons and any related recommendations, may be construed as a declaration, recognition or extrajudicial admission of professional, administrative or other misconduct capable of establishing the civil liability of a party in a judicial proceeding.	None.

	Quality assurance committee	Quality assurance record	Scope of the protection	Exceptions to Privilege/Permitted Disclosure
SK	10(1) “committee” means a committee designated as a quality improvement committee by a health services agency to carry out a quality improvement activity the purpose of which is to examine and evaluate the provision of health services for the purpose of: (a) educating persons who provide health services; or (b) improving the care, practice or services provided to patients by the health services agency; (« comité »)	See scope of protection in s. 10(2): … any report, statement, memorandum, recommendation, document, information, data or record that: (i) is prepared exclusively for the use of or made by a committee; or (ii) is used exclusively in the course of, or arises out of, any investigation, study or program carried on by a committee.	10(2) Subject to subsection (4), a witness in any legal proceeding, whether a party to it or not: (a) is not liable to be asked any question, and is not permitted to answer any question or to make any statement, with respect to any proceeding before a committee; and (b) is not liable to be asked to produce, and is not permitted to produce, any report, statement, memorandum, recommendation, document, information, data or record that: (i) is prepared exclusively for the use of or made by a committee; or (ii) is used exclusively in the course of, or arises out of, any investigation, study or program carried on by a committee. (3) Subject to subsection (4), no report, statement, memorandum, recommendation, document, information, data or record mentioned in clause (2) (b) is admissible as evidence in any legal proceeding. 10(5) When made in good faith: (a) the disclosure of any information or document or anything in it to a committee for the purpose of its being used in the course of any investigation, research, study or program carried on by the committee does not raise or create any liability on the part of the person making the disclosure; (b) the submission of any report, statement, memorandum, recommendation, document, information, data or record to a committee for the purpose of its being used in the course of any investigation, research, study or program carried on by the committee does not raise or create any liability on the part of the person making the submission; and (c) the disclosure of any information or document or anything in it that arises out of any investigation, research, study or program described in clause (a) or (b) does not raise or create any liability on the part of the person making the disclosure.	10(4) The privileges set out in subsections (2) and (3) do not apply: (a) with respect to records that are: (i) prepared for the purpose of providing a health service to an individual; (ii) prepared as a result of an incident that occurred in a facility operated by a health services agency or in the provision of a health service by a health services agency, unless the facts relating to that incident are also fully recorded on a record described in subclause (i); or (iii) required by law to be kept by the health services agency; (b) to legal proceedings founded on defamation, inducing breach of contract or civil conspiracy that are based directly on any proceeding before a committee or any report, statement, memorandum, recommendation, document, information, data or record mentioned in clause (2) (b); or (c) to disciplinary proceedings where the impugned conduct is a disclosure or submission to a committee.

	Quality assurance committee	Quality assurance record	Scope of the protection	Exceptions to Privilege/Permitted Disclosure
YT	13(1) “quality assurance committee” means a committee that is established by a hospital to conduct and is engaged in the conduct of any study, investigation, evaluation, or program for the purpose of medical education or improvement in hospital care or practice; « Comité hospitalier sur la qualité » 13(4) This section does not apply to a committee performing functions pertaining to appointment to the medical staff or the privileges of being a member of the medical staff.	See scope of protection in s. 13(2): … a document or information about the content of a document that was used in the course of or that arose out of a study, investigation, evaluation, or program carried on by a quality assurance committee when the dominant purpose of the study, investigation, evaluation, or program is medical education or improvement in medical or hospital care or practice and the document (i) was made for the purpose of being communicated to a quality assurance committee, (ii) was made at the request or direction of a quality assurance committee, (iii) is a transcript of proceedings before a quality assurance committee, or (iv) is a report or summary, whether interim or final, of the findings of a quality assurance committee.	13(2) The following evidence is not admissible in a legal proceeding (a) information about a proceeding before a quality assurance committee; and (b) a document or information about the content of a document that was used in the course of or that arose out of a study, investigation, evaluation, or program carried on by a quality assurance committee when the dominant purpose of the study, investigation, evaluation, or program is medical education or improvement in medical or hospital care or practice and the document (i) was made for the purpose of being communicated to a quality assurance committee, (ii) was made at the request or direction of a quality assurance committee, (iii) is a transcript of proceedings before a quality assurance committee, or (iv) is a report or summary, whether interim or final, of the findings of a quality assurance committee. 13(5) A person who discloses information or a record or who makes a recommendation to a quality assurance committee for the purpose of the information or record or recommendation being used in the work of the committee is not liable for the disclosure or recommendation if it is made in good faith.	13 (3) Subsection (2) does not apply to (a) records maintained by a hospital as required by the Hospital Act, the Health Act, or any other Act of the Legislature or of Parliament; or (b) medical or hospital records pertaining to a patient; or (c) legal proceedings for (i) defamation, or (ii) inducing breach of contract, or (iii) civil conspiracy based on a proceeding before a quality assurance committee or information or a report or recommendation communicated to or by the committee; or (d) any other records the Commissioner in Executive Council prescribes.

APPENDIX 3
General Privacy Laws

In addition to the general privacy laws set out below, the provinces of Alberta, Manitoba, Saskatchewan and Ontario have legislation specifically relating to health information, and Ontario has legislation that is specific to "quality of care information". Consequently, in the foregoing provinces, the provisions below do not apply to individual's personal health information to the extent that the health-specific legislation applies.

	Disclosure Without the Individual's Consent
AB*	40(1) A public body may disclose personal information only (c) for the purpose for which the information was collected or compiled or for a use consistent with that purpose, (e) for the purpose of complying with an enactment of Alberta or Canada or with a treaty, arrangement or agreement made under an enactment of Alberta or Canada, (f) for any purpose in accordance with an enactment of Alberta or Canada that authorizes or requires the disclosure, (h) to an officer or employee of the public body or to a member of the Executive Council, if the information is necessary for the performance of the duties of the officer, employee or member, (i) to an officer or employee of a public body or to a member of the Executive Council, if the disclosure is necessary for the delivery of a common or integrated program or service and for the performance of the duties of the officer or employee or member to whom the information is disclosed, (q) to a public body or a law enforcement agency in Canada to assist in an investigation (t) in accordance with section 42 (statistical research) or 43 (achieves), (v) for use in a proceeding before a court or quasi-judicial body to which the Government of Alberta or a public body is a party, (ee) if the head of the public body believes, on reasonable grounds, that the disclosure will avert or minimize an imminent danger to the health or safety of any person.
BC	33.2 A public body may disclose personal information referred to in section 33 inside Canada as follows: (a) for the purpose for which it was obtained or compiled or for a use consistent with that purpose (see section 34);… (c) to an officer or employee of the public body or to a minister, if the information is necessary for the performance of the duties of the officer, employee or minister;… (k) in accordance with section 35 (disclosure for research or statistical purposes).
MB*	17(4) Despite subsection (2), disclosure of personal information is not an unreasonable invasion of a third party's privacy if (b) there are compelling circumstances affecting the mental or physical health or the safety of the applicant or another person and notice of the disclosure is mailed to the last known address of the third party; (c) an enactment of Manitoba or Canada expressly authorizes or requires the disclosure; (d) the disclosure is for research purposes and is in accordance with section 47;
NB	3.4 Consent is not required when a public body collects, uses or discloses personal information (a) to protect the health, safety or security of the public or of an individual,… (f) as required or expressly authorized by law, or… (g) for some other substantial reason in the public interest, whether or not it is similar in nature to paragraphs (a) to (f).
NL	39 (1) A public body may disclose personal information only (c) for the purpose for which it was obtained or compiled or for a use consistent with that purpose as described in section 40 ; (d) for the purpose of complying with an Act or regulation of, or with a treaty, arrangement or agreement made under an Act or regulation of the province or Canada ; … (r) in accordance with an Act of the province or Canada that authorizes or requires the disclosure; or … (s) in accordance with sections 41 (research or statistical purposes) and 42 (archival or historical purposes). 39(2) The disclosure of personal information by a public body shall be limited to the minimum amount of information necessary to accomplish the purpose for which it is disclosed.

	Disclosure Without the Individual's Consent
NT	48 A public body may disclose personal information (a) for the purpose for which the information was collected or compiled or for a use consistent with that purpose;… (p) for the purpose of complying with a law of the Territories or Canada or with a treaty, written agreement or arrangement made under a law of the Territories or Canada; (s) for any purpose when, in the opinion of the head,… (i) the public interest in disclosure clearly outweighs any invasion of privacy that could result from the disclosure, or… (u) for any purpose in accordance with any Act that authorizes or requires the disclosure; or….
NS	27 A public body may disclose personal information only (a) in accordance with this Act or as provided pursuant to any other enactment; … (c) for the purpose for which it was obtained or compiled, or a use compatible with that purpose; … (q) in accordance with Section 29 (research purpose) or 30 (public archives).
ON*	21. (1) A head shall refuse to disclose personal information to any person other than the individual to whom the information relates except, (b) in compelling circumstances affecting the health or safety of an individual, if upon disclosure notification thereof is mailed to the last known address of the individual to whom the information relates; (d) under an Act of Ontario or Canada that expressly authorizes the disclosure; (e) for a research purpose if, (i) the disclosure is consistent with the conditions or reasonable expectations of disclosure under which the personal information was provided, collected or obtained, (ii) the research purpose for which the disclosure is to be made cannot be reasonably accomplished unless the information is provided in individually identifiable form, and (iii) the person who is to receive the record has agreed to comply with the conditions relating to security and confidentiality prescribed by the regulations. 42. (1) An institution shall not disclose personal information in its custody or under its control except, (c) for the purpose for which it was obtained or compiled or for a consistent purpose; (d) where disclosure is made to an officer, employee, consultant or agent of the institution who needs the record in the performance of their duties and where disclosure is necessary and proper in the discharge of the institution's functions; (e) for the purpose of complying with an Act of the Legislature or an Act of Parliament or a treaty, agreement or arrangement there under; (l) to the responsible minister.
PE	37(1) A public body may disclose personal information only (a.1) if the disclosure would not be an unreasonable invasion of a third party's personal privacy under section 15;… (b) for the purpose for which the information was collected or compiled or for a use consistent with that purpose;… (d) for the purpose of complying with an enactment of Prince Edward Island or Canada or with a treaty, arrangement or agreement made under an enactment of Prince Edward Island or Canada;… (e) for any purpose in accordance with an enactment of Prince Edward Island or Canada that authorizes or requires the disclosure;… (r) in accordance with section 39 or 40 (research purposes); 37(2) Only information that is reasonably required may be disclosed under subsection (1).

	Disclosure Without the Individual's Consent
QC	59 A public body shall not release personal information without the consent of the person concerned. Notwithstanding the foregoing, a public body may release personal information without the consent of the person concerned in the following cases and strictly on the following conditions: (5) to a person authorized by the Commission d'accès à l'information, in accordance with section 125, to use the information for study, research or statistics purposes; 60.1. The public body that releases information pursuant to section 59.1 may only release such information as is necessary to achieve the purposes for which the information is released. 68. A public body may, without the consent of the person concerned, release personal information (1) to a public body or an agency of another government if it is necessary for the exercise of the rights and powers of the receiving body or the implementation of a program under its management; (1.1) to a public body or an agency of another government if it is clearly for the benefit of the person to whom it relates; (2) to a person or a body where exceptional circumstances justify doing so; (3) to a person or body if it is necessary for the purposes of a service to be provided to the person concerned by a public body, in particular for identifying the person.
SK*	29(2) Subject to any other Act or regulation, personal information in the possession or under the control of a government institution may be disclosed: (h) pursuant to an agreement or arrangement between the Government of Saskatchewan or a government institution and: (i) the Government of Canada or its agencies, Crown corporations or other institutions; (ii) the government of another province or territory of Canada, or its agencies, Crown corporations or other institutions; (i) for the purpose of complying with: (i) an Act or a regulation; (ii) an Act of the Parliament of Canada or a regulation made pursuant to an Act of the Parliament of Canada; or (iii) a treaty, agreement or arrangement made pursuant to an Act or an Act of the Parliament of Canada; (k) to any person or body for research or statistical purposes if the head: (i) is satisfied that the purpose for which the information is to be disclosed is not contrary to the public interest and cannot reasonably be accomplished unless the information is provided in a form that would identify the individual to whom it relates; and (ii) obtains from the person or body a written agreement not to make a subsequent disclosure of the information in a form that could reasonably be expected to identify the individual to whom it relates; (l) for the purpose of: (i) management; (ii) audit; or (iii) administration of personnel; of the Government of Saskatchewan or one or more government institutions; (o) for any purpose where, in the opinion of the head: (i) the public interest in disclosure clearly outweighs any invasion of privacy that could result from the disclosure; or (ii) disclosure would clearly benefit the individual to whom the information relates; (t) for any purpose in accordance with any Act or regulation that authorizes disclosure;
YT	36 A public body may disclose personal information only: .. (c) for the purpose for which it was obtained or compiled or for a use consistent with that purpose; … (f) to an officer or employee of the public body or to a Minister, if the information is necessary for the performance of the duties of the officer, employee or Minister; … (n) if the public body determines that compelling circumstances exist that affect anyone's health or safety and if notice of disclosure is mailed to the last known address of the individual the information is about; or (q) in accordance with Section 38 (research or statistical purpose) or 39 (historical archives).

APPENDIX 4
Health Information Privacy Laws

	Disclosure Without the Individual's Consent
AB	35(1) A custodian may disclose individually identifying diagnostic, treatment and care information without the consent of the individual who is the subject of the information… (g) to a committee that has as its primary purpose the carrying out of quality assurance activities within the meaning of section 9 of the Alberta Evidence Act, (h) for the purpose of a court proceeding or a proceeding before a quasi-judicial body to which the custodian is a party, (p) if the disclosure is authorized or required by an enactment of Alberta or Canada,…. 35(2) A committee to which health information is disclosed pursuant to subsection (1)(g) must not disclose the information to any other person except in accordance with subsection (3). 35(3) A committee referred to in subsection (2) may disclose non-identifying health information to another committee that has as its primary purpose the carrying out of quality assurance activities within the meaning of section 9 of the Alberta Evidence Act. 35(4) A custodian may disclose individually identifying diagnostic, treatment and care information to a health professional body for the purpose of an investigation, a discipline proceeding, a practice review or an inspection if (a) the custodian has complied with any other enactment authorizing or requiring the custodian to disclose that information for that purpose, and (b) the health professional body agrees in writing (i) not to disclose the information to any other person except as authorized by or under the Act governing the health professional body, and (ii) repealed 2006 c18 s5. 37(1) A custodian may disclose individually identifying health services provider information without the consent of the individual who is the subject of the information (a) to a health professional body that requests the information for the purpose of an investigation, a discipline proceeding, a practice review or an inspection relating to the health services provider, or (b) if the disclosure is authorized or required by an enactment of Alberta or Canada.
MB	22(2) A trustee may disclose personal health information without the consent of the individual the information is about if the disclosure is… (e) required for (i) the purpose of peer review by health professionals, (ii) the purpose of review by a standards committee established to study or evaluate health care practice in a health care facility or health services agency, (iii) the purpose of a body with statutory responsibility for the discipline of health professionals or for the quality or standards of professional services provided by health professionals, or (iv) the purpose of risk management assessment; (g) for the purpose of (i) delivering, evaluating or monitoring a program of the trustee that relates to the provision of health care or payment for health care, or (ii) for research and planning that relates to the provision of health care or payment for health care by the trustee; (h) to a computerized health information network and database, established by the government or another trustee that is a public body specified in the regulations, in which personal health information is recorded for the purpose of facilitating (i) the delivery, evaluation or monitoring of a program that relates to the provision of health care or payment for health care, or (ii) research and planning that relates to the provision of health care or payment for health care; (n) for the purpose of complying with an arrangement or agreement entered into under an enactment of Manitoba or Canada; or (o) authorized or required by an enactment of Manitoba or Canada. 22(3) A trustee may disclose information under subsection (2) only to the extent the recipient needs to know the information.

	Disclosure Without the Individual's Consent
ON	43(1) A health information custodian may disclose personal health information about an individual,…. (b) to a College within the meaning of the Regulated Health Professions Act, 1991 for the purpose of the administration or enforcement of the Drug and Pharmacies Regulation Act, the Regulated Health Professions Act, 1991 or an Act named in Schedule 1 to that Act;…
SK	27(2) A subject individual is deemed to consent to the disclosure of personal health information: (a) for the purpose for which the information was collected by the trustee or for a purpose that is consistent with that purpose; 27(4) A trustee may disclose personal health information in the custody or control of the trustee without the consent of the subject individual in the following cases:…. (g) where the disclosure is being made to a standards or quality of care committee established by one or more trustees to study or evaluate health services practice in a health services facility, health region or other health service area that is the responsibility of the trustee, if the committee: (i) uses the information only for the purpose for which it was disclosed; (ii) does not make a further disclosure of the information; and (iii) takes reasonable steps to preserve the confidentiality of the information; (h) subject to subsection (5), where the disclosure is being made to a health professional body or a prescribed professional body that requires the information for the purposes of carrying out its duties pursuant to an Act with respect to regulating the profession;… (k) where the disclosure is being made for the purpose of:… (ii) planning, delivering, evaluating or monitoring a program of the trustee;… (l) where the disclosure is permitted pursuant to any Act or regulation; (p) in prescribed circumstances.

APPENDIX 5
Adverse Event/Critical Incident Reporting Laws

	What is reported?	How is the event reported?	To whom is the event reported?
MB	53.1 "critical incident" means an unintended event that occurs when health services are provided to an individual and 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 a hospital stay, and (b) does not result from the individual's underlying health condition or from a risk inherent in providing the health services. (« incident critique ») "critical incident review committee" means a committee of one or more individuals established under subsection 53.3(1) or 53.4(1). (« comité d'examen des incidents critiques »)	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; and (c) the record described in clause (b) is available to be examined and copied by the individual at no cost.	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 guidelines established by the regional health authority; and (b) in consultation with the regional health authority, establish a critical incident review committee, consisting of one or more individuals satisfactory to 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.

	What is reported?	How is the event reported?	To whom is the event reported?
QC	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 personnel member, a professional involved or a third person. 183.1. The organization plan of an institution must also provide for the creation of a risk management committee. The number of 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. 183.2 “incident” means an action or situation that does not have consequences for the state of health or welfare of a user, a personnel member, a professional involved or a third person, but the outcome of which is unusual and could have had consequences under different circumstances.	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 the measures taken to correct the consequences suffered, if any, or to prevent such an accident from recurring. 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.	233.1. 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 of the institution or to a person designated by 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. The executive director of the institution or the person designated by the executive director shall report, in non-nominative form, all reported incidents or accidents to the agency at agreed intervals or whenever the agency so requires. 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. 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. 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… 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]

	What is reported?	How is the event reported?	To whom is the event reported?
SK	58(1) In this section: (a) "critical incident" means an incident that: (i) arises as a result of the provision 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; 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.	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. Similar provisions require reporting by health care organizations (58(3)) and the cancer agency (58(4.1)). From the *Critical Incident Regulations*: 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. 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. 7 Subject to section 10, notice required by section 4 or 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 the case may be, and the names of those organizations, if any.	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 that it investigates. 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. 8(3) The regional health authority shall submit the written report to the minister immediately on completion of the report. 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 reasons 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. Similar provisions set out how a critical incident must be reported by a health care organization (9(1)-(4)).

APPENDIX 6
U.S. Adverse Event/Critical Incident Reporting Laws

	What is reported?	How is the event reported?	To whom is the event reported?
CA[1]	70737. (a) Reportable Disease or Unusual Occurrences. All cases of reportable diseases shall be reported to the local health officer in accordance with Section 2500, Article 1, Subchapter 4, Chapter 4, Title 17, California Administrative Code. Any occurrence such as epidemic outbreak, poisoning, fire, major accident, disaster, other catastrophe or unusual occurrence which threatens the welfare, safety or health of patients, personnel or visitors shall be reported as soon as reasonably practical, either by telephone or by telegraph, to the local health officer and to the Department. The hospital shall furnish such other pertinent information related to such occurrences as the local health officer or the Department may require. Reference should be made to the California Health and Safety Code § 1279.1 (2006) for a detailed list of adverse events that must be reported to the Department of Health. [This list is substantially similar to the list of adverse events in Saskatchewan legislation.]	1279.1. (a) A health facility licensed pursuant to subdivision (a), (b), or (f) of Section 1250 shall report an adverse event to the department no later than five days after the adverse event has been detected, or, if that event is an ongoing urgent or emergent threat to the welfare, health, or safety of patients, personnel, or visitors, not later than 24 hours after the adverse event has been detected. Disclosure of individually identifiable patient information shall be consistent with applicable law.	Department of Health (see § 1279.1.)
NY[2]	2805-l. Incident reporting. 1. All hospitals, as defined in subdivision ten of section twenty-eight hundred one of this article, shall be required to report incidents described by subdivision two of this section to the department in a manner and within time periods as may be specified by regulation of the department. 2. The following incidents shall be reported to the department: (a) patients' deaths or impairments of bodily functions in circumstances other than those related to the natural course of illness, disease or proper treatment in accordance with generally accepted medical standards; (b) fires in the hospital which disrupt the provision of patient care services or cause harm to patients or staff; (c) equipment malfunction during treatment or diagnosis of a patient which did or could have adversely affected a patient or hospital personnel; (d) poisoning occurring within the hospital; (e) strikes by hospital staff; (f) disasters or other emergency situations external to the hospital environment which affect hospital operations; and (g) termination of any services vital to the continued safe operation of the hospital or to the health and safety of its patients and personnel, including but not limited to the anticipated or actual termination of telephone, electric, gas, fuel, water, heat, air conditioning, rodent or pest control, laundry services, food or contract services.	2805-1. (cont.) 3. The hospital shall conduct an investigation of incidents described in paragraphs (a) through (d) of subdivision two of this section within thirty days of obtaining knowledge of any information which reasonably appears to show that such an incident has occurred, provided that, if the hospital reasonably expects such investigation to extend beyond such thirty day period, the hospital shall notify the department of such expectation and the reason therefor, and shall inform the department of the expected completion date of the investigation. The hospital shall provide to the department a copy of the investigation report within twenty-four hours of completion. Nothing herein shall limit the authority of the department to conduct an investigation of incidents occurring in general hospitals.	Department of Health (see § 2805-1)

1 Cal. Admin. Code tit.22, §70737; Cal Health & Saf Code § 1279.1.

2 New York Public Health Law, §2805-L.

APPENDIX 7
Federal Drug and Medical Device Reporting Laws

	Relevant Provisions
Drugs	C.01.001. (1) In this Part “adverse drug reaction” means a noxious and unintended response to a drug, which occurs at doses normally used or tested for the diagnosis, treatment or prevention of a disease or the modification of an organic function; “serious adverse drug reaction” means a noxious and unintended response to a drug that occurs at any dose and that requires in-patient hospitalization or prolongation of existing hospitalization, causes congenital malformation, results in persistent or significant disability or incapacity, is life-threatening or results in death; “serious unexpected adverse drug reaction” means a serious adverse drug reaction that is not identified in nature, severity or frequency in the risk information set out on the label of the drug; C.01.016. (1) No manufacturer shall sell a drug unless the manufacturer, with respect to any adverse drug reaction or any serious adverse drug reaction known to the manufacturer that occurs after this section comes into force, furnishes to the Director (a) a report of all information in respect of any serious adverse drug reaction that has occurred in Canada with respect to the drug, within 15 days after receiving the information; and (b) a report of all information in respect of any serious unexpected adverse drug reaction that has occurred outside Canada with respect to the drug, within 15 days after receiving the information. (2) The manufacturer shall, on an annual basis and whenever requested to do so by the Director, conduct a concise, critical analysis of the adverse drug reactions and serious adverse drug reactions to a drug referred to in subsection (1) and prepare a summary report in respect of the reports received during the previous twelve months or received during such period of time as the Director may specify. (3) Where, after reviewing any report furnished pursuant to subsection (1) and any available safety data relating to the drug, the Director considers that the drug may not be safe when used under the recommended conditions of use, the Director may, for the purpose of assessing the safety of the drug, request in writing, that the manufacturer submit (a) case reports of all adverse drug reactions and serious adverse drug reactions to that drug that are known to the manufacturer; and (b) a summary report prepared pursuant to subsection (2). (4) The manufacturer shall submit the case reports and summary report referred to in subsection (3) within 30 days after receiving the request from the Director. C.01.017. The manufacturer shall maintain records of the reports and case reports referred to in section C.01.016 for auditing purposes.

	Relevant Provisions
Medical Devices	59. (1) Subject to subsection (2), the manufacturer and the importer of a medical device shall each make a preliminary and a final report to the Minister concerning any incident that comes to their attention occurring inside or outside Canada and involving a device that is sold in Canada and that (a) is related to a failure of the device or a deterioration in its effectiveness, or any inadequacy in its labelling or in its the directions for use; and (b) has led to the death or a serious deterioration in the state of health of a patient, user or other person, or could do so were it to recur. (2) The requirement to report an incident that occurs outside Canada does not apply unless the manufacturer has indicated, to a regulatory agency of the country in which the incident occurred, the manufacturer's intention to take corrective action, or unless the regulatory agency has required the manufacturer to take corrective action. 60. (1) A preliminary report shall be submitted to the Minister (a) in respect of an incident that occurs in Canada (i) within 10 days after the manufacturer or importer of a medical device becomes aware of an incident, if the incident has led to the death or a serious deterioration in the state of health of a patient, user or other person, or (ii) within 30 days after the manufacturer or importer of a medical device becomes aware of an incident, if the incident has not led to the death or a serious deterioration in the state of health of a patient, user or other person, but could do so were it to recur; and (b) in respect of an incident that occurs outside Canada, as soon as possible after the manufacturer has indicated, to the regulatory agency referred to in paragraph 59(2), the manufacturer's intention to take corrective action, or after the regulatory agency has required the manufacturer to take corrective action. (2) The preliminary report shall contain the following information: (a) the name of the device and its identifier, including the identifier of any medical device that is part of a system, test kit, medical device group, medical device family or medical device group family; (b) if the report is made by (i) the manufacturer, the name and address of that manufacturer and of any known importer, and the name, title and telephone and facsimile numbers of a representative of the manufacturer to contact for any information concerning the incident, or (ii) the importer of the device, the name and address of the importer and of the manufacturer, and the name, title and telephone and facsimile numbers of a representative of the importer to contact for any information concerning the incident; (c) the date on which the incident came to the attention of the manufacturer or importer; (d) the details known in respect of the incident, including the date on which the incident occurred and the consequences for the patient, user or other person; (e) the name, address and telephone number, if known, of the person who reported the incident to the manufacturer or importer; (f) the identity of any other medical devices or accessories involved in the incident, if known; (g) the manufacturer's or importer's preliminary comments with respect to the incident; (h) the course of action, including an investigation, that the manufacturer or importer proposes to follow in respect of the incident and a timetable for carrying out any proposed action and for submitting a final report; and (i) a statement indicating whether a previous report has been made to the Minister with respect to the device and, if so, the date of the report. 61. (1) After the preliminary report is made in accordance with section 60, a final report shall be submitted to the Minister in accordance with the timetable established under paragraph 60(2)(h). (2) The final report shall contain the following information: (a) a description of the incident, including the number of persons who have experienced a serious deterioration in the state of their health or who have died; (b) a detailed explanation of the cause of the incident and a justification for the actions taken in respect of the incident; and (c) any actions taken as a result of the investigation, which may include (i) increased post-market surveillance of the device, (ii) corrective and preventive action respecting the design and manufacture of the device, and (iii) recall of the device. 61.1 (1) Despite subsection 59(1), the manufacturer of a medical device may permit the importer of the device to prepare and submit the preliminary and final reports on the manufacturer's behalf if the information that the manufacturer and importer must include is identical. (2) The manufacturer shall advise the Minister in writing if the manufacturer has permitted the importer to prepare and submit the reports on the manufacturer's behalf.

APPENDIX 8
List of Policies Reviewed

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

Summary of Policies

Jurisdiction	Title	Policy
Alberta Calgary Health Region	Reporting Harm, Close Calls and Hazards	The region requires its health care providers to report all situations where patients have suffered fatal or severe harm. The region strongly encourages 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 healthcare providers working, training or volunteering in region facilities or services. Healthcare 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.
British Columbia Vancouver Island Health Authority	Patient Safety: Communication of Adverse Events	The policy states that VIHA is committed to providing the best possible care to patients, residents and families. We are further committed to information clients promptly when AEs occur, out of respect for their right to be informed about their care, and in the interests of maintaining a relationship of trust and fostering ongoing communication. When communicating the AE, staff should acknowledge the event, express regret and explain what happened. When an Adverse Event occurs, the client will be informed of the AE in a compassionate and caring manner. Details of an AE must be factual, and the client must be advised of the AE in a timely manner. The staff will notify the MRP, supervisor/manager and/or program leader or Administrator-On Call, document a complete and factual description of pertinent clinical information and complete an incident report. The MRP represents the health care team in communicating the AE to the client. The Supervisor/Manager and/or Program Leaders or Administrator-On-Call will notify the Executive Director/Executive Medical Director, Risk Management Department and ensure an incident report has been submitted.
British Columbia Providence Health Care	CPV0300 -Incident Reporting	The Board of Directors of Providence Health Care requires that employees and medical staff shall document and report all incidents as part of the process of improving the quality of care and managing potential liabilities. The responsibility for overseeing this program is delegated to the Risk Manager, through the Board and the Medical Advisory Committee. It is the responsibility of the Program Directors and Leader(s) of a given Patient/Resident Care Area, Department or Program to ensure that adequate reporting and follow-up of incidents is completed. All documentation and discussion regarding incidents are considered privileged and may not be shared with anyone who is not involved in the incident, its investigation, follow up or review. If the incident is Serious (Severity Level 4 or 5), the Supervisor/Leader or Charge Nurse or the Director/Leader on Call is notified. A copy of the incident Report Form is sent to Data Quality/Admitting Services within two weeks. If follow up is appropriate, an Incident Quality Assurance Review Form is completed. A copy is sent to the Risk Manager. For medications, a copy of the Incident Report Form is sent to the appropriate Pharmacy Department

Jurisdiction	Title	Policy
Health Canada	Canadian Adverse Drug Reaction Monitoring Program Guidelines for the Voluntary Reporting of Suspected Adverse Reactions to Health Products by Health Professionals and Consumers	Adverse reactions to Canadian marketed health products including prescription, non-prescription, biologic, natural health and radiopharmaceutical products are collected by the Canadian Adverse Drug Reaction Monitoring Program. To report a suspected AR for health products, 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 AR Reporting Form which is available on the internet or from the Regional AR Centre or the National AR Centre and is also available in the appendices of the Compendium of Pharmaceuticals and Specialties. Adverse reactions to preventative vaccines are monitored by the Canadian Public Health Agency. For vaccines, the preferred route for reporting is to the local public health department, however completed forms can be sent by mail or fax to the Vaccine Associated Adverse Events Surveillance System.
Manitoba Health	Critical Incident Reporting and Management Policy	The professional culture in healthcare and the medical-legal system have traditionally viewed error as predominately an individual responsibility. It is important to acknowledge that error may be the responsibility of an individual and it may be the responsibility of the complex work environment. In order to encourage the reporting, disclosure and investigation of Critical Incidents and have individuals assume responsibility to their actions with the aim to prevent a similar event from occurring, legislative amendments have been undertaken. These include amendments to the Regional Health Authorities Act to outline requirements for the reporting and investigation of critical incidents occurring in the provision of healthcare by Regional Health Authorities, Health Corporation and Health Care Organizations designated by regulation under the Act. The Regional Health Authorities Act and The Manitoba Evidence Act outline the restrictions on access to, and use in legal proceedings or, information and reports generated by a Critical Incident Review Committee as well as notifications, reports and information provided to an RHA and/or the Minister (Manitoba Health). The amendments clearly outline a purposeful approach to management each Critical Incident in order to enhance and support patient safety. RHAs and provincial organizations will have written policies and procedures to govern and provide direction to their organization on the reporting and management of critical incidents that is consistent with adherence to legislative requirements for the reporting and investigation of critical incidents. An identified support system for staff includes: • Guidance through the critical incident reporting and disclosure process; • Education regarding the establishment and working details of a critical incident review committee; • Access to an Employee Assistance Program, and • Protection against reprisal for staff who report in relation to the reporting. Each RHA shall have a documented process for consultation with health corporations in relation to the establishment of a Critical Incident Review Committee by the health corporation as required by the Regional Health Authorities Act. Notification must be made with 24 hours on the critical incident to Manitoba Health, within 7 days a report outlining the steps taken to inform the person affected by the critical incident and within 30 days a report on the review.

Jurisdiction	Title	Policy
Manitoba Brandon Regional Health Authority Inc.	Occurrence (Incident) Reporting	The Brandon Regional Health Authority recognizes the importance of safety and the potential for errors in a health care organization. The Brandon Regional Health Authority promotes a culture of safety and fairness so that occurrences are reported, with an emphasis on process improvement. All staff are responsible for reporting occurrences. Staff members are protected from the assignment of blame and punitive action when reporting occurrences unless the staff member was involved in an intentionally unsafe act. Intentional unsafe acts are any events that result from a criminal act, a purposefully unsafe act, or an act related to alcohol or substance abuse or patient/resident/client abuse. Supervisors/Program Managers are responsible for investigating, creating and acting upon follow up actions, and monitoring occurrences related to their services. The Brandon RHA Critical Incident Review Committee conducts reviews of all critical occurrences. The Quality/Risk Manager or Executive Direct Planning & Evaluation is responsible for organizing and conducting a process review of critical occurrences with a team of staff members directly involved and who influence the related process. In accordance with the Amendments to the Regional Health Authorities Act and the Manitoba Evidence Act, information and reports generated by a Critical Incident Review Committee are protected from disclosure in legal proceedings. Brandon Regional Health Authority staff members that disclose information during a critical incident review are protected from reprisal when disclosing information to the Critical Incident Review Committee unless they committed an intentionally unsafe act. A regional database is maintained for tracking purposes. Occurrence trend reports shall not contain client or care provider identifiers.

Jurisdiction	Title	Policy
Northwest Hay River Health & Social Service Authority	Incident/Near Miss Reporting System	The HRHSSA's risk management program employs a number of systems to identify and provide notification of incidents or events that have occurred involving patients, visitors, staff, equipment, facilities, or grounds which are likely to give rise to potential liability, affect the quality of patient care or affect safety within the organization. The early identification of such incidents/occurrences allows the organization to immediately investigate the circumstances of the incident/occurrence, and if necessary, institute corrective action to prevent similar incidents in the future. One of the systems used to identify and report patient, staff and visitor related incidents is the HRHSSA Incident/Near Miss Reporting System. All staff are required to report incidents regarding any staff, patient, and visitor who, while within the organization's jurisdiction and/or while on the organization's premises, is involved in an incident which has caused or has the potential to cause injury or loss or damage to their personal property. This includes near misses where the possibility of injury existed although no injury was actually incurred and those incidents that are inconsistent with the routine care of a particular patient or routine operation of the hospital. The HRHSSA will report, classify and track incidents and near misses that immediately impact or have the potential for future impact on the health and well being of staff, clients, patients and their families. The HRHSSA recognizes the rights of patients, visits and staff to refuse treatment based on informed consent, after having been advised of the benefits and risks of treatment. This policy and procedures apply to all employees of the Hay River Health and Social Services Authority in the reporting of staff, patient, visitor incidents and near misses. Staff will complete the Incident and Near Miss Report or the Staff Occurrence Report for incidents and near misses. Incident reports are to be completed prior to the end of the shift. The levels of incidents will be utilized to track/trend significant incidents in an effort to identify issues needing further evaluation and/or action. The Severity Level of incidents are coded: Level 1 Minor Level 2 Moderate Level 3 Serious Completed incident/near miss, medication error and staff occurrence reports will be kept and filed by the Quality Improvement Coordinator. The QI Coordinator forwards staff occurrence reports to the HRHSSA Occupational Health & Safety Committee for their investigation and recommendations and provides quarterly reports to the HRHSSA Quality Council and the HRHSSA Board of Trustees.

Jurisdiction	Title	Policy
Nova Scotia South Shore Health Authority	Management of Sentinel Events	To provide for the continuous improvement to the quality of our service, the South Shore District Health Authority will provide a consistent and non-accusatory approach to managing, documenting, communicating and investigating sentinel events. The goals of SSH's Sentinel Event policy are: • To have a positive impact in improving patient care and preventing sentinel events • To focus attention on understanding the causes that underlie the event and on making changes in systems and processes to reduce the probability of such an event in future • To increase general knowledge about sentinel events, their causes and strategies for future • To share, via the Department of Health, hazards, recommendations and lessons learned that may have a positive benefit to the provincial health system in general • To maintain the confidence of the public in our Continuous Quality Improvement processes • To meet the requirements of our accrediting body (Canadian Counsel on Health Services Accreditation) The Manager and Attending Physician should be notified. The Risk Manager will inform the appropriate VP and CEO of the incident and prepares a summary report. The CEO notifies the Department of Health as per the Administrative Reporting Procedure. The Case Review Team files a report within 45 days of the event with the recommendations for improvement.
Nova Scotia South Shore Health Authority	Incident/Occurrence and Near Miss Reporting	All staff and physicians are responsible for reporting unusual or unplanned incidents/occurrences and near miss situations, as well as adhering to the practice and principles of risk management. Risk management is a process whereby risks to people and property under the care of SSH are minimized through active risk identification, assessment, control and evaluation. Objectives of the Incident/Occurrence Reporting Process: • Improve quality of care • Facilitate prioritization of improvement opportunities • Identify situations which require specific or immediate follow up • Identify trends • Identify issues that may be associated with organizational or departmental processes • Identify potential claims Severity level is assigned (none apparent, slight/no treatment, slight/minor treatment, moderate, serious) All incident/occurrence report forms should be completed within 24 hours and forwarded to the Risk Manager within 5 working days of an event. Serious incidents must be reported as soon as possible by telephone to the Departmental Manager and/or Nursing Resource Coordinator. The completed form is to be sent to the Departmental Manager for follow up and determination of severity level. For serious incidents, the Risk Manager will notify appropriate Vice President. The CEO must be informed of all serious or sentinel events and of all sentinel events by the appropriate VP and/or Risk Manager as soon as possible after the event. The Departmental Manager or designate assesses the incident by reviewing the report and competing any follow up as required. Consultation with the Clinical Department Head is to occur on all serious incidents/occurrences. The completed form is forwarded to the Risk Manager. A Manager's Incident Follow up Form is to be completed for all moderate and serious incidents. Incident/Occurrence reporting information, statistical data, and summary reports are confidential and are forwarded to the appropriate committees for the purposes of quality review and improvement. Information is treated in a "no name no blame" manner with no reference to individual employees, patients or clients.
Ontario Ministry of Health and Long-Term Care	No policy available	

Jurisdiction	Title	Policy
Ontario Sunnybrook Health Sciences Centre	Accountability for Patient Safety	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 agenda of the hospital as staff through this policy: • The organization and each individual staff member share the accountability for ensuring the safest possible patient care and service • 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. • The majority of errors, near misses and adverse events involve competent and caring staff interaction with complex systems. Sunnybrook responds to reports of errors, near misses and adverse events by carefully examining the improving the systems of care. • Sunnybrook needs and values the participation of staff and professionals in the investigation of the system of care, and in creating and testing improvements • Sunnybrook has a responsibility to address the actions of individuals when their actions fail to meet professional, patient care and/or service standards. These situations include intentional acts meant to harm or deceive, physical or mental impairment of staff, substance abuse by staff and staff incompetence.
Ontario Sunnybrook Health Sciences Centre	Patient/Visitor Incident Reporting	Every incident involving a patient/visitor must be reported on a Patient/Visitor Incident Report Form. This includes incidents which are witnessed but where the individual involved is not identified. While it is important to look at individual incidents, it is reported that four people were seen falling or slipping on separate dates, it may indicate a pattern that needs further investigation so that the risk to patients, visitors and staff are minimized. Record as much detail as is known and forward the Report to Process Management. While physician notification must occur with every inpatient and outpatient incident, it is discretional upon the caregiver to determine how quickly physician notification must occur. The Manager of each area involved in the incident is responsible for completing a thorough investigation for their area and forwarding their findings to the PCM of the patient's home Unit. The PCM of the patient's home unit is accountable for submitting the final Incident Report including the findings and recommendations from all involved departments to Process Management. Managers are accountable for providing appropriate feedback about incidents to their staff as this is critical to an effective Process Management program.
Ontario Sunnybrook Health Sciences Centre	Disclosure of Adverse Medical Events and Unanticipated Outcomes of Care	It is Sunnybrook's Policy, in keeping with our Mission, Vision, Values and philosophy or 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 Adverse Medical Events are separated into significant and non-significant events. 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. Health care practitioners are encouraged to seek out the available hospital resources to help them inform patients about an adverse medical event.

Jurisdiction	Title	Policy
Ontario Trillium Health Centre	Incident Reporting and Handling	This protocol describes the process for reporting and handling of all types of patient, visitor, employee and affiliate (physicians, volunteers, contractors, students) incidents. Three levels of risk have been defined: low, medium and high and will be assigned for every incident and near miss. When reporting an incident, the emphasis is to be on what happened when, where and what immediate steps were taken and any recommendations. The Risk Consultants, the Director, Patient Safety Director, Quality Outcomes and Evaluation and the WSIB Senior Advisory are available to assist with the use of the Risk Monitor software, assignment of risk severity level and to help guide and facilitate the follow up process, in particular for high risk incidents. The Risk Consultants will regularly review all new incident entries in the Risk Monitor. For all incidents, upon completion of follow up, the follow up coordinator documents all follow up actions in the Risk Monitor and closes the file. High risk incidents are reported to the VP within 20 working days.
Ontario University Health Network	Incident Reporting and Review	Any unexpected, unusual or unplanned event or near miss affecting or potentially affecting a patient or visitor or the Hospital generally must be reported using the Incident Report eForm. The Incident Report eForm is an administrative tool for quality improvement, risk management and business case purposes. It is an internal document and is intended for internal use only. Staff must use the Incident Report eForm to report all incidents and occurrences as set out in the policy. At UHN, all incidents classified as critical or severe are subject to a mandatory review to ensure that causes and contributing factors are identified and appropriate actions and learning can take place to eliminate or minimize a similar event from occurring. For those incidents as classified as moderate, minor or near miss, the Manager/delegate has the option of selecting the incident as one to review in more detail. As a minimum, each staff member and manager is responsible for demonstrating a questioning attitude e.g., “What can we learn from this situation?” Unit managers are responsible for reviewing incidents and holding meetings where all of the key staff people or their delegates are present. All critical and severe incident reviews are reviewed monthly by the UHN Quality of Care Committee or by a group designated by the QCC. If the incident is severe, the Physician, Manager/delegate or Nursing Administration Coordinator calls the Director of Patient Relations, Legal Counsel, and Risk Management within 24 hours of the incident. The Incident Report eForm is not documented on the patient’s chart.
PEI Department of Health	Incident Reporting Policy and Procedure	For the benefit of patients/clients, residents, staff and the organization, it is essential that an effective process is implemented whereby incidents are documented, investigated and appropriate action is taken. The reporting of incidents is key to maintaining a high standard of quality care and service. All employees who are involved in, discover or witness any incident or near miss in the workplace will complete an Incident Report Form and submit to their manager/supervisor or designate before the end of their shift or within 24 hours. All employees who are involved in or witness any serious incident will immediately verbally notify their manager/supervisor or designate and immediately complete an Incident Report Form. A copy of the incident report will not be permanently placed or recorded in the patient/client/resident file. Staff will report all incidents and near misses to their immediate manager/supervisor or designate within 24 hours and complete the required Incident Report Form. The Manager will report all serious incidents to the appropriate Director immediately. The Risk Management Coordinator and Occupational Health and Safety Officer will analyze and report to senior management, managers and appropriate committees all statistics and activities involving incident reporting, consult with the Provincial Risk Management Committee on issues of a provincial nature.

Jurisdiction	Title	Policy
Quebec McGill University Health Centre	Policy on Disclosure of Accidents to Patients, Patients'	Disclosure should be made at the earliest possible moment. It should include the details of the accident; the measures taken to correct the consequences suffered and an explanation of plans to prevent such an accident from recurring. This disclosure policy reflects the basic right-to-know of those who are in the care of the MUHC as well as demonstrating the intent of the institution to determine the cause of accidents and thereby improve the provision of health care. These policy guidelines are presented to clarify and consolidate hospital practice in order to assist doctors, nurses and other health care professionals in their duty to make disclosure with compassion and respect, including consideration for other members of the health care team. In most cases, the treating physician is responsible for disclosure. Before disclosure is made, the physician involved should discuss the matter with members of the treatment team and, depending upon the seriousness of the accident, the MUHC administration. Disclosure made in accordance with this policy is to be recorded immediately in the patient's hospital chart.
Quebec McGill University Health Centre	MUHC Policy on Sentinel Events	When a member of the MUHC community becomes aware that a potential sentinel event has occurred at 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 behaviours 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 or recurrence. All reports will be reviewed by the senior management team (Quality Management, Director Professional Services and/or Director Nursing and any other Director concerned or Chief Executive Officer) before being sent to the Committee on Quality and Risk.
University of Saskatchewan	Serious Adverse Events Reporting Policy	The Ethics Office at the University of Saskatchewan has developed a policy for submitting Serious Adverse Events (SAEs) to the Research Ethics Board (REB) during the course of a research study involving human subjects. The Ethics Office also has specific SAE submitting forms on which to summarize each event. The goal of this policy is to improve the process of SAE submission and review from both the researchers and REB perspectives. The REB of the University of Saskatchewan exists to ensure that all research involving human subjects conducted under the auspices of the University of Saskatchewan meets the highest ethical and scientific and safety standards in accordance with the Tri-Council Policy Statement: Guidelines on Research Involving Human Subjects and the International Conference on Harmonization Good Clinical Practice: Consolidated Guideline. The University of Saskatchewan REB forms must be used for submission of SAEs to the REB. It is the responsibility of the U of S Principal Investigator to promptly review and report all internal SAEs and any concerns, changes or new information to the REB. All information must be documented within 7 calendar days of the date that study staff became aware of the event.

APPENDIX 9
Summary of Policy Strengths and Weaknesses

Jurisdiction	Level	Responsible Party	What is reported	Report Send to Where	Strengths	Weaknesses
Alberta Calgary Health Region	Regional		All hazards and close calls	Calgary Health Region	Includes all incidents	Voluntary No sharing beyond health region Policy and procedure are separate documents
BC Vancouver Island Health Coastal Authority	Regional	VIHA- reporting Most Responsible Practitioner	Adverse events only	VIHA	Single document for policy and procedure	Voluntary Adverse events only
BC Providence Health Care	Local	Risk Manager through Board and MAC: overseeing program Program Directors and Leaders of Patient Resident Care Area, Department or Program: Reporting and follow-up of incidents	Incident	VP Medical Affairs, if serious incident	Includes all incidents Events are rated 0-5 according to severity	Voluntary
Health Canada	Federal	Regional and National Adverse Reactions Centre	Adverse reactions to health products and vaccines	Regional and National Adverse Reactions Centre	Federal	Voluntary
Manitoba Health	Provincial Regional	Directors, Regional Support Services	Critical incidents	Critical Incident Review Committee	Legislation	Limited to critical incidents
Manitoba Brandon Regional Health Authority Inc.	Regional	Quality/Risk Manager	Occurrences	Critical Incident Review Committee Risk Management Committee	Includes close calls Regional database used for tracking purposes	Voluntary
Newfoundland	Provincial	TBD	Adverse events, sentinel events	TBD	TBD	TBD
Northwest Territories Hay River Health & Social Service Authority	Regional	Risk Management	Incidents	HRHSSA Occupational Health & Safety Committee HRHSSA Board of Trustees	Includes all incidents Severity level is rated	Voluntary
Nova Scotia South Shore Health Authority	Regional	SSHA	Sentinel events	VP Continuous QI Committee	Uses root cause analysis	Incident/Occurrence and Near miss policy is a separate policy

Jurisdiction	Level	Responsible Party	What is reported	Report Send to Where	Strengths	Weaknesses
Nova Scotia South Shore Health Authority	Regional	Departmental Manager	Incident/ Occurrence and Near Miss	Risk Manager Vice President	Includes all incidents/ occurrences and near misses Objectives of the process are stipulated in the policy Severity is rated	Sentinel Event policy is a separate policy
Ontario Sunnybrook Health Sciences Centre	Hospital	Manager	Includes adverse medical events and unanticipated outcomes of care	n/a	Policies include accountability for patient safety, disclosure of Adverse Medical Events and Unanticipated Outcomes of Care and Patient/Visitor Incident Reporting Electronic form	Voluntary Separate policy from disclosure of AE and Patient/Visitor Incident Reporting
Ontario Trillium Health Centre	Hospital	Manager/Director	Includes all incidents	Chief of Staff Department Head Monthly report to CEO	Includes all incidents Electronic system	Voluntary
Ontario University Health Network	Hospital	Risk Management	All incidents	Internal document only Quality of Care Committee	Electronic form Includes all incidents	
PEI Department of Health	Provincial	Director of Corporate Services	Incident	Risk Management Coordinator & Occupational Health and Safety Officer	Includes all incidents	
Quebec McGill University Health Centre	Hospital	Treating physician: disclosure	Accidents	n/a		Limited to accidents Separate policy from Sentinel Events policy
Quebec McGill University Health Centre	Hospital	Risk Management	Sentinel events	Committee on Quality and Risk	Uses root cause analysis	Sentinel events only
Saskatchewan University of Saskatchewan REB	University	REB	Internal/external Serious Adverse Events	REB	Provincial Legislation	Limited to serious adverse events

APPENDIX 10
Summary of Policy Interviews Re: Barriers and Enablers

Jurisdiction	Entity	Enablers	Barriers
Alberta	Calgary Health Region	• An event must be recognized as adverse • Reporting must be confidential but not anonymous with distribution of de-identified reports • Reporting must not be punitive • Reporting should result in a change in practice • Follow up information must be available to individuals who report • Reporting must be easy and quick • Culture of trust must be established	• Failure to recognize an event as adverse is the biggest barrier • Incident reporting used to be used for performance management so staff may be reluctant to report • Legislation is perceived as a barrier and is not enforceable
BC	Providence Centre	• Non punitive • Culture of patient safety • Voluntary reporting • "good catch" program focus rather than incident or near miss • Instill a culture of reporting e.g. no duplicate of form kept on unit • Clearly identify what is reportable • Positive reinforcement through education including "safety huddles" • Aggregate data are available on a cube for reporting • Web based data collection is being developed • Reporting must be easy and quick	• Perception that data collection is time consuming • Culture barrier : fear of blame • Health disciplines other than nurses may not recognize that it is their responsibility to participate in reporting • Paper based system is a disincentive because people feel that there is no follow up and this is a disincentive to complete forms
Manitoba	Manitoba Health	• Voluntary reporting system in place from 2003 paved the way for mandatory reporting • Legislation • Face to face education to RHAs e.g. disclosure training, root cause analysis training • Lack of punishment • Standardize definition of what is to be reported • Culture of open reporting	• Adequate resource for regions especially rural regions for the amount of work; must establish Critical Incident Review Committee • Required additional education • Staff turnover made it difficult to meet new requirements • Subjective nature of critical incident varies across regions (definition is being rewritten) • Critical incident definition may overlap with other legal acts • Time frames for reporting needs to be reviewed related to resources and communication • Should have completed a Treasury Board submission to fund the initiative adequately
Newfoundland	Labrador Health Board Association	• Legislation • No blame environment • Empowerment to report something dangerous at every staff level • Report facts only • Standardize definitions	• Anxiety about liability • Commissioners who report to the House may make people nervous to report • Resource availability • Need a central agency to develop reports

Jurisdiction	Entity	Enablers	Barriers
Northwest Territories	Hay River Health and Social services Authority	• Availability of a champion to educate staff • Accreditation process includes mind set of patient safety • Leadership in organization • Development of a Quality Council • Reporting should be easy and quick • Focus on encouragement • Clear articulation of rules for disclosure	• Staff did not see follow up when an event was reported • No means of tracking each incident or resolution and no way to notify staff that something had been done • Culture of blame • Enforcement is not possible • Legislation is not important if awareness is raised e.g. through accreditation • Difficult to report near misses
Nova Scotia		• Non blaming environment; lack of punishment • Easily accessible form • Universal data collection form • Extensive education • Health care providers do not have to sign the form • Focus on QI	• Voluntary • Fear of punishment • Physician hesitation
Ontario Ministry of Health and Long-Term Care		• Patient Safety strategy is currently being drafted	
Ontario	Sunnybrook Health Sciences Centre	• Training of health care professional in a climate of patient safety • Anonymous reporting • Education programs • De-identified reports • Non disciplinary climate	• People are not well trained in patient safety • Staff may not appreciate when a patient is injured • No access to clear guidelines • Reporting process may be complicated • No change in outcome makes staff skeptical about the important of reporting • lack of commitment • lack of resources for patient safety agenda • Unsure of motives of Sr. management • Fear of consequences; professional misconduct, legal action • No incentives for reporting – no rewards
Quebec		• Well known position that senior management fully supports patient safety • Need commitment from the top • System of AE reporting must be kept separate from competency and discipline • Anonymous reporting • Must be a person in the organization that can facilitate the process of AE reporting • Legislation • Acknowledgement that incompetency is rare	• absence of a patient safety culture • lack of a team approach for patient safety puts staff in silos and they do not see the resolution of issues

Jurisdiction	Entity	Enablers	Barriers
Saskatchewan	Acute and Emergency Services Branch, Saskatchewan Health	• Legislation for critical incident reporting • Provide tools for reporting • Enthusiasm for QI • Extensive education about policy e.g. root cause analysis course • Non blaming environment • Limit to critical events • Regular collaboration with regions • Report aggregate data • Prepare and distribute Issue Alerts	• Saskatchewan was first so there were no successes to follow • Worried about backlash against legislation • Resource capacity re: workload of reporting and investigation • Reporting must be done within the confines of privacy legislation

APPENDIX 11
Adverse Event, Sentinel Events and Near Miss Reporting Survey
Acute Care Hospitals Version

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

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

Hospital

Hospital Name _____

Hospital Size - Number of acute care beds: _____

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

Reporting Systems and Analytical Tools

Definitions

Safety Occurrence Taxonomy:

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

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

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

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

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

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

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

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

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

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

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

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

Organizational Policies and Practices

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

Please check ✓ your response ☐ **YES** ☐ **NO**

If yes, please answer the following questions.

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

Please describe the specific events that your policy covers.

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

Please check ✓ your response ☐ **YES** ☐ **NO**

Please describe.

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

Please check ✓ your response ☐ **YES** ☐ **NO**

Please describe.

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

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

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

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

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

1	2	3	4	5
None	Limited Extent	Somewhat	Frequently	Always

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

1	2	3	4	5
None	Limited Extent	Somewhat	Frequently	Always

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

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

Other, please describe_____

Enablers and Barriers for Reporting

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

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

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

External

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

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

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

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

APPENDIX 12
Interview Questions For CSPI Proiect on Adverse Event Reporting

Introduction

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

Definitions

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

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

Questions

1. Is there a need for information on patient safety events or critical incidents to be shared more broadly beyond the institutions in which these events are identified?

    a. If so, what types of information?

    b. To whom should this information be reported?

    c. Should this reporting be mandatory or voluntary?

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

3. One of the critical issues in reporting is the privileging of information on patient safety events. Are the current protections in your province/state adequate to support reporting or sharing of information on patient safety events?

    a. If not, in your view is it clear what types of legislative or other protections are needed in your province/state?

    b. What is the likelihood that such protection might be established in the near term (i.e., next two to three years)?

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

5. Do you think that it would be possible to share information on patient safety events across provinces/states?

    a. What are the barriers to such sharing?

    b. Could a set of principles be established to harmonize the reporting and sharing of such information?

    c. Would you think this is likely?

6. What are other critical barriers to reporting and sharing of information on patient safety events?
    a. To what extent could these be addressed without new legislation?
    b. What resources are needed to remove these barriers?
    c. Do you think efforts to remove these barriers would be successful?
7. Some have suggested that a good first step would be the creation of a policy framework and best practices on sharing of information. Do you think this would be useful? Is it feasible? Who should take the lead?
8. A commonly stated barrier is the culture of blame that limits reporting. What do you think is needed to address this barrier?

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