Healthcare Excellence Canada | Excellence en santé Canada

Background Paper on Comprehensive Patient Safety Incident Legislation

April 25, 2024

Contents

About Healthcare Excellence Canada

Healthcare Excellence Canada (HEC) works with partners across the country to shape a future where everyone in Canada has safe and high-quality healthcare. We bring together people, evidence and action to move Care Forward - spreading and scaling quality and safety improvements, strengthening capacity and collective leadership and catalyzing change in policy and practice.

At HEC, healthcare excellence means improving safety, quality and value for everyone. It means care grounded in what matters most to patients, caregivers, communities and people in the workforce. It also means care that respects and responds to First Nations, Inuit and Métis priorities and is culturally safe, equitable and supported by the appropriate use of technology. Together with our partners, we embed these foundations across the health system.

Our work also focuses on expanding access to safe, connected, high-quality care closer to home and community. This includes supporting people with primary health care needs and older adults with health and social needs.

HEC is an independent, not-for-profit charity funded primarily by Health Canada. The views expressed herein do not necessarily represent the views of Health Canada.

150 Kent Street, Suite 200
Ottawa, Ontario, K1P 0E4, Canada
1-866-421-6933 | info@hec-esc.ca

LinkedIn | Bluesky | Instagram | Facebook

Healthcare Excellence Canada honours the traditional territories upon which our staff and partners live, work and play. We recognize that the stewardship of the original inhabitants of these territories provides for the standard of living that we enjoy today. Learn more

Introduction

This background paper builds on earlier work undertaken by the Canadian Patient Safety Institute (now Healthcare Excellence Canada) in relation to legislative requirements for mandatory reporting and mandatory disclosure of patient safety incidents, protection of quality assurance information[1], and apology protection. The chart attached as Appendix A shows the legislative provisions that are in force in all four categories (protection of quality assurance information, mandatory disclosure, mandatory reporting, and apology protection). A comprehensive paper that considers all four topics highlights the overlapping policy purposes behind the legislative initiatives and provides a foundation for the consideration of model statutory provisions. Together these topics will be referred to as "patient safety incident legislation".

This paper will consider the key policy issues and illustrate how they have been addressed by different jurisdictions across Canada. This paper will provide policy recommendations for jurisdictions that are considering future legislative development.

What are the policy purposes behind patient safety legislation?

There are a number of policy purposes that must be accommodated and reconciled when legislatures are developing or amending patient safety legislation. The key policy issues are:

- encourage healthcare professionals to share information and hold open discussions in order to lead to improvements in patient care and safety;
- promote disclosure of patient safety incidents to patients and their families;
- encourage trust in the healthcare system through transparency;
- provide a fair system for compensating patients who are harmed through patient safety incidents; and
- encourage analysis of patient safety incidents and sharing of results in order to learn from those incidents.

The investigation of patient safety incidents should assume good intentions from all parties; be

[1] There are a variety of terms used in legislation to identify committees that receive protection for confidential discussions. For example, Alberta uses the term "quality assurance committee", Saskatchewan uses the term "quality improvement committee" , Quebec uses the term "risk management committee" , while Ontario uses the term "quality of care committee." In other jurisdictions, there is no definition of "committee" but the functions of the committee are set out in the legislation (see, for example, the Evidence Act of New Brunswick or of Nova Scotia). For ease of reference, the term "quality of care committee" will be used throughout this document. In general, in order for information to be protected, it must be connected to a committee in the way that is specified in the legislation. For ease of reference, protected information will be referred to as "quality assurance information".

patient inclusive and transparent; entail an obligation to share lessons; and be consistent and predictable. Staff need to communicate effectively with patients and families before, during and after patient safety incident investigations.[2]

These are all compelling policy interests that must be carefully balanced in order to ensure that all policy objectives are achieved.[3] The policy purposes behind legislation are often examined in the legislative assembly while a bill is progressing through various readings. In some situations, these policy purposes are articulated in a preamble or purpose statement. Preambles are used to assist in explaining the purpose and objects of an enactment.[4]

As such, preambles are an important part of the statute, and help to ensure that the legislation is interpreted in a manner that facilitates the objects of the act.

The most notable example of the use of a preamble to articulate patient safety and quality of care goals is found in Ontario's Quality of Care Information Protection Act, 2016. The preamble was developed and included in the statute after extensive consultation on the Quality of Care Information Protection Act, 2004. Similarly, Ontario's Excellent Care for All Act begins with a preamble that deals with transparency and public confidence in health services.

The following legislative provisions illustrate how preambles can be used to frame the legislation and provide a tool for interpretation of patient safety legislation.

Legislative Provision

The preamble for Ontario's Quality of Care Information Protection Act, 2016 states as follows:

> *The people of Ontario and their Government:*
>
> *Believe in patient-centred health care;*
>
> *Remain committed to improving the quality of health care provided by health facilities and maintaining the safety of patients;*
>
> *Believe that quality health care and patient safety is best achieved in a manner that supports openness and transparency to patients and their authorized representatives regarding patient health care;*
>
> *Recognize that health care providers and other staff in health facilities sometimes need to hold confidential discussions to identify and analyze errors affecting patients, systemic problems and opportunities for quality improvement in patient health care;*
>
> *Believe that protections are needed to encourage and enable health care providers and*

---

[2] Quality of Care Information Protection Act (QCIPA) Review Committee. (2014). QCIPA Review Committee Recommendations. Retrieved from: http://www.health.gov.on.ca/en/common/legislation/qcipa/docs/qcipa_rcr.pdf.

[3] Louise Bélanger-Hardy & Caroline Quesnel, "Patient Safety Incidents and Protection of Quality Assurance Activities: Legislative and Jurisprudential Responses in Canada" (2016) 9:1 McGill JL & Health 69, at 77.

[4] See, for example, Interpretation Act, RSBC 1996, c 238, s. 9; Interpretation Act, RSC 1985, c I-21, s. 13; Interpretation Act, RSNB 1973, c I-13, s. 15; Interpretation Act, R.S.O. 1990, c.I.11, ss 8, 10.

other staff of health facilities to share all available information, provide honest assessment and opinions and participate in discussions to improve patient health care without fear of retaliation;

Believe that sharing information about critical incidents and quality improvement helps to improve the quality of health care for patients;

Are committed to ensuring that measures to facilitate the sharing of information for quality improvement purposes do not interfere with the right of patients and their authorized representatives to access information about their health care or with the obligations of health facilities to disclose such information to patients and their authorized representatives; and

Affirm that the inclusion of patients and their authorized representatives in the process of reviewing a critical incident helps to improve patient care, and therefore quality of care information protection must be implemented in a manner that supports such inclusion.

The preamble for Ontario's Quality of Care Information Protection Act, 2016 states as follows:

The people of Ontario and their Government:

Believe in patient-centred health care;

Remain committed to improving the quality of health care provided by health facilities and maintaining the safety of patients;

Believe that quality health care and patient safety is best achieved in a manner that supports openness and transparency to patients and their authorized representatives regarding patient health care;

Recognize that health care providers and other staff in health facilities sometimes need to hold confidential discussions to identify and analyze errors affecting patients, systemic problems and opportunities for quality improvement in patient health care;

Believe that protections are needed to encourage and enable health care providers and other staff of health facilities to share all available information, provide honest assessment and opinions and participate in discussions to improve patient health care without fear of retaliation;

Believe that sharing information about critical incidents and quality improvement helps to improve the quality of health care for patients;

Are committed to ensuring that measures to facilitate the sharing of information for quality improvement purposes do not interfere with the right of patients and their authorized representatives to access information about their health care or with the obligations of health facilities to disclose such information to patients and their authorized representatives; and

Affirm that the inclusion of patients and their authorized representatives in the process of reviewing a critical incident helps to improve patient care, and therefore quality of care information protection must be implemented in a manner that supports such inclusion.

Policy Recommendations

Include a preamble in the statute that clearly articulates the policy goals for patient safety incident legislation. The preamble for Ontario's *Quality of Care Information Protection Act*, 2016 serves as a good model and template for other jurisdictions.

Cultural Safety

The *Health Authority Act* (Bill 38) was introduced in the Yukon legislature on March 11, 2024 and received second reading on March 26, 2024.[5] On March 19, 2024, the Council of Yukon First Nations passed a resolution in support of the legislation, and noted in a news release that the *Health Authority Act* was co-developed with Yukon First Nations.[6]

Bill 38 introduces the concept of cultural safety as part of patient safety. Specifically, Division 3 of the *Health Authority Act* deals with Quality Assurance, Patient Safety and Cultural Safety. Sections 42-44 provide as follows:

42 Quality assurance and patient safety

(1) Subject to the regulations, the health authority must establish and maintain a quality assurance and patient safety framework, consistent with the health authority's purposes, the goals of which are improvement in

(a) the quality of health and social services provided by the health authority; and

(b) the safety of patients.

(2) The quality assurance, patient safety and cultural safety committee established under paragraph 25(1)(b) must oversee implementation of the framework.

(3) The framework must include cultural safety as a component of quality assurance and patient safety.

(4) The framework may include policies, procedures, protocols and other mechanisms to achieve its goals.

(5) The framework must include complaint procedures and response and reporting protocols.

(6) Subject to this section, the health authority may amend the framework from time to time.

(7) Before establishing or amending the framework, and subject to the timeline set out in subsection 71(4), the health authority must consult with the Yukon First Nations' health committee.

---

[5] https://yukonassembly.ca/sites/default/files/2024-03/35-1-bill038-health-authority-act.pdf.
[6] NEWS RELEASE: CYFN and the Chiefs Committee on Health Support Health Authority Legislation; March 20, 2024, https://cyfn.ca/news-release-cyfn-and-the-chiefs-committee-on-health-support-health-authority-legislation/.

(8) Before establishing or amending the framework, the health authority must seek input from

(a) employees of the health authority and medical staff, or their labour unions or representatives; and

(b) any other persons as considered appropriate by the health authority or as may be prescribed in the regulations.

(9) In implementing the framework, the quality assurance, patient safety and cultural safety committee must provide for periodic feedback from

(a) the Yukon First Nations' health committee;

(b) employees of the health authority and medical staff, or their labour unions or representatives; and

(c) any other persons as considered appropriate by the health authority or as may be prescribed in the regulations.

43 Cultural safety — board training

(1) All members of the board must undertake a cultural safety and cultural humility training program, as determined by the Minister, so that they fulfill their responsibilities and duties in a culturally safe manner.

(2) Before the Minister determines the cultural safety and cultural humility training program for the board members, and subject to the timeline set out in paragraph 71(2)(e), the Minister and the Yukon First Nations' health committee must make reasonable efforts to reach consensus on the training program and, in doing so, must take into consideration input received under subsection (3).

(3) In determining the training program for the board members under subsection (1), the Minister must seek input from other persons or representatives of groups that are impacted by issues of cultural safety and cultural humility in relation to the delivery of health and social services.

44 Cultural safety — framework

(1) Subject to the regulations, the health authority must establish and maintain a cultural safety framework, consistent with the purposes of the health authority, the goals of which are

(a) respectful engagement with people receiving health and social services from the health authority and their families, that recognizes and strives to address power imbalances inherent in the delivery of health and social services;

(b) an environment free from all forms of racism, including anti-Indigenous racism, and free from discrimination, where people receiving health and social services from the health authority and their families, feel safe; and

(c) care that is culturally inclusive.

(2) The quality assurance, patient safety and cultural safety committee established under paragraph 25(1)(b) must oversee implementation of the framework.

(3) The framework may include policies, procedures, protocols and other mechanisms to achieve its goals.

(4) The framework must

(a) include provisions respecting the prevention of racism and discrimination in the provision of health and social services by the health authority;

(b) include provisions for the training of employees of the health authority and medical staff on cultural safety and cultural humility;

(c) be culturally sensitive and reflect the perspectives of those most impacted by issues of cultural safety in relation to the delivery of health and social services;

(d) include provisions to raise awareness of cultural safety issues within the health authority;

(e) include provisions to raise awareness of the framework within the health authority and with people receiving health and social services from the health authority and their families;

(f) include complaint procedures and response and reporting protocols;

(g) include provisions related to accountability for implementation of the framework; and

(h) meet any prescribed requirements with respect to the development, content and publication of the framework.

(5) Subject to this section, the health authority may amend the framework from time to time.

(6) Before the health authority establishes or amends the cultural safety framework, and subject to the timeline set out in paragraph 71(5)(b), the health authority and the Yukon First Nations' health committee must make reasonable efforts to reach consensus on the framework or the amendment and, in doing so, must take into consideration input received under subsection (7).

(7) In establishing or amending the cultural safety framework, the health authority must seek input from

(a) persons or representatives of groups that are impacted by issues of cultural safety in relation to the delivery of health and social services by the health authority;

(b) employees of the health authority and medical staff, or their labour unions or representatives; and

(c) any other persons as considered appropriate by the health authority or as may be prescribed in the regulations.

(8) In implementing the framework, the quality assurance, patient safety and cultural safety committee must provide for periodic feedback from

(a) the Yukon First Nations' health committee;

(b) persons or representatives of groups that are impacted by issues of cultural safety in relation to the delivery of health and social services;

(c) employees of the health authority and medical staff, or their labour unions or representatives; and

(d) any other persons as considered appropriate by the health authority or as may be prescribed in the regulations.

Further details will be included in the regulations that have yet to be developed.

Policy Recommendation

Consider including cultural safety as a component of quality assurance and patient safety.

Mandatory Reporting of Patient Safety Incidents

Introduction

There are a number of different strategies that are used to promote patient safety through communication about patient safety events. The term "disclosure" is generally used to describe advising those who are impacted by a patient safety event. In addition to those who are directly impacted by the patient safety event, the public may be informed about the event.[7] The term "reporting" is focused on advising third parties (e.g. regional health authorities, governments, accreditation bodies) generally about adverse events. This type of reporting to third parties may be combined with public reporting.

- The World Health Organization published "Draft Guidelines for Adverse Event Reporting and Learning Systems" in 2005 ("WHO Guidelines").[8] The four core concepts underlying the WHO Guidelines are:

---

[7] See, for example, Alberta heart patients warned of exposure risk to bacteria during surgery, CBC News, December 1, 2016, https://www.cbc.ca/news/canada/edmonton/alberta-heart-patients-warned-of-exposure-risk-to bacteria-during-surgery-1.3876372.

[8] World Alliance for Patient Safety. 2005. World Health Organization Draft Guidelines for Adverse Event Reporting and Learning Systems: From Information to Action. Geneva: World Health Organization ("WHO Guidelines"), page 4.

- The fundamental role of patient safety reporting systems is to enhance patient safety by learning from failures of the health-care system.
- Reporting must be safe. Individuals who report incidents must not be punished or suffer other ill effects from reporting.
- Reporting is only of value if it leads to a constructive response. At a minimum, this entails feedback of findings from data analysis. Ideally, it also includes recommendations for changes in processes and systems of healthcare.
- Meaningful analysis, learning, and dissemination of lessons learned require expertise and other human and financial resources. The agency that receives reports must be capable of disseminating information, making recommendations for changes, and informing the development of solutions.

The following factors are identified in the WHO Guidelines as benchmarks for successful reporting systems:

- Non-punitive: Reporters are free from fear of retaliation against themselves or punishment of others as a result of reporting.
- Confidential: The identities of the patient, reporter, and institution are never revealed.
- Independent: The reporting system is independent of any authority with power to punish the reporter or the organization.
- Expert analysis: Reports are evaluated by experts who understand the clinical circumstances and are trained to recognize underlying system failures.
- Timely: Reports are analyzed promptly and recommendations are rapidly disseminated to those who need to know, especially when serious hazards are identified.
- Systems-oriented: Recommendations focus on changes in systems, processes, or products, rather than targeting individual performance.
- Responsive: The agency that receives reports is capable of disseminating recommendations. Participating organizations commit to implementing recommendations whenever possible.

There are differing perspectives on whether mandatory reporting legislation facilitates learning. Baker and Norton completed a review of patient safety initiatives elsewhere in the world and provided recommendations for initiatives within Canada. They recommended the development of better reporting systems, and stated as follows: "*Legislation change could enhance the reporting of errors and near misses and should be encouraged and supported."*[9] In contrast, a recent report of

[9] Baker, G.R., Norton, P.G., Flintoft, W., Blais, R., Brown, A., Cox, J., et al. (2004). The Canadian Adverse Events Study: The incidence of adverse events among hospital patients in Canada. CMAJ, 170 (11), 1678-1686, http://www.cmaj.ca/content/170/11/1678.

the Health Quality Council of Alberta suggests that the primary objective behind mandatory reporting systems is accountability and states as follows:

> *Reporting involves sharing information with appropriate responsible individuals or organizations for the purpose of system improvement. Reporting systems can be created for one of two primary objectives: accountability or learning. Accountability systems usually employ mandatory reporting. In contrast, when learning is the primary purpose, reporting is voluntary and without repercussions to the reporter*.[10]

The focus of this section is on mandatory reporting, and in particular legislative schemes in Canada that address mandatory reporting. In 2019, CPSI released Strengthening Commitment for Improvement Together: A Policy Framework for Patient Safety. The paper explains the overall goal as follows:

> *This Policy Framework will advance the agenda on patient safety in Canada as CPSI takes its place in the policy arena. CPSI proposes that several levers be used and evaluated to improve patient safety including legislation, professional regulation, standards, organizational policies and public engagement. The Policy Framework is based on a model of continuous improvement and knowledge exchange to support the development of effective, adaptable and evidence-based policies at different levels across Canadian healthcare system.*[11]

The policy levers noted in the Policy Framework are envisioned to improve patient safety in Canada and ultimately lead to the overall CPSI vision of Canada having the safest care in the world. Legislation was identified as one of the policy levers: "Provincial and territorial Health Ministries advance patient safety through legislation that ensures transparency in the reporting and disclosure of patient safety incidents, apology and quality assurance processes, and public reporting." As such, legislation may be a significant policy lever to improve patient safety in Canada. The implementation of mandatory reporting legislation has occurred unevenly with some provinces having comprehensive legislation in place for more than a decade (e.g. Saskatchewan, Manitoba, and Quebec) while other jurisdictions have no legislation at this time. Some jurisdictions address reporting requirements through policy initiatives. As an example, Nova Scotia has implemented a mandatory reporting system through the adoption of a policy.[12] Alberta Health Services (AHS) has an organization-wide Reporting and Learning System (RLS) for staff to report adverse events, close calls, or potential hazards, and reporting by practitioners is voluntary.[13]

---

[10] Health Quality Council of Alberta, Healthcare Quality and Safety Management: A Framework for Albertans, Calgary, Alberta, Canada: Health Quality Council of Alberta, July 2017.
[11] Canadian Patient Safety Institute. Strengthening Commitment for Improvement Together: A Policy Framework for Patient Safety. Edmonton, Alberta; 2019.
[12] Nova Scotia Health and Wellness Serious Reportable Event Interim Reporting Policy, Effective December 22, 2013, https://novascotia.ca/dhw/hsq/serious-reportable-events.asp.
[13] Alberta Health Services, "Adverse Events and Patient Safety", https://www.albertahealthservices.ca/medstaff/Page8393.aspx.

There are also mandatory reporting laws at the federal level. The *Protecting Canadians from Unsafe Drugs Act* (also known as Vanessa's Law) received royal assent on November 6, 2014.[14]

The goals of Vanessa's Law are set out in the statute as follows:

- to strengthen safety oversight of therapeutic products throughout their life cycle;
- to improve reporting by certain healthcare institutions of serious adverse drug reactions and medical device incidents that involve therapeutic products; and
- to promote greater confidence in the oversight of therapeutic products by increasing transparency.

Vanessa's Law is being brought into force in stages. Some of the amendments to the *Food and Drugs Act* came into force at the time that Vanessa's Law received Royal Assent. These amendments include:

- the ability of the Minister to compel information when the Minister believes that a therapeutic product may present a serious risk of injury to human health (s. 21.1);
- the ability of Minister to order label change or package modification if necessary to prevent injury to health (s. 21.2);
- the ability to recall unsafe therapeutic products (s. 21.3); and
- stronger fines and penalties for contravention of the Act (ss. 31, 31.2, 31.4).

In addition, there were provisions in Vanessa's Law that could not be brought into force until regulations were in place to support them.[15]

Regulations relating to mandatory reporting are being brought into force in stages. In June 2017 Health Canada released a Consultation Paper to inform the design of the regulations relating to the obligations of healthcare institutions to report serious adverse drug reactions and medical device incidents.[16] The Consultation Paper states that the following key principles should be applied in developing a mandatory reporting approach for healthcare institutions:

- enable the capture of meaningful, quality data;
- minimize burden on healthcare institutions and the healthcare system;
- where possible, leverage existing processes, systems or technology; and
- be effectively implemented by Health Canada and be sustainable.

---

[14] Protecting Canadians from Unsafe Drugs Act (Vanessa's Law), SC 2014, c. 24. Vanessa's Law amends the Food and Drugs Act, RSC 1985, c. F-27.

[15] For example, in April 2018 regulations came into force that allow the Minister to: direct a manufacturer to conduct tests and studies or gather information; order a manufacturer to conduct a reassessment of a drug; and require manufacturers to provide Health Canada with information about risk communications and other safety related activities in other countries. These powers allow the Minister to decide whether this is a significant change to the safety profile of a product.

[16] Toward Mandatory Reporting of Serious Adverse Drug Reactions and Medical Device Incidents by Health Care Institutions, Health Canada, June 2017.

Common Characteristics of the Legislation

This section of the paper will contain a discussion of the following common characteristics of mandatory reporting legislation:

- What events are reportable
- People who report
- Recipient of the report
- The contents of the report
- Timing of the report
- Protection of reporters
- Protection of information generated through the investigating and reporting of critical incidents.

What events are reportable?

The question of what must be reported varies from jurisdiction to jurisdiction. In CPSI's Canadian Disclosure Guidelines, CPSI encouraged use of the following "preferred terms for consistency and clarity":

> **Patient safety incident**: An event or circumstance which could have resulted, or did result, in unnecessary harm to a patient.
>
> **Harmful incident**: A patient safety incident that resulted in harm to the patient. Replaces "adverse event".
>
> (Example: The wrong unit of blood was infused and patient died from a haemolytic reaction.)
>
> **No harm incident**: A patient safety incident which reached a patient but no discernable harm resulted.
>
> (Example: The wrong unit of blood was infused, but was not incompatible.)
>
> **Near miss**: A patient safety incident that did not reach the patient. Replaces "close call."
>
> (Example: A unit of blood was being connected to the wrong patient's intravenous line, but this was detected before the infusion started.)[17]

[17] Disclosure Working Group. Canadian disclosure guidelines: being open and honest with patients and families. Edmonton, AB: Canadian Patient Safety Institute; 2011, page 22.

These suggestions were based on work that was undertaken by the World Health Organization to develop a conceptual framework for patient safety.[18]

The terminology in mandatory reporting legislation is not consistent, and the same term is defined differently. British Columbia requires the reporting of "serious adverse events". Saskatchewan, Manitoba, Ontario and the Northwest Territories require reporting of "critical incidents", but there are variations in the definition in different jurisdictions. Quebec requires reporting of "accidents" and "incidents". New Brunswick requires reporting of "patient safety incidents". Newfoundland and Labrador require reporting of "adverse health events", "close calls", and "occurrences".

In general, the event must be "unintended" or not expected to occur (e.g. Manitoba, Ontario, Newfoundland / Labrador, New Brunswick, British Columbia). The most severe events are subject to mandatory reporting, such as death or disability. Psychological injuries are specifically included in some jurisdictions, such as British Columbia. In some jurisdictions, the undesired consequences are extended to include unplanned admission to hospital or unusual extension of a hospital stay (e.g. Manitoba, Northwest Territories).

In some jurisdictions, the definition of critical incident appears to require the reporting of "near misses". For example, in Saskatchewan "critical incident" is defined to include the actual "or potential" loss of life, limb or function. In contrast, in Manitoba the definition of "critical incident" requires that the event result in consequences that are serious and undesired.

In other jurisdictions, different terms are used to make it clear that "near misses" are included. As an example, the *Patient Safety Act* for Newfoundland and Labrador defines the term "close call" to mean a potential occurrence that "did not actually occur due to chance, corrective action or timely intervention." In Quebec, a distinction is made between "accident" and "incident". Both are reportable, and both appear to include "near misses" (e.g. accident is defined to include a situation which "has or could have consequences", and incident is defined to include a situation that does not have consequences but "the outcome of which is unusual and could have had consequences under different circumstances...").

Legislative Provision

New Brunswick – Health Quality and Patient Safety Act

"patient safety incident" means an unintended event that

> *(a) occurs when health services are received by a patient, and*
>
> *(b) contributes to or results in, or could have contributed to or resulted in, harm to the patient or the death of the patient.*

---

[18] World Health Organization. World Alliance for Patient Safety. More than words: Conceptual Framework for the International Classification for Patient Safety. Geneva: World Health Organization; 2009 Jan. 154 p. Report No.: WHO/IER/PSP/2010.2. Available from: https://iris.who.int/bitstream/handle/10665/70882/WHO_IER_PSP_2010.2_eng.pdf?sequence=1&isAllowed=y

Policy Recommendation

Legislation should require reporting of all patient safety incidents, with an expanded view of harm, including those where an unintended event could have contributed to or resulted in harm to the patient or death (such as “near misses” or “good catches”).

People who Report

Mandatory reporting legislation stipulates the person or entity that is responsible for the preparation of the report, such as the organization or health services providers. As well, some legislation provides that patients and their relatives may submit reports. There is broad agreement that patients and relatives should be able to submit reports. The following arguments were put forward in a report prepared by Health Quality & Safety Commission New Zealand:[19]

Patients and relatives are a potentially rich resource for learning and improving patient safety. Patients can provide timely and important information about the safety of care that complements information recorded in staff reporting systems.

- Patients can report safety incidents that would otherwise go undetected.
- Patients may be in a better position than their caregivers to identify failures in handovers and gaps between providers across the continuum of care.
- A patient may experience an injury that is not obvious until after they are discharged from a hospital and therefore no one other than the patient or relative could report it.
- Patients are highly motivated to report errors or problems in their care. They are often experts in their disease and health condition and eager to participate in developing interventions to prevent clinical incidents.

The Manitoba *Health System Governance and Accountability Act* provides for notification of a critical incident by the individual who received health services; a relative of the individual; or an individual working at or for the health authority, the health corporation or the prescribed healthcare organization. The health authority, the health corporation or the prescribed healthcare organization must determine if a critical incident occurred, and if so, it must ensure that the incident is investigated and reported. Ultimately, the health authority must provide a written report to the Health Minister upon completion of the critical incident review committee’s investigation.

Legislative Provision

Manitoba – The Health System Governance and Accountability Act

Critical incident: health authority

---

[19] Health Quality & Safety Commission New Zealand. 2016. Patient safety reporting systems: A literature review of international practice, page 19.

53.4(1) *If a critical incident occurs when health services are provided to an individual by a health authority, the authority must promptly*

(a) notify the minister about the critical incident; and

(b) establish a critical incident review committee to investigate and report respecting the critical incident.

Investigation and reports of review committee

53.4(2) *A critical incident review committee established under subsection (1) must, in accordance with the health authority's directions,*

(a) investigate the critical incident and, during the investigation, provide information and reports to the authority as requested; and

(b) upon completing the investigation, report its findings and recommendations to the authority in writing.

Reports to minister

53.4(3) *The 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.*

Critical incident: notification by others

53.4.1(1) *Any of the following who believes that a critical incident has occurred in respect of health services provided to an individual may notify the health corporation, prescribed health care organization or health authority which provided the health services:*

(a) the individual himself or herself;

(b) a relative of the individual;

(c) an individual working at or for the health authority, the health corporation or the prescribed health care organization.

Action where notification received

53.4.1(2) *Promptly upon being notified under subsection (1), the health corporation, prescribed health care organization or health authority must determine if a critical incident occurred.*

Review committee provisions apply

53.4.1(3) *If the health corporation, prescribed health care organization or health authority determines that a critical incident has occurred, it must ensure that the incident is investigated and reported on, and sections 53.3 and 53.4 apply, with necessary changes.*

Policy Recommendation

The legislation should specify who is required to prepare and submit the report following a patient safety incident. The reporting should be mandatory when a patient safety incident occurs. Individuals who received the health service and / or their family should be permitted to give

notification of a patient safety incident. In those circumstances, reporting is not mandatory by the patient and / or their family, but the recipient of the report should be required to take certain actions in order to conduct an assessment and act on the notification.

Recipient of Report

There are a variety of entities that a report must be sent to. In some legislation, the requirement is to submit an internal report. For example, the New Brunswick *Health Quality and Patient Safety Act* stipulates that a healthcare organization's quality of care and safety of patients committee must, following a review of a patient safety incident, report the relevant facts of the incident and its recommendations to the board of directors of the healthcare organization for the purposes of improving the quality of healthcare and the safety of patients and to prevent the occurrence of similar incidents. In Ontario, critical incidents must be disclosed to the medical advisory committee and administrator. In other jurisdictions, the requirement is to submit an external report. For example, the British Columbia Hospital Act Regulation requires that a serious adverse event be reported to the Health Minister, by either the chief administrative officer of a public hospital or the licensee of a private hospital. Some jurisdictions, such as Saskatchewan, have a requirement to submit reports internally and externally.

As noted in the WHO Guidelines, reporting is only of value if it leads to a constructive response. Research shows that a crucial step to learn from incident reporting is about "closing the loop" between reporting and feedback for learning.[20]

> *Feedback cannot just be a passive dissemination of information if it is to become a meaningful portion of the overall improvement project. It is instead better understood as an active process of communication which sustains a continuous cycle of learning, reporting, and learning. Feedback also plays a role in establishing accountability, as staff are more likely to report incidents when they are certain that it will be reviewed and acted upon.*

The EU Patient Safety and Quality of Care Working Group also emphasized the importance of ensuring that analysis occurs at different levels and that recommendations are communicated.[21]

> *In seeking to improve safety, one of the most frustrating aspects for both patients and professionals is the apparent failure of healthcare systems to learn from their mistakes. It is very important that healthcare providers and organizations share what they have learned when an investigation has been carried out. It is a great opportunity to share lessons learned as widely as possible in order to improve healthcare. Health professionals should immediately report any accident or incident and to that end, it is needed that there is*

---

[20] NIHR Imperial Patient Safety Translational Research Centre. 2016. NRLS Research and Development. A report prepared for NHS England, pages 18-19. www.imperial.ac.uk/media/imperial-college/institute-of-global-health innovation/IMPJ4219-NRLS-report_010316-INTS-WEB.pdf.

[21] European Commission, Patient Safety and Quality of Care working group. 2014. Key findings and recommendations on Reporting and learning systems for patient safety incidents across Europe. Report of the Reporting and learning subgroup of the European Commission PSQCWG, page 13, http://buonepratiche.agenas.it/documents/More/8.pdf.

> *a reporting and learning system in place and a no-blame culture in relation to reporting injuries at their workplace.*

We have to avoid the recurrence of mistakes in different settings exposing patients to harm or risk of harm from preventable errors.

> *One way to solve this problem is reporting, analyzing the data and developing specific measures. Reporting should come through healthcare providers, patients, and relatives to their local healthcare organization, and by the organization to a broader audience through a regional or nationwide reporting system.*

Despite the importance of "closing the loop" between reporting and feedback, there is very little guidance in the legislation regarding what must be done by the external entity that receives the report. In Quebec, the Health Minister is required to establish and maintain a national register of incidents and accidents 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.

Legislative Provision

Quebec – An Act Respecting Health Services and Social Services

***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;

Policy Recommendation

Reporting of patient safety incidents can come through healthcare providers, patients, and relatives to their local healthcare organization, and by the organization to a broader audience through a provincial or national reporting system. The organizations that are the recipients of the report should be required to act on them through analysis and dissemination of results (findings and recommendations for system improvement).

The contents of the report

Highly structured reporting helps with data analysis. Narrative reporting can capture context, allowing the conditions that contributed to the patient safety event to be better understood.

Jurisdictions vary in the level of detail that is prescribed in the legislation for the contents of the report. In Quebec accidents and incidents must be reported “in the form provided for such purposes.” In others, the contents of the report are specified in the legislation itself (e.g. Alberta’s legislation provides that the report must contain the date, time, place and nature of the incident; the name and age of the client affected; the names of any witnesses to the incident; and the action taken or planned).

Legislative Provision

Northwest Territories – Hospital Insurance and Health and Social Services Administration Act

> *25.3(6) An investigator shall, in accordance with the regulations, prepare a written report of the critical incident investigation and include any recommendations that the investigator considers appropriate.*

Critical Incident Reporting and Investigation Regulations

3. (1) A report required under subsection 25.3(6) of the Act must include

(a) a complete description of the circumstances and facts that led to the critical incident or alleged critical incident;

(b) an analysis of whether or not a critical incident occurred;

(c) if the investigator finds that a critical incident occurred, a statement identifying any current practice, procedure or factor involved in the provision of the health or social services or the operation of the program that

(i) caused or 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; and

(d) an appendix containing any recommendations arising from the investigation.

Policy Recommendation

It is helpful when the contents of the reports at all levels are specified. The report to the Health Minister or other centralized body with authority for analysis and dissemination of results should contain the following information: a complete description of the circumstances and facts; an analysis of whether or not a patient safety incident occurred; a statement identifying any current practice, procedure or factor that caused or contributed to the occurrence of the patient safety incident and if corrected or modified, may prevent the occurrence of a similar critical incident in the future; and any recommendations.

Timing of the report

The timing of the report varies. For example, in British Columbia the report must be made immediately after the adverse event occurred. In Manitoba, steps must be taken "promptly" (e.g. if a critical incident occurs when health services are provided by a health corporation or a prescribed healthcare organization, the corporation or organization must "promptly" notify the health authority, and the health authority must notify the Health Minister "promptly" upon being notified about the critical incident).

Legislative Provision

Northwest Territories - Critical Incident Reporting and Investigation Regulations

2(2) A notice referred to in subsection (1) must be given within three business days, or as soon as possible after the day

(a) the critical incident occurs or allegedly occurs; or

(b) The Territorial board of management or Board of Management, as applicable, becomes aware of the critical incident or alleged critical incident.

(3) For the purposes of subsection (1), notice may be given

(a) orally by telephone or in person; or

(b) in writing, including by fax or email.

(4) If notice is given orally, written notice must also be given within five days of the original notice.

Policy Recommendation

The timing of the initial report should be specified, as well as the timing of the report to the Health Minister or other centralized body with authority for analysis and dissemination of results.

Protection of Reporters

The WHO Guidelines identify as one of the characteristics of successful patient safety reporting systems that reporters are free from fear of retaliation against themselves or punishment of others as a result of reporting. There is an important role for legislation in this regard. This type of

protection "enables sanction-free reporting and is crucial for the willingness of healthcare professionals to report."[22]

The Newfoundland and Labrador Report of the Task Force on Adverse Health Events notes as follows in relation to protection of reporters:

> *To encourage reporting within RHAs, there must be no doubt that it is a supported and valued activity. All employees and managers must understand that reporting an occurrence is a learning opportunity that the organization rewards, and there are no reprisals or repercussions when a report is filed. Legislative protection of employees can emphatically make this statement.*[23]

The *Patient Safety Act* for Newfoundland and Labrador provides that a person shall not dismiss, suspend, demote, harass or otherwise disadvantage or penalize a healthcare provider who reported a close call or an occurrence.[24]

Similar protection is provided in some jurisdictions, for example the Manitoba *Health System Governance and Accountability Act* protects from retaliation a person who has complied with a requirement to provide information related to the reporting of a critical incident.[25]

Policy Recommendation

The legislation should protect reporters from retaliation, and provide that a person shall not dismiss, suspend, discipline, demote, harass or otherwise disadvantage or penalize an individual who has reported a patient safety incident.

Protection of Patient Safety Incident Information

There are several types of legislative provisions that are used to protect patient safety incident information. First, in some jurisdictions there is a requirement that reports do not contain information that identifies patients and / or health services providers.[26] Second, legislation may clarify that patient safety incident information cannot be accessed through public sector freedom of information and / or health information legislation.[27] Third, some jurisdictions have created laws to protect patient safety incident reports from being used in legal proceedings similar to the types of laws that are used to protect quality assurance information.

---

[22] European Commission, Patient Safety and Quality of Care working group. 2014. Key findings and recommendations on Reporting and learning systems for patient safety incidents across Europe. Report of the Reporting and learning subgroup of the European Commission PSQCWG, page 28, http://buonepratiche.agenas.it/documents/More/8.pdf.
[23] Newfoundland and Labrador Report of the Task Force on Adverse Health Events, December 2, 2008, page 53, para. 4.1.4, https://www.gov.nl.ca/ahe/AEHealthReport.pdf.
[24] Patient Safety Act, S.N.L. 2017, c. P-3.01, s 11.
[25] The Health System Governance and Accountability Act, C.C.S.M. c. H26.5, s. 53.4.
[26] See, for example, Critical Incident Regulations, 2023, R.R.S. c. P-30.3 Reg. 2.
[27] See, for example, Health Quality and Patient Safety Act, SNB 2016, c 21, ss 5-6.

The WHO Guidelines identify as one of the characteristics of successful patient safety reporting systems that the identities of the patient, reporter and institution are never revealed. Research shows that systems should preserve anonymity without compromising learning.[28]

Anonymity or confidentiality may be assured at different stages of the process.[29]

> *There are various ways to keep incidents confidential and anonymous. In some reporting systems, the person reporting is fully anonymous throughout the process; in others, there is a manual or automatic anonymization after having made a first analysis. In still other systems, anonymization is implemented on transfer to the central system. In some Member States, the patient's identity is kept anonymous, while the reporter's identity is stored but confidentiality of the identity is secured.*

In Saskatchewan, the regulations state that when a provincial health authority submits a report about a critical incident to the Health Minister, the report shall not include any information that would be reasonably expected to identify: any individual to whom the critical incident relates; any healthcare provider involved in providing health service to the individual or in operating a program to which the critical incident relates; or any other person who has knowledge of the critical incident.[30]

The WHO Guidelines identify as one of the characteristics of successful patient safety reporting systems that the reporting system is independent of any authority with power to punish the reporter. There is an important role for legislation in this regard as legislation can protect the data from incident reports from being used in court or other legal actions.[31] This protection is distinct from the protection that is provided to quality assurance information. Provisions in provincial and territorial statutes have been used to protect quality assurance information, usually through the establishment of quality of care committees. However, information regarding the investigation of patient safety incidents may be protected, regardless of whether or not it falls within the strict parameters of legislation protecting quality assurance information.

In Saskatchewan, information regarding the investigation of critical incidents is protected from disclosure. These provisions were examined by the Court of Queen's Bench for Saskatchewan in a 2015 decision *Pryznyk v Gilliland*.[32] The Saskatoon Regional Health Authority ("SRHA") had disclosed a Critical Incident Report to the plaintiffs. The SRHA requested that the Critical Incident Report be ruled inadmissible in further proceedings. The court declared that the

---

[28] NIHR Imperial Patient Safety Translational Research Centre. 2016. NRLS Research and Development. A report prepared for NHS England, page 16, www.imperial.ac.uk/media/imperial-college/institute-of-global-health innovation/IMPJ4219-NRLS-report_010316-INTS-WEB.pdf.)

[29] European Commission, Patient Safety and Quality of Care working group. 2014. Key findings and recommendations on Reporting and learning systems for patient safety incidents across Europe. Report of the Reporting and learning subgroup of the European Commission PSQCWG, page 26, http://buonepratiche.agenas.it/documents/More/8.pdf.

[30] Critical Incident Regulation, 2023, R.R.S. c. P-30.3 Reg. 2, s. 5.

[31] Ibid, page 28.

[32] Pryznyk v Gilliland, 2015 SKQB 285 (CanLII). The court was examining provisions in the Regional Health Services Act, SS 2002, c R-8.2, s 58, which has since been repealed and replaced by The Provincial Health Authority Act, SS 2017 c P-30.3. However, the provisions protecting information generated as a result of critical incident notices and investigations remain the same.

Critical Incident Report was inadmissible in evidence in any further proceedings and stated as follows:

> *[23] As pointed out by counsel for the SRHA, the critical incident reporting legislation, unlike the quality improvement committee legislation in s. 10 of The Evidence Act, does not require that the investigation be carried out by any particular committee or person, nor does it require that the investigation be exclusively for the purpose of reporting to the Minister. It simply requires that a critical incident be investigated.*
>
> *[…]*
>
> *[25] The suggestion that a critical incident can only become such after it is formally designated as such is not accepted….*
>
> *[…]*
>
> *[27] The purpose of the critical incident reporting legislation is to ensure that all critical incidents are investigated and reported to the Minister. The reporting requirements require that a health authority do an evaluative investigation directed at determining what went wrong, if anything, and recommendations on how such an incident can be avoided in the future. Cooperation and candidness on the part of healthcare providers involved in any such incident are critical to the success of the mandate set out in the legislation. The legislation clearly contemplates that legal proceedings can result from a critical incident. It is equally clear that the legislature decided a critical incident investigation and reporting requirements should not be the subject of questioning in such legal proceedings. The legislation leaves the parties free to pursue legal proceedings in the normal course. It leaves the parties free to utilize information contained in any portion of a critical incident report made available to the parties. What it does not allow is questioning with reference to the report itself.*

As such, protection for materials associated with the investigation of a critical incident is much broader, although the underlying policy rationale is similar to the reasons for the protection of quality assurance information.

The underlying policy rationale for protection of materials associated with the investigation of critical incidents was emphasized in a subsequent decision of the Saskatchewan Court of Queen's Bench.[33]

> *[40] These statutory critical incident reviews do not come about as a result of concerns about the type or quality of patient care delivered by doctors or nurses. Rather, the result or outcome for the patient is assessed to determine if the matter qualifies as a critical incident, and a review is required. Such incidents are reported to the Ministry of Health and there is public reporting.*
>
> *…*
>
> *[41] The holding of a critical incident review does not connote any wrongful act or omission on the part of any members of the patient care team. It is, rather, a part of the process by*

[33] Abouhamra v Prairie North Regional Health Authority, 2016 SKQB 293.

which health authorities evaluate their delivery of care to determine if adequate standards are being met, or how things could be improved.

They are designed to be collaborative in nature. They are not punitive. The reports emanating from such reviews are privileged ….

The *Manitoba Evidence Act* also protects critical incident information from being used in a legal proceeding. Sections 9(2) and 9(3) state:

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 health authority under section 53.3 or 53.4 of The Health System Governance and Accountability 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.[34]

Section 9(4) excludes from protection the personal health information contained in the records, the facts as to what occurred with respect to the critical incident, and certain other records mandated by law.[35]

The Northwest Territories' *Hospital Insurance and Health and Social Services Administration Act* was amended in 2016 to include provisions concerning the protection of critical incidents investigations.

Section 25.5(2) of the *Hospital Insurance and Health and Social Servies Administration Act* states:

25.5(2) Subject to subsection (4), a witness to a legal proceeding, whether a party to it or not,

(a) is not liable to be asked any question, is not permitted to answer any question and is not permitted to make any statement with respect to a critical incident investigation; and

---

[34] Manitoba Evidence Act, CCSM c. E150, ss 9(2)-9(3).
[35] Ibid, s 9(4).

(b) is not liable to be asked to produce, and is not permitted to produce [any documents or reports made by the review committee.][36]

Similar to Manitoba, disclosure of the critical incident is required by the *Hospital Insurance and Health and Social Services Administration Act*, but its use in a legal proceeding is prohibited.

The *Evidence Act* in Newfoundland / Labrador was amended in 2017 to provide that a report of a close call or occurrence by a healthcare provider, or a notice to the Health Minister of an adverse health event, shall not be disclosed in connection with a legal proceeding, and a person who appears as a witness in a legal proceeding shall not be asked to produce a report or notice.[37]

Legislative Provision – Limitations on Access

New Brunswick – Health Quality and Patient Safety Act

Confidentiality of information

6 Despite the Right to Information and Protection of Privacy Act, a statement, declaration, record or document provided to the quality of care and safety of patients committee in the course of a quality review is confidential and shall not be communicated to any person.

Policy Recommendation

Reports that are required by mandatory reporting legislation should not be subject to access under the provincial / territorial public sector freedom of information and protection of privacy legislation, or health information legislation.

Legislative Provision – Confidentiality of Patient and Staff involved in Patient Safety Incident

Northwest Territories - Critical Incident Reporting and Investigation Regulations

3. (1) A report required under subsection 25.3(6) of the Act must include

(a) a complete description of the circumstances and facts that led to the critical incident or alleged critical incident;

---

[36] Hospital Insurance and Health and Social Services Administration Act, RSNWT 1988, c T-3, s 25.5(2). Section 25.5(4) states "The limits in subsections (2) and (3) do not apply to information (a) in a notification or report that discloses the facts of a critical incident, unless the facts relating to that incident are also fully recorded in a record other than the notification or report and are available to the patient or client; or (b) that is prepared for the purpose of providing care or treatment to a patient or client, unless that information is also fully recorded in a record other than the notification or report and is available to the patient or client."
[37] Evidence Act, R.S.N.L. 1990, c. E-16, s. 8.1(2)-(4).

(b) an analysis of whether or not a critical incident occurred;

(c) if the investigator finds that a critical incident occurred, a statement identifying any current practice, procedure or factor involved in the provision of the health or social services or the operation of the program that

(i) caused or 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; and

(d) an appendix containing any recommendations arising from the investigation.

(2) Recommendations made in an appendix to a report described in paragraph (1)(d) must not include any information that would reasonably be expected to identify

(a) any individual to whom the critical incident or alleged critical incident relates;

(b) any health care or social services provider involved in providing health or social services to any individual described in paragraph (a) or in operating a program to which the critical incident or alleged critical incident relates; or

(c) any other individual who has knowledge of the critical incident or alleged critical incident.

Policy Recommendation

Recommendations in a report to the Health Minister or other centralized body with authority for analysis and dissemination of results should not include identifying information relating to the patient to whom the patient safety incident relates, any health services provider, or any other person who has knowledge of the patient safety incident.

Legislative Provision – Protection in Legal Proceedings

Saskatchewan – Provincial Health Authority Act

8-2(6) Subject to subsection (7), a witness in a legal proceeding, whether a party to it or not:

(a) is not liable to be asked any question, is not permitted to answer any question and is not permitted to make any statement, with respect to an investigation of a critical incident; and

(b) is not liable to be asked to produce, and is not permitted to produce:

(i) any notice or report mentioned in this section; or

(ii) any information in a notice or report mentioned in this section or any documentation used to prepare a notice or report mentioned in this section.

(7) Subject to subsections (8) and (9), a notice or report mentioned in this section is not admissible as evidence in any legal proceeding.

(8) The privileges described in subsections (6) and (7) do not apply:

(a) to information in a notice or report that discloses the facts of a critical incident unless the facts relating to that incident are also fully recorded in a record other than the notice or report and are available to the patient; or

(b) to information that is prepared for the purpose of providing care or treatment to a patient, unless that information is also fully recorded in a record other than the notice or report and is available to the patient.

(9) Nothing in this section affects any privilege that may exist pursuant to section 10 of The Evidence Act with respect to:

(a) a notice or report mentioned in this section;

(b) any information provided in a notice or report mentioned in this section; or

(c) any documentation used to prepare a notice or report mentioned in this section.

Policy Recommendation

Reports required under mandatory reporting legislation should be protected and not subject to production in subsequent legal proceedings.

Conclusion

As the above analysis illustrates, there are key policy issues that should be considered in the development of comprehensive patient safety legislation including provisions addressing mandatory reporting. The next section of this paper will consider mandatory disclosure of patient safety incidents.

Mandatory Disclosure of Patient Safety Incidents

Introduction

There have been significant legislative changes since the CPSI Background Paper for the Development of National Guidelines for the Disclosure of Adverse Events was finalized.[38]

[38] Canada, Canadian Patient Safety Institute, Background Paper for the Development of National Guidelines for the Disclosure of Adverse Events, November 2, 2006, https://www.patientsafetyinstitute.ca/en/toolsResources/disclosure/Documents/Background%20Paper%20for%20the %20Canadian%20Disclosure%20Guidelines.pdf.

As noted in the Background Paper for the Development of National Guidelines for the Disclosure of Adverse Events, the following are key considerations for legislation:

- Healthcare is most often provided by a team, and when a patient safety incident occurs, there are likely several healthcare professionals involved or aware of the patient safety incident. It is important to clarify who is under a duty to disclose.
- Clearly defining the event which triggers the duty to disclose is essential, as health services providers must be aware of when they are under a duty to disclose.
- Disclosure can be limited to the bare information that the patient safety incident occurred, and can extend to a full expression of how it happened. Uncertainty about what should be disclosed can result in concerns about admissions of liability for the purposes of civil liability.
- Disclosure should be made as soon as possible, with regard to the health of the patient. Disclosure is a continuing obligation, and certain information may not become available until a later time, and must be disclosed as it becomes available.
- Requirements relating to documentation of the disclosure, reporting of the safety incident, and investigation of the causes of the patient safety incident should also be considered.

Common Characteristics of the Legislation

This section of the paper will contain a discussion of the following common characteristics of legislation mandating disclosure of patient safety incidents:

- Who must disclose
- Events that trigger the duty to disclose
- Information to be disclosed
- Timing of disclosure
- Information to be recorded in the patient record

Who Must Disclose

In some jurisdictions, the requirements are limited to particular sectors. In Alberta a recently enacted statute, the *Mental Health Services Protection Act*, requires a service provider who operates or provides residential addiction treatment services to notify specified persons about a critical incident. In Saskatchewan, a licensee of a personal care home is required to disclose information about a serious incident to specified persons. In other jurisdictions, there is much broader coverage. For example, in Manitoba, the health authority, health corporations, and prescribed healthcare organizations all have disclosure obligations under the *Health System Governance and Accountability Act*. As these examples illustrate, the duty to disclose information about a patient safety incident depends on the type of entity that is subject to the legislation.

Events that Trigger the Duty to Disclose

The question of what events trigger the duty to disclose varies from jurisdiction to jurisdiction. In some jurisdictions, harm must have occurred. For example, in Newfoundland / Labrador there is a duty to disclose when an occurrence results in an unintended outcome which negatively affects a patient's health or quality of life. In Manitoba, the duty to disclose is triggered by an unintended event that results in a consequence that is serious and undesired, such as death, disability, injury or harm, unplanned admission to hospital or unusual extension of hospital stay. In contrast, in New Brunswick, there is a duty to disclose patient safety incidents which include unintended events that contribute to or result in, or could have contributed or resulted in, harm to the patient or death of the patient. As such, it is not necessary for harm to have actually occurred before the duty to disclose arises in the circumstances.

As noted earlier in this paper, the terminology used in legislation is not consistent, and the same term is defined differently. Manitoba, Ontario and the Northwest Territories require disclosure of "critical incidents" but there are variations in the definition in these jurisdictions. Quebec requires disclosure of "accidents". New Brunswick requires disclosure of "patient safety incidents". Newfoundland / Labrador requires disclosure of "adverse health events".

Legislative Provision – Events that Trigger Duty to Disclose

New Brunswick - Health Quality and Patient Safety Act:

1 "patient safety incident" means an unintended event that

(a) occurs when health services are received by a patient, and

(b) contributes to or results in, or could have contributed to or resulted in, harm to the patient or the death of the patient.

Policy Recommendation

The obligation to disclose patient safety incidents should include an unintended event that contributes to or results in, or could have contributed to or resulted in, harm to the patient or the death of the patient (such as a "near miss" or a "good catch").

Information to be Disclosed

There is a varying level of detail relating to the information that must be disclosed. In some jurisdictions, the legislation states that specified persons must be notified about the patient safety incident. The *Health System Governance and Accountability Act* in Manitoba provides that the individual must be "fully" informed 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. The Ontario Hospital Management Regulation requires disclosure of the material facts of what occurred with respect to the critical incident; a description of the cause or causes of the critical incident, if known; the consequences for the patient

of the critical incident, as they become known; and the actions taken and recommended to be taken to address the consequences to the patient of the critical incident, including any healthcare or treatment that is advisable. Following initial disclosure, there must be further disclosure of the systemic steps, if any, that the hospital is taking or has taken in order to avoid or reduce the risk of further similar critical incidents. New Brunswick's *Health Quality and Patient Safety Act* stipulates the information that must be disclosed following review by a Quality of Care and Safety of Patients Committee (i.e. the relevant facts of the incident; the recommendations of the Quality of Care and Safety of Patients Committee; and any steps that will be taken to improve the quality of care and the safety of patients).

Legislative Provision – Information to be Disclosed

Newfoundland / Labrador - Patient Safety Act

> *17(2) The Provincial Health Authority shall disclose the following information relating to an adverse health event to the patient affected by the adverse health event in accordance with the regulations:*
>
> > *(a) the facts of the adverse health event and any new or otherwise unknown facts as they become known;*
> >
> > *(b) the consequences to the patient as they become known;*
> >
> > *(c) the details of the health services provided to the patient as a result of the adverse health event; and*
> >
> > *(d) any recommendations from quality assurance activities respecting the adverse health event.*

Policy Recommendation

The following information should be disclosed following a patient safety incident: the facts and any new or otherwise unknown facts as they become known; the consequences to the patient as they become known; the details of the health services provided to the patient as a result of the patient safety incident; and any recommendations from quality assurance activities respecting the patient safety incident.

Timing of Disclosure

The initial disclosure is generally required as soon as possible or practicable. There may be further disclosure as additional facts become known in a review or investigation. In some jurisdictions, there are also provisions for disclosure following a quality assurance review (see, for example, New Brunswick's *Health Quality and Patient Safety Act*). These provisions make it clear that disclosure is an ongoing obligation.

Legislative Provision – Initial Disclosure

Ontario – Hospital Management Regulation

> *(4) The board shall ensure that the administrator establishes a system for ensuring the disclosure of every critical incident, as soon as is practicable after the critical incident occurs…*

Policy Recommendation

The initial disclosure should take place as soon as is practicable after the patient safety incident.

Legislative Provision – Ongoing Disclosure

New Brunswick - Health Quality and Patient Safety Act

> *4 After a quality review of a patient safety incident has been conducted by the quality of care and safety of patients committee, the health care organization shall notify the patient of*
>
> > *(a) the relevant facts of the incident,*
> >
> > *(b) the recommendations of the quality of care and safety of patients committee, and*
> >
> > *(c) any steps that will be taken to improve the quality of health care and the safety of patients.*

Policy Recommendation

The legislation should provide for further disclosure following a review of the patient safety incident including: any facts discovered during the review; the recommendations of the committee or entity conducting the review; and any steps that will be taken to improve the quality of healthcare and the safety of patients.

Information to be Recorded in the Patient Record

Manitoba, Ontario and Newfoundland / Labrador specify what information must be included in the client or patient record. All of them require that the patient or client record contain the facts, the consequences to the individual as they become known, as well as the actions taken to address the consequences. The *Patient Safety Act* for Newfoundland / Labrador also requires that the patient record contain any recommendations from quality assurance activities respecting the adverse health event.

Legislative Provision

Manitoba – The Health System Governance and Accountability Act

> ***53.2(2)*** *If a critical incident occurs when a health authority, health corporation or prescribed health care organization is providing health services to an individual, the authority, corporation or organization must ensure that*
>
> > *(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.*

Policy Recommendation

The patient record must contain the following information: a record of when disclosure was made; the material facts of what occurred with respect to the patient safety incident; a description of the cause or causes if known; the consequences for the patient as they become known; and the actions taken and recommended to be taken to address the consequences to the patient.

Relationship to Reporting Requirements

Saskatchewan's Critical Incident Regulations were amended in 2023 to clarify that disclosure to a patient or the patient's family about the actions taken and intended to be taken as a result of an investigation of a critical incident does not constitute a waiver of the privilege set out in section 8-2 of the *Provincial Health Authority Act* dealing with the investigation of critical incidents. This provision is meant to facilitate openness during disclosure without impacting protection extended to investigation and reporting of critical incidents.

Legislative Provision – Impact of Disclosure on Protection in Legal Proceedings

Saskatchewan – Provincial Health Authority Act

> *8-2(6) Subject to subsection (7), a witness in a legal proceeding, whether a party to it or not:*
>
> > *(a) is not liable to be asked any question, is not permitted to answer any question and is not permitted to make any statement, with respect to an investigation of a critical incident; and*

(b) is not liable to be asked to produce, and is not permitted to produce:

(i) any notice or report mentioned in this section; or

(ii) any information in a notice or report mentioned in this section or any documentation used to prepare a notice or report mentioned in this section.

(7) Subject to subsections (8) and (9), a notice or report mentioned in this section is not admissible as evidence in any legal proceeding.

(8) The privileges described in subsections (6) and (7) do not apply:

(a) to information in a notice or report that discloses the facts of a critical incident unless the facts relating to that incident are also fully recorded in a record other than the notice or report and are available to the patient; or

(b) to information that is prepared for the purpose of providing care or treatment to a patient, unless that information is also fully recorded in a record other than the notice or report and is available to the patient.

(9) Nothing in this section affects any privilege that may exist pursuant to section 10 of The Evidence Act with respect to:

(a) a notice or report mentioned in this section;

(b) any information provided in a notice or report mentioned in this section; or

(c) any documentation used to prepare a notice or report mentioned in this section.

***Saskatchewan* - Critical Incident Regulations**

5(3) The provincial health authority may disclose to a patient or the patient's family the actions taken and intended to be taken by the provincial health authority as a result of an investigation pursuant to this section, and that disclosure does not constitute a waiver of the privilege set out in section 8-2 of the Act.

Policy Recommendation

Disclosure to patients and their families should not impact the protection given to reports that are required under mandatory reporting legislation, and they should remain protected and not subject to production in subsequent legal proceedings.

Conclusion

As the above analysis illustrates, there are key policy issues that should be considered in the development of comprehensive patient safety legislation that includes provisions addressing mandatory disclosure. The next section of this paper will consider apology protection legislation.

Apology Protection Legislation

Introduction

Apology protection legislation has developed differently than legislation relating to quality assurance, mandatory reporting, and mandatory disclosure, and there has been more consistency in the approach across jurisdictions. In 2007, the Uniform Law Conference developed a *Uniform Apology Act* following the enactment of apology protection legislation in British Columbia and Saskatchewan.[39] The Uniform Law Conference concluded that uniform apology legislation is desirable, and noted as follows:

Torts are not necessarily confined within provincial or territorial borders. People may do or suffer harm away from home. The human and legal consequences should be predictable across the country. Thus a harmonized legal approach would be beneficial.[40]

The *Uniform Apology Act* contains the following components:

- "Apology" is defined to include admissions of fault, as distinct from being limited to expressions of sympathy. The breadth of the definition is intended to strengthen the usefulness of apologies in the resolution of disputes and in the furtherance of inter-personal reconciliation.
- "Court" is given an extended definition to encompass administrative tribunals, arbitrators, and persons acting in a judicial or quasi-judicial capacity.
- The Act applies to all persons, natural and corporate.
- The application of the Act is not limited to certain types of wrongdoing such as negligence.
- The Act declares that an apology, whether express or implied, is not an admission of fault or liability, and accordingly must not be taken into account in any determination thereof. To ensure the general efficacy of the Act, it is also provided that an apology cannot be used as confirmation or acknowledgment of a cause of action to extend a limitation period; and that an apology does not void or injure any insurance coverage available to the person making the apology.
- The Act expressly addresses and clarifies the status and scope of an apology for evidentiary purposes by providing that, despite any other law, an apology is not admissible in court as evidence of the fault or liability of the person apologizing. The Act does not prevent an apology from being admitted for other purposes, such as the determination of damages.

As a result of this work, legislation across Canada has developed in a similar manner although there are some differences, most notably in the impact of an apology on the extension of a limitation period.

---

[39] See Uniform Law Conference, Uniform Acts, Uniform Apology Act (2007).
[40] See Uniform Law Conference, Articles, Policy Paper on Apology Legislation September 9-13, 2007, at para. 55.

Since 2006, twelve Canadian jurisdictions have enacted statutory protection concerning apologies.[41] These are: British Columbia; Alberta; Saskatchewan; Manitoba; Ontario; Quebec; Newfoundland Labrador; Nova Scotia; Prince Edward Island; New Brunswick; Nunavut and the Northwest Territories.

Purpose of Apology Protection

Apology protection is put into place in order that a defendant (or potential defendant) not hesitate to apologize to a plaintiff (or potential plaintiff) out of concern that the plaintiff will use the apology against him or her, or otherwise impact the defendant negatively. By providing this protection, defendants may be more likely to apologize. Apologies are believed to be helpful to persons who have suffered harm, and can enhance communications between plaintiffs and defendants.

The Uniform Law Conference summarizes the goals of apology protection as follows:

- to encourage timely, less litigious modes of resolving legal disputes,
- to encourage inter-personal reconciliation, and
- to encourage personal responsibility.

According to the Attorney General of B.C., when that province's Act was introduced in 2006, the Act:

> *"…is designed to reduce litigation and to promote an early resolution of legal disputes… It is becoming accepted wisdom that an apology often will go a long way towards resolving a matter. Many times, persons who have been injured simply want an explanation and an apology as to what happened… As well, we know that litigation in the United States has been eliminated, particularly in medical malpractice cases, where apologies have been offered."*

According to the CEO of the Canadian Patient Safety Institute (CPSI), commenting on Ontario's proposed *Apology Act*:

> *"Recent studies show that physicians and nurses want to apologize when an error is made, but worry that an expression of regret, an apology, might be construed by the patient and the family as an admission of legal liability..."*[42]

---

[41] Apology Act, S.B.C. 2006, c. 19, s. 2; Alberta Evidence Act , R.S.A. 2000, c. A-18, s. 26.1; Evidence Act, S.S. 2006, c. E 11.2, s. 23.1; Apology Act, C.C.S.M. c.A98, s. 2; Apology Act, 2009, S.O. 2009, c.3; Civil Code of Quebec, C.Q.L.R. c. CCQ-1991, art. 2853.1; Apology Act, S.N.S. 2008, c. 34, s. 3; Health Services Act, R.S.P.E.I. 1988, c. H-1.6, ss. 26, 32; Apology Act, S.N.L. 2009, c. A-10.1; Apology Act, S.N.W.T. 2013, c. 14; Legal Treatment of Apologies Act, S. Nu. 2010, c. 12; Health Quality and Patient Safety Act, R.S.N.B. 2016, c. 21, s. 8. Quebec is the only civil law jurisdiction in Canada, and the most recent jurisdiction in Canada to adopt apology protection legislation. See Vandenbussche, Wannes, Introducing Apology Legislation in Civil Law Systems. A New Way to Encourage Out-of-Court Dispute Resolution (August 23, 2018). Available at SSRN: https://ssrn.com/abstract=3237528 or http://dx.doi.org/10.2139/ssrn.3237528.

[42] See. https://news.ontario.ca/en/backgrounder/193/introduction-of-the-apology-act.

There have been few decisions across Canada that have dealt with the impact of apology protection legislation in the healthcare context. The general purpose of apology protection legislation was explored in *Pollard Windows Inc. v 1736106 Ontario Inc.*, 2019 ONSC 4859:

> *[54] The Apology Act provides that non-testimonial apologies cannot be used to imply liability or as a ground to terminate a person's insurance coverage. The statute is designed to encourage apologies by those whose conduct causes harm whether by negligence or otherwise. Anecdotally, the lack of apology by professionals in particular, may have led to litigation where a well-timed and heartfelt apology might otherwise have been accepted by the victim. Yet people who cause harm, whether, for example, in motor vehicle accidents or in professional relationships, have been precluded from apologizing for fear that doing so would be seen either as an admission of liability or guilt and thereby provide a basis for an insurer to decline insurance coverage in a subsequent lawsuit. One can readily envisage people in car accidents or professionals whose clients suffered an adverse outcome, being sincerely sorry even though they resolutely believe that they committed no negligence or wrongdoing. A person whose car is hit by another, a lawyer who loses a trial, a doctor whose very best efforts could not cure the patient's condition, may all be sympathetic, empathetic, and truly sorry for the suffering of the other. An apology might be helpful for the giver and the receiver. Yet, prior to the enactment of the Apology Act, apologies could not be made without fear of adverse legal consequences.*
>
> *[55] Case law under the statute is still sparse. It seems apparent from the definition in s.1 of the statute that an apology is not be the same thing as an admission of liability. The section makes clear that a statement of regret remains an apology even if it contains or implies an admission of liability. The section therefore contemplates that some apologies may not imply any admission of fault, but says that even where they admit or imply fault, the words remain protected apologies.*

Elements of Apology Protection

The protection, whether found in a standalone act or part of a province's *Evidence Act* or the Civil Code of Quebec, generally includes the following common elements:

- A broad definition of an "apology," which includes an "expression of sympathy or regret"
- Statement that an apology made by or on behalf of a person in relation to any matter does not constitute an admission of fault or liability by the person
- Prohibition on taking an apology into account in any determination of fault or liability in connection with the matter to which the apology relates
- Statement that an apology does not affect any insurance or indemnity coverage for any person in connection with the matter to which the apology relates
- Statement that evidence of an apology made by or on behalf of a person in connection with any matter is not admissible in any court as evidence of the fault or liability of the person in connection with that matter

In Prince Edward Island, apology protection is included in the *Health Services Act* and, as such, protection is limited to apologies in the context of health services. However, the five elements noted

above are found in the *Health Services Act* provisions. In New Brunswick, protection is included in the *Health Quality and Patient Safety Act*, and protection is limited to apologies that are made in connection with a "patient safety incident" or other incidents that could have resulted in a "patient safety incident". Patient safety incident is defined to mean an unintended event that contributes to or results in, or could have contributed to or resulted in, harm to the patient or the death of the patient.

Apologies on Behalf of an Institution

In some cases, a representative of an institution may make an apology on behalf of that institution. Although the legislation does not speak to its application to such apologies in any specific way, the language of the legislation is such that it applies to such cases. For example, British Columbia's *Apology Act* refers to "an apology made by or behalf of a person…" Therefore, under that Act, apologies can be made on behalf of another "person," and, under the *Interpretation Act*, the term "person" includes "a corporation, partnership or party, and the personal or other legal representatives of a person to whom the context can apply according to law" (s. 29). The other provinces take a similar approach, although the definition of "person" can vary.

Impact of apology on limitation periods

Limitation periods are established in order to set a time limit as to when legal proceedings may be commenced. Although each jurisdiction has its own rules, they are similar across Canada. In general, an acknowledgment of liability may trigger a new limitation period.[43] Apology protection legislation across Canada differs in approach to this issue. Some statutes specifically provide that an apology does not constitute an acknowledgment of liability for the purpose of extending limitation periods.[44] Other statutes are silent, while the Ontario Apology Act specifically states that it does not affect whether an apology constitutes an acknowledgment of liability, and does not prevent an apology from being admitted in evidence for the purposes of s. 13 of the *Limitations Act* which deals with acknowledgment of liability and extension of limitation periods.[45]

Relationship with Disclosure Guidelines

Apology protection is compatible with requirements and guidelines for the disclosure of patient safety incidents to patients. Both encourage transparency and open communication. The CEO of CPSI, again in the context of Ontario's proposed Act, stated:

> *"The proposed Apology Act, consistent with our Canadian Disclosure Guidelines, released earlier this year, aims to increase transparent and open communication among health care professionals, patients and the public, and is an important and consistent step forward for the people of Ontario. What we're seeing is a cultural shift, which recognizes that offering a*

---

[43] West York International Inc. v. Importanne Marketing Inc., 2012 ONSC 6476, para. 91.
[44] Apology Act, S.B.C. 2006, c. 19, s. 2(1)(b); Alberta Evidence Act, R.S.A. 2000, c. A-18, s. 26.1(2)(b); Evidence Act, S.S. 2006, c. E-11.2, s. 23.1(2)(b); Apology Act, S.N.S. 2008, c. 34, s. 3(1)(b); Apology Act, S.N.L. 2009, c. A-10.1, s. 3(1)(b); Apology Act, S.N.W.T. 2013, c. 14, s. 2(1)(b); Legal Treatment of Apologies Act, S. Nu. 2010, c. 12, s. 2(1)(b).
[45] Apology Act, 2009, S.O. 2009, c.3, s. 4.

sincere apology or expression of regret is simply the right thing to do. It is a sign of caring, compassion and empathy — not blame or guilt."

Legislative Provisions

UNIFORM APOLOGY ACT

Definitions

1 In this Act:

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

• ["court" includes a tribunal, an arbitrator and any other person who is acting in a judicial or quasi-judicial capacity.]

Effect of apology on liability

2(1) An apology made by or on behalf of a person in connection with any matter

(a) does not constitute an express or implied admission of fault or liability by the person in connection with that matter,

(b) does not constitute [a confirmation of a cause of action or acknowledgment of a claim] in relation to that matter for the purposes of [appropriate section of the applicable limitation statute],

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

(d) may not be taken into account in any determination of fault or liability in connection with that matter.

(2) Despite any other enactment or law, evidence of an apology made by or on behalf of a person in connection with any matter is not admissible in any court as evidence of the fault or liability of the person in connection with that matter.

Policy Recommendation

Apology protection legislation should contain the following elements:

- A broad definition of an "apology," which includes an "expression of sympathy or regret"
- Statement that an apology made by or on behalf of a person in relation to any matter does not constitute an admission of fault or liability by the person
- Prohibition on taking an apology into account in any determination of fault or liability in connection with the matter to which the apology relates

- Statement that an apology does not affect any insurance or indemnity coverage for any person in connection with the matter to which the apology relates
- Statement that evidence of an apology made by or on behalf of a person in connection with any matter is not admissible in any court as evidence of the fault or liability of the person in connection with that matter

Conclusion

As the above analysis illustrates, there are key policy issues that should be considered in the development of comprehensive patient safety legislation that includes provisions addressing apology protection. The next section of this paper will consider protection of quality assurance information.

Protection of Quality Assurance Information

Introduction

The policy rationale for protection of quality assurance information was explored by the Prince Edward Island Court of Appeal.[46] The decision refers to provisions of PEI's *Health Services Act* that contain the statutory provisions protecting quality assurance information.[47] The decision notes as follows:[48]

> *[49] Prior to the enactment of Part IV of the HSA hospitals often found themselves in a bind. If there was something in a hospital that needed improvement, staff, including physicians and nurses, were often reluctant to come forward. If the hospital initiated any sort of investigation into a matter, an adverse party could obtain access to the investigation through litigation or by way of a FOIPPA request. The witnesses could then see their statements analyzed in public and the reports could be used as legal weapons against the hospital as well as hospital staff and physicians in courts of law and other legal arenas. This situation encouraged a do-nothing, say-nothing approach which quite obviously would be detrimental to the quality of health care in this province. Part IV is designed to combat that situation. Part IV allows a full, open, candid discussion and thorough review of incidents at the hospital without the spectre of the report ending up as evidence in a legal proceeding or on the front page of the paper. This, in the long run, will increase the efficiency and effectiveness of health services on Prince Edward Island…. This is an important policy objective.*

[46] Health PEI v. Privacy Commissioner, 2019 PECA 7.
[47] Health Services Act, R.S.P.E.I. 1988, c. H-1.6, ss. 26-31.
[48] Health PEI v. Privacy Commissioner, 2019 PECA 7, paras. 49-50.

However, as noted in the Health Canada report, From Silos to Systems, there are countervailing public policy concerns relating to transparency, openness and accountability.[49]

> *There is a public interest in the management and operation of public funded activities being transparent and open to scrutiny by the public. The public should be aware of information about adverse events and of safety and quality improvement mechanisms. Openness encourages effective accountability for the use of public funds and provision of public services…*

Common Characteristics of the Legislation

This section of the paper will contain a discussion of the following common characteristics of legislation protecting quality assurance information:

- What type of healthcare body is establishing the committee
- Whose communications are protected
- What communications and information are protected
- Definition of Legal Proceedings
- Impact of Legislation Governing Access to Information
- Prohibition on Use in Legal Proceedings
- Involvement of Patients
- Legislative Review

What type of healthcare body is establishing the committee

Some legislation limits protection to quality of care committees created by hospitals. In others, protection is granted to quality of care committees created by other healthcare bodies, such as regional health authorities. Some jurisdictions permit the Health Minister to designate quality of care committees. The type of entity that may establish a quality of care committee depends on the structure of the healthcare system in the particular jurisdiction.

Whose communications are protected

Generally, communications relating to quality of care that do not involve a quality of care committee are not entitled to protection. For example, Ontario's *Quality of Care Information Protection Act*, 2016 only protects information prepared by, or for, a committee that has been established,

---

[49] Jocelyn Downie, et al. Patient Safety Law: From Silos to Systems, Report for Health Policy Research Program, Health Canada (2006), online: http://www.eprints.qut.edu.au/62121/1/HLI_Patient_Safety-Main_Report_(final).pdf.

appointed or approved as a quality of care committee.[50] Before acting as a quality of care committee, it must be designated as such in writing by the health facility or entity that established, appointed, or approved it. The terms of reference of the committee and its designation must be publicly available.[51] Similarly, Nunavut's *Evidence Act* specifies that the committee must be established or designated by the Health Minister in order to receive protection.[52]

Recent court decisions illustrate the importance of ensuring that the situation is reviewed by a properly constituted quality assurance committee. In *Estate of Faye Carter v. Flemming et al*,[53] a 2015 decision of the Prince Edward Island Court of Appeal, Queen Elizabeth Hospital contracted an Ontario physician, Dr. Hill, to review the circumstances surrounding Faye Carter's death ("the Hill report"). The estate commenced an action against the hospital and three physicians, and requested a copy of the Hill report. The hospital refused. The Court of Appeal noted that "a trial is a search for the truth and, therefore, all relevant material evidence is, subject to any exclusionary rule, admissible".[54] However, the legislature can change or modify common law rules of evidence, which it did by enacting protection for quality assurance information in PEI's *Health Services Act*.[55] The decision of the Court of Appeal emphasizes the importance of ensuring that the review is conducted strictly in accordance with the legislation, and concluded that the report was not protected.

> *[13] The only way quality improvement information can be protected under Part IV of the Health Services Act is if it is part of a quality improvement activity. Only a quality improvement committee can conduct a quality improvement activity. A quality improvement committee is a creature of statute. Without the statute it does not exist. Section 27 of the Act is a constating provision; it must be fulfilled. This provision is clear and unambiguous. It states how a quality improvement committee must be created. It is exhaustive. Only a quality improvement committee established under the Act can carry out a quality improvement activity under the Act. The protection of s.29 of the Act applies only to quality improvement information communicated or created under the auspices of a quality improvement committee under the Act.*
>
> [14] Section 27 provides for the creation of quality improvement committees by specific means. It is permissive and exhaustive. The Hospital's position is that because it is permissive anyone can create a quality improvement committee. Were that the case, anyone, even the janitor, could claim that he/she was a quality improvement committee and keep relevant evidence from production. This position is not tenable. A quality improvement committee may only be established by the Minister or the board or their delegates pursuant to s.27. Neither Dr. Henderson nor Dr. Hill was a quality improvement committee established under the Act. Counsel for the Hospital admits as much. That being the case, the Hill Report cannot be a quality improvement activity nor can it contain quality

---

[50] Quality of Care Information Protection Act, 2016, S.O. 2016, c 6, s. 2(1) – definition of "quality of care committee".
[51] Definitions, O Reg 483/16, s 2.
[52] Evidence Act, R.S.N.W.T. (Nu) 1988, c. E-8, s 13 – definition of "committee".
[53] Estate of Faye Carter v. Flemming et al, 2015 PECA 9.
[54] Ibid, para 3.
[55] Health Services Act, PSPEI, 1988, c H-1.6, ss 26-31.

improvement information. The Hill Report is not protected by Part IV of the Health Services Act.

Legislative Provision – Designation and Publication

Ontario QCIPA 2016

1. Before beginning to act as a quality of care committee, the committee must be designated in writing as a quality of care committee for the purposes of the Act or of the Quality of Care Information Protection Act, 2004 by,

i. the health facility or the quality oversight entity that established, appointed or approved it, or

ii. if the quality of care committee was established, appointed or approved by a combination of health facilities or quality oversight entities, each such facility or entity.

2. The terms of reference of the quality of care committee and its designation must be available on request to members of the public.

Policy Recommendation

Quality of care committees must be designated in order to receive statutory protection. The terms of reference and the designation must be available on request to members of the public.

What Communications and Information are Protected

Sole or Primary Purpose

Protection is generally extended to information, documents and opinions. In some statutes, only documents that have been prepared exclusively or primarily for the quality of care committee will receive protection.

The Saskatchewan *Evidence Act* extends protection to any report, statement, memorandum, recommendation, document, information, data, or record that is prepared exclusively for the use of, or made by, a committee; or used exclusively in the course of, or arising out of, any investigation, study or program carried on by a committee. Under Ontario's *Quality of Care Information Protection Act*, 2016, information that is collected by, or prepared for, a quality of care committee is protected if it was prepared for the "sole or primary purpose" of assisting the committee, if it relates to the discussions and deliberations of a quality of care committee, or when it relates "solely or primarily to any activity" of the quality of care committee.[56]

[56] QCIPA, 2016 ss 2(a)-(c).

Legislative Provision – Sole or Primary Purpose Test

Ontario QCIPA 2016 – Definition of "Quality of Care Committee"

2(2) "quality of care information" means information that,

> *(a) is collected or prepared by or for a quality of care committee for the sole or primary purpose of assisting the committee in carrying out its quality of care functions,*
>
> *(b) relates to the discussions and deliberations of a quality of care committee in carrying out its quality of care functions, or*
>
> *(c) relates solely or primarily to any activity that a quality of care committee carries on as part of its quality of care functions, including information contained in records that a quality of care committee creates or maintains related to its quality of care functions.*

Policy Recommendation

Information should be protected if it is collected or prepared for the sole or primary purpose of assisting the committee in carrying out its quality of care functions, or relates solely or primarily to any activity that a quality of care committee carries on as part of its quality of care functions.

Specific Exclusions from Protection

In some jurisdictions, the statutes make it clear that protection does not extend to "facts" relating to a patient safety incident.[57] "Quality improvement information" is defined in the Prince Edward Island *Health Services Act* as information that is communicated for the purpose of, or created in the course of, carrying out a quality improvement activity but does not include information contained in a record, such as a hospital chart or a medical record, that is maintained for the purpose of providing health services to an individual; facts contained in a record of an incident involving the provision of health services to an individual; and the fact that a quality improvement committee met or conducted a quality improvement activity.[58]

The Saskatchewan *Evidence Act* does not protect records that are prepared for the purpose of providing a health service to an individual; 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 prepared for the purpose of providing a health service to an individual; or required by law to be kept by the health services agency.[59]

However, this is not uniform. In Alberta, for example, the *Evidence Act* does not specifically refer to "facts" discovered during the quality assurance review. The Alberta *Evidence Act* provisions were

---

[57] See, for example, the Saskatchewan Evidence Act, s 10(4)(a)(ii).
[58] Health Services Act, s 26(g).
[59] Evidence Act, SS 2006, c E-11.2, s 10(4)(a). While facts not otherwise recorded in the patient's hospital records are to be disclosed, the balance of the quality assurance report receives statutory protection: Lancaster v Minnaar, 2006 SKQB 380, 288 Sask R 31.

interpreted in the decision of the Court of Queen's Bench in *Forsberg v Naidoo*.[60] In that decision, the court came to the conclusion that facts discovered during the quality assurance process are also protected. Section 9 of the Alberta *Evidence Act* does not make a distinction "between the factual component and the other portions of the record."[61]

The Government of Ontario established a Review Committee in 2014 to examine the *Quality of Care Information Protection Act*, 2004 ("QCIPA, 2004"). The QCIPA Review Committee released its report in March 2015.[62] Concerns had been raised that QCIPA, 2004 was being used to prevent patients and families from being fully informed about what went wrong in a particular incident and what would be done to improve care in the future. As part of the process, the QCIPA Review Committee interviewed patients and their families, and the Committee received the following input:

> *Most patients and family members expressed that they saw no obvious conflict between creating a safe space for open discussion amongst health care workers and providing sufficient information to patients and families about the proceedings of the investigation. All interviewees believed that there was no justification for not releasing detailed factual results of investigations to patients and their families. Most felt that substantive disclosure could be organized in a manner so as to avoid breaching the confidentiality of those who spoke to the quality of care committee. Interviewees also generally believed that health care organizations should be expected to disclose to the patient any actions the hospital planned to take to prevent similar future occurrences. Most felt that full disclosure of all details of the investigation was not required, but that disclosure practices were sometimes too narrow.*[63]

The QCIPA Review Committee's report contains twelve recommendations that address the concerns that prompted the review, including amendments to QCIPA.[64] The report notes that the privilege of invoking QCIPA comes with the responsibility of fulfilling disclosure obligations in all circumstances, and that QCIPA should be amended to add a preamble that describes the intent of the protection.[65] As well, QCIPA should be amended to clearly indicate that when QCIPA is invoked patients and families must be fully informed about the results of the investigation, including what happened, why it happened and what measures (if any) the organization intends to take to prevent future incidents.

The *Quality of Care Information Protection Act*, 2016 specifies information that is not considered to be quality of care information including the facts of what occurred and what the quality of care committee has identified as the cause or causes of the critical incident.

Legislation Provision – Exclusions from Definition

Ontario QCIPA 2016

2(3) "Quality of care information" does not include any of the following:

---

[60] Forsberg v. Naidoo, 2009 ABQB 369.
[61] Ibid.
[62] QCIPA Review Committee Recommendations, Submitted December 23, 2014.
[63] Ibid at 22.
[64] Ibid at 26-30.
[65] Ibid at 27.

1. Information contained in a patient record.

2. Information contained in a record that is required by law to be created or to be maintained.

3. Information relating to a patient in respect of a critical incident that describes,

i. facts of what occurred with respect to the incident,

ii. what the quality of care committee or health facility has identified, if anything, as the cause or causes of the incident,

iii. the consequences of the critical incident for the patient, as they become known,

iv. the actions taken and recommended to be taken to address the consequences of the critical incident for the patient, including any health care or treatment that is advisable, or

v. the systemic steps, if any, that a health facility is taking or has taken in order to avoid or reduce the risk of further similar incidents.

4. Information that consists of facts contained in a record of an incident involving the provision of health care to a patient.

Policy Recommendation

The following categories of information should not receive protection:

- information contained in a patient record;
- information that consists of facts contained in a record of a patient safety incident;
- information relating to a patient in respect of a patient safety incident that describes,
- facts of what occurred with respect to the patient safety incident,
- what the quality of care committee or entity establishing the committee has identified as the cause or causes of the incident,
- the consequences of the patient safety incident for the patient, as they become known,
- the actions taken and recommended to be taken to address the consequences of the patient safety incident for the patient, including any healthcare or treatment that is advisable, or
- the systemic steps that a health facility or the entity establishing the committee is taking or has taken in order to avoid or reduce the risk of future similar incidents.

Disclosure Among Quality of Care Committees

The QCIPA Review Committee examined concerns that QCIPA, 2004 had inhibited the sharing of information about critical incidents among institutions in Ontario. The report notes that hospitals do not share information about their critical incidents or their plans to prevent future incidents with each other, except on an ad hoc basis, and that patients have the right to expect that organizations will

share what they have learned with others.[66] The report recommends that QCIPA should be amended to explicitly allow for the sharing of critical incident investigation. QCIPA, 2016 permits the sharing of quality of care information between quality of care committees at separate healthcare facilities.

Legislative Provision – Disclosure Among Quality of Care Committees

Ontario QCIPA 2016

Disclosure among committees

> *8(2) Any quality of care committee may disclose any information, including quality of care information, to any other quality of care committee for the purpose of carrying out quality of care functions, and any person may disclose information that has been disclosed to any quality of care committee to any other quality of care committee.*
>
> *(3) A disclosure permitted under this section shall not contain more personal health information, as defined in the Personal Health Information Protection Act, 2004, than is reasonably necessary for the purpose of the disclosure.*

Policy Recommendation

Legislation should specifically permit sharing of quality assurance information among quality of care committees.

Definition of Legal Proceedings

Most statutes prohibit disclosure in legal proceedings, although the scope of the definition of "legal proceedings" varies. The question of whether quality assurance information may be disclosed to professional regulatory bodies has been the subject of concern and debate. Legislatures have approached this issue differently, and there is not a consistent policy position. In some jurisdictions professional regulatory bodies and their disciplinary committees are specifically included in the definition of legal proceedings in order to clarify that quality of care information is protected in this context. As an example, the *Evidence Act* for Newfoundland and Labrador specifies that protection is extended to proceedings in which evidence may be given before a "committee, including a disciplinary committee, or a governing body of a regulated health profession".[67] Similarly, Nova Scotia's Quality-improvement Information Protection Act specifically provides that protection in legal proceedings includes the disciplinary committee of a regulated health-profession body.[68]

---

[66] QCIPA Review Committee Recommendations, Submitted December 23, 2014, at 28.
[67] Evidence Act, R.S.N.L. 1990, c. E-16, s. 8.1(a)(iii)
[68] Quality-improvement Information Protection Act, SNS 2015, c. 8, s 2(d).

In some jurisdictions, the legislation specifically excludes professional bodies and disciplinary matters. For example, Quebec's *Act Respecting Health Services and Social Services* provides that no person may have access to the minutes of the risk management committee except the committee members, the representatives of accreditation bodies, or the representatives of a professional order.[69] Similarly, the definition of legal proceedings in British Columbia's *Evidence Act* specifically excludes proceedings before a body connected with an organization of health professionals that is a hearing or appeal concerning the conduct or competence of a member of the profession.[70]

Legislative Provision – Disclosure to Regulatory Bodies

Quebec – An Act Respecting Health Services and Social Services:

183.4. No person may have access to the minutes of a risk and quality management committee except the members of the committee, the representatives of accreditation bodies in the exercise of functions pertaining to the accreditation of the health services and social services provided by institutions or the representatives of a professional order in the exercise of the functions assigned to them by law.

Policy Recommendation

Legislation should specify whether there is a prohibition on disclosing quality assurance information to professional regulatory bodies.

Impact of Legislation Governing Access to Information

There are two main categories of legislation that have created a right of access to records held by healthcare bodies: public sector legislation dealing with freedom of information and protection of privacy, and comprehensive health information legislation.

All provinces and territories have public sector legislation dealing with freedom of information and protection of privacy. Many of them cover public bodies such as hospitals and regional health authorities. These acts have two core purposes:

- freedom of information: to make public institutions more open and accountable by providing a right of access to records under their custody or control; and
- protection of privacy: to protect personal information from unauthorized collection, use or disclosure by public institutions.

The right of access is very important because it encourages and enhances transparency and accountability in decision-making by public bodies. Any person can ask for access to any record, subject to specific limitations. The identity or the motivation of requestors is largely irrelevant in

---

[69] An Act Respecting Health Services and Social Services, CQLR, c S-4.2, s 183.4.
[70] Evidence Act, R.S.B.C. 1996, c.124, s. 51(1) – definition of "legal proceedings".

processing an access request. For example, requests could be made by former employees or the news media, without any variation in the public body's treatment of the access request.

Certain records may be subject to mandatory or discretionary exemptions to the right of access. These exemptions often include records that contain:

- personal information (other than the personal information of the requester);
- third party confidential information;
- information affecting economic and other interests of the public body;
- legally privileged information;
- law enforcement information; or
- information that could seriously threaten safety or health.

In some jurisdictions, quality of care information has been excluded from the scope of access to information legislation. For example, Alberta's *Freedom of Information and Protection of Privacy Act* states that it does not apply to a quality assurance record as defined in the Alberta *Evidence Act*.[71] The reason for the exclusion was explained during consideration of amendments to the *Freedom of Information and Protection of Privacy Act*:

> *Mr. Speaker, under section 9 of the Alberta Evidence Act there are certain quality assurance activities that are now protected. This is a protection that has existed for many years. The participant in such a review process is not allowed to testify in court regarding the deliberations of the review committee, and records relating to the proceedings are not admissible in court. These provisions protect a process that has long been recognized to be in the public interest. If members of that quality assurance committee could be compelled to testify or if documents relating to such a review could be accessed, health care providers would be reluctant to serve on such a committee....*
>
> *The extension of freedom of information protection to health care bodies on October 1, 1998, raised concerns that the protection historically afforded to quality assurance activities might be compromised by the rights of access contained in the freedom of information legislation..... If this amendment is not passed, physicians may not be willing to participate in these important processes, and we will lose a very important tool in improving patient care.*[72]

In *Health PEI v. Privacy Commissioner*,[73] the Supreme Court of Prince Edward Island interpreted section 30 of the *Health Services Act* as precluding access by the Information and Privacy

---

[71] Freedom of Information and Protection of Privacy Act, RSA 2000, c F-25, s 4(1).
[72] Alberta Hansard for March 22, 1999 (Mr. Doerksen, page 668):
[73] Health PEI v. Privacy Commissioner, 2018 PESC 11. In Health PEI v Privacy Commissioner, 2015 PECA 9, the PEI Court of Appeal agreed that it was not the role of the Commissioner to look at information which was communicated for the purpose of a quality improvement activity to ensure that it is quality improvement information. The Court of Appeal found that the information was gathered for accountability discipline processes and was not subject to protection.

Commissioner for Prince Edward Island to determine whether the records fell within the category of "quality improvement information". Section 30 provided that:[74]

> *Notwithstanding the Freedom of Information and Protection of Privacy Act, no person has a right of access to quality improvement information, regardless of whether it includes personal information about the person.*

The issue was whether the Commissioner has the authority to order production of records, for his or her independent review, where the public body alleges that the records or parts of the records fall within the scope of section 30 of the *Health Services Act*. The Commissioner answered that question in the affirmative. The court concluded that the Commissioner had no authority to require Health PEI to produce a quality assurance record to her for examination. The legislature protected the integrity of the quality improvement provisions in the *Health Services Act* by enacting section 30, and the Commissioner could not order production of the records for her review.

Health information legislation grants patients a right of access to their health information subject to specific and limited exceptions. This is one of the main objectives of health information, and this objective is often included in statutory purpose statements.

Health information legislation has been developed across Canada over the past 20 years. At present, ten jurisdictions have comprehensive health information legislation.

Manitoba - *Personal Health Information Act* - December 11, 1997

Alberta - *Health Information Act* - April 25, 2001

Saskatchewan - *Health Information Protection Act* - September 1, 2003

Ontario - *Personal Health Information Protection Act* - November 1, 2004

New Brunswick - *Personal Health Information Privacy and Access Act* – September 1, 2010

Newfoundland / Labrador - *Personal Health Information Act* - April 1, 2011

Nova Scotia – *Personal Health Information Act* – June 1, 2013

Northwest Territories – *Health Information Act* – October 1, 2015

Yukon – *Health Information Privacy and Management Act* – August 31, 2016

Prince Edward Island – *Health Information Act* – July 1, 2017

On April 4, 2023, Quebec's health information legislation, *An Act respecting health and social services information and amending various legislative provisions* (Bill 3), received royal assent.[75] Bill 3 is Quebec's first comprehensive health information legislation and will come into force at a date yet to be set.

---

[74] Health Services Act, R.S.P.E.I. 1988, c. H-1.6, s 30. Section 30 has since been amended to provide a similar prohibition in relation to the right of access under health information legislation.
[75] An Act respecting health and social services information and amending various legislative provisions, SQ 2023, c 5.

Although one of the central purposes of health information legislation is to provide individuals with a right of access to their personal health information, quality of care information continues to be an exception to that right of access. For example, the *Health Information Act* came into force in the Northwest Territories on October 1, 2015. Section 111 provides that a custodian shall refuse to disclose to an applicant proceedings of a quality assurance committee in respect of a quality assurance activity, as well as quality assurance records created in respect of a quality assurance committee.[76] However, section 111(3) states that a custodian may disclose a quality assurance record that consists of "results of or recommendations in relation to a quality assurance activity".[77]

Yukon's *Health Information Privacy and Management Act* came into force on August 31, 2016. The *Evidence Act* was amended to state that in the event of an inconsistency between section 13 of the *Evidence Act* which provides protection for quality assurance information and the provisions of the *Health Information Privacy and Management Act*, section 13 prevails.[78]

In a 2016 decision by the Ontario Information and Privacy Commissioner, an individual requested that a hospital provide her access to records relating to her deceased mother.[79] The hospital denied access to certain of the requested records on the basis that those records were exempt under the *Personal Health Information Protection Act*, 2004 (PHIPA) and the *Freedom of Information and Protection of Privacy Act* (FIPPA). The Commissioner agreed with the hospital and supported the decision to deny access to certain records on the basis that, among other reasons, the records contained quality of care information and so were exempt under PHIPA section 51(1)(a).[80]

Legislative Provisions – Application of Public Sector Access and Privacy Legislation

Ontario QCIPA 2016

> *3 The Freedom of Information and Protection of Privacy Act does not apply to quality of care information.*

Policy Recommendation

Quality assurance information should not be subject to the right of access in public sector access to information legislation.

Legislative Provision – Access to Health Information

Nova Scotia Quality-Improvement Information Protection Act

---

[76] Health Information Act, SNWT 2014, c 2, s 111(2).
[77] Ibid, s 111(3).
[78] Evidence Act, RSY 2002, c 78, s 13.1.
[79] PHIPA Decision 33, 2016 CanLII 72690.
[80] Ibid, para 32.

5(3) Notwithstanding the Personal Health Information Act, no person may disclose or access quality-improvement information except as permitted under this Act, regardless of whether it includes the personal health information of the individual.

Policy Recommendation

Quality assurance information should not be subject to the right of access in health information legislation.

Prohibition on Use in Legal Proceedings

In order to further the policy objective of open communication, legislation protecting quality assurance information creates an absolute prohibition. In general, this prohibition stands in contrast to the legal concept of privilege which may be waived in certain circumstance. The impact of the prohibition was explored in the decision of the Alberta Court of Queen's Bench in *Bruce Estate*.[81] The court determined that a Quality Assurance Report prepared by a subcommittee of the Health Quality Council of Alberta ("HQCA") was protected by section 9 of the Alberta *Evidence Act*. The HQCA can establish its own quality assurance committee and undertake its own quality assurance activities under section 9 of the Alberta *Evidence Act*.[82] On a request from the Minister of Health in April 2007, a subcommittee of the HQCA quality assurance committee was appointed to inquire into the infection control procedures and MRSA at the St. Joseph's General Hospital and East Central Health Region. The Court held that the report was protected by section 9 despite the fact that the committee report was prepared with the understanding that it may be made public. The Court noted as follows:

> *[16] While some reports resulting from quality assurance activities are held in confidence, reports of incidents and recommendations are publicized in some cases in order to support a patient safety culture and to improve the health care system. Public disclosure of a report makes it accessible to other organizations in the health care system and assists in preventing similar incidents or adverse events. Public disclosure also facilitates systemic change by educating those who make the policies and rules for the system. It facilitates the education of patients and their families who play an active part in health care in the modern health system.*
>
> *[17] The Report was made public together with the News Release that summarized its contents. Ultimately the Report led to changes to standards for reporting, accountability and infection prevention and control, and prompted a number of significant legislative changes directed at the improvement of the quality of health care and health services.*
>
> *[41] On a plain reading of s. 9 of the Act, there is nothing that can be interpreted to mean that the production or disclosure of a quality assurance record in another forum nullifies the prohibition from production under s. 9(2). As stated earlier, s. 9(2) strictly prohibits a witness from producing any quality assurance record in that person's possession or control. It is an*

---

[81] Bruce Estate, 2010 ABQB 21.
[82] HQCA Regulation, s. 10(2)

> *outright prohibition against the admission into evidence of a quality assurance record, not dependent upon any privilege or other exclusionary rule of evidence that might attach to the document. (See* ***Goad v. Cavanagh*** *1992 CanLII 6129 (AB Q.B.), (1992), 3 Alta. L.R. (3d) 18, [1992] A.J. No. 1268 (Q.B.) at paras. 7 & 8). (emphasis added)*

The Court also notes that s. 9 does not create a privilege that the witness may waive.

> *[43] As a statutory rule of evidence, the prohibition on production is absolute. It is not a privilege or a confidence that a party or witness can elect to waive or that can be waived impliedly by public disclosure. As a statutory prohibition, it is not open for a witness to choose to produce the document as a witness may choose to waive a privilege. (emphasis added)*
>
> *[46] The publication of the Report and its availability from sources other than a witness in the proceeding does not undermine its status as a quality assurance record prohibited from production under s. 9(2) of the Act. It shall be excluded from evidence in the Plaintiffs' application for certification.*

Court decisions relating to protection of quality assurance information often occur in the context where a patient, or their family member, has been injured in a patient safety incident and they are seeking compensation. The patient is seeking to obtain a record that the health services provider has identified as protected. In the absence of a no-fault system, patients must seek compensation through the civil system and civil liability provides a means for obtaining compensation. The court will consider the applicable legislation and then determine whether the record is protected. At issue from a policy perspective is whether the patient is able to submit to the court the necessary information in order to make the case for compensation.

Legislative Provision – Prohibition

Ontario QCIPA 2016

> *10 (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.*
>
> *(2) Quality of care information is not admissible in evidence in a proceeding.*

Policy Recommendation

The legislation should specify that no person shall ask a witness and no body holding a legal proceeding shall permit or require a witness to disclose quality assurance information. Quality assurance information is not admissible in a legal proceeding. This protection applies regardless of whether or not quality assurance information has been disclosed publicly or in other settings.

Involvement of Patients

The importance of transparency and openness has been recognized by recent legislative initiatives to include patients and their families in quality improvement initiatives. As an example, section 8 of Ontario's *Excellent Care for All Act* states that every healthcare organization shall develop a quality

improvement plan for the next fiscal year and make the quality improvement plan available to the public.[83] The Annual Quality Improvement Plan regulation states:

> **1.** *Every health care organization shall engage the patients and former patients of the organization and their caregivers in developing its annual quality improvement plan, and the publicly available version of the annual quality improvement plan must contain a description of the patient engagement activities of the health care organization and of how these activities inform the development of the health care organization's quality improvement plan.*[84]

Also of note in terms of patient engagement requirements is section 2 of Ontario's Patient Relations Process Regulation made under the *Excellent Care for All Act*. It states:

> ***Complaint process***
>
> *2.(1) The health care organization shall have in place processes for receiving, reviewing and attempting to resolve expeditiously complaints from patients and caregivers of patients.*
>
> *(2) The health care organization shall engage patients and their caregivers in designing, reviewing and maintaining the processes referred to in subsection (1).*[85]

Legislative Provision – Involvement of Patients

Ontario QCIPA 2016

> *4 (1) Nothing in this Act interferes with a requirement under applicable law for a health facility or health care provider to,*
>
> > *(a) offer to interview a patient or the authorized representative of the patient or the patient's estate in any review of an incident or circumstances involving the provision of health care to the patient;*
> >
> > *(b) include a person responsible for patient relations or providing patient perspectives to the facility on a committee or other similar body conducting any review of a critical incident;*

Policy Recommendation

The legislation should provide for the involvement of patients and / or their families in the review of patient safety incidents.

---

[83] Excellent Care for All Act, 2010, SO 2010 c 14, s 8(1); Annual Quality Improvement Plan, O Reg 187/15.
[84] Annual Quality Improvement Plan, O Reg 187/15, s 1.
[85] Patient Relations Process, O Reg 188/15, s 2.

Legislative Review

The *Quality of Care Information Protection Act*, 2016 provides for a review within five years of it coming into force and every five years thereafter.[86] It is likely that the Ontario legislature will continue to consider whether the objectives set out in the preamble have been achieved with the enactment of the *Quality of Care Information Protection Act*, 2016.

Legislative Provision – Review of Legislation

Ontario QCIPA 2016

Review

> ***14*** *Within five years of the coming into force of this section, and at five-year intervals thereafter[86], the Minister shall conduct a review of this Act.*

Policy Recommendation

Patient safety incident legislation should be reviewed at five-year intervals in order to assess whether the current provisions are meeting the policy objectives. Preferably, there should be provisions for the reviewing body (e.g. a committee of the legislature) as well as provisions for the report resulting from the review to be made public (e.g. submitted to the legislature).

Conclusion

This comprehensive background paper discusses the legislative provisions that are in force in four categories of patient safety incident legislation (mandatory reporting, mandatory disclosure, apology protection, and protection of quality assurance information). This paper highlights the overlapping policy purposes behind the legislative initiatives, and provides a foundation for the consideration of model statutory provisions.

Glossary

Disclosure:	The process by which a patient safety incident is communicated to the patient by healthcare providers.
Event:	An event is something that happens to or involves a patient (ICPS, 2009).
Health Minister:	"Health Minister" means the following provincial and territorial ministers: Alberta Minister of Health; British Columbia Minister of Health; Saskatchewan Minister of Health; Manitoba Minister of Health, Seniors and Active Living; Ontario Minister of Health and

[86] QCIPA, 2016 s 14.

	Long-Term Care; Quebec Minister of Health and Social Services; New Brunswick Minister of Health; Nova Scotia Minister of Health and Wellness; Prince Edward Island Minister of Health and Wellness; Newfoundland and Labrador Minister of Health and Community Services; Northwest Territories Minister of Health and Social Services; Nunavut Minister of Health; Yukon Minister of Health and Social Services.
Healthcare associated harm:	Harm arising from or associated with plans or actions taken during the provision of healthcare, rather than an underlying disease or injury.
Inherent risks of an investigation or treatment:	Most investigations and treatments have inherent risks (e.g., recognized complications, adverse reactions or side effects) that may occur and are independent of who is providing care.
Near miss:	A patient safety incident that did not reach the patient.
No harm incident:	A patient safety incident which reached a patient but no discernable harm resulted.
Patient safety incident:	An event or circumstance which could have resulted, or did result, in unnecessary harm to a patient.
Patient safety:	The reduction of risk of unnecessary harm associated with healthcare to an acceptable minimum.
Patient:	In this document, “patient” refers to residents, clients or customers of a healthcare service. (A person who is a recipient of healthcare.)
Reporting:	The communication of information about a patient safety incident by healthcare providers, through appropriate channels inside or outside of healthcare organizations, for the purpose of reducing the risk of occurrence of patient safety incidents in the future.
Safety:	The reduction of risk of unnecessary harm to an acceptable minimum.
System failure:	A fault, breakdown or dysfunction within an organization’s operational methods, processes, or infrastructure.

APPENDIX A - QUALITY ASSURANCE PROTECTION, MANDATORY DISCLOSURE, MANDATORY REPORTING, AND APOLOGY PROTECTION LEGISLATION IN CANADA

Jurisdiction	QA Protection	Mandatory Disclosure	Mandatory Reporting	Apology Protection
BC	*Evidence Act*, R.S.B.C. 1996, c.124, s. 51 Designation Regulation, BC Regulation 363/95 Designation Regulation No. 2, BC Regulation 125/99 *Hospital Act*, R.S.B.C. 1996, c.200, ss. 46.1(6), 46.1(7) *Patient Care Quality Review Board Act*, S.B.C. 2008, c. 35, ss. 7(1)(a), 7(2)(b), 13(5)	--	Hospital Act Regulation, BC Reg 121/97, s. 21(1)	*Apology Act*, S.B.C. 2006, c. 19
AB	*Alberta Evidence Act*, R.S.A. 2000, c. A-18, s. 9 Quality Assurance Committee Regulation, Alta. Reg. 294/2003 *Health Information Act*, R.S.A. 2000, c. H-5, ss. 35(1)(g), 35(2)-(3)	*Mental Health Services Protection Act*, S.A. 2018, c. M-13.2, Schedule, ss. 1, 5	*Mental Health Services Protection Act*, S.A. 2018, c. M-13.2, Schedule, ss. 1, 5	Alberta Evidence Act , R.S.A. 2000, c. A-18, s. 26.1

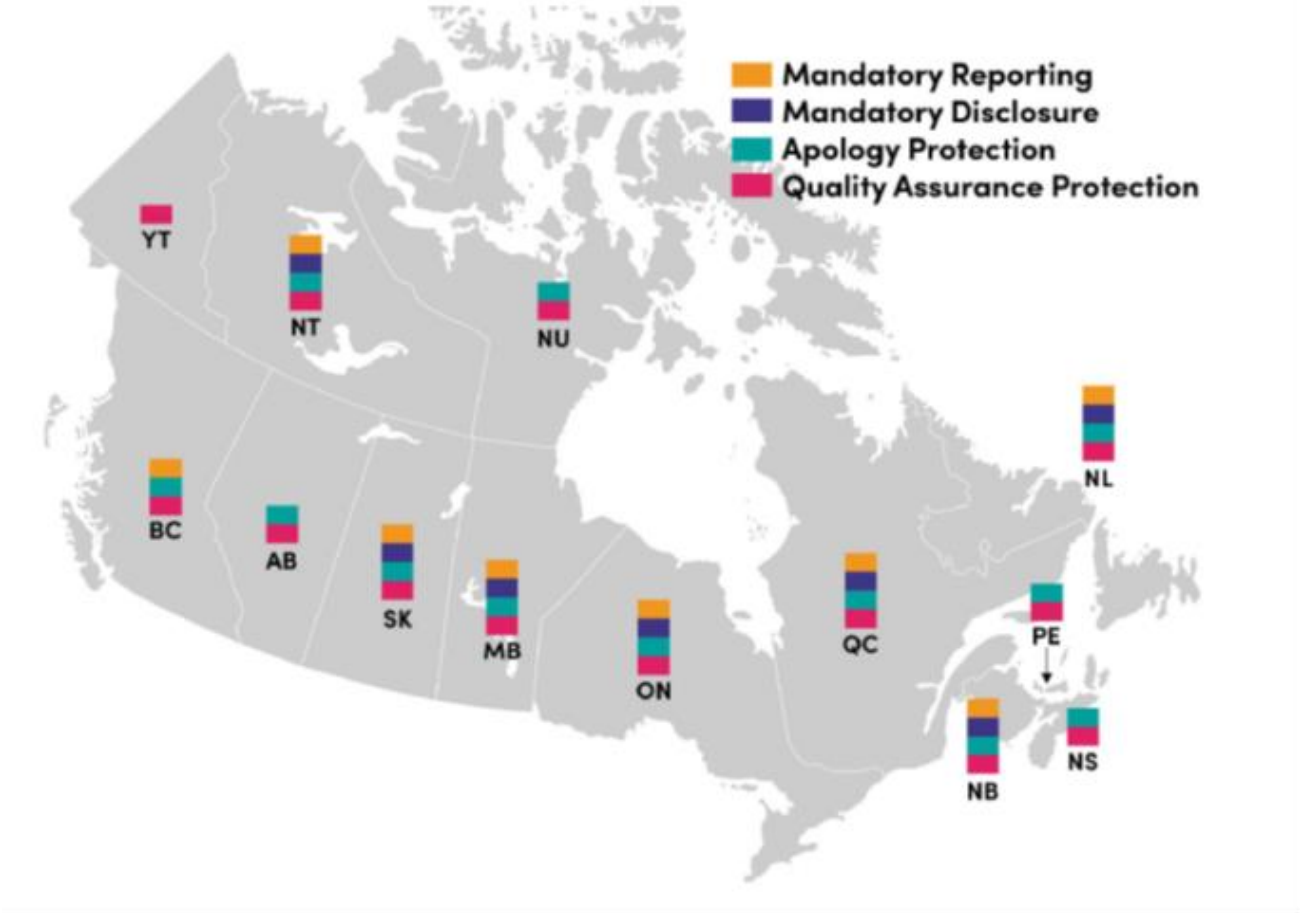
Jurisdiction	QA Protection	Mandatory Disclosure	Mandatory Reporting	Apology Protection
	Health Quality Council of Alberta Act, S.A. 2011, c. H-7.2, s. 6			
SK	*Evidence Act*, S.S. 2006, c. E-11.2, s. 10 *The Health Quality Council Act*, S.S. 2002, c. H-0.04, s. 22 *The Provincial Health Authority Act*, S.S. 2017, c. P-30.3, ss. 8-2(9), 9-5(1)(aa) *Health Information Protection Act*, S.S. 1999, c. H-0.021, ss. 27(4)(g), 38(1)(d) *The Patient Choice Medical Imaging Act*, S.S. 2016, c. P-4.11, s. 13	Personal Care Homes Regulations, 1996, R.R.S. c. P-6.01 Reg. 2, s. 13 Critical Incident Regulations, 2023, R.R.S. c. P-30.3 Reg. 2, ss. 5(3), 7(4), 8(3)	*The Provincial Health Authority Act*, S.S. 2017, c. P-30.3, ss. 8-2, 9-5(1)(aa) Critical Incident Regulations, 2023, R.R.S. c. P-30.3 Reg. 2 Personal Care Homes Regulations, 1996, R.R.S. c. P-6.01 Reg. 2, s. 13 The Patient Choice Medical Imaging Act, S.S. 2016, c. P-4.11, s. 13	*Evidence Act*, S.S. 2006, c. E-11.2, s. 23.1
MB	*Manitoba Evidence Act*, C.C.S.M. c. E150, ss. 9-10 Medical Research Committees Regulation, Man. Reg. 461/88 *Personal Health Information Act*, C.C.S.M. c.	*The Health System Governance and Accountability Act*, C.C.S.M. c. H26.5, ss. 53.2(2)-(3)	*The Health System Governance and Accountability Act*, C.C.S.M. c. H26.5, Part 4.1 Critical Incidents Regulation, Man. Reg. 211/2006, s. 4 *Manitoba Evidence Act*, C.C.S.M. c. E150, ss. 9-10	*Apology Act*, C.C.S.M. c. A98

Jurisdiction	QA Protection	Mandatory Disclosure	Mandatory Reporting	Apology Protection
	P33.5, ss. 11(1)(d), 22(2)(e)			
ON	*Quality of Care Information Protection Act*, 2016, S.O. 2016, c. 6, Sch. 2 General, O. Reg. 482/16 Definitions, O. Reg. 483/16 Annual Quality Improvement Plan, O. Reg. 187/15 *Personal Health Information Protection Act*, 2004, S.O. 2004, c. 3, Sch. A, ss. 7(4), 51(1)(a), 68(4)	*Excellent Care for All Act*, 2010, S.O. 2010, c. 14, s. 8(2) Hospital Management Regulation (*Public Hospitals Act*), R.R.O. 1990, Reg. 965, ss. 2(4) – (6), 19(4)(e), 19(5)(e), 19(6)(d) General, O. Reg. 246/22 (*Fixing Long-Term Care Act*, 2021) s. 147	*Excellent Care for All Act*, 2010, S.O. 2010, c. 14, s. 8(2) Hospital Management Regulation (*Public Hospitals Act*), R.R.O. 1990, Reg. 965, ss. 2(4) – (6), 23(d) General, O. Reg. 246/22 (*Fixing Long-Term Care Act*, 2021) ss. 1, 147	*Apology Act*, 2009, S.O. 2009, c.3
QC	*An Act respecting Health Services and Social Services*, CQLR c. S-4.2, ss. 76.2, 76.4, 76.5, 183.1, 183.3, 183.4, 190, 213, 214, 218	*An Act respecting Health Services and Social Services*, CQLR c. S-4.2, ss. 8, 235.1	*An Act respecting Health Services and Social Services*, CQLR c. S-4.2, ss. 8, 183.2, 233.1, 431(6.2)	*Civil Code of Quebec*, C.Q.L.R. c. CCQ-1991, art. 2853.1
NB	*Evidence Act*, R.S.N.B. 1973, c. E-11, s. 43.3 *Health Quality and Patient Safety Act*, R.S.N.B. 2016, c. 21, ss. 2(2)-2(3), 6-7	*Health Quality and Patient Safety Act*, R.S.N.B. 2016, c. 21, s. 4	*Health Quality and Patient Safety Act*, R.S.N.B. 2016, c. 21, s. 3 General Regulation, NB Reg 2018-60, ss. 4-5	*Health Quality and Patient Safety Act*, R.S.N.B. 2016, c. 21, s. 8

Jurisdiction	QA Protection	Mandatory Disclosure	Mandatory Reporting	Apology Protection
	General Regulation, NB Reg 2018-60 *Personal Health Information Privacy and Access Act*, S.N.B. 2009, c. P-7.05, ss. 14(1)(d), 40(2)(b)			
NS	*Quality-Improvement Information Protection Act*, S.N.S. 2015, c. 8 *Personal Health Information Act*, SNS 2010, c. 41, s. 72(1)(c) *Health Authorities Act*, SNS 2014, c. 32, s. 39	--	--	*Apology Act*, S.N.S. 2008, c. 34
PE	*Health Services Act*, R.S.P.E.I. 1988, c. H-1.6, ss. 26-31	--	--	*Health Services Act*, R.S.P.E.I. 1988, c. H-1.6, ss. 26, 32
NL	*Evidence Act*, R.S.N.L. 1990, c. E-16, s. 8.1 *Access to Information and Protection of Privacy Act*, 2015, S.N.L. 2015, c. A-1.2, s. 102(3)(d) *Personal Health Information Act*,	*Patient Safety Act*, S.N.L. 2017, c. P-3.01, s. 17	*Patient Safety Act*, S.N.L. 2017, c. P-3.01, ss. 4, 5, 6, 7 *Access to Information and Protection of Privacy Act*, 2015, S.N.L. 2015, c. A-1.2, s. 102(3)(c) *Evidence Act*, R.S.N.L. 1990, c. E-16, s. 8.1(2)-(4) *Personal Health Information Act*, S.N.L.	*Apology Act*, S.N.L. 2009, c. A-10.1

Jurisdiction	QA Protection	Mandatory Disclosure	Mandatory Reporting	Apology Protection
	S.N.L. 2008, c. P-7.01, ss. 41(2)(b), 58(1)(c)(i), 78(3)(b) *Public Inquiries Act*, 2006, S.N.L. 2006, c. P-38.1, s. 12(4)		2008, c. P-7.01, ss. 58(1)(c)(ii.1), 78(3)(c)	
YT	*Evidence Act*, R.S.Y. 2002, c. 78, ss. 13, 13.1	--	--	--
NT	*Evidence Act*, R.S.N.W.T. 1988, c. E-8, ss. 13-15 *Health Information Act*, SNWT 2014, c. 2, s. 111 *Hospital Insurance and Health and Social Services Administration Act*, R.S.N.W.T. 1988, c. T-3, ss. 1(1), 25.1, 25.5 General Administration Regulations, NWT Reg. 083-2016, s. 4	*Hospital Insurance and Health and Social Services Administration Act*, R.S.N.W.T. 1988, c. T-3, s. 25.2	*Hospital Insurance and Health and Social Services Administration Act*, R.S.N.W.T. 1988, c. T-3, ss. 25.1, 25.3, 25.4, 25.5 Critical Incident Reporting And Investigation Regulations, NWT Reg 002-2020	*Apology Act*, S.N.W.T. 2013, c. 14
NU	*Evidence Act*, R.S.N.W.T. (Nu) 1988, c. E-8, ss. 13-15	--	--	*Legal Treatment of Apologies Act*, S. Nu. 2010, c. 12
FEDERAL	--	--	*Protecting Canadians from Unsafe Drugs Act* (Vanessa's Law), SC 2014, c 24, amending the *Food and Drugs Act*, RSC 1985, c. F-27	--

Jurisdiction	QA Protection	Mandatory Disclosure	Mandatory Reporting	Apology Protection
			Food and Drugs Act, RSC 1985, c. F-27, s. 21.8 Food and Drug Regulations, C.R.C., c. 870, Part C, Division 1, ss. C.01.001(1.1), C.01.020.1 Medical Devices Regulations, SOR/98-282, s. 62	



Accessible description of map

A legend in the top right corner uses stacked color-coded squares to indicate which policies apply to each geographic region.

Legend
Orange: Mandatory Reporting
Dark Blue: Mandatory Disclosure

Teal: Apology Protection
Pink: Quality Assurance Protection

Data by Province and Territory
Regions with all four policies (Mandatory Reporting, Mandatory Disclosure, Apology Protection, and Quality Assurance Protection):

- Northwest Territories (NT)
- Saskatchewan (SK)
- Manitoba (MB)
- Ontario (ON)
- Quebec (QC)
- New Brunswick (NB)
- Newfoundland and Labrador (NL)

Regions with three policies:

- British Columbia (BC): Features Mandatory Reporting, Apology Protection, and Quality Assurance Protection.

Regions with two policies:

- Nunavut (NU): Features Apology Protection and Quality Assurance Protection.
- Alberta (AB): Features Apology Protection and Quality Assurance Protection.
- Nova Scotia (NS): Features Apology Protection and Quality Assurance Protection.
- Prince Edward Island (PE): Features Apology Protection and Quality Assurance Protection.

Regions with one policy:

- Yukon (YT): Features only Quality Assurance Protection.