Rapid Review

NORTH AMERICAN OBSERVATORY on Health Systems and Policies

Patient Safety Mandatory Reporting Legislation and Outcomes: A Jurisdictional and Scoping Review

A Rapid Review Prepared for The Canadian Patient Safety Institute

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Introduction and Background

Despite increasing attention paid to health system performance, quality, and safety of care, the safety of patients in Canadian healthcare institutions remains a major public health challenge. In 2004, the Canadian Adverse Events Study reported that 7.5% of all hospitalized patients experienced an incident that caused them harm (Baker et al., 2004). The rate of hospital standardized mortality has improved since then ("Hospital Deaths (HSMR)," 2019), but harm continues to be experienced by patients in approximately one out of every 18 hospitalizations (Canadian Institute for Health Information & Canadian Patient Safety Institute, 2016). RiskAnalytica (2017) estimates that by 2047, infections alone will drive nearly 40% of all patient safety incidents in acute care settings, increasing healthcare costs by an average of $480 million per year.

A systems thinking approach views patient safety as an outcome of the entire healthcare system that requires action at every level to sustain high standards. According to a systems thinking approach, aspects of the system itself cause most patient safety incidents. In his seminal book, James Reason (1997) illustrated system error through the "Swiss cheese model" wherein different layers of protection against preventable harm are placed at multiple levels but, like Swiss cheese, each layer has holes. When the holes at different levels align, harm reaches the patient.

The Canadian Patient Safety Institute (2018) identified five multi-level policy levers to improve patient safety: government legislation and policies; professional regulation; standards; organizational policies; and public engagement (p. 5). These levers create an environment that encourages organizational and team-based efforts to improve safety performance across healthcare systems. Recognizing that each of the five policy levers works in concert with the others to create environments conducive to safer care, this rapid review explores the specific role of legislation in improving patient safety.

Legislation in Canada has become increasingly supportive of patient safety in the past decade (Erdmann, 2018). The *Protecting Canadians from Unsafe Drugs Act*, also known as Vanessa's Law, is an example of the Canadian federal government strengthening the safety of therapeutic products and their regulation. However, the majority of patient safety legislation in Canada sits at the provincial and territorial levels. Variation among patient safety legislation across the provinces and territories provides a unique opportunity for comparative analysis.

In this rapid review, we focus on legislation that explicitly requires and governs mandatory patient safety incident reporting. The reporting of patient safety incidents is integral to driving patient safety learning systems (PSLS). Establishing a knowledge base about patient safety incidents, which can be shared in support of individual and organizational learning, is critical to building a culture of patient safety and, ultimately, delivering safer care. It is through a cycle of learning—reporting and investigating incidents, identifying activities to mitigate impact, and sharing lessons broadly—that additional similar incidents can be prevented (Baker et al., 2008).

We explore whether patient safety legislation related to mandatory reporting of incidents in hospital-based acute care settings is associated with patient safety outcomes, as well as how legislative

frameworks can be strengthened and aligned with other policy levers. This rapid review comprised a multi-phased approach:

1. Rapid scoping review of peer-reviewed academic literature to understand what is known regarding any associations between patient safety legislation and patient safety outcomes;
2. Jurisdictional review and assessment of the comprehensiveness of provincial and territorial government legislation for mandatory reporting of patient safety incidents; and
3. Assessment of the extent to which measured patient safety outcomes in hospital-based, acute care settings vary across the country and are associated with variations in legislative frameworks.

The concluding sections of this report highlight a number of implications that provincial and territorial governments may consider as part of their respective approaches to governing patient safety.

Definitions and Conceptual Framework

In accordance with international best practice, this report uses the following key terms proposed by the World Health Organization (2009) and endorsed by the Canadian Patient Safety Institute (Disclosure Working Group, 2011): patient safety incident, harmful incident, no harm incident, and near miss. These terms are defined in Table 1.

Table 1. International definitions of patient safety terms

Term	Definition
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.
No harm incident	A patient safety incident that reached a patient, but no discernable harm resulted.
Near miss	A patient safety incident that did not reach the patient.

Adapted from: Disclosure Working Group, 2011, p. 11

We organize our scoping and jurisdictional review of patient safety mandatory reporting legislation alongside the three system objectives proposed by Downie and colleagues (2006):

1. Know about patient safety incidents through reporting, investigation, analysis, and inquiry;
2. Respond to patient safety incidents through learning and accountability at both individual and systems levels; and
3. Prevent incidents through the regulatory or policy framework that controls or influences care delivery.

Furthermore, we complement these three system objectives with 10 elements of legislation related to patient safety incident reporting that Baker and colleagues (2008) propose are necessary to support the development of learning systems. Detailed in Table 2, these elements identify specific components of mandatory reporting legislation that should be in place as part of a systems governance approach to patient safety.

Table 2. Essential elements of Legislation for patient safety incident reporting

Element	Summary
1. What is reported?	The definition of a reportable incident(s) is clearly defined.
2. Who makes a report?	The group of persons (e.g., healthcare professionals, employees of healthcare institutions, patients, and families) who report is defined, and incident reporting mechanisms for persons outside the defined group are provided.
3. How is an incident reported?	Procedures and timelines for reporting and investigation are defined.
4. To whom is an incident reported?	Reports, including personal health information, to a patient safety incident review committee should be required by healthcare professionals or institutions. Reporting to the health ministry (or prescribed organization) should also be required for tracking and analysis.
5. Confidentiality	Reported information must exclude the name of the patient, healthcare provider, or the name of any other individual with knowledge of the incident.
6. Protection	All documentation resulting from the patient safety incident review process is protected and therefore not permitted as evidence in legal proceedings.
7. Non-retaliation	Persons who provide information are protected from personal liability, suspension, demotion, harassment, and other retaliatory behaviour.
8. Expert analysis	Critical issues described in reports must be reviewed by experts who have appropriate clinical skills and knowledge of system issues.
9. Incidents register	The minister or other prescribed organization must maintain a register of incidents on a de-identified basis for the purpose of aggregating and sharing data at the jurisdictional level. Legislation should encourage the use of electronic reporting systems.
10. Annual review	Institutions must report to the responsible minister or other prescribed organization, summarizing the reporting and recommendations, on an annual basis. The summary must include a report on the implementation of quality improvement recommendations of the previous year, including evaluation of success.

Adapted from: Baker et al., 2008, p. B16-17

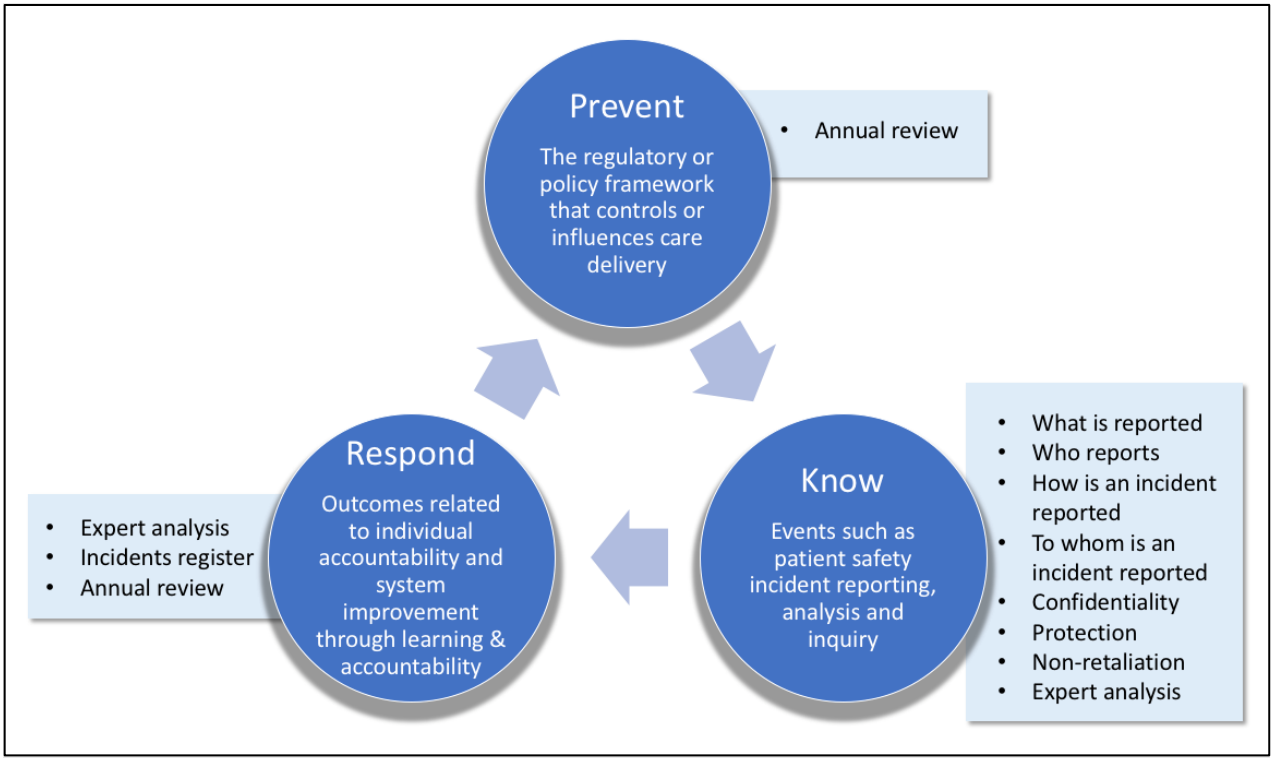
As depicted in Figure 1, the conceptual framework used in this rapid review combines the system objectives of knowing about, responding to, and preventing patient safety incidents with the 10 essential elements of legislation for patient safety incident reporting, thus building on scholarship with a specific focus on legislation for patient safety (Baker et al., 2008; Downie et al., 2006). It should be noted that this framework aligns clearly with the Canadian Incident Analysis Framework (Incident Analysis Collaborating Parties, 2012). Although the latter framework does not share a focus on legislation, it does provide methods to understand:

1. What happened in a patient safety incident, to whom and why (know about the incident);
2. What can be done to reduce the likelihood of recurrence and make care safer (respond to the incident through learning and accountability); and
3. How to follow through and close the loop on an incident, applying what has been learned (prevent new incidents).

Notably, the Canadian Incident Analysis Framework presents guidance and tools to implement and monitor corrective actions following a patient safety incident, including description of feedback and feed-

forward communication loops to share learning within the organization as well as externally. Our conceptual framework also underscores the significance of a cycle of learning as the link between responding to and preventing patient safety incidents. In other words, an effective response that includes thorough review of the patient safety incident and any lessons learned will contribute to preventing similar incidents in the future.

Figure 1. Patient Safety System Objectives (Know, Respond, & Prevent) and the Essential Elements of Legislation for Patient Safety Incident Reporting



Adapted from: Downie et al., 2006 and Baker et al., 2008

We used this conceptual framework to analyze and summarize the results of our literature review as well as to inform our assessment of legislation. In light of the strong connection between what is required to effectively respond to and then prevent patient safety incidents, we combine these system objectives in the presentation of our results below.

Methods

The scope of this rapid review is limited to an examination of scholarly literature, legislative frameworks for mandatory reporting of patient safety incidents, and patient safety outcomes data from hospital-based acute care settings. We do not intend this report to serve as a comprehensive systems analysis for patient safety. Data collection took place between January and May 2019 and followed a multi-methods approach, including a literature review, consultations with key informants in senior health system leadership positions, a legislative review, and a review of patient safety data.

Literature Review

We conducted a rapid scoping review to determine what is known in the peer-reviewed academic literature regarding the impact of patient safety legislation on patient safety outcomes. The scoping review followed well-established methodology described by Arksey and O'Malley (2005). Further detail related to our methodology and results is found in Appendix A.

Consultation with Key Informants in the Field

From March 13 to May 31, 2019, inclusive, we spoke to 13 senior executives and practitioners working in safety and quality of care in jurisdictions across Canada. The purpose of these conversations was to obtain contextual and experiential evidence to clarify and understand the interpretation and implementation of legislation in practice, with a focus on mandatory reporting. These conversations also helped clarify how professional regulation relates to patient safety legislation. Although we prepared points for discussion in advance, these were open-ended conversations. The key informants' contributions are integrated throughout the findings and recommendations of this report. Additional detail related to our key informants and the interviews is available in Appendix B.

Legislative Review

Building on a report produced by the Canadian Patient Safety Institute (2018a), we reviewed a selection of legislation from the eight Canadian jurisdictions that have instituted mandatory reporting legislation. The legislation that we reviewed, listed in Appendix C, explicitly relate to mandatory reporting of patient safety incidents. We then applied the 10 essential elements outlined by Baker (2008) as criteria to assess the comprehensiveness of legislation in support of patient safety reporting and learning systems. Drawing from our conversations with key informants, we also explored how legislation interacts with patient safety policies and initiatives at other system levels, such as professional regulation.

Review of Patient Safety Data

We relied on publicly available patient safety data related to incidents and outcomes that we obtained from the Canadian Institute for Health Information (CIHI) as well as ministries of health and quality council websites. Measures of in-hospital harm were also requested directly from the CIHI for the provinces that participated in the 2016 *Measuring Patient Harm in Canadian Hospitals* project (Canadian Institute for Health Information & Canadian Patient Safety Institute, 2016), as these were not available publicly. We

compared indicator rates for each province with the national average. Details on the indicators that were retrieved as well as their sources can be found in Appendices D and E.

Limitations

This report presents a single point in time based on a rapid review that focused on hospital-based acute care settings and on laws specific to mandatory reporting of patient safety incidents. We therefore present only a portion of the full range of laws and policy levers that may impact patient safety for the entire health system. Furthermore, the literature review component of this review did not include grey literature. For our consultation, we sought a purposive sample of key informants who worked in jurisdictions with various approaches to patient safety. Key informants were sought in one jurisdiction without mandatory reporting legislation (Alberta) and two jurisdictions with mandatory reporting legislation that appeared to follow contrasting approaches to implementation (British Columbia and Ontario). These key informants provided a range of experiences and insight to enrich our findings despite a limited review scope, be we consequently did not capture the views of all provincial or territorial jurisdictions or other relevant organizations working in patient safety across Canada. This report thus serves as a starting point for future research to examine a wider range of perspectives, including governments, on the optimal use of legislation to support improvements in patient safety, as well as to examine the impacts of legislative changes on outcomes over a longer period of time.

Results

In this section, we first summarize the results of the literature review we conducted to determine what is known from the empirical literature regarding the impact of patient safety legislation on patient safety outcomes. Second, we compare the approaches taken across the provinces and territories to legislate mandatory reporting of patient safety incidents, and discuss the role of professional regulation, with a focus on Ontario and British Columbia. Third, we summarize the types of patient safety data available in Canada and report comparable indicators of patient safety using data from CIHI. Finally, we conclude with considerations of the optimal role of legislation to improve patient safety and support continuous learning and improvement.

Literature Review

Our scoping review yielded 11 articles that examined the impact of patient safety legislation on patient safety outcomes, primarily in the United States and Canada, with one study from France, and one multi-jurisdictional study of England, France, Germany, and the United States.

In these articles, the measured impact of patient safety legislation (including mandatory and voluntary reporting laws) on patient safety outcomes varied. Two articles reported a statistically significant association between mandatory reporting and a reduction in patient safety incident rates (Daneman et al., 2012; Stone et al., 2011). The remaining studies found limited impact (Tu et al., 2009; Woodward & Umberger, 2016); inconclusive evidence of impact (Haustein et al., 2011; Lucet et al., 2013; Stone et al., 2007; Stone et al., 2015); or no statistically significant impact (Linkin et al., 2013; Marsteller et al., 2014; Pakyz & Edmond, 2013);. One article compared rates between mandatory reporting jurisdictions and voluntary reporting jurisdictions and found no difference in impact on outcomes (Stone et al., 2015). The 11 articles are described in greater detail in Appendix A.

In the following sub-sections, our findings are presented in line with our conceptual framework. We then discuss emergent themes regarding unintended consequences and measurement challenges, specifically that mandatory reporting legislation may lead to underreporting.

Knowing about patient safety incidents

Ten of the 11 articles examined the impact of legislation on healthcare-associated infections (HAI) (Daneman et al., 2012; Haustein et al., 2011; Linkin et al., 2013; Lucet et al., 2013; Marsteller et al., 2014; Pakyz & Edmond, 2013; Stone et al., 2007, 2011, 2015; Woodward & Umberger, 2016); three of which focussed on central line-associated bloodstream infections (CLABSI) in hospital intensive care units (ICUs) (Marsteller et al., 2014; Pakyz & Edmond, 2013; Woodward & Umberger, 2016). One article examined the impact of mandatory reporting legislation on two health outcomes that are broader than patient safety incidents - acute myocardial infarction (AMI) and congestive heart failure (CHF) (Tu et al., 2009).

Responding to and preventing patient safety incidents

Several studies described the mechanisms by which legislation may provide incentives to influence organizational and healthcare provider behaviour to improve patient safety. At the core of each

mechanism is the capacity for collaboration and peer-learning between and among hospitals to reduce incident rates (Marsteller et al., 2014; Stone et al., 2011, 2015). Many authors argued that a combination of legislation and organizational change is needed to improve patient safety outcomes, along with a strong patient safety culture (Marsteller et al., 2014; Pakyz & Edmond, 2013; Stone et al., 2011).

In seven articles, the introduction of patient safety legislation was associated with a move toward an organization-wide commitment to safety precautions and procedures (Daneman et al., 2012; Haustein et al., 2011; Lucet et al., 2013; Marsteller et al., 2014; Pakyz & Edmond, 2013; Tu et al., 2009; Woodward & Umberger, 2016). Marsteller et al. (2014) argued that mandatory reporting legislation may incentivize peer learning (i.e., learning and sharing best practices between and among hospitals) as evidenced by increased participation rates in the *On The CUSP: Stop B*SI program within states with mandatory reporting laws.[1] Marsteller et al. (2014) stressed that patient safety legislation does not teach healthcare organizations or systems how to reduce the rates of patient safety incidents, and that peer learning, among other actions, such as committing resources to identifying and remedying contributing factors to patient harm within individual units, and implementing teamwork tools (i.e., morning briefings on identified contributing factors), are also needed. Legislation may thus influence or create an incentive for hospitals to adopt best practices. However, best practices are often not easy to implement. Thus peer-learning structures and collaborative initiatives like *On The CUSP: Stop BSI* provide a means for hospitals to build, share, and improve patient safety culture and best practices. Finally, three articles (Haustein et al., 2011; Lucet et al., 2013; Marsteller et al., 2014) drew attention to increased appropriate hand-hygiene as an important organizational and healthcare provider behaviour change to improve patient safety that may have been motivated by the change in legislation.

Emergent themes: Unintended consequences and measurement challenges

Three articles (Linkin et al., 2013; Pakyz & Edmond, 2013; Stone et al., 2011) drew attention to under-reporting or incomplete reporting to manipulate the calculation of incident rates as unintended consequences of legislation. Pakyz and Edmond (2013) cited results from external validation reviews of hospital CLABSI rates to show that the true rates were higher than those reported by hospitals. Stone and colleagues (2011) also found over-reporting with regard to adherence to patient safety processes.

Two other articles described another unintended consequence whereby medical professionals in the United States may be less willing to admit higher-risk patients and instead deliberately select low-risk patients (Linkin et al., 2013; Stone et al., 2011). Moreover, the lack of standardized reporting methods set by United States government agencies appears to be a major limitation to improving patient safety within these study settings. Specifically, Stone and colleagues (2007, 2011, 2015) argued for standardized reporting across government bodies and healthcare organizations, along with incentives (i.e., to provide motivation and facilitation), to move towards peer learning and adoption of proven interventions to reduce patient incidents (Stone et al., 2015).

[1] The *On The CUSP: Stop PSI* program was a quality improvement collaboration aimed at reducing CLABSI rates and improving patient safety culture as a foundation for quality improvement efforts (Marsteller et al., 2014).

Review of Legislative Frameworks Across Canada

Governments may take a hands-on approach and directly regulate patient safety with mandatory reporting legislation. Alternatively, governments may leave room for an arm's-length body, professional regulatory bodies, or individual healthcare institutions to enact their own policies. In this section, we summarize the key results and themes of our review of legislation in the eight Canadian provincial and territorial jurisdictions with mandatory patient safety incident reporting.

Table 3 summarizes our assessment of each jurisdiction and depicts the variation in provincial and territorial legislative approaches to patient safety according to the 10 essential elements of legislation for patient safety incident reporting (Baker et al., 2008). The year that mandatory reporting legislation was introduced in each jurisdiction is indicated in the top row of the table. Full details of the assessment are found in Appendix C.

Table 3. Assessment of Legislation on mandatory reporting of patient safety incidents

Element	BC (2013)	SK (2004)	MB (2005)	ON (2011)	QC (2002)	NB (2018)	NL (2017)	NT (2016)
1: Detail on what is reported	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
2: Detail on who makes a report	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
3: Detail on how an incident is reported	Yes	Yes	Yes	Yes	Yes	Yes	No	No
4: Detail on to whom an incident is reported	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
5: Provisions for confidentiality	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes
6: Protections in legal proceedings	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
7: Provisions for non-retaliation	No	No	Yes	Yes	No	Yes	Yes	No
8: Provisions for expert analysis	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes
9: Mandated incidents register	No	No	No	No	Yes	No	No	No
10: Mandated annual review	No	No	No	Yes	No	No	No	No

Adapted from: Baker et al., 2008

Notes: The assignment of Yes and No provides a high-level summary of the legislation in order to draw comparisons, but this approach masks some of the variation that is seen even among jurisdictions with the same result. For example, while provisions for non-retaliation are evident in four provincial/territorial legislation, there is variation in the scope of these provisions which are more narrowly defined in Ontario than in the other three jurisdictions. More detail can be found in Appendix C.

Knowing about patient safety incidents

All eight jurisdictions with mandatory reporting legislation outline the patient safety incident information that must be reported. This legislation includes clear definitions of a patient safety incident, although there are variations in the terminology and definitions used. For example, New Brunswick legislation has adopted the all-encompassing definition of *patient safety incident* such that it closely resembles WHO terminology. By contrast, Ontario and British Columbia have adopted different WHO terminology, specifically the more narrowly defined *harmful incident*: *critical incident* in Ontario and *serious adverse event* in British Columbia.

Each jurisdiction has also legislated direction regarding who can make a report and to whom a report is submitted. Manitoba and Northwest Territories have the widest definition of who can report an incident. Although engagement with patients and their families is acknowledged as an integral component of incident analysis (Incident Analysis Collaborating Parties, 2012), these two jurisdictions are the only ones that include provisions enabling a patient or family member to report an incident under the same legislation as a person working for the health authority. Key informants further explained that patient safety incident reporting systems are usually limited to hospital settings, thus access to these reporting systems is limited to hospital-based healthcare providers. Despite the hospital-based and acute-care focus of this rapid review, our key informants clearly suggested that for mandatory reporting legislation to be impactful, it needs to be system-wide, not sector-based.

Except for Newfoundland and Labrador and Northwest Territories, where the legislation leaves room to develop more detailed regulation not yet in force, all jurisdictions have also clearly directed requirements for how an incident is to be reported. In many jurisdictions (i.e., British Columbia, Manitoba, New Brunswick, Newfoundland and Labrador, and Québec) this clear direction is provided in only minimal detail within legislation; rather, greater detail regarding how to report an incident is contained at the level of regulation or written procedures within individual healthcare institutions.

There is also variation in the extent to which the laws protect people who provide information about patient safety incidents from personal liability, suspension, demotion, harassment, and other retaliatory behaviour. Among the jurisdictions with mandatory reporting legislation, these provisions are not in place in Québec, Saskatchewan and Northwest Territories. In British Columbia, there is some protection afforded to people who report incidents through the *Apology Act,* which states an apology "must not be taken into account in any determination of fault or liability." However, apology protection does not provide protection from retaliatory behaviour. Non-retaliation provisions in several provinces, including Manitoba, New Brunswick, and Newfoundland and Labrador, are wide-ranging and consistently worded. For example, the *Patient Safety Act* of Newfoundland and Labrador states 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."

Confidentiality and privilege are specified in nearly all the jurisdictions' laws, although protections are in place to varying degrees. For example, in order for information to receive protection in Ontario, it must be information that is connected with a "quality of care committee" designated under the *Quality of Care Information Protection Act*. As such, the protection appears to be very narrow. In contrast, the protection in Manitoba is quite broad and covers "a notice, report or other record or information respecting a critical incident that is required to be provided by a health corporation, prescribed health care organization or regional health authority." British Columbia is the only jurisdiction whose mandatory reporting legislation does not contain specific provisions for confidentiality. Several key informants suggested that emphasis on confidentiality and privacy actually constrains the sharing of information across organizations and authorities. According to our key informants, the result is an inability to learn system-wide about the factors that lead to patient harm. In other words, they suggest that although legislation is clearly designed to gather information, the lack of a patient safety culture and effective learning system nonetheless obscures what is known about patient safety incidents.

Key informants from British Columbia and Ontario remarked on the value of real-time patient safety surveillance data. In both provinces, several key informants identified their lack of real-time patient safety surveillance data as a constraint in their oversight of practice aligned with patient safety. They described access to system-level surveillance data as particularly important to help health system stakeholders identify safety champions and outliers and be able to intervene before incidents occur. They also argued that individual healthcare professionals require access to their own performance data so as to address any shortcomings in their practice and do their part to contribute to improved patient safety.

Responding to and preventing patient safety incidents

Each of the jurisdictions we reviewed strongly emphasizes definitions and rules of reporting—vital for knowing about patient safety incidents. However, the mechanisms for consolidating, using and learning from reports mostly fall outside of the legislation. Ontario and Québec are the sole exceptions. The legislation in Ontario mandates aggregate patient safety incident reviews at least twice a year in every public hospital but does not mandate a province-wide incident register. Ontario hospitals maintain their own incident data in hospital-level registers from which the ministry of health may request information, but system-level monitoring may be constrained in the absence of a province-wide incident register. In Québec, a provincial register is managed by the ministry of health, which may enable the monitoring and analysis of incidents at the system level, but there is no mandated annual review to facilitate learning for system improvement.

Ontario's framework appears to be the most comprehensive as it covers all but one of the essential elements suggested by Baker et al. (2008). In comparison, British Columbia has adopted a lighter approach to legislation, with much of the responsibility for regulating and implementing patient safety is delegated to professions and organizations. British Columbia's legislation covers fewer essential elements than does legislation in any of the other jurisdictions with mandatory reporting.

Although protection in legal proceedings is narrowly focused on information put forward by a "quality of care committee," Ontario has created legislation that appears to address nine of the 10 elements of mandatory patient safety reporting. However, there may be trade-offs created by these requirements. Some key informants in Ontario suggested that rigid mandatory reporting frameworks encourage "gaming of the system" to artificially reduce incident rates. Key informants in British Columbia described their lighter approach as having empowered professional regulatory bodies to identify system factors that lead to harm and participate in collaborative policy making. British Columbia key informants also felt that organizational-level initiatives and policies (e.g., respectful workplace policies) have contributed to important system improvements for patient safety.

One British Columbia initiative introduced in 2013 is a robust Patient Safety Learning System (PSLS) that remains the only province-wide system of its kind in Canada. It uses real-time digital information and technology to facilitate reporting and learning from patient safety incidents across regional health authorities. British Columbian key informants acknowledged that with few exceptions, the PSLS is only accessible to individuals within health authority firewalls. There is also ongoing need to support health authorities to recognize patient safety incidents and see value in reporting them given that the PSLS relies on local capabilities and interest. The PSLS is run by a team that is governed by a provincial steering committee with senior-level representation from all health authorities. It is therefore able to work closely

with authorities and organizations in a way that supports incident investigation, sharing of information and learning across the provincial system, and promoting a culture of patient safety. By contrast, Ontario regulatory bodies operate in a more rigid, prescriptive environment where they are more distantly removed from points of care. Some observers view the Ontario regulatory oversight structure as outdated and incapable of effectively monitoring professional practice (Waddell et al., 2017).

Overall, there was agreement among key informants that legislation plays an important role in creating an environment conducive to patient safety. Key informants also raised a number of challenges and opportunities regarding the effective implementation of patient safety legislation and the interaction of legislation with professional regulation and other policies. These challenges and opportunities related to accountability in the health professions for improving patient safety, the role of legislation in supporting learning systems, the importance of patient safety culture, and the system governance perspective. The following sections review these in greater detail.

Accountability

A concern identified by the key informants was that providers were not held accountable for their adherence to professionally accepted standards of safety. This situation exists across jurisdictions, including those with mandatory reporting legislation, despite a perception that mandatory reporting serves as a system of accountability (Health Quality Council of Alberta, 2017). The *Public Hospitals Act* in Ontario was cited by one key informant as a specific piece of legislation that could be amended to remove legal deterrents to hospital oversight of physician performance. Similarly, the professional colleges currently face challenges with proactive monitoring of practitioner performance for patient safety. Moreover, key informants also suggested a need to strengthen accountability of professional colleges to government to strengthen the alignment between professional regulation, policy, and patient safety legislation. For example, it was noted that routine reporting of patient safety data by provider organizations and professional regulatory colleges to government could strengthen the accountability of providers to the government for patient safety.

Learning systems

Regardless of how patient safety concerns are brought forward—whether via mandatory reporting, voluntary reporting, or complaints—a PSLS would allow a health system to build on what it knows and appropriately respond to a patient safety incident, share information about it, and thus contribute to preventing further patient safety incidents. Unfortunately, this is where legislation in the majority of Canadian jurisdictions falls short. With British Columbia as a notable exception, there have been limited efforts to create and build learning systems. Even in Ontario, where the provincial government accepted a 2014 recommendation to develop a hospital-focused learning system (Morin & Laupacis, 2014), there has been no discernible movement toward developing this system.

According to our key informants, the ability of health system actors such as hospitals, regulatory bodies and quality councils to respond to, learn from and prevent patient safety incidents is hampered by silos and unclear channels of communication. Cross-jurisdictional collaboration is complicated by the various definitions and conceptualizations of patient safety that exist across the country. Notably, a number of key informants pointed to a need to elevate patient safety to a status as a field in its own right, citing

British Columbia as a model for distinguishing between patient safety and quality improvement as distinct fields. The Ontario framework, on the other hand, was seen to embed patient safety within quality improvement. Regardless of how patient safety is situated relative to other fields, dedicated patient safety incident reporting and learning systems are a valuable resource. A common language for patient safety would allow for greater sharing and comparability of data within these systems across professions and jurisdictions. Extensive attempts to develop this language and classify patient safety incidents have already been made (Davies, Hébert, & Hoffman, 2003; World Health Organization, 2009), albeit with limited meaningful uptake. In this light, there is opportunity to strengthen communication and learning through wider use of standardized terms, such as with CIHI's National System for Incidence Reporting.

Effective learning systems are characterized by continuous prospective and retrospective self-reflection and identification of strengths and weaknesses, including action to address weaknesses or gaps (Frankel et al., 2017; Incident Analysis Collaborating Parties, 2012). They combine local reporting and analysis with data sharing at provincial or territorial and pan-Canadian levels (Baker et al., 2008). However, legislation related to privacy and confidentiality may present a challenge to ensuring the sharing of data and important safety lessons across institutions and jurisdictional borders. For example, Baker et al. (2008) outline how confidentiality obligations can serve to limit sharing of useful incident information and removing details about a patient's unique characteristics can make reporting less effective. Numerous key informants suggested that leadership on this issue should come from the federal or pan-Canadian level, with multilevel and multisectoral collaboration to develop meaningful patient safety indicators as well as infrastructure to support data collection and access. Recognizing provincial and territorial jurisdiction in this area, scholars have argued that interprovincial efforts by those jurisdictions willing to commit to building a learning system may be more appropriate than pan-Canadian action (Baker et al., 2008). For example, Global Patient Safety Alerts,[2] a publicly available online collection of indexed patient safety incidents worldwide, is one initiative that aims to promote cross-jurisdictional learning and transparency. Canadian contributors currently include Alberta Health Services, Health Quality Council of Alberta, Manitoba Heath, Winnipeg Regional Health Authority, and the Institute for Safe Medication Practices Canada.

Patient safety culture

A robust patient safety culture, in which shame and blame are replaced with trust and proactive identification and resolution of system weaknesses, is often presented as a necessary underpinning of a learning system (Frankel et al., 2017; Incident Analysis Collaborating Parties, 2012). In the words of one key informant, patient safety incident reporting in the absence of a strong patient safety culture is "like you're ratting people out." System improvement is defined by the World Health Organization (2009) as: "…the result or outcome of the culture, processes and structures that are directed towards the prevention of system failure and the improvement of safety and quality" (p. 19). A fundamental part of this definition is culture. The World Health Organization (2009) describes a work culture that encourages the reporting of errors as well as open communication among staff about patient safety as indispensable to system improvement. Furthermore, the Canadian Incident Analysis Framework outlines how incident analysis processes are most effective when implemented within a safety culture (Incident Analysis Collaborating

[2] https://www.patientsafetyinstitute.ca/en/NewsAlerts/Alerts/Pages/default.aspx

Parties, 2012). Our key informants echoed these points and suggested a need to foster a patient safety culture across systems and professions. They described a blended concept of patient safety culture that encompasses reporting, learning, and sharing, consistent with the multidimensional notion of patient safety culture proposed by the Canadian Patient Safety Institute (2016).

Legislation, on its own, cannot create or sustain patient safety culture (Small & Barach, 2002). According to our key informants, phased organizational-level interventions with strong support from senior executives and managers are the most effective means to instill a robust patient safety culture. Organizational support for this culture, they said, is a decisive facilitator in successfully responding to and preventing patient safety incidents. A healthy organizational culture around patient safety incident reporting would, in fact, promote the interpretation of mandatory reporting legislation and regulation in a positive light and help to move patient safety culture forward as an everyday practice. Multiple key informants recommended that patient safety culture be developed before legislating mandatory reporting.

Systems governance perspective

Patient safety is a complex systems issue that demands response at individual, organizational, and system levels across all sectors of healthcare. Legislative frameworks in Canada must therefore support a systems governance perspective that supports a balance between individual accountability and the discovery and learning from factors contributing to patient harm (Downie et al., 2006). Though it is a blunt instrument with neither agility nor efficiency when it comes to addressing concerns such as team communication or missed lab results, legislation is useful to guide the development of organizational policy, professional regulation and other levers for patient safety, ensuring a collaborative approach to fulfilling all essential elements.

Just as legislation is used to create an environment where individuals feel protected to report patient safety incidents, it could also be used to extend reporting systems beyond the hospital to all healthcare and community care settings, or to make reporting systems accessible to a larger group of reporters than is currently the case. Governments can strengthen patient safety legislation by extending the range of its intended outcomes from knowing about patient safety incidents to also responding well and learning. Current legislation arguably does not reflect a systems governance perspective. Rather, system-oriented legislation for patient safety response and learning would contain provisions for investigation and analysis by experts, maintenance of a system-wide repository of data, regular review and sharing of lessons learned, and accountability with regard to system recommendations (Baker et al., 2008).

Well-crafted legislation has potential to play a major role in improving patient safety by providing a framework for evidence-based interventions, and learning and change at organizational and system levels. Where legislation has strong linkages with other levers throughout the healthcare system, policy can be translated into local action supported by organizational resources and capabilities.

Review of Patient Safety Data

To examine the association between legislation and patient safety, we review comparable data sources of patient safety in Canada. There are three broad sources of patient safety outcome data that can be used to monitor progress toward improved patient safety:

1. Patient safety incidents reported as part of legislative requirements;
2. Estimates of patient safety using administrative (hospital discharge) data; and
3. Chart or health record reviews aided by the Global Trigger Tool or similar tools used internally as part of local efforts to identify potential adverse events (Griffin & Resar, 2009).

Given our focus on publicly available data, this rapid review did not include internal reviews and is thus limited to an examination of the first and second data sources.

Among the jurisdictions with patient safety mandatory reporting legislation, data on critical incidents are publicly available in three provinces: Manitoba, Saskatchewan, and Québec. The critical incidents are categorized differently, and there are variations in the volume of incidents reported which likely relate in part to differences in definitions and categorization of critical incidents as well as to different reporting guidelines (details are available upon request). At the same time, it is important to acknowledge the challenges associated with comparing patient safety incidents across time and jurisdictions. Arguably, higher incident rates may be a function of more accurate reporting of incidents defined in legislation, a strong patient safety culture and greater willingness to report, and thus does not imply more harm to patients.

While only three provinces report the number of incidents publicly, there is a range of specific patient safety data publicly reported by provincial ministries of health or arm's-length agencies across jurisdictions. Hospital-acquired infections, notably methicillin-resistant staphylococcus aureus (MRSA) (in six provinces) and clostridium difficile infection (in five provinces), are the most frequently reported measures followed by central line associated primary bloodstream infection (CLI) (in two provinces) (see Appendix D for a description of each indicator). Finally, there are some indicators that are reported only by a single jurisdiction. For example, Ontario is unique in reporting data on additional specific hospital-acquired infections (vancomycin-resistant enterococci, and ventilator-associated pneumonia), and adherence to the surgical safety checklist, while British Columbia alone reports the total number of new cases of Carbapenemase-producing Organism (CPO). The time period and the interval/frequency of reporting also vary across jurisdictions. More details on the availability of indicator data are available upon request. The impact of the reporting of these indicators on local activity to reduce incidence is limited, although there are some positive reports (Daneman et al., 2012).

Estimates of patient safety based on administrative, hospital discharge data, and using common indicator definitions and codes are more directly comparable across jurisdictions than other available measures of patient harm. CIHI's Organisation for Economic Cooperation and Development (OECD) interactive tool (CIHI 2019a) reports several patient safety indicators across Canadian jurisdictions as well as other OECD countries. In addition, CIHI's *Your Health System* (CIHI 2019b) publicly reports in-hospital sepsis and obstetric trauma (with instrument) across Canada. Finally, CIHI's new measure of hospital harm draws on

the same hospital discharge data to identify several preventable harms that occurred during a hospital stay. Hospital harm measures are publicly reported at a national level over a four-year period (2014-2018) (CIHI 2019c).

The advantage of a single body reporting all indicators across jurisdictions is greater uniformity in data source, measurement, and interpretation of the indicator. Moreover, administrative data are not subject to the reporting bias that may impact the accuracy of incident data reported by provinces as part of reporting requirements. Thus, we pay closer attention to four comparable measures reported by CIHI, as well as three-year provincial averages of hospital harm measures.[3] Table 4 below presents four publicly reported indicators of patient safety and Table 5 reports the CIHI measures of hospital harm, by patient category. Appendix E reports the distribution of hospital harm across the categories, and across the top 10 most common events in Canada.

Table 4. Comparable indicators of patient safety, latest available year

Province	Foreign body left in, per 100,000 medical and surgical discharges (age 15+), 2014-2015 to 2015-2016	Post-operative pulmonary embolism, per 100,000 discharges for hip and knee replacement (age 15+), 2014-2015 to 2015-2016*	Obstetric Trauma (with instrument) (%) (per 100), 2017-2018	In-Hospital Sepsis (per 1,000 discharges), 2017-2018
British Columbia	7.4	611.4	15.4	3.2
Alberta	13.2	997	16.3	3.8
Saskatchewan	8.4	443.8	24.8	2.2
Manitoba	8	279.1	18.0	3.9
Ontario	6.7	624.3	13.9	4.3
Québec	13.1	716.6	28.3	3.2
Newfoundland and Labrador	-	327.3	7.9	3.2
New Brunswick	7.2	394.3	15.5	3.1
Nova Scotia	9.3	484.2	18.2	3.3
Prince Edward Island	-	-	10.7	3.5
Yukon	-	-	-	4.9
Northwest Territories	-	-	-	1.1
Nunavut	-	-	-	2.3
Average	9.3	641.7	18.4	4.0

Source: CIHI 2019a; 2019b

Notes: Colour coding is applied where confidence intervals are not overlapping with the Canadian average and indicator rates in the province are either higher (red) or lower (green) than the average. No shading indicates confidence intervals are unavailable or are overlapping with the Canadian average.
- data are not available
*Confidence intervals are not available for this indicator

[3] Facility-level, and provincial-level estimates of hospital harm measures are available only to registered CIHI data users through the CIHI *InDepth* data tool, or upon request from CIHI for a fee.

As shown in Tables 4 and 5, there is no one jurisdiction with less harm across all indicators, as measured by administrative data, than other provinces. In Ontario, described in the previous section as having the most comprehensive and prescriptive legislative framework, indicator rates are significantly lower than average for two indicators, and higher than the average for in-hospital sepsis as well (Table 4). Ontario also appears to be higher than average in terms of overall hospital harm (Table 5). British Columbia, which has the least strict legislative framework, had significantly lower-than-average rates for two indicators (Table 4), and an overall measure of hospital harm that is close to the average for Canada (Table 5).

Table 5. Harmful events by patient profile, three-year average (2015-2016 to 2017-2018)

Province	Three-Year Average (Number of harmful events per 100 hospitalizations)					
	Overall	Medical	Newborn	Pediatric	Surgical	Obstetric
British Columbia	5.0	4.4	0.9	1.5	8.9	3.7
Alberta	5.1	5.0	1.1	2.7	8.4	4.3
Saskatchewan	3.6	3.0	1.0	1.0	6.1	5.3
Manitoba	5.2	5.4	0.7	2.0	9.3	3.8
Ontario	5.8	6.0	0.9	2.8	9.9	3.4
Newfoundland and Labrador	5.3	4.5	1.3	2.4	9.5	2.8
New Brunswick	5.2	4.8	1.0	0.3	8.7	3.5
Nova Scotia	6.5	5.8	0.8	2.7	11.2	4.1
Prince Edward Island	4.2	4.5	1.0	0.3	7.0	3.1
Average for Canada	5.4	5.2	0.9	2.4	9.3	3.7

Source: Canadian Institute for Health Information

Notes: *Surgical* refers to patients who had a procedure in a main operating room within the first 24 hours of admission to hospital (Major Clinical Category (MCC) of "Intervention"); *Medical* refers to patients who were hospitalized but did not have an intervention (these were flagged as MCC of "Diagnosis"); *Newborn* is defined by the "Entry_code" of N; *Pediatric* refers to patients under 18 years; *Obstetric* captures patients with a MCC of 13 (CIHI 2019d). Confidence intervals are not available. Data for Québec and the three territories are not available. Differences in processes, documentation, and resources across provinces may result in differences in their ability to capture data about harmful events, so provinces with better documentation may have higher rates. All occurrences of harm are considered to be of the same weight in terms of contribution to the provincial rate, regardless of severity.

These data suggest there is no clear correlation between patient safety outcomes and a jurisdiction's legislative framework at a single point in time. These measures provide a baseline assessment of variations in patient harm across the country. Future work could monitor changes over time in patient harm alongside changes to legislation at the provincial and territorial level to provide further insight into these potential associations and to empirically assess impacts of legislation on outcomes in Canada. Interviews with more key informants from a greater number of jurisdictions, combined with an extensive review of grey literature, accreditation reports and other data sources would deepen and contextualize these findings.

Summary and Next Steps

This rapid review drew from the scholarly literature, consultation with senior health system leaders, a review of the comprehensiveness of legislative frameworks in Canada, and comparable patient safety data to better understand whether and how patient safety outcomes are improved by patient safety legislation related to mandatory reporting. The findings of this review provide a starting point for deeper examination of the impacts of mandatory reporting legislation on measures of patient harms in Canada.

Mandatory reporting legislation across Canada is designed to gather information about patient safety incidents. However, learning systems that enable responding to and sharing information to prevent patient safety incidents are largely absent from current legislative frameworks. As exemplified in British Columbia, legislation is just one tool among many that exist at different levels of the healthcare system. Our key informants perceived legislation as an enabler but not necessarily a prerequisite for patient safety policies and initiatives at other system levels.

Comparing indicators of patient safety using administrative data may be a promising avenue for assessing progress toward improved patient safety. Administrative hospital discharge data are not subject to the same reporting bias as patient safety incident data that are part of reporting requirements under legislation. Furthermore, the definitions and sources of administrative data are more easily comparable and accurate in the context of sophisticated and standardized hospital coding practices. Yet such indicators are limited in scope and the lag between the occurrence of events and the reporting back to organizations greatly limits their utility for local improvement. To date there are few publicly available indicators of patient safety in Canada. Using the indicators that are available, we were unable to identify any clear patterns between the comprehensiveness of patient safety legislation—as assessed against the 10 essential elements of legislation for patient safety incident reporting (Baker et al., 2008)—and patient safety outcomes. Yet on the basis of CIHI's Hospital Harm Indicator, British Columbia appears to have rates of harm that are lower on average than in Ontario, despite British Columbia's lighter legislative and regulatory approach.

The results of this rapid review raise several implications that provincial and territorial governments may consider as part of their respective approaches to governing patient safety.

- Patient safety incident data and surveillance, including the maintenance of a patient safety incident registry, represent an underutilized opportunity to enable regulators, professionals, and organizations to know about patient safety incidents, respond and learn from incidents, and prevent future harm. Data systems can be used to enhance transparency through system-wide and public reporting and to strengthen accountability of healthcare providers and system leaders.
- The need for privacy of information and confidentiality must be balanced with the need to allow relevant parties to share information for the purposes of learning, responding to, and preventing patient safety incidents.
- Employees and other practitioners outside hospital-based settings, as well as patients and families, face legislative and structural barriers to proactively reporting patient safety incidents. An environment with a strong patient safety culture, wide accessibility to reporting systems, and

clear channels of communication is foundational to knowing about patient safety incidents, developing an appropriate response, and enacting a cycle of learning to prevent future harm.

- There is room to strengthen legislation by extending its focus beyond knowing about patient safety incidents to effectively responding to and preventing further incidents. Our findings suggest that legislation need not be overly prescriptive but can nonetheless lay out a high-level mandate for organizations to implement requirements in ways most appropriate for their contexts.
- A common language for patient safety is needed for comparability and sharing across professions and jurisdictions. There is opportunity to strengthen communication and learning through wider use—and revision, if necessary—of existing standardized terms and resources. Whether through pan-Canadian or inter-provincial collaboration, there is need for greater coordination of this work, which includes the development of collaborative PSLS that enable sharing and learning across all Canadian jurisdictions.

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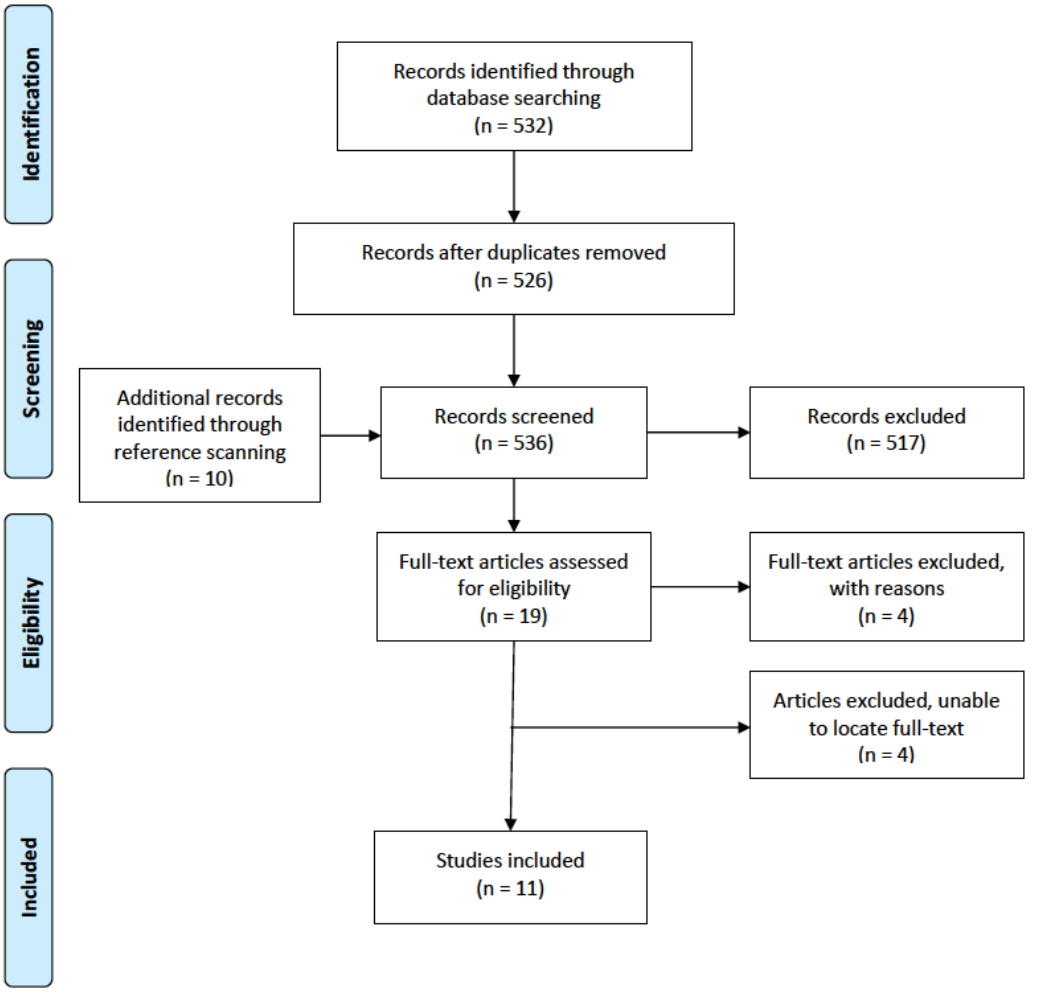
Appendix A: Literature Review Methods and Findings

We conducted a systematic scoping review to determine what is known in the peer-reviewed academic literature about the links between legislative and regulatory patient safety frameworks, and patient safety outcomes. Established scoping review methodology involves identifying the review question; identifying relevant studies; selecting studies for full-text review; charting the data; collating, summarizing, and reporting results; and consultation with key informants (Arksey & O'Malley, 2005). Although scoping review methodology does not include an assessment of the quality of reviewed articles, it is a common and efficient method for reviewing literature and synthesizing what is known about a given topic, thus helping to inform policy, practice, and future research (Arksey & O'Malley, 2005).

Figure A1. Scoping review PRISMA flow diagram



PRISMA – Preferred Reporting Items for Systematic Reviews and Meta-Analyses

Between February 18-20, 2019, we searched three academic databases: Ovid MEDLINE, CINAHL Plus with Full Text and ProQuest Research Library. First, Medline was searched using the key terms and Boolean operators 'Patient Safety OR (outcome* OR indicator* OR data OR measure*)', 'Patient Safety', 'Patient Safety OR (Law* OR regulation* OR Legal OR Legislation OR Policy)', 'Legislation Hospital', and 'Mandatory Reporting OR Voluntary reporting'. MEDLINE retrieved 231 results. We also searched CINAHL using the phrases and Boolean operators 'Patient Safety+' OR 'Patient Safety/LJ' OR 'Patient Safety or (outcom* or indicator* or Data or Measure*)' OR 'patient safety', AND 'Patient Safety OR Law* OR Regulation* OR Legal OR Legislation OR Policy', AND 'Legislation' OR 'Legislation, Hospital' OR 'Legislation, Nursing' OR 'Legislation, Medical' OR 'Legislation, Drug' OR 'legislation hospital', AND 'Mandatory Reporting' OR 'Voluntary Reporting'. The CINAHL Plus search yielded 121 results. Our third search was in the ProQuest Research Library, restricted to peer-reviewed articles, used 'Patient Safety Outcome' AND 'Patient Safety' AND 'in-patient OR in-hospital OR patient OR hospital' AND 'Healthcare Legislation AND Mandatory Reporting OR Voluntary Reporting'. The ProQuest search yielded 180 results.

As shown above in Figure A1, a total of 526 results were retrieved from the academic databases after de-duplication. A citation review of five relevant articles (Stone et al., 2007; Marsteller et al., 2014; Pakyz et al., 2013; Linkin et al., 2013; Woodward et al., 2018), yielded 10 additional articles that were included.

For an article to be included in the full-text review it had to meet the following eligibility criteria:

1. Be peer-reviewed;
2. Focus on an acute or hospital-based care setting; and
3. Reference or examine a law or regulation *in addition to* a measure of a patient safety outcome.

A total of 11 articles met these criteria and were included in the review.

Table A1: Literature review findings

Author/Year	Methods	Objective/Incident type/Legislation (mandatory or confidential reporting; mandatory surveillance but no reporting; or no legislation)	Conclusion
Daneman et al., 2012	Design: Retrospective, longitudinal population-based cohort study Data sources: Administrative data Study period: April 1, 2002 and March 31, 2010 Setting: 180 Acute Care Hospitals in Ontario	Objective: Determine whether mandatory public reporting by hospitals is associated with lower rates of clostridium difficile (*C. difficile*) infection in hospitals. Incident type: Health care-associated infections (HAI) Legislation: Mandatory public reporting	Public reporting associated with statistically significant reductions in *C. difficile* rates. Comments: Future research required to determine by which mechanism *C. difficile* rates were reduced in response to public reporting.
Haustein et al., 2011	Design: Retrospective cross-sectional study Data sources: Administrative data Study period: 2011 Setting: USA, England, France, and Germany	Objective: Examine the direct effect of public reporting of indicators alone on HAIs. Incident Type: HAI Legislation: Mandatory public reporting, and mandatory confidential reporting	Inconclusive. No significant impact of legislation on HAIs. Comments: Legislation has been associated with organizational changes, but not enough evidence exists to conclude whether legislation had a statistically significant impact on patient safety outcomes.
Linkin et al., 2013	Design: Cross-sectional study Data sources: Survey data Study period: May – June 2011 Setting: 137 U.S. SHEA-RN primary investigator sites	Objective: Determine whether state-legislated public reporting of HAIs is associated with perceived improvements in prevention program process measures or HAI rates. Incident Type: HAI Legislation: Mandatory public reporting	No impact or association of legislation with perceived improvements in infection prevention program process measures or HAI rates Comments: This study mainly featured large, academic hospitals with infection control protocols, meaning these sites represent a group that is vigorously combating HAIs regardless of reporting.
Lucet et al., 2013	Design: Synthesis Data sources: Administrative data Study period: 2010-2012 Setting: Hospitals in France	Objective: Determine the benefits of public reporting on healthcare-associated infections. Incident type: HAI Legislation: Mandatory reporting in some jurisdictions; Mandatory surveillance in others	Inconclusive.
Marsteller et al., 2014	Design: Retrospective cohort study Data sources: *On the CUSP: Stop BSI* program participant central line-associated bloodstream infections (CLABSI) data Study period: 2009-2011	Objective: Examine whether mandatory public reporting impacted participation and performance in reducing CLABSI in a national patient safety collaborative. Incident type: CLABSI	No statistically significant impact of legislation on outcomes or rates. Comments: Reporting requirements do not teach sites how to reduce rates.

Author/Year	Methods	Objective/Incident type/Legislation (mandatory or confidential reporting; mandatory surveillance but no reporting; or no legislation)	Conclusion
	Setting: Adult intensive care units in 44 states across the U.S.	Legislation: Mandatory public reporting	
Pakyz et al., 2013	Design: Cross-sectional study Data sources: Hospital-level administrative and U.S. Health and Human Services Hospital Compare website data Study period: 2011 Setting: U.S. academic hospitals within the University Health System Consortium	Objective: To evaluate the impact of state laws on reporting of healthcare-associated. CLABSI rates. Incident type: CLABSI Legislation: Mandatory public reporting	No evidence of impact of state legislation on CLABSI occurrence. Comments: Impact of state legislation may be lessened by other patient incident-prevention initiatives.
Stone et al., 2007	Design: Retrospective longitudinal cross-sectional study Data sources: Multi-hospital patient safety data Study period: 2002 Setting: 41 Intensive care units in 24 U.S. hospitals	Objective: To compare two methods of reporting HAIs in different states: 1) selected infections due to medical care Patient Safety Indicator (PSI-7); and 2) Centers for Disease Control and Prevention (CDC) protocols for CLABSI Incident type: HAI Legislation: Mandatory public reporting of all infections	HAI Reports generated by different reporting methods vary widely. Mandatory reporting mechanisms and processes should be standardized, and their accuracy confirmed.
Stone et al., 2011	Design: Longitudinal mixed methods study Data sources: Primary interview and administrative data Study period: 2008-2010 Setting: Hospitals in California, U.S.	Objective: Evaluate the impacts of mandatory reporting in California hospitals Incident type: HAI Legislation: Mandatory public reporting	Significant increase in adoption of and adherence to evidence-based practices and decreased HAI rates. Comments: Mandatory reporting had intended and unintended consequences. This study shows that technology and organizational factors are extremely important in preventing patient incidents.
Stone et al., 2015	Design: Qualitative public health law study Data sources: Semi-structured interviews Study period: 2012 Setting: 12 U.S. States, 6 with mandatory reporting laws, 6 without	Objective: Explore the impact federal and state HAI laws have on state departments of health in U.S. Incident type: HAI Legislation: Mandatory reporting (Arkansas, Colorado, New York, Ohio, Tennessee, and Texas); and no legislation (Arizona, Georgia, Kansas, Kentucky, Nebraska, and Wisconsin)	Limited evidence, not entirely conclusive. Comments: In theory, value-based purchasing programs (based on legislation that allowed Medicare to pay hospitals for reporting quality measures, rather than on service or patient counts) should be associated with decreasing instances of patient incidents.

Author/Year	Methods	Objective/Incident type/Legislation (mandatory or confidential reporting; mandatory surveillance but no reporting; or no legislation)	Conclusion
Tu et al., 2009	Design: Randomized trial Data sources: Primary collected reporting and trial data, and administrative data Study period: 1999-2001, 2004-2005 Setting: Acute care hospitals in Ontario, Canada	Objective: Evaluate whether the public release of data on cardiac quality indicators leads to adoption of quality improvement initiatives that improve patient outcomes. Incident type: AMI, CHF Legislation: No legislation cited; utilized public data performance report cards	Limited evidence of impact. Reporting did not significantly improve patient safety outcomes or rates.
Woodward et al., 2016	Design: Retrospective chart review Data sources: Administrative data Study period: 2008, 2012, and 2015 Setting: Intensive care units in southeast U.S.	Objective: Examine evidence-based practices related to CLABSI and how they are reported, as well as how the *Affordable Care Act*, mandatory reporting, and pay-for-performance programs have affected these best practices related to CLABSI prevention. Incident type: CLABSI Legislation: Mandatory reporting	Limited evidence. Comments: Larger sample over longer period needed to draw conclusions about the impact of legislation on patient safety outcomes and rates.

Commonly used acronyms: Acute myocardial infarction (AMI); Centers for Disease Control and Prevention (CDC); congestive heart failure (CHF); central line-associated blood stream infections (CLABSI)

Appendix B: Key Informants and Interview Guide

A purposive sample of key informants working in patient safety and quality of care in different jurisdictions of Canada were invited to participate in interviews. Interviews were sought in one jurisdiction without mandatory reporting legislation (i.e., Alberta) and two jurisdictions with mandatory reporting legislation that appeared to follow contrasting approaches to implementation (i.e., British Columbia and Ontario).

Between March 13 and May 13, 2019, inclusive, we conducted semi-structured interviews with 13 key informants. These were relatively informal conversations with senior executives and practitioners in the field that provided contextual and experiential evidence to clarify and understand the interpretation and implementation of legislation on patient safety in general, and mandatory reporting specifically. Contributions from these key informants are integrated throughout the findings and recommendations of this report.

Table B1: Organizations represented by key informants

Jurisdiction	Organization
British Columbia	BC Patient Safety and Quality Council
	BC Patient Safety Learning System Central Office
	College of Physicians and Surgeons of BC
	BC College of Nursing Professionals
	College of Pharmacists of BC
Alberta	Health Quality Council of Alberta
	University of Calgary
Ontario	Sinai Health System
	SickKids Children's Hospital
	Ontario Hospital Association
	Ontario College of Family Physicians
	Ontario College of Pharmacists

Through our professional networks and recommendations from some of the key informants we spoke with, we identified a purposive sample of senior executives and practitioners in the field of patient safety. Invitations to interview and scheduling were arranged by email. Information about the project, including preliminary findings and interview questions, were shared in advance. Two of the authors shared responsibility for conducting the interviews, which were done over the phone. Each interview began with a review of the project and preliminary findings, allowing the key informant to provide feedback before questions from the interview guide were asked. The interviews were semi-structured and tailored to each key informant and their context, so not all questions were asked in all interviews.

Semi-structured interview guide

1. What is your impression of patient safety legislation (including statutes and regulations) in your jurisdiction?
2. How would you assess the strength/weakness of current patient safety legislation in your jurisdiction (with regard to mandatory reporting and beyond)?
3. What elements might enhance the impact of patient safety legislation?
4. Are there any constraints of current legislation?
5. How does your jurisdiction's legislation compare to others'?
6. How does legislation fit within broader patient safety efforts?
7. What role(s) and responsibilities does your profession/regulatory body hold with regard to patient safety?
    - Where do these roles and responsibilities come from? Are they determined within the province or by a national body? Are they influenced by legislation?
8. Are there mechanisms used to regulate patient safety in your profession? If yes, what are they?
    - What are the strengths of current patient safety standards or guidelines within your profession?
9. Has the College adopted any guidelines related to patient safety?
    - How are these implemented in practice?
    - How are they enforced?
10. To what extent are patient safety standards or guidelines aligned with legislation? How are they implemented in practice? What are the opportunities for improvement?
11. Does your profession/regulatory body face any constraints or challenges with regard to supporting patient safety?
    - What is your impression of patient safety legislation in your province (specifically with regard to mandatory reporting)?
12. What, in your view, could enhance the impact of your profession/regulatory body on patient safety?
13. Is there anything else you would like to add?
14. Is there anyone you recommend we speak to regarding a) an assessment of your jurisdiction's legislation, or b) professional regulation for patient safety?

Appendix C: Assessment of Legislation Reviewed for Each Jurisdiction with Legislated Mandatory Reporting

Table C1: Legislation reviewed by jurisdiction

Jurisdiction	Provincial/Territorial Legislation
British Columbia (BC)	• *Hospital Act Regulation, BC Reg 121/97* • *Evidence Act,* R.S.B.C. 1996, c. 124 • Designation Regulation, BC Regulation 363/95 • *Apology Act,* S.B.C. 2006, c. 19
Saskatchewan (SK)	• *The Provincial Health Authority Act,* S.S. 2017, c.P-30.3, ss.8-2, 9-5(1)(aa) • Critical Incident Regulations, 2016, R.R.S. c. R-8.2 Reg. 10 • *The Patient Choice Medical Imaging Act, S.S. 2016, c. P-4.11, s. 13*
Manitoba (MB)	• *Regional Health Authorities Act,* C.C.S.M. c. R34, Part 4.1 • Critical Incidents Regulation, Man. Reg. 211/2006, s.4 • *Manitoba Evidence Act, C.C.S.M. c. E150, ss. 9-10*
Ontario (ON)	• *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 • *Quality of Care Information Protection Act, 2016, S.O. 2016, c.6, Sch. 2*
Québec (QC)	• *An Act respecting Health Services and Social Services,* CQLR c. S-4.2
New Brunswick (NB)	• *Health Quality and Patient Safety Act,* S.N.B. 2016, c. 21, s. 3
Newfoundland and Labrador (NL)	• *Patient Safety Act,* S.N.L. 2001 c.P-3.01, s. 17 • *Evidence Act,* R.S.N.L. 1990, c. E-16, s. 8.1 • *Personal Health Information Act,* S.N.L. 2008, c. P-7.01
Northwest Territories (NT)	• *Hospital Insurance and Health and Social Services Administration Act*, R.S.N.W.T. 1988, c. T-3 • *Evidence Act*, R.S.N.W.T. 1988, c. E-8, ss. 13-15

Table C2: Assessment of Legislation by jurisdiction

BC (2013)	SK (2004)	MB (2005)	ON (2011)	QC (2002)	NB (2018)	NL (2017)	NT (2016)
Element 1: Detail on what is reported							
Hospital Act s 21(1): Duty to report "serious adverse event"[1] in hospitals only.	*The Provincial Health Authority Act*, ss. 8-2: Health service providers, provincial health authority and the cancer agency must report critical incidents[2].	*Regional Health Authorities Act,* ss. 53.2(1): Regional health authorities, health corporations and prescribed healthcare organizations must establish written procedures respecting providing information about and recording critical incidents[1] as per 53.2(2).	*Hospital Management Regulation, ss. 1, 2(4):* Hospital administrators must report every critical incident[2].	*An Act Respecting Health Services and Social Services,* s. 8, 183.2, 233.I: Any person must report an incident or accident[2] as soon as possible.	*Health Quality and Patient Safety Act,* c. 21, ss 1-3: All patient safety incidents[2] must be reported.	*Patient Safety Act*, c. P-3.01, ss. 4-5: All occurrences and close calls must be reported[2].	*Hospital Insurance and Health and Social Services Administration Act*, ss. 25.2.1: All critical incidents[2] must be reported.
Element 2: Detail on who makes a report							
Hospital Act s 21(2): The hospital administrator (or licensee of a private hospital) must report.	*The Provincial Health Authority Act,* ss. 8-2: Health service providers, provincial health authority and the cancer agency must report critical incidents. Individual health service providers report to provincial health authority, which reports to minister, investigates and reports again to minister. No provisions stated for persons outside defined group to report incidents.	*Regional Health Authorities Act*, 53.2-53.3, 53.4.1(1): A regional health authority, health corporation or prescribed healthcare organization must report critical incidents. The regional health authority must notify the minister. Designated organizations (e.g., Shared Health, CancerCare Manitoba) notify	*Hospital Management Regulation, ss. 2(4):* The hospital administrator must establish a system to ensure reporting of every critical incident as soon as possible to the medical advisory committee and administrator. However, no provisions were found to describe these systems or define who makes a report.	*An Act Respecting Health Services and Social Services*, s. 233.I: Any person (an employee or other person on contract or undergoing training at the institution) must report an incident or accident. The executive director of the institution or other designate will regularly report in non-nominative form all incidents to the relevant agency at agreed intervals or	*Health Quality and Patient Safety Act*, c. 21, ss 3: The healthcare organization that provided the health services shall report any patient safety incident.	*Patient Safety Act,* c. P-3.01, ss. 4, 5, 7: Healthcare providers and regional health authorities must report incidents in accordance with regulations. No provisions stated for persons outside defined group to report incidents.	*Hospital Insurance and Health and Social Services Administration Act*, ss. 25.2.1: Critical incidents may be reported by any of the following persons: a patient or client, a relative of the patient or client; a person working for the Board of Management or territorial authority. Note that this is the widest definition of who can report an

BC (2013)	SK (2004)	MB (2005)	ON (2011)	QC (2002)	NB (2018)	NL (2017)	NT (2016)
		and report directly to the minister. Other individuals that may notify the regional health authority, health corporation or prescribed organization of a critical incident include patients, relatives of a patient or an individual working at or for the regional health authority, the health corporation or the prescribed organization.		whenever the agency so requires. No provisions stated for persons outside defined group to report incidents.			incident under the legislation.
Element 3: Details on how an incident is reported							
Hospital Act s 21(2): Reports must be made immediately and "in the form and manner specified by the minister."	*The Provincial Health Authority Act*, ss. 8-2: Health service providers, provincial health authority and the cancer agency must report critical incidents. The procedures and timelines for reporting are located in Critical Incident Regulations, 2016.	*Regional Health Authorities Act,* 53.2(2): Regional health authorities, health corporations and prescribed healthcare organizations must establish written procedures respecting providing information about and recording critical incidents as required in subsection (2), in accordance with	*Hospital Management Regulation, ss. 2(4):* Provisions are made for hospital administrators to establish a system to ensure reporting of every critical incident as soon as possible to the medical advisory committee and administrator. The report to medical advisory committee and administrator must include material facts, description of cause(s) if known,	*An Act Respecting Health Services and Social Services,* s. 233.I: Any person must report an incident or accident as soon as possible using a specific form that will also be placed in the patient record.	*Health Quality and Patient Safety Act,* c. 21, ss 2-4: Healthcare organizations must report as soon as possible to their quality-of-care and safety of patients committee as well as the patient involved. If an incident that could have resulted in a patient safety incident occurs, the healthcare organization has	*Patient Safety Act*, c. P-3.01: Timelines and procedures not specified in detail in legislation, but provisions made for reporting to occur in accordance with regulations. To date, no regulations are in force.	The *Hospital Insurance and Health and Social Services Administration Act* allows for regulations to set the details of critical incident reporting and disclosure, but no regulations are in force at this time.

BC (2013)	SK (2004)	MB (2005)	ON (2011)	QC (2002)	NB (2018)	NL (2017)	NT (2016)
		guidelines approved by the minister. Timelines for reporting are not mentioned.	consequences for patient, actions taken, and recommendations.		discretion to decide whether to notify the committee depending on ongoing safety risk.		
Element 4: To whom an incident is reported							
Hospital Act s 21(2): Reports must be made to the minister.	*The Provincial Health Authority Act*, ss. 8-2: Health service providers, provincial health authority and the cancer agency must report critical incidents. Individual health service providers report to provincial health authority, which reports to minister, investigates and reports again to minister. The provincial health authority must notify the minister and provide a copy of the report received from the health service provider(s).	*Regional Health Authorities Act*, 53.2-53.3: Health corporations or prescribed healthcare organizations must report to regional health authority. The regional health authority must notify the minister. Critical Incidents Regulation: Designated organizations (e.g., Shared Health, CancerCare Manitoba) notify and report directly to the minister.	*Hospital Management Regulation, ss. 2(4):* The hospital administrator must establish a system to ensure reporting of every critical incident as soon as possible to the medical advisory committee and administrator.	*An Act Respecting Health Services and Social Services,* s. 233.I: Incident or accident reports must be made to the executive director of the institution or to a person designated by the executive director.	*Health Quality and Patient Safety Act*, c. 21, 2-3: Healthcare organizations must report to their quality-of-care and safety of patients committee, which reports the incident and recommendations to the board of directors of the organization.	*Patient Safety Act*, c. P-3.01, ss. 4, 5, 7: The healthcare provider reports to the regional health authority and the regional health authority gives notice to the minister of adverse health events and occurrences that involve multiple patients or regions.	*Hospital Insurance and Health and Social Services Administration Act*, ss. 25.2.1, 25.3: A patient or client or relative or a person working for the Board of Management or Territorial authority may notify the territorial board of management, the applicable board of management, or the minister. The territorial board of management, a board of management or other prescribed person shall inform the minister.
Element 5: Provisions for confidentiality							
No provisions found.	Critical Incident Regulations, 2016, 6: Personal information would reasonably be expected to identify an individual to whom the critical incident relates	*Regional Health Authorities Act* 53.6(2): A critical incident review committee must limit personal health information	*Quality of Care Information Protection Act,* 9(8): A disclosure permitted under this section shall not contain more personal health information, as	*An Act Respecting Health Services and Social Services,* s. 233.I*:* The executive director other designate will regularly report in a	*Health Quality and Patient Safety Act*, c. 21, 6: The report of the quality-of-care and safety of patients committee must not contain	*Patient Safety Act*, c. P-3.01, s. 8-10: Personal information and personal health information are protected. The *Access to Information and*	*Hospital Insurance and Health and Social Services Administration Act,* ss. 25.1(3): The minister may establish reporting

BC (2013)	SK (2004)	MB (2005)	ON (2011)	QC (2002)	NB (2018)	NL (2017)	NT (2016)
	or any healthcare provider or any other individual knowledgeable about the incident is protected.	and personal information to the minimum amount necessary to properly carry out its duties.	defined in the *Personal Health Information Protection Act*, 2004, than is reasonably necessary for the purpose of the disclosure. Note that this refers to disclosures by a designated quality of care committee.	non-nominative form all incidents to the relevant agency. *s. 183.4:* Notwithstanding the *Act Respecting Access to Documents* held by public bodies and the protection of personal information (chapter A-2.1), the records and minutes of a risk management committee are confidential.	personal information or personal health information.	*Protection of Privacy Act, 2015* does not apply to the use, collection, disclosure, release, storage or disposition of, or any other dealing with, quality assurance information. *Personal Health Information Act*, c. P-7.01, s. 58(1)(cii.1): Information created or compiled for a patient safety incident report is protected.	and confidentiality requirements to support the work of quality assurance committees. *Evidence Act*, 15(3): Committees shall ensure the protection of confidentiality of any person whose treatment has been studied, evaluated, or investigated.
Element 6: Protection in legal proceeding							
Evidence Act s 51(2)*:* Information related to a proceeding before a committee or an investigation carried out by a committee is not permitted in legal proceedings. The only committee specified is the Critical Incident Report Sub-committee of the Quality Assurance Committee of the BC Anaesthetists' Society (Designation Regulation, BC	*The Provincial Health Authority Act,* ss. 8-2(6): Protects critical incident documentation from being shared in legal proceedings.	*Manitoba Evidence Act,* 9(2)-(3): Critical incident information cannot be used in legal proceedings. Sec 9(4) excludes from protection the personal health information in records; the facts on what occurred; and certain other records. Disclosure of these records is provided for under *Regional Health Authorities Act.*	*Quality of Care Information Protection Act*, 10(2): Quality-of-care information is not admissible in evidence in a proceeding. Note this protection is limited to quality of care committees designated under the Act.	*An Act Respecting Health Services and Social Services*, s. 75, 183.3: No legal proceedings may be brought against a person exercising their functions including a service quality and complaints commissioner or other person acting under their authority.	*Health Quality and Patient Safety Act*, c. 21, 7: Except on the trial of any person for an offence in respect of the person's sworn testimony, no statement made, answer or evidence given by that or any other person in the course of any quality review by the quality of care and safety of patients committee is admissible in evidence against any person in any	*Evidence Act, s. 8.1:* A report of a close call or occurrence, or a notice to the 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.	*Hospital Insurance and Health and Social Services Administration Act*, ss. 25.5(3-4): Information related to a critical incidents investigation are prohibited in legal proceedings.

BC (2013)	SK (2004)	MB (2005)	ON (2011)	QC (2002)	NB (2018)	NL (2017)	NT (2016)
Regulation 363/95).					court or at any inquiry or in any other proceedings.		
Element 7: Provisions for non-retaliation							
No provisions found.	No provisions found.	*Regional Health Authorities Act 53.9:* No person shall dismiss, suspend, demote, discipline, harass, or otherwise disadvantage another person because that other person has complied with a requirement to provide information, documents, or records.	*Quality of Care Information Protection Act*, *11*: No one shall dismiss, suspend, demote, discipline, harass, or otherwise disadvantage a person by reason that the person has disclosed information to a quality-of-care committee under section 8.	No provisions found.	*Health Quality and Patient Safety Act*, c. 21, 5: No person shall dismiss, suspend, demote, discipline, harass, or otherwise disadvantage a person by reason that the latter has disclosed information to a healthcare organization or a quality-of-care and safety of patients committee in connection with a patient safety incident or other incident.	*Patient Safety Act*, c. P-3.01, ss. 11, 23: A person shall not dismiss, suspend, demote, harass, or otherwise disadvantage or penalize a health care provider who reported a close call or an occurrence. An action does not lie against individuals for releasing information to the minister or regional health authority in good faith for improving services.	No provisions found.
Element 8: Provisions for expert analysis							
Reviewed legislation does not define whether incidents must be investigated by a	*The Provincial Health Authority Act,* ss. 8-2(2): The provincial health authority has a duty to investigate any critical incident and	*Regional Health Authorities Act* 53.3(3): A critical incident review committee must	Hospital Management Regulation, ss. 2(5.1): The hospital administrator must establish a system to ensure each incident is	An *Act Respecting Health Services and Social Services*, s. 183.1, 183.2: The institution must create a risk	*Health Quality and Patient Safety Act*, c. 21, 2: Each healthcare organization (including regional	*Patient Safety Act*, c. P-3.01, ss. 2, 12, 13: Every regional health authority shall establish and maintain a quality assurance committee	*Hospital Insurance and Health and Social Services Administration Act*, ss. 25.3(2,3): Designated

BC (2013)	SK (2004)	MB (2005)	ON (2011)	QC (2002)	NB (2018)	NL (2017)	NT (2016)
committee or is investigated at all.	provide a written report to the minister about the incident and investigation. The Critical Incident Regulations outline that the healthcare organization and the provincial health authority have an obligation to act on critical incidents and report how they are addressing them.	investigate the critical incident.	analyzed and a plan is developed with steps to avoid or reduce the risk of further similar incidents. *Excellent Care for All Act,* 3(1): Every healthcare organization shall establish and maintain a quality committee. As per the *Quality of Care Information Protection Act*, 2(1), the committee undertakes functions including reviews of critical incidents.	management committee, among whose tasks is to identify and analyze risk of incidents or accidents in order to ensure the safety of patients, prevent such risks, and reduce their recurrence.	authorities) is required to establish a quality-of-care and safety of patients committee. Quality-of-care and safety of patients committee must investigate and make recommendations following an incident.	whose purpose is to study, review, investigate, assess, or evaluate the provision of health services (including close calls and occurrences), either ongoing or case specific, in order to make recommendations to improve.	healthcare bodies or the minister must appoint or assign a person or committee to investigate to (a) review whether or not a critical incident occurred; (b) review factors that may have caused or contributed to a critical incident; and (c) prevent the occurrence of critical incidents in the future.
Element 9: Mandated incidents register							
No provisions found.	No provisions found.	No provisions found.	Hospital Management Regulation, ss. 2(5.2): Hospital administrator must provide aggregate critical incident data to hospital's quality committee twice a year (minimum). However, these provisions are limited to individual hospitals and no provisions are made for a provincial incidents register.	*An Act Respecting Health Services and Social Services, 183.2, 431(6.2)*: The risk management committee must establish a monitoring system including a local register of incidents. The minister maintains a provincial register of incidents and accidents in order to monitor and analyze causes, ensure measures are taken to prevent	No provisions found.	*Patient Safety Act*, c. P-3.01, ss. 16: A regional health authority shall develop and implement a patient safety plan in the form and manner prescribed in the regulations when requested by the minister. However, no provisions found mandating an incidents register.	*Hospital Insurance and Health and Social Services Administration Act*, ss. 25.1: Quality assurance committees conduct planned or systematic activities for the purpose of studying, reviewing, investigating, assessing, or evaluating the provision of health services or social services, either ongoing or case-specific and with a

BC (2013)	SK (2004)	MB (2005)	ON (2011)	QC (2002)	NB (2018)	NL (2017)	NT (2016)
				recurrence, and ensure control measures are implemented as appropriate.			view to improving services. However, no provisions found mandating an incidents register.
10. Mandated annual review							
No provisions found.	No provisions found.	No provisions found.	*Excellent Care for All Act*, 8*:* Every year, every healthcare organization must develop a quality improvement plan that includes performance improvement targets. In the case of public hospitals, the quality improvement plan must be based on aggregate critical incident data. Quality improvement plans are submitted to the Ontario Health Quality Council.	*An Act Respecting Health Services and Social Services*, s. 33, 183.2, 431(6.2): The local service quality and complaints commissioner prepares an annual summary of activities and complaints received, but not of quality improvement activities. The risk management committee identifies and analyzes the risk of incidents or accidents and maintains a local register. The minister maintains a provincial register of incidents and accidents in order to monitor and analyze causes, ensure measures are taken	*Health Quality and Patient Safety Act*, c. 21: The committee's report and recommendations are intended to support improving care and prevent occurrence of similar incidents. However, no provisions were found mandating annual review.	*Patient Safety Act*, c. P-3.01, ss. 16, 20: A regional health authority shall develop and implement a patient safety plan in the form and manner prescribed in the regulations when requested by the minister. The patient safety and quality advisory committee must report annually to the minister on its activities. However, the committee's legislated activities (ss. 2) focus on making recommendations rather than implementing or evaluating quality improvement recommendations.	No provisions found.

BC (2013)	SK (2004)	MB (2005)	ON (2011)	QC (2002)	NB (2018)	NL (2017)	NT (2016)
				to prevent recurrence, and ensure control measures are implemented as appropriate. However, the timing of any regular reviews is not mentioned.			

[1]Similar to WHO harmful incidents; [2] Similar to WHO patient safety incidents

Appendix D: Indicator Glossary

Table D1. Description of patient safety indicators available in Canada

Patient Safety Indicator	Unit of Measurement	Description
Accident	Number	An action or situation where a risk event occurs which has or could have consequences for the state of health or welfare of the user, a personal member, a professional involved, or a third person.
Carbapenemase-Producing Organisms (CPO)	Number	Number of new cases of Carbapenemase-Producing Organisms.
Central Line-Bloodstream Infection (CLABSI)*	Rate	Number of central line-associated bloodstream infection per 1,000 central line days.
Clostridium Difficile Infection (CDI)*	Rate	This rate is determined by the number of patients with hospital associated CDI per 10,000 patient days.
Foreign Body Left In	Rate	Rate of a foreign body left inside the patient's body during a procedure, per 100,000 medical and surgical discharges (age 15+).
Hand Hygiene Compliance (HH)	Percentage	Percentage of opportunities healthcare workers should and did clean their hands (data shown as before/after patient contact and as a general score).
Healthcare Worker Influenza Immunization (HCWI)	Percentage	Number of immunized healthcare workers divided by the number of healthcare workers in zone or area of the Nova Scotia Health Authority.
In-Hospital (IH) Sepsis	Rate	The risk-adjusted rate of sepsis that is identified after admission per 1,000 discharges.
Incident	Number	An action or situation that does not have consequences for the state of the health or welfare of a user, a personal member, a professional involved or a third person, but the outcome of which is unusual and could have had consequences under different circumstances.
Methicillin-resistant Staphylococcus aureus Infection (MRSA)*	Rate	This rate is determined by the number of hospitalized patients diagnosed with hospital associated MRSA bacteremia per 10,000 patient days.
OB Trauma: Instrument	Percentage	Percentage of vaginal deliveries with third- or fourth-degree obstetric trauma, per 100 instrument-assisted vaginal deliveries.
OB Trauma: No Instrument	Percentage	Percentage of vaginal deliveries with third- or fourth-degree obstetric trauma, per 100 vaginal deliveries without instrument assistance.
Post-OP PE: Hip and Knee	Rate	Rate of post-operative pulmonary embolism, per 100,000 discharges for hip and knee replacement (age 15+).
Post-OP Sepsis: Abdominal	Rate	Rate of post-operative sepsis, per 100,000 discharges for abdominal surgery (age 15+).
Surgical Safety Checklist Compliance (SSC)	Percentage	Percentage of surgeries in which a surgical safety checklist was performed.
Vancomycin-resistant Enterococcus (VRE)*	Rate	Incidence rate of nosocomial VRE infection associated with the reporting facility per 1,000 inpatient day.
Ventilator-Associated Pneumonia (VAP)*	Rate	Number of ICU patients with ventilator-associated pneumonia (VAP) per 1,000 ventilator days.

Adapted from: Health Quality Ontario Indicator Library,2019; Nova Scotia Department of Health and Wellness Public Reporting on Patient Safety,2019; Adverse Health Event Management Report- Task Force on Adverse Health Events, Newfoundland and Labrador, n.d.

**All values for Ontario have been changed to per 10,000 patient days*

Appendix E: Hospital Harm Data, by Province

Table E1. Distribution of harmful events by ten most-frequent clinical groups, number of events and % of total, 3-year average (2015-2016 to 2017-2018)

Province (total events)	Electrolyte & fluid imbalance	Urinary tract infection	Delirium	Pneumonia	Post-procedural infections	Aspiration Pneumonitis	Laceration/ Puncture	Patient trauma	Anemia - Hemorrhage	Sepsis	Top 10% (cumulative)
British Columbia (29305)	3345 (11.82%)	3318 (11.72%)	3601 (12.72%)	2359 (8.34%)	1721 (6.08%)	1615 (5.71%)	1388 (4.90%)	1125 (3.97%)	369 (1.30%)	1012 (3.58%)	70.14%
Alberta (27151)	3317 (12.22%)	2987 (11.00%)	2145 (7.90%)	2083 (7.67%)	1715 (6.32%)	1444 (5.32%)	1279 (4.71%)	1340 (4.94%)	1092 (4.02%)	831 (3.06%)	67.15%
Saskatchewan (6145)	587 (9.56%)	809 (13.17%)	183 (2.98%)	498 (8.11%)	344 (5.60%)	205 (3.34%)	421 (6.85%)	502 (8.18%)	234 (3.80%)	174 (2.83%)	64.42%
Manitoba (8951)	1350 (15.08%)	1296 (14.48%)	631 (7.05%)	839 (9.37%)	566 (6.32%)	319 (3.57%)	395 (4.42%)	367 (4.10%)	344 (3.85%)	284 (3.17%)	71.40%
Ontario (93246)	17705 (18.99%)	9974 (10.70%)	9838 (10.55%)	7031 (7.54%)	5928 (6.36%)	4083 (4.38%)	3596 (3.86%)	2982 (3.20%)	3734 (4.00%)	3346 (3.59%)	73.16%
New Brunswick (5411)	1040 (19.23%)	564 (10.43%)	360 (6.66%)	504 (9.32%)	276 (5.10%)	220 (4.07%)	278 (5.14%)	315 (5.83%)	143 (2.64%)	200 (3.70%)	72.11%
Nova Scotia (8485)	1215 (14.32%)	1044 (12.30%)	671 (7.90%)	689 (8.12%)	655 (7.72%)	331 (3.91%)	567 (6.68%)	588 (6.93%)	365 (4.31%)	233 (2.64%)	74.81%
Prince Edward Island (719)	72 (9.97%)	122 (16.92%)	37 (5.15%)	70 (9.78%)	55 (7.65%)	42 (5.80%)	35 (4.91%)	19 (2.64%)	33 (4.64%)	29 (4.08%)	71.53%
Newfoundland and Labrador (3907)	798 (20.43%)	485 (12.40%)	352 (9.02%)	266 (6.80%)	238 (6.08%)	126 (3.22%)	241 (6.18%)	250 (6.40%)	155 (3.96%)	146 (3.73%)	78.22%
Canada (excl. QC, NT, NU, NT) (182319)	29439 (16.14%)	20600 (11.30%)	17819 (9.77%)	14339 (7.86%)	11497 (6.31%)	8386 (4.60%)	8201 (4.50%)	7488 (4.11%)	6468 (3.55%)	6244 (3.42%)	71.56%

Source: Canadian Institute for Health Information.

Note: Data were only available for 9 provinces during the fiscal years 2015-2016 to 2017-2018

Table E2: Breakdown of harmful events by category of harm, three-year average with row percentage (2015-2016 to 2017-2018)

Province	Categories of Harm			
	A: Healthcare-Medication-Associated Conditions	B: Healthcare-Associated Infections	C: Patient Accidents	D: Procedure-Associated Conditions
British Columbia	10362 (42.7%)	8177 (33.7%)	835 (3.4%)	4894 (20.2%)
Alberta	9202 (39.9%)	7237 (31.4%)	853 (3.7%)	5774 (25.0%)
Saskatchewan	1667 (31.5%)	1765 (33.4%)	224 (4.2%)	1636 (30.9%)
Manitoba	3185 (41.2%)	2752 (35.6%)	236 (3.0%)	1553 (20.1%)
Ontario	37486 (46.7%)	24268 (30.2%)	2346 (2.9%)	16085 (20.0%)
New Brunswick	2124 (44.9%)	1493 (31.6%)	167 (3.5%)	938 (19.8%)
Nova Scotia	2697 (34.9%)	2428 (31.4%)	201 (2.6%)	1733 (22.4%)
PEI	230 (34.5%)	262 (39.3%)	38 (5.7%)	136 (20.4%)
Newfoundland and Labrador	1404 (42.8%)	1036 (31.6%)	86 (2.6%)	755 (23.0%)
Canada (Excl. QC, NT, NU, and YT)	68,357 (43.7%)	49,418 (31.6%)	4,986 (3.2%)	33,504 (21.4%)

Source: Canadian Institute for Health Information. Note: Data were only available for 9 provinces during the fiscal years 2015-2016 to 2017-2018

NORTH AMERICAN
OBSERVATORY
on Health Systems and Policies

The North American Observatory on Health Systems and Policies (NAO) is a collaborative partnership of interested researchers, health organizations, and governments promoting evidence-informed health system policy decision-making. Due to the high degree of health system decentralization in the United States and Canada, the NAO is committed to focusing attention on comparing health systems and policies at the provincial and state level in federations.