Patient Safety Incident Reporting: Current Trends and Gaps Within the Canadian Health System

Sarah Boucaud and Danielle Dorschner

Abstract

Patient safety incidents are a national-level phenomenon, requiring a pan-Canadian approach to ensure that incidents are reported and lessons are learned and broadly disseminated. This work explores the variation in current provincial and local approaches to reporting through a literature review. Trends are consolidated and recommendations are offered to foster better alignment of existing systems. These include adopting a common terminology, defining the patient role in reporting, increasing system users’ perception of safety and further investigating the areas of home and community care in ensuring standard approaches at the local level. These steps can promote alignment, reducing barriers to a future pan-Canadian reporting and learning system.

Patient safety incidents are a national phenomenon, currently addressed through a patchwork of national-, provincial- and local-level reporting programs and requirements. The impact of these incidents is wide reaching, felt by the patient, their family and care providers alike. The Canadian Adverse Events Study predicted that 1 in every 13 Canadian adults admitted to a hospital will encounter a patient safety incident, 36% of which are preventable (Baker et al. 2004).

The event itself is often the manifestation of a systemic failure. This highlights significant opportunity for the prevention of incidents before they occur. Coordinated reporting and large-scale dissemination of lessons learned are important in realizing these improvements. System failures are not only recognized, but shared widely, informing change, which extends locally, provincially and nationally, preventing incident reoccurrence. In fact, the failure to do this is a source of frustration for both patients and providers (WHO 2005).

A patient safety incident is defined as a circumstance or an event that could or did result in harm to a patient (CPSI 2012b). The term “patient safety incident” is used in this paper to reflect best practice. However, in staying true to the intent of reporting requirements, other versions and local adaptations of the term are referenced, including adverse event, critical incident, sentinel event and quality-related event.

This report consolidates existing patient safety incident reporting requirements throughout the Canadian provinces to identify trends. It provides an analysis of existing gaps in the system and offers recommendations in an effort to stimulate greater alignment between reporting systems. Improved alignment may serve as a foundation for better coordination in the dissemination of learnings from patient safety incidents.
Parameters
The scope of this paper is on both legislative and other reporting requirements that may exist in the form of policies and guidelines. Reporting refers to advising others about the patient safety incident (Gaulton 2014). In what concerns this research, reporting must extend a single organization and therefore be mandated to a higher entity, such as a regional health authority, provincial government or national-level program. Programs and systems for reporting patient safety incidents were also included to ensure the comprehensiveness of this search.

Disclosure requirements, although a valuable component of incident management, were excluded from this review process. Disclosure refers to advising those impacted by the event about a patient safety incident (CPSI 2011; Gaulton 2014).

Accreditation Canada is additionally a unique example of a national-level organization that offers voluntary participation in its program.

Both reporting and disclosure are elements of the Canadian Incident Analysis Framework (CPSI 2012b). The framework’s purpose is to help individuals and healthcare organizations determine what happened, how and why the incident occurred. Reporting is one step in this framework. While it is the focus of this paper, several other elements are involved in learning from patient safety incidents. Please refer to the framework for more information (CPSI 2012b).

Methods
Data have been gathered using two means: a literature review and key informant interviews. Because of the lack of available and current literature within academic databases, publicly available sources were largely sought. This included reports from quality councils, provincial governments and third-party organizations that drive quality care, such as the Canadian Patient Safety Institute (CPSI) and Accreditation Canada. Current legislation was also reviewed through the Canadian Legal Information Institute’s database (<www.CanLii.org>). Through this source, statutory reporting requirements were sought from applicable acts and regulations. Key search terms included: patient safety incident(s), adverse events, critical incidents, quality-related events and reporting, requirements, guidelines, systems or policies. Key informant interviews were used to support and elaborate upon evidence found in the literature review.

Trends: The Patchwork of Requirements
The investigation revealed a patchwork of reporting requirements and systems throughout the provinces and territories. Trends are consolidated in this paper through four levels of analysis: international, national, provincial/territorial and local.

International level
A single, comprehensive international reporting program was observed. It is included in this synthesis of the literature, as Canadian organizations voluntarily participate and report to this program. Global Patient Safety Alerts was launched in 2011 as a joint initiative between CPSI and the World Health Organization (WHO). It permits public sharing of information and alerts across international borders to be used in improving patient safety globally (CPSI 2012a). CPSI’s annual review 2014-2015 counted more than 1,200 patient safety alerts and an estimated 6,100 recommendations from organizations within Canada and abroad (CPSI 2015).

National level
It was found that national-level reporting programs, while several exist, are generally narrow in scope. They focus ultimately on the collection of information from medication and vaccination incidents and participation is voluntary in nature. Provincial acts and regulations may, however, place participation in these national programs as a statutory requirement. This approach is quite common in what concerns reporting to the Public Health Agency of Canada’s (PHAC) Canadian Adverse Events Following Immunization Surveillance System (CAEFISS). For example, the Immunization Regulations of the Northwest Territories require, under s. 3(2), that if a healthcare professional is notified that a person has experienced an adverse reaction to an immunization, he or she shall provide the Chief Public Health Officer, within 24 hours of the notification, a copy of the Report of Adverse Events Following Immunization required by PHAC. Manitoba, New Brunswick, Nova Scotia and Prince Edward Island also have similar statutory requirements in place.

Additionally, the Ontario Ministry of Health and Long-Term Care (MOHLTC) has a directive in place that requires all Ontario hospitals to report critical incidents related to medication/IV fluids to the Canadian Institute for Health Information’s (CIHI) National System for Incident Reporting (MOHLTC 2013). Please see Table 1 for a complete list of national reporting programs (CIHI 2014; Health Canada 2011a, 2011b; ISMP 2015; PHAC 2013, 2014).

An exception to these trends is the Canadian Forces Health Services Centres’ (2015) reporting and follow-up program. This program both mandates reporting and collects information on a comprehensive list of patient safety incidents. Within the Health Services Centres, policies call for immediate reporting of all patient safety incidents, regardless of the type. Investigation and follow-up protocols are also referenced in these policy documents (Canadian Forces Policy Documents).

Accreditation Canada is additionally a unique example of a national-level organization that offers voluntary participation in its program. However, this organization is able to strongly incentivize the use of reporting systems.
As part of the Qmentum accreditation program, organizations must meet designated Required Organizational Practices (ROPs). An ROP exists with regards to patient safety incident management, where “a patient safety incident management system that supports reporting and learning is implemented” (Accreditation Canada 2015: 13). The high priority placed on ROPs encourages patient safety incident reporting for healthcare organizations that wish to receive an accreditation designation.

**Provincial/Territorial Level**

Extreme variability exists between the provinces and territories with regards to patient safety incident reporting requirements and systems. Some provinces have their own provincial reporting systems in place: Nova Scotia, Newfoundland and Labrador, Prince Edward Island, British Columbia and Alberta (Alberta Health Services 2015; BC PSLS Central 2015; Elliot 2010; Elliot et al. 2014; Health PEI 2013). Other provinces have strong statutory reporting requirements that are supported through protocols and guidelines. Prince Edward Island’s *Practice of Pharmacy Technicians Regulations* was the only legislation identified, particular to a health professional group that required patient safety incident reporting. Both Manitoba’s *Regional Health Authorities Act* and Saskatchewan’s *Regional Health Services Act* provide for healthcare organizations to report such events to their designated health authorities under certain conditions. Following specific sets of requirements, the health authorities may also have to report to the provincial minister of health.

Two provincial legislative requirements call for patient safety incident data to be collected in a manner beyond case reports or the individual incident. The *Excellent Care for All Act* in Ontario requires the collection of aggregate data upon which quality improvement reports are to be generated. Quebec’s *An Act Respecting Health Services and Social Services* requires the executive director to report all events to an agency at agreed-upon intervals (233.1).

This variability distinctly contrasts with the territories that have limited reporting requirements in place and no reporting systems at this time.

Several protocols and guidelines also exist for patient safety incident reporting and, while quite explicit in nature, they do not carry the legal weight of an act or regulation (Government of Saskatchewan 2004; Government of Manitoba 2010; Interior Health 2014; Nova Scotia Health and Wellness 2012). Please see Table 2 for further information.

**Local Level**

A unique approach to reporting requirements was found to be emerging at the local level. Two instances were identified where professional colleges leveraged their regulatory role to mandate patient safety incident reporting for community-based practices. The College of Physicians and Surgeons of Ontario (CPSO), as of 2013, requires out-of-hospital premises to report adverse events, as prescribed in s. 51 of by-law 77 (CPSO 2013). A two-tiered adverse event reporting system was put in place, ensuring data collection for both incident management and for quality improvement activities (CPSO 2013). Following the report submission, the college may choose to take further action (CPSO 2013).

The Nova Scotia College of Pharmacists (NSCP) (2010), in a similar instance, has mandated a continuous quality improvement process be undertaken by community pharmacies. This process incorporates patient safety incident reporting to a third-party organization. Reporting has traditionally occurred to Institute for Safe Medication Practices (ISMP), but a new system, SafetyNET-Rx, has recently been pilot tested in Nova Scotia and may begin to gain acceptance (NSCP 2010). Leveraging their regulatory role, professional colleges are in a unique position to mandate reporting.

**TABLE 1. National-level reporting programs in Canada**

<table>
<thead>
<tr>
<th>Organization</th>
<th>Program Name</th>
<th>Patient Safety Incident Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>CIHI</td>
<td>National System for Incident Reporting</td>
<td>Medication or IV fluids</td>
</tr>
<tr>
<td>PHAC</td>
<td>Canadian Adverse Events Following Immunization</td>
<td>Adverse events following immunization</td>
</tr>
<tr>
<td>Health Canada</td>
<td>Canada Vigilance Program</td>
<td>Prescription and non-prescription medications, biologics, natural health products and radiopharmaceuticals</td>
</tr>
<tr>
<td>Institute for Safe Medication</td>
<td>Canadian Medication Incident Reporting and Prevention System</td>
<td>Medication incidents</td>
</tr>
<tr>
<td>Practices (ISMP)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Canadian Forces Health Services</td>
<td>Patient Safety Incident Reporting and Follow-up</td>
<td>All patient safety incidents</td>
</tr>
<tr>
<td>Centres</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**TABLE 2. Provincial protocols, guidelines and policies**

<table>
<thead>
<tr>
<th>Province</th>
<th>Guideline/Protocol/Policy</th>
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</thead>
<tbody>
<tr>
<td>British Columbia</td>
<td>Protocol for Health System Response to Adverse Events and Service Issues</td>
</tr>
<tr>
<td>Manitoba</td>
<td>Critical Incident Reporting Guidelines</td>
</tr>
<tr>
<td>Nova Scotia</td>
<td>Serious Reportable Events Interim Reporting Policy</td>
</tr>
<tr>
<td>Saskatchewan</td>
<td>Critical Incident Reporting Guidelines</td>
</tr>
</tbody>
</table>
Pulling the Pieces Together: Gaps and Recommendations

The gaps identified are strategic in nature. The first gap speaks to a vision for a national-level reporting system. The recommendations provided for the remaining identified gaps have been leveraged to provide foundation building steps for this national system. Five gaps are identified below:

The lack of a comprehensive, pan-Canadian reporting system

A national system that collects all types of patient safety incident information would not only enhance analysis at the local level, but foster improved decision-making and promote the broader dissemination of advisories and lessons learned. The PHAC’s CAEFISS is exemplary of these benefits, where case reports for AEFIs are analyzed nationally to better perceive trends that may not be visible at either local or provincial levels (PHAC 2013).

Over a decade ago, the value of a pan-Canadian reporting and learning system was recognized (Hoffman, Beard and Yu 2008). CPSI released a consultant’s report that offered recommendations towards a Canadian Adverse Event Reporting and Learning System. Since this report, no further national developments were observed from the literature. Evidently, such a project would require significant financial and human resources, as well as commitment and engagement from stakeholders nationwide. It is an endeavour that Canadians may not yet be prepared to undertake.

Recommendation

It is recommended that small steps be taken to improve alignment between the various reporting systems and requirements in Canada. This will begin to build a foundation for a pan-Canadian reporting and learning system, reducing barriers and facilitating future implementation of this system in the right climate.

A need for greater standardization of patient safety incident terminology

Although the CPSI and Accreditation Canada have moved to adopt the WHO’s International Classification for Patient Safety, an extensive variety of terminology is used within the provinces and territories to communicate patient safety incident information (CPSI 2012b; WHO 2009). These preferred terms and definitions are encased in acts, regulations, protocols and guidelines, including critical incidents in Manitoba, quality-related events in Nova Scotian community pharmacies and the term adverse events in which AEFIs are analyzed nationally to better perceive trends that may not be visible at either local or provincial levels (PHAC 2013).

The undefined role of the patient in reporting

The patient lacked a standardized role in the reporting literature. Some reporting systems offered a separate portal for reporting by patients. This is true of the PHAC’s reporting program for AEFIs (PHAC 2014). Accreditation Canada has further emphasized the importance of the patient’s awareness of organizational reporting mechanisms. This is incorporated into Accreditation Canada’s ROPs (Accreditation Canada 2015).

A common language for patient safety incidents creates a unified tool for communication, reporting, information dissemination and learning.

In fact, the role of patients in reporting and learning was an interest in early conversations concerning a pan-Canadian reporting and learning system (Hoffman et al. 2008). However, further research was required at the time (Hoffman et al. 2008). Questions that were put forward included: (1) What type of information can patients provide; (2) What options exist for reporting mechanisms for this unique group; and (3) What infrastructure is needed to support patient reporting?

The undefined patient role indicates that reporting systems and requirements are still strongly provider-focused. While this is important in fostering use of reporting systems, it cannot be completely emphasized at the expense of the patient-centred model. Defining what role patients are expected to play in patient safety incident reporting will ensure the patient-centred care model is not a secondary discussion.

Recommendation

It is recommended that national leaders in the field of patient safety begin to draft expectations towards the patient’s role in reporting and integrate these into subsequent frameworks and programs.

The system users’ perception of safety

It was identified that health professionals are generally still hesitant in their use of reporting systems. Fear of being blamed or of litigation impairs the use of these systems. Successful adoption of reporting practices stems from a culture of continuous quality improvement and learning.
Recommendation

It is important that these fears are addressed by leadership at local levels. If greater adoption and ownership of an organization’s internal reporting structures are fostered, this will strengthen commitment to reporting, perhaps extending to the provincial, territorial or national levels. This paper proposes a call to action for emerging and working healthcare leaders to openly communicate with staff on the topic of reporting and to continue to promote cultures of continuous quality improvement within their organizations.

Home and Community Care and Reporting at the Local Level

Targeted efforts have been made at the local level to respond to a lack of reporting requirements for community healthcare practices. While room exists for a standardized approach to reporting among healthcare organizations, a particular need was revealed within the home and community care environment. To the extent of this scan, no specific legislative requirements were revealed within these settings. Manitoba’s Personal Care Homes Standards Regulation was the closest example. Under s. 24(2), the operator of a personal care home must ensure that established written policies and procedures exist for pharmacy services. This includes policies for reporting, documenting and ensuring follow-up of medication incidents and adverse reactions.

Patient safety incident reporting is a small piece of the incident management system with significant potential for realizing better outcomes for patients.

The complexity of home care and community care systems did not always fall within broader patient safety incident legislation. An example is found within the Saskatchewan context. The Regional Health Services Act states in s. 58(3) that a healthcare organization shall give notice to the regional health authority of the occurrence of a critical incident. While this statement is seemingly comprehensive, in s. 2, a “healthcare organization” is described as an affiliate or a prescribed person that receives funding from a regional health authority to provide services. This statement, therefore, excludes a potentially large number of community organizations that do not receive funding from a regional health authority.

This gap has not gone unnoticed. A 2013 study by CPSI acknowledged limited data availability concerning client safety in home care and sought to explore the incidence and magnitude of adverse events. A key finding and recommendation for policy makers was to expand the use of electronic reporting (CPSI 2013).

Recommendation

It is recommended that further research be conducted in home care and community care environments. This will be a critical area to explore as provincial governments continue to move towards healthcare delivery in the community in response to an aging Canadian population.

Conclusion

The purpose of this paper was to investigate patient safety incident reporting requirements in different Canadian jurisdictions. This allowed for the identification of gaps within these systems. The literature review uncovered a patchwork of patient safety incident reporting requirements and programs. Clear dichotomies existed between the current roles played by the federal and provincial governments. At a national level, distinct, voluntary reporting programs were found, with little support from federal legislation. However, some provinces supported the use of these programs through their own statutes. Significant variability existed amongst the provinces and territories, with less of a legislative emphasis for patient safety incident reporting within the territorial systems. Hospital and community healthcare centres were also exposed to a unique dichotomy with the regulatory role of the professional colleges. The gaps identified were as follows: (1) the lack of a central and comprehensive pan-Canadian reporting and learning system; (2) a need for the standardized adoption of patient safety incident terminology; (3) the undefined role of the patient in reporting systems; (4) the users’ perceptions of reporting; and (5) home and community care and reporting at the local level.

Recommendations were provided that would enable better alignment of reporting systems and requirements throughout Canada, creating a foundation upon which a pan-Canadian system may eventually take root. Recommendations focused on the gradual adoption of the WHO’s patient safety classification and defining the patient role in reporting. In addition, it was recommended that leadership continue to foster the use of reporting systems at the local level through communication and education and, lastly, that further research be conducted in the home and community care environments. This research will help build a centralized reporting system that extends to the various sectors of Canadian healthcare.

Patient safety incident reporting is a small piece of the incident management system with significant potential for realizing better outcomes for patients. If reporting is embraced and conducted at a broad level, it can catalyze management of and learning from patient safety incidents, building safer, more proactive and better systems for the patients and communities of tomorrow.
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Acts and Regulations

British Columbia

Manitoba
Regional Health Authorities Act, CCSM c R34. Retrieved April 10, 2015.

New Brunswick

Nova Scotia

Northwest Territories

Ontario

Prince Edward Island

Quebec
An Act Respecting Health Services and Social Services, CQLR c S-4.2. Retrieved April 10, 2015

Saskatchewan

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