Governance, Policy and System-Level Efforts to Support Safer Healthcare

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Abstract

Over the past 10 years there have been concerted efforts across Canada to create safer healthcare systems both by improving practices at the frontline and by creating an environment that encourages the development of effective safety practices and a safety culture. There have been major changes in organizational policies regarding the disclosure of adverse events to patient and families, the reporting of patient safety incidents to facilitate learning, and new accreditation requirements. Governing bodies for healthcare organizations have been given clearer accountabilities for quality of care and patient safety, and improved performance

measurement, greater engagement of patients and families, and a trend toward greater transparency have aided efforts to improve patient safety. However, some areas where changes were anticipated, including the reform of medical liability processes and changes to regulations that govern health professional practices have not progressed as much as some expected. Overall, a decade following the release of the Canadian Adverse Events Study and the creation of the Canadian Patient Safety Institute many healthcare organizations have made only limited progress toward the creation of "a culture of safety" and a safer healthcare system.

n May 2004, the Canadian Adverse Events Study identified a substantial burden of injury among hospital patients resulting from adverse events (Baker et al. 2004). The Canadian Patient Safety Institute (CPSI) had just been launched and its first major national initiative was Safer Healthcare Now! - a pan-Canadian campaign targeting ventilator-associated infections, central line infections, medication adverse events and other common sources of hospital adverse events. Safer Healthcare Now! was targeted at frontline teams responsible for patient care to provide an immediate answer to the safety gaps in daily practice. But efforts to improve safety at the "sharp end" (Reason 1990) needed to be linked to broader changes in the healthcare system. Accordingly, CPSI, provincial governments, healthcare associations and others have also focused on changes in policy, regulation and governance to create a healthcare system that could more effectively identify and address patient safety and quality problems. These efforts were guided in part by the earlier National Steering Committee report in 2002 recommending the creation of CPSI that could create a safer system (National Steering Committee on Patient Safety 2002). A decade has now passed since the creation of the CPSI and the publication of the Canadian Adverse Events Study. What have we learned about supporting patient safety "at the blunt end"? This paper provides an overview of some key changes across Canada in the policy, programs and governance and leadership developed to support safer healthcare.

Disclosure

The current policies of health professional associations across Canada clearly state that when a patient is harmed during his or her care, the physician or other care provider must disclose this harm to the patient and family (for example, see College of Physicians and Surgeons of Ontario 2010). Such disclosure is an important step in helping the patient and family deal with the aftermath of this event and in ensuring that information about the event can be analyzed and used to limit the chances of reoccurrence. However, this practice has not always been the case and the failure to disclose harm and the commission or omission of actions that led to harm produced anger, mistrust and ill will. One of the positive impacts of the focus on patient safety in the past decade has been the development and general acceptance of disclosure of harm to patients and families as a common practice.

Failure to disclose harm to patients has always been ethically questionable, and threatens patients' confidence in their physicians, other care providers and the larger healthcare system. But concerns about medical malpractice liability, disciplinary action and reputation made disclosure, particularly about major events, difficult for care providers. Moreover, risk managers, lawyers, insurers and colleagues frequently counselled against disclosure. Physicians, nurses and other care providers thus found themselves often uncomfortably caught between a desire to share information about these incidents with their patients and advice from others not to disclose it.

This situation has changed dramatically in the past decade, benefiting patients, physicians, other staff and the organizations they work in. The Canadian Patient Safety Institute (CPSI) working with a broad group of stakeholders released a set of disclosure guidelines in 2008 (updated in 2011) (CPSI 2011) that have provided clear directions and helpful advice about disclosure. The Canadian Medical Protective Association (which insures physicians) endorses the CPSI guidelines and encourages physicians to disclose harm to patients, as well as offering a set of resources to physicians including a disclosure checklist (Canadian Medical Protective Association 2008). Attitudes around disclosure are viewed as an important component of patient safety culture (Etchegaray et al. 2012) and a critical factor contributing to the ability of individuals and organizations to learn from patient safety incidents. Still, disclosure behaviours in many settings do not correspond with recommended practices (O'Connor et al. 2010). While disclosure policies have explicitly urged practitioners to discuss events with patients, there continue to be challenges. These include continuing concerns about liability for the actions being disclosed, caution about what practitioners should tell patients about the actions of their colleagues and the need to coordinate disclosure among team members (Jeffs et al. 2010). Moreover, some organizations that have attempted open disclosure of events affecting larger groups of patients have found themselves the subject of class action lawsuits (Dudzinski et al. 2010).

Incident Reporting and Learning

The publication of the Canadian Adverse Events Study made it clear that adverse events were more frequent than many had previously believed and that similar events occur in many organizations. Few formal mechanisms existed to transfer knowledge gained about addressing safety gaps in one organization to similar organizations - and tragic events like the death of cancer patients from the administration of chemotherapeutic agents by the wrong route have been repeated in hospitals across Canada and abroad (Nobel and Donaldson 2010; National Steering Committee on Patient Safety 2002).

Developing effective incident reporting systems and mechanisms for analyzing these reports, identifying strategies and tactics to limit the occurrence of such events and sharing this learning across organizations and healthcare systems have been a major focus in Canada as in a number of other countries. Saskatchewan was the first jurisdiction in Canada to require healthcare organizations to report all major adverse events to the Department of Health in 2004, and a number of other provinces followed suit. Saskatchewan leaders saw the need for a provincial strategy to ensure that knowledge about safety gaps could be communicated across the province and that analysis of the contributing causes of these events could also be shared (Beard and Smyrski 2006). Other provinces, including Manitoba, British Columbia, Quebec and Ontario, also have reporting

systems for critical incidents. CPSI developed and offered for several years a course in Root Cause Analysis to provide quality and patient safety professionals and others the skills to analyze these events. The Institute for Safe Medication Practices Canada (ISMP Canada) collaborated with CPSI in the development of these resources and launched its own reporting system focused on medication-related events.

The approach used by healthcare organizations for incident reporting, incident analysis and learning and the communication of key lessons across organizations was based partly on strategies used in aviation and other industries. But the complexity and politics of healthcare have made this strategy difficult, if not problematic. Studies have shown that staff, particularly physicians, do not report many incidents (Lawton and Parker 2002), although the development of new electronic reporting systems has reduced some of the barriers to entering reports. There are continuing concerns that staff will not report incidents if they feel this information may be used to hold them accountable for the outcomes of these incidents. More critically, incidents provide relatively limited information about their associated causes (Cook, Woods and Miller 1998; Vincent 2004). And, even when events are reported, only a small number are analyzed and the techniques for identifying potential solutions are often cumbersome, time-consuming and frequently yield few sustainable and actionable recommendations. Recognizing these challenges, there have been recent efforts to develop strategies for improved reporting and more effective incident analysis techniques (CPSI 2012). Efforts to develop a pan-Canadian national reporting and learning strategy (apart from medication safety) have not been successful, despite efforts to identify obstacles and consult with and recruit interested organizations and provinces (Weisbaum and Hyland 2007; CPSI 2010).

Medical Liability

Historically, one of the most important avenues for redressing injuries resulting from care has been the legal system. Lawsuits for negligence and substandard care provide a means to seek damages for injuries suffered by patients and their families and help ensure that practitioners are competent and that organizations provide environments that support safe and effective care. But, in fact, relatively few injured patients sue their physicians or other caregivers, and few among these receive compensation (Flood and Bryan 2011). Joan Gilmour (2011) notes that "the [Canadian] medical liability system is inadequate in providing compensation or reducing the likelihood of harm." But, at the same time, there appears to be little appetite for reform. In fact, patient safety advocates have argued that the medical legal system serves as a deterrent to improving safety because it decreases the reporting of critical incidents, limits the information available about the context and contributing causes and creates an adversarial relationship between patients and their care providers. Indeed, the greatest change in medical-legal

aspects of patient safety has been the growing protections for information gathered to investigate incidents and to recommend changes in care processes and systems. These protections have been enacted or strengthened in provinces across the country to encourage reporting and investigations. But, in some jurisdictions, these protections have come at the cost of the availability of information outside of the hospital (or other organization) in which the investigation occurs. In Ontario, for example, information protected under the Quality of Care Information Protection Act ensures that interpretations and findings made in the review of an incident are protected against disclosure in the courts. But often the findings are not conveyed to patients, other organizations and practitioners who may find themselves vulnerable to committing similar harms, or to government and other bodies who wish to share this knowledge more broadly. Such legislative changes made to create a culture of learning have created inadvertent roadblocks to a safer system.

Health Professional Regulation

Legislation and the regulation of health professionals is another area that offers opportunities to create safer practice. In spite of a number of high-profile incidents and inquiries that involved health professional incompetence or malfeasance as a contributor to patient harm, there have been surprisingly few changes in the structures and processes of health profession regulation in the past decade in Canada. Health profession regulation is a provincial and territorial responsibility (although the medical licensing authorities have agreed to a national standard for licensing), and each province or territory has jurisdiction over the licensing, standards of practice and discipline. Some changes have occurred. For example, most provinces require physicians to participate in continuing education (Shaw et al. 2009), but efforts to ensure continuing competence through revalidation have not led to changing requirements (Levinson 2008).

Healthcare organizations also have a legal duty to ensure that healthcare practitioners are appropriately educated, supervised and monitored. Most non-physician staff are employees, and their recruitment and practice is supervised by their managers. A great majority of hospital-based physicians are independent professionals who are credentialed to practice in hospitals. The privileges of hospital-based physicians are reviewed annually and approved by boards. But in many organizations, this review is perfunctory and does not assure that the privileges of poor performers will be limited or withdrawn. Some hospitals have experimented with more rigorous performance reviews (Forster et al. 2011), and greater attention to the board's responsibilities in the governance of quality and patient safety has raised the profile of credentialing and the annual review and renewal of physician privileges. But in many healthcare organizations, board review of these activities likely remains limited.

Dennis Kendel offers reflections on the role of healthcare workers, both professionals and other staff, and their part in creating a safer healthcare system (Kendel 2014).

Accreditation

Accreditation Canada is an independent, not-for-profit organization that has assessed and certified the operations and performance of hospitals – and now a wide range of healthcare organizations – for more than 50 years using standards developed by healthcare managers, clinicians and other experts, and site surveys based on these standards. While accreditation has no official regulatory status, many provincial governments require acute care facilities or regional authorities to participate in the accreditation program. Accreditation status has thus become a de facto requirement signifying acceptable performance.

Accreditation Canada has taken an important leadership role in identifying effective patient safety practices and integrating them into the accreditation process. In 2004, Accreditation Canada convened an expert group to identify actions that would promote safer care and this group selected a small number of these as "Required Organizational Practices" (ROPs), whose status would be assessed in accreditation surveys. This list of practices has grown over the past decade and covers a variety of actions and policies related to safety culture, communication and medication use (Accreditation Canada 2013). After the first several years of assessing organizations on the ROPs, Accreditation Canada recognized that establishing standards for clinical safety practices related to medication use, safety checklists and infection control was insufficient for improving patient safety. More recently, Accreditation Canada has emphasized leadership and governance accountability for performance and the roles of leaders and boards in creating a broader environment that supports safer care (Accreditation Canada 2012). Working closely with CPSI and ISMP Canada, Accreditation Canada has established a pan-Canadian approach to patient safety through the development of these ROPs and a continuing emphasis on patient safety as a core element of high-quality healthcare organizations. In an era where the Canadian government has withdrawn from a leadership role in shaping the direction of the healthcare system, Accreditation Canada's efforts to promote patient safety have established explicit pan-Canadian patient safety standards and expectations of leadership and governance.

Performance Measurement

The data on adverse events and initial efforts to improve performance highlighted the lack of patient safety measures. Not surprisingly, in the aftermath of the creation of CPSI and the publication of studies of adverse events and incidents, patient safety became a new focal area for performance measurement. In 2004, the Canadian Institute for Health Information (CIHI) offered a detailed analysis on the information available

on patient safety and the relevance to the Canadian healthcare system (CIHI 2004). CIHI has continued to provide reports on patient safety and to select measures that assess patient safety performance (CIHI 2007; CIHI 2008).

One measure that raised considerable controversy, but also contributed significantly to efforts to improve safety was the hospital-specific mortality ratio (HSMR). The HSMR is a measure of actual versus expected mortality calculated on the most common types of acute care hospital patients. It was initially developed in England by Sir Brian Jarman and used in several countries prior to its adoption in Canada. The strength of HSMR was its role in providing a clear comprehensive and comparative measure of hospital performance. The CIHI reports on HSMR generated considerable media attention and leadership action on patient safety. However, a number of researchers published critical assessments of HSMR and challenged its utility (Shojania and Forster 2008; Penfold et al. 2008). Still many organizations continue to use HSMR as a measure of overall patient safety in conjunction with more specific measures of patient safety events and key processes linked to these events. A number of patient safety measures have been publicly reported in Ontario and used in the Quality Improvement Plans mandated by the Ontario Ministry of Health and Long-Term Care for acute care hospitals. The growing sophistication of performance measurement in healthcare, coupled with the number of performance measures linked to patient safety and quality of care, has accentuated a clear trend towards greater transparency of hospital and health system performance. Many hospitals and regions now publish their performance on these metrics on their websites, and, in British Columbia, Saskatchewan, Ontario and other provinces, there is a growing expectation that performance measures will be open to government and public scrutiny - and used by boards to review the performance of senior leaders.

Growing Investments in Quality Improvement Capacity and Capability

Performance measurement highlights the strengths and weaknesses of organizations, but improvement requires understanding how to redesign care processes and use human resources, technology and other resources more effectively. Efforts to improve patient safety require, first, recognizing the need to change; second, support for clinicians and managers in reviewing their practices; and third, testing and implementing changes that improve results. Over the past decade, many provinces established patient safety and quality councils (or similar bodies) charged with supporting improvement efforts and monitoring performance. More than any other factor in the past decade, patient safety helped to raise the visibility of the gap between existing and possible performance, leading to substantial investments in oversight and investments in quality

improvement efforts. The creation of quality councils in many provinces also helped to spur greater investments in capability and capacity to support organizational and system quality improvement efforts.

Governance for Safety and Quality

Efforts to improve performance in patient safety also led to recognition that responsibility for quality of care in the Canadian healthcare system was often diffuse and ill-defined. Governments provided much of the funding but had limited powers to create change, except in extreme cases where they could replace the leadership and board of healthcare organizations. Medical advisory committees in hospitals (or regions) have responsibility for advising hospital/region boards on quality-ofcare issues and reviewing the credentials of physicians applying for privileges or their renewal. Patient safety incidents could be reported to the board, although this practice varied from organization to organization. Overall then, the "governance" of patient safety and quality of care was ambiguous and often contested. In Ontario, the Ontario Hospital Association commissioned a report in 2008 to review legislation, policy and practice to clarify of the role of boards in regard to patient safety (Corbett and Baker 2008). In Quebec, the Ministry of Health passed legislation (Bill 113) that required disclosure of patient safety incidents to those who were harmed, mandated risk management committees to follow up on incidents and made boards accountable for the safe provision of care (Ste-Marie 2005). But in most provinces, it was not clear what the responsibilities of boards were for quality of care and patient safety.

In 2010, the CPSI and the Canadian Health Services Research Foundation created a training program and a set of resources for healthcare board members focused on improving governance for quality and patient safety. Based on research that reviewed evidence and leading practices in Canada and the USA (Baker et al. 2010), the program has been offered in a number of provinces across the country and adapted for members of primary care organization boards in Ontario. One key component of this training has been an emphasis on the strategies that boards can use to monitor and improve performance, including more informed use of information about critical incidents and performance measures and more explicit identification of quality and safety goals.

While other pressures besides patient safety have increased the pressures on accountability of healthcare organizations, the visibility of safety incidents and the attention garnered by reviews of large-scale system failures such as the Cameron Inquiry in Newfoundland and Labrador on the failure to accurately test and report the diagnostic status of breast cancer patients (Commission of Inquiry on Hormone Receptor Testing 2009) has greatly increased governance and leadership accountability for quality performance.

Patient Engagement in Healthcare Organizations

Efforts to make healthcare more patient-centred have a long history, and include initiatives to increase patient input into decisions about their care and strategies to make healthcare organizations more "patient friendly" with changes in visiting policies, improved communications with patients and families and other practices (Conway 2011).

Patient safety incidents and initiatives have greatly accelerated the integration of patients into healthcare organization decisionmaking and the visibility of patient perspectives and preference in improving care. High-profile incidents led to greater involvement of patients in patient safety and broader organizational oversight. For example, the death of Betsy Lehman, a Boston Globe reporter who received a massive chemotherapy overdose at the Dana Farber Cancer Center in the US, led to a transformation in that hospital's operations where patients are now integrated into all decision-making bodies in the hospital, an example that influenced practice in the US and elsewhere. The high visibility given by Sir Liam Donaldson in the World Health Organization (WHO) to patients and families involved in patient safety incidents demonstrated the power and impact of the patient voice in recognizing safety lapses and improving care. Donaldson created a group, Patients for Patient Safety, that invited patients and families to work in the WHO patient safety program. The CPSI, following the WHO example, created Patients for Patient Safety Canada and recruited and supported patients, encouraging their efforts to improve patient safety at an organization level and policy deliberations. Many healthcare organizations have followed suit, so that the practice of inviting patients to participate in patient safety and quality improvement efforts has become increasingly common.

The patient perspective has also influenced the structure and focus of broad patient safety and quality initiatives. For example, the Saskatchewan Patient First Review has emphasized the need to change patient experience and to alter the delivery of care to improve how services are delivered and administered (Saskatchewan Ministry of Health 2011). Increasingly then, patient safety initiatives have included patients as key stakeholders and participants.

Building a Safer System

Efforts to create more a systematic focus on patient safety have had an important impact on the Canadian healthcare system. Ten years ago, there was limited knowledge about the safety of healthcare in this country, and little appreciation for the interventions, leadership and systems needed to reduce unintended harm. Today, healthcare organizations have detailed knowledge about their safety and quality performance generated by internal reporting systems and external measures of patient safety indicators. CIHI has continued to develop useful measures of quality and patient safety that enable benchmarking across

organizations and regions. And provincial governments and health quality councils have developed dashboards and defined accountabilities around patient safety and created a range of initiatives aimed at critical issues.

Several provinces, including British Columbia and Saskatchewan, have developed sophisticated systems for reporting incidents, analyzing contributing causes and disseminating learning about effective practices. There is also a much greater understanding about the need to develop capabilities from "board to ward" to understand patient safety and quality improvement, and, at the front line, to link improvement skills to knowledge of evidence-based patient care.

Still challenges remain. Despite continuing efforts to integrate quality improvement education in the preparation of healthcare professionals, many practitioners graduate with only limited knowledge of these skills. And continuing education resources are just as scant, a situation that limits the ability of teams and organizations to improve the safety and quality of their care. Efforts to share learning from critical incidents across provinces have not been successful, although the work of ISMP Canada has helped to create a broader understanding of safe medication systems.

The National Steering Committee report identified "creating a culture of safety" as the central goal for Canada in developing a safer healthcare system. Some of the elements identified in that report, such as altering existing tort and insurance systems, have received limited attention, but, in general, investments across Canada to raise awareness, build supportive education and engage leadership and governance have moved patient safety from a hidden issue to a prominent focus. In the process, work on patient safety has become more closely linked to quality of care, patient engagement and integrated care, performance transparency and professional competencies, strengthening not only those efforts, but broadening perspectives on what constitutes safety in a complex healthcare system. Improving patient safety requires concerted efforts to integrate new behaviours into daily care practices and to develop systems of learning and effective work environments that support safer care. HQ

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