Improving patient safety through disclosure and quality improvement reviews

A report from Getting it Right - A policy forum to advance quality improvement in Canada, November 2010

Canadian Medical Protective Association
Royal College of Physicians and Surgeons of Canada
College of Family Physicians of Canada
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Contents

Preamble

On November 16, 2010, the Royal College of Physicians and Surgeons of Canada (Royal College), the Canadian Medical Protective Association (CMPA), the Canadian Medical Association (CMA), and the College of Family Physicians of Canada (CFPC) co-sponsored *Getting it right: a policy forum to advance Quality Improvement in Canada* to discuss how to facilitate quality improvement in health care and promote a just culture of safety.

Attendees included representatives of medical regulatory colleges, health associations, provincial and federal governments, patient safety organizations, as well as practicing physicians and physician trainees. The policy forum revealed that although physicians and health care organizations have been making solid efforts to disclose and report adverse events, [*] patients are not entirely satisfied with these disclosure and reporting processes. In particular, patients feel that more information about these events should be shared with them and the public at large.

At the conclusion of the policy forum, participants agreed a white paper should be developed to capture the main issues. While there was not complete clarity as to the way ahead, participants indicated a white paper would be a helpful mechanism to share ideas about how to accelerate quality improvement in health care.

This white paper sheds light on critical issues affecting disclosure to patients, articulates recommendations for effective quality improvement reviews, and discusses necessary supports to champion safe health care delivery and to protect patients and providers.

The principles discussed within the paper are relevant in all Canadian jurisdictions and take notice of the international discourse on patient safety. For example, the World Health Organization is developing an *International Classification for Patient Safety* framework to standardize safety language and make it easier to share leading practices and learn from others on the subject[1] — a recommendation embraced in this paper.

The key to success lies in learning from avoidable adverse events and by addressing system and/or individual performance issues, rather than resorting to adversarial or punitive "blame and shame" approaches. By fairly examining and addressing the root causes of problems, a just culture of safety can be achieved.

Importantly, this cultural change requires a paradigm shift in clinical practice whereby safety dominates all aspects of health care delivery. Systems and processes are needed to make this happen. The Institute for Healthcare Improvement[2] for example, uses a *Model for Improvement* to help organizations achieve rapid and significant improvements in care delivery and outcomes.

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[*] Different terminologies are used in Canada. The *Canadian Disclosure Guidelines* published by the Canadian Patient Safety Institute in 2008, defined an adverse event broadly as "harm resulting from health care delivery." The 2011 revision of the *Guidelines* encourages the adoption of terminology from the World Health Organization's *International Classification of Patient Safety* (WHO *ICSP, 2009*) that uses the term patient safety incident, defined as "an event or circumstance which could, or did, result in unnecessary harm to a patient." Organizations are considering the implications of adopting this new terminology and framework, which emphasizes the context in which an "incident" can occur. In Québec law (an *Act respecting Health Services and Social Services*), an incident is "an action or situation that does not have consequences for the state of health or the welfare of the user, a personnel member, a professional involved, or a third person, but the outcome of which is unusual and could have had consequences under different circumstances."

The processes for reporting and reviewing adverse events and near misses should be conducted in a manner that provides procedural fairness for all involved, including patients and physicians. In this regard, physicians need reassurances that the reporting of adverse events and the ensuing investigation will not be used or disclosed outside of the quality improvement process, while patients want reassurances that improvements will be made so that these events will not occur again.

This document strives to express the collective vision of the medical profession regarding quality improvement. Although extensive literature has been published on this subject from the CMPA and the Canadian Patient safety Institute, this white paper attempts to tie in the various positions from the Royal College, CFPC, and CMA.

Not to be overlooked are the other interdisciplinary providers and their integration in facilitating quality improvement in health care.

1. Background

Health care is delivered in a complex system involving patients, providers, settings, and many other factors. For example, nearly 25 per cent of discharged patients experienced an adverse event in the transition from hospital care to care at home or in the community. [3] Quality and safety are the ultimate goals for all stakeholders. The Canadian Patient Safety Institute (CPSI) has developed a framework for the key knowledge, skills, and attitudes necessary for all healthcare workers to prove safe patient care. The Patient Safety Competencies can act as a benchmark for training, educating, and assessing health care professionals in patient safety. [4]

Despite the best efforts of all health care professionals and health care institutions, clinical outcomes sometimes differ from what is desired or anticipated. Unexpected changes in a patient's clinical condition most often reflect the worsening of the disease process, but some are related to the delivery of care. The latter outcomes are known as adverse events. Most adverse events result from the inherent risks of investigations and treatments. However, sometimes harm results from system failures or issues related to the performance of individual providers.

Physicians and other health care providers have an ethical, professional and legal duty to disclose adverse events to their patients. Disclosing adverse events to patients and reporting such events to quality improvement committees are separate and distinct processes. While the disclosure of adverse events to patients is an integral part of individual patient care, the reporting of adverse events to quality improvement committees is generally part of a much broader initiative aimed at identifying and addressing systemic problems.

The purpose of a quality improvement review should not be to single out and blame health care providers, rather to focus on identifying the system and process failures that contribute to the majority of avoidable adverse events. A quality improvement review should be conducted under the auspices of a properly constituted quality improvement committee. Separate from this process, an accountability review of an individual provider may or may not be indicated. An accountability review should be considered when the performance of an individual health care provider appears to be the dominant factor that contributed to the adverse event or close call. [5]

Legislation exists in each Canadian province or territory to protect quality improvement information, records, and documents from being disclosed in legal proceedings. This legislation encourages health care providers to participate in quality improvement programs. However, provincial and territorial legislation differs as to what quality improvement information can be disclosed to patients. In some provinces for example, non-implemented quality improvement recommendations cannot be disclosed.

2. The health care environment

Rapid evolution

The health care landscape is evolving rapidly. Changing patient demographics, complex clinical conditions, new technologies and medications, treatment plans requiring strong interprofessional communication and collaboration, and evolving scopes of practice all may contribute to the increased complexity of health care delivery.

Just culture of safety

A health care organization's *culture* is vital to encourage and sustain safer patient care. An organization's values, beliefs and actions must support open and transparent disclosure of harm and also address areas for improvement. The CPSI notes that the ultimate objective of implementing *The Safety Competencies* is wholesale and systemic change in the culture of healthcare. [6]

When discussing organizational culture, the term "just culture" is now often used. A just culture of safety may be defined as a health care approach in which the provision of safe care is a core value of the healthcare organization. [7] There are many elements to a just culture of safety, including not prejudging the reasons for clinical outcomes and events, and ensuring the analyses of adverse events are conducted within the relevant legal frameworks and in accordance with established organizational policy.

An organization with a just culture of safety accepts appropriate responsibility and accountability. Individuals are not held accountable for system failures over which they have little or no control. Organizations with a just culture of patient safety do, however, fairly address issues of individual provider performance and behaviour. A just culture finds the balance between system and individual provider accountability.

The organizational culture required to support effective disclosure and quality improvement also recognizes the value of every member of the interdisciplinary team. The health care organization should strive to create an environment where every provider and patient has a voice and is confident that their opinions will be respectfully heard and acted upon.

A just culture of safety also supports disclosure as a step towards learning of adverse events and close calls to make improvements. In this regard, important elements of organizational culture include providers' confidence in the organization's response to an adverse event, which ensures quality improvement information will not be used against providers in legal, regulatory, or other proceedings. Health care providers should be appropriately supported, protected, and educated. At the same time, patients are provided with factual information about an adverse event, as well as any follow-up information.

Physicians, particularly physician leaders, play an important role in supporting and sustaining a just culture of safety. Physicians also have the opportunity to play a guiding role in the quality improvement process that, increasingly, recognizes that health care delivery and quality improvement are collaborative, interdisciplinary undertakings. All those involved need information and tools to understand quality improvement and make improvements.

Legislation

When harm has occurred, patients want to be informed of the factual reasons for what happened, which may include an acknowledgement of accountability and an appropriate apology from the health care organization and/or individual providers.

Most patients want to know that there was learning from an avoidable adverse event and how similar harm might be prevented in the future. However, quality improvement information can only be disclosed to patients according to the applicable provincial/territorial laws and organizational bylaws. The protection of and access to quality improvement information varies, however, across the country. For example:

- In most jurisdictions, the legislative protections only function to prohibit the disclosure of quality improvement records or information in the context of legal proceedings (which includes regulatory authority (College) proceedings).

- In British Columbia, Québec, Northwest Territories, and Nunavut, the relevant legislation prohibits the disclosure of quality improvement information to anyone outside of the quality improvement committee, with the exception that these records and information may be disclosed to the regulatory authority (College) for the purpose of a hearing concerning the conduct or competence of a member or in circumstances the committee considers appropriate. In Ontario, the legislation prohibits the disclosure of quality improvement information to anyone outside the quality improvement committee except in very limited circumstances, including to eliminate or reduce a significant risk of serious bodily harm to a person or a group of persons.

Patients should be informed that quality improvement information and recommendations are protected by provincial and territorial legislation to varying degrees. Patients should know that these laws mean that patient and family access to this information and these recommendations may not be permitted. Nevertheless, patients should learn the facts, as well as the underlying reasons, related to what happened.

Patients should be advised that the intent of the legislation that protects quality improvement information is not to hide facts from them, but rather to allow health care providers a "safe haven" in which to provide their opinions and speculate as to how things could be done differently to improve the system and processes of care. These opinions and speculations should not be misconstrued or misused against the provider in a fault finding forum such as civil litigation. Rather, the judgment in the legal action is based on the court's interpretation of the facts of the case and the testimony of experts.

Physicians and other health care professionals generally accept that adverse events must be disclosed to patients and families. Patients want the facts about what

occurred, what it means for them, and what might be done to prevent recurrence. Nevertheless, rules and regulations on the disclosure of adverse events can also be confusing. In Ontario for example, *Regulation 423/07* under the *Public Hospitals Act* mandates hospitals to establish a system/process to disclose "critical incidents" to patients. These rules may or may not specify what to disclose, to whom, when, and whether it should be done at all.

Physicians need advice on what information to disclose. Disclosure guidelines, checklists to support initial disclosure, and appropriate training for providers are also required. The *Canadian Disclosure Guidelines* [8] from the Canadian Patient Safety Institute, and *Communicating with your patient about harm: Disclosure of adverse events*[9] from the Canadian Medical Protective Association provide more information in this regard.

Physicians also need to know how/what information will be protected when complete legal protection doesn't exist. This would encourage more physicians to participate in quality improvement, and would lessen physicians' feelings of vulnerability and risk associated with the quality improvement process. Increased physician involvement in quality improvement may also help to strengthen their engagement with other health care providers and thereby enhance interdisciplinary collaboration.

3. Understanding patient needs

When an adverse event occurs, patients have clinical, emotional, and information needs that must be addressed as soon as possible after the event. Patients expect to be told of the facts about harm they have experienced and the reason for it. This information needs to be delivered in a caring and empathetic manner. Open, honest, and timely communication can be important factors in whether a trusting relationship continues after an adverse event. [10]

Regardless of the health care setting, situation, timing, or care provider, there is widespread agreement about the need to better understand patient needs throughout the care process. To do so, physicians and other health care providers recognize the benefits of actively listening to the concerns of patients and families, and responding with respect and compassion in a timely manner.

In November 2011, the Canadian Patient Safety Institute released its most recent Canadian Disclosure Guidelines titled *Being Open with Patients and Families*. [11] The guidelines emphasize that disclosure is based on the guiding principles of safety, openness, transparency, accountability, and compassion.

The efforts to understand patient needs should be an ongoing process. Patients' needs and perspectives may change, and may vary among individual patients, settings, cultures, and other circumstances. Physicians and health care providers are encouraged to listen to patients' concerns and perspectives on a continual basis. Organizations such as Patients for Patient Safety Canada (PFPSC) may be good sources of information about the perspective of patients and families.

When investigating adverse events, the patient and family's perspective is important in helping to understand what happened. Opportunities exist for the health care system to better facilitate the contribution of patients and/or family members in quality improvement reviews. In some circumstances, it may be helpful for patients to work directly with health care providers to assist in the identification of patient care issues

and the safety challenges of the system. These opportunities should be further explored.

Liability and compensation

Litigation may or may not result after poor clinical outcomes, including adverse events, irrespective of how well the facts are communicated or disclosed to the patient. In Canada, disclosure and quality improvement procedures are separate from the civil litigation process. This distinction is important in order to advance quality improvement. Disclosing adverse events is not about reducing the likelihood of litigation. Rather, disclosure is driven by law and ethics.

Apology legislation is also seen as facilitating the disclosure of adverse events to patients. In Canada, almost all provinces and territories have enacted apology legislation, which protects an apology from being used in civil litigation and in some other forums (e.g. College proceedings). The legislation typically provides that an apology does not constitute an admission of fault or liability. Liability can only be determined based on a claim of negligence (or a claim of civil liability in Québec). These protections also assist in separating the disclosure process from the civil legal system. As of 2010, apology legislation has not been challenged in any court. Apologies help to show respect and concern for what has happened.

4. Education

What's needed and for whom

The importance of education about quality improvement in health care cannot be understated. Patients and families, physicians, other healthcare providers, and quality improvement committees all require education and/or training.

Patients and families would benefit from knowing more about the factors that can contribute to adverse events, as well as information about the disclosure and quality improvement processes. Patients and families need to understand the quality improvement process, and their role in it, so as to have trust in the process. This would include information about the purpose and process for reviews of adverse events, as well as the applicable legislation protecting quality improvement information and recommendations. Patients could also be educated to better understand the complexity of health care delivery and system accountability, where applicable.

While a lot has been done to train physicians about the process of disclosing and reporting adverse events, much more can be accomplished. Physicians should be aware of the quality improvement processes within their organizations, and they should participate in these as needed. Physicians should also be familiar with existing provincial or territorial quality improvement legislation. Physicians should determine whether the quality improvement processes within their organizations are properly constituted under the relevant legislation and, if not, should promote the use of properly constituted quality improvement committees. Improvements in physician understanding of changing health care delivery models, changing organizational cultures, and the importance of physician engagement in quality improvement would benefit the profession and their patients.

While physicians practising in hospitals may benefit from the organizational structure and supports around them for disclosure and quality improvement, community-based physicians generally do not have this advantage. That said, the disclosure activities for physicians in private practice or community clinics are the same as for those working in hospitals or health authorities. This potential gap is worrisome, and presents opportunities to educate and support physicians working in community settings. This is an area that requires increased attention.

Quality improvement programs must be properly resourced to carry out the appropriate reviews. Education is required for members of quality improvement committees so that they include the right people with the right expertise. Members of these committees should understand their roles and responsibilities, develop clear objectives, and abide by the established conditions for quality improvement reviews, including confidentiality requirements. Quality improvement committee members require knowledge of recognized quality improvement approaches and tools, including the ability to distinguish between system-related adverse events and those adverse events resulting from the conduct or performance of an individual provider.

Learning from quality improvement reviews

Over the past several years, Canadian health care organizations and providers have made significant progress in reporting adverse events and disclosing these to patients. That said, learning from adverse events and quality improvement recommendations can be improved so that the occurrence of similar adverse events may be further reduced in the future. This approach to learning must be anchored in the principles of fairness and justice, and requires a safe "learning environment" for quality improvement.

Organizations should be accountable for prioritizing and implementing recommendations arising from quality improvement reviews. Physicians and other health care providers should follow policies, procedures, and improved care plans that result from quality improvement reviews.

Notwithstanding the increasing efforts in Canada to improve both the quality and safety of health care, there appears to be a lack of consensus as to how to carry out a quality improvement review, including what is disclosed to patients and to other health care facilities. This is partly related to varying provincial and territorial legislation that protects quality improvement information from being shared with third parties outside the review process.

While physicians and other health care providers remain committed to delivering the safest care possible, one cannot underestimate the importance of helping physicians, especially physician leaders, to understand the best approach for reporting and reviewing adverse events. A physician's clinical expertise and experience in leadership does not necessarily imply sufficient understanding of patient safety, quality improvement concepts, and quality improvement tools. Further education and engagement of physicians including physician trainees are required. Appropriate incentives and support should be explored.

Measuring success and getting feedback

The policy forum participants identified several ways to measure or capture successful outcomes attributed to quality improvement processes, including completing

administrative audits after the investigation of adverse events and the ensuing system improvements. Discussions also occurred regarding the appropriateness of making public the recommendations from quality improvement reviews.

Measuring outcomes requires the identification of standards and metrics, as well as the implementation of measurement methodologies and feedback mechanisms. Provincial or regional quality councils play an important role in benchmarking and developing quality indicators, even if limited to an advisory capacity. [12,13] This is an area that requires further discussion and corresponding education.

The growth and uptake of information technology in health care should help to measure progress in quality improvement initiatives and to foster accountability from both individual providers and health care systems.

5. Recommendations

Based on policy forum discussions, secondary research, and professional insights, the following recommendations are proposed to advance a more refined approach to quality improvement.

For patients

- Contribute to the quality improvement process by offering their perspective.
- Know their role in the quality improvement process to be able to trust in it.

For physicians

- Participate in disclosure discussions using the principles of The *Canadian Disclosure Guidelines* from the Canadian Patient Safety Institute and *Communicating with your patient about harm: Disclosure of adverse events* from the Canadian Medical Protective Association.
- Be aware of the relevant legislation that protects quality improvement information and recommendations.
- Be familiar with the quality improvement processes within their organizations, and fully participate in systems-oriented quality improvement reviews.
- Learn appropriate quality improvement techniques to advance quality improvement in practice.

For regulatory authorities (Colleges)

- Encourage and support physicians to play an active role in establishing a quality improvement process that recognizes the increasing collaborative, interdisciplinary approach to healthcare delivery.
- Refine continuing professional development curricula to highlight how to prevent and respond to adverse events, including participation in appropriate disclosure and quality improvement processes.

- Support legislation which allows adverse event disclosure to patients (including sharing all facts and quality improvement recommendations), and also the protection of quality improvement information from being actively disclosed to others (including safe harbors for reporting and review across the continuum of care).

For hospitals and institutions

- Encourage and support physicians to play an active role in evolving a quality improvement process that recognizes the increasing collaborative, interdisciplinary approach to healthcare delivery.

- Embrace quality improvement and develop a just culture of patient safety, thereby championing learning from quality improvement activities across the continuum of care.

- Emphasize prevention by using when appropriate, surgical checklists, standard operating procedures, care pathways and injury reduction practices.

- Ensure a fair process is used in the evaluation of individual and interdisciplinary performance.

- Make it easier for physicians — particularly physician trainees who may feel intimidated — to report safety issues or suggest QI recommendations; remove barriers due to bureaucratic feedback mechanisms and rigid hierarchy structures.

- Where there are concerns that an individual provider's performance may be the dominant factor that contributed to an adverse event, employ a properly structured accountability review of that individual's care in the case.

For governments and regional health authorities

- Support adverse event disclosure to patients (including sharing all facts and quality improvement recommendations), and also the appropriate protection of quality improvement information from being actively disclosed to others.

- Enable sharing of appropriate quality improvement information and lessons learned across regions, across the country, and beyond.

- Address the potential gap in disclosure activities for physicians in private practice or community clinics who do not have the same support mechanisms available as physicians working in hospitals or health authorities.

For medical professional and health associations

- Standardize operational definitions for terms such as harm, incidents, adverse events, close calls, just culture, and quality improvement.

- Supports adverse event disclosure to patients (including sharing all facts and quality improvement recommendations), and also the protection of quality improvement information from being actively disclosed to others.

For universities

- Refine educational curricula (at the medical student, physician trainee and CPD levels of education) to highlight how to prevent and respond to adverse events, including disclosure and the importance and methods of quality improvement.

- Encourage physicians to model the educational goals by playing an active role in evolving a quality improvement process that recognizes the increasing collaborative, interdisciplinary approach to health care delivery.

6. Conclusion

An adverse event can be devastating for everyone involved. Patients and families live with the consequences of avoidable adverse events, and physicians and other health care providers live with the burden of the event. Health care executives, physicians, and other providers have a collective responsibility to ensure that they create and maintain a supportive and fair culture in which everyone can fully learn from such events and, in so doing, help prevent their recurrence. Physicians are increasingly recognizing the need for change and for improvements in quality and safety.

Health care providers must be able to trust that the initial responses to an adverse event, as well as any subsequent analysis or proceedings, will be conducted fairly and in accordance with established law and policy. Comments made by physicians in the quality improvement process should not be used against them at any stage of the process or in subsequent legal proceedings.

Living a culture of safety should be central to the practice of medicine. The corollaries triggered by the important discussions at the policy forum are:

- The health care environment is constantly changing and is increasingly complex, making it necessary for quality improvement processes to accelerate and be adaptable and flexible.

- Physicians are well-positioned to play an active role in quality improvement, recognizing that care is increasingly delivered as part of an interdisciplinary team.

- Patients, families, regulatory authorities (Colleges), and governments are all potential quality improvement participants. Collaboration, teamwork, and professionalism are required by all.

- Physician education is required about the tangible benefits of quality improvement and how to appropriately carry out quality improvement activities. Physicians need education and support to meaningfully engage in these activities.

- Legislation should support quality improvement processes and learning from quality improvement.

- A just culture of safety must include support mechanisms to encourage physician participation in quality improvement reviews by promoting transparency and trust in the process, as well as ensuring appropriate protection for and accountability of all involved.

7. Definitions

For the purpose of this white paper, the following definitions were used:

Adverse event — an event which results in unintended harm to the patient, and is related to the care and/or services provided to the patient rather than to the patient's underlying medical condition. (CPSI)

Disclosure — the process by which an adverse event is communicated to the patient by healthcare providers. (CPSI)

Quality improvement — system/process enhancement to arrive at a positive outcome. (Mayo Clinic Proceedings, 2010)

Quality improvement review — an analysis by healthcare organizations (usually by a quality review/improvement committee) of patient outcomes, clinical practices and systems of care in order to recommend improvements. Quality improvement committees, as part of an ongoing program to improve patient care, should be structured under the relevant provincial/territorial legislation and include formal terms of reference. Quality improvement committees, depending on the province or territory, may have different titles, for example: Quality of Care, Critical Incident Review, and Risk Management. (CMPA)

Endnotes

1. Canadian Patient Safety Institute (CPSI), 2011, *Canadian Disclosure Guidelines*, 11
2. Institute for Healthcare Improvement, 2011, *Model for Improvement*, 1
3. Baker and Norton, 2004, *Adverse events patient safety*, 1
4. CPSI, 2008, *The Safety Competencies*, 1
5. Canadian Medical Protective Association (CMPA), 2009, *Learning from adverse events*, 1
6. CPSI, 2008, *The safety competencies*, 33
7. CMPA, 2009, *Learning from adverse events*, 24
8. CPSI, 2008, *Canadian Disclosure Guidelines*, 1
9. CMPA, 2008, *Communicating with your patient*, 1
10. Duclos et al., 2005, *Patient perspectives patient-provider communications*, 479
11. CPSI, 2011, *Canadian Disclosure Guidelines*, 4
12. Leatt, 2006, *Quality councils as mechanisms*, 1
13. Plumb and Cowell, 2006, *Quality councils as change*, 1

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