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LEARNING FROM ADVERSE EVENTS:

Fostering a just culture of safety in Canadian hospitals and health care institutions



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INTRODUCTION

It is well recognized that health care providers continuously strive to ensure the best possible clinical outcomes for their patients. They do so cognizant that no one individual or system can ever fully eliminate the risk and occurrence of adverse events. Despite the fallibility inherent to health care delivery, the health care community remains firmly dedicated to reducing adverse events through its commitment to quality improvement.

The booklet describes the requirements and processes for reporting adverse events and close calls, and the best approach for reviewing these events. This booklet also explains how CMPA members and other health care providers can foster a just culture of safety within a hospital/institution, whether they are in a leadership/management role or a participant in the reporting and review process. This booklet does not discuss in any depth the disclosure of adverse events to patients, recognizing that a companion booklet titled *Communicating with your patient about harm — Disclosure of adverse events* covers this topic more thoroughly and can be obtained from the CMPA (www.cmpa-acpm.ca).

A complementary position paper by the CMPA, *Reporting and responding to adverse events: A medical liability perspective*, addresses policy issues associated with the reporting of and response to adverse events. It provides recommendations for policy makers, regulatory authorities, health institutions and individual health care providers to further enhance patient safety in the delivery of health care, while also establishing a fair and equitable accountability framework for health care providers. This paper can be obtained from the CMPA (www.cmpa-acpm.ca).

REPORTING ADVERSE EVENTS AND CLOSE CALLS WITHIN HOSPITALS/ INSTITUTIONS

The reporting and analysis of adverse events and close calls (and other potential-for-harm and no-harm events) are important opportunities to recognize weaknesses in the system and to put in place safeguards to prevent similar occurrences in the future. The ultimate goal is to critically review these events and evaluate the effectiveness of the health care institution’s practices and procedures to improve patient safety.

Hospitals and institutions become aware of adverse events and close calls through various means, including:

- Direct reporting by providers involved in the adverse event or close call;
- Concerns and complaints brought forward by patients and families, or by health care providers; and
- Audits (e.g., using trigger tools).

Most health care institutions have policies guiding the reporting of adverse events or close calls. If such is not the case, the CMPA supports the development of policies and procedures regarding adverse event and close call reporting. Such policies should specify a person or committee whose duty it is to receive incident/occurrence reports (sometimes called patient safety reports). These reports should only be submitted to those specified in the policy, be they a medical or nursing leader, risk manager, patient safety officer, or an internal quality improvement committee.

UNDERSTANDING HARM

Unexpected changes in a patient’s clinical condition most often reflect the worsening of the disease process, disorder or the natural condition. However, some unexpected outcomes are related to health care delivery itself, and are called adverse events.

Most adverse events result from the inherent risks of investigations and treatments. Certain recognized complications or side effects may occur and are independent of who is providing the care. However, sometimes harm results from system failures. Furthermore, sometimes harm results from issues in the performance of individual provider(s). Harm may result from combinations of all of the above.

IMPORTANT TO MEMBERS: Members providing care in a hospital/institutional setting should be familiar with policies regarding the reporting of adverse events and close calls, the likely approach to analysis of these events, and to what extent, if any, information related to these analyses will be communicated to a patient or others.

6 ■ Reporting adverse events and close calls within hospitals/institutions

In addition to reporting policies, most health care organizations have introduced adverse event and close call incident/occurrence reporting systems. These systems should focus on capturing only factual information, recognizing that speculations or opinions might lead to misunderstandings and inaccurate conclusions. It is important to note that incident/occurrence reports may not benefit from the legislation that generally protects quality improvement information from being used in subsequent legal, regulatory or other proceedings.

The legal obligation for reporting adverse events or close calls varies across Canadian jurisdictions. Providers will need to know which occurrences require reporting, what information must be included in a report and how these reports must be communicated. For example, in Québec, the law requires the completion of an incident report for close calls (near misses) in government-run institutions such as hospitals.

IMPORTANT TO MEMBERS: When completing incident/occurrence reports, members should provide only facts and not statements of blame, speculation, opinion or other commentary as to the reasons for what happened, or any recommendations. These reports are usually not considered quality improvement information and are unlikely to be protected by legislative protection. Incident/occurrence reports should not be kept in the medical record, unless where required by law¹.

MANDATORY REPORTING OF ADVERSE EVENTS BEYOND THE HOSPITAL/INSTITUTION

Certain provinces/territories have enacted legislation that requires institutions/hospitals or regional health authorities to report to a government representative (i.e., the Minister or government agency) that an adverse event/critical incident has occurred in their facility. This is generally an institutional responsibility and individual health care providers usually do not play any direct role in fulfilling these reporting obligations.

¹ To date, Québec and Ontario require a copy of “incident” or “accident” reports to be kept in the patient’s hospital record. In Québec, a close call is termed an “incident” and an adverse event an “accident.” In Ontario, the term “critical incident” is used, which is akin to an adverse event.

REVIEWS WITHIN HOSPITALS/INSTITUTIONS

While it is important to report adverse events and close calls, what is done with these reports is equally significant. Thorough reviews of adverse events and close calls, when properly structured, are considered one of the more effective approaches to improving patient safety in a hospital/institution.

Within the context of hospital or institutional care, there are two categories of reviews of adverse events and close calls:

1. Quality improvement review, where the focus is on system issues;
2. Accountability review, where the focus is on the conduct or performance of an individual care provider (page13).

PEER REVIEW

The term peer review is used with varied meanings. For the purposes of this booklet, peer review refers to a retrospective review by peers, or subject matters experts, of an individual or groups of individuals looking at specific indicators of quality of care. The goal is to identify, within a confidential process, areas for practice improvement. Under certain conditions, a peer review may be undertaken to assess the clinical competency of an individual; such reviews should be considered under a properly constituted accountability framework.

QUALITY IMPROVEMENT REVIEWS

Quality improvement reviews are designed to identify the causes of adverse events or close calls by looking at the system in which health care is provided. The results of quality improvement reviews can lead to system improvements that will prove beneficial to all future patients.

HOW IS A QUALITY IMPROVEMENT REVIEW STRUCTURED?

Quality improvement reviews should be anchored in a properly constituted quality improvement committee. The name of these committees can vary by province or territory (e.g., Quality of Care Committee, Quality Assurance Committee, Risk Management Committee, etc.)

The structure and procedure for a quality improvement committee should be prescribed in hospital/institution policies based on the relevant provincial/territorial legislation. A properly constituted quality improvement committee will usually have terms of reference outlining its purpose, reporting structure, scope of activities and membership. Hospital/institutional policies may also provide guidance on sources or triggers for event analysis, the content and retention of committee documents and minutes, and instructions on the access to and the distribution of committee documents, minutes and recommendations.

Once established within the boundaries of a quality improvement committee, the review structure promotes candid and detailed assessment of adverse events by the health care providers involved. In reviewing known facts, it is often helpful to consider what could have happened or what the participants wished had happened. Discussion may include hypothesizing about weaknesses in system processes, which can be a useful way to identify reasons for clinical outcomes and to develop strategies to try to prevent re-occurrences.

IMPORTANT TO MEMBERS: Members should determine whether their hospital's quality improvement committee is properly constituted under the relevant legislation and seek assurances that quality improvement reviews will be conducted in a confidential manner. If such is not the case, members should promote the use of properly constituted quality improvement committees.

WHO CONDUCTS THE QUALITY IMPROVEMENT REVIEW?

Reviewers should be chosen for their skills and knowledge in how to analyze unexpected outcomes, adverse events and close calls, their clinical expertise and/or their ability to effect change in response to recommendations from the review.

Leadership/management must be careful of possible conflict of interest. It is generally inappropriate for those who play a role in annual performance reviews, and accountability and disciplinary matters (for example, a chief of department) to be involved in a quality improvement review involving providers for whom they have responsibility.

WHEN SHOULD THE REVIEW TAKE PLACE?

The review should be done as soon as reasonably practical, ideally within days of an event. This optimizes recall of the facts and allows actions to be taken promptly to deal with any identified system failures.

WHO SHOULD PARTICIPATE IN THE REVIEW?

Participants may include any of the providers involved in the care of the patient, selected experts, and others who can contribute to the analysis of the event and to the development of practical recommendations to improve patient safety. Inter-professional participation provides a broader perspective of what happened, and when conducted in a respectful manner, may strengthen professional collaborative relationships. All participants must commit to the established conditions for participation, including keeping confidential all information and marking documents as being prepared for quality improvement review.

The attendance of the health care providers involved in the adverse event may be required by law or institution/hospital policies and/or bylaws. Other individuals, including patients (and/or their substitute decision makers or selected family members), clinical experts, and equipment manufacturers may be invited to attend the review to clarify details from their perspective or area of expertise, but should not sit in on all of the discussions.

IMPORTANT TO MEMBERS: Even if participation is not mandatory, CMPA members are encouraged to participate in properly structured quality improvement reviews in the interest of improving patient safety.

If a quality improvement review is not structured in accordance with the legislation protecting quality improvement records and information, members should seek assurances in writing that the review process is intended to remain confidential and discussions and disclosure of information will be restricted. If uncertain how to proceed, members should call the CMPA for advice.

HOW IS INFORMATION ANALYZED?

Many accepted methods and tools may be employed, such as root cause analysis (reactive) and failure mode effect analysis (proactive), to identify the possible reasons for the occurrence of adverse events and close calls. To gain a broader perspective it may also be helpful to review a group of related cases or institution/hospital processes. Trends can be identified by collecting and analyzing consolidated data, although these should be aggregated without identifying information pertaining to the patient or provider.

When reviewing system factors in an individual patient case, or a cluster of similar cases, the following questions could be explored:

- What were the reasons for the outcomes, adverse events or close calls?
- Were the existing relevant policies clear, realistic, known and available?
- Were current clinical guidelines and up-to-date care maps used in the system?
- Was access to care or resource availability an issue?
- Were appropriate diagnostics available, and was the interpretation of these facilitated?
- Was the health care team appropriately trained? Was communication among team members an issue?
- Are there recommendations for changes to the system, and has it been established who would likely be responsible for implementing them?

To the extent possible, strategies to recognize and reduce hindsight bias should be employed in reviewing unexpected outcomes and adverse events.

HINDSIGHT BIAS

Knowing an undesirable outcome has occurred increases the belief that it was predictable and therefore preventable. This is called “hindsight bias,” and its existence is well proven in many fields, including medicine and psychology². This bias makes it easier to believe an unexpected outcome was related to poor clinical care, rather than consider the context or work environment in which the individual provider was functioning at the time.

² Dekker, S. *Just culture: balancing safety and accountability*. Burlington, VT: Ashgate Publishing, Ltd.; 2007.

► **WHAT IF PERFORMANCE ISSUES SURFACE DURING A QUALITY IMPROVEMENT REVIEW?**

If serious concerns regarding a health care provider's performance or conduct are discovered in the course of a quality improvement review, the quality improvement committee should suspend its analysis so these issues may be appropriately reviewed in a separate and independent accountability process.

► **HOW SHOULD THE REVIEW BE DOCUMENTED?**

Information gathered for quality improvement reviews should be treated in a consistently confidential manner, and direct access should be limited to those involved in the review process. It is helpful, wherever possible, to use headers and/or footers marking the material as being prepared for a quality improvement review pursuant to the relevant legislation. The working documents should be retained only for as long as needed by the committee to generate its report or to meet legislated requirements, following which the information should be properly disposed. To the extent possible, the final report should not name individuals and should avoid other identifying information.

► **WILL THE DOCUMENTATION RELATED TO THE REVIEW BE PROTECTED?**

To foster continuous quality improvement and to encourage the participation of providers, the legislation in each province/territory generally protects the information and documents prepared for or generated by a quality improvement committee from being used in subsequent legal, regulatory or other proceeding. ***This does not protect the fact that the review itself was conducted.*** The extent to which any quality improvement information can be disclosed varies among the jurisdictions³.

Depending on the applicable provincial/territorial legislation, a properly constituted quality improvement committee may be able to delegate functions to subcommittees. In order for this protection to extend to the work of a subcommittee, the subcommittee must comply with the legislative requirements for a properly constituted quality improvement committee. Delegated functions to appropriately structured subcommittees might include, but are not limited to, reviews of incident/occurrence reports, critical incident investigations, case reviews, care audits, morbidity and mortality rounds, utilization reviews and tissue audits.

IMPORTANT TO MEMBERS: In most jurisdictions, the legislation that protects quality improvement records and information from being disclosed in legal actions extends to other proceedings such as regulatory authority (College) investigations. However, the legislation does not generally preclude a hospital/institution from reporting to the College any suspected incompetence or misconduct uncovered by the quality improvement process.⁴

3 Each Canadian jurisdiction has enacted legislation that protects quality improvement information from being disclosed in legal proceedings. However, each jurisdiction is different in its categorization of what constitutes a quality improvement committee, quality improvement activity and quality improvement information. Furthermore, the extent of the protection that is afforded to quality improvement information differs among jurisdictions. Members are encouraged to familiarize themselves with the relevant legislation in their respective jurisdictions.

4 The exception is in Ontario, where the *Quality of Care Information Protection Act, 2004* prohibits disclosure of quality of care information to the College.

► **WHAT SHOULD BE DONE WITH THE REVIEW FINDINGS?**

Review findings should generally be wide-ranging and may confirm that the unexpected poor clinical outcome resulted from the patient’s underlying medical condition or the risks inherent in an investigation or treatment. Conversely, the review may identify system vulnerabilities or failures that can be addressed through quality improvement measures.

Review findings, including recommendations on quality improvement changes, should be transmitted to those in leadership/management. The legislation in some jurisdictions explicitly prohibits the sharing of findings, conclusions or recommendations of quality improvement committees to anyone other than those in leadership/management. Quality improvement information should not contain names or other personal identifiers. Information shared with leadership/management from a quality improvement review should be limited to the following:

- new facts, if any, related to a patient’s care that were discovered during the review and that are not already contained in the medical record of an individual patient;
- the final conclusions as to the reasons for an unexpected outcome, adverse event or a series of events, focusing on the “system” contributors; and
- the recommendations of the committee on how to improve the system of care.

Leadership/management has a responsibility for prioritizing any recommendations and implementing any appropriate changes. Importantly, leadership/management may also have a responsibility to further report the findings and recommendations to an appropriate health or regulatory authority.

► **HOW SHOULD THE REVIEW FINDINGS BE SHARED WITH PATIENTS/FAMILIES?**

To maintain fairness and objectivity, the quality improvement committee should not be responsible for the disclosure of facts and recommendations directly to a patient (post-analysis stage of disclosure).

It is up to the leadership/management to decide, on a case-by-case basis, preferably in consultation with legal counsel and the providers involved, what information should be disclosed to a patient and by whom. In many cases, leadership/management will likely be involved in the post-analysis disclosure to patients/families. Depending on the circumstances, providers should still be offered an opportunity, with the patient’s permission, to be involved in these discussions.

A patient should be informed of new facts identified in the analysis of the event and the conclusions (but not the opinions leading to the conclusion) as to the reasons for the clinical outcome. The review may have confirmed the clinical outcome resulted from the patient’s underlying medical condition or the risks inherent in an investigation or treatment. Conversely, the review may have identified system vulnerabilities or failures. Speculations are not provided, and blaming is avoided. An apology may be warranted.⁵ Understandably, patients often want to learn of any steps that have been implemented to prevent similar harm to others. In some cases,

⁵ See *Communicating with your patient about harm — Disclosure of adverse events* from the CMPA (www.cmpa-acpm.ca).

it may be appropriate to share with the patient information about actual system changes/improvements implemented by the hospital/institution as a result of the quality improvement review.

► **HOW SHOULD “LESSONS LEARNED” BE SHARED WITH OTHER HEALTH PROVIDERS?**

It may be beneficial to use the review recommendations to educate other health care providers and trainees. In such circumstances identifiable information about patients and/or health care providers involved in an event should not be made available. While it may be reasonable to share any actual improvements that were made arising out of a quality improvement review, it would be inappropriate to reveal information that can easily be tied back to a particular event.



ACCOUNTABILITY REVIEWS WITHIN HOSPITALS/INSTITUTIONS

An accountability review focuses on the conduct or performance of an individual health care provider but does not preclude the identification of system failures and improvements. This type of review generally occurs in response to a concern that a provider’s performance may be the main cause of an adverse event.

► **HOW SHOULD AN ACCOUNTABILITY REVIEW BE STRUCTURED?**

The procedure for an accountability review is usually prescribed in hospital/institution bylaws and policies and may also be set out in legislation. There may be a number of stages in the process, including rights of appeal or review. It is important that such reviews be conducted in a manner that is fair to all involved parties, and that any relevant policies, bylaws or legislation are respected.

► **WHO CONDUCTS THE REVIEW?**

The leadership and management of the provider’s department are usually responsible for the review. Their role is to ensure that during the review process, all parties are treated fairly and all applicable institution/hospital bylaws, policies and legislation are followed.

► **WHEN SHOULD THE REVIEW TAKE PLACE?**

The review should be done as soon as reasonably practical. This increases the likelihood of accurate recall of the facts and allows action to be taken promptly.

► **WHO SHOULD PARTICIPATE IN THE REVIEW?**

The health care provider is usually obliged by institution/hospital bylaws and/or policies to cooperate with an accountability review. Patients, substitute decision makers and selected family members may be asked to contribute to the review by providing information about their knowledge of the facts. Contributors might also include other providers involved in the care of the patient. On occasion, independent peer experts may participate in an accountability review.

Participants in the accountability review process should limit their comments to facts of which they have first-hand knowledge. They should factually answer any questions asked, but should not speculate, hypothesize, self-blame or blame others.

► **HOW IS THE INFORMATION ANALYZED?**

An accountability review may or may not identify or confirm concerns about the competency or conduct of an individual provider. During an accountability review the challenge is to understand the reasonableness of a provider’s decision at the time of an adverse event, taking into account all the circumstances in the working environment.⁶

HINDSIGHT BIAS

Knowing an undesirable outcome has occurred increases the belief that it was predictable and therefore preventable. This bias makes it easier to believe an unexpected outcome was related to poor clinical care, rather than consider the context or work environment in which the individual provider was functioning at the time.

⁶ Dekker, S., *supra* note 2.

Sometimes, in the course of an accountability review, system issues are also identified, and these should be referred to the quality improvement committee.

► **WILL THE DOCUMENTATION RELATED TO THE REVIEW BE PROTECTED?**

The information generated in an accountability review is not collected for or produced by a quality improvement committee and therefore is not protected by quality improvement legislation. The process and records of such a review should nonetheless be treated as confidential. The participants in an accountability review should be informed that it is an accountability review and to what extent information generated will be shared with others and the circumstances under which it will be shared.

IMPORTANT TO MEMBERS: The information generated in an accountability review will not be protected by quality improvement legislation. Members participating in such a review should ask to what extent information generated will be shared with others and the circumstances under which it will be shared.

► **WHAT SHOULD BE DONE WITH THE REVIEW FINDINGS?**

As mentioned previously, an accountability review may not necessarily identify concerns about the conduct or performance of a provider. However, if concerns are identified, organizations are encouraged to consider an approach that favours appropriate remedial action and education. Discipline and other sanctions should be only be used if appropriate.

IMPORTANT TO MEMBERS: If members' privileges are restricted, cancelled or suspended as a result of any review, the hospital/institution may also be required by law to report this information to the College.⁷

► **HOW SHOULD THE REVIEW FINDINGS BE SHARED WITH PATIENTS/FAMILIES?**

Once an accountability review has taken place, it is appropriate to reassure the patient the event has been fully examined and that appropriate actions have been taken. It is up to leadership/management to decide, on a case-by-case basis, whether additional information should be disclosed to patients and families. Despite a patient's appeal for additional information, the provider's right to privacy must be respected. For example, it would be improper for leadership/management to disclose personal health information about a health care provider without the provider's permission. The decision to share the review findings with patients/families will typically require prior consultation with hospital/institution legal counsel.

⁷ A mandatory reporting requirement of hospital disciplinary measures is imposed by legislation in British Columbia, Alberta, Ontario, Québec, New Brunswick, Nova Scotia, Prince Edward Island, and Newfoundland and Labrador.

CHOOSING THE BEST TYPE OF REVIEW

Prior to determining which type of review should be initiated, the suitability and the ensuing benefits of a review process must be established. This initial assessment is contingent on the collection of preliminary facts as they relate to the unexpected clinical outcome, adverse event or close call. An examination of the salient facts will help determine whether further analysis is required. If such is the case, the next step is to select the best type of review.

► STEP 1: COLLECTING ALL THE FACTS

To determine if a review is indicated,⁸ a preliminary collection of salient facts will be required. This will support an initial understanding of the event and assist in determining whether a review will be beneficial.

► STEP 2: DETERMINE IF FURTHER ANALYSIS/REVIEW IS REQUIRED

In general, a review should be considered when a serious unexpected clinical outcome or adverse event has occurred. The legal framework of each province and territory may dictate what kinds of events (e.g., critical incidents) require a formal review. Consideration should also be given to quality improvement review of less serious clinical outcomes, close calls and, on a case-by-case basis, concerns or complaints (associated with unexpected outcomes and/or adverse events) from patients or health care providers.

Each health care hospital/institution must decide, preferably using pre-established and objective criteria, which events should be reviewed, the type of review and the extent of the analysis.

While most adverse events are related to the inherent risks of an investigation or treatment, harm should not be prematurely attributed to being simply “a complication” of an investigation or treatment. An examination of some of these events should be considered to determine whether system issues were contributing factors.

► STEP 3: DETERMINE WHAT TYPE OF REVIEW SHOULD BE INITIATED

Recognizing adverse events most often originate from system failures, quality improvement reviews are generally preferred. The systems theory of patient safety emphasizes that focusing on the system rather than on the individual will prevent more adverse events. However, 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.

The following three questions will assist leadership in determining whether an accountability review is appropriate:

- Is it alleged there is a deliberate violation of sound policy by an individual provider?
- Is there a concern about the health of the provider?

⁸ The quality improvement review process may also be used to examine groups of other clinical outcomes, not just those triggered by a single patient’s outcome or experience.

- Is the dominant concern in this case about the clear lack of knowledge or skills or significant unprofessional conduct by an individual provider? (Note: unprofessional conduct in this context refers only to behaviour that may have significantly contributed to the adverse event or close call.)

Unless the answer to any of these questions is positive, a quality improvement review is the most suitable approach, recognizing that it effectively identifies system improvements.

Recognizing the differing focuses and purposes of the quality improvement and accountability reviews, occasionally it may be necessary to conduct both. These should be done independently with a strict information firewall between the two.

THE IMPORTANCE OF AN INFORMATION FIREWALL

Sometimes it may be necessary to initiate two review processes: a quality improvement review and an accountability review. The two types of reviews must be conducted distinctly and be separated by an “information firewall.” By separating the two processes, health care providers in a quality improvement review will be more likely to contribute their opinions and advance their perspectives on possible system improvements.

IMPORTANT TO MEMBERS: CMPA members should contact the Association for advice if:

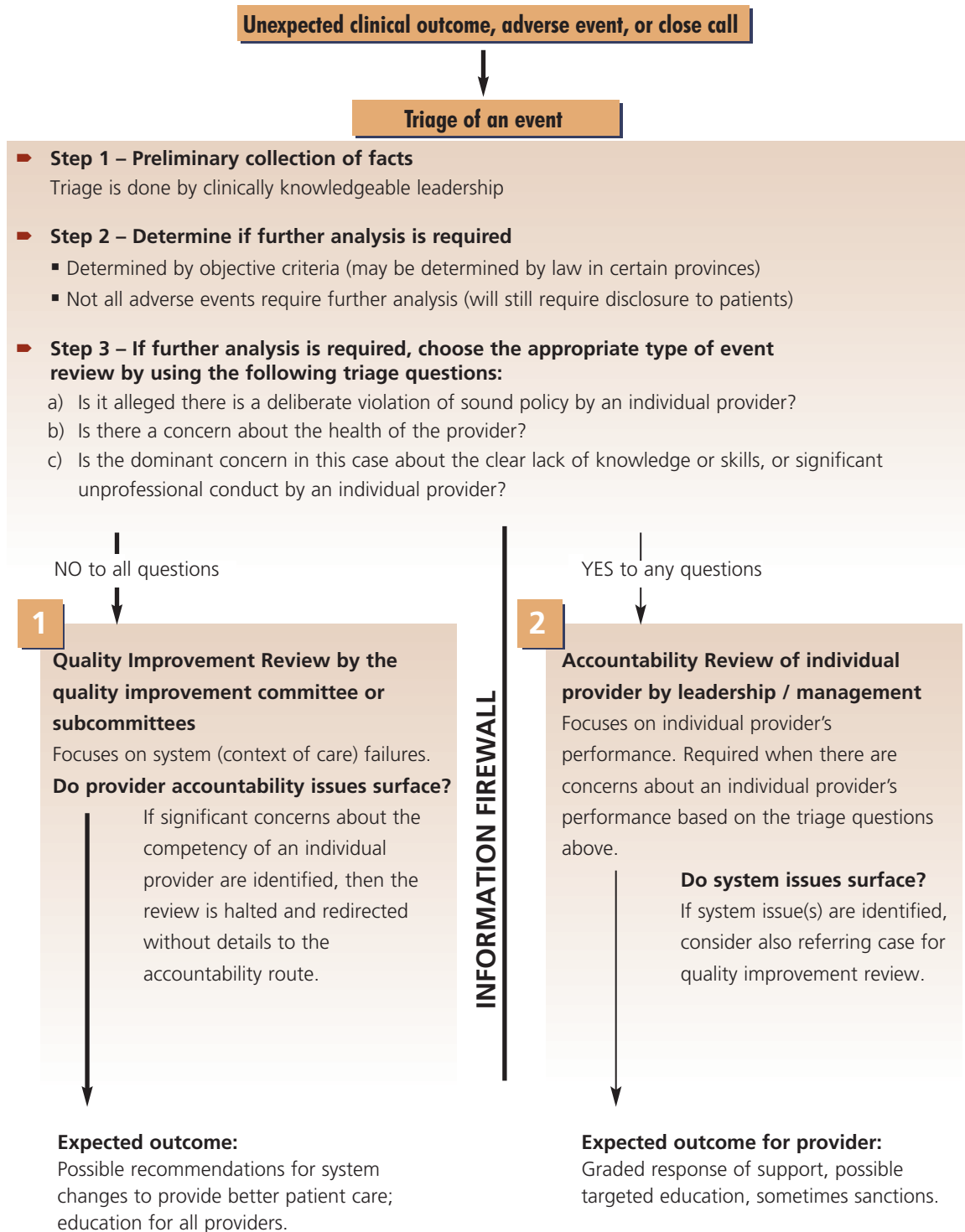
- Obligated to participate in a quality improvement review structured outside the parameters of the relevant provincial/territorial legislation;
- Privileges are threatened;
- A coroner/medical examiner is requesting information from a review, or a disciplinary proceeding by a College and/or litigation is threatened or has already begun; or
- Uncertainty exists on how to proceed.

TRIAGE PROCESS

The use of the triage process will help determine whether a review will be beneficial and if so, what type of review is required. The triage of information must be done objectively by leaders who are knowledgeable in clinical practice and patient safety, and who understand the distinct goals of the two types of reviews.

The following diagram (Figure 1) illustrates the recommended triage process for unexpected outcomes, adverse events and close calls, and the two types of reviews generally available at the hospital/institution level.

Figure 1: Choosing the best type of review in hospitals/healthcare institutions



FOSTERING A JUST CULTURE OF SAFETY

Patients and health care providers will significantly benefit from a health care environment that fosters a just culture of safety. In such an environment, health care providers, patients and those in leadership/management share a collective commitment to quality improvement processes that are anchored in fairness and trust.

ELEMENTS OF A PATIENT SAFETY CULTURE

A patient safety culture is one that demonstrates an organizational-wide commitment to providing the safest possible care to patients. As such, safety is a core value. In these organizations, the leadership drives improvements in safety by providing adequate resources to achieve results.

Moreover, organizations that embrace a just culture of safety support their health care providers by ensuring they can report adverse events without fear of inappropriate reprimand or punishment. Instead, they are lauded for providing the information necessary to help organizations make improvements. In the absence of a culture anchored in trust and respect, a provider “might focus on efforts to hide and defend”⁹ rather than on efforts to learn from what has happened.

A JUST CULTURE OF SAFETY

A health care approach in which the provision of safe care is a core value of the organization. The culture encourages and develops the knowledge, skills and commitment of all leaders, management, health care providers, staff, and patients for the provision of safe patient care. Opportunities to proactively improve the safety of care are constantly identified and acted on. Providers and patients are appropriately and adequately supported in the pursuit of safe care. The culture encourages learning from adverse events and close calls to strengthen the system, and where appropriate, supports and educates health care providers and patients to help prevent similar events in the future. There is a shared commitment across the organization to implement improvements and to share the lessons learned. Justice is an important element. All are aware of what is expected, and when analyzing adverse events any professional accountability of health care providers is determined fairly. The interests of both patients and providers are protected.

⁹ Dekker, S., *supra* note 2.

The use of the term “just” reflects a fair and supportive system. The following are important elements¹⁰:

- The reasons for clinical outcomes and events are not prejudged, and any rush to blame individuals is avoided. Rather, there is an attempt to understand at the time the event occurred the circumstances and context for the actions and decision-making. The main focus of this analysis is on system failures. These are identified and to the extent possible corrected.
- The organization accepts appropriate responsibility and accountability. Individuals are not held accountable for system failures over which they have little or no control.
- Health care providers are able to trust that the initial responses to the adverse event, as well as any subsequent analyses and proceedings, will be conducted with **fairness, within the legislative and legal frameworks, and in accordance with established hospital policy and/or bylaws**. The rights of all individuals, including patients, are protected.
- The relevant policies and procedures to support quality improvement are understood by providers and followed by leadership/management.
- Providers are confident of the organization’s response to an adverse event, which appropriately protects quality improvement information from legal, regulatory or other proceedings.
- The organization does not tolerate intentionally unsafe actions, reckless actions, disregard for the welfare of patients or staff, or other willful misconduct and misbehaviour.
- There is “a collective understanding of where the line should be drawn between blameless and blameworthy actions.”¹¹
- Disclosure of adverse events to patients is important. Patients are provided factual information about an adverse event.
- Providers are appropriately supported, protected and educated.



¹⁰ Adapted from Dekker, S., *supra* note 2.

¹¹ Reason, J. Human error: models and management. *BMJ*. 2000;320:768-770.

CONCLUSION

The identification and reporting of adverse events is a cornerstone of modern patient safety and is vital to improving the quality of care.

Properly structured quality improvement reviews are an important way to encourage health care providers to assess and improve the health care system. Quality improvement reviews and the implementation of any resulting recommendations are considered to be one of the most effective methods of identifying opportunities, of optimizing lessons to be learned from adverse events, and ultimately of helping to prevent future patient harm.

Health care providers and hospitals/institutions have a responsibility to Canadians to create and maintain a just culture of safety that supports improvements to quality of care.

IMPORTANT TO MEMBERS PARTICIPATING IN REPORTING AND REVIEWS:

- Be familiar with and follow the policies and procedures regarding the reporting of adverse events and close calls.
- Provide only factual information in incident/occurrence reports and refrain from statements of blame, speculation, opinion or other commentary as to the reasons for what happened.
- Inquire as to whether the institution's quality improvement committee is properly constituted under the relevant legislation and seek assurances that quality improvement reviews will be conducted in a confidential manner.
- Fully participate in systems-oriented quality improvement reviews.
- Understand the differences between a quality improvement review and an accountability review, in terms of their different purposes, procedures, information protections and consequences.
- If uncertain how to proceed, contact the CMPA for advice.

IMPORTANT TO MEMBERS IN LEADERSHIP/MANAGEMENT ROLES IN HOSPITALS/INSTITUTIONS

- Consider developing policies and procedures to support quality improvement, including the reporting of adverse events and close calls, and ensure that these are understood by providers and followed by leadership/management.
- Promote the implementation of policies and procedures that separate the systems-oriented quality improvement reviews in support of patient safety from accountability reviews that focus on the actions of individual health care professionals.
- Accept appropriate responsibility and accountability. Individuals should not be held accountable for system failures over which they have little or no control.
- When authorized by the legal provisions within the jurisdiction, establish procedures for the release of the system improvement recommendations of quality improvement reviews while ensuring continued protection for the other information collected during the review process.
- Develop recommendations and implement system changes based on the outcome of quality improvement processes.

Building on the belief that quality improvement processes lead to better health outcomes, the CMPA continues to work with others to improve patient safety in Canada.



GLOSSARY

For consistency, the CMPA encourages the use of the following definitions:

- Accountable** To be professionally responsible or answerable. (CMPA)
- 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.
(Disclosure Working Group. *Canadian Disclosure Guidelines*.
Edmonton, AB: Canadian Patient Safety Institute; 2008)
- Other unintended events:
- **Potential-for-harm event**
The event reached the patient (touched or entered the patient), and no harm occurred at the time, but a potential for harm might exist in the future.
 - **No-harm event**
The event reached the patient and no harm occurred at the time and no potential for harm realistically exists in the future.
 - **Close call**
An event with the potential for harm that did not result in harm because it did not reach the patient due to timely intervention or good fortune (sometimes called a near miss).
- Competency** Possessing the knowledge and skills to practice clinically in accordance with the generally accepted standards of care. (CMPA)
- Critical incident** An incident resulting in serious harm (loss of life, limb, or vital organ) to the patient, or the significant risk thereof. Incidents are considered critical when there is an evident need for immediate investigation and response.
(Royal College of Physicians and Surgeons, *The Canadian Patient Safety Dictionary*, 2003)

Disclosure The process by which an adverse event is communicated to the patient by health care providers.
(Disclosure Working Group. *Canadian Disclosure Guidelines*. Edmonton, AB: Canadian Patient Safety Institute; 2008)

Initial disclosure: The initial communications with the patient as soon as reasonably possible after an adverse event, focusing on the known facts and the provision of further clinical care.

Post-analysis disclosure: Subsequent communications with a patient about known facts related to (the harm and) the reasons for the harm after an appropriate analysis of the adverse event

Error, Provider (medical) An act (plan, decision, choice, action or inaction) that when viewed in retrospect was not correct and resulted in an adverse event or a close call. (CMPA)

The use of the term “error” should generally be avoided, especially before all the facts are known, because it can inappropriately suggest there was blameworthy conduct on the part of the health care provider. The term may be misunderstood to mean the care provided was substandard or negligent in law. Errors may or may not be the result of negligence.

Physicians are not necessarily in breach of their duty toward a patient simply because they have committed an error of judgment after a careful examination and thoughtful analysis of a patient’s condition. Errors in judgment may occur, for example, in diagnosing a condition or in choosing among different therapeutic approaches.

Failure mode effect analysis As used in patient safety, the components of a system or steps in a process for the provision of clinical care are studied prior to the occurrence of adverse events (proactively) to determine the probability and impact of a failure in a component or step. (CMPA)

Harm An outcome that negatively affects the patient’s health and/or quality of life.
(Disclosure Working Group. *Canadian Disclosure Guidelines*. Edmonton, AB: Canadian Patient Safety Institute; 2008)

Hindsight bias Knowing an undesirable outcome has occurred increases the belief that it was predictable, should have been foreseen and therefore was preventable. (CMPA)

Incident/occurrence report A report of an adverse event or close call (sometimes called by other terms such as patient safety reports). The information contained therein may not be protected from disclosure. (CMPA)

Just culture of safety A health care approach in which the provision of safe care is a core value of the organization. The culture encourages and develops the knowledge, skills and commitment of all leaders, management, health care providers, staff, and patients for the provision of safe patient care. Opportunities to proactively improve the safety of care are constantly identified and acted on. Providers and patients are appropriately and adequately supported in the pursuit of safe care. The culture encourages learning from adverse events and close calls to strengthen the system, and where appropriate, supports and educates health care providers and patients to help prevent similar events in the future. There is a shared commitment across the organization to implement improvements and to share the lessons learned. Justice is an important element. All are aware of what is expected, and when analyzing adverse events any professional accountability of health care providers is determined fairly. The interests of both patients and providers are protected. (CMPA)

Morbidity and mortality rounds A quality improvement activity in which the members of a hospital/institution department review the clinical care provided to a specific patient or group of patients in order to educate or increase awareness of all those involved and provide recommendations for improved care for all patients in the future. (CMPA)

Negligence/fault A legal concept. In all provinces/territories of Canada except Québec, to establish negligence by a physician, a plaintiff patient must prove to the satisfaction of a court that harm to the patient was caused by the failure to exercise a reasonable standard of care by the physician. In the courts, the medical standard of care to determine negligence is not one of perfection but rather the standard of care that might reasonably have been applied by a colleague in similar circumstances.

In Québec, the concept of fault is at the heart of civil liability. Every person has a duty to abide by certain rules of conduct or standards, and if a person does not, he or she has committed a fault. The plaintiff must demonstrate the physician committed a fault, that is, did not act as a reasonably prudent physician of similar training and experience would have under the circumstances. The plaintiff must also have suffered an injury as a result of the fault committed, and the plaintiff must establish the fault caused the injury. (CMPA)

(For more on negligence/fault, see CMPA Education online at www.cmpa-acpm.ca.)

Patient safety The pursuit of reduction and mitigation of unsafe acts within the health care system, as well as the use of best practices shown to lead to optimal patient outcomes.

Frank, JR, Brien, S, (Editors) on behalf of The Safety Competencies Steering Committee. *The Safety Competencies: Enhancing Patient Safety Across the Health Professions*. Ottawa, ON: Canadian Patient Safety Institute; 2008.

Peer review A retrospective review by peers, or subject matter experts, of an individual or groups of individuals looking at specific indicators of quality of care. The goal is to identify, within a confidential process, areas for practice improvement. Under certain conditions, a peer review may be undertaken to assess the clinical competency of an individual. (CMPA)

Privilege An exception to the general rule in civil litigation that all relevant information in the possession, power or control of a party must be disclosed to all opposing parties. The law of privilege protects certain communications (whether written or oral) from disclosure in legal proceedings. A claim of privilege is also recognized as an exception to the provisions in provincial/territorial and federal privacy legislation that individuals have a general right of access to their personal information. (CMPA)

Procedural fairness The legal concept that administrative proceedings should be conducted in a manner that is fair to the parties involved. While the extent of fairness varies with the nature of the proceedings, **at minimum**, affected parties should be given a fair opportunity to participate in the proceedings. This includes providing parties with notice of the proceedings and the ability to respond to any prejudicial argument or evidence. (CMPA)

Quality improvement review The analysis by health care organizations (usually by a quality improvement committee) of patient outcomes, clinical practices, and systems of care in order to recommend improvements. (CMPA)

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, Risk Management.

Reporting The communication of information about an adverse event or close call by health care providers, through appropriate channels inside or outside of health care organizations, for the purpose of reducing the risk of reoccurrence of adverse events in the future.

(Disclosure Working Group. *Canadian Disclosure Guidelines*. Edmonton, AB: Canadian Patient Safety Institute; 2008)

Root Cause Analysis (RCA) An analytic tool that can be used to perform a comprehensive, system-based review of critical incidents. It includes the identification of the root and contributory factors, identification of risk reduction strategies, and development of action plans along with measurement strategies, to evaluate the effectiveness of the plans.

(Hoffman, C., Beard P., Greenall, J. U, D. & White, J. (2006). *Canadian Root Cause Analysis Framework*. Edmonton, AB: Canadian Patient Safety Institute)

Substitute decision-maker (SDM) A person who is legally authorized to make decisions on behalf of the patient. This authority may be granted by the patient himself or herself with a legal document such as an advance medical directive, by legislation in each province/territory or by the courts. (CMPA)

System failure The lack of, malfunction or failure of policies, operational processes, or the supporting infrastructure for the provision of health care. (CMPA)

Trigger tool An approach to retrospective audit in which certain occurrences (e.g., readmission to hospital, abnormal laboratory values, or the use of certain medications) are used as indicators to identify possible adverse events. (CMPA)

ABOUT THE CMPA

The Canadian Medical Protective Association provides advice, legal assistance, and risk management education to 76,000 member-physicians. As the principal provider of medical liability protection in the country, the Association is governed by an elected Council of physicians. A valuable contributor to the health care system since 1901, the CMPA is firmly committed to protecting the integrity of physicians and promoting safer medical care.

ABOUT THIS PUBLICATION:

The booklet describes the requirements and processes for reporting adverse events and close calls, and the best approach for reviewing these events. It also explains how CMPA members and other health care providers can foster a just culture of safety within a hospital/institution, whether they are in a leadership/management role or a participant in the reporting and review process. A companion publication titled *Communicating with your patient about harm — Disclosure of adverse events* covers the topic of disclosure more thoroughly. Both handbooks are available on the CMPA website at

www.cmpa-acpm.ca



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