

QCIPA Review Committee Recommendations

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About the Committee

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Letter to the Minister

Dear Minister,

On behalf of our committee, we are pleased to submit the report of the *Quality of Care Information Protection Act* Review Committee, which focuses on the use of QCIPA in the investigation of critical incidents.

We appreciate the opportunity to consider this important legislation and hope that our report and recommendations are of value.

Please do not hesitate to contact us if you have any questions or would like to discuss the report.

Yours sincerely,

Original signed by

Angela Morin
QCIPA Review Committee Co-Chair

Original signed by

Andreas Laupacis
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Executive summary

Introduction

This Committee was asked to review current practice in the interpretation and implementation of the *Quality of Care Information Protection Act* (QCIPA) and its intersection with other related legislation, and to make recommendations for improvement, if needed.

QCIPA was introduced in 2004. One of its purposes was to improve the identification and investigation of critical incidents, so that their causes are fully understood and changes can be instituted to prevent similar incidents occurring in the future. A critical incident is an unintended event that occurs when a patient receives treatment in an institution and results in death or serious disability, injury or harm to the patient, and the event does not result primarily from the patient's underlying medical condition or from a known risk inherent in providing the treatment.

QCIPA stipulates that when workers within a health care institution discuss the factors that may have caused a critical incident and the measures that could be instituted to prevent future incidents, that information is held in confidence and cannot be publicly released. The rationale for this is that without a "safe place" to share speculations, some workers will not be fully transparent about the potential causes of a critical incident.

Some individuals and organizations feel that QCIPA is working well. Others have raised concerns that QCIPA is being used to prevent patients and families from being fully informed about what went wrong in a particular incident and what will be done to improve care in the future. There are also concerns that QCIPA has inhibited the sharing of information about critical incidents among institutions in Ontario.

What we did

The committee reviewed over 90 research and policy documents, interviewed more than 30 individuals and experts, consulted with over 30 patients and family members who had experience with critical incidents or quality issues in hospitals, met with 18 patients and family members for one day and received on-line submissions.

Our findings and recommendations

The committee focused its attention on the use of QCIPA in the investigation of critical incidents in hospitals. The committee heard a variety of opinions about how well QCIPA is currently fulfilling its purpose, and was struck by the large variation in how QCIPA is used in Ontario's hospitals; some hospitals invoke QCIPA for virtually every critical incident while others almost never invoke it. We heard patients and members of the public say that they supported QCIPA's intent of providing a protected environment in which health care workers can freely speculate about why a critical incident happened and what could have been done to prevent it, but they felt that this privilege should come with the obligation of being honest with patients and families about what happened and what will be done to prevent future incidents, and that hospitals should share the lessons learned from the investigation of critical incidents with each other.

QCI.

During their one day deliberative dialogue, the patients suggested six principles that should guide the investigation of critical incidents. The committee agreed with these principles and adopted them as the principles underlying the report. They are:

- Critical incident investigations should assume good intentions from all parties
- Critical incident investigations should be patient inclusive
- Critical incident investigations should be transparent
- Staff need to communicate effectively with patients and families before, during and after critical incident investigations
- Critical incident investigations should entail an obligation to share lessons
- Critical incident investigations should be consistent and predictable

The committee made twelve recommendations, which fall under the following broad categories:

- In order to improve quality, Ontario's health care system must strive for a "just culture" which includes a system-wide commitment to monitor the quality of care, unbiased assessment of performance, commitment to learning from mistakes, support not blame when things go wrong, openness with patients and the public, and the sharing of lessons learned with others.
- The intent of QCIPA remains valid, and a modified version of the legislation should be retained. However, the legislation should be amended to clearly indicate that when QCIPA is invoked, patients and families must be fully informed about the results of the investigation, including what happened, why it happened and what measures (if any) the organization intends to take to prevent future incidents. This should be done in a way that respects the confidentiality protections of QCIPA.
- The current variation in how QCIPA is used across Ontario hospitals needs to be addressed. QCIPA should only be invoked when the nature of the contributing causes to a critical incident is unclear and there is the need for considerable discussion and speculation about the causes of the incident. Ontario hospitals, with the help of Patients for Patient Safety, the Canadian Medical Protection Association, Health Quality Ontario and others, should learn from each other and develop clear guidance about the circumstances under which QCIPA should be invoked to investigate a critical incident, and when it should not be invoked.
- If patients and families are unhappy with a hospital's investigation of a critical incident, they should be able to request an investigation that is independent of the hospital in which the incident occurred. The newly established Office of the Patient Ombudsman could be the independent body of last resort.
- Ontario should establish a publicly available database or registry that contains information about all of the critical incidents investigated in Ontario hospitals. This database could be housed at Health Quality Ontario, should be scanned on a regular basis, and the critical incidents that deserve special attention by Ontario hospitals should be identified and proactively shared with Ontario hospitals and other relevant organizations.
- The Boards of hospitals, through their Quality Committees, must ensure that critical incidents are appropriately identified and investigated, the lessons learned are shared with patients and families, the recommendations from the investigations are implemented, the hospital complies with its reporting requirements to share information with other hospitals, and the hospital is learning from the critical incidents that have been investigated at other Ontario hospitals and elsewhere.

- Patients and families must be informed of the process that will be used to investigate their critical incident, they must be interviewed as part of the investigation of an incident, they must be kept informed of the progress of the investigation, and their voice must be represented throughout the review process.
- Establish a provincial program to train and support highly skilled hospital staff to investigate critical incidents and communicate with and support patients and families
- Hospital staff can be traumatized by a critical incident, and should have access to support during the investigation of a critical incident.

We hope this report will be helpful in guiding improvements to this important piece of legislation and ensuring consistent, high-quality, safe and patient-centred care in Ontario.

1. Background

In August, 2014, the Minister of Health and Long Term Care established this Committee to review current practice in the interpretation and implementation of the *Quality of Care Information Protection Act, 2004* (QCIPA) and its intersection with other related legislation. Based on its review, the Committee was asked to advise the Minister on potential improvements to ensure consistent, high-quality, safe, and patient-centred care (see Appendix A for Committee mandate, responsibilities and principles of approach to conducting its work).

“I am solidly in support of finding new ways to strengthen patient care”

~ Minister of Health and Long-Term Care Eric Hoskins (on announcing the Committee review and commenting to the Toronto Star July 8 2014)

The Committee was established in response to a number of concerns expressed by patients, families, health providers, system administrators and the media.

Important concerns raised about QCIPA include the following:

- Because of QCIPA, patients and families sometimes feel that they do not get full answers about what went wrong in particular incidents and what will be done to improve care in the future.
- There is confusion and lack of clarity across health care organizations about how QCIPA is to be used.
- Because of current interpretations of QCIPA there are lost opportunities to share lessons learned about quality improvement opportunities across organizations.

“It seems that when we use QCIPA, we are limited in what we can share with patients about the review but we sometimes need to use it to encourage providers to speak openly about an incident.” ~ Key informant interview

In addition to these concerns, the ten-year milestone since the introduction of the legislation represents an opportunity to reflect on the use of QCIPA in the context of the evolution of the provincial health system and international practices related to quality improvement. As well, during the last ten years, much has changed in the quality and information protection and disclosure landscape.

This review is set against the backdrop of a number of quality and patient safety improvement initiatives in Ontario that are part of the Excellent Care for All strategy and the Government’s commitment to advancing patient safety, transparency and accountability.¹ The landscape of legislation and regulation that impacts quality in health care organizations and patient and public disclosures has become increasingly complex since the introduction of QCIPA.

QCIPA was introduced at the same time as the *Personal Health Information Protection Act* (PHIPA). Since 2004, additional legislation relevant to quality, transparency and accountability includes the *Freedom of Information Protection Act* (FIPPA), the *Excellent Care for All Act* (ECFAA), the *Apology Act*, regulatory changes (Regulation 965) related to disclosures in the *Public Hospitals Act* and most recently the *Public Sector and MPP Accountability and Transparency Act*. An overview of each piece of legislation, its scope and intent and relationship to QCIPA is provided in the Table below. It illustrates the complexity of the Ontario legislation that attempts to balance access to information and the protection of privacy.

¹ Ontario’s Action Plan for Health Care http://www.health.gov.on.ca/en/ms/ecfa/healthy_change/docs/rep_healthychange.pdf

The number of pieces of legislation and their regulations may be at least partially responsible for some of the confusion about what can and cannot be disclosed related to the investigation of a critical incident.

Legislative Overview

Legislation	Year	Scope and Intent	Relationship to QCIPA
<i>Personal Health Information Protection Act (PHIPA)</i>	2004	<ul style="list-style-type: none"> Establishes rules for the privacy of personal health information (PHI), while facilitating the effective provision of health care Provides patients with a right of access to and correction of their own PHI Provides for independent review and resolution of complaints related to PHI by the Information and Privacy Commissioner 	<ul style="list-style-type: none"> PHI is used in critical incident reviews under QCIPA Patients are entitled to disclosure of any new facts that are learned about their care during the review
Regulation 965 under the <i>Public Hospitals Act</i>	Amended to address critical incidents in 2008	<ul style="list-style-type: none"> Requires disclosure to the patient/family following a critical incident of the facts of what occurred, the consequences to the patient and the remedial steps recommended for the patient Hospitals must also have a system for reviewing critical incidents for quality improvement Hospitals must advise the patient/family of any systemic steps taken following the review to improve quality 	<ul style="list-style-type: none"> A critical incident may be reviewed under QCIPA Following the review, hospitals must provide disclosure to the patient of the systemic steps taken to improve quality
<i>Apology Act</i>	2009	<ul style="list-style-type: none"> Defines “apology” as “an expression of sympathy or regret, a statement that a person is sorry or any other words or actions indicating contrition or commiseration, whether or not the words or actions admit fault or liability or imply an admission of fault or liability in connection with the matter to which the words or actions relate” Evidence of an apology is not admissible in a proceeding (except for a criminal proceeding 	<ul style="list-style-type: none"> Not directly relevant to a QCIPA review Disclosure following a QCIPA review could include an apology and this could not be used in a legal process

Legislation	Year	Scope and Intent	Relationship to QCIPA
		<p>or provincial offences proceeding) unless the apology is actually expressed in the course of the proceeding</p>	
<i>Excellent Care for All Act (ECFAA)</i>	2010	<ul style="list-style-type: none"> • All hospitals are to have a Quality Committee (QC) of the Board of Directors • The QC is to oversee the preparation of an annual Quality Improvement Plan (QIP) • Amongst other factors, the hospital must consider aggregate critical incident data in developing the QIP 	<ul style="list-style-type: none"> • The results of QCIPA reviews may be used by the hospital in developing the QIP
<i>Freedom of Information Protection Act (FIPPA)/ FIPAA exclusion and FIPPA exemption for QCI</i>	Applied to hospitals in 2012	<ul style="list-style-type: none"> • Provides for a general right of access to all records in the custody or control of hospitals • PHI is excluded from the general right of access, and is accessible only by the patient and other identified individuals or organizations under PHIPA • QCI is also excluded from the application of FIPPA • FIPPA includes a discretionary exemption for records related to quality reviews where the records are prepared for a committee and there is an expectation of confidentiality 	<ul style="list-style-type: none"> • QCIPA records are excluded from the right of access under FIPPA
<i>Public Sector and MPP Accountability and Transparency Act</i>	2014	<ul style="list-style-type: none"> • Extends the application of ECFAA to CCACs, long term care homes (N.B. the extension of ECFAA to CCACs and long-term care homes is only in respect of review by the Patient Ombudsman) • Creates a Patient Ombudsman (PO) to respond to complaints by patients about hospitals and other health sector organizations 	<ul style="list-style-type: none"> • A patient could complain to the PO about a situation that has been reviewed under a QCIPA review • The PO may make recommendations to the health sector organization following an investigation

QCIPA is used for a variety of system improvement purposes including quality assurance and quality improvement activities such as peer review and mortality and morbidity rounds. Because of the time available to us, our committee focused our efforts on the use of QCIPA as it relates to the investigation of critical incidents in hospitals. This is the area of QCIPA's application that has the greatest impact on patients and families and has been of the greatest area of public concern.

Over the course of 4 months, the Committee conducted a literature review, jurisdictional scan, completed interviews with over 50 key informants and patients, and received on-line submissions from 12 individuals and organizations. Three Committee working sessions were held as well as a separate Patient and Family consultation day in November to listen to the views of patients and their families about the investigation of critical incidents. This report includes a description of QCIPA, an overview of the investigation of critical incidents, a summary of the findings from our literature review and key informant interviews, a summary of the input received from patients and their families, and our recommendations.

Overview of QCIPA

The *Quality of Care Information Protection Act, 2004* and its regulations came into force November 1, 2004, together with the *Personal Health Information Protection Act, 2004 (PHIPA)*. QCIPA is designed to encourage health care providers to share information about the provision of health care within their organization² in order to improve health care, without fear that the information will be used against them.

The causes of many critical incidents are complex (see box for the definition of critical incident we used in preparing this report). Understanding a critical incident requires an environment where staff can explore what happened and why. QCIPA is intended to help health care workers identify system and process failures with a view to being able to prevent future incidents. It provides protection for health care providers who share speculation and opinion as part of an investigation of a critical incident. Even though QCIPA applies to health care organizations other than hospitals (independent health facilities³, long term care homes, laboratories, specimen collection centres) it appears to be rarely used outside of hospitals today. QCIPA does not currently apply to other Out of Hospital Premises (OHPs).

“Critical incident” means any unintended event that occurs when a patient receives treatment in the hospital, (a) that results in death, or serious disability, injury or harm to the patient, and (b) does not result primarily from the patient’s underlying medical condition or from a known risk inherent in providing the treatment” ~ Ontario Regulation 423/07, amending Regulation 965 under the Public Hospitals Act.

Under QCIPA, a hospital or other eligible organization can designate a Quality of Care Committee (QCC) “for the purpose of studying, assessing or evaluating the provision of health care with a view to

² QCIPA applies to hospitals, independent health facilities, long-term care homes, licensed medical laboratories and specimen collection centres.

³ Note: While QCIPA applies to Independent Health facilities, the *Independent Health Facilities Act* prevails over QCIPA. This means that disclosures mandated under the IHFA, including under its regulations including in connection with inspection/enforcement powers under that Act, would still be required despite QCIPA, e.g. information required by the IHF Director, or an assessor or inspector appointed under the IHFA, for the purposes of administering the IHFA (including compliance monitoring and enforcement, and including the CPSO Registrar, inspectors, and assessors where they are performing functions under the IHFA), and/or other functions as set out under the IHFA. All other restrictions on disclosure as set out in QCIPA, apart from those relating to disclosures required under the IHFA, would continue to apply to QCI.

improving or maintaining the quality of health care or the level of skill, knowledge and competence of the persons who provide health care.”

The rationale for the legislation is that:

- Errors in health care delivery are common, and a large proportion of these errors is preventable.⁴
- While undoing the effects of a particular error in healthcare delivery is often not possible, it is possible to make it less likely for the same error to occur in the future.
- The factors that contributed to a particular error are often only known by the health care providers who were involved in that error.⁵
- Peer reviews and quality assurance are critical and essential components of maintaining quality standards within a health care organization. However, “...without confidentiality assurances, physicians and other health professionals would refuse to participate in or fail to bring candour to such activities.”⁶

QCIPA ensures that information specifically prepared by or for a QCC, subject to various exclusions discussed below, is shielded from disclosure in legal proceedings and from most other disclosures.

QCIPA restricts all disclosures of quality of care information (QCI) (not just in a “proceeding”) with the exception of the following permitted disclosures:

- Disclosures to management for quality of care purposes
- Disclosure by management to employees/agents for quality of care purposes
- Disclosures to prevent serious bodily harm
- Disclosures to another quality of care committee
- Disclosures under other legislation that prevails

It is important to note that patients are not included in the scope of permitted disclosures.

In 2012, when the *Freedom of Information and Protection of Privacy Act* (FIPPA) – which governs a hospital’s general records that *do not contain* personal health information – was extended to Ontario hospitals, quality of care information (QCI) as defined under QCIPA was explicitly excluded from the scope of FIPPA. As a result, a person cannot make a Freedom of Information request to a hospital for records of QCI, even if all personal health information is removed from the records.

QCIPA itself (section 1.1 updated in 2012) states that the *Freedom of Information and Protection of Privacy Act* does not apply to quality of care information. This is an “exclusion” of quality of care information from FIPPA, which means that an access request under FIPPA cannot be made for any records containing quality of care information. There is also an “exemption” in FIPPA (under section 18) that provides the head of a hospital organization may refuse to disclose a record that contains “information provided in confidence to, or records prepared with the expectation of confidentiality by, a hospital committee to assess or evaluate the quality of health care and directly related programs and services provided by the hospital, if the assessment or evaluation is for the purpose of improving that care and the programs and services”. This means that some quality of care information may be protected from disclosure where the conditions for the exemption are met even if QCIPA was not invoked in a process.

⁴ Baker GR et al. (2004). The Canadian Adverse Events Study: The Incidence of Adverse Events Among Hospital Patients in Canada. *CMAJ*. 170(11): 1678-1686.

⁵ Dimitriadis F, Orr M, Perun HN. Guide to the Ontario Personal Health Information Protection Act. (Irwin Law, 2005).

⁶ Taylor KL. (2004) Quality Assurance Reviews – An Update: *Quality of Care Information Protection Act, 2004*. Presented at the HIROC-OHA conference held on June 7-8, 2004.

At the same time, according to QCIPA, the following information is specifically excluded from the definition of QCI in QCIPA, and can be released to patients if requested (subject to any other applicable legislation, e.g. PHIPA):

- Information contained in a record maintained for the purpose of providing health care to an individual (e.g. patient chart),
- Facts contained in a record of an incident involving the provision of health care to an individual, where the facts relating to the incident were not fully recorded in the patient's chart,
- Information contained in a record that is required by any law to be created or maintained, (e.g. all hospital critical incident information required to be reported under the Public Hospitals Act Regulation 965), and
- Information that a regulation under QCIPA specifies is not quality of care information and that a quality of care committee receives after the day on which that regulation is made (which currently excludes from QCI the fact that a QCC met or conducted a review, and when the meeting took place).

It is important to note that the perception and practice about how the “facts” exception is interpreted can be problematic because the definition of “fact” is open to varying interpretations. The generally accepted interpretation is that a “fact” is something that actually happened while care was being provided.

Disclosure and Reporting of Critical Incidents

In Ontario, an amendment to Regulation 965 under the *Public Hospitals Act* came into force on July 1, 2008, and intersects with QCIPA. Regulation 965 mandates every public hospital to disclose a critical incident as soon as practicable after it occurs to the hospital's medical advisory committee and administrator, as well as to the affected patient or a person lawfully authorized to make treatment decisions on behalf of the patient, or to the patient's estate trustee (in case of death). According to the Regulation, the disclosure, with regard to the critical incident, must include:

- The material facts of what occurred;
- The consequences for the patient, as they become known; and
- The actions taken and recommended to be taken to address the consequences to the patient, including any healthcare or treatment that is advisable.

Under Regulation 965 all such information and a record of the disclosure must be recorded in the patient record, and be accessible to the patient. The hospital must also ensure that every critical incident is analyzed and a plan developed with systemic steps to avoid or reduce the risk of re-occurrence⁷, and hospitals are required to disclose those steps to the patient/family.

Regulation 965 also requires hospital administrators to provide “aggregated critical incident” data to the hospital's “quality committee” (which is not a QCC) established under the *Excellent Care for All Act, 2010* (ECFAA) at least two times per year. The aggregated data must include information about all critical incidents occurring at the hospital since the previous aggregated data were provided.

Hospital boards are responsible for ensuring that hospital management establishes a process for carrying out the requirements described above.

⁷ Such a plan may constitute a “record required by law to be created... or maintained”, and as such would be excluded from the definition of QCI.

The lessons learned from critical incidents are meant to inform the development of hospital annual Quality Improvement Plans, but little visibility or Ontario-wide learning from critical incidents exists today. At present, reporting beyond facilities exists for medication and IV fluid incidents to the National System for Incident Reporting.⁸ CIHI's National System for Incident Reporting (NSIR) is a web-based application used by Canadian health care facilities to securely and anonymously share, analyze and discuss medication/IV fluid incidents. Its data and analyses inform quality improvement activities at local, regional, provincial, territorial and national levels to foster improvements in health care delivery.⁹ Provincial reporting on hospital acquired infections and a number of safety indications are reported by Health Quality Ontario.¹⁰ There are no formal requirements around critical incident reporting and investigation although useful guides have been developed by the Canadian Patient Safety Institute and other health system organizations that are used by some organizations.

Overview of QCIPA and Critical Incidents

The application of QCIPA to critical incident investigations in Ontario hospitals is varied. In general, QCIPA appears to be more likely to be used to investigate critical incidents when the causes appear to be multi-factorial, system related or unclear. In cases where the cause is clear, or where there is an obvious concern about professional practice, QCIPA is generally not used.

⁸ The MOHLTC issued a directive that as of October 1, 2011, all Ontario hospitals will be required to report all critical incidents related to medication / IV fluids through the National System of Incident Reporting (NSIR) within 30 days following the disclosure of the critical incident to the Medical Advisory Committee (MAC), administrator and/or patient.

<http://www.health.gov.on.ca/en/pro/programs/ecfa/legislation/criticalincident/update.aspx>

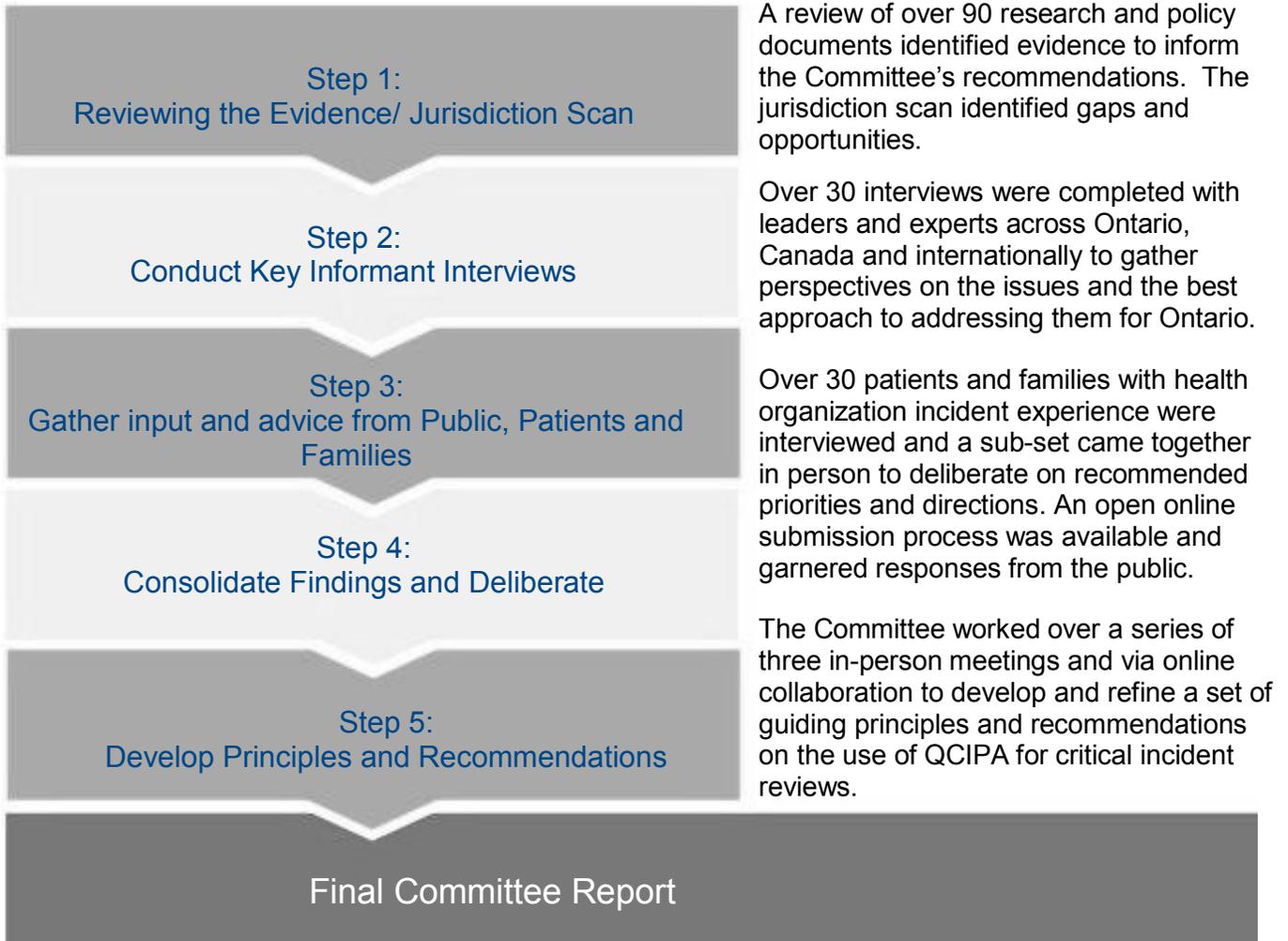
⁹ http://www.cihi.ca/cihi-ext-portal/internet/en/document/health+system+performance/quality+of+care+and+outcomes/patient+safety/services_cmirps

¹⁰ http://www.health.gov.on.ca/en/public/programs/patient_safety/

2. Our Approach

The following outlines the approach taken by the Committee during its consultation and deliberation about the use of QCIPA for the investigation of critical incidents in hospitals.

Figure 1: QCIPA Review Committee Approach



3. What We Heard

Step 1: Reviewing the Evidence/ Jurisdiction Scan

Evidence Review

A review of over 90 research and policy documents helped identify evidence to inform the Committee's recommendations.

The Committee commissioned a review of the literature and current practices in other Canadian and international jurisdictions. The Committee sought to understand:

1. How confidentiality provisions affect quality-of-care discussions
2. Practice and literature related to critical incident reporting

A limited amount of literature was identified about how confidentiality provisions affect quality of care discussions. Some sources discussed the importance of confidentiality provisions for facilitating quality-of-care discussions, and suggested that such confidentiality is crucial to maintain an environment in which providers are comfortable openly discussing and analyzing patient safety events, identifying causes, and suggesting ways to prevent future incidents. The literature suggests that it is difficult to empirically evaluate the effect of any law on a provider's willingness to identify incidents or participate fully in reviews, and that most of the discussion in the literature had been based on assumption, conventional wisdom, and/or opinion rather than rigorous evidence or empirical research.

Across jurisdictions, various centralized adverse event/ critical incident reporting systems have been developed to track incidents and to facilitate shared learning; however, each reporting system is unique. It is noted that standardized definitions and incident classifications are essential elements of successful adverse event reporting systems. Organizational leadership and culture are key elements of implementing and ensuring the ongoing effectiveness of quality improvement processes (including reporting and safety behaviour). All, including staff and administration, should share accountability for patient safety, while responsibility for the quality improvement review process rests with leadership/management, often at the board level, including any requirements to report to an appropriate health or regulatory authority.

There is limited literature evaluating the impact of quality of care information protection on improving quality of care. That said, there is emerging awareness and growing acceptance in the literature of the importance of a "cultural change" towards openness, transparency and sharing after critical incidents. A trend towards upfront disclosure and keeping the patient/substitute decision-maker and family¹¹ as informed and involved as they wish to be is felt to lead to better outcomes, even while keeping quality of care information protected. Although accountability usually applies to all staff, the literature posits that successful quality improvement requires consistent senior leadership support.

Key points from this literature include:

- Engagement of patients and families, as well as staff, is an essential element of creating a patient safety culture, to support openness and transparency.

¹¹ Note: Family as defined by the patient. Disclosure is made to the patient if he/she is capable or to the legally designated substitute decision-maker if the patient is not capable. Additional family may be involved as permitted by the patient or substitute decision-maker.

- Disclosure is an important step in helping the patient and family deal with the aftermath of an adverse event, as well as ensuring that information about the event can be analyzed and used to limit the chance of recurrence.
- Several tools and methods may be employed to investigate causes of adverse events; however there is no one size fits all approach.

Details of the findings from the evidence review can be found in Appendix C.

Jurisdiction Scan

Based on our review of the legislation and regulations governing the protection of quality of care information in other Canadian provinces, the US, the UK and Australia, most jurisdictions provide legislative protection with respect to the disclosure of quality of care information. In Canada, this protection is provided in other provinces under the provinces' *Evidence Act*. In the US and Australia, as in Ontario, quality of care information protection falls under health sector-specific legislation. No UK legislation explicitly defines quality of care information. However, confidential personal information held by the UK's Care Quality Commission is protected, and disclosure of hospital quality of care information is further regulated under the UK's *Freedom of Information Act, 2000*.

There are also provisions in each of the above jurisdictions for patients and families to receive information about a critical incident; for local authorities to be notified about particular critical incidents; and for aggregate data about critical incidents to be collected. Guidance from the Canadian Patient Safety Institute – *Canadian Incident Analysis Framework* and *Canadian Disclosure Guidelines: Being Open with Patients and Families* – on incident analysis and disclosure are widely used and accepted as a support in incident reporting, analysis and associated disclosure processes.

Saskatchewan and Manitoba, in particular, have moved from voluntary reporting of adverse events to a more comprehensive legislated process, including mandatory reporting and shared learning, in an effort to reduce the potential of critical incident reoccurrence.¹²

In 2002, Saskatchewan became the first Canadian province to enact legislation requiring mandatory reporting of adverse events to the provincial Department of Health. Furthermore, on September 15, 2004, the Government of Saskatchewan passed legislation requiring the reporting and investigation of critical incidents in health care. The aim of this legislation is reporting for learning to enhance patient safety. In 2005, the Manitoba government passed legislation to amend the *Regional Health Authorities Act* and the *Manitoba Evidence Act*. The amendments contain mandatory critical incident reporting requirements. Once a critical incident is identified, the health care organization is required to report the event to the regional authority, which in turn reports the incident directly to the Minister of Health. If a critical incident occurs, the regional health authority, health corporation, or health care organization must ensure that appropriate steps are taken to fully inform the individual as soon as possible about the facts of what actually occurred with respect to the critical incident, its consequences for the individual as they become known, and the actions taken and to be taken to address the consequences of the critical incident, including any health services, care, or treatment that are advisable.¹³

Consistent with Ontario's Regulation 965 of the *Public Hospitals Act*, the common elements across each of the jurisdictions of what is required to be communicated to patients includes:

¹² Gregory, D. (2008). *Adverse Health Event Management: International and Canadian Practices*.

¹³ Gregory, D. (2008). *Adverse Health Event Management: International and Canadian Practices*.

- That an incident had occurred
- The facts of the incident
- The consequences of the incident for the health of the individual, and
- The action required to address the immediate health issues for the patient.

Within Canada and across international jurisdictions, centralized incident reporting systems have been developed for tracking adverse events as well as identifying strategies and tactics to limit the occurrence of such events, and sharing this learning across organizations and health care systems. In Canada, efforts have included¹⁴ :

- The Canadian Medication Incident Reporting and Prevention System, a system that reports, analyzes and manages voluntarily reported medication incident data on a national basis;
- The Canadian Patient Safety Institute's Canadian Adverse Event Reporting and Learning System; and
- Regional systems such as the Incident Reporting Information System (British Columbia), Regional Occurrence System Enhanced project (Newfoundland and Labrador), and the Patient Safety Reporting System (Nova Scotia). Similar systems are also in place in Saskatchewan, Manitoba and Quebec.
- The British Columbia Patient Safety and Learning System (BCPSLS) is the first province-wide system of its kind in Canada and is used by all health authorities across acute, residential, community and ambulatory care settings to identify, manage, and learn from adverse events, near misses and hazards.
- Many hospitals in Ontario and other provinces maintain local systems.
- In Ontario, since May 30, 2013, Out of Hospital Premises have been required to report adverse events to the College of Physicians and Surgeons of Ontario (see s. 51(3.1) of the CPSO general bylaw).

In **Australia**, the Australian Advanced Incident Monitoring System (AIMS) is used as a confidential error reporting system. According to a 2008 report prepared by Gregory for the Newfoundland and Labrador Task Force on Adverse Health Events, this software tool is used in over 400 Australian hospitals (as well as sites in South Africa, New Zealand, and the US) and is designed to consistently capture information on close calls and critical incidents, allowing for in-depth analysis of both types of events. According to Gregory, unlike other such systems, AIMS includes a standardized classification system that is recognized by the World Health Organization and the US Institute of Medicine. The software allows for comparison of critical incidents and appropriate interventions to reduce the risk of recurrences among those participating in the surveillance system.¹⁵

In the **UK**, the National Patient Safety Agency (NPSA) was created to coordinate efforts to report and learn from mistakes and problems that affect patient safety in health care. It is a system for reporting and tracking adverse events and near misses. A core function of the NPSA was the development of the National Reporting and Learning System (NRLS), an anonymous mandatory reporting system that is responsible for collecting reports of patient safety incidents (actual and potential adverse events) from all NHS service settings across England and Wales, and learning from such reports.

¹⁴ Baker, G.R. (2014). Governance, policy and system-level efforts to support safer healthcare. *Healthcare Quarterly*, 17(Special Issue), 21-26.

¹⁵ Gregory, D. (2008). Adverse health event management: International and Canadian practice.

In 1999, the **US** Institute of Medicine recommended the establishment of a national mandatory reporting system in hospitals, followed by an expansion to all sites engaged in patient care. As of 2005, 25 states had passed legislation or regulations related to reporting critical incidence and adverse events occurring at hospitals; however the requirements of these reporting systems varied from state to state.

In several jurisdictions, further non-statutory guidelines exist for communicating with patients, including:

- **Expression of regret.** Apologies are key components of the Harvard Consensus Statement, UK's Being Open framework, Australia's Open Disclosure Framework, the Canadian Patient Safety Institute's Being Open with Patients and Families Disclosure Guidelines, and Patients for Patients Safety Canada's Disclosure Principles. For example, the UK's *Being Open* framework recognizes the importance of making the health care professional feel supported when apologizing to patients and their families, as well as the perspective of the patient in receiving a meaningful apology. Since 2009, Ontario has had Apology legislation in place with the same intent.
- **Action taken or proposed action to prevent future occurrences.** An explanation of what will be done to prevent future events is a key part of ensuring full communication in the Harvard hospitals Consensus Statement.
- **Offer of support.** Supports offered to the patient or patient's family, including potential financial supports to address any treatment or accommodation required as a result of the incident.

Details of the findings from the jurisdiction scan can be found in Appendix D.

Step 2: Key Informant Interviews

Over 30 interviews were completed with leaders and experts across Ontario, Canada and internationally to gather perspectives on the issues and the best approach to addressing them for Ontario (see Appendix E for the list of individuals interviewed). The interviews with senior management in Ontario hospitals highlighted the large amount of variation in the interpretation and application of QCIPA today in the province's hospitals. Some hospitals don't invoke the legislation at all, some previously invoked QCIPA but now only do so rarely, some invoke it some of the time (usually when the cause of the critical incident isn't clear) and others invoke it all the time. Most hospital leaders we talked with were convinced that their current method of using QCIPA was right for their hospital.

Many informants underscored the specific barriers – real or perceived – that QCIPA can create for hospitals wishing to practice open disclosure to patients. Many felt that while QCIPA encouraged full physician and staff participation in critical incident reviews, it could complicate the extent to which the findings and related actions of the reviews were communicated to patients. Specifically, there was concern that application of QCIPA could result in a very narrow definition of “facts”, removing any ability to speculate on the potential less direct causes of the incident, and that actions being taken to prevent a future incident could only be shared once they had been implemented (resulting in delays in communicating important information on what might be done to try to ensure a similar incident would not occur again). On the other hand, other interviewees indicated that they did not find that QCIPA inhibited their ability to openly disclose the results of their investigation of a critical incident with the patient and family. A number of informants identified the opportunity of the system today to encourage and support the sharing of lessons learned from critical incident investigations. The majority of those interviewed pointed to the paramount importance of building a “just culture” that emphasizes the need for sharing of information with patients and others within the system, starts with the assumption of health professional competence and good intentions, emphasizes accountability and paves the way for patient safety and quality improvement. “Just culture” does have a place for discipline, but it needs to be reserved for gross or repeated misconduct. The focus on critical incidents is on fixing the system rather than blaming the individual. Traditionally, health care's culture has held individuals accountable for all errors or mishaps that befall patients under their care. By contrast, a just culture recognizes that individual practitioners should not be held accountable for system failings over which they have no control. A just culture also recognizes that many individual errors represent predictable interactions between human operators and the systems in which they work.^{16 17}The side box highlights the principles of a just culture.¹⁸

Principles of a Just Culture¹⁶

For Patients

- Organizational commitment to deliver & monitor quality care
- Organizational commitment to investigate and remediate adverse events or concerns about quality of care
- Openness, honesty and support if things go wrong

For health care providers

- Safe systems in which to work
- Support to participate
- A presumption of competence
- Unbiased assessment of competence
- Support if things go wrong, not blame
- Support for education and training with action taken if provider does not meet standards
- Transparent, evidence-based investigation of adverse events

For Organizations

- A professional culture that supports organizational efforts to improve quality and address adverse events
- A professional commitment to self-regulation
- Professional compliance with reasonable policies/procedures

¹⁶ Marx D. Patient Safety and the “Just Culture”: A Primer for Health Care Executives. New York: Trustees of Columbia University in the City of New York, Columbia University; 2001—

¹⁷ Reason, James. (2000). Human error: models and management. *BMJ : British Medical Journal*, 320(7237), 768-770.

¹⁸ Heather Wellington http://www.health.vic.gov.au/clinicalengagement/downloads/dhs_cr_and_sop_workshop_hw.pdf

Leadership training and provincial support are identified as key enablers for a shift to a just culture.

“We need to prepare the health care and health systems workforce for the new consumer who expects to be informed and participate” ... “it’s outrageous that we don’t share learnings” ~ Key informant interview

The importance of the role of the patient voice and patient experience advisor in the process was also identified by a number of informants as evolving and critical. A number of informants pointed to the increased emphasis on health system quality through the *Excellent Care for All Act*, including the development of Quality Improvement Plans and the proposed Office of the Patient Ombudsman. Among informants in Ontario and in Canada, there was recognition of the need to increase patient engagement and system learning. Of note, both the Canadian Patient Safety Institute and the Canadian Medical Protection Association have worked in collaboration on a number of useful tools to support quality and transparency, with the development of the CPSI Incident Analysis Framework¹⁹, Disclosure Guidelines²⁰ and associated training.

Informants in jurisdictions outside Canada experience similar challenges and have adopted various tools to support achieving the balance between protection and sharing. In Australia, informants spoke of the value of the Qualified Privilege approach which “is designed to encourage hospitals and health professionals to conduct quality improvement activities and investigate the causes and contributing factors of clinical incidents by protecting certain information from disclosure and protecting clinicians involved in the activity from civil liability”.²¹ A relatively recent review of this approach in Australia confirmed the importance of retaining the privilege, with an understanding that the results of the review be shared with patients and families.

“It’s a paradox – secrecy to get openness. But in Australia, it’s a quid-pro-quo. With the privilege of protection comes the obligation of learning/ sharing” ~ Key informant interview

Almost all informants emphasized the importance of patient-focus and consistency as key drivers of success. Many indicated that the large variability in how QCIPA is used across Ontario hospitals inevitably leads the public to ask why there isn’t more consistency, and whether some organizations are hiding something.

Step 3: Gather Input From Patients and Families

Three separate methods were employed to gather input from patients and families about QCIPA. The following provides a description of each process and associated findings – more details can be found in Appendix F.

Patient, Family and Public Interviews

Interviews were conducted with 31 patients and family members who were recruited through health care and patient organizations from across Ontario.

¹⁹<http://www.patientsafetyinstitute.ca/english/toolsresources/incidentanalysis/documents/canadian%20incident%20analysis%20framework.pdf>

²⁰<http://www.patientsafetyinstitute.ca/English/toolsResources/disclosure/Documents/CPSI%20Canadian%20Disclosure%20Guidelines.pdf>

https://www.cmpa-acpm.ca/cmpapd04/docs/resource_files/ml_guides/disclosure/pdf/com_disclosure_toolkit-e.pdf

²¹ http://www.safetyandquality.health.wa.gov.au/clinical_incident_man/qualified_priv.cfm

Almost all participants felt that QCIPA-style protection for critical incident investigations could contribute to advancing quality of care by encouraging health care providers to come forward and speak freely. However, few felt that health care organizations could be fully trusted to investigate internal failures in a completely impartial manner, and many felt that the use of non-disclosure protections was likely to instill a level of distrust amongst patients, families, and the public.

"I think there has to be a shift in the culture so that people come to know how to deal with things when they don't go right" ~ Patient Interview

Interviewees raised several concerns about QCIPA: that it could prevent valuable patient and family input into investigations, heighten distrust of health care organizations, undercut psychological healing, enable hospitals to conceal or downplay serious organizational failures and systemic risks, and prevent the general public and other hospitals from becoming aware of incidents and potential solutions.

All interviewees agreed that patients and families need to be kept informed about the proceedings of the quality of care committee in order to build trust and support the psychological wellbeing of patients and families. All acknowledged that good communication about the proceedings would build the patient and family members trust that results would be forthcoming and appropriate action would be taken. Clearly describing what would happen, and on what timeline, was seen as especially important; regular, predictable updates were often cited as critical to good communication about the proceedings.

Most patients and family members expressed that they saw no obvious conflict between creating a safe space for open discussion amongst health care workers and providing sufficient information to patients and families about the proceedings of the investigation. All interviewees believed that there was no justification for not releasing detailed factual results of investigations to patients and their families. Most felt that substantive disclosure could be organized in a manner so as to avoid breaching the confidentiality of those who spoke to the quality of care committee. Interviewees also generally believed that health care organizations should be expected to disclose to the patient any actions the hospital planned to take to prevent similar future occurrences. Most felt that full disclosure of all details of the investigation was not required, but that current disclosure practices were sometimes too narrow.

Everyone agreed about the importance of making the results of the critical incident investigations, including any recommendations, available to other health care organizations so they can learn from others' mistakes and solutions. Many interviewees believed that trust and a sense of accountability can be fostered in Quality Care Committee investigations by having someone from outside the hospital, or at least someone who is neither a health care professional nor an executive at the hospital, as a participant on the quality care committee.

Many felt that Ontarians should be given the tools to make informed choices about where they go to receive care, and that information about the rate of critical incidents is an important consideration for those undergoing high risk procedures. Many suggested some sort of minimal mandatory critical incident reporting system.

Patient, Family & Public Panel

On November 1, 2014, eighteen individuals from across the province met at the Li Ka Shing Knowledge Institute in Toronto to participate in a full-day discussion of the merits and shortcomings of the QCIPA for the investigation of critical incidents. All had participated in an earlier phone interview with a member of the public consultation team. Patient and Public Panel members were asked to develop principles to guide the development of the committee's recommendations, and to identify priorities for critical incident investigations. Below are the principles suggested by the Patient and Public Panel. Highlights of the recommended priorities can be found in the side box. Additional details can be found in Appendix F.

Patient Suggested Principles

- We believe critical incident investigations should be **patient inclusive**.
We believe critical incident investigations should be **transparent**.
- We believe staff needs to **communicate effectively with patients and family** before, during, and after critical incident investigations.
- We believe critical incident investigations should be **consistent and predictable**.
- We believe critical incident investigations should entail an **obligation to share lessons**.
- We believe critical incident investigations should **assume good intentions** from all parties.

Priorities: What Patients and Families Expect

- Improve the flow of information to patients and family members
- Address the power differential between hospitals, and patients and family
- Shift the perception away from one that sees potential legal liability as a chill, freezing out patient involvement
- Standardize the use of QCIPA across hospitals, but leave open the option to deviate
- Involve patients and families throughout the investigation
- Introduce external oversight to critical incident investigations
- Give patients and family members recourse to an external body
- Ensure that lessons emerging from critical incident investigations are widely shared
- Encourage and verify that relevant recommendations from investigations are acted on by other organizations
- Track the number of critical incidents in Ontario
- Address the grey area between speculation and fact in QCIPA
- Improve how clinicians engage with patients after critical incidents
- Ensure QCIPA investigations involve organizations and staff that need to participate

Online Submissions Summary

From October 31st to November 17th 2014, Ontario residents were invited to make a written submission via Health Quality Ontario's (HQO) website. This opportunity was advertised on the front page of HQO's website and shared on social media through the members of the QCIPA Review Committee and others. An e-mail containing information about the submission process and the link was sent to patient organizations and health care providers. This e-mail contained a poster that could be shared with list

serves or printed and put up in public spaces. Through this process, the committee received 12 submissions.

Generally, the written submissions closely aligned with feedback from the interviews and the one-day meeting. Respondents wanted to ensure that the process was transparent, that the results of investigations were shared with patients and families, and that hospitals are responsive to the needs of different patients and families. Several suggested that written summaries of meetings with patients and family members be provided for further review and reflection. Though preventing future harm was generally seen as the most important priority, many expressed distrust in health care organizations and worried that protections would allow organizations and health care workers to inappropriately keep information from public view. Several submissions highlighted that external, independent advocacy support should be provided to patients and families to help them navigate the investigations process. Recourse of some sort was also suggested for patients and families who believed that investigations were not undertaken appropriately. The complete report on the Patient, Family and Public Engagement can be found in Appendix F.

Step 4: Consolidate Findings and Deliberate in Committee

The Committee considered all of the information described above, and agreed on the principles and recommendations described below. The committee is aware that in addition to hospitals, QCIPA also applies to independent health facilities; long-term care facilities, laboratories and specimen collection centres. The broader use of QCIPA for quality processes (such as peer review, morbidity and mortality rounds, etc.) and its use in non-hospital settings is a subject that should be explored as part of a separate process. The committee is aware that the Minister of Health and Long Term Care has asked Health Quality Ontario (HQP) to lead a process to provide advice that can help ensure there is sufficient protection and transparency of information about quality of care and critical incidents for patients receiving out of hospital procedures.

4. Our Findings

We start by articulating six principles that we believe should guide the investigation of critical incidents. As mentioned previously, 19 patients, family members and members of the public were asked to identify the principles that **they** thought should guide critical incident investigations. The committee has accepted those principles without modification, and has provided its interpretation of how those principles should be applied.

Six principles that should guide the investigation of critical incidents

1. Critical incident investigations should assume good intentions from all parties

In the majority of instances, patients and families (and/or substitute decision makers/ patient designate) want to understand what happened and why, and hear what the organization will do to prevent something similar from happening to other patients; they are not focused on unreasonably litigating or damaging reputations. In the majority of instances, organizations and their staff genuinely want to understand what happened so they can explain this to patients and families, and so they can improve their processes of care so similar incidents are less likely to occur in the future; they are not trying to hide information. The investigation and learning from critical incidents should start with these assumptions.

2. Critical incident investigations should be patient inclusive

Patients and family members should be interviewed during the investigation of a critical incident, they should be kept up to date with the progress of the investigation, and the findings and recommendations of the investigation should be shared with the patient and family in an understandable and compassionate manner. Patients and families differ in the amount of information they wish to hear, and how they wish to hear it; these differences should be respected.

3. Critical incident investigations should be transparent

The process of critical incident investigation should be clearly explained to the patient and family involved, and should also be clearly described on the organization's web site and through other means as appropriate. At the end of the investigation, the patient and family should be clearly told what happened, why it happened (respecting the confidentiality about discussion and speculation afforded by QCIPA if QCIPA was invoked), and what the organization plans to do to minimize the chance of a similar incident occurring in the future.

4. Staff need to communicate effectively with patients and families before, during and after critical incident investigations

The results of the investigation should be explained in a compassionate, honest and understandable manner, tailored to the needs of the patients and families. Organizations must ensure that their staff has the training and skills to do so.

5. Critical incident investigations should entail an obligation to share lessons

Patients have a right to expect that the organization in which they are receiving care has learned from the investigation of critical incidents conducted in other organizations in Ontario and elsewhere, and that the organization will share what it has learned with others.

6. Critical incident investigations should be consistent and predictable

There is currently great variability in how critical incidents are investigated and reported in Ontario hospitals. This degree of variability is undesirable and understandably raises concerns that some hospitals are not appropriately investigating, reporting and learning from critical incidents. Concerted efforts must be made to decrease this variability. Patients and their families should expect the following to be consistent and predictable across all hospitals immediately: a thorough investigation of each critical incident, clear understanding of the process of investigation, clear explanation of the results of the investigation and the recommendations, the opportunity for an appeal to a body outside the organization in which the incident occurred, sharing of lessons learned among Ontario organizations, and a mechanism to ensure that organizations across the province are doing the above.

Recommendations

1. Strive for a “Just Culture”

The Ontario health care system must strive to achieve a “Just Culture^{22 23}”, and must have a firm commitment to quality improvement, part of which is the identification, investigation and learning from critical incidents. For patients it means the expectation that they will be included in the process – they will be informed when a critical incident has occurred, the incident will be thoroughly investigated, the results of the investigation will be accurately and clearly explained to them, and changes will be made to minimize the likelihood of a similar incident occurring in the future. For the system, this means a system-wide commitment to deliver quality care, monitor the quality of care, investigate and remediate adverse events or concerns about quality of care, and openness, honesty and support if things go wrong. For health care workers it means a safe place in which to work, a commitment to participate in quality improvement activities, a presumption of competence, unbiased assessment of performance, support not blame if things go wrong, and transparent investigation of adverse events. Underperforming health professionals should be helped to improve, but removed from their role if they do not. For organizations it means a culture that supports efforts to improve quality and address adverse events, a commitment to self-regulation and professional compliance with reasonable policies and procedures, ensuring that health care providers are aware of what is professionally expected, treating all staff fairly, and a commitment to learning from others. For the media and the public, it means respecting patient privacy, avoiding “shame and blame” and having the right to access up to date and accurate aggregate information about quality of care and quality improvement activities in Ontario.

2. The intent of QCIPA remains valid and QCIPA should be retained, with recommended amendments, as a tool to further the understanding of what caused some critical incidents

The causes of many critical incidents are complex. Understanding them requires an environment where staff can explore what happened without concern that their speculations will be disclosed in

²² From a blame culture to a just culture in health care. Khatri N1, Brown GD, Hicks LL. *Health Care Manage Rev.* 2009 Oct-Dec;34(4):312-22. doi: 10.1097/HMR.0b013e3181a3b709.

~~Marx D.~~ Patient Safety and the “Just Culture”: A Primer for Health Care Executives. New York: Trustees of Columbia University in the City of New York, Columbia University; 2001

²³ Reason, James. (2000). Human error: models and management. *BMJ : British Medical Journal*, 320(7237), 768-770

court, to the media or to colleagues not involved in the investigation of the critical incident. QCIPA provides such a “protected place” and encourages staff (clinical providers and administrators) to freely share information and speculation. Therefore QCIPA should be retained - see below for recommendations about when it should be used. Without it, there is real concern that in some instances staff will not be as forthcoming as desired with their observations about what might have contributed to a critical incident.

However, the privilege of invoking QCIPA comes with the responsibility of only invoking it when necessary and fulfilling disclosure obligations in all circumstances. Patients and families should have access to the supports they need to deal with the aftermath of the incident. If the competence of an individual is a concern, then a separate accountability review is required, that includes the potential for reporting to the appropriate regulatory college.

We recommend adding a preamble to QCIPA that describes the intent of the protection afforded by QCIPA, written in a manner that is understandable by all stakeholders including patients and families.

3. Develop clear guidance on when and how to use QCIPA

The committee feels that the current variation in how QCIPA is used across Ontario hospitals needs to be addressed. QCIPA should only be invoked when the nature of the contributing causes to a critical incident is unclear and there is the need for considerable discussion and speculation about the causes of the incident. We believe that Ontario hospitals and the Ontario Hospital Association, with the help of Patients for Patient Safety, the Canadian Medical Protection Association, Health Quality Ontario and others, can learn from each other and develop clear guidance about the circumstances under which QCIPA should be invoked to investigate a critical incident, and when it should not be invoked. This process should start immediately.

Knowing the large variation in how QCIPA is currently used by Ontario hospitals, and with the expectation that the group mentioned above will be working towards decreasing that variation, the committee feels that it would be unwise to immediately mandate a uniform approach to when QCIPA is invoked at individual Ontario hospitals.

4. QCIPA should be amended to ensure appropriate disclosure to patients and families following a critical incident investigation

There is currently considerable confusion about what can be disclosed at the end of a critical incident review conducted under QCIPA. The QCIPA legislation should be amended to clearly indicate that when QCIPA is invoked, patients and families must be fully informed about the results of the investigation, including what happened, why it happened and what measures (if any) the organization intends to take to prevent future incidents. This should be done in a way that respects the confidentiality protections of QCIPA.

5. Establish an appeal mechanism for the investigation of critical incidents

If the investigation of a critical incident is thorough, communication about the investigation process is excellent, and the results of the investigation and recommended actions are clearly communicated to patients and families, the vast majority of critical incident investigations will be resolved at the hospital level.

Litigation or complaint to a regulatory body is always an option, although the jurisdiction of regulatory bodies is over its members only and may not address systemic issues.

There will be circumstances (hopefully rare) when patients and families are not satisfied with the hospital's investigation. Patients and families should be able to request an investigation that is independent of the hospital in which the incident occurred. This review should not duplicate reviews conducted by the coroner's office or the regulatory colleges. Information that clearly explains the appeal processes to patients and families must be made available. Legislation allowing for the establishment of an Office of the Patient Ombudsman has passed, and consideration could be given to making the OPO the independent body of last resort. The specifics of this role should involve consultation with patients and families, the Ministry of Health and Long Term Care, health care providers, Health Quality Ontario, the Ontario Hospital Association, the Office of the Information and Privacy Commissioner of Ontario, the Coroner's Office, the Canadian Medical Protective Association, the regulatory colleges and others.

6. Establish a mechanism through which hospitals must share what they have learned from their investigations of critical incidents and their recommendations to prevent future incidents with each other

Currently, hospitals do not share information about their critical incidents or their plans to prevent future incidents with each other, except on an ad hoc basis. Patients have the right to expect that the hospital in which they are receiving care has learned from the investigation of critical incidents conducted in other hospitals in Ontario and elsewhere, and that the organization will share what it has learned with others.

We recommend the establishment of a publicly available database or registry that contains information about all of the critical incidents investigated in Ontario hospitals, including the type of incident, the cause(s), and the recommendations to prevent future incidents. This information should be shared in such a way that patient, individual staff or physician and organizational confidentiality is maintained. The database could be developed and maintained by Health Quality Ontario. A multi-stakeholder group should be established to a) establish a common set of definitions for critical incidents, b) determine the information to be contained in the database (we recommend starting with critical incidents that led to death or patient harm), c) how information is collected and shared (ensuring that the confidentiality provided by QCIPA, if invoked, is not broken), and d) ensure compliance with the requirement that information be shared with the registry.

QCIPA should be amended to explicitly allow the sharing of data as mentioned above.

This database is unlikely to promote system wide quality improvement on its own. Health Quality Ontario should be tasked with identifying, on a regular basis, the quality incidents that deserve special attention by Ontario hospitals because of their severity, their frequency, and other criteria to be

developed. This information should be proactively shared with Ontario hospitals and other relevant organizations.

7. Ensure that critical incidents that occur in organizations other than hospitals are thoroughly investigated and the lessons learned are shared with patients, families and other organizations

Ontarians have a right to expect that critical incidents will be thoroughly investigated and learned from, no matter where they occur.

It is beyond the scope of this committee to make specific recommendations about how this can be ensured outside of hospitals, although we note that a committee has been established to make recommendations about quality improvement in independent health facilities and out of hospital facilities.

Some critical incidents that are recognized in hospitals involve a patient who has transitioned between two hospitals or another organization and a hospital (e.g., an organization that performs diagnostic imaging or endoscopy). These transitions between organizations are occurring more frequently.²⁴ The investigation of a critical incident that becomes apparent in a hospital might require the involvement of personnel within another hospital or a non-hospital organization to fully understand what transpired. The protection afforded by QCIPA, if used as we recommend in this report, should be applied to individuals working in those other facilities.

8. Reinforce the role of the Quality Committee of the hospital Board to provide oversight to critical incident related processes and the recommendations of this report

The Board of the hospital, through its Quality Committee, must ensure that critical incidents are appropriately identified and investigated, the lessons learned are shared with patients and families, the recommendations from the investigation are implemented, the hospital complies with its reporting requirements to share information with other hospitals, and the hospital is learning from the critical incidents that have been investigated at other Ontario hospitals and elsewhere.

9. Patients and families must be informed of the process that will be used to investigate their critical incident, they must be kept informed of the progress of the investigation, and their voice must be represented throughout the review process

An individual from the hospital who is familiar with the critical incident investigation process should be assigned to patients and their families as their primary contact. The process by which the incident will

²⁴ Solet, DJ, Norvell, JM, Rutan, GH, Frankel, RM. Lost in translation: challenges and opportunities in physician-to-physician communication during patient handoffs. (Academy of Medicine, 2005)

be investigated and a realistic estimate of the time it will take, as well as the patient's right to seek legal advice and contact the regulatory colleges, should be explained to patients and families as soon as the incident is identified. The occurrence of a critical incident is usually an exceptionally stressful time for patients and families. Excellent resources for how to do this, such as the Canadian Patient Safety Institute's Canadian Disclosure Guidelines: Being Open with Patients and Families are available.

A person whose role is to represent the voice of the patient and family must be present throughout the process including during the review of the critical incident and when reporting to the Board Quality Committee. These individuals must be well trained in how to support and involve the patient and family, how to bring their voice to the investigation, how to respect the views of the hospital staff involved and how to maintain confidentiality and the obligations of QCIPA. This might involve a trained Patient and Family Experience Advisor, who is not a hospital employee.

10. Patients and families must be interviewed as part of the process of investigating the critical incident and be fully informed of the results

The observations and experience of patients and families are an important part of the investigation of a critical incident, and they must be interviewed in a manner and time that respects the grief and anxiety that they are experiencing.

At the end of a quality investigation, whether or not QCIPA is invoked, patients and families must be told what happened, why it happened and what measures (if any) the organization intends to take to prevent future incidents. This should be done in a way that protects the speculations of the individuals involved in the investigation.

11. Establish a provincial program to train and support highly skilled staff to investigate critical incidents and communicate with and support patients and families

Each hospital must ensure that it has staff with the appropriate training and skills to fulfill their roles in identifying critical incidents, reporting them, investigating them and communicating the results. A province-wide training program should be established to train staff and patient and family experience advisors who are involved in the investigation of critical incidents and the communication of the results to patients and families. Many excellent resources already exist, including those developed by the Canadian Patient Safety Institute and others.

12. Support hospital staff involved in critical incidents

Hospital staff members are often traumatized by a critical incident, with feelings of sadness, guilt inadequacy and embarrassment. Staff should have access to support during the investigation of a critical incident. The training program mentioned above should also involve training hospital staff on how to support their employees who were involved in a critical incident and its review.

Glossary

Critical incident: Any unintended event that occurs when a patient receives treatment in the hospital, (a) that results in death, or serious disability, injury or harm to the patient, and (b) does not result primarily from the patient's underlying medical condition or from a known risk inherent in providing the treatment" ~ Ontario Regulation 423/07, amending Regulation 965 under the *Public Hospitals Act*.

Family: Defined by the patient. May or may not be biological.

Independent Health Facilities (IHF): IHFs are licensed and funded by the Ministry of Health and Long Term Care and are governed by the *Independent Health Facilities Act* (IHFA). Facilities may be established in a variety of settings, for example, completely free-standing, located on the site of an existing health organization (e.g. public hospital, community health centre or doctor's office), or located in a multi-office complex. Some facilities are operated on a mobile basis at specifically approved sites. IHFs are either:

- Diagnostic facilities that are funded by the ministry to provide specific classes of diagnostic imaging, pulmonary function or sleep study tests, or
- Ambulatory care facilities providing surgical, therapeutic and diagnostic procedures such as dialysis, abortion, laser dermatologic surgery and ophthalmic, vascular, plastic and gynaecologic surgery, MRI/CT and PET/CT scans.

An IHF may be either for profit or not-for-profit. The licensee of an IHF may be either an individual or a corporation, but may not be a corporation that operates a public hospital.

Laboratory: an organization where operations or procedures are performed on specimens taken from the human body to obtain information for diagnosis or treatment.

Out of Hospital Premises (OHPs): OHPs are defined by use of anesthesia and sedation.

- General anesthesia for Parenteral sedation or regional anesthesia
- Local anesthesia for tumescent procedures, injection or insertion of permanent fillers, autologous tissue, synthetic devices for cosmetic purposes; nerve blocks for management of chronic pain.

Personal Health Information (PHI): Generally refers to information that on its own that can be used to identify an individual and his or her health status and activity. PHI generally includes demographic information, medical history, procedure, test and laboratory results, OHIP information, provider of care and other data that is collected by a health care provider to identify an individual and determine what type of care that individual should receive.

Quality Improvement Plan (QIP): With the introduction of the *Excellent Care for All Act*, hospitals must develop Quality Improvement Plans outlining their approach to quality and patient safety. Accountability is through the public reporting of Quality Improvement Plans (QIP). The QIP provides a brief overview of the organization's quality improvement plan, highlighting and listing priorities for the year and a set of improvement targets and initiatives along with a core set of indicators that all similar organizations across the province are working on.

Quality Committee: With the introduction of the *Excellent Care for All Act*, hospital boards must now have a Quality Committee that reports to the board. The Quality Committee is responsible to assist the Board in the performance of its governance role for the quality of patient care and services and to perform the functions of the Quality Committee under ECFAA including:

- Monitor and report to the Board on quality issues and on the overall quality of services provided in the Hospital, with reference to appropriate data including critical incident and sentinel event reports.
- In addition to other responsibilities, the Quality Committee oversees preparation of the Hospital's annual quality improvement plan.

Quality of Care Committee (QCC): A QCC under QCIPA is set up with formal designation in writing by the health organization/ entity that establishes it, and sets out terms of reference that are available on public request. The QCC performs the following function:

- Carry on activities for the purpose of studying, assessing or evaluating the provision of health care with a view to improving or maintaining the quality of the health care or the level of skill, knowledge and competence of the persons who provide the health

Quality of Care Information (QCI): Quality of Care Information is not defined by type of record, but rather by purpose for, and the QCC's use of, that information. QCI means information that is: (a) collected by or prepared for a quality of care committee for the sole or primary purpose of assisting the committee in carrying out its functions, or (b) relates solely or primarily to any activity that a quality of care committee carries on as part of its functions.

Quality of Care Information Exclusions: The following information is specifically excluded from the definition of QCI in QCIPA, and can be released to patients if requested (subject to any other applicable legislation, e.g. PHIPA):

- Information contained in a record maintained for the purpose of providing health care to an individual (e.g. patient chart)
- Facts contained in a record of an incident involving the provision of health care to an individual, where the facts relating to the incident were not fully recorded in the patient's chart

Required PHA Reg 965 Disclosures: Specifically, the hospital must disclose the following to a patient following a critical incident (and record all this information in the patient's record/chart):

- (a) the material facts of what occurred with respect to the critical incident;
- (b) the consequences for the patient of the critical incident; and
- (c) the actions taken or recommended to address the consequences to the patient of the critical incident, (e.g. recommended health care or treatment.)

None of the above information is QCI under QCIPA.

Specimen Collection Centre: Place where specimens are taken or collected from the human body for examination to obtain information for diagnosis or treatment.

Substitute Decision Maker: The Substitute Decision Maker is someone whose responsibility is to make decisions for a person who is not able to make his or her own health care decisions.

