PATIENT SAFETY
FORWARD WITH

DETAILED ANALYSIS

Surgical Safety in Canada:
A 10-year review of CMPA and HIROC medico-legal data

CMPA
Empowering
better healthcare

HIROC
Healthcare Insurance
Reciprocal of Canada

Detailed Analysis

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04/16

Background

In January 2014, the Canadian Patient Safety Institute (CPSI), in conjunction with key healthcare stakeholders, formed the National Patient Safety Consortium to create an Integrated Patient Safety Action Plan. The action plan identified four priority areas: safe surgical care, medication safety, home care safety, and infection prevention and control.

A strategy to advance a national surgical care safety action plan was the focus of the March 2014 Surgical Care Safety Summit. The summit was attended by over 30 stakeholder representatives that included professional associations, provincial ministries, health authorities, quality councils, and patient safety groups. The summit report, A Surgical Care Safety Action Plan, outlined seven themes: measurement and analysis, access to care, best practices, patient engagement, teamwork and communication, quality improvement infrastructure, and learning from surgical patient safety incidents. The action plan identified the need for a retrospective analysis of surgical incident data and the publication of these findings in a report to be circulated nationally.[1]

The Consortium requested that the Canadian Medical Protective Association (CMPA), which provides medical liability protection for most Canadian physicians, and the Healthcare Insurance Reciprocal of Canada (HIROC), which provides liability insurance for healthcare organizations and their employees, conduct a retrospective analysis of Canadian surgical incident data. While providing medical liability protection for different groups, the two organizations are engaged in a broad and comprehensive effort to analyze data derived from their experiences and advance learning from these cases. Indeed, the CMPA and HIROC are dedicated to using their expertise in the medico-legal domain for advancing collaborative efforts in shared learning and identifying priority areas for health system improvements.

Purpose

More than one million surgical procedures are performed annually in Canada,[2] with every procedure offering benefits and associated with potential risks. While healthcare providers, teams, and organizations strive to provide safe care, patient safety incidents still occur.

The suggested improvements in care outlined in this report are based on a detailed analysis of lessons learned from complaints and settlements involving Canadian healthcare providers and organizations, and findings from closed medico-legal cases.

A patient safety incident is an event or circumstance which could have resulted, or did result, in patient harm. A landmark study of Canadian acute care hospitals reported that 7.5 of 100 admissions resulted in a patient safety incident, and found 36.9% of these were considered preventable.[3] Other studies have shown that over half of hospital patient safety incidents can be attributed to surgical treatment and care.[4,5]

In advancing quality improvement, hospitals have a different mandate and use different terms and approaches than the courts. This analysis supports learning from medico-legal cases to advance quality and safety improvement. Patient safety is a collective responsibility, achievable only through the collaboration of government, healthcare organizations, educational institutions, individual providers, and patients.[6,7] Accurately identifying surgical incidents and analyzing contributing factors are crucial to reducing harm.

A glossary is provided to assist readers in understanding the terminology used in this report.

Methods

The analysis identified 1,583 CMPA and 1,391 HIROC medico-legal cases involving an in-hospital surgical incident. The data consisted of resolved or settled medico-legal cases that occurred between 2004 and 2013. Analysis of Canadian surgical medico-legal cases involving all surgical specialties focused on frequency, severity, and patient clinical outcomes.

The CMPA captures medical conditions and interventions using the Canadian Enhancement to the International Statistical Classification of Disease and Related Health Problems, 10th revision (ICD-10-CA) and the Canadian Classification of Health Interventions (CCI). HIROC uses exposure risk codes in addition to the ICD-10-CA and CCI codes.

A surgical incident is a patient safety incident that occurred prior to, during, or after a surgical procedure. Contributing factors were identified as resulting from system failures, provider issues, or the inherent risks of the surgical care.

Limitations

The following factors must be taken into account when evaluating the data presented in this report:

- Not all surgical incidents are reported to the CMPA or HIROC.
- Obstetrics-related cases were excluded as the issues and costs are unique to this area of care. Class actions were excluded to avoid overweighting of an issue.
- Only aggregate data was shared. Overlap of data was likely present, but it was not quantified.
- The CMPA and HIROC employ distinct coding methods to capture contributing factors; therefore, interpretation may differ between the organizations.
- Analysis was limited to the information contained in the CMPA's and HIROC's files; not all medical records were available for review.

Results

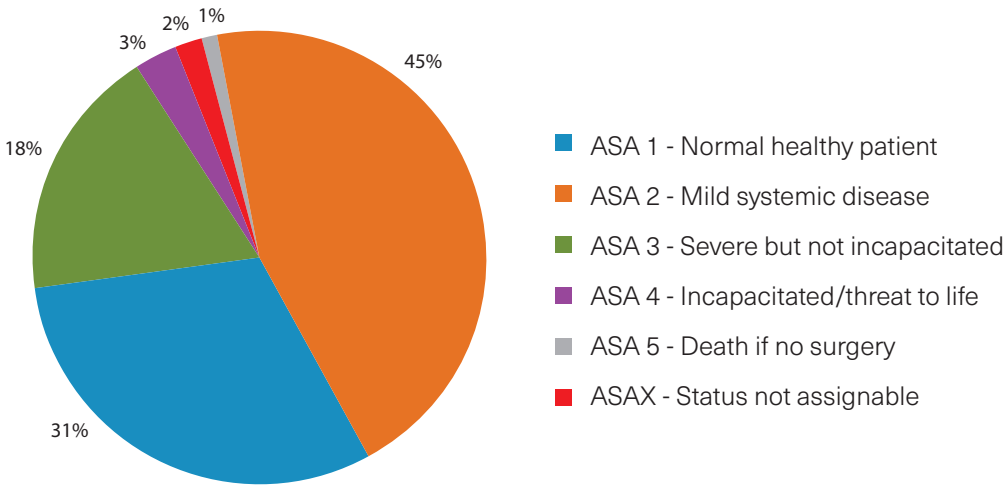
Patient factors

The analysis included patients of all ages; 70% of patients in CMPA cases were older than 40 years, and the average age was 49 years.

Comorbid conditions were documented for over half of the patients in the CMPA cases, but may have been underreported in the medico-legal documentation. Smoking and obesity were the most frequent comorbidities, followed by diabetes and cardiac conditions such as hypertension and coronary artery disease.

The American Society of Anesthesiologists physical status (ASA PS), used for classifying the pre-operative health status of patients,[8] was identified for 80% (1274/1583) of the CMPA cases, of which 76% were classified as either ASA 1 (normal healthy patient) or ASA 2 (mild systemic disease), indicating the patient was relatively healthy going into surgery.

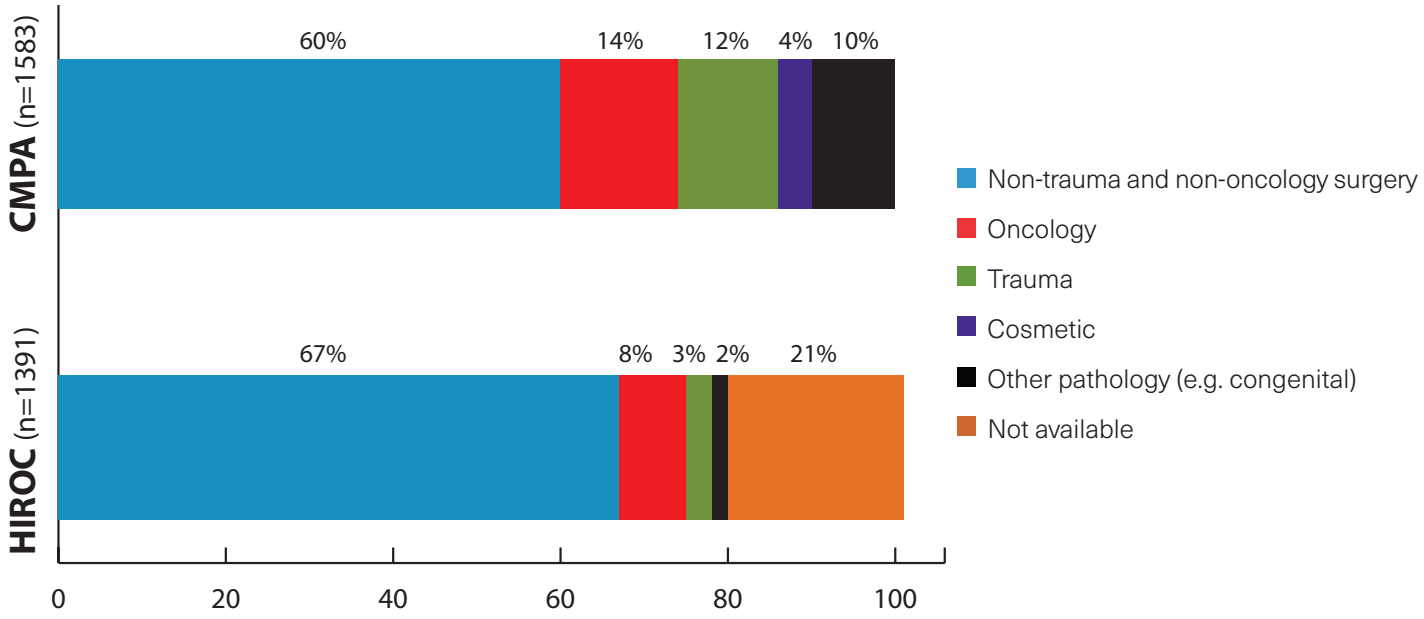
Figure 1. ASA Physical Status, CMPA closed cases, 2004 - 2013 (n=1274)



Nature of the surgical treatment

Patients most often underwent surgical treatment for repairs or excision of non-cancerous and non-trauma condition (e.g. inflammatory or infectious conditions). The CMPA review revealed that the top five surgical sites involved in medico-legal matters were the uterus, gallbladder, colon, muscles of the chest or abdomen (hernia repair), and breast.

Figure 2. Distribution of type of surgical treatment, CMPA and HIROC closed cases, 2004 - 2013



Note: *Cosmetic refers to procedures performed for cosmetic reasons.*

Who was involved, and when and where surgical incidents took place

Surgeons work closely with other healthcare providers in all phases of care. As expected, the CMPA, the principal provider of medical liability protection to Canadian physicians, reported the involvement of one or more physician in all of its surgical incident cases, and other healthcare providers (including residents and nurses) in 18% of the cases. HIROC, the largest provider of liability insurance for Canadian healthcare organizations and their employees, reported the involvement of nurses and other healthcare personnel (not including residents) in 31% of its surgical incident cases, and physicians and residents in 77% of the cases.

Figure 3. Distribution of healthcare providers, CMPA and HIROC closed cases, 2004 - 2013

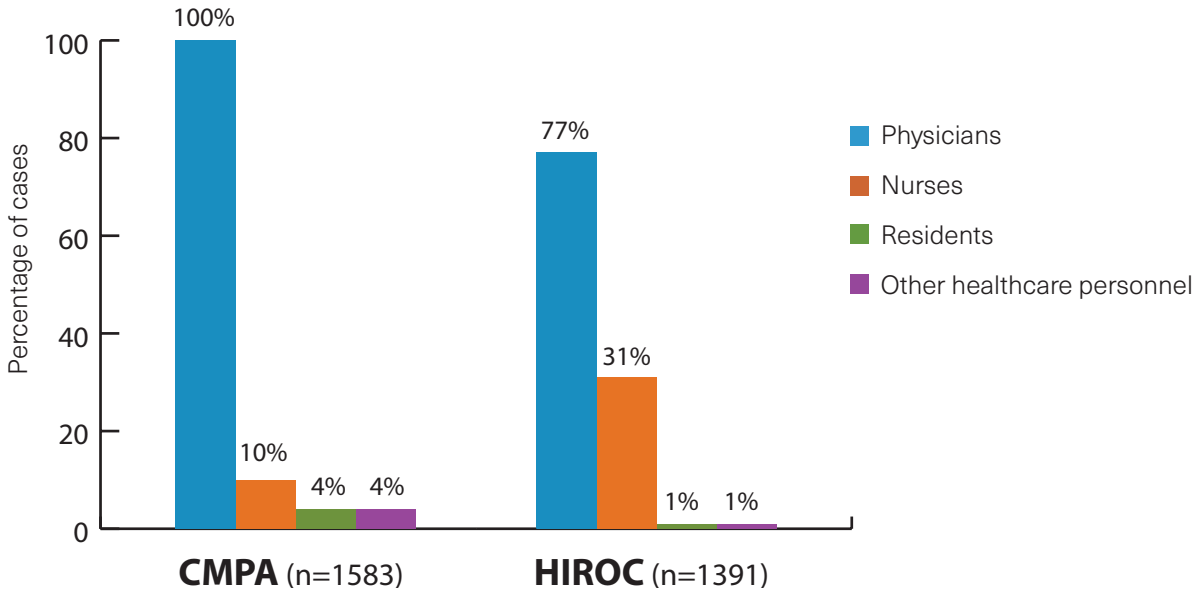
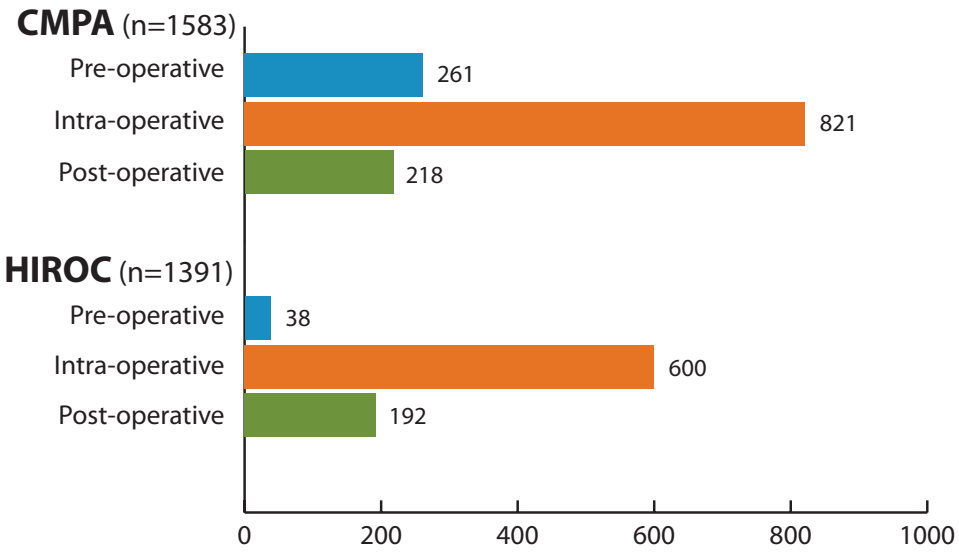


Table 1. Location of surgical incident, CMPA and HIROC closed cases, 2004 - 2013

Location of surgical incident	CMPA (n=1583)	HIROC (n=1391)
	No. (%) of cases	No. (%) of cases
Operating room (OR) and surgical day care unit OR	**1401 (89)**	**975 (70)**
Ward	**106 (7)**	**80 (6)**
Intensive care unit	**37 (2)**	**33 (2)**
Emergency department	**93 (6)**	**19 (1)**
Doctor's office	**62 (4)**	**6 (0.4)**
All others (e.g. hospital clinic, treatment room, diagnostic imaging)	**237 (15)**	**45 (3)**

Note: *A surgical incident could involve multiple locations.*

Figure 4. Phase of care when surgical incident occurred, CMPA and HIROC closed cases, 2004 - 2013



Note: *The phases of care could not be determined in all incidents.*

Patient harm

The severity of patient harm ranged from death to minor harm, and included infection, burns, hemorrhage, and complications due to progression of a disease.

Figure 5. Severity of patient harm, CMPA and HIROC closed cases, 2004 - 2013

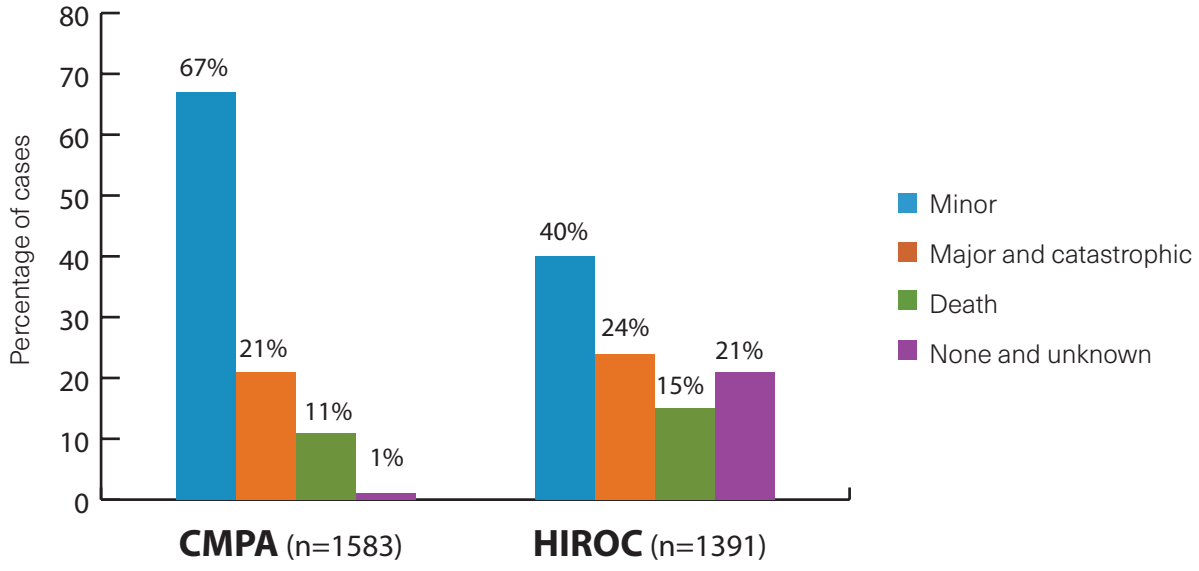
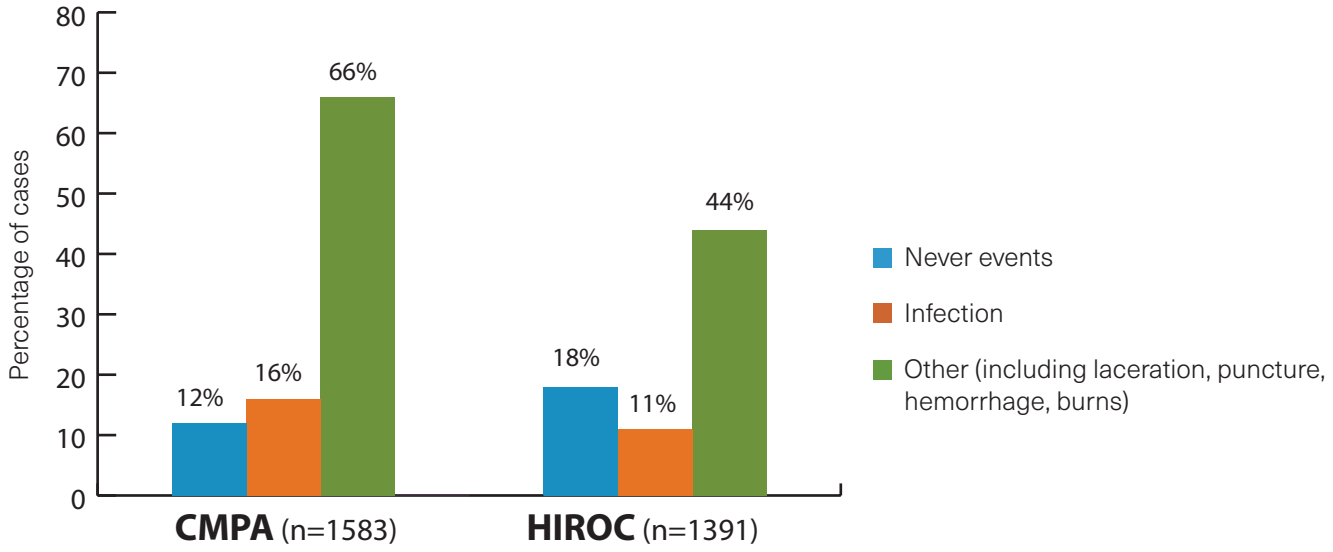
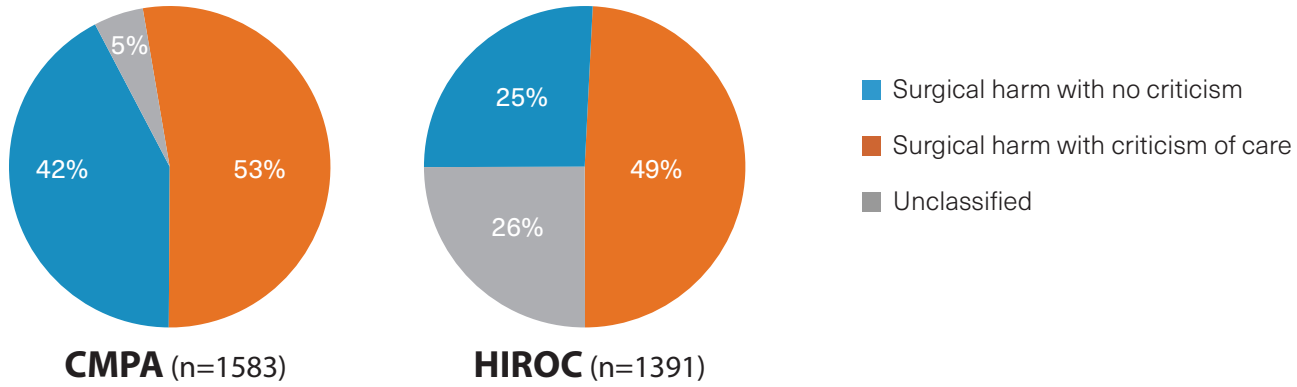


Figure 6. Type of surgical incident, CMPA and HIROC closed cases, 2004 - 2013



Surgical procedures are complex and may carry significant risks for patients even in the best hands. Peer experts, of similar training and working in the same kind of practices, interpreted or provided their opinion on clinical, scientific, or technical issues surrounding the incidents, and identified deficiencies in the clinical care of physicians and other healthcare providers.

Figure 7. Criticism of care identified by peer expert reviews, CMPA and HIROC closed cases, 2004 - 2013



Contributing factors in surgical incidents

Surgical harm results in human and monetary costs to the patients and their families, but also to providers, institutions, and society. The CMPA and HIROC contribute to the compensation received by patients and their families through awards or settlements.

Peer experts identified system, physician, and other healthcare provider factors that contributed to the surgical incidents.

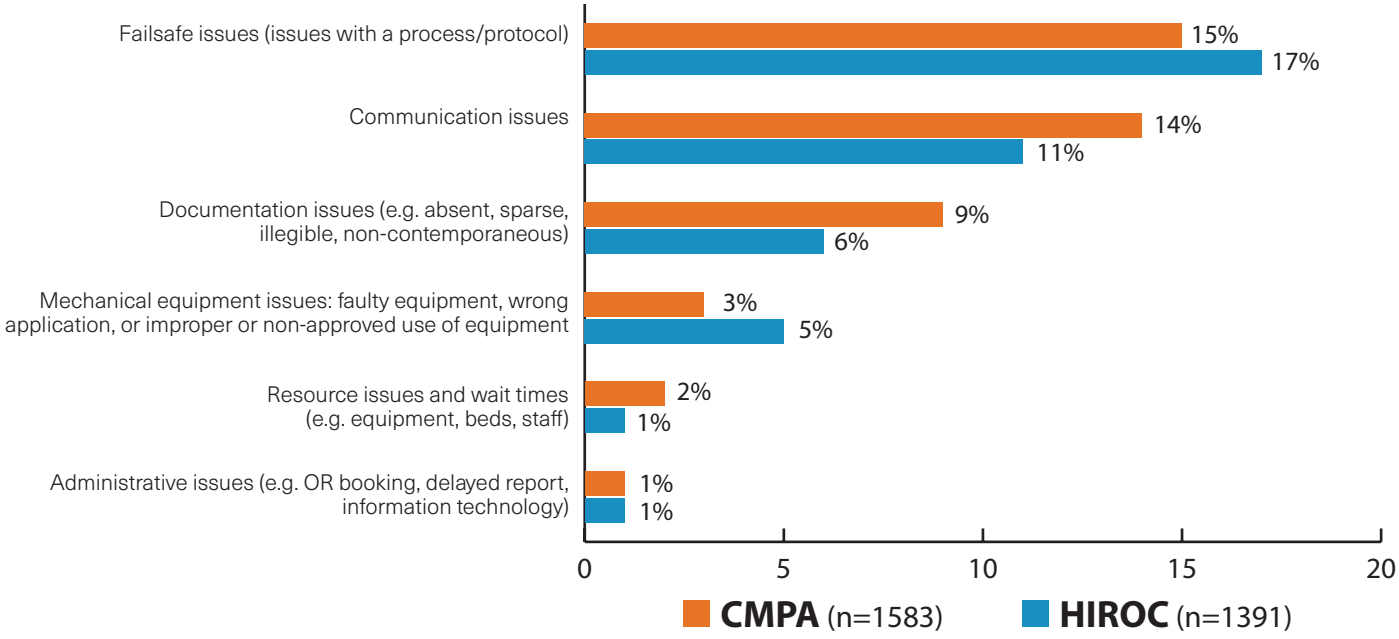
Table 2. Contributing factors identified by peer experts, CMPA and HIROC closed cases, 2004 - 2013

Contributing factors	CMPA (n=1583)	HIROC (n=1391)
	% cases	% cases
System factors	45	43
Physician factors	64	93
Other healthcare provider factors (excluding physicians)	12	31

Note: *Cases usually involve multiple contributing factors which are often overlapping. Surgical care is provided by physicians in collaboration with other healthcare providers, and as a team they work together within the healthcare system.*

Contributing factors included inadequate system processes to prevent or mitigate the impact of surgical incidents, non-adherence to surgical safety protocols, communication breakdowns, and deficient documentation.

Figure 8. System factors identified in peer expert reviews, CMPA and HIROC closed cases, 2004 - 2013



Peer experts also identified deficiencies in the clinical care of physicians and other healthcare providers such as issues with decision making or situational awareness.

Figure 9. Physician factors identified in peer expert reviews, CMPA and HIROC closed cases, 2004 - 2013

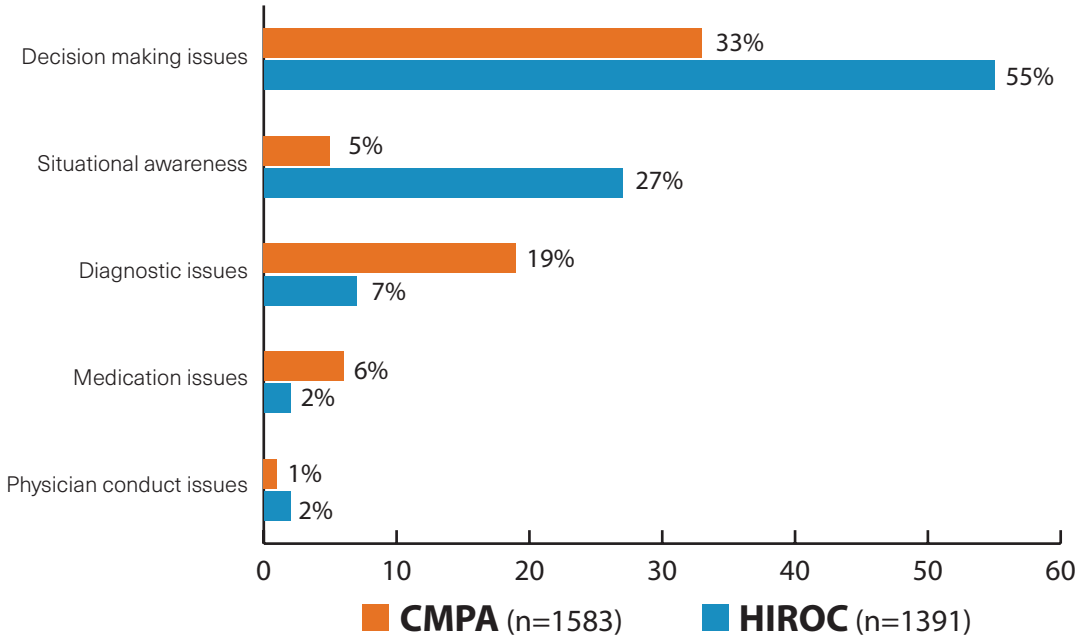
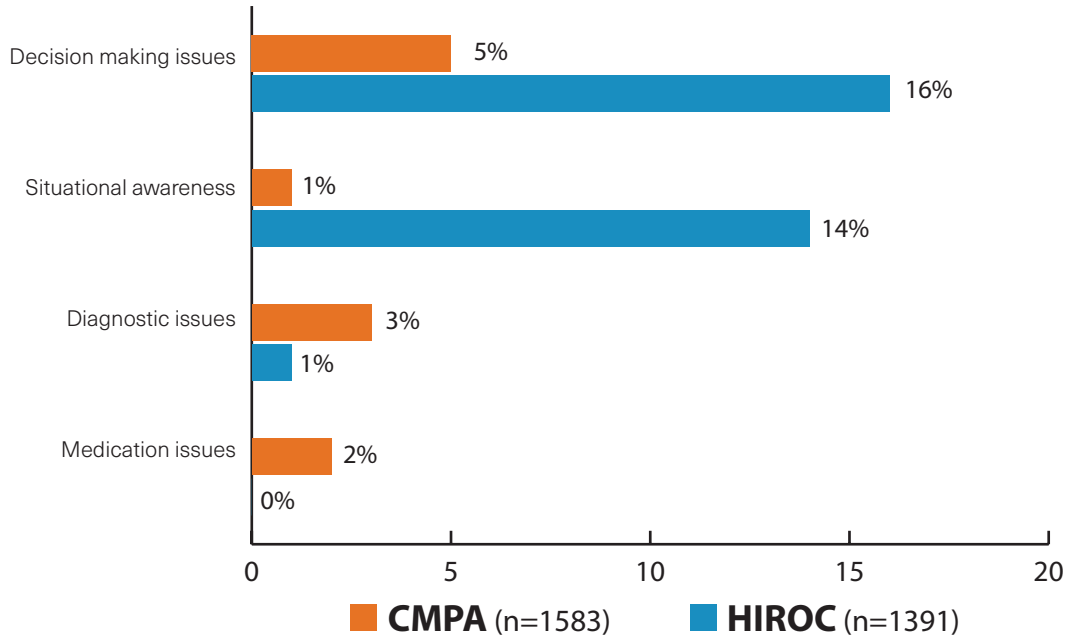


Figure 10. Healthcare provider factors identified in peer expert reviews, CMPA and HIROC closed cases, 2004 - 2013



The recommendations in this report are based on peer expert reviews which often acknowledged that surgical incidents rarely occur in isolation, but are often the culmination of individual and system factors. In some cases, a review of the surgical incident by the hospital led to changes in practice or improved protocols to assist the hospital and healthcare providers in delivering safer surgical care.

This collaborative retrospective analysis of Canadian surgical safety incident data supports the CPSI's Surgical Care Safety Action Plan and provides the opportunity for shared learning. The CMPA and HIROC are committed to improving patient safety through the continued sharing of data to identify and address priority areas for system and practice improvements.

CIHI data on pan-Canadian health system performance

The Canadian Institute for Health Information (CIHI) has developed a framework for pan-Canadian health system performance reporting that incorporates safe, effective care as central to achieving a high performing healthcare system. Within this framework, CIHI publishes reports on indicators that demonstrate effective surgical care. For example, Canada's recent downward trend in 30-day post-operative deaths may reflect an increased focus on surgical safety protocols. On the other hand, Canada's high rate of retained foreign bodies following a procedure in comparison to other member countries of the Organisation for Economic Cooperation and Development (OECD) and an upward trend in post-operative readmission rates, suggests there is room for improving intra- and post-operative care and care coordination in Canada.

For more information on these and other healthcare indicators, please visit the CIHI website at https://www.cihi.ca/en.

Hospital deaths following major surgery
http://yourhealthsystem.cihi.ca/hsp/indepth?lang=en#/indicator/020/2/C5001/

Retained foreign bodies following a procedure
https://www.cihi.ca/en/health-system-performance/performance-reporting/international/oecd-interactive-tool-health-status

Surgical patients readmitted to hospital
http://yourhealthsystem.cihi.ca/hsp/indepth?lang=en#/indicator/028/2/C5001/

Resources for safe surgical care

Accreditation Canada (https://www.accreditation.ca/)
- Accreditation Canada program
- Standards
- Required organizational practices (ROPs)

Canadian Medical Protective Association (https://www.cmpa-acpm.ca)
- CMPA Good Practices Guide (https://www.cmpa-acpm.ca/gpg)
- Handbooks (https://www.cmpa-acpm.ca/handbooks)
  - Disclosing harm from healthcare delivery: Open and honest communication with patients
- Articles (https://www.cmpa-acpm.ca/browse-articles)
  - Surgical safety checklists: A team approach to patient safety
  - Thinking ahead: the value of situational awareness
  - Discharging patients following day surgery
- ACTION for safe medical care (https://www.cmpa-acpm.ca/cmpa-risk-fact-sheets)
  - Medical-legal risks associated with wrong site, wrong procedure, wrong patient surgery
  - Pre-operative period – patient assessments
  - Intra-operative period – unintentionally retained surgical items
  - Post-operative period – patient discharge and follow-up

Canadian Patient Safety Institute (http://www.patientsafetyinstitute.ca)

- Surgical Safety Checklist (http://www.patientsafetyinstitute.ca/en/toolsResources/Pages/SurgicalSafety-Checklist-Resources.aspx)
- Patients for Patient Safety Canada (http://www.patientsafetyinstitute.ca/en/About/Programs/PPSC/Pages/default.aspx)
- Patient Safety and Incident Management Toolkit (http://www.patientsafetyinstitute.ca/en/toolsresources/patientsafetyincidentmanagementtoolkit/pages/default.aspx)
- Surgical Site Infection Toolkit (http://www.patientsafetyinstitute.ca/en/toolsResources/Pages/SSI-resources-Getting-Started-Kit.aspx)

Healthcare Insurance Reciprocal of Canada (https://www.hiroc.com/risk-management.aspx)

- Risk Reference Sheets (e.g. Medical/Surgical - Unnecessary/obsolete surgery and Medical/Surgical – Retained surgical items)
- Risk Notes (e.g. Medical directives and obtaining informed consent or treatment)
- Webinars (e.g. Lessons learned from closed cases and seeing yellow? Hyperbilirubinemia)
- Risk Resource Guides (e.g. Documentation Guide for Healthcare Providers and Management of Critical Incidents)
- Risk Watch (insightful synopses of “hot off the press” peer-reviewed articles)
- Case Study Library

JGH SpeakUp! Campaign (http://www.jgh.ca/en/qiSpeakUp)

National Surgical Quality Improvement Program (NSQIP)
(https://www.facs.org/quality-programs/acs-nsqip)

- Canadian NSQIP Collaborative (https://bcpsqc.ca/clinical-improvement/nsqip/canadian-nsqip-collaborative/)
- Surgical Quality Improvement in Ontario (http://www.hqontario.ca/Quality-Improvement/Surgical-Quality-Improvement-in-Ontario)
- Jewish General NSQIP (http://jgh.ca/en/news?id=405)

Patient safety glossary

Term	Definition
Cognitive bias	A way of thinking that influences reasoning and decision making, sometimes resulting in inaccurate judgments.[9]
Clinical decision making	The use of knowledge to guide decisions to elicit clinical clues, to formulate diagnostic impressions, to order investigative or follow-up procedures, to acquire data to monitor a course of action or evaluate the severity or probability of an outcome, or to select a management course. [10]
Continuum of care	The integrated delivery of healthcare over multiple periods of time, involving a range of services and levels of care, to achieve a patient's healthcare goals. [9]
Disclosure	The process by which a patient safety incident is communicated to the patient by healthcare providers.[11]
Escalation procedures	Communication to escalate concerns across authority gradients to match the seriousness of the clinical situation.[12]
Event	A significant occurrence involving a patient. [9]
Failsafe	Protocols, procedures, or systems in hospitals, offices, and clinics designed to prevent or mitigate errors. [9]
Handover (transfer of care)	The transfer of responsibility and accountability for some or all aspects of care for a patient or group of patients, on a temporary or permanent basis. [9]
Harm	An outcome that negatively affects the patient's health and/or quality of life.[9]
Informed consent	The provision of information about the nature, consequences, and material and special risks of the proposed investigation or therapy and any alternative procedures a reasonable person would likely want to know in determining whether or not to agree to proceed. [9]
Informed discharge	The communication, post-assessment or post-treatment, between a health professional and a patient to make the patient aware of the signs and symptoms that warn of a need to seek further medical care. [9]
Just culture of safety	A healthcare 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, healthcare providers, staff, and patients for the provision of safe patient care. 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 patient safety incidents, any professional accountability of healthcare providers is determined fairly.[9]
Never event	Patient safety incidents that result in serious patient harm or death, and are preventable using organizational checks and balances. Never events do not imply blame; "never" is a call-to-action, not a demand or an attempt to shame mistakes. Providing care to patients is a complex endeavour, and risk is unavoidable. However, health organizations and workers have the knowledge and ability to reduce the occurrence of these events and should strive to prevent them entirely (e.g. surgery on the wrong body part, the wrong patient, or the wrong procedure, or unintended foreign object left in a patient following a procedure).[13]

Term	Definition
Patient safety incident	An event or circumstance which could have resulted, or did result, in unnecessary harm to the patient.[14] • *Harmful incident:* A patient safety incident that resulted in harm to the patient. Replaces the terms "adverse event" and "sentinel event." • *No harm incident:* A patient safety incident which reached the patient but no discernible harm resulted. • *Near miss:* A patient safety incident that did not reach the patient. Replaces "close call." In Québec, the terms "accident" and "incident" are defined in the applicable legislation. Neither term corresponds exactly to the WHO terminology. An "accident" in Québec means "an action or situation where a risk event occurs which has or could have consequences for the state of health or welfare of the user, a personnel member, an involved professional, or a third person."[15] The term "incident," on the other hand, is defined as "an action or situation that does not have consequences for the state of health or welfare of a user, a personnel member, an involved professional or a third person, but the outcome of which is unusual and could have had consequences under different circumstances." [16] As the CMPA interprets the Québec legislation, the term "accident" would align with the WHO term "harmful incident" whereas the term "incident" would include the WHO terms "no harm incident" and "near miss."
Practice improvement	Professional activities aimed at improving care delivery, based on the principle of identifying and satisfying the healthcare providers unique learning needs. [9]
Quality improvement	A systematic approach to making changes that improve clinical practice and health system performance, enhance professional and/or organizational development, and improve patient and population health outcomes.[17]
Reporting	The communication of information about a patient safety incident through appropriate channels inside or outside of healthcare organizations, for the purpose of reducing the risk of occurrence of patient safety incidents in the future.[11]
Self-reflective practice	Conscious reflection and analysis of the decision-making process, within the framework of relevant clinical knowledge and standards of care, to allow for professional and personal growth. [9]
Situational awareness	A person's perception and understanding of the dynamic information that is present in the environment. It involves keeping track of what is happening and includes anticipating what might need to be done. [9]
Surgical incident	A patient safety incident that occurred prior to, during, or after a surgical procedure.[18]

Term	Definition
Surgical process of care	A framework that reflects the phases of care for a patient undergoing surgery. Phases and definitions: 1. *Pre-operative:* Begins with the indication for a surgical intervention, the patient's decision to undergo surgery, and ends with the patient's transfer to the operative team. 2. *Intra-operative:* Begins with the receipt of the patient by the operative team and ends with the patient's transfer to the receiving team, e.g. PACU, ICU. 3. *Post-operative management:* Begins with the receipt of the patient by the receiving team and ends with the patient's discharge from the surgeon's care.
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 patient safety incidents. [9]

Medico-legal glossary[9]

Term	Definition
Causation	The act of causing something to happen (producing an effect). In law, to prove causation, the plaintiff must establish there is a relationship, or causal connection, between the alleged breach of duty (or *faute professionnelle* in Québec) and the stated harm or injury.
Clinical judgment	A reasonable decision or choice made carefully given the circumstances at the time.
Damages	In law, money paid as compensation for loss or injury.
Duty of care	The doctor-patient relationship creates a series of obligations including the requirement, as appropriate, to attend, diagnose, advise, treat, and seek consultation.
Expert	A professional who is engaged to provide an opinion based on his/her special skill or knowledge in a particular area.
Litigation (Civil legal action)	In medico-legal (civil) cases, the plaintiff seeks from the court an order of monetary compensation (damages) for harm or injury suffered as a result of the negligence or wrongful conduct of the defendant. Almost all Canadian medico-legal cases are civil and not criminal actions. Several different defendants, such as individual health professionals, hospitals/institutions, equipment manufacturers, and pharmaceutical companies may be named in a medical lawsuit. The "cause of action" or central focus is usually an allegation of negligence, including substandard care and a lack of informed consent. Other allegations in medico-legal cases include assault and battery, breach of contract, and breach of fiduciary duty. In civil actions, the plaintiff is usually awarded monetary compensation if the cause of the action is admitted by the defendant or proven in law. In civil actions, these issues are decided on the balance of probability.
Negligence	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 and acceptable standard of care. 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 *faute professionnelle* 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.
Settlement	An agreement, usually monetary, made between opposing parties in a lawsuit to resolve the legal dispute. For instance, when a review of the medical facts reveals the health professional breached his or her duty of care resulting in harm to the patient, a financial settlement, fair to all concerned, is made. A lawsuit can be settled at any stage before the trial is concluded.
Standard of care	The court considers the standard of professional care and skill that might reasonably have been provided by a colleague in similar circumstances. The appropriate measure is the level of reasonableness, not a standard of perfection. The court determines that reasonable standard through the evidence of experts. Lawyers for both the patient plaintiff and the defendant physicians may seek opinions from both medical and non-medical experts.

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