Measuring Patient Harm in Canadian Hospitals

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Institut canadien pour la sécurité des patients

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Many patient safety experts were also involved in the development of the *Hospital Harm Improvement Resource*. See the Improvement Resource for a full list of contributors.

Please note that the analyses and conclusions in the present document do not necessarily reflect those of the individuals or organizations mentioned above.

Definitions

It is important to be clear about the meanings of and differences between specific words. A great deal of attention was paid to terminology by consulting with patients, clinicians and patient safety experts. Every attempt has been made to balance what we heard as we aligned the concept behind this work with international efforts in patient safety reporting and measurement, including the *International Classification for Patient Safety* of the World Health Organization (WHO).[1] To that end, we are using the term "harm" because it is internationally accepted language and reflects patients' understanding of the term.

For the purposes of this report, the following definitions apply:

Harmful event: An unintended outcome of care that may be prevented with evidence-informed practices and that is identified and treated in the same hospital stay. Harm is a term used by the WHO and Institute for Healthcare Improvement (IHI) as reflecting the patient experience.

hospital harm: Acute care hospitalizations with at least 1 unintended occurrence of harm that could be potentially prevented by implementing known evidence-informed practices.

occurrence of harm: Harmful event is synonymous with occurrence of harm.

patient safety: The reduction of risk of unnecessary harm associated with health care to an acceptable minimum. An acceptable minimum takes into consideration current knowledge, the resources available and the context in which care was delivered, weighed against the risk of non-treatment or other treatment.

preventable: Accepted by the community as potentially reducible using evidence-informed practices.

Herbert's story

Herbert was a very active, apparently healthy 72-year-old when he suddenly lost strength in his legs and collapsed at his home on the morning of August 3, 2011. He was rushed to hospital. Surgeons wondered whether he had suffered a spinal stroke or a disc compression requiring urgent surgery. The next day he had spinal decompression surgery for what doctors diagnosed as cauda equina syndrome — a severe compression of nerves in the lower back. After 10 days in the hospital, Herbert was transferred to a rehabilitation centre. 5 days later he was transferred back to the hospital with a urinary tract infection and dangerously elevated blood sugar.

After Herbert was readmitted to hospital, he continued to experience high blood sugar levels. He then developed sepsis from an infection at the site of his operation. After treatment and being deemed stable, Herbert started vomiting and became dehydrated. He was unable to eat or drink and had dangerously low blood pressure. He was diagnosed with a *Clostridium difficile* (*C. difficile*) infection.

Herbert had suffered multiple complications from the surgery for his nerve compression 6 weeks earlier. On September 19, 2011, Herbert died. A coroner's investigation determined that the causes of death were the spinal abscess that had developed at the surgical site and complications of the *C. difficile* infection, which had severely damaged his colon. After he died, his daughter Carole was told that an important antibiotic for his spinal abscess had been accidentally discontinued. The coroner termed Herbert's story a "perfect storm" of miscues and false assumptions.

The hospitals involved in Herbert's care have made several changes in response to what happened to him. New protocols have been initiated to identify patients at high risk for *C. difficile*; patient reports are given at the patient's bedside; transfers are limited on weekends and off hours; and physicians give doctor-to-doctor reports.

Herbert's daughter Carole, who manages 2 long-term care facilities, has changed the way she works, because she identifies so strongly now with worried families. If she had a single message to pass on to health care providers out there, what would it be?

"What I would say to health care providers across the country is that it's an honour to care for people — we went into health care for a reason. Don't forget what that reason is and always think with your hearts and use compassion."

Adapted from Canadian Patient Safety Institute. Father's death fuels quest for healthcare improvement. Accessed July 7, 2016. Used with permission.

Introduction

Patients expect hospital care to be safe, and for most people it is. However, a small proportion of patients experience some type of unintended harm as a result of the care they receive. Hospital patients are particularly vulnerable, because many are very frail and hospital care is increasingly complex. According to the 2004 Canadian Adverse Events Study, 7.5% of all hospital patients experienced an adverse event, where an unintended injury caused by health care led to a longer hospital stay, disability or death; 37% of those events were deemed preventable.[2] A more recent study of pediatric patients found that 9.2% of children hospitalized in Canada experience adverse events.[3]

Awareness of patient safety and how patients can be harmed by health care has grown steadily over the past decade (see Figure 1). Additionally, media reports of fatal medication errors and *C. difficile* outbreaks have made the public increasingly aware of the issue. In response, campaigns such as *Safer Healthcare Now!* have been launched to improve safety. Clinical teams are looking for ways to reduce infections, surgical complications and other potentially preventable harm. Governments are also acting on health care safety. Some provinces have legislated that critical incidents must be reported.[4] Accreditation Canada has made safety part of its accreditation criteria, including Required Organizational Practices for infection control, medication use, risk assessment and safety culture.[5]

There is good reason to be concerned. Data gathered for this study estimates that patients suffered harm in more than 138,000 different hospitalizations in Canada[i] in 2014–2015, and that 1 in 5 of these hospitalizations involved more than 1 occurrence of harm. It's estimated that on any given day more than 1,600 hospital beds across the country are occupied by a patient who suffered harm that extended his or her hospital stay. In addition to what these patients and their families go through, their continued need for treatment also has a cost to the system, in that it keeps other people from getting the help they need.

The growing awareness of and interest in safety puts pressure on health system leaders and care providers to take decisive action. But they cannot act without good information on the extent of safety problems — the types of issues, the frequency with which they occur and the harm each causes. With that information, leaders can set priorities for safety and support improvements at the point of care. Information on safety must be updated regularly so leaders can track whether safety issues are in check, and monitor whether specific efforts to improve quality of care are making a difference.

i. Data from Quebec as well as data for some mental health patients has been excluded due to methodological issues. See the technical report for details.

Figure 1 Canadian milestones in patient safety

2002	• *Building a Safer System: A National Integrated Strategy for Improving Patient Safety in Canadian Health Care* published[6]
2003	• Creation of the Canadian Patient Safety Institute (CPSI) announced by the federal, provincial and territorial ministers of health • Canadian Medication Incident Reporting and Prevention System launched by Health Canada and the Institute for Safe Medication Practices Canada • First patient safety strategy announced by Accreditation Canada
2004	• Landmark Canadian Adverse Events Study finds nearly 7.5% of patients experience an adverse event; approximately one-third of events are deemed preventable[2]
2005	• *Safer Healthcare Now!* launched in Canada as the first pan-Canadian quality improvement campaign • First Canadian Patient Safety Week held
2006	• Patients for Patient Safety Canada created
2007	• First report on patient safety indicators released by the Organisation for Economic Co-operation and Development[7]
2010	• National System for Incident Reporting launched by CIHI
2012	• Canadian Paediatric Adverse Events Study demonstrates that 9.2% of children hospitalized in Canada experience adverse events[3] • CPSI study estimates the economic burden of preventable acute care patient safety incidents at $397 million annually[8]
2013	• A study on home care adverse events finds 4.2% of home care patients experienced an adverse event; 56% of events are judged preventable[9]
2015	• Progress on patient safety described in *Beyond the Quick Fix: Strategies for Improving Patient Safety*[10]
2016	• A new method for measuring hospital harm linked to improvement resources introduced by CIHI and CPSI

The information on safety available to health system leaders has limitations. There has not, for example, been a single measure that gives an overview of harm in Canadian hospitals. The chart review method used in the Canadian Adverse Events Study is considered the gold standard for identifying patient safety events, but it is expensive and difficult to do regularly enough to see trends. Some provinces require hospitals to report specific measures (e.g., *C. difficile* infections).[11] These are important but narrowly focused, and they do not create an overall view of patient safety. Some hospitals track quality measures on specific topics for quality improvement projects, but that tells only part of the patient safety story. There is also the National System for Incident Reporting, which collects information about patient safety incidents in acute care from several provinces. However, because most reporting on harm is voluntary, there is no assurance that health system leaders understand the full extent of safety issues.

Health system leaders need better information on patient safety. CIHI and CPSI have been working together since 2011 to meet that need. The result is a methodology to capture harm that occurs in hospital, which will be the foundation of a future measure called the Hospital Harm indicator. The methodology uses administrative data that CIHI collects regularly from hospitals across Canada, so the data will be easy to update on an ongoing basis with no additional cost or reporting requirements for those who use it.

Reporting does not by itself increase safety, so CIHI and CPSI have linked the harm captured by this measure to a compilation of evidence-informed practices for improving patient safety to help drive changes that will make care safer. The *Hospital Harm Improvement Resource*, described in the second half of this report, makes information on improving patient safety easily available, so teams spend less time researching what they need to do and more time optimizing patient care.

The data in this report provides a pan-Canadian overview of patient harm in hospitals using this new approach to measuring hospital harm. Most important, the report illustrates how the Hospital Harm data and the Improvement Resource, used in combination, will be powerful tools in every hospital’s patient safety improvement toolkit.

Hospital harm: A broader look at patient safety

Definition

Hospital harm captured by this measure is defined as **the number of hospitalizations with at least 1 unintended occurrence of harm that could potentially be prevented by implementing known evidence-informed practices**. The harm must have occurred after admission and have required treatment within the same hospital stay.[ii] It is not intended to capture outcomes related to the natural course of disease. Our definition of harm reflects patients' understanding of the term and is in line with definitions used by the WHO and the IHI.

The Hospital Harm Framework includes 4 major categories of harm: Health Care–/Medication-Associated Conditions (e.g., pressure ulcers), Health Care–Associated Infections (e.g., sepsis), Patient Accidents (e.g., falls) and Procedure-Associated Conditions (e.g., laceration/puncture). Within each category is a series of individual clinical groups or types of harm, which connect to evidence-informed practices for improvement (see Figure 2). Some clinical groups may appear under multiple categories of harm, depending on whether or not they are associated with a procedure; for example, birth trauma related to a Caesarean section or instrument delivery would be captured under Procedure-Associated Conditions, and birth trauma related to non-instrument delivery would be captured under Health Care–/Medication-Associated Conditions.

In Herbert's case, after he returned from the rehabilitation centre, he acquired sepsis and *C. difficile*. Using this methodology, both would be captured as Health Care–Associated Infections. The conditions present when he was admitted, such as the urinary tract infection, however, would not be counted.

It's also important to note that the measure does not cover all harmful events that happen in hospitals — only harmful events that fit into at least 1 of the 31 clinical groups are included. In Herbert's story, the accidental discontinuation of medication would not be captured. Other important things to note about the methodology are discussed in detail in the Limitations section near the end of this report.

ii. The harm must have been recognized prior to discharge and have required treatment, altered treatment or prolonged the hospital stay. Data from Quebec as well as data for patients with selected mental health diagnoses have been excluded due to methodological issues.

Any harmful event captured in the data was significant enough to require medical treatment or to extend the patient's stay in hospital. The harm captured in this methodology ranges from events that usually have relatively minor consequences — such as some urinary tract infections — to trauma such as broken bones or medication errors that trigger serious adverse outcomes. The measure does not report on the severity of harm.

Finally, although only types of harm that are potentially preventable by known evidence-informed practices are included, there is no way to know whether any individual occurrence of harm could have been prevented. There are, for example, many things that can be done to reduce injury from falls, but despite best intentions it is unlikely that all harm from falls can be eliminated. The data will help identify areas where additional review and detail are required. Exploration at the clinical group level will help determine whether care can be improved.

Figure 2 Hospital Harm Framework

Notes

MRSA: Methicillin-resistant *Staphylococcus aureus*.

VRE: Vancomycin-resistant enterococci.

In the Hospital Harm Framework, each occurrence of harm is captured only once for each patient, even though the event may fall into more than 1 clinical group. This is to prevent overestimating harm if a patient's condition were included in more than 1 clinical group. Thus a urinary tract infection after surgery is counted in the UTI clinical group, not as a post-procedural infection. The exception to this rule is infections due to MRSA or VRE, as these could also be captured in other clinical groups. However, if a patient experienced more than 1 type of harmful event (e.g., a UTI and a fall), each event would be counted within its respective clinical groups, but only once in the overall rate of hospital harm. See the technical report for details.

The Hospital Harm measure is designed to provide health care leaders with an overall picture of patient safety in their organization and to give them the ability to drill down into individual clinical groups. To use it to improve care, they must work with direct-care providers to understand the contextual factors that led to local variations from safe care. This will help them set priorities and make decisions on resources for improvement. With more information about the broader safety picture, leaders can do a better job balancing decisions about safety with other important initiatives to improve quality of care and patient outcomes.

Ultimately, better patient care comes from continually working to promote a culture of safety at every level in a hospital or health care organization. Safety is improved by optimizing use of evidence-informed practices — practices that are known to reduce the occurrence of harmful events, such as pressure ulcers, infections or patient falls. While each hospital or health care organization works independently to improve safety, their work is supported by regulators, funders and provincial health quality organizations.

Source of data

The key advantage of the Hospital Harm methodology is that it uses existing data on all discharges from acute care hospitals across Canada found in CIHI's Discharge Abstract Database.[iii] The database is well established; has clear, common standards for data collection; and has built-in methods for auditing and assuring data quality. As an administrative database, it does not provide the same level of detail as a patient's chart; however, the data it captures does allow us to identify harmful events and their timing. For example, we can identify whether an event occurred before or after admission, whether it occurred after treatment and, in some cases such as medication incidents, any contributing factors to the harmful event. For more information on the limitations of administrative data, see the Limitations section of this report.

Using the Hospital Harm data in conjunction with other sources of information — such as patient safety incident reports, patient experience surveys, infection control data and global trigger tools ("clues" in charts that suggest harmful events) — will help make hospitals safer.

For more information on the source of the data and steps that were taken to assess its quality, see Appendix A.

iii. Data from Quebec as well as data for some mental health patients has been excluded due to methodological issues.

Steps taken to develop a measure of hospital harm

CIHI and CPSI initially consulted with 5 of the authors of the Canadian Adverse Events Study to develop the concept for a measure that would help hospitals understand how safely they are delivering care to their patients. The additional steps taken to develop the methodology included

- Scanning the literature to understand past and current efforts to measure patient safety;
- Drawing on CIHI's Data Quality and Classifications and Terminologies experts to ensure every code captured in the methodology identifies harm to a patient;
- Conducting 2 rounds of testing with pioneer hospitals to get feedback that was essential in developing the Hospital Harm Framework;
- Consulting with the WHO's Topic Advisory Group for Quality and Safety to compare the ICD-10-CA codes used in its patient safety indicators with those included in this measure;
- Organizing a modified Delphi panel with clinicians to ensure the measure had the right scope and good face validity, and captured potentially preventable harm;
- Consulting with obstetricians, cardiac specialists and general surgeons on the selected clinical groups where agreement was not reached during the Delphi process;
- Conducting an extensive literature search to verify the list of evidence-informed practices for each clinical group;
- Continuing consultation with coding and classifications experts to refine the definitions of each clinical group; and
- Undertaking more work to understand data quality (see Appendix A).

Further work is needed to develop the Hospital Harm measure into a comparable indicator. Next steps include establishing a risk-adjustment methodology that can account for differences in patient populations.

Hospital harm rates may never be zero

Some of the harmful events captured by this methodology are considered “never events” — those that should not happen under any circumstances and are considered completely preventable. It also captures events that can be reduced but may not be completely eliminated because the degree to which a patient experiences harm is influenced by the natural course of his or her illness.

As an example, consider aspiration pneumonia, a common type of harm. After an acute stroke, some patients have difficulty swallowing, and food may inadvertently pass through the trachea into the lungs and cause pneumonia.[12] In some instances, this is unavoidable. However, hospitals can protect stroke patients by systematically assessing their ability to swallow and, after identifying who’s at risk, by following evidence-informed clinical practice guidelines — which include strategies such as offering smaller bites, alternating solids and liquids, checking whether the patient finds it easier to swallow thickened liquids and avoiding medications that dry out the mouth or impair coughing and swallowing.[13]

As the data is used more extensively, the degree of preventable harm may become more evident. For example, in the future, some organizations may achieve a particularly low rate of aspiration pneumonia compared with their peers by following evidence-informed practices. Their results could be used to set benchmarks for this type of harm, and rates above a threshold known to be achievable could mean there is an opportunity to prevent some occurrences.

Harmful events in Canadian hospitals

Harm experienced in 1 of every 18 hospitalizations

While further work is required to develop the Hospital Harm measure into a comparable indicator, it has produced a baseline set of pan-Canadian data on harm to hospital patients. This is not, as explained above, a complete picture. It does not capture all types of harm, and it is likely underestimating harm’s true extent. Nevertheless, it will help give a sense of the overall state of patient safety in Canadian hospitals and help organizations monitor progress in the future. The following section lays out the information that has been gathered so far using this new approach.

More than 138,000 hospitalizations — or 5.6% of all hospitalizations in Canada[iv] — involved at least 1 occurrence of harm in 2014–2015. This equates to approximately 1 out of every 18 acute care hospitalizations. The rate has remained constant over the past 3 years. Although definitions and methodologies used are not directly comparable, the rate is lower than those seen in the Canadian Adverse Events Study[2] and in subsequent studies in other countries, including the United States, Australia and Spain (see Table 1).[14–17]

Table 1 International studies of harm

Author	Description	Rate
Baker et al., 2004 (Canada)[2]	Canadian Adverse Events Study conducted hospital chart reviews of 20 hospitals in British Columbia, Alberta, Ontario, Quebec and Nova Scotia. Data extrapolated for national rate of adverse events. Excludes obstetric and pediatric patients.	7.5%
Jackson et al., 2006 (Australia)[14]	Administrative data used to identify adverse events in public and private hospitals in Victoria, Australia. Researchers acknowledged administrative data likely underestimated the rate of adverse events.	8.3%
ENEAS, 2006 (Spain)[15]	Retrospective cohort study of 24 hospitals in Spain conducted to identify the incidence of harmful events.	8.4%
Levinson et al., 2010 (U.S.)[16]	Physician review of a random sample of Medicare patient charts done throughout the U.S. for adverse events.	13.5%
Perla et al., 2013 (U.S.)[17]	A 2-year study used administrative data to gauge the incidence of 14 highly undesirable events across 161 hospitals in the U.S.	7.7%

iv. Data from Quebec as well as data for some mental health patients has been excluded due to methodological issues.

Harmful events occur across all types of care

The Hospital Harm data is meant to support quality improvement efforts and is not intended to assign blame. Most care takes place in a context that includes many people, situations, actions and decisions combining to produce each result. Harmful events are the result of a multiplicity of factors, and everyone in an organization has a responsibility to learn from these events and work to reduce the potential for harm.[10, 18]

Thousands of Canadians go to hospital every year, suffering from an immense range of problems. Although medical patients outnumber surgical patients almost 3 to 1, the overall rate of harm in the 2 groups differs only slightly. Obstetric and newborn patients are exceptions, however. They each represent about 12% of hospitalizations and have a lower rate of harm (see Table 2). The way harm is distributed across all patient groups highlights the importance of looking for opportunities to improve safety in all areas of hospitals.

Table 2 Rate of harmful events, by patient profile

Patient profile	Proportion of all admitted patients	Harm rate (per 100)
Surgical*	19.8%	7.6
Medical	56.6%	6.2
Obstetric	11.7%	4.2
Newborns	11.9%	1.0

Notes

* Surgical patients had a procedure in a main operating room within the first 24 hours of admission.

Data from Quebec as well as data for some mental health patients has been excluded due to methodological issues.

Source

Discharge Abstract Database, 2014–2015, Canadian Institute for Health Information.

Patients experience different types of harm

The Hospital Harm Framework (Figure 2) includes 4 categories of harm, which align with the WHO's *International Classification for Patient Safety*:[1]

- **Health Care–/Medication-Associated Conditions**
  - Harm related to general care provided and/or medication administered during a hospital stay
- **Health Care–Associated Infections**
  - Infections that occur during a hospital stay, including those related to or following a medical or surgical procedure
- **Patient Accidents**
  - In-hospital injuries (e.g., fractures, dislocations, burns) due to an accident, not directly related to medical or surgical procedures
- **Procedure-Associated Conditions**
  - Misadventures to patients during surgical and medical procedures
  - Events associated with medical devices used for diagnosis and treatment
  - Abnormal reactions or complications of surgical or medical procedures

How are harmful events counted?

Harm is captured only once at each level of the framework. For example, when more than 1 harmful event occurs during a hospitalization, each is counted within its clinical group. However, if the events fall within the same category of harm they will be counted as only 1 event within that category.

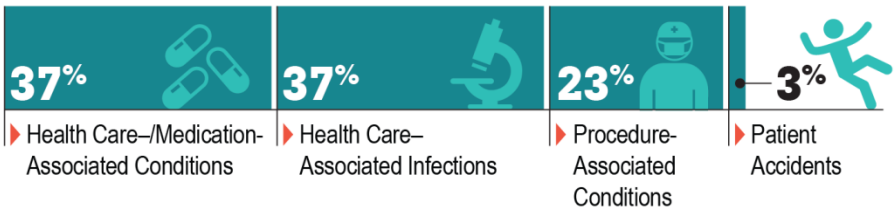
Hospital Harm: The rate of hospitalizations where at least 1 harmful event occurred.

Category: The number of hospitalizations with at least 1 harmful event in that category.

Clinical group: The number of hospitalizations with at least 1 harmful event in that clinical group.

To illustrate using Herbert's story, the sepsis and *C. difficile* infections would be counted once within their respective clinical groups, but since they both fall under the category of Health Care–Associated Infections, they are counted as 1 incident of harm in that category. So for this hospital stay, there would be 2 occurrences of harm in 1 category and 1 case of hospital harm. Figure 3 shows the proportion of cases that fall into each category.

Figure 3 Breakdown of harmful events by category of harm, 2014–2015



Health Care–/Medication-Associated Conditions

Top 2 clinical groups	% of all harmful events	Number
Electrolyte and fluid imbalance	15%	27,000
Delirium	10%	18,000

Health Care–Associated Infections

Top 2 clinical groups	% of all harmful events	Number
Urinary tract infections	12%	22,000
Pneumonia	7%	12,000

Procedure-Associated Conditions

Top 2 clinical groups	% of all harmful events	Number
Anemia — hemorrhage	7%	13,000
Laceration/puncture	4%	8,000

Patient Accidents

Top clinical group	% of all harmful events	Number
Patient trauma	3%	5,000

Notes
The percentages for the clinical groups represent their proportion among all harmful events. The percentages for the categories of harm represent the proportion of hospitalizations where there was at least 1 occurrence of harm within each category.
Data from Quebec as well as data for some mental health patients has been excluded due to methodological issues.
Source
Discharge Abstract Database, 2014–2015, Canadian Institute for Health Information.

There is no single category of harm that accounts for a majority of events. In 2014–2015, the most common harmful events were in the categories of Health Care–Associated Infections (37%) and Health Care–/Medication-Associated Conditions (37%). Next came Procedure-Associated Conditions (23%). Patient Accidents (3%) was the least frequent category.

What we know about events associated with medication

Events associated with medication are among the most frequent of all harmful events possible in a hospital.[19,20] However, not all of them are captured in the measure, such as events that were not recorded as having reached or affected the patient. Medication events captured in the Hospital Harm data are recorded in 1 of 2 ways:

- As an unintended reaction from a medication that was appropriately administered. These are captured in various clinical groups; for example, an appropriate dose of insulin that adversely affects the patient will be captured under Altered Blood Glucose Level With Complications.
- As an error in dosage or administration. These are captured in the clinical group Medication Incidents (e.g., insulin incorrectly administered).

The National System for Incident Reporting (NSIR), a database housed at CIHI, captures a broader set of data on medication incidents — including near misses, reportable events, contributing factors and the degree of harm involved — which can provide context to this data.

NSIR data is used to inform national and local quality improvement activities. It reveals that

- 15% of reported incidents resulted in some level of harm to the patient.
- The 3 drug products most commonly involved with reported incidents are
    - Insulin (9%), which could appear under Altered Blood Glucose Level With Complications in the framework;
    - Hydromorphone hydrochloride (7%), which could be captured in the Delirium clinical group; and
    - Heparin (4%), which may contribute to events captured either in Anemia — Hemorrhage or in Infusion, Transfusion and Injection Complications.
- 27% of reported incidents involved “distractions or interruptions,” the most commonly reported contributing factor.

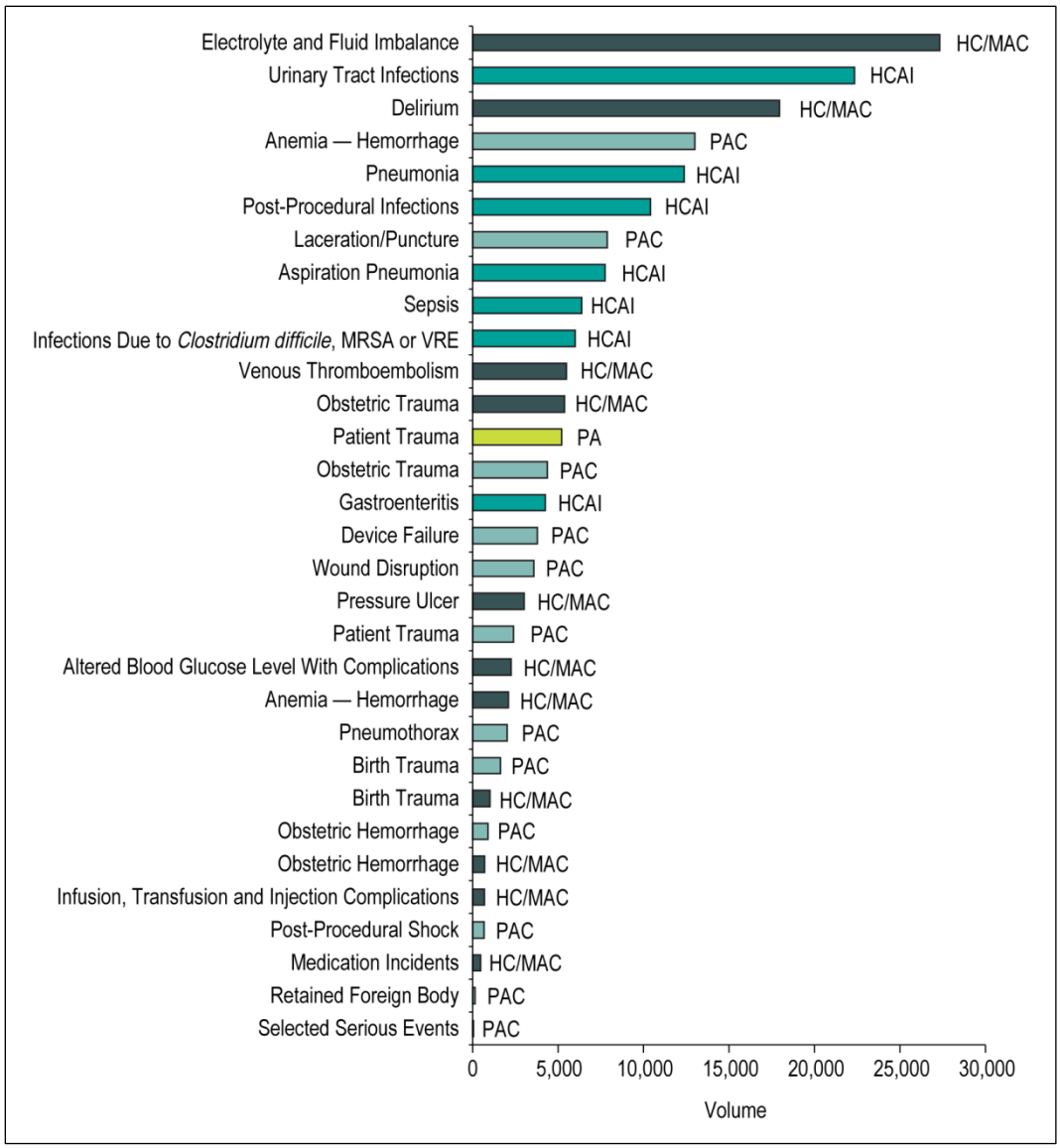
The number of medication incidents captured in the Hospital Harm measure is low compared with other clinical groups, at 475 cases in 2014–2015 (Figure 4). That might create the impression that medication is not a problem area for hospital harm. However, the 3 clinical groups with the highest rates of events in the Health Care–/Medication-Associated Conditions category are Electrolyte and Fluid Imbalances, Delirium and Venous Thromboembolism — all conditions that can be affected by medication practices.[21–23] Yet because cases in those groups do not necessarily involve either incorrect administration or dosage issues, they will not be captured under Medication Incidents.

Figure 4 shows the distribution of harm captured by each clinical group. The 5 most common clinical groups, accounting for 51% of harmful events, are Electrolyte and Fluid Imbalance, Urinary Tract Infections, Delirium, Anemia — Hemorrhage and Pneumonia.

A small percentage of cases (<1%) are seen in Retained Foreign Body and Selected Serious Events. Many of these are never events[24] — things that should not happen under any circumstances, that can lead to serious harm or death and that are completely preventable with proper checks and balances. In 2015, the National Patient Safety Consortium prepared the report *Never Events for Hospital Care in Canada*.[24] These events include operating on the wrong body part or unintentionally leaving a foreign object in a patient, among others. Many of these events will be captured as hospital harm. Some that are not related to clinical care, such as an infant who is abducted or discharged to the wrong person, are not captured in the measure.

It is important for hospitals to implement evidence-informed practices to prevent never events (such as counting tools at the end of surgery to ensure nothing has been left in a patient), as well as to monitor the effectiveness of those practices. However, hospitals must also take a balanced approach to improving safety. Focusing on this most serious subset of harmful events may mean hospitals are overlooking opportunities to prevent events that may be less serious but happen more frequently.

Figure 4 Distribution of harmful events by clinical group



Notes

HC/MAC: Health Care–/Medication-Associated Conditions.
HCAI: Health Care–Associated Infections.
PA: Patient Accidents.
PAC: Procedure-Associated Conditions.
Data from Quebec as well as data for some mental health patients has been excluded due to methodological issues.

Source

Discharge Abstract Database, 2014–2015, Canadian Institute for Health Information.

Some patients experience more than 1 harmful event in hospital

Some patients experienced more than 1 occurrence of harm during their hospital stay. Of the 138,000 hospitalizations involving a harmful event, 30,000 — or 1 in 5 — involved more than 1. Overall, there were no strong patterns in what types of events occurred together. More often than not, however, they involved the most common types of harm — urinary tract infections, sepsis, delirium, electrolyte and fluid imbalance, or pneumonia. Administrative data does not provide enough detail to determine whether the events are linked in every case (e.g., did the urinary tract infection lead to the delirium?). It is possible that these events are seen together simply because each individual event happens frequently. All that can be said for certain is that they occurred during the same hospital stay.

Complex patients are at higher risk of harm

Complex patients are people with diseases in addition to the one they are being hospitalized for (called “comorbidities”) and/or those who are treated by several types of physicians. For this analysis, each patient was given a complexity score and then categorized as high, medium or low complexity; highly complex patients scored 4 and above; medium-complexity patients scored 2 to 3, and patients who scored 1 are low complexity. By this measure, about 10% of patients were highly complex and 1 in 5 of them experienced harm during their stay.

Medical patients have a lower rate of harm across complexity levels than surgical patients; however, medical patients have more occurrences of harm in total because there are more medical patients than surgical patients (Figure 5).[v]

v. Obstetric and newborn patients have been excluded from this analysis, as they represent a different patient population and the majority are low complexity.

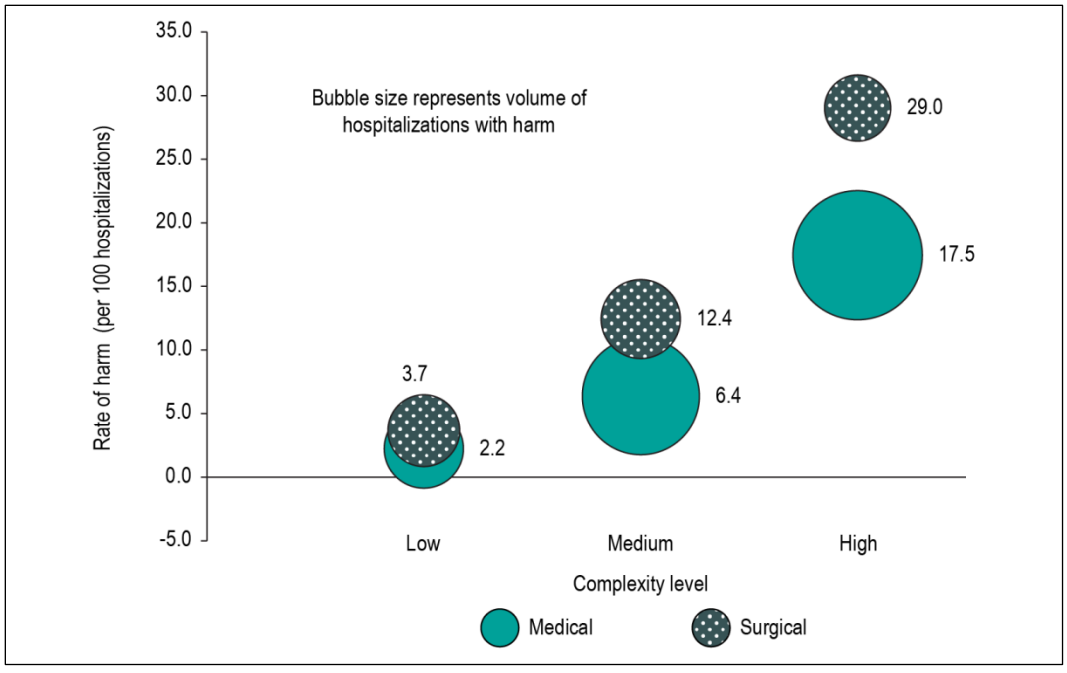
What is a complex patient?

For the purposes of this study, complexity was defined by the additional diseases (comorbidities) a patient had when he or she was admitted to hospital, and how many different types of physicians cared for that patient. For example, a patient with osteoarthritis getting a hip replacement who was treated by an orthopedic surgeon is low complexity because he or she has only 1 provider and no reported comorbidity. A patient with dementia who is admitted for a cardiac arrest and who is treated in hospital by both a cardiologist and a general physician would be more complex.

It should be noted that the data does not show whether patients had multiple physicians involved in their care because of the nature of their condition or because they experienced a harmful event.

There are more details about this in the technical report.

Figure 5 Rates of at least 1 harmful event among medical and surgical patients, by complexity level



Notes

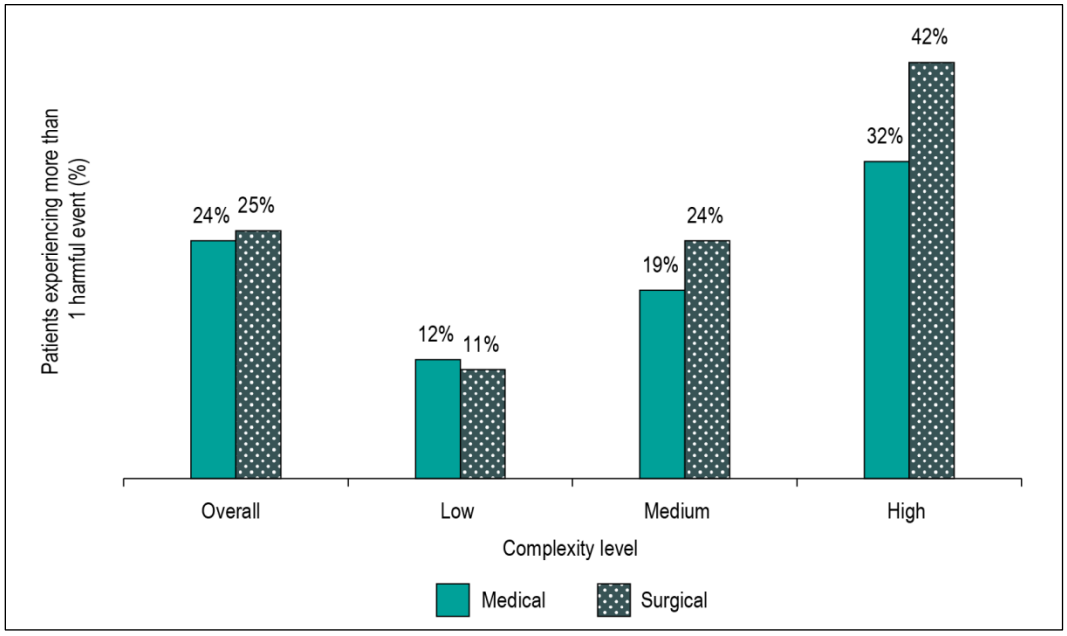
Patients' complexity scores have been classified as low (1), medium (2 to 3) or high (4+). See the sections Complex patients are at higher risk of harm and What is a complex patient? for how complexity score is determined. Obstetric and newborn patients have been excluded from this analysis, as they represent a different patient population and the majority are low complexity. Data from Quebec as well as data for some mental health patients has been excluded due to methodological issues.

Source

Discharge Abstract Database, 2014–2015, Canadian Institute for Health Information.

Patients with high complexity scores were more likely to experience harm and were also more likely to experience more than 1 harmful event. Of all patients who experienced harm, patients who ranked high in complexity were 3 to 4 times more likely to experience multiple occurrences of harm compared with low-complexity patients (see Figure 6).

Figure 6 Multiple harmful event rates among medical and surgical patients who experienced harm, by complexity level



Notes

Patients' complexity scores have been classified as low (1), medium (2 to 3) or high (4+). See the sections Complex patients are at higher risk of harm and What is a complex patient? for how complexity score is determined. Obstetric and newborn patients have been excluded from this analysis, as they represent a different patient population and the majority are low complexity. Data from Quebec as well as data for some mental health patients has been excluded due to methodological issues.

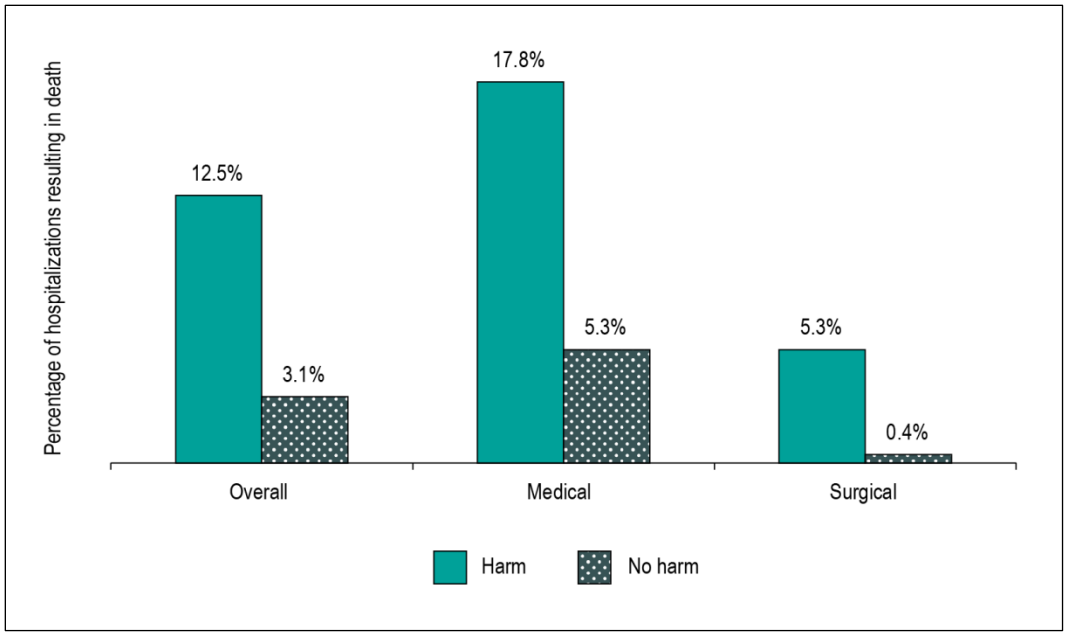
Source

Discharge Abstract Database, 2014–2015, Canadian Institute for Health Information.

1 in 8 hospitalizations with a harmful event ends in death

Harmful events have the potential to cause serious illness and even death, but whether there is a causal relationship between the harm and death cannot be determined from the administrative data. Death might be due to the harmful event, or it could be that the patient was at higher risk of dying because he or she had more complex conditions. However, patients who experience a harmful event have higher mortality rates than those who do not (Figure 7). In 2014–2015, 17,300 (12.5%) patients with at least 1 harmful event died in hospital. That is 4 times higher than the death rate of patients who did not experience a harmful event (3.1%). Across all levels of complexity, mortality rates were higher among patients who experienced harm. Overall, medical patients were at higher risk of death than surgical patients, whether they experienced harm or not.

Figure 7 Rates of hospital death in medical and surgical patients, with and without harm



Notes

Obstetric and newborn cases are included in the overall rates but are not reported separately, as death is rare in these patient populations.

Data from Quebec as well as data for some mental health patients has been excluded due to methodological issues.

Source

Discharge Abstract Database, 2014–2015, Canadian Institute for Health Information.

Reducing harmful events could free up resources for unmet needs

The impact of harmful events on patients and their families can be overwhelming. Beyond physical harm, there may be emotional, mental and social effects on everyone involved. Economically, both society and individuals suffer from the impact of wages lost to hospital harm, which can keep both patients and their families from their jobs. The effects can reach even further — seeing a patient hurt by care can be extremely stressful for staff. Harmful events also hurt the overall health system because they increase use of resources. Using the Hospital Harm data, it's estimated that patients who experienced harm spent more than half a million additional days in hospital beds in 2014–2015; these beds were therefore not available for other patients. That is equivalent to more than 1,600 beds each day, or roughly 4 large hospitals.

The additional care provided to patients who experience a harmful event also costs money. The hospital costs (excluding physician fees) attributed to harmful events are estimated to have totalled an **additional** $685 million[vi] in 2014–2015, or 1% of Canada's estimated total hospital spending ($63.6 billion in 2014). Infections acquired in hospital are a major source of patient harm, occurring in 1 out of every 41 hospitalizations (2.4%). Of the $685 million that harmful events cost health care systems, $281 million, or 41% of the total cost, was associated with Health Care–Associated Infections. It is not likely that all infections can be eliminated, but there is evidence a high proportion could be prevented.[25]

Note, too, that the $685 million reflects only acute care costs. There may also be costs from follow-up care after discharge or from patients having to be readmitted to hospital. Although it is not reasonable to expect that all of the extra dollars spent because of patient harm might be recovered, saving even a small percentage of the total would make money available to meet other demands for care.

vi. This excludes approximately 10% of patients experiencing harm who were atypical (had long lengths of stay, etc.) for whom a cost cannot be comparably calculated. Regression analysis was used to determine additional costs after accounting for comorbidities, age, high-cost interventions and other factors. See the technical report for additional information.

What can be done to improve patient safety?

Clinical evidence-informed practices for reducing harm: Working together for safer care

The harmful events included in this measure were chosen because they can potentially be prevented by implementing evidence-informed practices (Table 3 below gives some examples). Aiming to eradicate all unintended harm from care, as this report has said, is unfortunately not realistic. However, focusing on following recommended evidence-informed practices should reduce the occurrence of harm and also foster a stronger overall awareness of patient safety issues and commitment to mitigating them.

To assist hospitals in improving care, the *Hospital Harm Improvement Resource* describes activities clinicians and managers can undertake to improve safety. It also offers tips on how to use the data to improve care. The Improvement Resource was developed through extensive review of literature, consultations with CPSI's faculty advisors and clinical expert review.

The Improvement Resource will cover all the clinical groups included in the Hospital Harm Framework and gives, for each one, a summary of evidence-informed practices that reduce the likelihood of harm, as well as suggested measures for outcomes and processes. There are also patient stories, success stories and Accreditation Canada's Standards and Required Organizational Practices associated with each clinical group. Additional resources offer further detail about the evidence-informed practices.

The Improvement Resource will be updated regularly as new tools and approaches are developed and more evidence-informed practices emerge.

What do we mean by evidence-informed practice?

When patients are being cared for, there are usually specific drugs, treatments, procedures, services or equipment that should be used to deliver high-quality care. The effectiveness of these specific drugs, treatments, etc., has been established through research (including randomized trials, meta-analyses or other methods), and they are often described in clinical practice guidelines for a specific condition.

Research has shown, for example, that pressure ulcers among hospital patients can be reduced through steps such as frequently repositioning the patient and optimizing nutrition and hydration.[26] Delirium can be reduced by implementing strategies such as identifying and treating its underlying causes, assessing sedation every day, displaying calendars and clocks, and encouraging visitors.[27]

Actions to reduce harmful events

This table gives samples of evidence-informed practices known to be useful in reducing the harm associated with some of the clinical groups included in the Hospital Harm Framework. See the Improvement Resource for complete details.

Table 3A Examples of actions to reduce harm in the **Health Care–/Medication-Associated Conditions** category

Type of harm	Description	Examples of evidence-informed practices
Delirium	Temporary disturbance in consciousness with changes in cognition	Develop a standardized protocol for preventing or managing delirium, including identifying and treating underlying causes; implement non-drug strategies such as early mobility; implement environmental strategies such as visible daylight; reassess sedation daily.
Venous Thromboembolism (VTE)	Embolism, thrombosis, phlebitis or thrombophlebitis of the pulmonary vein or other veins (excluding superficial veins)	Conduct VTE risk assessment; provide appropriate thromboprophylaxis (anticoagulant or, if anticoagulant contraindicated, mechanical); reassess patients if significant change in status and at transitions of care.
Pressure Ulcer	Any stage of pressure ulcer identified during a hospital stay	Conduct a pressure ulcer admission assessment for all patients; inspect skin daily; reassess risk for all patients daily; manage moisture on skin; minimize pressure, friction and shear; optimize nutrition and hydration; use pressure redistributing devices; avoid skin massage.
Medication Incidents	Medication-related events involving incorrect administration of medications or dosage	Conduct an organizational Medication Safety Self Assessment; implement medication reconciliation and high-alert medication safety processes; improve core processes for ordering, dispensing and administering medications.

Table 3B Examples of actions to reduce harm in the **Health Care–Associated Infections** category

Type of harm	Description	Examples of evidence-informed practices
Urinary Tract Infections	Urinary tract infections identified during a hospital stay	Catheter-associated urinary tract infection (CAUTI): Assess risk; use appropriate technique for inserting catheter; appropriately maintain indwelling catheters; review catheter daily; establish protocol for managing post-operative urinary retention.
Post-Procedural Infections	Infections associated with a medical or surgical procedure	Surgical site infections (SSIs): Provide antimicrobial coverage peri-operatively, including appropriate use of prophylactic antibiotics and antiseptic prophylaxis; perform appropriate hair removal; maintain peri-operative glucose control and peri-operative normothermia.
Pneumonia	Pneumonia identified during a hospital stay, excluding aspiration pneumonia	Health care–associated pneumonia: Educate and involve staff in infection prevention; clean, sterilize or disinfect and maintain equipment, devices and environment; vaccinate staff and high-risk patients (i.e., flu shots); encourage deep breathing exercises and ambulation; isolate infected patients as indicated.
Aspiration Pneumonia	Inflammation and infection of the lungs caused by aspiration of solids or liquids during a hospital stay	Preventing aspiration in older adults with dysphagia: Offer smaller bites; alternate solids and liquids; check whether the patient finds it easier to swallow thickened liquids; avoid rushed or forced feeding; avoid medications that dry out the mouth or impair coughing and swallowing.
Sepsis	Sepsis identified during a hospital stay, excluding neonatal sepsis	Prevent UTI, CAUTI, CLI, VAP and SSI; screen for sepsis; identify infection source and control early, according to the clinical situation; reassess antimicrobial therapy daily for de-escalation, when appropriate.

Table 3C Examples of actions to reduce harm in the **Patient Accidents** category

Type of harm	Description	Examples of evidence-informed practices
Patient Trauma	In-hospital injuries (fractures, dislocations, burns, etc.) **not** related to medical or surgical procedures	Falls prevention: Implement strategies to prevent falls and reduce injuries, such as creating a safe environment and assisting with mobility; conduct a multifactorial risk assessment; communicate and educate about risk; promote alternatives to use of restraints.

Table 3D Examples of actions to reduce harm in the **Procedure-Associated Conditions** category

Type of harm	Description	Examples of evidence-informed practices
Obstetric Hemorrhage	Hemorrhage from the pelvic area, genital tract, perineum or surgical incision after an instrument-assisted delivery or Caesarean section delivery that requires blood transfusion	Prevention of Primary Postpartum Hemorrhage (PPH): Construct a sterile tray that provides rapid access to instruments used to surgically treat PPH; assess hemorrhage risk on admission, throughout labour, postpartum and at every handoff; active management of the third stage of labour (using interventions such as uterotonics, clamping of the umbilical cord and controlled traction of the cord).
Patient Trauma	In-hospital injuries (fractures, dislocations, burns, etc.) related to medical or surgical procedures	Health care–associated accidents are both complex and multifactorial. It is recommended that clinical and systems reviews be undertaken to identify contributing factors and preventive measures. For a list of potential contributing factors and recommended mitigation strategies, refer to the Improvement Resource.
Pneumothorax	Pneumothorax associated with a medical or surgical procedure	Identify patients at risk; follow safe insertion techniques during pleural procedures; develop training components and criteria and a plan for continued competency; standardize practices for site identification, marking and procedural practice.
Wound Disruption	Disruption of a surgical or obstetric wound	Assess for and mitigate risk factors preoperatively (e.g., treat preoperative anemia); prevent surgical site infections; mitigate peri-operative risk factors (e.g., use optimal technique to close wounds); assess and manage pain postoperatively; implement steps to manage open surgical wounds; educate patients to avoid heavy lifting.

What organizations can do to improve safety

Creating safer care is much more difficult than simply implementing a to-do list of evidence-informed practices. Hospitals are complex and often large organizations, which makes introducing organization-wide change extremely difficult. Even unit by unit, where the need for and impact of safer care will be most immediately felt, evidence-informed interventions can take hold only in a receptive environment. Providers may not be able to support these interventions or sustain the changes needed for safer practice if they feel they are already struggling with too heavy a workload, if resources or skilled staff are lacking, or if they feel too much is expected of them.

Just as critical, then, is creating supportive environments where effective interventions can be introduced and sustained. That requires building trust between providers and their organizations so that a broader commitment to creating a strong patient safety culture will be accepted.[28]

In a strong patient safety culture, everyone — from administrators and board members to clinicians and service workers — always considers the safety implications of their actions. Safety is a constant and conscious concern, not something assumed as a given. When a culture of safety has taken hold, safety interventions are more likely to succeed.

Improving safety requires strong, determined leadership over the long term.[10] Hospital leaders must ensure that patient safety incidents are viewed as opportunities for learning, not for blame. If errors are not recognized, or if they are hidden or their harm is downplayed, opportunities to learn and prevent future harm are lost. Another important ingredient for success is to have interventions planned and implemented by the people most involved, including front-line providers, patients and their family members. Follow-up, through regular measurement and assessment of results, is also important so practice can be reinforced or improved.

The Hospital Harm measure is an important addition to safety improvement, but like other safety tools it will require careful, diligent work to be effective. Activities that will allow hospitals to take best advantage of this data and guide effective use of the Improvement Resource may include the following:

1. **Make monitoring patient safety an organizational priority.** Hospital or health authority board members and senior executives should use the Hospital Harm data in conjunction with other data sources to monitor harm in the hospital. Boards can direct staff to gather good-quality data on patient safety and strongly encourage physicians and staff to document all harmful events.

2. **Engage individuals and groups to use the data to improve safety.** This can be done at either the hospital or regional level. People to be engaged include the board, the CEO and executive team, quality committees, medical advisory committees, unit or department managers, clinical educators, infection prevention and control professionals, physicians and other care providers and support staff, and patients and family representatives.

3. **Prioritize a quality improvement topic.** Choose where to begin the review of clinical groups with the help of a multidisciplinary team. In making the decision, the safety team may consider both frequency of occurrence and severity of harm for each clinical group.

   Other considerations in deciding where to begin include

   - Priorities the organization is already working on or planning (e.g., where staff have identified variations in outcomes among clinicians or departments);
   - Priorities identified through accreditation surveys or risk assessments; and
   - Priorities from incident reports, reviews for patient safety or quality assurance, or patient complaints.

   Hospitals may also need to align with regional priorities. Periodically, health regions, provincial quality councils or ministries establish quality improvement initiatives to encourage work on a common topic and promote learning across organizations.

4. **Create quality improvement teams.** Quality improvement initiatives are most successful when done by a multidisciplinary team. The team should include physicians, nurses, other key providers of the service and individuals with expertise in patient safety, quality and decision support. The team should include patient and family representatives as well, and a senior executive to act as a sponsor.

5. **Review institutional data for accuracy.** Once teams have drilled down into their data and a clinical group has been selected as the focus for quality improvement, the team may wish to ask practitioners whether the data seems reasonable and reflects their experience. If there are areas where clinical group counts appear lower or higher than expected, then a more detailed exploration of how the events are recorded (either by doctors or coders) could be undertaken. Sharing the findings of these reviews with CIHI could contribute to the development of a comparable indicator in the future. In addition, Clinical Documentation Improvement[29] initiatives can be established to ensure the recording of harmful events and their chronology. In this way, clinical data input staff are able to accurately review optimal documentation to ensure good-quality data capture.

6. **Establish specific goals.** CPSI recommends the use of the Model for Improvement,[30] in which aims, measures and change ideas must be clearly specified for any quality improvement initiative. The Improvement Resource offers evidence-informed practices for improvement teams, but it's the responsibility of the teams to set aims and develop change ideas for applying that evidence in their environment. For measures, hospitals can use the Hospital Harm clinical group data, but they should supplement it with process measures to track the extent to which a suggested evidence-informed practice is being followed. The Improvement Resource provides examples of process measures.

Over time, teams might want to set goals based on clinical group counts. However, because the lowest attainable number of such events is not yet known, comparison with a benchmark is not possible. As the Hospital Harm data is used more, the degree of preventable harm may become more evident and could be used to set benchmarks in the future.

7. **Identify contributing factors that make it challenging to implement and sustain evidence-informed practice for the selected quality improvement topic.** Such factors may be related to patient and provider characteristics or behaviour, environmental issues, resources, or policies and processes. Analyzing local challenges to change is essential because the main factors that get in the way of evidence-informed practice can vary from one hospital to the next. For example, a high rate of pressure ulcers in one hospital may be due to variation in how risk for them is scored and how skin assessments are done. In another hospital, the problem may be a shortage of pressure-relieving mattresses for patients at high risk of an ulcer. Addressing any single factor will not eliminate all harm. Hospitals should design their interventions based on which factors seem most relevant to their situation.

   Hospitals can use the Canadian Incident Analysis Framework[18] to identify factors that contribute to harm and also the Patient Safety and Incident Management Toolkit[31] to learn from previous patient safety incidents. Tools such as the Failure Mode and Effects Analysis Framework[32] can also help organizations anticipate problems with adopting best practices.

8. **Identify specific improvement strategies to address contributing factors.** Tap into the wisdom of care providers and the experience of patients and their families to identify improvement strategies to address local issues. They might include
   - Providing decision supports such as checklists, standard orders, audits and electronic reminders to help providers remember everything they are supposed to do;
   - Employing human factors engineering to design a work environment that prevents human errors, or makes it easier to do the right thing;
   - Streamlining procedures to make them efficient, and monitoring these processes to ensure they are followed and functioning without glitches; and
   - Engaging patients in their own care, by providing written instructions and using techniques like “teach back” to ensure they understand information they are given.

9. **Review and provide recognition.** Ensure that boards and senior teams provide timely, constructive reviews and recognition of improvement efforts to teams who are undertaking this work. Reviews can include monitoring and publishing statistics on patient safety throughout the organization, and providing results specific to different wards or departments. Make sure successful improvement efforts are highlighted.

10. **Be transparent.** Patients, families and the community at large need and deserve transparency in the operations and outcomes of their health systems. Some provinces require hospitals to publicly report on key safety indicators, but reporting voluntarily, without being ordered to, shows particular commitment to transparency. Publicly reporting improvements over time will also demonstrate the hospital's ongoing commitment to quality and safety and potentially confirm trust and confidence in the organization.

    Posting results of patient safety initiatives in public places, in areas of the hospital where staff congregate and on easily accessible areas of the website will draw attention to quality and safety.

Limitations

The Hospital Harm data is easily reproduced and is a broad measure allowing hospitals to track patient safety information. Having said that, the methodology has a number of limitations. First, it does *not* capture several patient safety issues, including

- Harm in the emergency department;
- Harm to patients outside acute inpatient care (e.g., in rehabilitation or mental health);
- Harm that started in the hospital, was undetected during the stay and was then discovered on a subsequent emergency department visit or admission;
- "Near misses," where an error occurred but was caught before it caused harm;
- Harm that occurred in hospital but did not affect treatment of the patient or prolong his or her hospital stay;
- Harm due to misdiagnosis; and
- Safety issues related specifically to mental health (such as suicide attempts while in care).

All of these issues are important, and hospitals may wish to find other ways of monitoring them. Keeping track of near misses and errors that do not cause harm can help identify system-wide problems in the delivery of care that, if corrected, might help prevent a subsequent harmful event.

The quality of the underlying clinical data can also affect the results. The data is captured by professional coders from clinical documentation, based on standards set by CIHI. Errors in the captured data can arise when the documentation is inconsistent or unclear, has conflicting information or is missing. They can also happen during the coding process, due to coders' interpretation of physicians' documentation, or incomplete or incorrect coding. CIHI regularly conducts reabstraction studies to assess the quality of its data. The most recent study focused on some of the clinical groups in the Hospital Harm Framework and found that harm captured in these groups was generally confirmed in patient charts. For more information on the results of CIHI's reabstraction studies, see Appendix A.

Hospital harm is likely under-reported, leading to an underestimate of the extent of the patient safety issues. If, for example, harm occurred and was recorded only in the nurse's notes, it would not be captured, as CIHI's coding standards stipulate that to be coded (and captured in the Hospital Harm data), diagnoses must be documented in the chart by a physician or the primary care provider. Also, under-reporting may occur if the coding is not specific enough (e.g., if anemia was noted on the chart, but not that it was the result of a hemorrhage).

The measure is intended to capture conditions arising after a patient is admitted to hospital. Sometimes information on when a condition began is unclear or ambiguous and coders cannot determine whether it started before or after admission. That can lead to both under- and over-reporting of harm.

The measure also does not distinguish levels of harm — every harmful event has equal weight, no matter how severe its impact.

Data in this report is presented at a national level, but work will continue to further develop the measure as a useful tool for monitoring and improving patient safety in acute care facilities. Work will continue with hospitals to understand and improve the data and the documentation behind it. Investigations into the feasibility of risk-adjustment to make the Hospital Harm measure a comparable indicator will continue.

Conclusions

The WHO estimates that an enormous amount of money — between 20% and 40% of all health spending — is wasted due to poor quality of care.[33] The costs of patient safety go far beyond actual money spent, however; patients who experience harm pay with discomfort, uncertainty and more time spent in the hospital away from family and work. Some experience temporary or permanent disability, and some die. Unsafe care can also undermine health care providers' morale and leave them frustrated and stressed. These cumulative costs of unsafe care clearly show the critical importance of continuing to improve safety for patients in Canadian hospitals.

Over the past decade, there have been large improvements in how patient safety incidents are approached in Canada and worldwide. The tradition of blaming and shaming those involved in a safety incident is being replaced with a culture of openness and learning.[4, 34] Health care leaders have come to understand the importance of keeping a constant focus on safety and demonstrating through their planning and actions that safety is a consideration in every aspect of hospital operations.[34] As well, measuring, reporting, learning and introducing improvements after patient safety events is becoming the norm, but there is still a long way to go.

Despite a decade of improvement efforts in Canada, the rate of harmful events measured in this report shows that patient safety is still a concern. Harm is experienced by patients in 1 of every 18 hospitalizations, and about 20% involve more than 1 occurrence of harm.

As this report has shown, harm included in this measure is potentially preventable by implementing evidence-informed practices that can reduce the rates of many types of harm. That is why the potential for reducing the occurrence of harm was the main criterion used to determine what to include in the Hospital Harm Framework. The measure is intended to be useful — useful for planning and setting priorities, useful for educating and above all useful for keeping patients from being inadvertently harmed.

To help with that, the Improvement Resource identifies practices for reducing the occurrence of harm. These range from surgical safety checklists to medication reconciliation to regularly turning patients who have pressure ulcers. Linking the measure to the Improvement Resource will give hospitals a direct connection between what their data is telling them and what steps they should take to reduce harm.

With input from hospitals, clinical leaders and patient safety experts, this methodology to capture hospital harm will become more refined and provide a greater level of detail and accuracy.

Developing a measure of hospital harm is a complicated process that requires a phased approach, with review and evaluation built in. At this point, the methodology for measuring harm gives hospitals a useful tool for monitoring rates of harm and identifying potential issues for further investigation.

There is still much work to be done to develop this into a comparable indicator. Each type of harm captured by this measure can have different risk factors. Risk-adjustment methodologies need to be developed to account for differences in patient populations. This will require extensive consultation with hospitals and experts, and CIHI and CPSI will continue to work with stakeholders across the country to determine the feasibility of this goal.

No single action or individual can ensure safe care, but through collaboration and evidence-informed practices, health care can be made safer for all Canadians. Clinicians, hospital management, quality and decision-support representatives, patients and their families all need to have a hand in moving toward safer care for all.

Appendix A: Assessing the quality of Hospital Harm data

CIHI has a comprehensive data quality program that includes a variety of data quality activities, from setting standards for collecting data and implementing hard/soft edits when it is submitted, to post-hoc data quality analyses and studies. During the development of the Hospital Harm methodology, additional steps were taken to determine how useful administrative data is for measuring the occurrence of harm in hospital. These steps included

1. An initial review of CIHI's reabstraction study on 2009–2010 data to evaluate the agreement between data in the patient's health records (discharge summary, records, notes, charts, lab reports, etc.) and data collected in the Discharge Abstract Database (DAD);
2. A clinical chart review study at 4 acute care facilities to examine agreement between harm captured in CIHI's data and harm recorded in patients' health records;
3. A 2015 reabstraction study focused, in part, on the capture of codes from selected clinical groups of the Hospital Harm Framework, including sepsis, obstetric (OB) hemorrhage, OB trauma, and infections due to *C. difficile*, MRSA or VRE; and
4. Validation of facility-level results by hospitals across Canada.

The first 2 steps determined the focus of the 2015 reabstraction study. Results from it indicated that, overall, 89% of diagnoses captured in the DAD were confirmed by the chart review (true positives), while 9% of diagnoses captured during the chart review were not found in the DAD (false negatives or undercoded in the administrative data). The study also assessed the accuracy of 6[vii] clinical groups. More than 90% of OB trauma and infections (*C. difficile*, MRSA and VRE), 89% of OB hemorrhage and 77% of sepsis cases were confirmed in the chart review. These results are as good as or better than previous reabstraction studies, particularly when capturing post-admission conditions.

These results are encouraging and support the use of the DAD for monitoring hospital harm, but there are important limitations to note. While the reabstraction study confirmed that harm captured by the Hospital Harm methodology was present on the chart, the study was not designed to identify the full extent of undercoding (i.e., harm documented in the chart but not captured in the DAD). Coding variation across hospitals may result in either under- or over-reporting of harm. In addition, only conditions documented by physicians in the patients' health record can be captured by coding. The quality of documentation therefore influences these results.

vii. OB trauma and OB hemorrhage each represent 2 clinical groups, as they fall under 2 categories: Health Care–/Medication-Associated Conditions and Procedure-Associated Conditions.

Overall, there is sufficient reason to be comfortable using the DAD for monitoring purposes in conjunction with other sources of data, such as incident reporting. Over time, as awareness of the importance of the link between documentation and coding increases among clinicians, the quality of the data will improve.

More information on the findings from the 2015 reabstraction study can be found in the report *Data Quality Study of the 2015–2016 Discharge Abstract Database — A Focus on Hospital Harm*, available on CIHI's website.

Appendix B: Text alternative for figures

Text alternative for Figure 2: Hospital Harm Framework

The Hospital Harm Framework includes 4 broad categories of harm, which are further broken down into 31 clinical groups.

The first category is Health Care–/Medication-Associated Conditions, which includes the following clinical groups: Anemia — Hemorrhage; Obstetric Hemorrhage; Obstetric Trauma; Birth Trauma; Delirium; Venous Thromboembolism; Altered Blood Glucose Level With Complications; Pressure Ulcer; Electrolyte and Fluid Imbalance; Medication Incidents; and Infusion, Transfusion and Injection Complications.

The second category is Health Care–Associated Infections, which includes the following clinical groups: Urinary Tract Infections; Post-Procedural Infections; Gastroenteritis; Pneumonia; Aspiration Pneumonia; Sepsis; and Infections Due to *Clostridium difficile*, MRSA or VRE.

The third category is Patient Accidents, which includes the Patient Trauma clinical group.

The fourth category is Procedure-Associated Conditions, which includes the following clinical groups: Anemia — Hemorrhage; Obstetric Hemorrhage; Obstetric Trauma; Birth Trauma; Patient Trauma; Device Failure; Laceration/Puncture; Pneumothorax; Wound Disruption; Retained Foreign Body; Post-Procedural Shock; and Selected Serious Events.

The framework has 3 levels:

1. Hospital Harm: The rate of hospitalizations where at least 1 harmful event occurred.
2. Category: The number of hospitalizations with at least 1 harmful event in that category.
3. Clinical group: The number of hospitalizations with at least 1 harmful event in that clinical group.

Data table for Figure 3: Breakdown of harmful events by category of harm

Category	Percentage of all categories*	Top 2 clinical conditions driving each category (percentage and number of events)
Health Care–/Medication-Associated Conditions	37%	• Electrolyte and fluid imbalance (15%; 27,000) • Delirium (10%; 18,000)
Health Care–Associated Infections	37%	• Urinary tract infections (12%; 22,000) • Pneumonia (7%; 12,000)
Patient Accidents	3%	• Patient trauma (3%; 5,000)
Procedure-Associated Conditions	23%	• Anemia — hemorrhage (7%; 13,000) • Laceration/puncture (4%; 8,000)

Note

* The percentages for the categories of harm represent the proportion of hospitalizations where there was at least 1 occurrence of harm within each category.

Data table for Figure 4: Distribution of harmful events by clinical group

Clinical group	Number of events	Category
Electrolyte and Fluid Imbalance	27,324	HC/MAC
Urinary Tract Infections	22,341	HCAI
Delirium	17,947	HC/MAC
Anemia — Hemorrhage	12,998	PAC
Pneumonia	12,383	HCAI
Post-Procedural Infections	10,401	HCAI
Laceration/Puncture	7,884	PAC
Aspiration Pneumonia	7,752	HCAI
Sepsis	6,386	HCAI
Infections Due to *Clostridium difficile*, MRSA or VRE	6,000	HCAI
Venous Thromboembolism	5,488	HC/MAC
Obstetric Trauma	5,378	HC/MAC
Patient Trauma	5,204	PA
Obstetric Trauma	4,377	PAC
Gastroenteritis	4,247	HCAI

Clinical group	Number of events	Category
Device Failure	3,788	PAC
Wound Disruption	3,581	PAC
Pressure Ulcer	3,023	HC/MAC
Patient Trauma	2,396	PAC
Altered Blood Glucose Level With Complications	2,259	HC/MAC
Anemia — Hemorrhage	2,106	HC/MAC
Pneumothorax	2,019	PAC
Birth Trauma	1,634	PAC
Birth Trauma	1,015	HC/MAC
Obstetric Hemorrhage	900	PAC
Obstetric Hemorrhage	716	HC/MAC
Infusion, Transfusion and Injection Complications	692	HC/MAC
Post-Procedural Shock	680	PAC
Medication Incidents	475	HC/MAC
Retained Foreign Body	151	PAC
Selected Serious Events	51	PAC

Notes
HC/MAC: Health Care–/Medication-Associated Conditions.
HCAI: Health Care–Associated Infections.
PA: Patient Accidents.
PAC: Procedure-Associated Conditions.

Data table for Figure 5: Rates of at least 1 harmful event among medical and surgical patients, by complexity level

Complexity level	Total medical population: Number of cases with harm	Total medical population: Rate of harm per 100	Total surgical population: Number of cases with harm	Total surgical population: Rate of harm per 100
Low	14,701	2.2	12,118	3.7
Medium	32,143	6.4	14,668	12.4
High	39,218	17.5	10,268	29.0

Data table for Figure 6: Multiple harmful event rates among medical and surgical patients who experienced harm, by complexity level

Complexity level	Percentage of medical patients with multiple harmful events	Percentage of surgical patients with multiple harmful events
Overall	24%	25%
Low	12%	11%
Medium	19%	24%
High	32%	42%

Data table for Figure 7: Rates of hospital death in medical and surgical patients, with and without harm

Patient group	Harm	No harm
Overall	12.5%	3.1%
Medical	17.8%	5.3%
Surgical	5.3%	0.4%

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