



Never Events for Hospital Care in Canada

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Foreword from the Canadian Patient Safety Institute

Patients rightfully expect safe care, and health care providers strive to deliver care that results in better health and safe outcomes for patients. Unfortunately, events that harm patients do occur while care is being provided, or as a result of that care. While risk is an inherent part of care, many of the events that cause harm can be prevented using current knowledge and practices.

There is tremendous activity to improve patient safety in Canada. There are quality and patient safety councils in most provinces, leaders from regional authorities and hospitals, as well as many national organizations who dedicate all or part of their mandate to patient safety.

In January 2014, the Canadian Patient Safety Institute (CPSI) brought together key health sector partners to form a National Patient Safety Consortium. The consortium strives to advance a national call to action for patient safety, and it is made up of more than 50 Canadian health care organizations that represent governments, health care professionals, patients and families, regulators, researchers, educators, enforcement agencies, and national and provincial agencies and associations. These partners share their expertise and work together to accelerate the pace, spread and scale of patient safety improvement.

Last year, the consortium identified a number of priority actions, one of which was to bring together a group of volunteer partners to research and recommend a list of never events in Canadian health care; this group became the Never Events Action Team. Health Quality Ontario provided leadership in collaborating with the organizations that volunteered to join this team.

This report represents the collective work of the National Patient Safety Consortium to identify, for the first time, a list of 15 never events for hospital care in Canada. *Never events* are patient safety incidents that result in serious patient harm or death and that are preventable using organizational checks and balances. Never events are not intended to reflect judgment, blame or provide a guarantee; rather, they represent a call-to-action to prevent their occurrence.

But a list of never events won't solve anything on its own. For it to have meaning, we need to take deliberate steps to identify when they occur, and harness the knowledge in hospitals across the country to prevent never events from happening. CPSI encourages a culture of continuous quality improvement — where mistakes are openly reported, disclosure occurs routinely and open discussion and problem solving are encouraged — with patients and families as full and active participants.

CPSI would like to acknowledge the leadership of Health Quality Ontario and all the organizations that participated on the Action Team for providing their review, support and advice. We also extend special thanks to Patients for Patient Safety Canada for bringing the patient's voice to this project.

Patient safety is a collective responsibility, achievable only through collaboration and drawing on the expertise of many organizations and individuals, including patients and their families. These are not efforts CPSI or any other single organization can or should pursue alone. Now that this list of never events has been established, we look forward to promoting awareness and supporting best practices in measurement and prevention. The list is a living document, and so will be kept up-to-date and relevant to care. We're hopeful that providers of hospital care will welcome this work, and grab the baton and run with it.

Chris Power
Chief Executive Officer, Canadian Patient Safety Institute



Foreword from Patients for Patient Safety Canada and Health Quality Ontario

The safety of our care when we are in your care needs to be a priority in Canada's health care system.

— Patients for Patient Safety Canada

England and the United States have defined never events for their jurisdictions. In Canada, Saskatchewan and Nova Scotia have been leaders in adopting similar patient safety event lists that include select never events. However, as a country we have not pursued agreement on a list of never events — until now. National consensus on never events is an important step in identifying situations where harm can occur and sharing solutions to prevent them from happening.

Health Quality Ontario was honoured to be asked by the National Patient Safety Consortium to lead the Never Events Action Team. It has been a pleasure to champion this work and to engage health care organizations, professionals, patients and family members and the general public throughout the process.

Patients for Patient Safety Canada welcomed the invitation to participate and contribute to the patient perspective on this work. We know first-hand that the provision of medical care is complex, involving numerous health care providers and transitions in care. Providing safe care is a continual and evolving process that requires input and collaboration by everyone in the system, and we strongly encourage patients and families to be partners in their care by asking questions and speaking up when something doesn't seem right or if they don't feel safe. Being a part of the Never Events Action Team was a great fit for Patients for Patient Safety Canada, and allowed us to make sure the voice of the patient was heard.

Initiatives such as this demonstrate the power of organizations and individuals collaborating to improve the care and safety of patients. Now that these never events have been identified for hospitals across Canada, we at Patients for Patient Safety Canada and Health Quality Ontario look forward to working with health care providers, system leaders and patients to develop and implement mechanisms that prevent them from occurring. Patients and their family members deserve no less.

Barb Farlow
Member, Patients for Patient Safety Canada

Dr. Joshua Tepper
President and Chief Executive Officer, Health Quality Ontario

Introduction

Patients rightfully expect safe care, and health care providers strive to deliver care that results in better health and safe, effective outcomes for patients. Unfortunately, events that harm patients do occur while care is being provided, or as a result of that care. While risk is an inherent part of care, we know that many of these events that cause harm can be prevented using current knowledge and practices.

Never events are patient safety incidents that result in serious patient harm or death, and that can be prevented by using organizational checks and balances.

Many of these events occur only rarely, but all can have a severe impact on the lives and well-being of patients.

Several jurisdictions, including the American National Quality Forum and the English National Health Service, (1, 2) have identified and reported lists of never events. The terminology and scope vary, but these reports have increasingly focused on events that are *reliably* preventable, rather than *sometimes* preventable. In Canada, Saskatchewan and Nova Scotia have been leaders in adopting similar patient safety event lists that include select never events. (3, 4) However, as a country we have not pursued agreement on a list of never events — until now.

Patient safety involves more than just never events, which account for only a small proportion of patient safety issues in health care settings. For example, patient safety also addresses *adverse events*, such as post-surgical infections and electrolyte imbalances. Such events may never be fully prevented but still can be reduced. But while patient safety must be addressed on a broad level, we also need to focus on incidents that can be prevented outright. (5)

In that spirit, our Never Events Action Team has sought consensus on the top priorities for Canadian never events in hospitals. The current focus is on events that can occur while a patient is admitted in hospital, where care providers have a higher amount of control over care. Events include aspects such as safe environments, surgical care and accurate drug administration.

Never events can raise the profile of patient safety and provide an opportunity to concentrate on reducing and eliminating these harmful events. An organizational culture that minimizes or eliminates never events is also likely to reduce other preventable harms.

Never events do not imply blame; “never” is a call-to-action, not a demand or an attempt to shame mistakes.

Rather, we encourage a culture of continuous quality improvement, where mistakes are openly reported, disclosure occurs routinely and open discussion and problem solving are encouraged, with patients and families as full and active participants.

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.

What follows here is the team’s final report outlining 15 never events for hospital care in Canada, as well as strategies that are effective in identifying and reducing these events.

A list of never events won’t solve anything on its own. For it to have meaning, we need to know when these events occur and harness the knowledge in hospitals across the country, the expertise of providers and the experiences of patients to prevent these events from occurring again.

Who We Are

In January 2014, the Canadian Patient Safety Institute (CPSI) brought together key health sector partners to form the National Patient Safety Consortium. The consortium strives to advance a national call to action for patient safety (6) and is made up of more than 50 Canadian health care groups that represent governments, health care professionals, patients and families, regulators, researchers, educators, enforcement agencies and national and provincial agencies and associations.

The consortium identified a number of actions, including that Health Quality Ontario would lead a group of partners to research and recommend a list of never events in Canadian health care. A number of organizations volunteered to join the Never Events Action Team, including:



The Newfoundland and Labrador Provincial Safety and Quality Committee and two representatives from Patients for Patient Safety Canada also participated on the Action Team. In addition, the College of Family Physicians Canada was engaged in this work and is open to future opportunities to identify the most frequent incidents that impact the safety of patients in primary and ambulatory care settings.

Our Approach

To benefit from a wide diversity of opinions and perspectives, the Never Events Action Team pursued a modified Delphi process to reach consensus. An initial environmental scan generated a list of potential events identified in other jurisdictions as never events, serious reportable events, critical events and related terms. In particular, we gathered events from Saskatchewan, Nova Scotia, the United Kingdom, United States (especially Minnesota), Australia, New Zealand and Global Patient Safety Alerts. The Action Team then agreed on a final candidate event list by addressing gaps, omitting duplication and removing events that were not deemed to be serious or reliably preventable. We erred on the side of inclusion, to advance events to the later surveying phase.

The team sought input from a number of stakeholder organizations on specific issues, such as accreditation, professional regulation and liability, and priorities in medication safety. The Canadian Institute for Health Information (CIHI) was also consulted on its hospital safety work, and the Institute for Safe Medication Practices Canada was instrumental in identifying five pharmaceutical-related events (David U, President, personal communication, March 3, 2015). Clinical input was an essential component of the work and was sought at all stages of the review.

The team considered the incidences of potential never events, based on existing evidence and experience from jurisdictions that specifically track and report never event occurrence, while recognizing the limitations of varying approaches to measurement, data availability and possible under-reporting. (7, 8) We also studied preliminary data from CIHI in-hospital patient safety analyses.

We used the candidate event list and stakeholder feedback to draft an online survey to gather input from health system stakeholders and care providers. Our goals were to determine whether events met the criteria for a never event, to establish priority areas of focus and to gather specific comments and suggestions. English- and French-language versions of the survey were created, and Action Team members distributed the survey to their networks, including health care workers, leaders, managers, patient safety and quality leads, researchers, policymakers, patients and families. At the end of the survey, we asked respondents to identify 10 events they believed to be of highest priority. We also requested they review a list of events deemed by the Action Team to be low priority, giving them the opportunity to disagree; in addition, we invited responders to submit any new events for consideration. We collected demographics to gauge representation from professional groups and across health sectors.

The criteria presented in the survey were modelled on the international uses of the term never events, adjusting for slight variances. Respondents were asked to rate each event based on the extent it met all of the following criteria:

- **Serious** – *A high risk that the event would cause serious harm or death (serious harm: a significant permanent change in the ability of patients to function as they did before the event)*
- **Recurring** – *The event is likely to happen to another patient if not addressed*
- **Identifiable** – *The event is easily recognized, clearly defined and not attributable to other possible causes*
- **Avoidable** – *Appropriate organizational barriers will prevent the event from occurring*

Following the environmental scan and Action Team review, 32 events were identified as potential never events and included in the pan-Canadian survey. In total, 158 surveys were completed (136 in English and 22 in French). Health care workers (45%) comprised the largest group of respondents, followed by

administrators/managers (40%). Of health care workers, 46% identified as physicians, 35% as nurses, 3% as pharmacists and 21% as “other.”

The Never Events Action Team reviewed survey results and reached agreement on which events to include or exclude, any exceptions to include in event definitions and areas for further exploration with clinical and policy experts. After further document review, we reached consensus on a set of proposed never events.

We posted the draft document online for public comment from June 17 through July 10, 2015. Action Team members notified stakeholders in their respective jurisdictions as well as contacting survey respondents, if they had elected to provide their contact information. Following the public comment period, the Action Team reviewed comments received and reached consensus on changes to the final list of never events. Appendix 1 outlines events that were considered, and the rationale for why they were ultimately not selected as never events.

Pan-Canadian Never Events

The Never Events Action Team presents the following list of 15 never events for hospital care in Canada.

1. **Surgery on the wrong body part or the wrong patient, or conducting the wrong procedure**

Examples of this event include surgery on the wrong side of the body, or a surgical procedure performed in the wrong patient due to a mislabelled biopsy sample or because two patients have the same name.

This event does not include surgery on the wrong spinal level as current intraoperative imaging can contribute to wrong-level incisions. Surgeries resulting from incorrect diagnoses are excluded from this event, as are surgeries altered to adjust for unexpected anatomical abnormalities.

2. **Wrong tissue, biological implant or blood product given to a patient**

This event refers to any incorrect tissue or device introduced into a patient’s body. This can include blood products and organs that are incompatible with a patient’s blood type, a wrong product or the wrong donor egg or sperm. This event does not include instances where a provider exercises clinical judgment to deviate from a surgical plan (i.e. intentionally opting for a different implant), or where the correct implant proves to be suboptimal following surgery.

3. **Unintended foreign object left in a patient following a procedure**

Examples of this event are a sponge or a towel left inside a patient after surgery and are never events regardless of whether harm occurred or not, or whether the object was discovered in hospital or after discharge. Instances where objects are intentionally left in a patient (e.g., sutures, stents, medical devices, or at the surgeon’s discretion due to risk of retrieval) are excluded from this never event, as are instances where an object was left in the patient following an emergency procedure but discovered by immediate post-operative imaging.

4. **Patient death or serious harm arising from the use of improperly sterilized instruments or equipment provided by the health care facility**

This event includes instances where a sterile instrument becomes contaminated prior to use (e.g., a patient receives an injection from a contaminated vial), and where equipment (e.g., a scope) is improperly cleaned.

Manufacturer contamination is *not* included in this event as this is an industrial safety concern, not an error at the point of care.

5. **Patient death or serious harm due to a failure to inquire whether a patient has a known allergy to medication, or due to administration of a medication where a patient’s allergy had been identified**

This event involves a situation where a patient is aware of a medication allergy but is given the medication anyway because either the hospital failed to ask about allergies, or because they knew about the allergy but failed to avoid administering that medication.

This event does not include instances where the allergy was unknown to the patient, or instances where a medication had to be administered in an emergency (e.g., contrast agents for imaging), or to an unconscious patient. However, it is important to acknowledge that harm from these emergency events can still be minimized by effective monitoring and response.

6. Patient death or serious harm due to the administration of the wrong inhalation or insufflation gas

This event includes the administration of the wrong gas due to any cause, such as provider error, a labelling error or the incorrect use of gas-specific connectors. These gases may be inhaled or blown into a body cavity, such as to sinuses or the abdomen.

7. Patient death or serious harm as a result of one of five pharmaceutical events

The following five pharmaceutical events represent errors that can result in serious consequences for patients:

- Wrong-route administration of chemotherapy agents, such as vincristine administered intrathecally (injected into the spinal canal)
- Intravenous administration of a concentrated potassium solution
- Inadvertent injection of epinephrine intended for topical use
- Overdose of hydromorphone by administration of a higher-concentration solution than intended (e.g., 10 times the dosage by drawing from a 10 mg/mL solution instead of a 1 mg/mL solution, or not accounting for needed dilution/dosage adjustment)
- Neuromuscular blockade without sedation, airway control and ventilation capability

8. Patient death or serious harm as a result of failure to identify and treat metabolic disturbances

This event will initially focus only on hypoglycaemia in an admitted patient and hyperbilirubinemia in neonates.

Metabolic disturbances occur when abnormal chemical reactions in the body (e.g., diabetes) interfere with important biological processes. Hypoglycaemia is also called low blood sugar and can result in extremely serious consequences such as seizures and death if not identified and managed. Hyperbilirubinemia occurs when the blood contains too much bilirubin (created when red blood cells break down). The condition is also known as jaundice and is a common condition in newborn babies. Symptoms can include the

newborn being sluggish and cranky and not feeding well and progress to serious harm, such as seizures and brain damage (kernicterus). While this event focuses only on in-patient cases, it is important to acknowledge that hyperbilirubinemia can also be diagnosed following discharge from hospital.

9. Any stage III or stage IV pressure ulcer acquired after admission to hospital

Pressure ulcers are also known as bed sores and they are categorized in four stages:

- Stage I — The skin is a slightly different colour, but there are no open wounds
- Stage II — The skin breaks open and an ulcer forms
- Stage III — The sore becomes worse and creates a crater in the tissue
- Stage IV — The sore is very deep causing extensive damage; these sores can harm muscle, bone and tendons

Stage III and IV ulcers can lead to serious complications such as infections of the bone or blood (sepsis).

10. Patient death or serious harm due to uncontrolled movement of a ferromagnetic object in an MRI area

Magnetic resonance imaging (MRI) equipment creates very powerful magnetic fields. When metallic and magnetic objects, such as metal in clothing, an implanted device, a pair of scissors, or even a hospital wheelchair are in the same area as an MRI machine they can become dangerous, rapidly moving projectiles that can injure or even kill patients.

A number of patient safety protocols exist that, once implemented, prevent these events from happening. (9-13)

11. Patient death or serious harm due to an accidental burn

This event includes burns that occur during the care process, such as those due to oxygen fires, unintended burns occurring during surgery, and heat or cold burns from assisted bathing, the use of hot or cold packs and wound care. This event does not include burns due to other environmental risks, such as patient use of kitchen equipment.

12. Patient under the highest level of observation leaves a secured facility or ward without the knowledge of staff

This event pertains only to patients whose condition (e.g., dementia, psychosis, at risk of suicide) requires them to be cared for in a secure facility or unit. It can involve a patient deliberately leaving the ward or facility, or accidentally wandering away.

13. Patient suicide, or attempted suicide that resulted in serious harm, in instances where suicide-prevention protocols were to be applied to patients under the highest level of observation

We recognize that suicide is not always preventable. Health facilities are not designed or resourced to continuously monitor a patient. However, in cases where a patient has been identified as being at high risk of suicide, monitoring and safe-environment protocols should be set and followed.

14. Infant abducted, or discharged to the wrong person

This event includes all instances where an infant is abducted or discharged to someone who is not the parent or legal guardian, or to a biological parent who does not have legal custody. In the latter case, the failure point would be not establishing legal status with the legal parent, or failing to check a documented status at discharge.

15. Patient death or serious harm as a result of transport of a frail patient, or patient with dementia, where protocols were not followed to ensure the patient was left in a safe environment

When frail patients or those with dementia are transported home or to another facility or ward, they must be left with appropriate support. It is crucial that those providing transport ensure the patient is left in a safe environment and with proper notification given to caregivers.

Using Never Events To Further Patient Safety

The Never Events Action Team has sought input from the public, including policymakers, patients and families, caregivers and health care providers. We have incorporated their input and produced this hospital never events list. However, this does not mark the end of our work, and will certainly not prevent incidents on its own.

Our Action Team does not hold authority to require changes to practice, nor should it.

Efforts to improve patient safety should be led by both the provincial/territorial and local health systems and, most importantly, the workers on the front lines of care.

Our work aims to provide some areas and targets for continually improving patient safety.

Providing care to patients is an inherently complex endeavour, and risk is an unavoidable part of care. Recognizing and addressing never events constitute only one aspect of efforts to provide safe care. The identification of never events is not intended to replace other efforts to ensure safe care; instead, it is meant to complement these efforts and provide a focus on which events can be prevented outright through strong clinical and organizational systems. The list is only a basis – depending on the institution and their patient safety culture and focus, they may include other events in this category. Boards should be monitoring other events that can and should be improved and might indeed be included in the never event category in the future.

We believe various strategies can be effective in identifying and reducing never events, including cultural changes, reporting and learning systems, identification of opportunities for improvement and continuous improvement supported by measurement and evaluation.

Culture

Our system must nurture just and trusting cultures that recognize that never events can occur but can also be prevented.

Organizations should support and provide an environment where health care professionals, staff, patients and families feel safe to report and discuss adverse events or system failures. Organizations should embrace these opportunities to learn and improve. Strong leadership within teams and organizations and the involvement of patients and families can and should propel this culture.

Reporting and Learning

Patient safety reporting requires quality data, which are more likely to be produced in environments where staff and patients feel safe to report and discuss adverse events and shortcomings in system safeguards. Organizations and stewards of the provincial and territorial health system should be encouraged to track

and report the incidence of never events to better understand how often they occur, facilitate prompt management and analysis of the events and follow progress over time. They should also be encouraged to publicly share what was learned from the review of events and their recommendations whenever it is permitted by relevant legislation. Efforts to prevent never events in one jurisdiction are undoubtedly of interest to other organizations across Canada and globally.

In the future, reporting could help inform revisions to this never event list. Reporting systems could also complement other broader patient safety measurement initiatives, such as those in Saskatchewan, British Columbia and Nova Scotia, and being pursued nationally by CIHI.

Identification of Opportunities for Improvement

Reporting and open discussion of never events should also help identify what can be done to avoid future occurrences and how patient safety can be improved.

A common focus on key never events can also encourage the sharing of best practices and quality improvement successes within and across organizations and geographies.

Continuous Improvement Supported by Measurement and Evaluation

Quality improvement is continuous and has no end point, just as there is no point where care is entirely free of risk. Ongoing measurement and evaluation are essential in assessing and furthering efforts. System stewards and care organizations should consider how to support this measurement, such as through training on how to measure rare events (e.g., time-between measurement) and measures of process improvement. (14)

Next Steps

The National Patient Safety Consortium will continue to promote the adoption and impact of this never events list. We will continue to publicize and promote awareness of never events with health system partners and service providers, align supports such as best practices in measurement, incident management and prevention, and ensure that the Canadian list of never events is relevant and updated. These updates will consider any new or improved data on occurrence and trends.

Two related pieces of work have also been identified as priorities. The first is to find a similar consensus on serious patient safety risks in primary and ambulatory care settings, recognizing that provider locus of control is lower than that found in acute care. Members of our Action Team have expressed an interest in pursuing work focused on minimizing risk.

Second, the National Patient Safety Consortium has from the outset seen value in a companion to never events: *always events*. These would indicate best practices that should always occur in the care process. Organizational checks like these can further strengthen patient safety in Canadian health care to prevent serious harm and loss of life.

The creation of this never events list is just a first step. We now call upon hospital administrators and staff to give life to this list by creating and adopting procedures that will help ensure these 15 events don't happen in Canadian hospitals.

Patients deserve our best efforts.

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Appendix I – Events Considered But Not Deemed To Be Never Events

- **Opioid overdose in hospitalized patients** — May not always be preventable using system barriers, even following proper execution of appropriate orders. Preference given instead to focusing on the specific risk of hydromorphone dosing
- **Maternal death due to post-partum hemorrhage after elective Caesarean section** — Not always entirely preventable due to undiagnosed underlying conditions (e.g., bleeding disorders) and complications
- **Maternal death or serious harm associated with labour or delivery in a low-risk pregnancy while the patient is in a health care facility** — Not always entirely preventable due to undiagnosed underlying conditions and complications. “Low risk” can very quickly become “high risk”
- **Patient death or serious harm associated with the use of contaminated drugs, devices or biologics provided by the health care facility, including generally detectable contaminants such as infectious matters or foreign substances, regardless of the source of contamination** — Better covered by the never event on improper sterilization. Concern that some instances of contamination result from manufacturer error, which is beyond the scope of never events
- **Patient death or serious harm due to a fire associated with oxygen use** — Better captured under the never event on accidental patient burns
- **Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist or other licensed health care provider** — This is a criminal act. Risk can be minimized, but this is hard to reliably prevent
- **Patient death or serious harm due to spinal manipulation while the patient is being cared for in a health care facility** — May not always be possible to anticipate or prevent this fully. If movement is therapeutic, there are concerns around necessary manipulation for surgery, how the event could be identified/attributed, known risk factors for manipulation therapy, etc.
- **Patient death or serious harm associated with a fall, while the patient is being cared for in a health care facility** — Not always avoidable. Fully preventing falls would require full restriction of a patient’s mobility, which carries its own health risks as well as concerns around personal freedom
- **Patient death or serious harm associated with an intravascular air embolism that occurs while the patient is being cared for in a health care facility** — Emboli are complications and can be difficult to fully prevent. There is concern involving central venous devices, as well as confused patients removing their own lines
- **Patient death or serious harm caused by the use of restraints or bed rails while the patient is being cared for in a health care facility** — Restraints are sometimes needed for both patient and health care worker protection. There is further concern about balancing risk of harm with benefits (e.g., restraints can prevent patient falls). Also, injuries are multi-factorial
- **Abduction of a patient of any age** — This is a criminal act. Risk can be minimized, but this is hard to reliably prevent in non-neonatal wards
- **Sexual assault of a patient at a health care facility** — This is a criminal act. Risk can be minimized, but this is hard to reliably prevent
- **Patient death or significant harm resulting from a physical assault (i.e., battery) that occurs at a health care facility** — This is a criminal act. Risk can be minimized, but this is hard to reliably prevent
- **Intraoperative or immediate postoperative death in healthy person (defined by the American Society of Anesthesiologists as a class I patient)** — Concern over underlying conditions (e.g., unknown arrhythmias) and unforeseen complications in otherwise-healthy patients. Not always preventable
- **Misuse of equipment resulting in patient harm** — Concern that this event is too broad. Never events will have greater impact on patient safety if they are specific to a known risk with clear methods of prevention
- **Harm as a result of improper patient transfer between units** — Focuses on continuity of care. Concern involves the attribution of error, as well as the strength of communication protocols to prevent the event