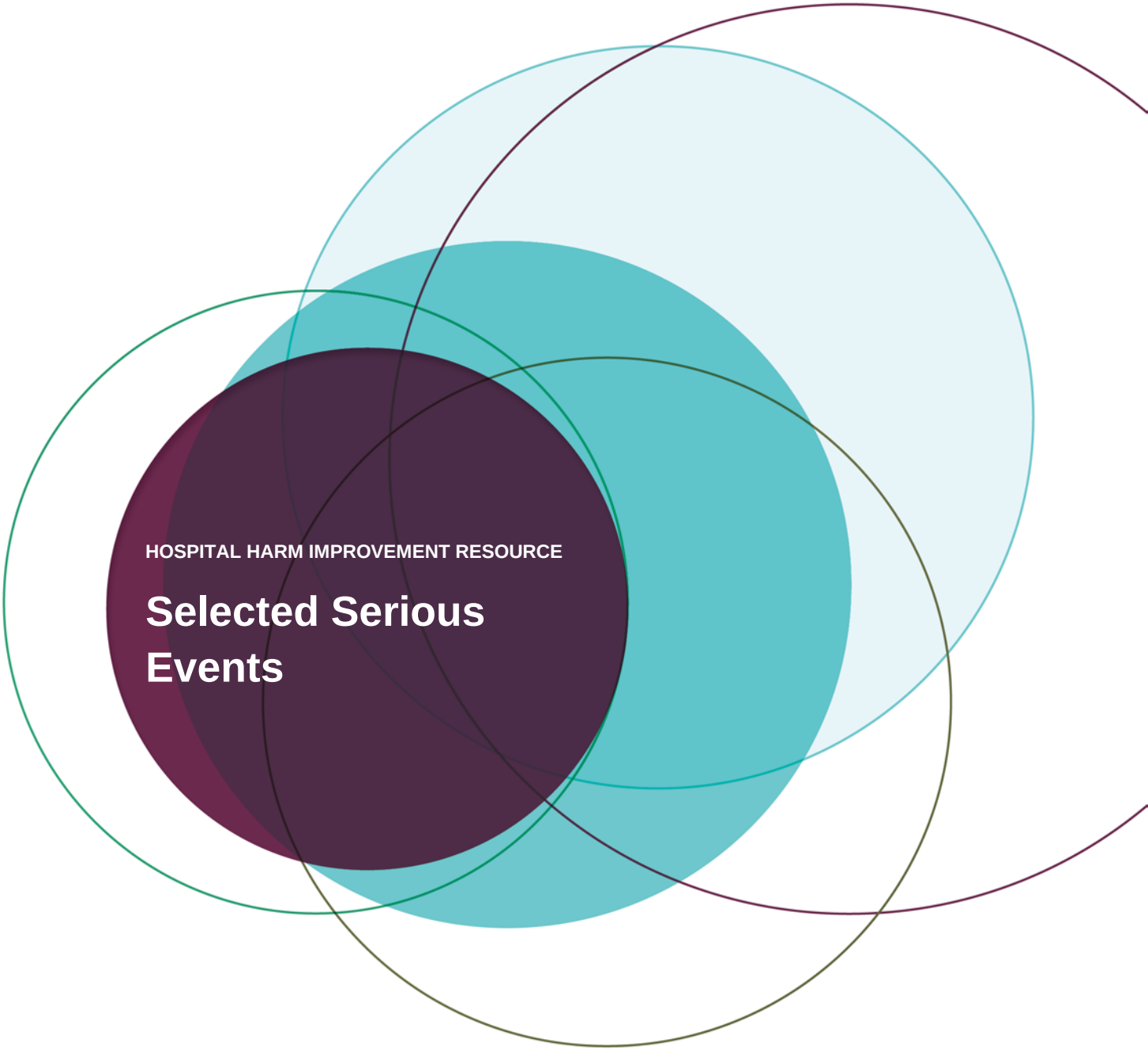

HOSPITAL HARM IMPROVEMENT RESOURCE

Selected Serious Events

cpsi icsp
Canadian Patient Safety Institute
Institut canadien pour la sécurité des patients

ACKNOWLEDGEMENTS

The Canadian Institute for Health Information and the Canadian Patient Safety Institute have collaborated on a body of work to address gaps in measuring harm and to support patient safety improvement efforts in Canadian hospitals.

The Hospital Harm Improvement Resource was developed by the Canadian Patient Safety Institute to complement the Hospital Harm measure developed by the Canadian Institute for Health Information. It links measurement and improvement by providing resources that will support patient safety improvement efforts.

DISCHARGE ABSTRACT DATABASE (DAD) CODES INCLUDED IN THIS CLINICAL CATEGORY:

D26: Selected Serious Events

Concept	Harm to patients resulting from failure of sterile precautions, contaminated medical or biological substances, failure in suture or ligature, wrong placement of endotracheal tube or performance of inappropriate operation.
Notes	This clinical group includes serious, largely preventable patient safety events that should not occur.
Selection criteria	
Codes	**Conditions**
Y62.0 Y62.1 Y62.2 Y62.3 Y62.4 Y62.5 Y62.6 Y64.– Y65.2 Y65.3 Y65.5	Identified as diagnosis type (9) **AND** at least 1 additional diagnosis coded as diagnosis type (2) **in the same diagnosis cluster**
Codes	**Code descriptions**
Y62.0	Failure of sterile precautions during surgical and medical care; during surgical operation
Y62.1	Failure of sterile precautions during surgical and medical care; during infusion or transfusion
Y62.2	Failure of sterile precautions during surgical and medical care; during kidney dialysis, or other perfusion
Y62.3	Failure of sterile precautions during surgical and medical care; during injection or immunization
Y62.4	Failure of sterile precautions during surgical and medical care; during endoscopic examination
Y62.5	Failure of sterile precautions during surgical and medical care; during heart catheterization
Y62.6	Failure of sterile precautions during surgical and medical care; during aspiration, puncture, and other catheterization
Y64.–	Contaminated medical or biological substances
Y65.2	Failure in suture or ligature during surgical operation
Y65.3	Endotracheal tube wrongly placed during anesthetic procedure
Y65.5	Performance of inappropriate operation

OVERVIEW AND IMPLICATIONS

Selected Serious Events and select Never Events in Canada

Patients expect safe care, and healthcare providers strive to deliver care that results in better health and safe, effective outcomes for patients. However, 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. Many of these events occur only rarely, but all can have a severe impact on the lives and well-being of patients. Health Quality Ontario (HQO), and the Canadian Patient Safety Institute (CPSI) partnered with several jurisdictions and organizations in Canada to create a list of 15 Never Events (NE). Never Events are patient safety incidents that result in serious patient harm or death and that are preventable using organizational checks and balances (HQO & CPSI, 2015).

The selected serious events included in this resource are:

- Failure of sterile precautions during surgical and medical care during:
    - surgical operation*
    - infusion or transfusion
    - kidney dialysis or other perfusion
    - injection or immunization
    - endoscopic examination
    - heart catheterization
    - aspiration, puncture, and other catheterization
- Contaminated medical or biological substances
- Failure in suture or ligature during surgical operation
- Endotracheal tube wrongly placed during anesthetic procedure
- Performance of inappropriate operation*

  * Correspond with Never Events #1 and #4: NE #1 surgery on the wrong body part or the wrong patient or conducting the wrong procedure. NE #4 patient death or serious harm arising from the use of improperly sterilized instruments or equipment provided by the healthcare facility.

Failure of sterile precautions

The purpose of maintaining sterile precautions is to reduce the number of microbes present to as few as possible. The sterile field is used in many situations outside the operating room as well as inside the operating room when performing surgical cases. Sterile fields should be used outside the operating room when performing any procedure that could introduce microbes into a patient. A few examples of this would be inserting a foley catheter, an arterial line, and a central line. Inside the operating room, sterile fields are created relative to the back table, the mayo stand, and

finally the patient and the surgical site itself (Tennant, 2021). Failure of sterile precautions during medical and surgical procedures has resulted in the spread of infection and disease transmission. This has led to increased morbidity and mortality for patients as well as increased length of stay and increased costs (Siegel, Rhinehart, Chiarello et al., 2007, Ontario Agency for Health Protection and Promotion, 2013).

Aseptic, Sterile, and clean techniques

Historically, the practice of protecting patients from contamination and infection during clinical procedures has generated an inaccurate and confusing paradigm based on the terminology of sterile, aseptic, and clean techniques. The use of accurate terminology is important in order to promote clarity in practice (National Health and Medical Research Council - NHMRC, 2019). The Australian Guidelines for the Prevention and Control of Infection in Healthcare (NHMRC, 2019) offers the following definitions:

> **Sterile 'Free from microorganisms'** Due to the natural multitude of organisms in the atmosphere it is not possible to achieve a sterile technique in a typical healthcare setting. Near sterile techniques can only be achieved in controlled environments such as a laminar air flow cabinet or a specially equipped theatre. The commonly used term, 'sterile technique' (i.e., the instruction to maintain sterility of equipment exposed to air), is obviously not possible and is often applied inaccurately.
>
> **Asepsis 'Freedom from infection or infectious (pathogenic) material'** An aseptic technique aims to prevent pathogenic organisms, in sufficient quantity to cause infection, from being introduced to susceptible sites by hands, surfaces and equipment. Therefore, unlike sterile techniques, aseptic techniques are possible and can be achieved in typical hospital and community settings.
>
> **Clean 'Free from dirt, marks or stains'** Although cleaning followed by drying of equipment and surfaces can be very effective it does not necessarily meet the quality standard of asepsis. However, the action of cleaning is an important component in helping render equipment and skin aseptic, especially when there are high levels of contamination that require removal or reduction. To be confident of achieving asepsis an application of a skin or hard surface disinfectant is required either during cleaning or afterwards.

The aim of any aseptic technique is asepsis.

As defined above, aseptic technique is the purposeful prevention of transfer of microorganisms from the patient's body surface to a normally sterile body site or from one person to another by keeping the microbe count to an irreducible minimum. Aseptic techniques are measures designed to render the patient's skin, supplies and surfaces maximally free from microorganisms. Such practices are used when performing procedures that expose the patient's normally sterile sites (e.g., intravascular system, spinal canal, subdural space, urinary tract) in such a manner as to keep them free from microorganisms (NHMRC, 2019; PHAC, 2012).

To practice safely it is essential that healthcare workers understand the principles and practice of aseptic technique. An example of an aseptic technique is Aseptic Non-Touch Technique (ANTT),

a comprehensively defined practice framework for aseptic technique developed by the Association for Safe Aseptic Practice (The-ASAP, 2015).

Sterilizations of medical and surgical instruments and equipment: Infection is a major risk of surgery and despite modern technologies and procedures, infections related to improper equipment reprocessing still occur.

Achieving effective disinfection and sterilization is essential for ensuring that medical and surgical equipment/devices do not transmit infectious pathogens to clients/patients/residents or staff. The goals of safe reprocessing of medical equipment/devices include:

- preventing transmission of microorganisms to personnel and clients/patients/ residents.
- minimizing damage to medical equipment/devices from foreign material (e.g., blood, body fluids, saline, and medications) or inappropriate handling (Ontario Agency for Health Protection and Promotion, 2013).

Contaminated medical or biological substances

The tainted blood tragedy is one of the worst public health disasters that Canada has ever faced. When AIDS appeared in the early 1980s and soon became an epidemic, the entire Canadian blood supply system was affected. More than 1,100 transfused Canadians were infected by HIV, of whom 700 had hemophilia and other bleeding disorders, and 400 were transfusion recipients for other reasons (trauma, surgery, childbirth, cancer). Up to 20,000 were infected with the hepatitis C virus (HCV) through blood and blood products before testing was introduced in 1990 (Canadian Hemophilia Society, retrieved April 2021). This tragedy led to the Royal Commission of Inquiry on the Blood System in Canada, led by Justice Horace Krever. In 1997, Justice Krever tabled his report in the House of Commons, putting forward a set of 50 recommendations that, to this day, guide the blood system to ensure safety for all Canadians (Canadian Blood Services-Transfusion, 2019).

The transplantation of a human tissue allograft introduces the risk of complications to the recipient including the fatal and nonfatal transmission of infectious organisms such as bacteria, fungi, viruses, parasites, and prions. Tissue banks are considered to be manufacturers of human biologics where donor tissue is processed and enhanced using good manufacturing practices and good tissue practices to optimize safety and clinical outcomes. As biological manufacturers of tissue allografts that present a risk of disease transmission, tissue bank practices that reduce and eliminate infectious organisms must be effective, evidence-based and validated (Canadian Blood Services- Organs and Tissues, 2016).

Failure in suture or ligature during surgical operation

Most of the knot and suture failures exist due to technical errors in tying and wrong selection of sutures or knots in different scenarios. Common failure modes of knots and sutures are suture breakage, knot loosening, knot breakage, and tissue breakage. Failure of any of these factors can destroy the repair construct (Öçgüder, 2018).

Endotracheal tube wrongly placed during anesthetic procedure

Endotracheal intubation is a routine procedure in anesthetic care. Immediate verification of endotracheal placement of the ETT is necessary as esophageal or endobronchial intubation is a significant source of avoidable anesthetic-related morbidity and mortality (Miller, 2015). Serious complications can occur from inadvertent placement of the endotracheal tube in a main stem bronchus, such as hypoxemia caused by atelectasis formation in the unventilated lung and hyperinflation and barotrauma with development of a pneumothorax of the intubated lung. Proper positioning of the endotracheal tube in relation to the carina is clinically important (Sitzwohl et al, 2010).

Performance of inappropriate operation*

Surgery on the wrong body part or the wrong patient or conducting the wrong procedure: Surgery is one area of healthcare in which preventable medical errors and near misses can occur. Of great concern is wrong-site surgery (WSS), which encompasses surgery performed on the wrong side or site of the body, wrong surgical procedure performed, and surgery performed on the wrong patient. WSS has also been defined as a sentinel event (i.e., an unexpected occurrence involving death or serious physical or psychological injures, or the risk thereof) by the Joint Commission, which found WSS to be the third-highest-ranking event (Mulloy & Huges, 2008).

Wrong site surgeries have been associated with the failure to identify incorrect information in the documents related to surgery, such as the schedule, consent, and patient's history and physical examination. The opportunities for wrong site surgery are minimized when all the information is in agreement, and when all members of the operating room (OR) team assume a personal responsibility for the procedure (Pennsylvania Patient Safety Authority, 2007). The Pennsylvania Patient Safety Authority study (Yonash, 2020) showed that the frequency of WSS varied according to a range of variables, including error type (e.g., wrong side, wrong site, wrong procedure, wrong patient); year; facility type; hospital bed size; hospital procedure location; procedure; body region; body part; and clinician specialty. Many clinicians, patient safety professionals, and organizations take the position that WSS events are preventable and should never occur (Yonash, 2020).

Distractions and/or interruptions related to human communication, equipment such as surgical alarms or technology (e.g., phone calls, pagers) are a threat to patient safety in the OR as they have been found to contribute to patient safety incidents and have been reported to be linked to wrong-side surgery and wrong-site surgery. Guidelines and tools have been developed by perioperative professional associations and patient safety agencies to limit and/or ameliorate the negative impact of distraction and these include application of the “sterile cockpit” concept from aviation, reducing distractions from technology and noise, use of surgical safety checklists and briefings and teamwork training. Engagement of surgeons and multidisciplinary teams is necessary to address the problem of distractions in the OR (Pennsylvania Patient Safety Authority, 2014).

Unnecessary/obsolete procedure involves the performance of a surgery that was deemed unnecessary given the clinical situation. It may also involve the performance of a procedure or the

use of a technique that is no longer considered to be standard. The performance of an unnecessary or an obsolete procedure may be related the failure of monitoring individual surgeon's practices or due to a misinterpretation of diagnostic tests (HIROC, 2016).

GOAL

Reduce the incidence of serious selected events captured in this clinical group.

IMPORTANCE FOR PATIENTS AND FAMILIES

Patients expect hospital care to be safe, and for most hospital stays 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. When patients are harmed in hospital, they can experience increased length of stay and are at an increased risk for morbidity and mortality. 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 (CIHI & CPSI, 2016). Patients need to take an active role in their healthcare to prevent errors. Although wrong-site surgery is rare it still can occur. Communication between the healthcare team and the patient is important (Pennsylvania Patient Safety Authority, 2018).

Patient Story

Brampton Civic Hospital operates on wrong leg

A Brampton family is frustrated after their 72-year-old grandmother had the wrong leg cut open during surgery on Christmas Day at the city's new hospital. Amar Kaur Brar, 72, fractured her thigh bone when she slipped from the stairs at the family's Brampton home, her granddaughter Kanwaljot Brar, 21, told The Sun yesterday. "In the operating room, doctors cut Amar's right leg open," Brar said, adding the cut ran almost the entire length of her grandmother's thigh. When they realized that the bone in Amar's right leg was okay, they stitched her up and performed surgery on her left leg….

For case studies of various "Selected Serious Events" refer to Appendix A.

CLINICAL AND SYSTEM REVIEWS, INCIDENT ANALYSES

Given the broad range of potential causes of hospital associated selected serious events, clinical and system reviews should be conducted to identify latent causes and determine appropriate recommendations.

Occurrences of harm are often complex with many contributing factors. Organizations need to:

1. Measure and monitor the types and frequency of these occurrences.
2. Use appropriate analytical methods to understand the contributing factors.

3. Identify and implement solutions or interventions that are designed to prevent recurrence and reduce risk of harm.
4. Have mechanisms in place to mitigate consequences of harm when it occurs.

To develop a more in-depth understanding of the care delivered to patients, chart audits, incident analyses and prospective analyses can be helpful in identifying quality improvement opportunities. Links to key resources for conducting chart audits and analysis methods are included in the Hospital Harm Improvement Resource Introduction.

If your review reveals that your cases of selected serious events are linked to specific processes or procedures, you may find these resources helpful:

- Agency for Healthcare Research and Quality (AHRQ) www.ahrq.gov
  - Never events [Internet]. Rockville (MD): The Agency; 2014 [updated 2019 Sept;]. Available from: https://psnet.ahrq.gov/primer/never-events
- American College of Surgeons https://facs.org
  - *National surgical quality improvement program*. www.facs.org/quality-programs/acs-nsqip
- American Society for Gastrointestinal Endoscopy https://www.asge.org/
  - *Guidelines* http://www.asge.org/publications/publications.aspx?id=352
- American Society of Anesthesiologists. www.asahq.org
- Association for Safe Aseptic Practice (THE-ASAP)
  - Asceptic Non-Touch Techniquie (Antt) http://www.antt.org
  - *Aseptic non touch technique: The ANTT clinical practice framework*. London; The-ASAP; 2015. http://www2.nphs.wales.nhs.uk:8080/WHAIPDocs.nsf/61c1e930f9121fd080256f2a004937ed/e4528983f2eddd3a80257f10003dd2f3/$FILE/ANTT%20Framework%20v4.0.pdf
- Association of Perioperative Registered Nurses (AORN) https://www.aorn.org
  - *Wrong site surgery.* https://www.aorn.org/education/staff-development/prevention-of-sentinel-events/wrong-site-surgery
- Association of Surgical Technologists (AST) https:/www.ast.org/
  - Association of Surgical Technologists. *Standards of practice for the decontamination of surgical instruments.* AST; 2009. http://www.ast.org/uploadedFiles/Main_Site/Content/About_Us/Standard_Decontamination_%20Surgical_Instruments_.pdf
  - Association of Surgical Technologists. *AST standards of practice for packaging material and preparing items for sterilization.* AST; 2009. http://www.ast.org/AboutUs/Sterilization_and_Disinfection/
- Canadian Anesthesiologists' Society www.cas.ca
  - *Guidelines.* http://www.cas.ca/English/Guidelines

- Canadian Association of Gastroenterology www.cag-acg.org
  - *Guideline library.* https://www.cag-acg.org/membership/publications/guideline-library
- Canadian Association of Interventional Cardiology http://caic-acci.org/
- Canadian Blood Services - Professional Education https://professionaleducation.blood.ca/en
  - Clinical Guide to Transfusion. 2019. https://professionaleducation.blood.ca/en/transfusion/clinical-guide-transfusion
  - Bioburden Reduction and Control in Tissue Banking. *Leading evidence based practice guidelines for: tissue recovery, microbial sampling, processing of musculoskeletal tissue, processing of cardiac tissue, processing of skin tissue.* November 2016. https://professionaleducation.blood.ca/en/organes-et-tissus/pratiques-phares-et-directives-cliniques/tissus/bioburden-reduction-and-control
- Canadian Medical Protective Association https://www.cmpa-acpm.ca/en
  - Canadian Medical Protective Association (CMPA), Healthcare Insurance Reciprocal of Canada (HIROC). *Surgical safety in Canada: A 10-year review of CMPA and HIROC medico-legal data*. CMPA, HIROC; 2016. http://www.patientsafetyinstitute.ca/en/toolsResources/Surgical-Safety-in-Canada/Pages/default.aspx
  - *Good practice guide*. https://www.cmpa-acpm.ca/serve/docs/ela/goodpracticesguide/pages/index/index-e.html
- Canadian Patient Safety Institute www.patientsafetyinstitute.ca
  - National Patient Safety Consortium. Never Events for Hospital Care in Canada. September 2015. https://www.patientsafetyinstitute.ca/en/toolsResources/NeverEvents/Pages/default.aspx
- Canadian Society of Nephrology. https://www.csnscn.ca/committees/clinical-practice-guidelines/library
- Canadian Standards Association (CSA) http://www.csagroup.org/
  - Blood and Blood Products and Cells, Tissues and Organ Transplantation. https://www.csagroup.org/store/search-results/?search=all~~Blood%20and%20Blood%20Products%20and%20Cells,%20Tissues%20and%20Organ%20Transplantation
- Canadian Vascular Access and Association http://www.cvaa.info/
- Centers for Disease Control and Prevention. www.cdc.gov
  - O'Grady NP, Alexander M, Burns LA, et al. *Guidelines for the prevention of intravascular catheter-related infections, 2011.* Centers for Disease Control and Prevention; 2011. http://www.cdc.gov/hicpac/pdf/guidelines/bsi-guidelines-2011.pdf

- Difficult Airway Society https://das.uk.com/
    - Difficult Airway Society (DAS). *Guidelines for management of unanticipated difficult intubation in adults 2015.* DAS; 2015. https://www.das.uk.com/guidelines/das_intubation_guidelines
- Gastrointestinal Endoscopy www.giejournal.org
    - ASGE Ensuring Safety in the Gastrointestinal Endoscopy Unit Task Force, Calderwood AH, Chapman, et al. Guidelines for safety in the gastrointestinal endoscopy unit. *Gastrointest Endosc.* 2014; 79 (3): 363-372. doi: 10.1016/j.gie.2013.12.015. http://www.asge.org/assets/0/71542/71544/4a572112-29a4-4313-8ab8-b7801e8f84e2.pdf
    - ASGE Standards of Practice Committee, Banerjee S, Shen B, et al. Infection control during GI endoscopy. *Gastrointest Endosc.* 2008; 67 (6): 781-790. doi: 10.1016/j.gie.2008.01.027. http://www.asge.org/assets/0/71542/71544/51E78060-CD85-4281-B100-6ABEBCB04C49.pdf
    - Reprocessing Guideline Task Force, Petersen BT, Cohen J, et al. Multisociety guideline on reprocessing flexible GI endoscopes: 2016 update. *Gastrointest Endosc.* 2017; 85 (2): 282-294. doi: 10.1016/j.gie.2016.10.002. http://www.giejournal.org/article/S0016-5107(16)30647-2/fulltext
- Infection Prevention and Control (IPAC) Canada. www.ipac-canada.org
- Joint Commission www.jointcommission.org
    - The universal protocol for preventing wrong site, wrong procedure, and wrong person surgery™: Guidance for health care professionals. The Joint Commission; 2012. https://www.jointcommission.org/assets/1/18/UP_Poster1.PDF
- National Health and Medical Research Council (NHMRC) www.nhmrc.gov.au
    - National Health and Medical Research Council (NHMRC). Australian guidelines for the prevention and control of infection in healthcare. Commonwealth of Australia; 2019. https://www.nhmrc.gov.au/about-us/publications/australian-guidelines-prevention-and-control-infection-healthcare-2019
- National Institute for Health and Care Excellence (NICE). www.nice.org.uk
- Operating Room Nurses Association of Canada www.ornac.ca
- Pennsylvania Patient Safety Authority http://patientsafety.pa.gov/
    - Patient safety topics – Wrong Site Surgery 2018. http://patientsafety.pa.gov/pst/Pages/Wrong%20Site%20Surgery/hm.aspx?psapst=Wrong-Site%20Surgery
    - Patient safety topics – Intubation. http://patientsafety.pa.gov/pst/Pages/Intubation/hm.aspx#
    - Yonash, R., &Taylor, M. (2020). Online Supplement to “Wrong-Site Surgery in Pennsylvania During 2015–2019: A Study of Variables Associated With 368

Events From 178 Facilities." Patient Safety. 2(4), i-x. https://doi.org/10.33940/supplement/2020.12.10

- Pennsylvania Patient Safety Authority. Distractions in the operating room. *Pa Patient Saf Advis.* 2014; 11 (2): 45-52. http://patientsafety.pa.gov/ADVISORIES/Pages/201406_45.aspx
- Pennsylvania Patient Safety Authority. Insight into preventing wrong-site surgery. *Pa PSRS Patient Saf Advis.* 2007; 4 (4): 109, 112-23. http://patientsafety.pa.gov/ADVISORIES/Pages/200712_109b.aspx

- Public Health Agency of Canada. http://www.phac-aspc.gc.ca/index-eng.php
  - Public Health Agency of Canada (PHAC). *Routine practices and additional precautions for preventing the transmission of infection in healthcare settings*. Ottawa, ON: PHAC; 2012. http://publications.gc.ca/collections//collection_2013/aspc-phac/HP40-83-2013-eng.pdf
- Public Health Ontario https://www.publichealthontario.ca/
  - Provincial Infectious Diseases Advisory Committee. https://www.publichealthontario.ca/en/BrowseByTopic/InfectiousDiseases/PIDAC/Pages/PIDAC.aspx
- Royal College of Anaesthetists www.rcoa.ac.uk
  - Safety, standards, and quality. https://www.rcoa.ac.uk/safety-standards-quality
- World Health Organization (WHO) www.who.int
  - *WHO guidelines for safe surgery: Safe surgery saves lives 2009*. Geneva: WHO; 2009. http://apps.who.int/iris/bitstream/10665/44185/1/9789241598552_eng.pdf

MEASURES

Vital to quality improvement is measurement, and this applies specifically to implementation of interventions. The chosen measures will help to determine whether an impact is being made (primary outcome), whether the intervention is being carried out (process measures), and whether any unintended consequences ensue (balancing measures).

In selecting your measures, consider the following:

- Whenever possible, use measures you are already collecting for other programs.
- Evaluate your choice of measures in terms of the usefulness of the results and the resources required to obtain them; try to maximize the former while minimizing the latter.
- Try to include both process and outcome measures in your measurement scheme.
- You may use different measures or modify the measures to make them more appropriate and/or useful to your setting. However, be aware that modifying measures may limit the comparability of your results to others.

- Posting your measure results within your hospital is a great way to keep your teams motivated and aware of progress. Try to include measures that your team will find meaningful and exciting (IHI, 2012).

GLOBAL PATIENT SAFETY ALERTS

Global Patient Safety Alerts (GPSA) provides access and the opportunity to learn from other organizations about specific patient safety incidents including alerts, advisories, recommendations, and solutions for improving care and preventing incidents. Learning from the experience of other organizations can accelerate improvement.

Recommended search terms:

- Surgical safety
- Wrong site surgery
- Serious events
- Sterilization
- Aseptic
- Infection
- Intubation
- Suture failure
- Contaminated

SELECTED SERIOUS EVENTS SUCCESS STORIES

Building a culture of safety in the operating room

At the foundation of successful patient safety and quality improvement efforts is a culture of patient safety within the hospital or surgical center. A strong safety culture can help minimize medical errors and strong support from leadership is crucial to truly moving the needle on patient safety and quality.

Minnesota hospitals and ambulatory surgery centers performed 2 .6 million invasive procedures during the 2012-13 reporting year, including procedures in the operating room, radiology, diagnostic/labs, and other settings. Dr. Mark Migliori, chair of the perioperative safety committee at Abbott Northwestern Hospital in Minneapolis, part of Allina Health, believes a culture of safety is a prerequisite for delivering good care for every patient, every procedure, every time.

“Patients deserve for safety to be front and center,” said Dr. Migliori. “It is the essential first step. They are entrusting us with their care and implicit in that trust is that we will be their guardian when they are under our care.” He believes surgeon leadership is critical in building a culture of safety in the operating room. While Minnesota hospitals and surgical centers have done a great job of developing multidisciplinary teams where everyone has a voice, some traditional hierarchies still persist.

“On one hand, the surgeon should have the same role as other team members in building a culture of safety,” said Dr. Migliori. “In reality though, the surgeon has the capability to level the hierarchy within the operating room. By acting as a servant leader yourself — sharing power, putting the needs of others first and helping people develop and perform as highly as possible — it sends the message to the rest of the team that their professionalism demands the emphasis on safety.” By fostering a culture that enables staff to feel comfortable to speak up, Dr. Migliori feels listening goes a long way in giving people a voice.

“One of the most obvious steps we can take is to listen — to let staff talk,” he says. “We create so many barriers to let someone give their opinion. We need to break down those barriers and then give them a place to carry their idea forward.” As a leader, Dr. Migliori hears the suggestion or concern and then gives the staff member ownership to carry the idea forward. He also feels it is important to recognize people when they speak up, as it creates a positive outcome. That’s why he feels it is important to talk about near misses and recognize the person who caught it. “It sends the message that people are watching and this is important,” says Dr. Migliori.

Dr. Migliori gives the example of the early days of implementing one of components of the Universal Protocol — the team briefing process. As chief of staff, he embraced the concept, yet was initially resistant to the idea that everyone needed to introduce themselves, feeling that people on the team already knew one another. Others felt strongly about its importance and so the team kept that critical piece of the protocol in place. He soon realized its significance. “It helps people talk. When the tech introduces herself, it gives her a reason to talk. So next time there’s a reason to speak up for safety, she’s less intimidated to do so,” he explained. “When you don’t know someone well, you’re less likely to speak up and question them.”

Dr. Migliori says a strong leader is one who has balance. Balance between confidence and humility; competence and being unsure enough to look at a situation from a different angle; and someone who is passionate and yet can observe and allow others to impact. A strong leader is always looking to give a voice to those who don’t have one, and advocating for those who are the most vulnerable, whether it is staff, a patient or someone else.

Building a culture of safety takes continuous improvement. Hospitals and staff must be willing to constantly re-evaluate what they’re doing and say, what can we do to make it better? Dr. Migliori feels it’s good to have the awareness that mistakes can happen at any time. It’s realizing that while you’re good, it’s not good enough. “Any organization that does safety work has glimpses of a safety culture,” he says. “It’s maintaining it that is hard. And that takes energy and humility.”

Collaboration and communication are key to driving forward a culture of safety. Dr. Migliori encourages surgeon leaders to discard old approaches where members of the team are separate and instead create opportunities for groups to come together and have a dialogue around safety. “We must create the constant message that we’re in this together. It all falls to communication and doing everything you can to enable voices to be heard,” he says. “I’m so appreciative of the effort to make safety culture bigger than hospital versus hospital, but rather something that if we want to provide care in Minnesota, this is the standard.”

(Minnesota Department of Health, 2014)

Utilization of Safety Crosses as a Quality Management Tool in Sterile Processing Department

At Markham Stouffville Hospital the Sterile Processing Department is responsible for the decontamination, cleaning, reprocessing and sterilization of instruments and equipment for the entire hospital. The Sterile Processing Department follows stringent criteria, best practice guidelines and standards to ensure the delivery of quality safe services to stakeholders such as the Operating Room and the Emergency Department. The department's commitment to safety and quality aligns with the hospital's belief statement "we must deliver safe, high quality care".

Although the department strives to exceed standards of practice, frontline staff identified the following two gaps:

1. Audit results such as instrument set error rate, missing chemical indicators, sterilization record accuracy and the frequency of sharps being found on used/soiled trays were inconsistently tracked and shared with frontline staff.
2. The lack of a systematic process such as a weekly audit tool to capture all reprocessing volume/activities, including thermal and high level disinfection, sterilization, weekly testing, and maintenance, and descaling of reprocessing equipment such as instrument, ultrasonic and cart washers.

Simultaneously, while the Sterile Processing Department was exploring solutions to the above concerns, some of the acute inpatient units were implementing Releasing Time to Care. Releasing Time to Care is a process used to capture and report quality outcome indicators such as falls and pressure ulcer rates. The Sterile Processing Department, after visiting these acute inpatient units, adopted the Safety Crosses as a format to capture and disseminate the audits results as outlined above in Gap 1. The team also developed a weekly departmental audit tool to monitor and report their various departmental reprocessing volumes and activities as noted above in Gap 2.

After many months of hard work, the department now boasts a quality board that proudly displays their four Safety Crosses: instrument/set errors, missing chemical indicators (internal and external), sterilization completion and accuracy rates and sharps sent to the Sterile Processing Department by end-users. The quality board also serves as a mode to track and report the department's weekly reprocessing activities and volume. Staff now has immediate access to reports and audits results. They are also a part of the process because they actively complete the Safety Crosses on a daily basis. Through education, completion of iReports and direct follow-ups with sending departments, the team has noticed a decline in the frequency in which sharps are returned to Sterile Processing Department.

(Health Standards Organization, 2013)

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APPENDIX A: HIROC CASE STUDIES

Case Studies – Sterility/Reprocessing

Case 1 – Shortly after an uneventful surgery for a total hip arthroplasty, a 62-year-old patient experienced abrupt neurological deterioration. She was transferred to the intensive care unit and diagnosed with acute Streptococcus meningitis. The patient sustained an acquired brain injury with severe frontal lobe impairment. Investigations into the incident showed the meningitis was likely caused by a break in aseptic technique during the time of the epidural anesthesia. During anesthesia induction, the anesthesiologist wore a mask and gloves, however the nurse involved, who had set up for the epidural and remained in a supportive role for the patient, had not washed her hands and did not wear gloves, a gown, or a cap.

Case 2 – A number of patients were operated on with instruments that were not properly sterilized. This was discovered post operatively, when OR staff checked the sterilization indicator strips on the instrument packages and noticed that the strips had not changed colour as they should have. A review of the incident revealed that the sterilizer had not reached the appropriate temperature during a sterilization cycle. It was also determined that staff responsible for sterilizing instruments were not appropriately certified and that OR staff did not routinely check monitoring strips to ensure instruments had been properly sterilized.

Case 3 – A number of instrument trays used in at hospital's labour and delivery program were not reprocessed prior to use. The instruments had been washed, cleaned and heat disinfection in the automatic washer but not sterilized as evident by the fact the autoclave tape had not changed colour. The unsterile equipment was used during vaginal deliveries and episiotomy repairs; 20 maternal patients and 20 infants were potentially affected. Disclosure was made. Expert infectious disease specialist assessed the risk to the patient as extremely low however all were advised to have scheduled blood testing and receive prophylactic medication.

Case 4 – Instruments used during an orthopedic surgery were not properly sterilized before use on another patient undergoing spinal-related surgery. The instrument was cleaned and placed in a flash sterilizer however the indicator was not checked, and it was subsequently discovered that the sterilization cycle had not run. Disclose was made three days after the event. The patient was advised to have scheduled blood testing and receive prophylactic medication.

Case 5 – The case involves three machines used to clean scopes. The manufacturer required both disinfectant and detergent. When the machines needed chemical replacement, the technician loaded two containers of detergent (versus one detergent and one disinfectant). The error was identified nine days later. Over 150 patients were potentially exposed. Given the need for a large scale disclosure, expert legal counsel was involved, and a process was established to immediately notify the exposed patients. The patients were advised to have scheduled blood testing and receive prophylactic medication. While there was no evidence of seroconversion, the patients initiated legal action claiming fear of contracting the disease and associated stress.

(HIROC, 2012)

Case Studies: Wrong Patient/Site/Procedure

Case 1 – The wrong baby at a hospital was circumcised, an unfortunate incident compounded by the fact that the family's religious beliefs did not permit circumcisions. Review of the case found that the consent form on the health record belonged to another baby. Both the nurse and the physician did not verify the baby's identification before the procedure and the physician failed to correctly obtain consent from the parents. The hospital policy at the time was that two patient identifiers should be verified but timeouts were not occurring in the birthing centre. Liability was split amongst the members of the healthcare team involved in the procedure.

Case 2 – A patient was booked for a right knee arthroscopy. An incision was made on the left knee before the error was noticed. Once the error was realized, a decision was made to carry out the procedure on both knees because there was some damage to the left knee as well. This confined the patient to a wheelchair for a number of weeks and extended the patient's course of physiotherapy. The patient's recovery was complicated by an infection in the left knee. Review of the case revealed that although the surgeon marked the correct knee and consent was for the right knee, a tourniquet was applied to the wrong knee. In addition, a three-phase surgical safety checklist was not completed in its entirety.

(HIROC, 2016)

Case Studies: Unnecessary/Obsolete Procedures

Case 1 – Over the course of several years, a number of female patients expressed their concern regarding surgeries provided by a surgeon. Allegations included that the organization failed to monitor the surgeon's practices and continued to grant privileges despite known complaints and claims related to unnecessary hysterectomies, oophorectomies, and loss of reproductive capability. Focusing on the surgeon's overall practice, experts suggested the physician had a tendency to perform surgical procedures where the average prudent surgeon would have elected to provide medical treatment or no treatment at all. Several lawsuits, including class-actions, were commenced.

Case 2 – A hospital's surgical program leaders noticed an increased number of a particular gynecological procedure being performed over a three-year period by one surgeon. An internal review was conducted which revealed some concerns. Unfamiliar with the procedure, the Chief of Staff requested external expert reviews to help determine the appropriateness of the procedure. The reviews suggested the procedure had been considered 'unacceptable' for over 10 years. Based on the findings, the surgeon's privileges were not renewed. Patient disclosure took place. The hospital did not have a system in place at the time to proactively identify whether a surgeon was performing an obsolete procedure. Multiple class-action proceedings were commenced.

(HIROC, 2016)