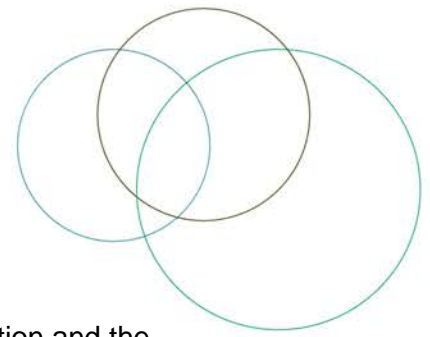




HOSPITAL HARM IMPROVEMENT RESOURCE

Selected Serious Events



ACKNOWLEDGEMENTS

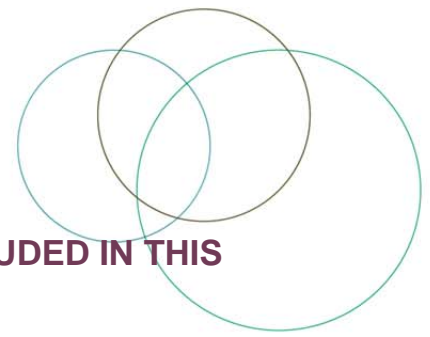


The Canadian Institute for Health Information and the Canadian Patient Safety Institute have collaborated on a body of work to address gaps in measuring harm and to support patient safety improvement efforts in Canadian hospitals.

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

The Canadian Patient Safety Institute acknowledges and appreciates the key contributions of Dr. Giuseppe Papia, (Sunnybrook Hospital); Dr. Trina Montemurro (St. Joseph's Hospital); and Joanna Noble (HIROC) for the review and approval of this Improvement Resource.

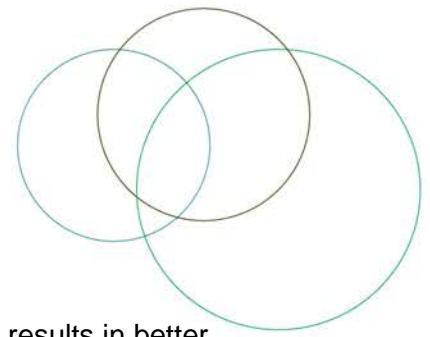




DISCHARGE ABSTRACT DATABASE (DAD) CODES INCLUDED IN THIS CLINICAL CATEGORY:

D26: Selected Serious Events		
Concept	Harm to patients resulting from failure of sterile precautions, 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	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. Recently, Health Quality Ontario (HQP), and the Canadian Patient Safety Institute (CPSI) partnered with several jurisdictions and organizations in Canada to create a list of 15 Never Events. Never Events are patient safety incidents that result in serious patient harm or death and that are preventable using organizational checks and balances (HQP & CSPI, 2015). Two of the 15 Never Events are included in the clinical group - Selected Serious Events. They are:

- patient death or serious harm arising from the use of improperly sterilized instruments or equipment provided by the healthcare facility; and
- surgery on the wrong body part or the wrong patient, or conducting the wrong procedure.

Failure of sterile precautions

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).

Ineffective aseptic technique causes Healthcare Associated Infections (HAI)

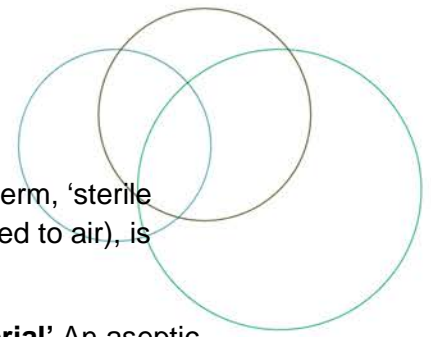
The contamination of patients with microorganisms during invasive clinical procedures is largely an invisible process. However, a broad range of research provides clear evidence for an indirect and direct causal relationship between failed aseptic technique and HAI. For example, it has been demonstrated that approximately eight per cent of manually prepared saline flushes are contaminated prior to patient administration due to breaks in aseptic technique and blood culture samples have been found to have contamination rates of five to 10 per cent (Association for Safe Aseptic Practice, 2015).

Terminology: sterile, aseptic 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 (NHMRC, 2010). The Australian Guidelines for the Prevention and Control of Infection in Healthcare (NHMRC, 2010) 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. For the purpose of this resource, "failure of sterile precautions" will be addressed through actions to maintain asepsis through appropriate use of aseptic technique.

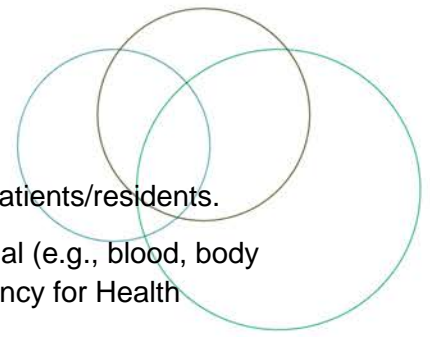
As defined above, **aseptic technique** is the purposeful prevention of transfer of microorganisms from the patient's body surface to a normally sterile body site or from one person to another by keeping the microbe count to an irreducible minimum. Aseptic techniques are measures designed to render the 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, 2010; PHAC, 2012).

To practice safely it is essential that healthcare workers understand the principles and practice of aseptic technique. Although aseptic technique is recognized universally as an essential clinical competency, actual education and competency assessment has historically been neglected. There is significant variability in understanding, interpretation, practice and ultimately effectiveness of aseptic technique. To help reduce the gap in appropriate aseptic technique the Association for Safe Aseptic Practice has developed the Aseptic Non Touch Technique (ANTT), a comprehensively defined practice framework for aseptic technique (The-ASAP, 2015). The ANTT Clinical Practice Framework is based upon a set of principles, safeguards and rules for aseptic technique and applies to all clinical procedures from surgery to community care.

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).

Performance of inappropriate operation

Surgery on the wrong body part or the wrong patient, or conducting the wrong procedure:

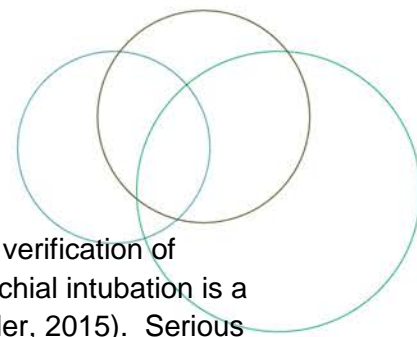
Surgery is one area of healthcare in which preventable medical errors and near misses can occur. Of great concern is wrong-site surgery (WSS), which encompasses surgery performed on the wrong side or site of the body, wrong surgical procedure performed, and surgery performed on the wrong patient. WSS is also defined as a sentinel event (i.e., an unexpected occurrence involving death or serious physical or psychological injuries, or the risk thereof) by the Joint Commission which found WSS to be the third-highest-ranking event (Mulloy & Huges, 2008). Based on statistics provided by HIROC, wrong patient, site, treatment/procedure made up 2.07 per cent of all claims reported to HIROC by insured healthcare organizations (HIROC, personal communication, February 9, 2017).

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)

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). According to statistics from HIROC, unnecessary/obsolete procedure makes up 0.21 per cent of all claims reported to HIROC by insured healthcare organizations (HIROC, personal communication, February 9, 2017).





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).

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).

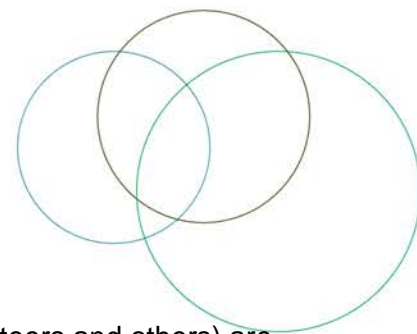
Patient Story

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 B](#).





EVIDENCE INFORMED PRACTICE

Aseptic technique

All healthcare workers (e.g. physicians, nurses, allied HCWs, students, volunteers and others) are responsible for complying with routine practices (hand hygiene, glove use, aseptic technique, etc.) and for tactfully calling infractions to the attention of offenders. No one is exempt from complying with routine practices (PHAC, 2012).

The Foundation Principles and Safeguards of ANTT (The-ASAP, 2015)

Principles:

1. Asepsis is the aim for all invasive clinical procedures, including the maintenance and use of invasive clinical devices ('for surgery to community care').
2. Asepsis is achieved by protecting Key-Parts and Key-Sites from microorganisms transferred from the healthcare worker and the immediate environment.
3. ANTT needs to be efficient as well as safe; therefore Surgical-ANTT is used for complicated procedures and Standard-ANTT for uncomplicated procedures (see detailed description in [Appendix A](#)).
4. The need for Surgical or Standard-ANTT is determined by ANTT risk assessment that is based on the technical difficulty of achieving asepsis (see [Appendix A](#) for more details).
5. Aseptic practice should be standardized.
6. Safe aseptic technique is reliant upon effective healthcare worker training and environments and equipment that are fit for purpose.

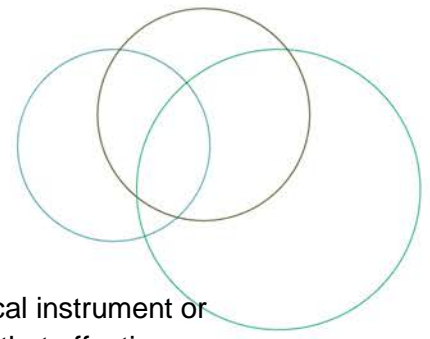
Safe Guards:

1. Basic infective precautions such as environmental controls, hand cleaning and disinfecting medical devices significantly reduce the risk of contaminating Key-Parts and Key-Sites.
2. Key-Parts are the critical parts of the procedure equipment that if contaminated are most likely to cause infection. Key-Sites are open wounds and medical device access sites.
3. Non-Touch Technique is a critical skill that protects Key-Parts and Key-Sites from the healthcare worker and the procedure environment. It is essential in Standard-ANTT and desirable in Surgical-ANTT

For more information on the [Aseptic Technique](#) refer to:

- [Association for Safe Aseptic Practice](#)
- The Public Health Agency of Canada. [Routine Practices and Additional Precautions for Preventing the Transmission of Infection in Healthcare Settings](#) (page 38 and 55)
- Association of Surgical Technologists: [Aseptic Technique](#)





Sterilizations of medical and surgical instruments and equipment

(Ontario Agency for Health Protection and Promotion, 2013)

- It is the shared responsibility of each person involved with each surgical instrument or piece of medical equipment throughout the process of care to ensure that effective reprocessing will take place.
- Prior to purchase, the way that a device will be reprocessed must be taken into consideration.
- Reprocessing must be carried out in a centralized area (medical device reprocessing centre - MDRC) by trained staff, with monitoring and quality control parameters built into the process.
- Contaminated equipment/devices must be cleaned and then disinfected or sterilized according to defined procedures that are based on accepted standards and best practices.
- In the event of equipment failures or emergency situations, there are recalls and safeguards built into the system to protect the end user.
- Finally, there should be observations at point-of-use to ensure sterilization indicators demonstrate that effective sterilization has occurred. All of these components must be in place to achieve success

Effective reprocessing of medical equipment/devices is a process comprised of many components

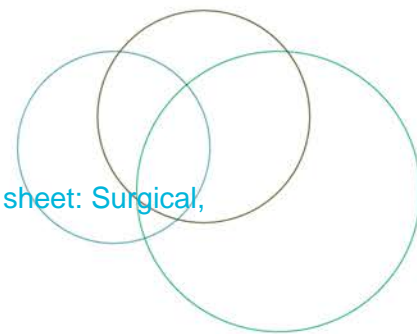
- Trained Staff
- Written Policies and Procedures
- Quality Monitoring
- Contingencies for Equipment Failures
- Point-of-Use Observation
- Equipment Purchase
- Centralized Reprocessing

For full details on sterilizations of medical and surgical instruments and equipment refer to:

- Ontario Agency for Health Protection and Promotion, Public Health Ontario. [Best Practices for Cleaning, Disinfection and Sterilization of Medical Equipment/Devices in all Health Care Settings, 3rd edition](#)
- [Association of Surgical Technologists: Disinfection and Sterilization](#)

For additional mitigation strategies refer to:



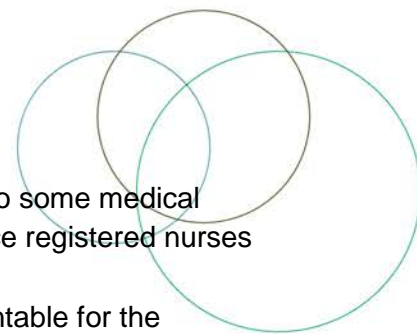


- [Healthcare Insurance Reciprocal of Canada \(HIROC\), Risk reference sheet: Surgical, inadequate sterility](#)

Prevention of inappropriate operation

1. **Implement the Surgical Safety Checklist:** Effective communication and teamwork are foundational to improving safety in surgical care. A tool specific to surgical care that is intended to strengthen communication and teamwork is the Canadian Patient Safety Institute's [Surgical Safety Checklist](#) (CPSI 2009). Surgical teams can use the checklist to ensure that key care information is communicated throughout the patient's surgical journey and to enhance teamwork. The checklist has three phases:
 - a. Briefing – before the induction of anesthesia
 - b. Time out – before skin incision
 - c. Debriefing – before the patient leaves the operating room
2. **Implement Universal Protocol for Prevention of Wrong Site, Wrong Procedure, and Wrong Person Surgery™** (Joint Commission, 2012):
 - A. Conduct a pre-procedure verification process. Address missing information or discrepancies before starting the procedure:
 - Verify the correct procedure, for the correct patient, at the correct site.
 - When possible, involve the patient in the verification process.
 - Identify the items that must be available for the procedure.
 - Use a standardized list to verify the availability of items for the procedure. This list may vary by jurisdiction. At a minimum, these items include:
 - Relevant documentation (Examples: history and physical, signed consent form, pre-anesthesia assessment)
 - Labeled diagnostic and radiology test results that are properly displayed (Examples: radiology images and scans, pathology reports, biopsy reports)
 - Any required blood products, implants, devices, special equipment
 - Match the items that are to be available in the procedure area to the patient.
 - B. Mark the procedure site. At a minimum, mark the site when there is more than one possible location for the procedure and when performing the procedure in a different location could harm the patient.
 - For spinal procedures: Mark the general spinal region on the skin. Special intraoperative imaging techniques may be used to locate and mark the exact vertebral level.
 - Mark the site before the procedure is performed.
 - If possible, involve the patient in the site marking process.
 - The site is marked by a licensed independent practitioner who is ultimately accountable for the procedure and will be present when the procedure is performed.





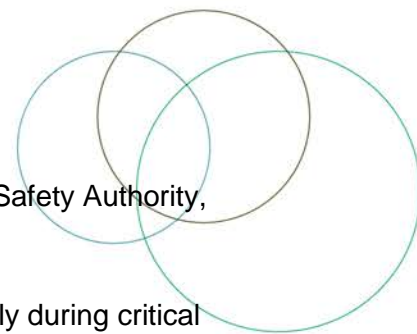
- In limited circumstances, site marking may be delegated to some medical residents, physician assistants (P.A.), or advanced practice registered nurses (A.P.R.N.).
- Ultimately, the licensed independent practitioner is accountable for the procedure – even when delegating site marking.
- The mark is unambiguous and is used consistently throughout the organization.
- The mark is made at or near the procedure site.
- The mark is sufficiently permanent to be visible after skin preparation and draping.
- Adhesive markers are not the sole means of marking the site.
- For patients who refuse site marking or when it is technically or anatomically impossible or impractical to mark the site (see examples below): Use your organization's written alternative process to ensure that the correct site is operated on.

Examples of situations that involve alternative processes:

- mucosal surfaces or perineum
- minimal access procedures treating a lateralized internal organ, whether percutaneous or through a natural orifice
- teeth
- premature infants, for whom the mark may cause a permanent tattoo

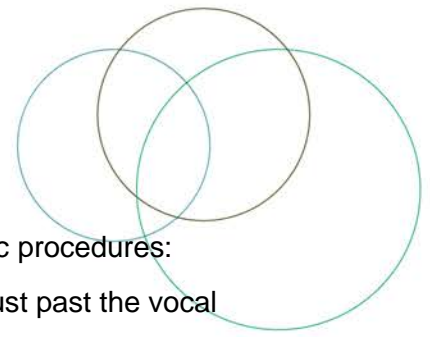
- C. Perform a time-out. The procedure is not started until all questions or concerns are resolved.
- Conduct a time-out immediately before starting the invasive procedure or making the incision.
 - A designated member of the team starts the time-out.
 - The time-out is standardized.
 - The time-out involves the immediate members of the procedure team: the individual performing the procedure, anesthesia providers, circulating nurse, operating room technician, and other active participants who will be participating in the procedure from the beginning.
 - All relevant members of the procedure team actively communicate during the time-out.
 - During the time-out, the team members agree, at a minimum, on the following:
 - correct patient identity
 - correct site
 - procedure to be done
 - When the same patient has two or more procedures: If the person performing the procedure changes, another time-out needs to be performed before starting each procedure.
 - Document the completion of the time-out. The organization determines the amount and type of documentation.





3. **Reduce Distractions in the operating room** (Pennsylvania Patient Safety Authority, 2014).
 - A. Environment / Equipment
 - Reduce noise level in the OR whenever possible, especially during critical phases in the procedure (e.g., limit conversation not relevant to the current procedure; lower the volume of background music; adjust surgical equipment settings to reduce excess noise, as able).
 - Customize alarm settings for individual patients, and use smart alarms, when available, to reduce distraction from false or nuisance alarms.
 - B. Rules / Policies / Procedures
 - Assemble multidisciplinary teams to identify critical phases in operative procedures, specific to individual teams and procedure types that should not be interrupted.
 - Implement a “sterile cockpit” or “no interruption zone” protocol during critical phases of operative procedures.
 - Use preoperative and procedural checklists.
 - Design and implement a multidisciplinary briefing tool.
 - Use a structured communication tool, such as SBAR (Situation, Background, Assessment, Recommendation), especially during critical phases of a procedure.
 - Minimize communication by members of the OR team that is irrelevant to the current procedure, and limit interruptions from outside staff and other visitors to the OR.
 - Establish guidelines and expectations, applicable to all members of the surgical team, for the appropriate use of cell phones, pagers, smartphones, and other PEDs in the OR, and monitor for compliance.
 - Provide teamwork training, such as *Crew Resource Management (CRM)*; *Team Strategies and Tools to Enhance Performance and Patient Safety (TeamSTEPPS)* (AHRQ, 2017), or *TeamSTEPPS Canada™* (CPSI, 2018) using case study scenarios specific to the OR.
 - Engage surgeons in patient safety teamwork training and quality improvement projects targeted to reducing distraction.
 - Ensure that surgeons and other OR team leaders promote a culture of patient safety, encouraging all team members to practice skills necessary for situation monitoring and to voice concerns at any point during a procedure.
 - C. Training
 - Educate staff about electronic distraction and its potential detrimental effect on patient safety.
 - D. Audit and Feedback
 - Encourage the collection and audit of local data for continuous quality improvement (Dr. G. Papia, personal communication, October 24, 2017)





Endotracheal tube placement

Ensure correct positioning of endotracheal tube placement during anaesthetic procedures:

1. Ensure the endotracheal tube is placed so that the cuff is visualized just past the vocal cords and approximately 2-3 cm above the carina (Miller, 2015).
2. Perform bilateral auscultation to ensure breath sounds are equal and bilaterally over the chest wall and there is a lack of breath sounds over the epigastrium (Miller, 2015; Sitzwohl et al, 2010).
3. Observe for symmetrical chest movements and condensation in the endotracheal tube (Sitzwohl et al, 2010; Miller, 2015).
4. Identify carbon dioxide in the expire gas using continual end-tidal carbon dioxide analysis from the time of intubation until extubation or transfer to a postoperative care location using a quantitative methods such as capnography or capnometry (Committee on Standards and Practice Parameters, et al., 2015; Miller, 2015; Dobson, et al. 2017).
5. Ensure that the end tidal CO₂ alarm and the oxygen saturation alarm is visual and audible at all times to the anesthesiologist or the anesthesia care team personnel (Committee on Standards and Practice Parameters, et al., 2015; Dobson, et al. 2017).
6. When ventilation is controlled by a mechanical ventilator, there shall be in continuous use a device that is capable of detecting disconnection of components of the breathing system. The device must give an audible signal when its alarm threshold is exceeded (Committee on Standards and Practice Parameters, et al., 2015; Dobson, et al. 2017).
7. If patient remains ventilated in the post-operative period, a chest X-ray should be considered to ensure correct placement of endotracheal tube.

For additional [Mitigation Strategies for Wrong Patient/Site/Procedure](#), please refer to the HIROC Risk Reference Sheet (HIROC, 2016).

For mitigation strategies for the [Prevention of the Performance of Unnecessary/Obsolete Procedures](#) refer to the HIROC Risk Reference Sheet (HIROC, 2016).

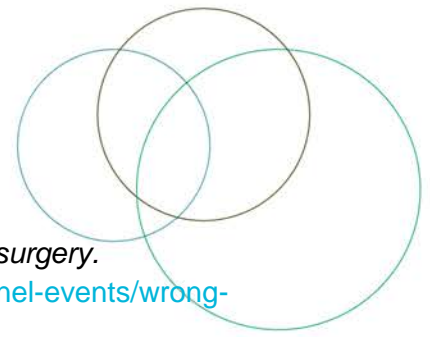
Conduct Clinical and System Reviews

Given the broad range of potential causes of complications from serious events, in addition to the recommendations listed above, we recommend conducting clinical and system reviews to identify latent causes and determine appropriate recommendations.

If your review reveals that the healthcare facility's serious event cases are linked to specific processes or procedures, you may find guidelines related to the specific procedure here:

- American College of Surgeons. *National surgical quality improvement program*. <https://www.facs.org/quality-programs/acs-nsqip>
- American Society for Gastrointestinal Endoscopy. *Guidelines*. <http://www.asge.org/publications/publications.aspx?id=352>





- American Society of Anesthesiologists. <http://www.asahq.org>
- Association of periOperative Registered Nurses (AORN). *Wrong site surgery*. <https://www.aorn.org/education/staff-development/prevention-of-sentinel-events/wrong-site-surgery>
- Canadian Association of Gastroenterology. *Guideline library*. <https://www.cag-acg.org/publications/guideline-library>
- Canadian Association of Interventional Cardiology. <http://caic-acci.org/>
- Canadian Medical Protective Association. *Good practice guide*. <https://www.cmpa-acpm.ca/serve/docs/ela/goodpracticesguide/pages/index/index-e.html>
- Canadian Society of Nephrology. <https://www.csnsn.ca/committees/clinical-practice-guidelines/library>
- Canadian Vascular Access and Association. <http://www.cvaa.info/>
- Centers for Disease Control and Prevention. www.cdc.gov
- CSA Group. <http://www.csagroup.org/>
- Infection Prevention and Control (IPAC) Canada. www.ipac-canada.org
- National Institute for Health and Care Excellence (NICE). www.nice.org.uk
- Operating Room Nurses of Association of Canada. www.ornac.ca
- Pennsylvania Patient Safety Authority. *Patient safety topics*. <http://patientsafety.pa.gov/pst/Pages/PSAPatientSafetyTopicList.aspx>
- Public Health Agency of Canada. <http://www.phac-aspc.gc.ca/index-eng.php>
- Public Health Ontario, Provincial Infectious Diseases Advisory Committee. <https://www.publichealthontario.ca/en/BrowseByTopic/InfectiousDiseases/PIDAC/Pages/PIDAC.aspx>

CLINICAL AND SYSTEM REVIEWS, INCIDENT ANALYSES

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



HOSPITAL HARM IMPROVEMENT RESOURCE

Selected Serious Events



opportunities. Links to key resources for analysis methods are included in Resources for Conducting Incident and/or Prospective Analyses section of the Introduction to the Hospital Harm Improvement Resource.

Chart audits are recommended as a means to develop a more in-depth understanding of the care delivered to patients identified by the Hospital Harm measure. Chart audits help identify quality improvement opportunities.

Useful resources for conducting clinical and system reviews:

- [Chart Audit Review Process](#) (see Introduction to the Improvement Resource)
- [Canadian Incident Analysis Framework](#)
- [Canadian Patient Safety Institute Patient Safety and Incident Management Toolkit](#)
- [HIROC Critical Incident & Multi-Patient Events Risk Resource Guide](#)
- [Institute for the Safe Medication Practices Canadian Failure Mode and Effects Analysis Framework](#)
- [Institute for Healthcare Improvement Failure Mode and Effects Analysis Tool](#)

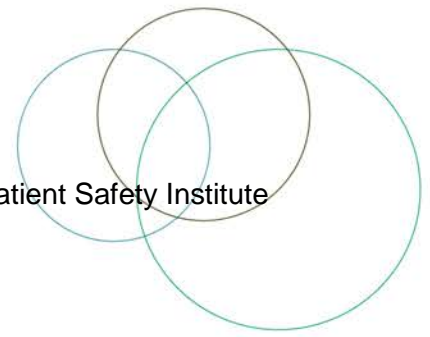
MEASURES

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 actually being carried out (process measures), and whether any unintended consequences ensue (balancing measures).

Below are some recommended measures to use, as appropriate, to track your progress. 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 final 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 described below to make them more appropriate and/or useful to your particular 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).





For more information on measuring for improvement contact the Canadian Patient Safety Institute Central Measurement Team at measurement@cpsi-icsp.ca

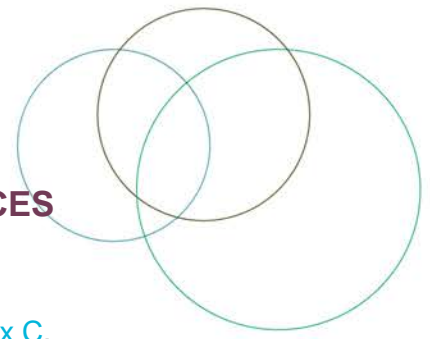
Outcome Measures

1. Per cent of medical and surgical procedures with failure to maintain aseptic technique.
2. Number of medical and surgical instruments and equipment that failed to be appropriately sterilized.
3. Per cent of surgical patients with the endotracheal tube wrongly placed during an anesthetic procedure.
4. Number of inappropriate operations (wrong site, wrong patient or wrong procedure).

Process Improvement Measures

1. Asepsis: Refer to the Association of Safe Aseptic Practice's Audit Tool available free upon request at enquiries@annt.org
2. Percent of intubated patients in which all of the following components are performed:
 - a. the endotracheal tube is inserted to so the cuff is visualized past the vocal cords.
 - b. bilateral auscultation is performed to ensure breath sounds are equal and heard in both lungs.
 - c. symmetrical chest movements are observed.
 - d. quantitative method to continually analyze end-tidal carbon dioxide level from the time of intubation until extubation or transfer to a postoperative care area.
 - e. the end tidal CO₂ and oxygen saturation alarm is visible and audible to the anesthesiologist or the anesthesia care team personnel at all times.
 - f. there is continuous use of a device that is capable of detecting disconnection of components of the ventilation system. The device must give an audible signal when its alarm threshold is exceeded.
 - g. A chest X-ray is performed on patients who remain ventilated in the post-operative period.
3. Per cent of Surgical Patients with appropriate use of the Surgical Safety Checklist: All three phases - Briefing, Time out and Debriefing.
4. Percentage of surgical patients who had a pre-procedure verification process.
5. Percentage of surgical patients that had their procedure site appropriately marked.
6. Per cent of surgical procedures not started until a time-out is performed and all questions or concerns are resolved.
7. Per cent of surgical staff that participated in teamwork training





STANDARDS AND REQUIRED ORGANIZATIONAL PRACTICES

Health Standards Organization (HSO)

For HSO Standards relevant to Selected Serious Events please see [Appendix C](#).

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
- Sterilization
- Aseptic
- Infection

SELECTED SERIOUS EVENTS SUCCESS STORIES

Building a culture of safety in the operating room

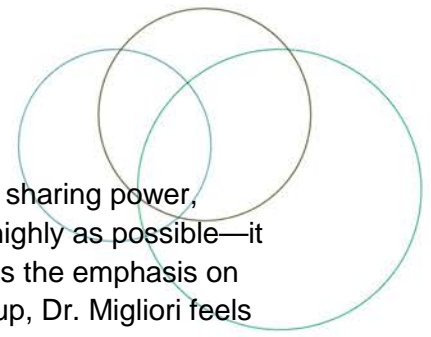
At the foundation of successful patient safety and quality improvement efforts is a culture of patient safety within the hospital or surgical center. A strong safety culture can help minimize medical errors and strong support from leadership is crucial to truly moving the needle on patient safety and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

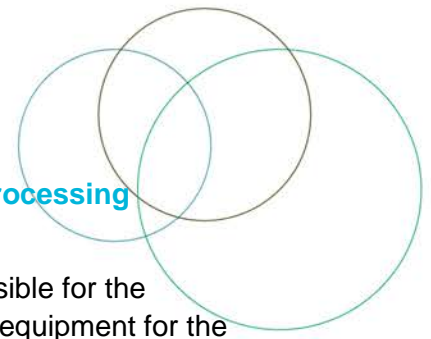
Dr. Migliori says a strong leader is one who has balance. Balance between confidence and humility; competence and being unsure enough to look at a situation from a different angle; and someone who is passionate and yet can observe and allow others to impact. A strong leader is always looking to give 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:

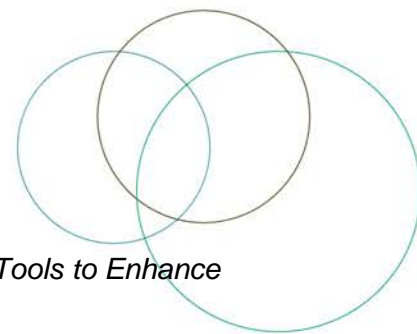
1. Audit results such as instrument set error rate, missing chemical indicators, sterilization record accuracy and the frequency of sharps being found on used/soiled trays were inconsistently tracked and shared with frontline staff.
2. The lack of a systematic process such as a weekly audit tool to capture 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.

(Markham Stouffville Hospital Corporation, 2013)





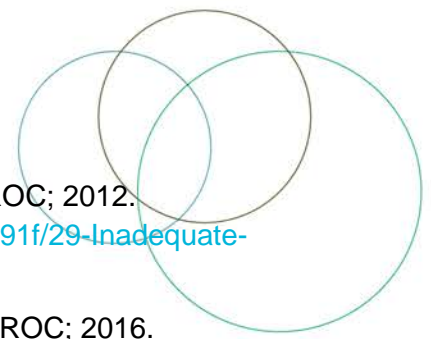
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HOSPITAL HARM IMPROVEMENT RESOURCE

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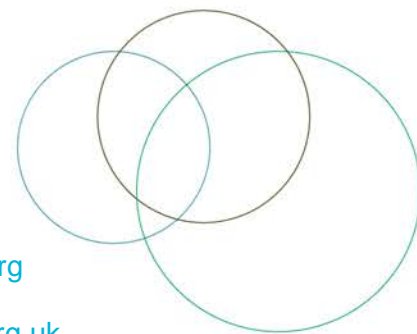
Professional Associations and Helpful Websites

- American College of Surgeons. *National surgical quality improvement program*. <https://www.facs.org/quality-programs/acs-nsqip>
- American Society for Gastrointestinal Endoscopy. *Guidelines*. <http://www.asge.org/publications/publications.aspx?id=352>
- American Society of Anesthesiologists. <http://www.asahq.org>
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- Canadian Association of Gastroenterology. *Guideline library*. <https://www.cag-acg.org/publications/guideline-library>
- Canadian Association of Interventional Cardiology. <http://caic-acci.org/>
- Canadian Medical Protective Association. *Good practice guide*. <https://www.cmpa-acpm.ca/serve/docs/ela/goodpracticesguide/pages/index/index-e.html>
- Canadian Society of Nephrology. <https://www.csnscn.ca/committees/clinical-practice-guidelines/library>
- Canadian Vascular Access and Association. <http://www.cvaa.info/>
- Centers for Disease Control and Prevention. www.cdc.gov



HOSPITAL HARM IMPROVEMENT RESOURCE

Selected Serious Events



- CSA Group. <http://www.csagroup.org/>
- Infection Prevention and Control (IPAC) Canada. www.ipac-canada.org
- National Institute for Health and Care Excellence (NICE). www.nice.org.uk
- Operating Room Nurses of Association of Canada. www.ornac.ca
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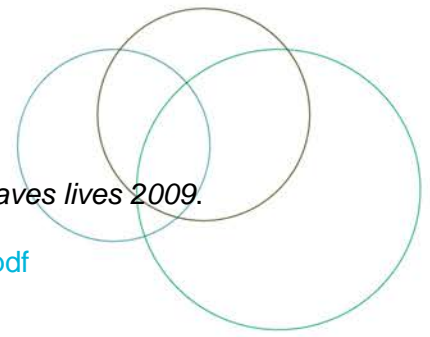
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HOSPITAL HARM IMPROVEMENT RESOURCE

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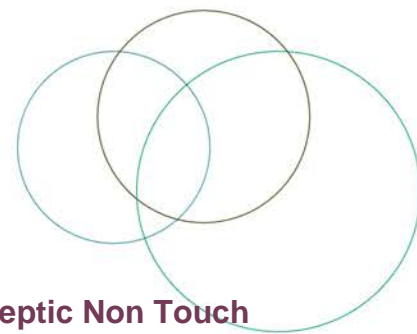
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APPENDIX A

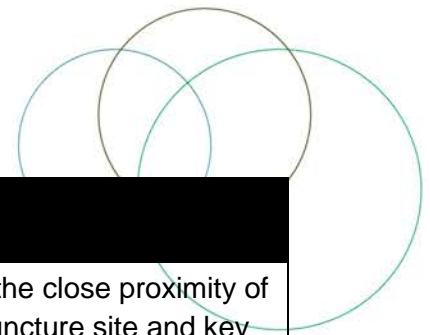
Standard- Aseptic Non Touch Technique (ANTT) and Surgical- Aseptic Non Touch Technique (ANTT)

Different clinical procedures present different levels of complexity. Therefore, in order to be efficient as well as safe, any practice framework for aseptic technique must define what type of aseptic technique and precautions are required for both simple and complex procedures, and how to decide between the two approaches. In ANTT, uncomplicated and complex approaches to technique are termed Standard-ANTT and Surgical-ANTT respectively. It is important to note that the two approaches adhere to exactly the same ANTT-Approach

- Standard ANTT**—Clinical procedures managed with Standard ANTT will characteristically be technically simple, short in duration (approximately less than 20 minutes), and involve relatively few and small key sites and key parts. Standard ANTT requires a main general aseptic field and non-sterile gloves. The use of critical micro aseptic fields and a non-touch technique is essential to protect key parts and key sites.
- Surgical ANTT**—Surgical ANTT is demanded when procedures are technically complex, involve extended periods of time, large open key sites or large or numerous key parts. To counter these risks, a main critical aseptic field and sterile gloves are required and often full barrier precautions (Pratt et al, 2007). Surgical ANTT should still utilise critical micro aseptic fields and non-touch technique where practical to do so.

Procedure	Standard/Surgical ANTT	Rationale/typical procedure
IV therapy	Standard ANTT	Key parts can typically be protected by optimal critical micro fields and non-touch technique. Key sites are small. Procedures are technically simple and <20 mins duration.
Simple wound dressings	Standard ANTT	Key parts and sites can be protected by optimal critical micro fields and non-touch technique. Procedures are technically simple and <20 mins duration.
Complex or large wound dressings	Surgical ANTT	The complexity, duration or number of key parts may demand a critical aseptic field.
Urinary catheterisation	Standard/Surgical ANTT	An experienced healthcare worker can perform catheterisation with the use of a general aseptic field, micro-aseptic fields and a non-touch technique. However, less experienced healthcare workers may require a critical aseptic field.

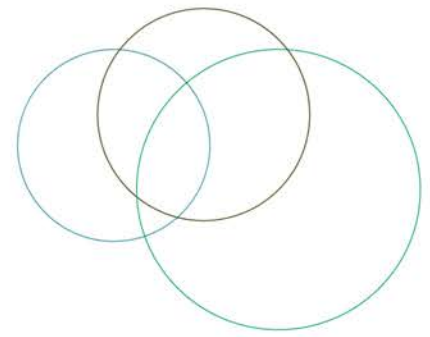




Procedure	Standard/Surgical ANTT	Rationale/typical procedure
Cannulation	Standard/Surgical ANTT	Although technically quite simple the close proximity of healthcare worker hands to the puncture site and key parts may demand sterile gloves – dependent upon healthcare worker competency.
PICC/CVC insertion	Surgical ANTT	The size of the CVC or PICC line, invasiveness, numerous key parts and equipment and duration will demand a critical aseptic field and full barrier precautions.
Surgery	Surgical ANTT	Surgical access involves deep or large exposed wounds, numerous key parts and equipment and long procedures. Standard operating room precautions required.

(National Health and Medical Research Council, 2010; Association for Safe Aseptic Practice, 2015)





APPENDIX B: 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.

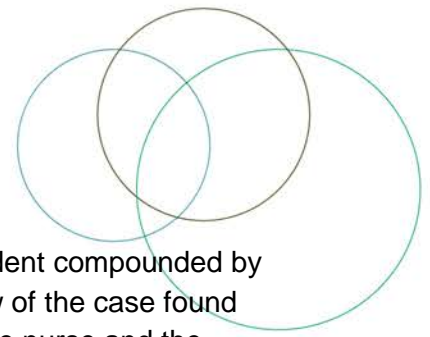
Case 3 – A number of instrument trays used in at hospital's labour and delivery program were not reprocessed prior to use. The instruments had been washed, cleaned and heat disinfection in the automatic washer but not sterilized as evident by the fact the autoclave tape had not changed colour. The unsterile 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)

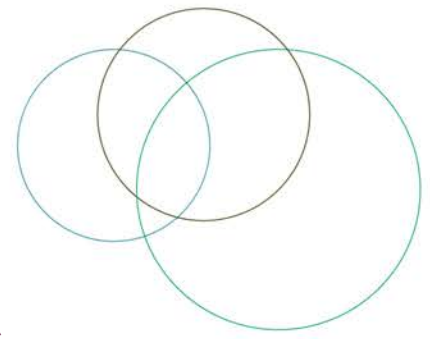
Case Studies: Unnecessary/Obsolete Procedures

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)



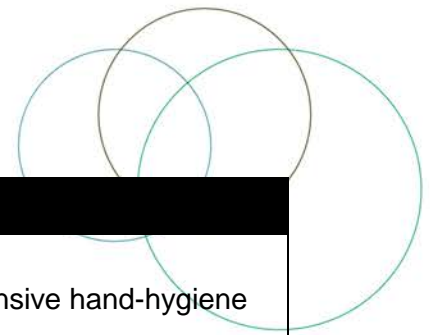


APPENDIX C

Health Standards Organization Relevant Standards for Selected Serious Events

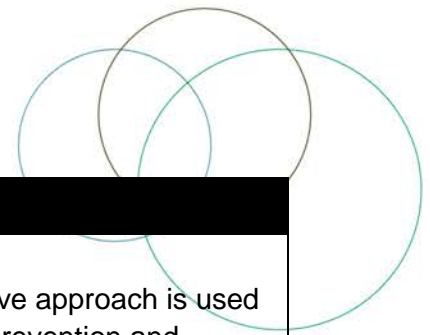
CPSI Evidence	HSO Criteria
<p>Aseptic technique: All healthcare workers (e.g. physicians, nurses, allied HCWs, students, volunteers and others) are responsible for complying with routine practices (hand hygiene, glove use, aseptic technique etc.) and for tactfully calling infractions to the attention of offenders. No one is exempt from complying with routine practices. (PHAC, 2012)</p>	<p>IPC Standard: Section 4.0 Infection prevention and control policies and procedures are maintained based on applicable regulations, evidence and best practices, and organizational priorities.</p>
<p>The Foundation Principles and Safeguards of ANTT (The-ASAP, 2015) Principles:</p> <ol style="list-style-type: none"> 7. Asepsis is the aim for all invasive clinical procedures, including the maintenance and use of invasive clinical devices ('for surgery to community care'). 8. Asepsis is achieved by protecting Key-Parts and Key-Sites from microorganisms transferred from the healthcare worker and the immediate environment. 9. ANTT needs to be efficient as well as safe; therefore Surgical-ANTT is used for complicated procedures and Standard-ANTT for uncomplicated procedures (see detailed description in Appendix A). 10. The need for Surgical or Standard-ANTT is determined by ANTT risk assessment that is based on the technical difficulty of achieving asepsis (see Appendix A for more details). 11. Aseptic practice should be standardized. 12. Safe aseptic technique is reliant upon effective healthcare worker training and environments and equipment that are fit for purpose. 	<p>Service Excellence Standard: Section 3.0 Team members are qualified and have relevant competencies.</p> <p>Perioperative Services Standard: Section 8.0 All equipment, devices, and supplies needed for the procedure are checked.</p>





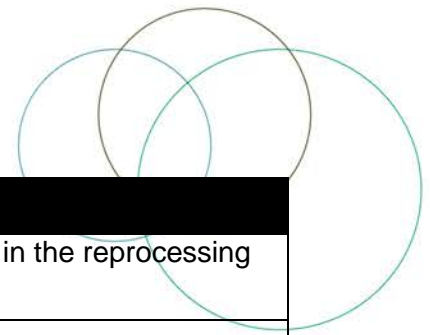
CPSI Evidence	HSO Criteria
<p>Safe Guards:</p> <p>4. Basic infective precautions such as environmental controls, hand cleaning and disinfecting medical devices significantly reduce the risk of contaminating Key-Parts and Key-Sites.</p>	<p>IPC Standard: Section 8.0 A comprehensive hand-hygiene strategy is in place.</p> <p>Perioperative Services Standard: Section 10.0 Medication is administered safely in the sterile field. Section 12 Steps are taken to prevent and minimize infections.</p>
<p>Sterilizations of medical and surgical instruments and equipment It is the shared responsibility of each person involved with each surgical instrument or piece of medical equipment throughout the process of care to ensure that effective reprocessing will take place.</p>	<p>Perioperative Services Standard: Section 2.0 Surgical equipment and medical devices are safe to use.</p>
<p>Prior to purchase, the way that a device will be reprocessed must be taken into consideration.</p>	<p>Reprocessing of Reusable Medical Devices Standard: Section 4.0- Reprocessing equipment is installed and maintained according to manufacturers' specifications and installation qualifications.</p> <p>IPC Standard: Section 2.0 A collaborative approach is used to support the infection prevention and control program.</p>
<p>Sterilizations of medical and surgical instruments and equipment It is the shared responsibility of each person involved with each surgical instrument or piece of medical equipment throughout the process of care to ensure that effective reprocessing will take place.</p>	<p>Perioperative Services Standard: Section 2.0 Surgical equipment and medical devices are safe to use.</p>
<p>Prior to purchase, the way that a device will be reprocessed must be taken into consideration.</p>	<p>Reprocessing of Reusable Medical Devices Standard: Section 4.0 Reprocessing equipment is installed and maintained according to manufacturers' specifications and installation qualifications.</p>





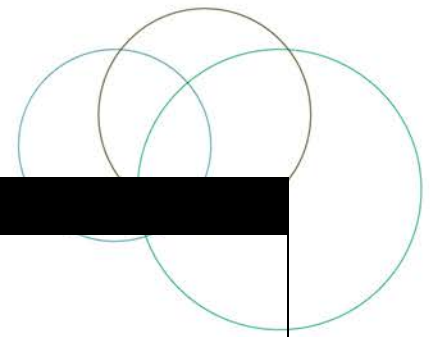
CPSI Evidence	HSO Criteria
	<p>IPC Standard: Section 2.0 A collaborative approach is used to support the infection prevention and control program.</p>
<p>Reprocessing must be carried out in a centralized area (medical device reprocessing centre - MDRC) by trained staff, with monitoring and quality control parameters built into the process.</p>	<p>Reprocessing of Reusable Medical Devices Standard: Section 2.0 Sufficient resources are available to provide safe and high-quality services. Section 5.0 Team members are qualified and have relevant competencies.</p>
<p>Contaminated equipment/devices must be cleaned and then disinfected or sterilized according to defined procedures that are based on accepted standards and best practices.</p>	<p>Reprocessing of Reusable Medical Devices Standard: Section 3.0 The Medical Device Reprocessing (MDR) department, centralized or de-centralized, is organized to facilitate one-way workflow to prevent cross-contamination. Section 5.0 Team members are qualified and have relevant competencies.</p>
<p>Finally, there should be observations at point-of-use to ensure sterilization indicators demonstrate that effective sterilization has occurred. All of these components must be in place to achieve success.</p>	<p>Reprocessing of Reusable Medical Devices Standard: Section 9.0 Medical devices are reprocessed according to the Spaulding classification and manufacturers' instructions.</p>
<p>Effective reprocessing of medical equipment/devices is a process comprised of many components:</p> <ul style="list-style-type: none"> • <i>Trained Staff</i> • <i>Written Policies and Procedures</i> 	<p>Reprocessing of Reusable Medical Devices Standard: Section 15.0 Indicator data is collected and used to guide quality improvement activities.</p>
<p>Quality Monitoring</p> <ul style="list-style-type: none"> • <i>Contingencies for Equipment Failures</i> • <i>Point-of-Use Observation</i> • <i>Equipment Purchase</i> • <i>Centralized Reprocessing</i> <p>(Ontario Agency for Health Protection and Promotion, et al., 2013).</p>	<p>Reprocessing of Reusable Medical Devices Standard: Section 7.0 Policies and Standard Operating Procedures (SOPs) are developed, maintained, and evaluated for medical device reprocessing services. Section 8.0 Check Occupational Health and Safety and infection prevention and control requirements are followed to ensure the</p>





CPSI Evidence	HSO Criteria
	safety of team members in the reprocessing area.
<p>Prevention of inappropriate operation:</p> <p>4. Implement the Surgical Safety Checklist: Effective communication and teamwork are foundational to improving safety in surgical care. A tool specific to surgical care that is intended to strengthen communication and teamwork is CPSI's Canadian Surgical Safety Checklist</p> <p>Surgical teams can use the checklist to ensure that key care information is communicated throughout the patient's surgical journey and to enhance teamwork.</p>	<p>Perioperative Services Standard: Section 9.0 The client is prepared for the procedure.</p>
<p>Implement Universal Protocol for Prevention of Wrong Site, Wrong Procedure, and Wrong Person Surgery™ (Joint Commission, 2012).</p> <p>Conduct a pre-procedure verification process. Address missing information or discrepancies before starting the procedure.</p> <p>Verify the correct procedure, for the correct patient, at the correct site.</p> <p>When possible, involve the patient in the verification process.</p> <p>Identify the items that must be available for the procedure.</p> <p>Use a standardized list to verify the availability of items for the procedure. (It is not necessary to document that the list was used for each patient.)</p> <p>At a minimum, these items include:</p> <ul style="list-style-type: none"> • Relevant documentation Examples: history and physical, signed consent form, pre-anesthesia assessment. • Labeled diagnostic and radiology test results that are properly displayed Examples: radiology images and scans, pathology reports, biopsy reports. 	<p>Perioperative Services Standard: Section 9.0 The client is prepared for the procedure.</p> <p>Section 11.0 Medications are safely administered in the non-sterile field.</p>





CPSI Evidence	HSO Criteria
<ul style="list-style-type: none"> Any required blood products, implants, devices, special equipment. <p>Match the items that are to be available in the procedure area to the patient.</p> <p>Mark the procedure site. At a minimum, mark the site when there is more than one possible location for the procedure and when performing the procedure in a different location could harm the patient.</p>	
<p>Perform a time-out. The procedure is not started until all questions or concerns are resolved.</p> <p>Conduct a time-out immediately before starting the invasive procedure or making the incision.</p> <p>A designated member of the team starts the time-out.</p> <p>The time-out is standardized.</p> <p>The time-out involves the immediate members of the procedure team: the individual performing the procedure, as providers, circulating nurse, operating room technician, and other active participants who will be participating in the procedure from the beginning.</p> <p>All relevant members of the procedure team actively communicate during the time-out.</p> <p>During the time-out, the team members agree, at a minimum, on the following:</p> <ul style="list-style-type: none"> correct patient identity correct site procedure to be done <p>When the same patient has two or more procedures: If the person performing the procedure changes, another time-out needs to be performed before starting each procedure.</p> <p>Document the completion of the time-out. The organization determines the amount and type of documentation.</p>	<p>14 Perioperative Services Standard: Section 9.0 The client is prepared for the procedure.</p>



HOSPITAL HARM IMPROVEMENT RESOURCE

Selected Serious Events



Health Standards Organization (HSO). *HSO 4001:2015 – Infection prevention and control*. Toronto, ON: HSO; 2015. <https://healthstandards.org/standard/infection-prevention-control/>

HSO. *HSO 11009:2015 – Perioperative services and invasive procedures*. Toronto, ON: HSO; 2015. <https://healthstandards.org/standard/perioperative-services-invasive-procedures/>

HSO. *HSO 11011:2015 – Reprocessing and sterilization of reusable medical devices*. Toronto, ON: HSO; 2015. <https://healthstandards.org/standard/reprocessing-sterilization-reusable-medical-devices/>

