

Selected Best Practices and Suggestions for Improvement

PSI 05: Retained Surgical Item or Unretrieved Device Fragment Count

Why Focus on Retained Foreign Objects?

- Complications of retained foreign objects can include perforation of the bowel, sepsis, and even death.¹ These complications can occur early in the postoperative period, or even months or years later.
- Many consider retained foreign objects avoidable.¹
- Retained foreign objects represent a serious and significant patient adverse event. From 2005 to 2012, 772 retained foreign objects were reported to The Joint Commission, although this number may be higher, as these data are voluntarily reported.²
- The estimated cost of a retained foreign object is estimated to be between \$166,000 – \$200,000 per incident.³
- At least part of this cost is likely to be shouldered by hospitals. In 2008 the Centers for Medicaid and Medicare Services (CMS) identified retained foreign objects as one of a number of conditions for which hospitals do not receive the higher payment for cases when the condition was acquired during hospitalization.⁴
- As value-based purchasing evolves, quality will be increasingly linked to payment. Postoperative respiratory failure is not currently part of Medicare’s Hospital Value-Based Purchasing, but could be considered for future inclusion.⁵

Recommended Practice	Details of Recommended Practice
Counts at Appropriate Points During Surgery	Perform a sponge, sharp, and instrument count when instruments/sponges are opened, as surgery begins, as closure begins, and during subcuticular or skin closure in the same sequence. ^{1-3,6-10}
Appropriate Staff Education	Create an education model that promotes development of knowledge and research for perioperative staff consistent with national criteria. ^{2,11}
Team Collaboration	Promote and maintain a collaborative and ethical work environment that facilitates trust and confidence to allow all members of the interdisciplinary team the opportunity to speak up if patient safety is compromised. ¹¹⁻¹³
Use of Equipment and Instruments	Integrate new instruments or equipment into practice that prevents retention of foreign bodies, including incorporating technology, such as radio frequency identification devices and barcoding, as a safety practice. ^{10,11,14,15}
Standardized Practices	Integrate use of innovative surgical techniques, radiographic technology, and standardized practices and protocols for all procedures. ^{1,6,7}

Best Processes/Systems of Care

Introduction: Essential First Steps

- Engage key perioperative/procedure personnel, including nurses, physicians and other providers, technicians, anesthesiologists, and representatives from the quality improvement department, to develop evidence-based protocols for care of the patient preoperatively, intraoperatively, and postoperatively to prevent retention of foreign objects.²
- The above team:
 - Identifies the purpose, goals, and scope and defines the target population for this guideline.
 - Analyzes problems with guidelines compliance, identifies opportunities for improvement, and communicates best practices to frontline teams.
 - Establishes measures that would indicate if changes are leading to improvement, identifies process and outcome metrics, and tracks performance using these established metrics.
 - Determines appropriate facility resources for effective and permanent adoption of practices.

Recommended Practice: Counts at Appropriate Points During Surgery

- Count all sponges and instruments for a procedure where sponges or instruments could be retained.^{2,6,7}
- Count sharps and miscellaneous items (e.g., cautery tips and scratch pads) on all procedures.⁶
- Perform at least three or four counts:
 - When instruments/sponges are opened,
 - Before surgery begins,
 - As closure begins, and
 - During subcuticular or skin closure in the same sequence (i.e., start at surgical field, progress to table and then off the field).^{1,2,9}
- Complete the count audibly and have the count concurrently viewed by the circulator and one other person.^{2,6,10}
- Separate items being counted; place used sponges in a clear bag for visualization when performing final counts.^{3,6,9,10}
- Have circulators or another designee monitor sponges or other items that are not x-ray detectable and ensure that they are disposed of separately.
 - Note: Needles less than 17 mm may not be detectable with plain x-ray.³
- Do not remove any sponges, sharps, or instruments from the operating room or procedural area until the case has been completed.⁶
- Ensure that the surgeon performs a methodical wound check prior to count.^{2,3}
- Use a time-out when final count occurs.^{2,9-10}
- Document the results of the final count in the surgical record or operative note.²

- Develop a protocol for staff to handle discrepancies, including use of x-ray detectable sponges and towels only.^{2,3,6,8}
 - If there is a discrepancy, the surgeon and surgical team should be notified immediately.
 - A manual inspection of the incision site should occur, along with inspection of the surrounding surgical area, including tables, linens, and the floor.
 - If the object still is not found, a x-ray should be obtained and read immediately.
 - Document all appropriate steps taken to retrieve the object in the patient's medical record.

Recommended Practice: Appropriate Staff Education

- Create an education model that promotes development of knowledge and research for perioperative staff consistent with national criteria.^{2,11} The model should include:
 - Orientation for new hires.
 - Continuing education.
 - Multidisciplinary team communication.

Recommended Practice: Team Collaboration

- Promote and maintain a collaborative and ethical work environment that facilitates trust and confidence to allow all members of the interdisciplinary team the opportunity to speak up if patient safety is being compromised.^{2,11-13}
 - Create a safe environment for team members to report unsafe practices and unprofessional team behaviors; develop a mechanism for acquiring this information and a clear set of expectations for how this information is addressed.
 - Create a process to address staff that are noncompliant.

Recommended Practice: Use of Equipment and Instruments

- Integrate new instruments or equipment into practice that prevents retention of foreign bodies (e.g., absorbent mesh plug).
- Consider use of computer-assisted method for counting, including use of a barcoding system on surgical sponges and instruments.^{6,7}
- Consider use of radio frequency identification devices (RFIDs) on surgical sponges and instruments.^{2,11,14}
- Consider use of numbered surgical sponges and instruments for a more comprehensive, thorough count to reduce the risk for miscounting.¹⁰

Recommended Practice: Standardized Practices

- Integrate use of innovative surgical techniques, including the use of minimally invasive procedures when applicable.
- Consider routine use of a closing x-ray and radio-opaque surgical materials for all patients, especially high-risk patients (e.g., bariatric patients) or high-risk situations (e.g., emergency procedures).^{1,6,7}
- If not implemented routinely, then consider implementing additional screening methods for high-risk cases even when counts are documented as correct (e.g., obese patients, multiple

handoffs, long procedures, procedures that convert from laparoscopic to open, emergency procedures).¹

Educational Recommendation

- Plan and provide education on any protocols related to foreign body retention to physicians and other providers, nursing, and all other staff involved in operative or procedural cases. Education should occur upon hire, annually, and when this protocol is added to job responsibilities.²

Effectiveness of Action Items

- Track compliance with elements of established protocol by using checklists, appropriate documentation, etc.²
- Follow a standard for performance improvement such as PDSA (Plan-Do-Study-Act) or Lean Six Sigma. Also consider performing a failure mode and effects analysis to better understand the process and where breakdowns occur.
- Mandate that all personnel follow the safety protocols developed by the team to prevent foreign body retention and develop a plan of action for staff in noncompliance.
- Provide feedback to all stakeholders (physicians and other providers, nursing, and ancillary staffs; and executive leadership) on level of compliance with process.
- Conduct a root cause analysis for any occurrences of foreign body retention.²
- Monitor and evaluate performance regularly to sustain improvements achieved.

Additional Resources

Systems/Processes

- Statement on the Prevention of Retained Foreign Bodies After Surgery, American College of Surgeons
<https://www.facs.org/about-ac/s/statements/51-foreign-bodies>
- Prevention of Retained Foreign Objects, American College of Surgeons
<https://www.facs.org/~media/files/publications/bulletin/2009/2009%20november%20bulletin.ashx>

Policies/Protocols

- Institute for Clinical Systems Improvement. Perioperative Protocol. Health Care Protocol: Prevention of Unintentionally Retained Foreign Objects During Vaginal Deliveries. Updated November 2012
https://www.icsi.org/_asset/3xvmi8/RFO.pdf
- NoThing Left Behind®: Prevention of Retained Surgical Items Multi-Stakeholder Policy
http://www.nothingleftbehind.org/uploads/NoThing_Left_Behind_Policy_v5.pdf
- Department of Veterans Affairs, VHA Directive, Prevention of Retained Surgical Items
http://www.va.gov/vhapublications/viewpublication.asp?pub_id=3183

Tools

- Pennsylvania Patient Safety Authority. Retained Foreign Object Audit Form
<http://patientsafetyauthority.org/EducationalTools/PatientSafetyTools/rfo/Pages/audit.aspx>

- World Health Organization Surgical Safety Checklist
http://who.int/patientsafety/safesurgery/tools_resources/SSSL_Checklist_finalJun08.pdf

Staff Required

- Surgeons
- Radiologist
- Resident physicians
- Other providers involved in perioperative care
- Anesthesia professionals
- Perioperative registered nurses
- Surgical technologists

Equipment

- X-ray and other imaging technologies to ensure that no surgical equipment is left within the body cavity
- Radio-opaque surgical materials

Communication

- Systemwide education on policy/protocol
- Time-out performed before start and at closing of surgical procedure

Authority/Accountability

- Operating room staff responsible for conducting counts at appropriate times
- All staff within the operating room to actively participate in the time-out and be empowered to stop the procedure if there are concerns

References

1. Gawande AA, Studdert DM, Orav EJ, et al. Risk factors for retained instruments and sponges after surgery. *N Engl J Med* 2003;348:229-35. The Joint Commission. Preventing unintended retained foreign objects. Sentinel Event Alert Issue 51, October 17, 2013.
http://www.jointcommission.org/assets/1/6/SEA_51_URFOs_10_17_13_FINAL.pdf. Accessed May 20, 2016.
2. Retained surgical items. NoThing Left Behind[®]: A National Surgical Patient Safety Project to Prevent Retained Surgical Items. <http://www.nothingleftbehind.org>. Accessed May 20, 2016.
3. Hospital-acquired conditions and present on admission indicator reporting provision. . Baltimore, MD: Centers for Medicare & Medicaid Services; October 2012.
<https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/wPOA-Fact-Sheet.pdf>. Accessed February 24, 2016.
4. Hospital Inpatient Quality Reporting (IQR) Program measures (calendar year 2014 discharges). (Prepared by Telligen under contract to the Centers for Medicare & Medicaid Services.)
<http://qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic/Page/QnetTier3&cid=1138900298473>. Accessed May 20, 2016.

5. Recommended practices for prevention of retained surgical items. In: *Perioperative Standards and Recommended Practices*. Denver: Association of Perioperative Registered Nurses; 2010. Publication No. AORN MAN-875-A-2014 (revises AORN-MAN-875-2013).
6. King CA. To count or not to count. In Watson DS, ed. *Perioperative safety*. St. Louis: Mosby Elsevier; 2011. p. 128-33.
7. Rogers A, Jones F, Oleynikov D. Radiofrequency identification (RFID) applied to surgical sponges. *J Surg Endosc* 2007;21(7):1235-7.
8. Raso R, Gulinello C. Creating cultures of safety: risk management. *Nurs Manage* 2010;41(12):27-33.
9. Pelter M, Stephens K, Loranger D. An evaluation of a numbered surgical sponge product. *AORN J* 2007;85(5):931-40.
10. Kasatpibal N. Safe surgery implementation in Thailand. *AORN J* 2009;90(5):743-9.
11. Bogner M. *Human error in medicine*. New Jersey Hove, UK: Lawrence Erlbaum Associates; 1994.
12. Riley R, Manias E, Polgase A. Governing the surgical count through communication interactions: implications for patient safety. *Qual Saf Health Care* 2006;15:369-74.
13. Greenberg C, Diaz-Flores R, Lipsitz S. Bar-coding surgical sponges to improve safety: a randomized controlled trial. *Ann Surg* 2008;247(4):612-6.
14. LeFever G. Chasing zero events of harm: an urgent call to expand safety culture work and customer engagement. *Nurs Patient Care* 2010;28-42.
15. Reason J. Human error: models and management. *BMJ* 2000;320(7237):768-70.
<http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1117770/>. Accessed June 25, 2014.