

Selected Best Practices and Suggestions for Improvement

PDI 03: Retained Surgical Item or Unretrieved Device Fragment Count

Why focus on retained foreign objects in children?

- 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.
- Like adults, children are at risk for having foreign bodies left in the surgical field following a procedure. The 2006 National Healthcare Quality Report found an incidence of 0.05 events per 1,000 discharges in pediatric populations (0-17 years old) (compared with 0.09 at 18-44 years, 0.12 at 45-64 years, and 0.08 at 65 or more years).²
- In addition to the considerable morbidity and mortality risks for pediatric patients, retained foreign objects are costly. One study found that retained surgical items or unretrieved device fragments in children resulted in an increased mean length of stay (5.7 days) and an average increased charge of \$31,366 even after adjusting for age, gender, expected payer, comorbidities, and hospital characteristics.³
- Part of this cost is likely to be shouldered by hospitals, as the Centers for Medicare & Medicaid Services will not reimburse for foreign objects retained after surgery for Medicaid patients.⁴

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. ^{1,5-11}
Appropriate Staff Education	Create an education model that promotes development of knowledge and research for perioperative staff consistent with national criteria. ^{5,12}
Team Collaboration	Promote and maintain a collaborative and ethical work environment that facilitates trust and confidence to allow all members of the interdisciplinary team to speak up if patient safety is compromised. ¹²⁻¹⁴
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. ^{11,12,15-17}
Standardized Practices	Integrate use of innovative surgical techniques, radiographic technology, and standardized practices and protocols for all procedures. ^{1,7,8}

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 pediatric patient preoperatively, intraoperatively, and postoperatively to prevent retention of foreign objects.⁵
- 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.^{5,7,8}
- Count sharps and miscellaneous items (e.g., cautery tips and scratch pads) on all procedures.⁷
- Perform at least 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).^{1,5,10,17}
- Complete the count audibly and have the count concurrently viewed by the circulator and one other person.^{5,7,11}
- Separate items being counted; place used sponges in a clear bag for visualization when performing final counts.^{6,7,10,11}
- 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.⁶
- Do not remove any sponges, sharps, or instruments from the operating room or procedural area until the case has been completed.⁷
- Ensure that the surgeon performs a methodical wound check prior to count.^{2,3}
- Use a “timeout” when final count occurs.^{5,10,11,18}
- Document the results of the final count in the surgical record or operative note.⁵

- Develop a protocol for staff to handle discrepancies, including use of x-ray detectable sponges and towels only.^{5,6,7,9}
 - 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, an x-ray should be obtained and read immediately.
 - When obtaining a postsurgical x-ray after a count discrepancy, be sure to indicate this reason when ordering the film so radiology staff are aware.¹⁸
 - 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.^{5,12,18} 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 to speak up if patient safety is being compromised.^{5,12-14,18}
 - 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 who are noncompliant.

Recommended Practice: Use of Equipment and Instruments

- Integrate new instruments or equipment into practice that prevents retention of foreign bodies.
- Consider use of computer-assisted methods for counting, including use of a barcoding system on surgical sponges and instruments.^{7,8,17}
- Consider use of radio frequency identification devices on surgical sponges and instruments.^{5,12,15}
- Consider use of numbered surgical sponges and instruments for a more comprehensive, thorough count to reduce the risk of miscounting.¹¹

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 pediatric patients, especially high-risk patients (e.g., bariatric patients) or high-risk situations (e.g., emergency procedures).^{1,7,8}

- If they are not implemented routinely, consider implementing additional screening methods for high-risk cases even when counts are documented as correct (e.g., obese pediatric 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.⁵

Effectiveness of Action Items

- Track compliance with elements of established protocol by using checklists, appropriate documentation, etc.^{5,18}
- 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 can 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 staff; and executive leadership) on level of compliance with process.¹⁸
- Conduct a root cause analysis for any occurrences of foreign body retention.⁵
- 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-acf/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

- Children’s Hospital of Boston Pediatric Surgical Safety Checklist
http://www.aaos.org/news/aaosnow/aug11/clinical12_f1.pdf
- Pennsylvania Patient Safety Authority. Retained Foreign Object Audit Form
<http://patientsafetyauthority.org/EducationalTools/PatientSafetyTools/rfo/Documents/audit.pdf> (hit Cancel when prompted for login, and wait for file to open)
- World Health Organization Surgical Safety Checklist
http://who.int/patientsafety/safesurgery/tools_resources/SSSL_Checklist_finalJun08.pdf

Staff Required

- Surgeons
- Radiologists
- 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
- Timeout 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 timeout and be empowered to stop the procedure if there are concerns

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