OPSC Review of Unintended Retained Foreign Objects

A Patient Safety Reporting Program Report Review

Lessons from Oregon's Patient Safety Reporting Program

The Oregon Patient Safety Commission (OPSC) received a request from a participating facility on lessons learned from reports of unintentionally retained objects during orthopedic surgery. OPSC reviewed unintended retained foreign object (URFO) adverse event reports submitted to the Patient Safety Reporting Program (PSRP) and recent literature to support URFO prevention work.

Key Takeaways

- The strongest PSRP action plans were broadly in line with best practices recommended in the Association of periOperative Registered Nurses (AORN) guidelines. According to the 2017 AORN guidelines[1] (p. 379):

  > *"Establishing a system that accounts for **all surgical items opened and used during a procedure** constitutes a primary and proactive strategy **to prevent patient harm**. Reason's model of human error states that errors involve some kind of deviation from routine practice. The ideal RSI prevention measures are standardized, transparent, verifiable, and reliable. Deliberate, consistent application of and adherence to standardized procedures are necessary to prevent the retention of surgical items."*

- The overarching goal of guidelines for URFOs prevention is to ensure there are standardized systems in place to account for **all items** that are opened or used during a procedure.
- URFO reports from PSRP echo many of the same themes we see in recent literature that call out the important role of a culture of safety in preventing these events on an ongoing basis.

URFO Events

Our review included PSRP reports of URFO events from both ambulatory surgery centers (ASCs) and hospitals related to orthopedic surgery. We found 23 reports of URFO events impacting Oregon patients (2012 to 2020) that met these criteria.

Where the URFO Events Occurred

- Operating or procedure room (91%)
- Inpatient (adult) setting (4%)
- Preop area (4%)

Types of URFOs

- Instrument fragments, (35%)
- Whole instruments (26%)
- Sponges (17%)
- "Other" objects (17%)
- Guidewire (4%)

Most Common Contributing Factors to URFO Events

- Policy or procedure factors (70%)
  - Most frequent: Clarity of policy or procedure
- Device, equipment, or supply factors (65%)
  - Most frequent: Design
- Communication factors (48%)
  - Most frequent: Between providers and staff
- Human and environmental factors (48%)
  - Most frequent: Interruptions and distractions

Action Plans from Oregon Facilities

Because the circumstances surrounding and contributing to every event are unique, the action plans that come out of a facility's event review and analysis process are often specific to an event's root causes and the organization where the

[1] Association of periOperative Registered Nurses (AORN). 2017. *Guidelines for Perioperative Practice*. Denver, CO: AORN

event occurred. There may, however, still be some valuable lessons for other organizations to glean from those action plans. Please find a summary of the strongest action plans from the PSRP URFO reports we reviewed.

Counting Process

- System- or facility-wide standardization of:
  - The overall count to allow visualization of the item being counted.
  - Sweeps upon completion of all surgeries and procedures.
  - Tracking atypical items.
  - Reduce staff changes during surgical procedures when surgical counts are pending.
  - Education for policy on surgical counts and clarify counts for all items.
- Separate sterile packaging for surgical items.
- Audit counts after implementation of new or revised policy and processes to ensure ongoing effectiveness.

Device Integrity and Design

- System- or facility-wide standardization of:
  - Sterile processing process for visual inspection of instrument and insert integrity, and documentation of its presence and/or absence during cleaning, testing, and assembly process to report and sequester any defective instrument.
  - Inspection of instrument and insert integrity at set-up and inspection for presence/absence of instruments or inserts at take down. Label and sequester defective instruments.
- Report any adverse events involving a device, equipment, or supply to FDA MAUDE.

Team Communication

- For all items, announce placement and removal. Document and track all items.
- Change EHR documentation fields to support workflow with a reminder of need for removal of items from patient. Alter post-op note template to support documenting use and removal of items.

Manage Interruption and Distractions

- Updated visitor policy to limit vendors and/or visitors in the operating room during critical times (e.g., open/closing counts) to minimize interruptions and distractions.

Additional Reading

Making Health Care Safer II: An Updated Critical Analysis of the Evidence for Patient Safety Practices
Agency for Healthcare Research and Quality (AHRQ), 2013 | Shekelle, Paul G., Robert M. Wachter, Peter J. Pronovost, Karen Schoelles, K M McDonald, S M Dy, Kaveh G. Shojania, et al.

Key takeaway: This AHRQ report includes a chapter on retained objects. They conclude that one significant area for improvement is that guidelines are not being adequately followed and that internal policies and procedures following are not being audited for compliance. Practice drift sets in and is not caught in a timely manner.

Unintentionally Retained Foreign Objects: A Descriptive Study of 308 Sentinel Events and Contributing Factors
Joint Commission Journal on Quality and Patient Safety, 2019 | Steelman, Victoria M., Clarissa Shaw, Laurel Shine, and Abbey J. Hardy-Fairbanks

Key takeaway: This article has a good list of recommendations for prevention of retained objects that are the commonly missed elements of the AORN guidelines, plus some good culture of safety tips. Take note of the following content:

- **Orthopedic instruments are complex and often not owned and maintained by a facility creating risk** (p.254): "The most frequently identified type of retained instrument was orthopedic instruments, including joint arthroplasty instrumentation. These instrument sets are complex, with numerous components for individual instruments. The sets are commonly owned by the implant manufacturer and used on consignment, brought in the day of or the day before the surgical procedure. The instruments change with manufacturers' changes in implants, creating challenges for providing the ongoing education and risk assessments necessary. It is apparent that URFOs are a concern in orthopedic surgery."
- **Leadership's role in supporting a culture of safety necessary for consistent use of safe practices** (p. 256): "Policies should also include steps to account for objects and verification of the integrity of objects used. The desired risk reduction behaviors should be facilitated and reinforced. Routine observation of practices should be conducted to determine the level of compliance with risk reduction strategies. Compliance should be celebrated as a success, and any noncompliance should be addressed. Finally, reporting near misses should be encouraged."

A Qualitative Content Analysis of Retained Surgical Items: Learning from Root Cause Analysis Investigations
International Journal for Quality in Health Care, 2020| Hibbert, Peter D., Matthew J. W. Thomas, Anita Deakin, William B. Runciman, Andrew Carson-Stevens, and Jeffrey Braithwaite

Key takeaway: This is a small study that identified that some of the more commonly retained objects in their dataset are implanted outside the times when surgical counts and timeouts are happening.