The Joint Commission
Sentinel Event Alert

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Published for Joint Commission accredited organizations and interested health care professionals, *Sentinel Event Alert* identifies specific types of sentinel and adverse events and high risk conditions, describes their common underlying causes, and recommends steps to reduce risk and prevent future occurrences.

Accredited organizations should consider information in an Alert when designing or redesigning processes and consider implementing relevant suggestions contained in the Alert or reasonable alternatives.

Preventing unintended retained foreign objects

The unintended retention of foreign objects (URFOs) – also called retained surgical items (RSIs) – after invasive procedures can cause death, and surviving patients may sustain both physical and emotional harm, depending on the type of object retained and the length of time it is retained. There may be an extended time frame between occurrence and detection of an URFO. Retained foreign objects are most commonly detected immediately post-procedure; by X-ray; during routine follow-up visits; or from the patient's report of pain or discomfort.

URFOs refer to any item or foreign object related to any operative or invasive procedure that is left inside a patient.[1] Objects most commonly left behind after a procedure are:

- Soft goods, such as sponges and towels
- Small miscellaneous items, including unretrieved device components or fragments (such as broken parts of instruments), stapler components, parts of laparoscopic trocars, guidewires, catheters, and pieces of drains
- Needles and other sharps
- Instruments, most commonly malleable retractors[1]

A *New York Times* article published in September 2012 illustrates the adverse effects of an URFO. Four years after having a hysterectomy, a woman in Kentucky began to experience severe abdominal pain. A CT scan revealed a surgical sponge left behind by the surgical team that had performed the hysterectomy. Upon surgical exploration, the retained sponge was found to have caused a serious infection, which required bowel resection. The patient suffered from severe health issues, anxiety, depression, disability and social isolation.[2]

Not only does an URFO harm the patient, it adds significantly to the average total cost of caring for the patient. In a recent review, the Pennsylvania Patient Safety Authority estimated that the average total cost of care related to an URFO is about $166,000.[3] This cost includes legal defense, indemnity payments, and surgical costs not reimbursed by the Centers for Medicare & Medicaid Services. Another study estimated medical and liability costs to be $200,000 or more per incident.[4]

Events, risk factors and root causes

From 2005 to 2012, 772 incidents of URFOs were reported to The Joint Commission's Sentinel Event database.* Sixteen deaths resulted from these incidents. About 95 percent of these incidents resulted in additional care and/or an extended hospital stay. In hospital settings, these incidents occurred in operating rooms, labor and delivery areas, as well as ambulatory surgery centers and other areas where invasive procedures are performed (e.g., cath lab, GI lab, interventional radiology, emergency department).

According to the sentinel event data, the most common root causes of URFOs reported to The Joint Commission are:

- The absence of policies and procedures
- Failure to comply with existing policies and procedures

* The reporting of most sentinel events to The Joint Commission is voluntary and represents only a small proportion of actual events. Therefore, these data are not an epidemiologic data set and no conclusions should be drawn about the actual relative frequency of events or trends in events over time.

- Problems with hierarchy and intimidation
- Failure in communication with physicians
- Failure of staff to communicate relevant patient information
- Inadequate or incomplete education of staff

According to one study, the most common risk factors for URFOs include: patients with high body mass index (risk ratio for each one-unit increment, 1.1 [95 percent confidence interval, 1.0 to 1.2]); an emergent or urgent procedure; and unanticipated/ unexpected change during the procedure.[5] (Some examples of changes that can occur during a procedure include: a change in approach/incision, type of procedure, added procedure, or the development of a complication during the procedure). Other risk factors include intra-abdominal surgery; more than one surgical procedure; involvement of multiple surgical teams; multiple staff turnovers during the procedure; and unexpected intraoperative development. Occurrence of an URFO was nine times as likely when an operation was performed on an emergency basis and four times as likely when the procedure changed unexpectedly (see examples of change above).[3] An additional risk factor is long procedure duration.[6,7] URFOs also occur in patients who exhibit none of these risk factors.

In order to prevent retained surgical items and sponges, surgeons and operating room staff have traditionally relied on "cavity sweeps" and manual counting protocols – both of which are prone to human error. Current practices for counting sponges have a 10 to 15 percent error rate.[8] In addition, 80 percent of retained sponges occur with what staff believe is a correct count.[8] Sentinel event data show an incorrect or "discrepant" count in 52 of the 772 URFO sentinel events reported to The Joint Commission. The Pennsylvania Patient Safety Authority's Reporting System database shows 22.3 percent of URFOs were associated with a discrepant count.[9]

Many counting procedures lack the elements of high reliability but are entrenched and difficult to change, said Verna C. Gibbs, M.D., professor of clinical surgery, University of California, San Francisco, and director of No Thing Left Behind®, a national surgical patient safety project to prevent retained surgical items. High reliability science studies organizations such as those in the commercial aviation industry, which manage great hazard extremely well, and in which the goal is zero harm. In order to achieve high reliability, leadership must commit to this goal; the culture must support workers who identify and report unsafe conditions; and systematic quality improvement approaches need to be implemented that reliably measure the magnitude of the problem (e.g., days between procedures with an URFO), identify the contributing factors and root causes, and develop solutions for the most important causes.[10,11]

Studies show that the risk of URFOs is significantly reduced following improvements to counting procedures. Team members need to move from varying practices to standardized practices – to develop and sustain reliable counting practices that ensure all surgical items are accounted for (i.e., are reconciled).[12] One children's hospital reduced the number of reported incorrect counts and count discrepancies by 50 percent between 2009 and 2010, and also improved its entire count process.[13]

Recommendations and potential strategies for improvement

Guidelines, processes and tools have become available to help team members develop risk-reduction strategies that can be adopted and followed organization-wide.[1,12,14] These strategies include improved multi-stakeholder perioperative processes, enhanced team communication, and the use of assistive technology.[1,12,14,15,16] Organizations should provide continuous education or training to appropriate staff about new and existing policies and procedures that are in place to prevent URFOs. The following recommendations and potential strategies can be used to help prevent URFOs. Should your organization discover and remove an URFO, follow your organization's established policy for reporting, analyzing and communicating the event to staff and the patient and his or her family.

Effective processes and procedures

1. Create a highly reliable and standardized counting system to prevent URFOs – making sure all surgical items are identified and accounted for. The counting system should be supported by organizational leaders, and developed using a multidisciplinary approach, involving surgeons, proceduralists, nurses, surgical technologists, anesthesiologists, radiologists, and radiology technologists working together as a team in an environment that promotes the exchange of knowledge and information.[1,12,14,16,17]

2. Develop and implement effective evidence-based organization-wide standardized policy and procedures for the prevention of URFOs through a collaborative process promoting consistency in practice to achieve zero defects. Use resources published by The Joint Commission,[17] World Health Organization, American College of Surgeons,[14] Association of periOperative

Registered Nurses,[12] No Thing Left Behind, and other organizations and publications as a guide. The **policy** should apply to all operative and other invasive procedures, and should address the following.

A **counting procedure** should:

- Be performed audibly and visibly by two persons engaged in the process, usually scrub tech or scrub nurse and circulating registered nurse. The surgical team should verbally acknowledge verification of the count.
- Include counts of items added to the surgical field throughout the surgery or procedure.
- Include counts of soft goods (including therapeutic packing), needles/sharps, instruments, and small miscellaneous items, and document unretrieved device fragments.[1,12]
- Verify that counts printed on prepackaged sponges and instrument sets are correct.[1,12] Handle the discrepancy per the organization's policy.
- Be performed before the procedure begins, in order to establish a baseline count; before the closure of a cavity within a cavity; before wound closure begins; at skin closure or end of procedure; and at the time of permanent relief of either the scrub person or the circulating registered nurse.[18]
- Be applicable in all settings where invasive procedures are performed.
- Be reviewed periodically and revised as appropriate.[12,14]

Wound opening and closing procedures should include:

- Inspection of instruments for signs of breakage – before and after use – to prevent the retention of device fragments.[19]
- Adherence to the organization's established counting procedure.
- Methodical wound exploration,[1,14] including visual and, whenever possible, manual examination.[20] This can and should be done for laparoscopic procedures as well.
- Empowerment of any member of the operative team to call a "closing time out" prior to the initial closing count to allow for an uninterrupted count.

Intra-operative radiographs should be performed:

- When the surgical count is "incorrect" (i.e., discrepant).The entire surgical field should be radiographed, and it should be interpreted by a physician at the completion of the operative procedure, prior to the patient's transfer from the OR. Ensure direct communication between the surgical team and radiologist. The requisition should include the name of the missing item and the results of the radiologic image should be directly communicated to the surgical team.
- When the operative procedure is determined by the surgical team to be at high risk for retained surgical items, even though methodical wound exploration has been performed and the surgical item count is correct.
- If counts remain unreconciled after initial radiologic examination, the surgical team should consider additional imaging or further wound exploration.[12,21]

Effective communication

3. Institute team briefings and debriefings as a standard part of the surgical procedure to allow the opportunity for any team member to express concerns they have regarding the safety of the patient, including the potential for an URFO. This will promote open communication among surgical team members. Examples: Before the procedure or as part of the time out, the surgeon could remind the team that the patient or procedure is at risk for an URFO; during the procedure, a white board could be used to display the count and to help foster team awareness and shared responsibility;[22,23] at the end of the procedure, team members can raise or be asked about any concerns related to the procedure or the patient's recovery.[21] Team training, based on crew resource management (CRM), is effective in promoting assertiveness and overcoming hierarchical barriers to communication.

4. Ensure that the surgeon verbally verifies the results of the counting procedure.

Appropriate documentation

5. Document the results of counts of surgical items, instruments, or items intentionally left inside a patient (such as needle or device fragments deemed safer to remain than remove), and actions taken if count discrepancies occur.[14] Tracking discrepant counts is important to understanding practical problems; tracking reports and data also can be discussed at improvement meetings. Collecting, analyzing and sharing accurate data is key to understanding your organization's frequency or risk of URFOs, identifying the types of URFOs that occur most frequently, and determining how to address certain kinds of URFOs.

Safe technology

6. Research the potential of using assistive technologies[1,12,14,16,24,25] to supplement manual counting procedures and methodical wound exploration. More commonly used technologies

include bar-coding to aid counting, radio-opaque material or radiofrequency (RF) tags to detect technology-enabled soft goods, and radio frequency identification (RFID) systems to aid counting and detection.[8,26]

Related Joint Commission requirements

The unintended retention of a foreign object in a patient after surgery or other invasive procedure is considered a reviewable sentinel event by The Joint Commission. Accredited organizations are expected to respond to sentinel events as part of a patient safety program outlined in the following standards and elements of performance (EP) for hospitals, ambulatory and office-based surgery facilities.

LD.04.01.07: The organization has policies and procedures that guide and support patient care, treatment and services.

LD.04.04.05: The organization has an organization-wide, integrated patient safety program [within its performance improvement activities]. (Wording in brackets is added for hospitals only.)

EP 5: As part of the safety program, the leaders create procedures for responding to system or process failures.

EP 7: The leaders define "sentinel event" and communicate this definition throughout the organization.

EP 8: The organization conducts thorough and credible root cause analyses in response to sentinel events as described in the "Sentinel Events" (SE) chapter of the manual.

EP 9: The leaders make support systems available for staff who have been involved in an adverse or sentinel event.

RI.01.02.01: The organization respects the patient's right to participate in decisions about his or her care, treatment, and services.

EP 21: The organization informs the patient or surrogate decision-maker about unanticipated outcomes of care, treatment, and services that relate to sentinel events considered reviewable by The Joint Commission.

EP 22: [Hospitals only] The licensed independent practitioner responsible for managing the patient's care, treatment, and services, or his or her designee, informs the patient about unanticipated outcomes of care, treatment, and services related to sentinel events when the patient is not already aware of the occurrence or when further discussion is needed.

Resources

WHO guidelines for safe surgery 2009: safe surgery saves lives: See Objective 7: The team will prevent inadvertent retention of instruments and sponges in surgical wounds, and Objective 9: The team will effectively communicate and exchange critical information for the safe conduct of the operation

World Health Organization: Surgical Safety Checklist

Pennsylvania Patient Safety Authority: Retained Foreign Object Audit Form

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