Update on the Prevention of Retained Surgical Items

INTRODUCTION
The Pennsylvania Patient Safety Authority reported on the risk of the retention of foreign objects related to the failure to account for all sponges, sharps, and instruments postoperatively in the June 2009 article “Beyond the Count: Preventing the Retention of Foreign Objects.” Retained foreign objects are now more commonly referred to as retained surgical items (RSIs) in order to differentiate them from “foreign objects,” which may include swallowed pennies, pins, shrapnel, bullets, and other objects. The surgical team routinely relies on sponge, sharp, and instrument counts to reduce the risk of RSIs. Because counting alone may be insufficient, the Authority presented multipronged risk reduction strategies, including improved perioperative processes, perioperative team communication, and the use of assistive technology.

ABSTRACT
Surgical items such as sponges, sharps, and instruments may be retained following surgery and lead to serious patient harm. In June 2009, the Pennsylvania Patient Safety Authority reported that the prevention of retained foreign objects, now commonly referred to as retained surgical items (RSIs), requires application of a multidisciplinary, consistent approach utilizing current best practices. Since publication of the June 2009 Pennsylvania Patient Safety Advisory, the Association of periOperative Registered Nurses (AORN) has published additional guidance for the prevention of RSIs. Further guidance to assist in implementation of recommended best practices since the Authority’s report include strategies related to therapeutic packing, minimally invasive procedures, and unidentified device fragments. Ongoing analysis of events reported to the Authority showed that 2011, Pennsylvania healthcare facilities reported 452 events involving RSIs. This time, Pennsylvania healthcare facilities also reported 1,930 events involving incorrect counts of needles, sponges, or equipment. An incorrect count may be a significant patient safety risk because RSIs have been reported to be 100 times as likely to occur when there is a surgical count discrepancy.

Of the 452 reports to the Authority involving RSIs, 101 (22.3%) of the RSIs were associated with an incorrect count. In 153 (33.8%) of the 452 total reports, the RSI caused patient harm, and in 132 (29.2%), the patient could have been harmed if the event was not prevented (i.e., “near miss”). Forty-nine reports (10.8%) were events in which objects were intentionally left in the patient. Thirty-six (73%) of these intentionally retained objects were sponges left in place as packing for the wound. According to AORN-recommended practices, these objects are considered therapeutic packing and not RSIs. The remaining intentionally retained objects, which included a needle, surgical instruments, a plastic cap, and other objects, were left in place because the risk of removal was deemed greater than the risk of leaving the object in place. Those items are considered unretrieved device fragments and are reportable as RSIs.

Not all of the 452 reports identified the type of retained item. A total of 301 reported events identified the RSIs as follows:
- Sponges, 30.2%
- Medical instruments, 16.3%
- Needles, 13.0%
- Other (e.g., guidewires), 40.5%

ADDITIONAL GUIDANCE FOR THE PREVENTION OF RSIs
As reports to the Authority indicate, RSI events continue to occur. The first update
related to RSI prevention since publication of the June 2009 Advisory is a revision to the definition of when surgery ends. NQF previously defined when surgery ends as “after counts have concluded, the surgical incision has been closed, and/or operative device(s) such as probes have been removed, regardless of setting.” In 2011, NQF modified its definition for the end of surgery to “after all incisions or procedural access routes have been closed in their entirety, and, if relevant, final surgical counts confirming accuracy of counts and resolving any discrepancies have concluded and the patient has been taken from the operating/procedure room.” The revised definition is significant because it encourages OR staff to use all available measures to prevent RSIs after the incision is closed while the patient is still under anesthesia and in the OR. Further guidance issued since the publication of the June 2009 Advisory include additional strategies related to teamwork, the surgical count, therapeutic packing, sharps and needles, instruments, minimally invasive procedures, unretrieved device fragments, and radiographic screening. Recent reports to the Authority illustrate the continued importance of adopting effective strategies to mitigate this ongoing safety risk.

**Multidisciplinary Approach**

An Authority report illustrates an instance in which multidisciplinary team efforts prevented an RSI:

> Throughout the procedure, many instruments were added to the counts and two surgeons were operating together. All counts were reconciled at the end of the case except for needle holders. The circulator’s initial counts were 10, but only 9 were accounted for. The circulator made the surgeon aware of discrepancy in count, an x-ray was done at the end of case, and the patient was cleared of any retained instrument.

A successful RSI prevention program requires a consistent, multidisciplinary approach that involves all members of the perioperative team during all surgical and invasive procedures. AORN-recommended practices emphasize that the responsibility for preventing RSIs is shared among the perioperative team, including the registered nurse (RN) circulator, scrub person, surgeon, anesthesia professionals, and others assisting in the procedure. Significantly, the entire surgical team may be held legally responsible for RSIs. AORN makes recommendations specific to members of the perioperative team. Recommendations for surgeons and first assistants to prevent an RSI include the following:

- Maintaining awareness of items used
- Using radiopaque soft goods
- Communicating to the perioperative team when placing an item in the wound
- Acknowledging the start of the count process
- Performing a methodological exploration of the wound at the start of the first closing count
- Notifying the perioperative team when items have been returned to the field after counts have been completed

The RN circulator is assigned the responsibility to notify the team if there is a discrepancy in the count and to receive acknowledgement from the team so that other actions can be taken to find the missing item, such as a search of the operative field, floor, and trash buckets. Anesthesiologists are urged to maintain situational awareness during surgical procedures by planning actions that do not interfere with the counting process. Anesthesiologists should communicate with the perioperative team about items inserted or removed from the oropharynx. Radiologists and radiologic technologists and the perioperative team must communicate effectively when imaging is needed about what item is being searched for specifically, the best type of imaging to locate the missing item, and the most appropriate views; providing a sample of the item will also help with its identification in x-ray images.

**Surgical Count**

Reports to the Authority show that incorrect surgical counts may lead to an RSI.

An incorrect sponge count was identified. The surgeon proceeded with closure, and an x-ray was completed. A retained sponge was noted. A laparotomy to remove the foreign body was completed immediately.

The sponge count was incorrect. The surgeon stated he was not going back in to get it at this time due to a planned re-exploration in several days. The OR supervisor was present and aware of all the above. At the end of the surgery, the sponge count was incorrect. An x-ray was obtained and read by the radiologist. The x-ray confirmed a retained sponge in the incision. The retained sponge was removed by surgeon and counts were correct.

Surgery was performed for a ruptured abdominal aortic aneurysm. The abdomen was left open. A postoperative abdominal x-ray was obtained, and an area of densities that could have been within the body was identified. An abdominal computed axial tomography showed the possibility of a retained object. An exploratory laparotomy was performed, and the retained laparotomy sponge was removed.

AORN provides a number of specific recommended actions related to the surgical count. The following are best practices not previously reported by the Authority:

- Use only radiopaque soft goods in the wound, including towels.
- Separate sponges completely.
- View sponges concurrently (e.g., two perioperative team members should view and count the sponges together).
Therapeutic Packing

AORN-recommended practices now specify strategies related to therapeutic packing, which is when soft goods are left in place intentionally for therapeutic reasons. A patient may leave the OR with packing in place, but items used in therapeutic packing are not considered RSIs. However, if not accounted for, therapeutic packing may increase the risk of an incorrect count at subsequent operations. Authority reports demonstrate the importance of accounting for therapeutic packing during the counting process.

The patient underwent an exploratory laparotomy. The sponge count was incorrect, as sponges remained in the abdomen with a vacuum dressing from a previous surgery. Sharps, instruments, and soft goods were not counted as the abdomen was closed. Nurses requested the surgeon to stop and allow surgical counts. The surgeon closed the abdomen with vacuum dressing, and a portable abdominal x-ray was performed in the surgical intensive care unit. Nine radiopaque markers from sponges were visualized in the pelvis. The surgical team was aware of the intended retained packing material. No harm to patient.

A trauma patient had previous surgery in which eight sponges were intentionally retained, according to a previous OR record. Eight sponges were removed during the current procedure; at completion of surgery, an x-ray was taken to confirm no retained sponges.

AORN recommends that healthcare organizations develop policies and procedures to standardize processes related to therapeutic packing and the plan for removal that include communication about therapeutic packing to the perioperative staff and documentation requirements. Additional AORN guidelines include the following:

- Isolate and identify the therapeutic packing as being from the original procedure; do not include therapeutic packing that has been removed in the count for the removal procedure.
- Require the surgeon to conduct a methodical wound exploration and to consider ordering an intraoperative radiograph to confirm that all items have been removed.
- Document the count as reconciled if all soft goods have been removed and accounted for.
- Inform the patient and family members if any items have been intentionally left in the wound.

Sharps and Needles

Sharps such as needles and blades may be opened onto the sterile field and must be accounted for during the counting process. Reports to the Authority demonstrate the importance of reconciling an incorrect sharp or needle count.

The needle count was incorrect at closing. No needle was located despite exam of drapes, sterile field, and floor and using magnet. Fluoroscopy [was performed] for a possible retained needle prior to transfer from the OR bed. No needle was seen by the surgeon in the room. The case is pending review by a radiologist.

The staff verbalized that they had seen a needle fall onto the floor and out of vision. The needle was not found. Final counts were conducted to find one needle that was missing. An x-ray was taken. The radiologist reported a foreign body was seen on the image. The surgeon examined the image and verbalized the foreign body was not a needle but were clips used during the procedure, not a retained object.

The patient had abdominal surgery and the needle count was off. An x-ray was taken but nothing was found. Later, a CT [computed tomography scan] showed the retained needle. The patient was taken back to the OR for removal.

The patient had open-heart surgery completed with the count showing a knife blade was missing. A post-op x-ray was done and read as no retained radiopaque surgical instruments identified.

AORN recommends the following best practices to help prevent the retention of a needle or blade:

- The RN circulator and the scrub person should view packaged items when they are opened because packaging errors may occur that may lead to incorrect counts.
- Needles in the surgical field should be carefully tracked so the team can identify what type of needle is missing if there is a count discrepancy.
- If small needles are used frequently, policies should specify what size needles should be searched for on a radiograph, who should read the films, and who should inform the patient.
- Containment devices should be used for sharps to decrease the chance of needlestick injuries.
- The scrub person should verify that needles returned from the operative field are intact.
- The surgeon should notify the entire team and perform a wound exploration when a broken needle is identified.

Instruments

Reports to the Authority show that instruments (e.g., forceps) and pieces of instruments (e.g., drill bits) may be
retained if not accounted for in the counting process.

On the initial count in the OR, forces were not recorded on the count sheet. An x-ray was taken prior to closure to confirm no instruments were retained; none were found.

A drill pin was misplaced. An x-ray was done. Radiology verified that the pin was in the femoral canal. The pin was removed using a laparoscopic grasper and fluoroscopy during the same procedure.

The patient came to the OR for resection of a thoracic tumor. During the closing count and final count, there were two missing instruments from the thoracotomy tray. An x-ray was obtained that showed the instruments were not retained in the patient. The patient was awakened and transferred to the postanesthesia care unit.

A patient was scheduled for a cystoscopy. During the procedure, a tip from the resectoscope (from a previous procedure) was found lodged in the urethra.

AORN recommends the following best practices to help prevent the retention of instruments or pieces of instruments:

- Perform a count when sets are being assembled before sterilization to provide an inventory; however, this count should not be considered the initial surgical count.
- Count multiple pieces of instruments separately, and document the information on the count sheet.
- Use preprinted count sheets for instruments to provide an inventory of what is in the instrument set.
- If possible, limit the number and type of instruments to streamline the counting process.

Minimally Invasive Procedures

The Authority reported on the risk of RSIs during minimally invasive procedures and presented a number of risk reduction strategies. Previously published literature about prevention of RSIs was generally focused on prevention strategies in the OR setting. The following reports to the Authority demonstrate the continuing importance of RSI prevention strategies during any minimally invasive procedure, including those performed outside the OR, to prevent the risk of patient harm.

An interventional nurse using a guidewire through the brachial vein encountered resistance and withdrew the needle. The nurse observed a frayed end of guidewire. The procedure was terminated, and an x-ray was obtained revealing a small retained portion of the guidewire. Vascular surgery was consulted, and a plan was developed to remove the fragment as an outpatient procedure within the next week.

When removing a drain at the bedside, one piece retracted back inside. The patient was taken to interventional radiology, where the foreign body was removed.

The patient was undergoing a robotically assisted laparoscopic hysterectomy. Early in the case, the surgeon requested placement of a vaginal cuff occluder to prevent the loss of insufflated air. At the conclusion of the case, the patient had a laryngospasm. The registered nurse later noted the vaginal cuff occluder was still in place. The physician removed the occluder that day. No harm occurred to the patient.

AORN also recommends that counts should be performed during minimally invasive procedures such as laparoscopy and thoracoscopy.

Unretrieved Device Fragments

A device fragment may be noticed and not retrieved because the risk of retrieval is considered by the surgeon to be greater than the risk of retention. Such unretained device fragments are considered RSIs. A fragment of a medical device that separates or breaks and is unintentionally left in a patient after a procedure is also considered an RSI. Authority reports show the risk of the retention of a device fragment if not accounted for during a procedure.

The patient was undergoing a cataract removal. The phacoemulsification handpiece was introduced into the eye, and a piece of metal was spotted in the eye. The metal piece was successfully removed and sent to pathology. There was concern that this may have come from a handpiece device. The physician reports that this piece of metal came through the phacoemulsification, and the physician believes the metal was in the sleeve at assembly of the handpiece and, once infusion started, was flushed into the eye.

The patient underwent a robot-assisted laparoscopic gynecological procedure without apparent complication. One week later, the patient called the physician, stating there was something in her vagina. An examination revealed that a piece of a device used to position the uterus remained following the procedure. The device piece was removed without complication.

During surgery, the tip of the arthroscopic ablation wand fell off in the patient. An x-ray obtained at the end of the procedure verified no retained material in the knee.

AORN recommends adding any device that may separate or fragment to the final time-out checklist so that all perioperative team members are aware of this risk. The surgeon should announce to the perioperative team during the final time-out that the device could fragment or detach in order to raise awareness and to remind the team to check for this possibility prior to wound closure. If a device fragment is left in the wound intentionally
(i.e., because the device cannot be retrieved or because the risk to the patient of removal of the device fragment is greater than the benefit of removal), the patient must be informed of the risks associated with the intentionally retained device fragment, which may include migration of the device fragment and the potential for infection, and of the types of procedures that should be avoided in the future (e.g., magnetic resonance imaging).10

**Radiographic Screening**

The Authority previously reported on the effectiveness of intraoperative and postoperative radiographic screening.1 The Authority presented risk reduction strategies that included radiographic screening at the end of cases involving an incorrect count, an emergent procedure, an unexpected change in procedure, or a high patient body mass index.11,12 AORN recommends implementing the following best practices:4

- If a facility does not have radiograph capabilities, develop detailed policies and procedures outlining steps for the perioperative team to follow, including transfer of the patient to a facility with radiograph capability.
- Use language on a radiograph request that can be understood by non-OR personnel.
- Create an educational board depicting commonly retained items for the radiology department staff to use for comparison.

**CONCLUSION**

Ongoing analysis of reports to the Authority demonstrates that Pennsylvania healthcare facilities would benefit by continuing efforts to prevent the retention of surgical items. Implementation of current best practices may be accomplished by emphasizing that a consistent multidisciplinary team effort be made to reduce the risk of RSIs, including strict adherence to a standardized counting process and reconciliation of the count before the patient is taken from the OR or procedure room. These preventive strategies are critical and apply equally to minimally invasive procedures.

**NOTES**

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