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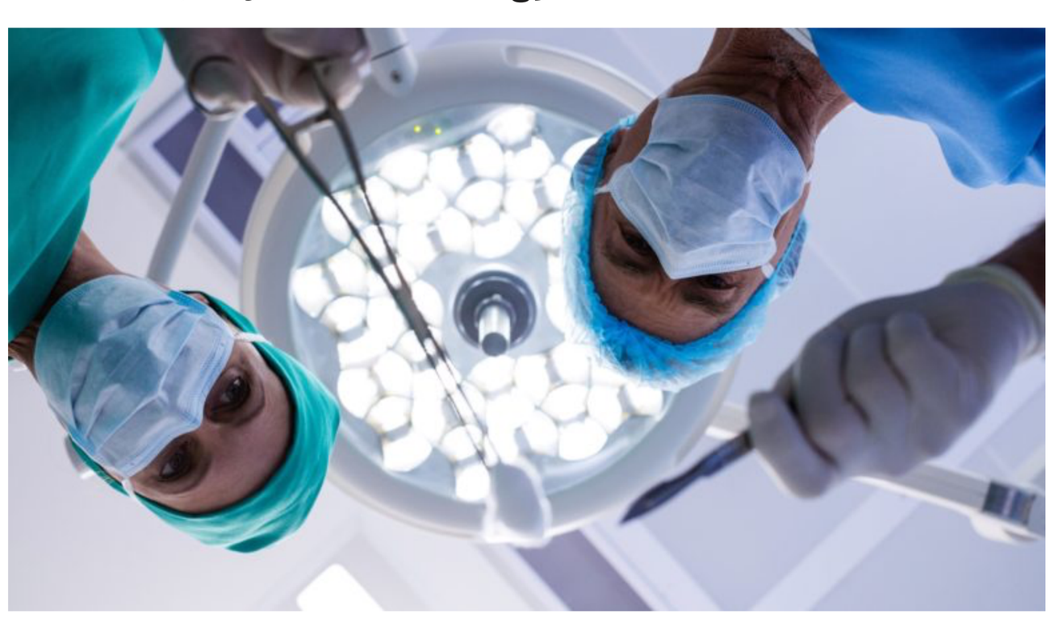
Preventing Retained Surgical Objects: Using Best Practices, Adjunct Technology



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Unintentionally retained surgical items (RSIs) in patients undergoing operative and other invasive procedures represent a significant infection and mortality risk. The Association of perOperative Registered Nurses (AORN) has recently strengthened its position on this adverse event by providing updated guidance on implementing a consistent interdisciplinary approach and using standardized procedures to prevent RSIs, accounting for surgical items, preventing retention of device fragments, and reconciling count discrepancies. Guidance is also provided for use of adjunct technology during manual counting procedures.

As the AORN guidance explains, "Perioperative team members are ethically and morally obligated to protect patients by implementing measures to prevent RSIs." This creed is registering with perioperative personnel; in a survey conducted by Steelman et al. that included 3,137 responses from perioperative registered nurses (RNs), 61 percent of participants identified the prevention of RSIs as one of the top priorities for perioperative patient safety.

RSIs continue to be one of the most common sentinel events reported to The Joint Commission, but experts express concern that these events are likely underreported and underestimated. AORN explains this might be due in part to the lack of a universal definition of RSI and varying reporting requirements. As AORN points out, "The true incidence of RSIs remains unknown in part because retained items may be undetected for months or years." AORN adds, "Reported methods of RSI discovery include symptoms, radiological evaluation, and physical examination. Time to diagnosis of an RSI can vary greatly. Reports suggest that many RSIs are discovered between the time of occurrence and two months, some have been found between two months and five years and others have been found after five years."

While surgical sponges are the most commonly retained items, AORN notes that "as the rates of minimally invasive procedures and the use of adjunct technologies to prevent retained soft goods increases, there could be a shift in the number and types of items that are retained compared to soft goods. Other reported RSIs are instruments, needles, device fragments, items such as guidewires, and miscellaneous items. Most counting discrepancies involve needles."

Many states require public reporting when RSI events occur. Federal and state agencies, accrediting bodies, third-party payers, and professional associations consider an unintentionally retained foreign object or RSI to be a serious and largely, if not entirely, preventable event (never event, healthcare-associated condition, sentinel event, serious reportable event). Consequently, healthcare organizations and providers will not be reimbursed for additional care provided because of an RSI.
A long-standing and evidence-based strategy for preventing RSIs is to account for all items opened or used during the operative or other invasive procedure. Healthcare organizations are responsible for employing standardized, transparent, verifiable, reliable practices to account for all surgical items used during a procedure. Counting radiopaque soft goods, sharps, miscellaneous items, and instruments is one method to account for all items used on the surgical field. However, there is a significant potential for inaccurate counts with the use of manual counting practices. The use of adjunct technology can decrease counting discrepancies and has the potential to reduce the risk of RSIs.

The biggest change to AORN's Guideline for Preventing Unintentionally Retained Surgical Items is the new recommendation for adjunct technology to account for soft goods.

"Evidence on retained surgical soft goods suggests that the accuracy of manual counting is unlikely to dramatically improve without assistance," says Julie Cahn, DNP, RN, CNOR, RN-BC, ACNS-BC, CNS-CP, senior perioperative practice specialist at AORN, and author of the RSI guideline. She says some types of adjunct technology devices have been shown to reduce the rate of count discrepancies, decrease time reconciling count discrepancies related to soft goods, and decrease costs associated with count discrepancies, such as costs for radiological imaging."
C
ahn stresses that adjunct technology should never replace manual counting because it remains an important step to account for surgical items used in the wound.
Other practice updates specific to preventing unintentional RSIs include a new section on preventing retained foam pieces from negative-pressure wound therapy devices, such as by cutting the foam only when necessary to fit in the wound and limiting the number of pieces of foam used when possible. New recommendations in the section on preventing retained fragments during intravascular device use, such as guidewire fragments, provides new practices for instrument inspection before and immediately after use at the point of care.

Beyond the process of counting, systems and human factors play a significant role in contributing to RSIs. Therefore, behavioral changes and education about risk-reduction strategies unique to each setting used during the adoption of systems may improve accounting for surgical items. Improving system reliability to enhance the performance of human factors (such as compliance with policies and procedures, effective hand-over communication) may reduce the incidence of errors and improve patient safety.

"There are known risk factors for RSI but they are not modifiable," says Cahn. "This means we have little control to change them. There are also many contributing factors for RSIs and they are almost all modifiable (see attached sheet). The three main categories of contributing factors identified by Steelman et al in three recent studies of retained items reported to the Joint Commission between 2012 to 2018 were problems related to human factors, ineffective leadership, and communication breakdown. When these risk factors occur, they could increase the likelihood of contributing factors to occur as well. For instance, RSIs may occur more frequently during stressful situations such as when an unexpected change in the procedure occurs, not because of the situation itself but because of the impact these conditions have on communication and human factors (e.g., teamwork, mindfulness). Therefore, interdisciplinary interventions that focus on improving the system culture and human factors may help decrease the risk of RSIs. Focusing on modifiable interventions that target improvement of human factors or the system culture to prevent RSIs is important because many of the risk factors identified by early research were not modifiable. However, there is little research on the impact of human factors on RSIs."
AORN recommends a systems approach to preventing RSIs includes using standardized counting and reconciliation procedures, methodical wound exploration, radiological confirmation, adjunct technology, team training, and enhanced communication to promote optimal perioperative patient outcomes.

The AORN recommendation of using adjunct technology has existed since 2016, Cahn explains, noting that, "This year we strengthened the recommendation because it is clear that manual counting procedures will not improve in accuracy by themselves. Additionally, research is available to show that use of adjunct technology for the prevention of surgical soft goods will decrease the rates of count discrepancies, time spent reconciling count discrepancies, and use of radiologic imaging. All these things will reduce time, money, and potentially reduce the risk of an RSI. Therefore, with the backing of evidence, a strengthening of the recommendation to use adjunct technology for the prevention of retained soft goods, may improve patient safety which is part of the mission of AORN."

Regarding the evaluation of adjunct technology devices, AORN recommends that "Perioperative RNs, surgical technologists, physicians, infection preventionists, material management personnel, quality and risk managers, radiology personnel, sterile processing personnel, and other healthcare personnel involved in the use of the products and medical devices for prevention of RSIs should be part of the interdisciplinary product evaluation and selection committee when the healthcare organization is evaluating the purchase of adjunct technology. The interdisciplinary team composition may differ depending on the device being evaluated. For instance, if the device selected for evaluation includes specialized instruments with radio-frequency identification (RFID) tags, then sterile processing personnel may provide important insights on the cleaning, disinfection, and sterilization processes."

AORN outlines an interdisciplinary approach as comprising the following steps:
• Use a consistent interdisciplinary approach for preventing RSIs during all surgical and invasive procedures.
• Implement measures for all perioperative team members to improve teamwork and communication as part of a collaborative interdisciplinary approach to RSI prevention.
• Actively participate in team training as a measure to prevent RSIs.
• Minimize distractions, noise, and unnecessary interruptions during the surgical count.

AORN also recommends that facilities "Evaluate the manufacturer's instructions for feasibility in practice; process for cleaning, disinfection, and sterilization of reusable devices (such as instrument tags); process for cleaning and disinfection of equipment; preferences of perioperative personnel; associated costs; radio-frequency (RF) interference with temporary pacemakers when applicable; and RFID interference with pacemakers, implantable cardioverter defibrillators, and other electronic medical devices."

Cahn points to the guideline's synthesized account of the identified evidence on all the available adjunct technology devices on the market. "This was included to help perioperative teams evaluating these products understand the evidence available on the different types of adjunct technology," she says. "It is important to note that evidence on a specific type of adjunct technology device is not generalizable to all devices and is specific to that manufacturer, even if the system uses the same type of technology."

Other guidance can be found in AORN's document, Prevention of Retained Surgical Items: Product Evaluation of Adjunct Technology, which explains, "The process of selecting adjunct technology devices gives healthcare organizations a systematic way to determine and document which devices will best meet their needs. The selected devices must be acceptable for clinical care and prevent unintentionally retained surgical items. The selection process includes collecting information that will allow the organization to make informed decisions about which devices to implement. The more this process can be standardized across clinical settings, the more information can be used to compare experiences among healthcare facilities."

AORN says that a key feature of the process is an in-use product evaluation, which, it points out, is not the same as a clinical trial: "Whereas a clinical trial is a sophisticated scientific process requiring considerable methodological rigor, a product evaluation is simply a pilot test to determine how well a device performs in the clinical setting. Although the process does not need to be complex, it does need to be systematic." AORN provides a 10-step approach for selecting a product for implementation:
1. Organize a product selection and evaluation team
2. Set priorities for product consideration
3. Establish criteria for product selection and identify other issues for consideration
4. Obtain information on available products
5. Obtain samples of devices under consideration
6. Develop a product evaluation survey form
7. Develop a product evaluation plan
8. Tabulate and analyze the evaluation results
9. Select and implement the preferred product
10. Perform post-implementation monitoring

Standard Procedure for Preventing RSI

AORN's Guideline for Preventing Unintentionally Retained Surgical Items makes the following recommendations:
• Use a consistent accounting methodology for all surgical counts.
• Conduct a count of soft goods, sharps, miscellaneous items, and instruments during the phases of the procedure.
• Conduct a count before the procedure to establish a baseline (the initial count) before the patient enters the OR or procedure room, when possible.
• An additional count may be performed at designated intervals (as part of a second time out) during lengthy procedures.
• Establish the standardized sequence in which the counts should be conducted in the organization. The counting sequence should have a logical progression (order of standardized count board or sheet, proximal to distal from the patient).
• Items being counted should be viewed concurrently by two individuals, one of whom should be the RN circulator, and counted audibly.
• The scrub person should separate and point out items on the sterile field while audibly counting. The RN circulator should separate and point out items off the sterile field while audibly counting.
• During the initial count and when adding items to the sterile field, count packaged items according to the number in which the item is packaged.
• When introducing items to the sterile field, verify that the package contains the number of items on the product label. Packages that contain an incorrect number of items or items with a manufacturing defect (e.g., missing marker, tag, or chip) should be
• If the count is interrupted, restart the count for the type of item (e.g., laparotomy sponge) that was being counted when the interruption occurred.
• Do not consider the final count complete until all surgical soft goods, sharps, instruments, and miscellaneous items (e.g., viscera retainer) used in closing the incision are removed from the patient and returned to the scrub person.
• A count can be requested by any perioperative team member. When any member of the perioperative team requests a count, the count should be performed.
• If an item is passed or dropped from the sterile field, the RN circulator should retrieve it using standard precautions, show it to the scrub person, isolate it from the field, and include it in the final count.
• Do not subtract or remove items from the count.
• Keep all counted items inside the OR or procedure room until the counts are completed and reconciled.
• Do not remove linen and waste containers from the OR or procedure room until all counts are completed and reconciled and the patient has been transferred out of the room.
• Remove used or open counted items from the OR or procedure room before another procedure begins.
• Perform a structured hand-over communication of accounting procedures at times of relief of the RN circulator or scrub person.

In its 2019 Top 10 Health Technology Hazards report, ECRI addressed the hazards associated with retained surgical sponges and recommended broader adoption of technologies that supplement the manual sponge-counting process.

Surgical sponges that are unintentionally left inside the patient after the surgical site is closed can lead to infection and other serious complications, including the need for secondary operations. Although accurate data is hard to come by, available research suggests that every year thousands of U.S. patients could experience a retained surgical item (RSI), with surgical sponges being the most commonly retained item.
Manual counts – in which the surgical team verifies that all sponges are accounted for before concluding the procedure – are standard practice, but counts can be inaccurate. If miscounts result in a retained sponge, complications can ensue, with consequences for both the patient and the healthcare facility.

These include:
• Subsequent patient health impacts, such as infections or the need for secondary operations.
• Prolonged surgical times when a sponge is, or is thought to be, missing. In addition to potential adverse health consequences for the patient – such as increased risks of infections, hypothermia, cardiac arrhythmias, and other postoperative complications – prolonged surgeries can lead to increased costs or reduced revenue for the facility.
• Financial and reputational harm to the healthcare facility when a retained surgical sponge results in litigation or negative publicity.

Technologies that supplement the manual counting process are available and have been found to be effective when used correctly and consistently. ECRI contends that broader adoption of these technologies could further reduce the risk that a surgical sponge will be unintentionally retained during a procedure.

ECRI states that manual counting protocols are standard practice for reducing the risk that sponges or any other surgical soft goods will be unintentionally retained within the patient. However, manual counts have limitations – the possibility of a miscount being an obvious one. For instance, staff may conclude that all sponges have been accounted for when in fact a sponge is missing. In this case, the surgical team might not learn of the discrepancy unless (or until) the patient returns with a complaint of pain or discomfort. Several studies have found that in most cases in which an unintentionally retained sponge was later identified, surgical staff had thought that the manual count was correct. In other situations, staff may determine that a sponge is missing. Whether this determination is correct or incorrect, the surgical team must try to locate the sponge before surgical closure, extending the surgery and likely requiring an intraoperative X-ray.
Technology options consist of a scanning device that can count or detect proprietary sponges that incorporate a detectable tag. These technologies can be used to aid in the counting and/or detection of sponges (and other soft goods), thus serving as a technological adjunct to manual counts.

Current systems offer the following:
• Counting, using a bar-coding system – These systems use a scanning mechanism to count uniquely coded items in and out of the procedure (i.e., before incision and then before any type of surgical closure).
• Detection, using a radio-frequency (RF) system – These systems can verify the presence of a misplaced or unaccounted-for sponge, which may be inside the patient or elsewhere in the OR (e.g., in the trash, on the floor).
• A combination of counting and detection, using a radio-frequency identification (RFID) system.
ECRI notes that despite their apparent effectiveness, such technologies have not yet been implemented widely. ECRI estimates that approximately 20 percent of U.S. hospitals use some form of adjunct technology to supplement the manual counting process or to aid in the detection of missing sponges.

Barriers to implementation likely include the added steps involved in incorporating the technologies into a surgical procedure as well as the added expense associated with their use. "It might take some time for OR staff to get used to a new workflow," notes Julie Miller, senior project engineer in ECRI's Health Devices Group, "but facilities should also take into account the time and expense associated with a retained sponge."

A cost analysis using ECRI's PriceGuide data shows that the use of proprietary tagged sponges could cost an additional $12 per procedure, compared with using traditional sponges. Additionally, ECRI found during its testing that using a sponge counting or detection technology added about one minute (or less) to each testing scenario. Miller counters: "A minute of OR time isn't cheap, but compare that to 18 minutes of OR time that might be required to locate a missing sponge, or to the unreimbursed costs associated with an RSI, which can add up to hundreds of thousands of dollars per occurrence if it results in litigation."

It's worth noting, however, that these systems are not designed to prevent retained suture needles, device fragments, or other types of RSIs. Rather, they address only surgical sponges, which are the most commonly retained items. While the use of counting or detection technologies is not currently required in the standard of care, ECRI encourages broader adoption of such technologies as a supplement to the manual counting process. When employing an adjunct technology, ECRI recommends that healthcare facilities:
• Use the technology correctly – that is, in accordance with the manufacturer's instructions for use.
• Use the technology in every procedure requiring the application of surgical soft goods, not just for selected cases.
• Remove untagged sponges from stock unless there is no tagged alternative.
• Inspect sponges removed from the sterile field for tears, verifying that all fragments are retrieved before closure.
• Make confirmation of adjunct technology use a mandatory field in your facility's electronic health record.

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