Retained surgical items (RSIs), such as instruments and sponges, are a risk of any surgery but are commonly seen in perinatal cases—both in vaginal births and cesarean deliveries. As a “never event,” the Centers for Medicare and Medicaid Services will not reimburse facilities for the additional patient care that an RSI may require (Steelman and Cullen). Instrument and soft-good counts are a manual, human process, so the potential for error exists even when a case is uncomplicated. Findings in the literature vary widely regarding the association of RSIs with instrument counts; some studies note that incorrect counts are linked to a higher probability of RSIs (Norton et al.; Goldberg and Feldman), while others note that most counts in RSI events are correct (Brisson). Therefore, other factors influencing the count process must be examined, and strategies to support the count must be developed and implemented.

Some of the most common universal risk factors for an RSI include distraction, noncompliance with protocol, confusion regarding steps to be taken, communication breakdowns, short staffing, and productivity pressure (Norton et al.). Indeed, communication failures are one of the most frequently discussed factors when reviewing RSI events (Cima et al.). The literature also shows that RSIs are more likely to be associated with an emergent procedure, an unplanned or last-minute change in the procedure, and high body mass index on the part of the patient (Goldberg and Feldman; “Beyond”).

All of these factors can and do occur frequently during labor and delivery, whether a vaginal birth, planned cesarean delivery, or unplanned cesarean delivery (Simpson). Nevertheless, because these factors are not correlated strongly enough with RSIs to be considered indicators, a broad approach may be a stronger method of mitigating RSI risk (Cima et al.). Likewise, a broad approach can be more effective because RSIs in labor and delivery are commonly reported to be “due to multiple related failures that cascade through the system” (“Did”).

It is the responsibility of the organization at its highest levels to set the tone that nothing may usurp quality of care—pressure to increase productivity and pressure to complete a procedure promptly for matters of convenience should never compromise patient safety. In every case possible (emergencies aside), the procedure should not even begin until all components of initial safety protocols, such as the initial instrument count and soft-good count (including sponges, sharps, and miscellaneous items), have been completed with the full participation of all members of the care team. (Simpson) Likewise, it is the responsibility of the organization to ensure that counts occur in as many surgical or invasive cases as possible. In labor and delivery, this means counting all items before even a standard delivery; doing this ensures that the initial counts have been completed and documented in the event that an unplanned cesarean section or emergent procedure is required.
A Standardization Success Story

In setting out to prevent the retention of surgical items, the Mayo Clinic (Rochester, Minnesota) found that standardization kept working its way into the discussion. Over four years, the organization reviewed and revamped its instrument count policies, procedures, and protocols. Robert Cima, M.D., M.A., vice-chair, quality and safety, at Mayo Clinic’s department of surgery, considers retained items symptoms of larger issues: communication, hierarchy, and teamwork.

Mayo began with a detailed analysis of its RSI events and near misses. This phase identified a cultural shift that needed to happen. “If a nurse says, ‘We’re missing a sponge,’ the surgeon’s response can’t be, ‘You counted wrong.’ The focus needs to be, ‘We as a team are missing a sponge,’” explains Cima (ECRI Institute).

Therefore, with the support of Mayo leadership, a mandatory all-hands meeting was called to ensure that all staff members understood their responsibilities in preventing RSIs. This meeting included all staff surgeons, anesthesiologists, resident physicians, nursing staff, and allied health personnel.

The new operational definition of an RSI (“Any item that is unintentionally left within a patient and discovered afterward. If the count seemed correct, and the doctor left, but an additional sponge was discovered afterward.”) was presented to staff at this time, along with the new policies to be implemented. In cases of procedures that do not have an incision, an item would be defined as an RSI if the tray was open and it was time to count the sponges. The doctor did not acknowledge her despite two attempts to get his attention for the count. The nurse and another staff member counted the items and informed the doctor the count was correct. . . . After the delivery, the doctor moved away from the delivery area but remained in the room. He refused to count despite being asked several times. The same nurse and staff member counted. The final count seemed correct, and the doctor left, but an additional sponge was discovered afterward.

Counts Require Coordination

Preventing RSIs and implementing a standardized count policy is a multidisciplinary effort requiring buy-in at all levels of the organization. Administration and leadership support of such a count initiative is key to its success (ICSI). For example, one successful effort was spearheaded by a team representing the organization’s surgeons, nurses, quality management personnel, sentinel event response team members, and administration (Cima et al.).

One of the first steps to be taken by an organization in reviewing its RSI policies is to determine what, precisely, constitutes an RSI—with no exceptions. Adding amendments to policies specifically in response to events (as “one-offs”) without reviewing policies as a whole can lead to confusion regarding appropriate actions. The organizational definition of an RSI should be reviewed, standardized, and shared across the organization. One institution did so and called a mandatory all-hands meeting to set goals, such as clearer communication among team members, based on the findings of its event and policy review. When its new, standardized count protocol was implemented across the organization, it was done in all surgical and specialty units, including labor and delivery. (Cima et al.) For more on this initiative, see “A Standardization Success Story.”

Organization leadership will need to develop and deliver a consistent message regarding the importance of thorough counts in all procedures possible and identify steps to be taken in the event of emergent cases when counts cannot be completed. The organization should institute and enforce clear, consistent, thorough policies and procedures that standardize the actual process of counts across the organization and ensure that they are a focal point of every procedure (Goldberg and Feldman). Standardization allows staff members to know who is responsible for counting and how this person is to be supported, what items need to be counted, and when and where counts are to occur, and how counts are to occur.

What We Are Seeing

THINK LIKE A TEAM

The American College of Surgeons highlights the importance of a team mentality among the healthcare practitioners caring for the patient, specifying that they share an “ethical, legal and moral responsibility to promote an optimal patient outcome” (ACS). As seen in the following event, this shared responsibility should be a goal for all practitioners during a delivery.

When the doctor arrived, the nurse told him the tray was open and it was time to count the sponges. The doctor did not acknowledge her despite two attempts to get his attention for the count. The nurse and another staff member counted the items and informed the doctor the count was correct. . . . After the delivery, the doctor moved away from the delivery area but remained in the room. He refused to count despite being asked several times. The same nurse and staff member counted. The final count seemed correct, and the doctor left, but an additional sponge was discovered afterward.

It’s commonly known that communication is a factor in RSI events (Agrawal); however, interactions between doctors and nurses in particular can either strengthen or weaken the reliability of the count (Riley et al.). The Association of periOperative Nurses (AORN) recommends that RSI prevention be a multidisciplinary effort among all perioperative team members (Goldberg and Feldman). When all team members do not support the count in appropriate ways, items may be missed. The bottom line is that all members of the team are responsible for the count (Cima et al.; Mahran et al.).

The organization should also examine environmental factors to determine if their effects can be reduced. Interruptions, ambient noise, background conversations, and other such distractions can all decrease the reliability of the count by taking the attention of the counter and hindering communication among team members. (“Beyond”) Such hindrances should be prevented or limited as much as possible.
Consider Adjunctive Technology

Another facet of the organization’s count initiative should examine tools that can aid in correct counting and the detection of any retained items. Technological aids, such as radio-frequency identification (RFID) tags and wands, have proven to be useful adjunctive tools (Brisson).

Another strategy in reducing the risk of item retention is to limit the items available for use to those that are detectable via adjunctive technology. For example, the risk that a sponge will go undetected by an x-ray is largely mitigated by limiting available sponges to those that are radiopaque or have an RFID tag. Such technologies should be considered for purchase by the organization after seeking input from frontline staff members.

The most obvious benefit of detection aids, such as RFID or x-ray imaging, is that they will detect an item that has gone unseen by the staff members. This may seem obvious, but in many cases of RSIs, the care team believed that the counts were correct (Simpson). For example, one organization implemented RFID and pocketed sponge collection bags as standard counting aids on every procedure, with the understanding that RFID will “not only detect a sponge in a patient when counts are incorrect but, more importantly, will detect a sponge when counts are considered correct” (Norton et al.). For more on adjunctive technologies, see the discussion How to Count.

Support Best Practices

Standardizing practices for counts is the responsibility of the organization (Goldberg and Feldman). For example, one potential strategy is to adopt a policy of scanning a patient with an RFID wand before closing, regardless of the findings of the instrument and soft-good counts (“Beyond”). For such a policy to be successful, everything must be tagged, wands must be readily available to staff members, and organization leadership must champion the adoption of such a policy with little to no exceptions regarding when RFID wand use is to occur.

An additional facet of several successful count initiatives is the adoption and enforcement of “red rules” (Cima et al.; ICSI). Red rules are universal, unbreakable, and able to be invoked by any member of the team during the procedure in the interest of patient safety and quality care. The Institute for Clinical Systems Improvement (ICSI) suggests three red rules for labor and delivery (ICSI):

1. Count all sponges and sharps for every delivery.
2. Allow only radiopaque sponges and other soft goods to be prepared on trays or to enter the sterile field.
3. Enforce imaging studies in every case with a count inaccuracy.

The organization should consider instituting count practices that enable every item used during a procedure to be counted and accounted for. Such an initiative would require the full support of leadership as well as the participation of all members of the perioperative team. (Goldberg and Feldman) One such policy is the Michigan Hospital Association’s (MHA) SAFE COUNT, which details the responsibilities of involved staff members as well as the steps to be taken as part of the count. For more, see MHAs SAFE COUNT web page at http://www.mnhospitals.org/patient-safety/current-safety-quality-initiatives/retained-foreign-objects. Likewise, refer to “ECRI Institute Guidance” for additional resources.

Prepare for Emergencies

The emergent nature of some cases can preclude counting, as seen in the following case received by ECRI Institute PSO.

A repeat cesarean section following spontaneous rupture of membranes converted to emergency hysterectomy. The original count was done of instruments, sharps, and laps at the beginning of the case. However, when case acuity increased to emergent, the additional hysterectomy instruments were not counted. Laps and sharps were counted, and an x-ray was ordered. The patient was in the operating room for an extensive amount of time waiting on the x-ray results.

In such emergent cases, coordination with radiology to order an x-ray is necessary, must be streamlined, and should follow a standardized template to decrease the amount of additional time that the patient is under anesthesia. One facility updated its policies to reflect the importance

(continued from page 2)

criteria; this whiteboard includes specialty labels to track unique items as well. (Cima et al.)

The final piece of this initiative was the introduction of two red rules directing staff to (1) follow Universal Protocol, including patient identification and time-outs, and (2) allow counts to be performed correctly, with all activity other than exploration stopped during the closing count (Cima et al.).

Before the initiative, Mayo Clinic had averaged one RSI or near miss once per 16 days. After, it averaged one RSI every 69 days (Cima et al.).

References


ECRI Institute PSO NAVIGATOR
of “stat” possible RSI imaging studies and required reading within 30 minutes (Cima et al.). Information to be provided to the radiology department should likewise be specified by organization policy. One expert recommends that the ordering physician provide clear information about any potentially retained items, including what and where they may be (Goldberg and Feldman), while another explains that missing items are specifically left out of imaging orders so as to prevent the radiologist from looking for that item to the exclusion of any other potential RSIs (Cima et al.).

Lessons Learned

BE PROACTIVE, NOT REACTIVE

Who Counts?
The staff member (in most cases, a licensed nurse) responsible for counting instruments, sharps, and soft goods prior to, during, and at the conclusion of the procedure should be clearly designated within organization procedures and policies, which in turn should refer to guidelines promulgated by professional and credentialing organizations as well as government laws and regulations. These individuals should be aware of the responsibilities of their role.

For example, ICSI recommends that one nurse and another person trained in the counting process should be responsible for performing the actual counts (ICSI). AORN recommends that, prior to initial counts, package contents should be viewed by the registered nurse circulator and scrub person to identify possible packing errors and to verify the accuracy of pack contents, preventing potential count errors later. (Goldberg and Feldman)

What Should Be Counted?
Organization policy should take into consideration recommendations in the literature and guidance from accrediting organizations in specifying what instruments and soft goods must be counted.

AORN recommends that all soft goods opened to the sterile field be included in the count (Goldberg and Feldman). ICSI recommends that sharps and other miscellaneous items be included in the count, as well as all sponges and soft goods, which should be radiopaque (ICSI).

When and Where to Count
The following are all counts that occur during a typical procedure:

- Initial count
- Relief count
- Count of new items opened to the field
- Closing count

Specifically, ICSI’s recommendations stipulate that, for labor and delivery procedures, counts should be performed immediately before the delivery pack is used as a baseline, when items are added to the field, after delivery, whenever any staff member is concerned about the count for any reason, and whenever staff changes. (ICSI) The timing of each of these counts must be standardized to reduce confusion and the risk of an RSI (Goldberg and Feldman). Each count plays an important role in preventing instrument, sharp, or soft-good retention. Therefore, instrument, sharp, and soft-good counts should take place with every procedure feasible.

In particular, “every effort” should be made to obtain complete and accurate counts before a procedure, such as a cesarean section, so that if the procedure diverts in any way from what is planned, the initial counts have been documented and are available for use as a reference (Simpson).

Some organizations also require the attending surgeon to stop all activity for the team’s final count after the wound is closed. Not only does this ensure that the surgeon is engaged in the final count, but if there are any count discrepancies,
the surgeon is present and available to reopen the wound if it is determined that an item was left behind. If the entire care team, including the surgeon, is involved in the count, the value of the count is underscored. The National Quality Forum has modified its definition of RSIs to ensure all measures have been taken to detect a retained item before the patient leaves the operating room (Goldberg and Feldman).

How to Count
When counting surgical instruments, sharps, and soft goods, consistency is important; the challenge inherent in such consistency is to resist going on “autopilot” during the count. The team members responsible for the count should count in “the same sequence every time” to help ensure that no objects are missed in any count during the procedure. (Goldberg and Feldman)

ICSI labor and delivery recommendations dictate that a labor and delivery nurse, one of two designated counters, should document the count on a preformatted worksheet or white board, while the second counter should provide verbal confirmation. Visual verification of RFID tags should occur as items are counted into the delivery field. Used sharps should be counted out as they are disposed of in a needle box, while used soft goods should be retrieved from their designated receptacle for counting. Visual inspection for broken fragments or missing pieces should occur during the initial and closing count. After the delivery procedure is completed, all counts and inspections should be completed before items are removed, and any items that remain with either patient should be documented and communicated to the appropriate staff member. (ICSI) For more on retained fragments, see “Retained Device Fragments.”

There are several adjunctive technological aids available for use that can help both to count objects and to ensure that none remain in the patient. Some technologies help to count, others help both to count and detect retained items, and others offer an additional layer of safety when a retained object is suspected. (ACS; Norton et al.) Such solutions also range from low-tech, such as bags and white boards, to high-tech, such as RFID wands.

Low-tech solutions, such as preprinted white boards or dedicated receptacles, can help track original, ongoing, and final counts, as well as help accurately document data in the record afterward. (ICSI) For example, a pocketed sponge holder contains and organizes soft goods once they are used. When considering these for purchase, seek input from those staff members who will be using them (e.g., perioperative nurses) to ensure that they will be effective (Goldberg and Feldman). Such counting aids, after all, are useful only when actually used appropriately (Berger and Sanders).

Bar-code systems, much like those used for medication administration, aid team members in accurately tracking the count of instruments and soft goods in use as they are added to or removed from the sterile field (Goldberg and Feldman). They will not, however, aid in locating items that are missing or potentially retained.

Another option, RFID systems, aids in both the counting and detection of items in the sterile field. With such a system, most items opened to the field are embedded with a radio-frequency tag, which can then be tracked by a wand. (Goldberg and Feldman)

Other system-based solutions to aid in increasing count accuracy include standardizing the quantities of soft goods and instruments in each pack so that the amount of each item is the same in packs across the organization. The initial count still carries the responsibility of determining how many of each item are in the sterile field, but standardizing the quantities in packs may provide a potential baseline for calculation in an emergency procedure.

Another strategy to reduce the occurrence of RSIs is to only use items that are radiopaque or have a radiopaque component. For example, one study using sponges tagged with RFID rings found that these sponges were more easily palpable during a search prior to closing (Brisson). If only items that can be found via x-ray or RFID are used, they are more likely to be identified upon the use of such adjunctive technologies—i.e., they are less likely to go unseen at the preclosing imaging study or wand scan.

Retained Device Fragments
In the following event received by ECRI Institute PSO, a retained fragment is identified and communicated about among the delivery team, with input from outside departments as needed.

The patient was admitted for a repeat cesarean section and sat on the bed for spinal anesthesia. The anesthetist attempted to place the spinal needle for anesthesia, but the needle broke off midshaft between the patient’s lumbar vertebrae. It was not able to be visualized. After consultation, it was determined that proceeding with the cesarean section would allow an x-ray to be performed. The patient was later accompanied by the anesthetist and a nurse for a radiology for an x-ray of the lumbar spine, where a 6 mm needle was seen between vertebrae.

AORN recommends that the organization assess and take measures to reduce the likelihood of retained instrument fragments. As items exit the field, they should be examined for wholeness. If an item appears broken, the entire team should immediately be made aware and act accordingly. If a fragment cannot be removed, the patient must be made aware, and a representative of the care team should discuss with the patient the risks, benefits, and other factors of retrieving or leaving the device fragment.

ACT FAST AFTER AN EMERGENCY OR HIGH-RISK CASE

Standardized Steps Identify Errors

The nurse circulator is responsible for notifying the rest of the team as soon as he or she identifies a discrepancy in a count. The rest of the team is responsible for verbally acknowledging the discrepancy and acting appropriately—i.e., looking for the item. Coordination may be required among departments if an x-ray is needed to locate an RSI before closure. Such communication should include clear language and optimal imaging strategies for the possible RSI’s location. (Goldberg and Feldman)

During an emergent procedure, steps to be taken in the event of a potential RSI may differ, but organization policies and procedures should clearly dictate the appropriate actions to be taken. (Goldberg and Feldman)

For example, if a patient’s condition requires that closing cannot wait for an imaging study, closing should proceed, the imaging study should take place at a later time, and all pertinent information should be detailed in the patient’s record.

When possible, however, it may be prudent to consider an x-ray after emergent surgeries prior to closing—especially if there was no time for initial counts to occur due to the nature of the emergency. Likewise, making standard an x-ray after a procedure with multiple risk factors for retained items may also be prudent—even if the instrument and soft-good counts are correct. (Simpson) Some organizations use specific criteria to determine when postprocedure imaging studies are mandatory, including criteria regarding quantity of sponges used, whether multiple sequential procedures were led by different surgeons (e.g., a cesarean section followed by a hysterectomy and bowel resection), length of cases, and number of relief counts that were required.

REFERENCES


Top Five Sentinel Events, 2010 to 2012

From 2010 through 2012, “unintentional retention of a foreign body” was the sentinel event most frequently reviewed by the Joint Commission. Here are the top five most frequently reported sentinel events from 2010 through 2012.

- Unintentional retention of a foreign item: 436
- Wrong-patient, wrong-site, or wrong-procedure event: 354
- Delay in treatment: 340
- Operative or postoperative complication: 302
- Suicide: 283