Recommended Practices for Prevention of Retained Surgical Items

Introduction

The following Recommended Practices for Prevention of Retained Surgical Items were developed by the AORN Recommended Practices Committee and have been approved by the AORN Board of Directors. They were presented as proposed recommendations for comments by members and others. They are effective July 15, 2010.

These recommended practices are intended as achievable recommendations representing what is believed to be an optimal level of practice. Policies and procedures will reflect variations in practice settings and/or clinical situations that determine the degree to which the recommended practices can be implemented.

AORN recognizes the various settings in which perioperative nurses practice. These recommended practices are intended as guidelines adaptable to various practice settings. These practice settings include traditional operating rooms (ORs), ambulatory surgery centers, physicians' offices, cardiac catheterization laboratories, endoscopy suites, radiology departments, and all other areas where surgery and other invasive procedures may be performed.

Purpose

These recommended practices (formerly titled "Recommended practices for sponge, sharp, and instrument counts") provide guidance to perioperative registered nurses (RNs) in preventing retained surgical items (RSIs) in patients undergoing surgical and other invasive procedures. Avoiding injuries from the care that is intended to help patients was identified by the Institute of Medicine as one of six goals to achieve a better health care system.\(^1\) Counts for soft goods (eg, radiopaque sponges, radiopaque towels); sharps; and instruments are performed to account for all items used on the surgical field and to lessen the potential for injury to the patient as a result of an RSI. Health care organizations are responsible for employing standardized, transparent, verifiable, reliable practices to account for all surgical items used during a procedure to lessen the potential for patient harm as a result of retention. There is a potential for inaccurate counts with both current variable manual counting practices and the use of adjunct technology.\(^2-7\) Therefore, behavioral change and an understanding of risk reduction strategies unique to each setting should be employed when adopting system(s) to account for all surgical items. A reliable system to account for all surgical items includes, but is not limited to, complete and accurate counting, radiological confirmation, and the use of adjunct technology, to promote optimal perioperative patient outcomes.

Current law does not prescribe what methodologies should be used, who should use them, or even that they need to be used. It does, however, require that surgical items not intended to remain in the patient be removed. The doctrine of *res ipsa loquitur* (ie, "the thing speaks for itself") is most applicable in RSI incidents. Therefore, the time and effort in legal tort cases is spent assigning blame or fault for the act because it is not always necessary to prove negligence. The "captain of the ship" doctrine is no longer assumed to be true, and members of the entire surgical team can be held liable in litigation for RSIs.\(^8-10\)
Retained surgical items are considered a preventable occurrence. Many states require public reporting when these events occur. Federal and state agencies, accrediting bodies, third-party payers, and professional associations consider an RSI a sentinel event or "never event." Health care organizations and providers will not be reimbursed for additional care provided as a result of "never events."[8,11-15]

The incidence of RSIs is well-documented in the literature dating as early as the 1800s.[2,3,5-7,16-18] There is immense variability, however, in the occurrence rates and identified risks. In a study of retained foreign items, 52% were radiopaque sponges and 43% were instruments.[2] The RSIs in this study were associated with multiple major procedures being performed at the same time. Another study reported count discrepancies in 29 procedures (ie, 45% for radiopaque sponges, 34% for instruments, 21% for needles).[3] The study suggests that emergency procedures and unexpected changes in procedures correlated to an increased risk of RSIs. Closed claim studies conducted between 1985 and 2001 demonstrated that roughly 69% of reported cases of RSIs involved radiopaque sponges.[2]

Although the majority of retained radiopaque sponges are found in the abdomen and pelvis, there are reports in the literature discussing retained radiopaque sponges in the vagina, thorax, spinal canal, face, brain, and extremities.[2,6,8] The risk exists for RSIs even in the smallest of incisions.[3] A general strategy for preventing RSIs is to account for all items opened or used in a procedure at the end of the procedure because the potential risk for retention cannot always be predicted.

Common strategies in the literature that have been used to mitigate the incidence of RSIs include development of standardized procedures combined with manual counting; enhanced communication; multidisciplinary teamwork; radiological verification; and use of adjuncts (eg, count bags, technology to supplement manual sponge count procedures). Health care organizations are responsible for drafting policies and procedures applicable to their practice setting. It is imperative to value teamwork and hold all perioperative personnel accountable for the adoption, implementation, and review of their designated procedures and practices.

**Recommendation I**

**A consistent multidisciplinary approach for preventing RSIs should be used during all surgical and invasive procedures.**

Retained surgical items are preventable events that can be reduced by implementing multidisciplinary system and team interventions.[12,19,20] Retained surgical items may result in morbidity and mortality for the patient and prove to be costly to health care organizations.[3,13,14,21]

Establishing a system that accounts for all surgical items opened and used during a procedure constitutes a primary and proactive injury-prevention strategy. Performing surgical item counts is one RSI-prevention strategy. Accounting systems that involve counting and detection are, at a minimum, team-based activities composed of input from multiple team members. The practices employed should be standardized, transparent, verifiable, and reliable. All items need to be accounted for at the end of a procedure so that all team members can be sure that a surgical item is not left in the patient.[22]

I.a. All perioperative team members should be responsible for the prevention of RSIs.
I.a.1. Any individual who observes an item dropped from the surgical field should immediately inform the RN circulator and other members of the perioperative team.2

I.a.2. Any perioperative team member (eg, anesthesia care provider, float RN) who assists the surgical team by opening sterile items such as extra sutures or radiopaque sponges onto the sterile field should count the items with the scrub person;

add the counted items to the count documentation (ie, count sheet, whiteboard); and promptly inform the RN circulator about what was added.3,4

Other team members may be asked to open supplies while the RN circulator is occupied with other patient care activities. Opening extra supplies without properly adding them to the count sheet or whiteboard may lead to a discrepancy at the end of the procedure.

I.a.3. A count may be initiated by any member of the perioperative team involved in the counting process.

I.a.4. Unnecessary activity and distractions should be curtailed during the counting process to allow the scrub person and RN circulator to focus on counting tasks.

An environment that is filled with noise and distractions is likely to result in ineffective communication.19-26 Distractions during counting can lead to incorrect counts.5,27,28 Other team members may be asked to open supplies while the RN circulator is occupied with other patient care activities. Opening extra supplies without properly adding them to the count sheet or whiteboard may lead to a discrepancy at the end of the procedure.

I.a.5. Counts and events that would require a count (eg, relief of scrub person or RN circulator) should not be performed during critical portions of the procedure.

I.b. The RN circulator should actively participate in safety measures to prevent RSIs during all phases of a procedure and observe the sterile field to assist in the reduction of RSIs.

Accurately accounting for items used during a surgical procedure is a primary responsibility of the RN circulator and the perioperative team members.31 The RN circulator plays a leading role in implementing measures to account for surgical items.

I.b.1. The RN circulator should facilitate the count process by initiating the count, performing count procedures in concert with the perioperative team, documenting count reconciliation activities, and reporting any count discrepancy. (See Recommendation VI.)

I.c. The scrub person and the RN circulator should perform standardized procedures when accounting for all surgical items opened or used during a procedure as required by the health care organization's policy.

Reason's study of human error has shown that errors involve some kind of deviation from routine practice.32 Deliberate, consistent application and adherence to standardized procedures are necessary to prevent the retention of surgical items.2,3,28-36

I.c.1. The scrub person should maintain an organized sterile field with minimal variation between scrub persons.

Maintaining an organized sterile field facilitates accounting for all objects during and after the operative procedure. Standardized sterile setups established by the health care organization's policy reduce variation and may lessen risk of error.

I.c.2. Sharps should be confined and contained in specified areas of the sterile field or within a sharps containment device.
I.c.3. The scrub person should maintain awareness of the location of soft goods (eg, radiopaque sponges, towels, textiles); miscellaneous items; and instruments on the sterile field during the course of the procedure. It is the scrub person's responsibility to

- know the character and configuration of soft goods, instruments, and devices that are used by the surgeons and first assistants;
- verify the integrity and completeness of soft goods when they are counted;
- ensure that the RN circulator sees surgical items being counted;
- confirm that instruments or devices that are returned from the operative site are intact; and
- speak up when a discrepancy exists.

A standardized, transparent, verifiable, reliable process of accounting for soft goods, sharps, needles, instruments, and small items may decrease the incidence of RSIs. Although there is a greater incidence of RSIs for soft goods, the risk also exists for retained instruments and device fragments.

I.d. Surgeons should engage in safe practices that support prevention of RSIs.

The American College of Surgeons recognizes patient safety as "the highest priority and strongly urges individual hospitals and health-care organizations to take all reasonable measures to prevent the retention of foreign bodies in the surgical wound." It is the responsibility of all perioperative team members to engage in safe practices for the prevention of RSIs.

I.d.1. The surgeon(s) and surgical first assistant(s) should maintain awareness of all soft goods, instruments, and sharps used in the surgical wound during the course of the procedure. The surgeon does not perform the count but should facilitate the count process by

- using only radiopaque surgical items in the wound;
- communicating placement of surgical items in the wound to the perioperative team for notation (eg, whiteboard);
- acknowledging awareness of the start of the count process;
- removing unneeded soft goods and instrumentation from the surgical field at the initiation of the count process;
- performing a methodical wound exploration when closing counts are initiated;
- accounting for and communicating about surgical items in the surgical field; and
- notifying the scrub person and RN circulator about surgical items returned to the surgical field after the count.

I.e. Anesthesia care providers should maintain situational awareness and engage in safe practices that support the prevention of RSIs.

Situational awareness is the process of recognizing a threat and taking steps to avoid the threat.

I.e.1. Anesthesia care providers should plan anesthetic milestone actions so that these actions do not pressure the perioperative team to perform insufficient accounting practices.

Completion of the proper counting procedures is the responsibility of the entire perioperative team.
I.e.2. Anesthesia care providers should not use counted items.

I.e.3. Anesthesia care providers should verify that throat packs, bite blocks, and other similar devices are removed from the oropharynx and communicate to the perioperative team when these items are inserted and removed.

I.f. Complete and detailed communication between OR personnel and radiologic technologists and radiologists should occur when requesting radiological support to prevent RSIs. (See Recommendation VI.)

These activities focus the radiologist's view and aid in the best chance of being able to see the surgical items on the radiograph. Radiological imaging along with other perioperative activities may mitigate the risk of RSIs.

**Recommendation II**

Radiopaque surgical soft goods (e.g., sponges, towels, textiles) opened onto the sterile field should be accounted for during all procedures for which soft goods are used.

Accurately accounting for radiopaque sponges throughout a surgical procedure should be a priority and requires a multidisciplinary effort.

Reports in surgical literature document that gossypiboma (i.e., the unintentional retention of soft goods) can occur after a wide variety of surgical procedures. Clinical presentation of gossypiboma is either acute or delayed. Acute presentations generally follow a septic course with abscess and/or granuloma formation. Delayed presentations may occur months or years after the original surgical intervention, with adhesion formation and encapsulation.

II.a. Initial counts of radiopaque soft goods should be performed and recorded for all surgical procedures.

Performing and recording initial counts establishes a baseline for subsequent counts on all procedures. Deliberate, consistent application and adherence to standardized procedures are necessary to prevent the retention of surgical items.

II.b. Counts of soft goods should be performed:

- Before the procedure to establish a baseline and identify manufacturing packaging errors (i.e., initial count);
- When new items are added to the field;
- Before closure of a cavity within a cavity (e.g., uterus);
- When wound closure begins;
- At skin closure at the end of the procedure or at the end of the procedure when counted items are no longer in use (i.e., final count); and
- At the time of permanent relief of either the scrub person or the RN circulator, although direct visualization of all items may not be possible.

Deliberate, consistent application and adherence to standardized procedures are necessary to prevent RSIs. A standardized count procedure assists in achieving accuracy, efficiency, and continuity among perioperative team members. Studies of human error have shown that...
many errors involve some kind of deviation from routine practice.\textsuperscript{32}

II.c. Radiopaque sponges should be completely separated, viewed concurrently by two individuals, one of whom should be an RN circulator, and counted audibly.

Concurrent verification of counts by two individuals may lessen the risk of inaccurate counts. Separating radiopaque sponges during the initial baseline count helps to determine whether a sponge has been added to or removed from a sterilized package and that a radiopaque marker or identifying tag is present on each surgical sponge.

II.c.1. Packages containing an incorrect number of radiopaque sponges or a manufacturing defect should be removed from the field, bagged, labeled, isolated from the rest of the radiopaque sponges in the OR, and excluded from the count. Packages containing an incorrect number of radiopaque sponges may be removed from the room before the patient's entry.

The initial sponge count is performed to determine that all packages of radiopaque sponges contain the correct number and the appropriate radiopaque marker or identification bar code, tag, or chip. Incorrect numbers of items or product defects within a package do occur.

Isolating the entire package containing an incorrect number of sponges may help reduce the potential for error in subsequent counts. Packages containing an incorrect number of radiopaque sponges may be removed from the room before the patient's entry to decrease confusion and the likelihood of error.

II.c.2. If the surgical sponge package is banded, the band should be broken and discarded before counting.

Leaving the package band in place may prevent the ability of each individual to see the sponges and allow one or more sponges to be undetected.

II.d. Additional radiopaque sponges added to the field should be counted at that time and recorded as part of the count documentation.

Counting and recording radiopaque sponges as they are added to the field is required to account for all items at the conclusion of the procedure.

II.e. Sponges should be left in their original configuration and should not be cut or altered in any way.

Altering a sponge by cutting or removing radiopaque portions invalidates counts and increases the risk of a portion being retained in the wound.

II.f. Soft goods counts should be conducted in the same sequence each time as defined by the health care organization. The counting sequence should be in a logical progression (eg, large to small item size, proximal to distal from the wound).

A standardized count procedure (ie, following the same sequence) assists in achieving accuracy, efficiency, and continuity among perioperative team members.\textsuperscript{7,36} Studies of human error have shown that many errors involve some kind of deviation from routine practice.\textsuperscript{35}

II.g. All soft goods used in the surgical wound should be radiopaque and easily differentiated from non-radiopaque soft goods (eg, sponges, towels).

Radiopaque indicators facilitate locating by radiograph an item presumed lost or left in the surgical field when a count discrepancy occurs.

Retained surgical towels have resulted in patient injury.\textsuperscript{2,20,47,48} Surgical towels found in the abdomen and chest have been reported, as have instances of surgical towels found at autopsy or as a retained item after root cause analysis or focused case review.\textsuperscript{49,50} When placed in a body cavity, an unmarked towel not included in the count may not be detected and increases the possibility of an RSI.

II.g.1. Non-radiopaque sponges used for skin preps that have a similar appearance to counted radiopaque sponges should be isolated before beginning the procedure to avoid possible
confusion with the counted radiopaque sponges.

II.g.2. Radiopaque sponges should not be used as postoperative wound dressings.

The use of radiopaque sponges as surface dressings may invalidate subsequent counts if the patient is returned to the OR. The use of surgical sponges as surface dressings may appear as foreign items on postoperative radiographs and suggest a retained item.\textsuperscript{51, 52}

II.g.3. Non-radiopaque gauze dressing materials should be withheld from the field until the final count is conducted.

Separating dressing materials from the actual counted radiopaque sponges may help prevent intermingling with the sponges used in the procedure.

II.g.4. Dressing sponges included in custom packs should remain sealed and isolated on the field until the final count is resolved.

II.h. The final count should not be considered complete until all sponges used in closing the wound are removed from the wound and returned to the scrub person.

Sponges used in closing the wound could be left in the wound.

II.i. All counted radiopaque sponges should remain within the OR or procedure room during the procedure.

Confining all counted radiopaque sponges to the OR may help eliminate the possibility of a count discrepancy and aid in the disposal of all the radiopaque sponges to prevent carryover to subsequent procedures.

II.i.1. Pocketed sponge bags or similar systems should be used on all procedures where a soft goods count is performed.

Using a pocketed bag or other system for separating used radiopaque sponges facilitates the ability to see sponges for counting. Separating radiopaque sponges after use minimizes errors caused by sponges sticking together.

Draping used surgical sponges over the sides of the kick bucket is discouraged because it may be difficult for all team members to see each individual sponge. Wet, used sponges may drip blood and other potentially infectious fluids on the floor.

II.i.2. If a sponge 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.

II.i.3. Linen and waste containers should not be removed from the OR or procedure room until all counts are completed and reconciled and the patient has been transferred out of the room.

II.i.4. Radiopaque surgical sponges should be disposed of and removed from the OR or procedure room at the end of the procedure after the patient has left the room.

Removing soft goods from the room at the end of the procedure may prevent potential count discrepancies between patients.

II.j. When soft goods are used as therapeutic packing (eg, intracavity, oral) and the patient leaves the OR with this packing in place, a standardized procedure should be defined and implemented to communicate the location of packing and the plan for eventual removal of the items.

II.j.1. When soft goods are intentionally used as therapeutic packing and the patient leaves the OR with this packing in place, the number and types of items placed should be documented in the medical record as reconciled and confirmed by the surgeon when this information is known with certainty, or as incorrect if the number and type of sponges used for therapeutic packing is not known with certainty.
II.j.2. The number and types of soft goods used for therapeutic packing should be included and communicated as part of the transfer of patient care information.  

II.j.3. When the patient is returned to the OR for a subsequent procedure or to remove therapeutic packing, the number and type of radiopaque soft goods removed should be documented in the medical record, the radiopaque sponges removed should be isolated and not included in the counts for the removal procedure, the surgeon and the surgical team should perform a methodical wound examination and consider taking an intraoperative radiograph, and the count on the removal procedure should be noted as reconciled if all radiopaque soft goods have been accounted for. Additional safety measures may help to ensure that no soft goods remain in the patient when the number and type of radiopaque soft goods used for therapeutic packing is not known.

II.j.4. The surgeon should inform the patient of any soft good(s) purposely left in the wound at the end of the procedure and the plan for removing the item.

Recommendation III

Sharps and other miscellaneous items that are opened onto the sterile field should be accounted for during all procedures for which sharps and miscellaneous item are used.

Needles may account for up to 50% of identified RSIs. Miscellaneous items may be non-radiopaque and unintentionally retained in the surgical wound. Accurately accounting for sharps and other miscellaneous items during a surgical procedure is a primary responsibility of the RN circulator and the perioperative team members.

III.a. Initial sharps (eg, scalpels, needles) counts should be performed and recorded for all surgical procedures. Performing and recording initial counts establishes a baseline for subsequent counts on all procedures. Deliberate, consistent application and adherence to standardized procedures is necessary to prevent the retention of surgical items.

III.a.1. Standardized practices, manual counting procedures, and containment devices for sharps and needles should be employed to prevent needle miscounts, needle loss, and needlestick injuries. Counting sharps and miscellaneous items is important to prevent item retention and reduce the risk of injuries to health care personnel and patients. Operating room, sterile processing, housekeeping, laundry, and morgue personnel are at an increased risk for needlestick injury resulting in undue exposure to transmissible infections. There are multiple reported cases of needlestick-associated injuries to health care personnel. A standardized count procedure (ie, following the same sequence) assists in achieving accuracy, efficiency, and continuity among perioperative team members. Studies of human error have shown that many errors involve some kind of deviation from routine practice.

III.a.2. All suture needles, regardless of size, should be counted for all surgical procedures. Even small needles left in the patient may cause injury. Needles less than 10 mm, however,
may be difficult to see radiographically when retention is suspected.\textsuperscript{55,56} One study showed that radiologists inconsistently see small needles on intraoperative imaging studies.\textsuperscript{55}

III.b. Counts of sharps and miscellaneous items should be performed

- Before the procedure to establish a baseline and identify manufacturing packaging errors (ie, initial count);
- When new items are added to the field;
- Before closure of a cavity within a cavity (eg, uterus);
- When wound closure begins;
- At skin closure at the end of the procedure or at the end of the procedure when counted items are no longer in use (ie, final count); and
- At the time of permanent relief of either the scrub person or the RN circulator, although the ability to directly see all items may not be possible.

III.b.1. Miscellaneous items that should be accounted for include, but are not limited to,

- Defogger solution bottle, bottle cap, and associated accessories (eg, wipe, sponge);
- Electrosurgery active electrode blades;
- Electrosurgery scratch pads;
- Endostaple reload cartridges;
- Laparotomy sponge rings;
- Raney clips;
- Trocar sealing caps;
- Umbilical and hernia tapes;
- Vascular inserts;
- Vessel clip bars; and
- Vessel loops.

III.c. Sharps and miscellaneous items should be counted audibly and viewed concurrently by two individuals, one of whom should be an RN circulator.

Concurrent verification of counts by two individuals may lessen the risk for count discrepancies.

III.d. Additional sharps and miscellaneous items added to the field should be counted when they are added and recorded as part of the count documentation.

Counting and recording sharps and miscellaneous items as they are added to the field may reduce the risk of error and may prevent an inaccurate count at the conclusion of the procedure.

III.e. Suture needles should be counted when the package is opened, verified by the scrub person, and recorded.

Viewing each needle will help ensure an accurate needle count.
III.e.1. Empty suture packages should not be used to rectify a discrepancy in a closing needle count.

The actual number of needles may not be the same as the number of empty packages.

III.f. The scrub person should account for and confine all sharps on the sterile field until the final count is reconciled.

Unconfined sharps remaining on the sterile field may be unintentionally introduced into the incision, dropped on the floor, or penetrate barriers. Confinement and containment of sharps may minimize the risk of needlestick injury to personnel as well as RSIs.

III.f.1. Used sharps on the sterile field should be kept in a puncture-resistant container.

Collecting used needles in a puncture-resistant container helps ensure their containment on the sterile field and assists in counting at the conclusion of the procedure.

III.g. Sharps counts should be conducted in the same sequence each time as defined by the health care organization. The counting sequence should be in a logical progression (eg, sterile field to table to off the field).

A standardized count procedure (ie, following the same sequence) assists in achieving accuracy, efficiency, and continuity among perioperative team members. Studies of human error have shown that many errors involve some kind of deviation from routine practice.\textsuperscript{32}

III.h. The scrub person should assess the condition of sharps or other items and verify that they are intact when returned from the operative site.

Breakage or separation of parts can occur during open and minimally invasive surgical procedures. Verifying that all broken parts are present or accounted for helps prevent RSIs within the patient.\textsuperscript{61,62}

III.h.1. If a broken or separated item is returned from the operative site, the scrub person should immediately notify the perioperative team.

III.i. The final count should not be considered complete until all the sharps used in closing the wound are removed from the wound and returned to the scrub person.

Suture needles and other sharp items used in closing the wound could be left in the wound.

III.j. All counted sharps should remain within the OR or procedure room during the procedure.

Confining all sharps to the OR or procedure room helps minimize the possibility of a count discrepancy.

III.j.1. If a sharp is passed or dropped from the sterile field, the RN circulator should retrieve it using standardized precautions, show it to the scrub person, isolate it from the field, and include it in the final count.

III.j.2. Linen or waste containers should not be removed from the OR or procedure room until all counts are completed and reconciled and the patient has been transferred out of the room.

**Recommendation IV**

**Instruments should be accounted for on all procedures in which the likelihood exists that an instrument could be retained.**

Instrument counts protect the patient by reducing the likelihood that an instrument will be retained in the patient, including during minimally invasive procedures (eg, laparoscopy, thoracoscopy). Instrument counts are a proactive injury-prevention strategy. Retention of surgical instruments accounts for approximately one-third of retained item case reports.\textsuperscript{3} Case studies demonstrate that many types and sizes of retained instruments have been found, ranging from small serrafine clamps to moderately sized hemostats (ie, 6 to 10 inches) to 13-inch-long retractors.\textsuperscript{3,4}
IV.a. Counts of instruments should be performed

- before the procedure to establish a baseline (ie, initial count);
- when new instruments are added to the field;
- at wound closure or at the end of the procedure when counted items are no longer in use (ie, final count); and
- at the time of permanent relief of either the scrub person or the RN circulator, although the ability to directly see all items may not be possible.

Deliberate, consistent application and adherence to standardized procedures are necessary to prevent RSIs (eg, surgical instruments). 2-4, 7, 28, 33-36

IV.a.1. Instruments should be counted when sets are assembled for sterilization.

A count of the instruments at assembly of the instrument set provides a basic inventory reference for the instrument set but is not considered the initial count before the surgical procedure. A count performed outside of the OR that is considered an initial count increases the number of variables that can contribute to a count discrepancy and unnecessarily extends responsibility to personnel not involved in direct patient care.

IV.b. The health care organization's policy should clearly define circumstances in which the instrument count may be waived.

Procedures in which accurate instrument counts may not be achievable or practical include, but are not limited to,

- complex procedures involving large numbers of instruments (eg, anterior-posterior spinal procedures); 6
- trauma; 2, 45, 63
- procedures that require complex instruments with numerous small parts; and
- procedures where the width and depth of the incision is too small to retain an instrument.

IV.c. Instruments should be counted audibly and viewed concurrently by two individuals, one of whom should be the RN circulator.

Concurrent verification of counts by two individuals assists in ensuring accurate counts.

IV.d. Individual pieces of assembled instruments (eg, suction tips, wing nuts, blades, sheathes) should be accounted for separately and documented on the count sheet.

Counting individual pieces of assembled instruments before and after a procedure reduces the risk of leaving a piece behind if the instrument becomes disassembled for any reason. Removable instrument parts can be purposefully removed or become loose and fall into the wound or onto or off of the sterile field. 51

IV.e. Additional instruments should be counted and recorded as part of the count documentation when they are added to the sterile field.

Counting and recording instruments as they are added to the sterile field may prevent an inaccurate count at the conclusion of the procedure.

IV.f. Members of the surgical team should account for instruments in their entirety that may have broken or become separated within the confines of the surgical site.

Breakage or separation of parts can occur during open or minimally invasive surgical
procedures. Verifying that the instrument is intact or that all broken parts are present and accounted for helps prevent RSIs within the patient.\textsuperscript{61,62}

IV.g. Instrument counts should be conducted in the same sequence each time as defined by the health care organization. The counting sequence should be in a logical progression (eg, large to small item size, proximal to distal from the wound).

A standardized count procedure (ie, following the same sequence) assists in achieving accuracy, efficiency, and continuity among perioperative team members. Studies of human error have shown that many errors involve some kind of deviation from routine practice.\textsuperscript{32}

IV.h. The final instrument count should not be considered complete until those instruments used in closing the wound (eg, malleable retractors, needle holders, scissors) are removed from the wound and returned to the scrub person.

Incidents of retained surgical instruments used in closing the wound have been reported.\textsuperscript{64,65}

IV.i. All counted instruments should remain within the OR or procedure room during the procedure until all counts are completed and resolved.

Confining all counted instruments to the room helps eliminate the possibility of a count discrepancy.

IV.i.1. Counted items either passed off or dropped from the sterile field should be retrieved by the RN circulator, isolated, and included in the final count.

IV.j. All instruments should be accounted for and removed from the room during end-of-procedure cleanup.

Accounting for all instruments facilitates inventory control, as well as patient and personnel safety. Removing all instruments from the room helps prevent potential count discrepancies during subsequent procedures.

IV.k. Preprinted count sheets should be used to record the counted instruments.

Preprinted count sheets provide organization and efficiency, which are key to preventing retained surgical instruments.

IV.k.1. The circulating nurse should record only the number of instruments opened for the procedure.

IV.l. Instrument sets should be standardized with the minimum number and variety of instruments needed for the procedure.

Reducing the number and types of instruments and streamlining standardized sets improves ease and efficiency of counting.

IV.l.1. Instruments that are not routinely used on procedures should be removed from sets.

Specialty instruments, if needed, can be opened and added to the count at the time of the procedure.

Recommendation V

**Measures should be taken to identify and reduce the risks associated with unretrieved device fragments.**

Each year, the US Food and Drug Administration (FDA) Center for Devices and Radiological Health receives nearly 1,000 adverse event reports related to unretrieved device fragments. Serious adverse events have been associated with unretrieved device fragments. The FDA defines an unretrieved device fragment as "a fragment of a medical device that has separated unintentionally and remains in the patient after a procedure."\textsuperscript{66}
V.a. In the event that an unretrieved device fragment is left in the surgical wound (eg, broken instrument tip), the surgeon should inform the patient of the nature of the item and the risks associated with leaving it in the wound.

Health care professionals are encouraged to maintain public confidence by communicating with patients regarding their treatment and outcomes. Organizations are held accountable for informing patients of their rights when they enter the health care system. 54

V.a.1. Information provided to the patient should include, but is not limited to,

- material composition of the fragment (if known);
- size of the fragment (if known);
- location of the fragment;
- potential mechanisms for injury (eg, migration, infection);
- procedures or treatments that should be avoided, such as magnetic resonance imaging (MRI) examinations in the case of ferrous metallic fragments, which may help reduce the possibility of a serious injury from the fragment; and
- risks and benefits of retrieving the fragment as opposed to leaving it in the wound.

**Recommendation VI**

**Standardized measures for investigation and reconciliation of count discrepancies should be taken during the closing count and before the end of surgery. When a discrepancy in the count(s) is identified, the surgical team should carry out steps to locate the missing item.** 27, 67

Rapid intervention when an incorrect count is identified may reduce procedural time. Assessing the surgical site before closure decreases the time a patient remains under anesthesia and the risk of extended surgical time if the wound has to be reopened. 5 Early identification of RSIs decreases the likelihood that a surgical wound would need to be reopened and reduces or eliminates the need for radiographs to detect an RSI. 8

VI.a. The RN circulator should inform and receive verbal acknowledgment from the surgeon and surgical team as soon as a discrepancy in a surgical count is identified. 5, 68

The RN circulator has a responsibility and ethical obligation to speak up promptly when a discrepancy is identified. Clear and timely communication reinforces a safe patient culture. 3, 31, 69 A count discrepancy is a potential RSI incident. 70

VI.a.1. The RN circulator should visually inspect the area surrounding the surgical field, including the floor, kick buckets, and linen and trash receptacles in an effort to locate the missing surgical item.

VI.a.2. The scrub person should assist with visual inspection of the area surrounding the sterile field when there is a count discrepancy.

VI.b. When a discrepancy in the count is identified, the surgeon(s) should

- suspend closure of the wound if the patient's condition permits,
- perform a methodical wound examination by actively looking for the missing item,
- cooperate in the attainment of radiographs or other modalities as indicated to find the missing
item, and remain in the OR until the item is found or it is determined with certainty not to be in the patient. 3, 4

VI.c. If a missing item is not recovered, intraoperative imaging should be performed to rule out a retained item before final closure of the wound if the patient’s condition permits. If the patient’s condition is unstable, a radiograph should be taken as soon as possible in the next phase of care. 3, 4, 60

Obtaining a radiograph when all other efforts have failed and before the patient's wound is closed allows the surgical team to remove a potential RSI before the wound is closed completely. In some jurisdictions, this also will prevent the necessity of reporting an RSI.

VI.c.1. In situations when accurate counting of surgical items is not possible, intraoperative imaging should be performed before the patient is transferred from the OR. 3, 12, 27, 34

VI.c.2. If intraoperative imaging is not available, the health care organization should have a policy and procedure describing the actions and communication required between referring and receiving organizations.

VI.c.3. A radiograph to locate a possible retained item may be waived under certain circumstances as defined in the health care organization's policy and procedure.

There are situations when it may be medically appropriate for the surgeon to determine it is not in the individual patient's best interest to perform an intraoperative radiograph to locate a potential RSI.

VI.c.4. Complete and detailed communication between OR personnel and radiologic technologists and radiologists should occur when requesting radiological support to prevent RSIs. The OR radiology request should include standardized information about the missing surgical item, including, but not limited to,

the room where the procedure is being performed or the patient is located,

the type of radiograph and views needed,

a description of the missing surgical item,

the operation performed, and

the surgical site. 21, 38

These activities focus the radiologist's attention and aid in his or her ability to see the surgical items on the radiograph. Radiological imaging along with other perioperative activities may mitigate the risk of RSIs. 25

VI.c.5. The radiologic technologist should be called promptly and respond expeditiously when an incorrect count occurs in the OR. 21

VI.c.6. Intraoperative imaging should provide coverage of the surgical site and should include any views deemed necessary by the surgeon or radiologist to exclude the potential for RSIs. Radiological views should be obtained using recommended techniques and quality films or digital images to capture the full extent of the wound.

Progressive radiological techniques are recommended for successful identification of RSIs, including, but not limited to, multiple images, which may be necessary for full coverage. Images may include

initial portable anterior and posterior (A&P) views followed by an oblique view if the A&P is negative;
fluoroscopy, which may be used as an alternative technique if the RSI cannot be excluded with the intraoperative study; and

unenhanced computerized tomography (CT), which should be considered if previous techniques are negative and a high suspicion remains for an RSI.38

VI.c.7. The radiologist should be consulted for guidance on the most appropriate available radiographic equipment to use to maximize the opportunity to identify a missing surgical item.38

Although some literature suggests that a radiograph taken in a radiology suite may be of better quality than a portable film taken in an OR, this would preclude finding a potential RSI before the wound is closed and the patient is taken out of the OR.38 There is no evidence to support the use of a portable radiograph versus an image intensifier (ie, fluoroscopy). Portable radiographs have limitations, such as lower tube power; reduced ability to determine the character (eg, needle size and type) of an RSI; and limited placement options for film cassettes.71

VI.c.8. Intraoperative imaging for RSIs should be read by a radiologist and the results communicated directly to the surgeon in a timely manner.38 Interpretation of intraoperative films should be communicated by direct report to the OR with read-back verbal confirmation between the radiologist and the surgeon.21,28

VI.c.9. Health care organizations should define needle size limit criteria where radiographs will effectively assist in identifying retained needles.

There is no definitive evidence to indicate how effective radiographs are in detecting small suture needles. Recent studies have demonstrated that needles 10 mm and smaller may not be consistently visible on a radiograph.38,72,73 There is conflicting evidence regarding the visibility of 10-mm to 13-mm needles on radiographs.3,12,20,35,60,72,73

VI.c.10. The surgeon should inform the patient of the possibility of a retained needle as a result of an unresolved needle count and counsel the patient on the possible risks.

Recommendation VII

**Perioperative staff members may consider the use of adjunct technologies to supplement manual count procedures.**

Soft goods, such as radiopaque sponges and towels, represent the majority of RSIs. Paradoxically, studies suggest that the final count was documented as correct in 62% to 88% of RSI cases.2,8,22,70,74 Manual counts can result in errors, especially during emergencies and unexpected surgical events. Intraoperative radiographs also are not always effective in identifying RSIs. In one study, 67% of intraoperative radiographs were read as negative when an RSI actually was present.21

Technologies have recently become available that are designed to supplement manual counting of soft goods, primarily radiopaque sponges, in an attempt to reduce RSIs.20,75,76 Early identification of a retained sponge reduces the likelihood of delaying patient care; requiring additional measures, such as intraoperative radiographs to locate and retrieve the retained sponge; having to reopen the wound; or returning the patient to surgery for removal of the retained item at a later date. Use of this technology may allow timely detection of retained sponges even when a manual sponge count does not reveal a missing sponge. These technologies can be classified as count, detect, or count and detect.20,70,75,77-81 In the future, adjunct
technologies for accounting of needles and instruments may become available as well.

VII.a. A mechanism for evaluating and selecting existing and emerging adjunct technology products should be implemented. Patient safety is a primary concern of perioperative personnel. Safety concerns are the impetus for perioperative personnel as they participate in evaluating and selecting medical devices and products for use in practice settings.

VII.a.1. Perioperative RNs, physicians, and other health care providers involved in the use of products and medical devices for prevention of RSIs should be part of a multidisciplinary product evaluation and selection committee when the health care organization is evaluating the purchase of adjunct technology.

VII.a.2. Perioperative personnel should evaluate existing and emerging adjunct technology to determine the application that may be most suitable in their setting.

Several adjunct technology products are currently available, and the technology is rapidly evolving.

VII.a.3. Technology product standardization and value analysis processes should reflect functional and reliable products that are safe, cost-effective, environmentally friendly, and that promote quality patient care.

VII.b. Adjunct technology may be used, where available, as an extra measure of safety to verify count accuracy throughout the reconciliation process.

The literature suggests that a combination of standardized procedures with manual counting; enhanced communication; multidisciplinary teamwork; radiological verification; and the use of adjuncts (eg, count bags, technology to supplement manual sponge count procedures) may decrease the incidence of RSIs.

VII.b.1. Perioperative personnel should be aware of and competent in the proper use and application of adjunct technologies if used within the health care organization.

Technological systems are dependent on proper usage and technique.

**Recommendation VIII**

**Personnel should receive initial and ongoing education and demonstrate competency in the performance of standardized measures to prevent RSIs.**

Initial and periodic education on practices for the prevention of RSIs provides direction for personnel in providing safe patient care. Additional periodic educational programs provide opportunities to reinforce previous learning and introduce new information on adjunct technology, its use, and potential risks. Competency validation serves as an indicator that personnel have an understanding of safe practices for the prevention of RSIs; the risks of injury (eg, needlesticks) to the patient and to health care personnel; and corrective actions that should be implemented when a process failure occurs.

VIII.a. An introduction and review of policies and procedures for prevention of RSIs should be included in orientation and ongoing education of personnel.

Reviewing policies and procedures assists health care personnel in developing knowledge, skills, and attitudes that affect patient outcomes.

VIII.b. Perioperative personnel should be knowledgeable about all accounting procedures, equipment, and technology used in the health care organization.
Rapid advances in clinical evidence and technology require continuous learning and skills updates to maintain competency.

VIII.b.1. Perioperative personnel should receive education and demonstrate competency in, but not limited to, the following:

- the performance of manual count procedures (eg, soft goods, instruments, sharps, miscellaneous items);
- the use of adjunct technology, following manufacturers' written instructions, if available;
- the roles, responsibilities, and accountability of each perioperative team member;
- measures for reconciliation of count discrepancies; and
- reporting of known or suspected RSIs.

Instruction and return demonstration in proper manual counting procedures and adjunct technology usage minimizes the risk of error. Competencies based on manufacturers' instructions provide personnel with information regarding the proper use of adjunct technologies. Incorrect use can result in RSIs and serious patient injury. Equipment instruction manuals assist in developing operational, safety, and maintenance guidelines and serve as a reference for safe, appropriate use.

**Recommendation IX**

**Measures taken for the prevention of RSIs should be documented in the patient’s medical record.**

Documentation of all nursing activities performed is legally and professionally important for clear communication and collaboration between health care team members and for continuity of patient care.⁸⁴

IX.a. Sponge, sharp, and instrument counts should be documented on the patient's intraoperative record by the RN circulator.⁸²

IX.b. Documentation of measures taken for the prevention of RSIs should include, but not be limited to,

- types of counts (eg, radiopaque sponges, sharps, instruments, miscellaneous items);
- number of counts;
- names and titles of personnel performing the counts;
- results of surgical item counts;
- surgeon notification of count results;
- any adjunct technology that was used and any associated records;
- an explanation for any waived counts;
- number and location of any instruments intentionally remaining with the patient or radiopaque sponges intentionally retained as therapeutic packing;
unretrieved device fragments left in the wound, including

data, composition,

size,

location (if known), and

manufacturer;

actions taken if count discrepancies occur, including all measures taken to recover the missing item or device fragment and any communication regarding the outcome;

rationale if counts are not performed or completed as prescribed by policy; and

the outcome of actions taken.

Documentation of nursing activities related to the patient’s perioperative care provides an account of the nursing care administered and provides a mechanism for comparing actual versus expected outcomes. Such documentation is considered sound professional practice and demonstrates that all reasonable efforts were made to protect the patient’s safety. Extreme patient emergencies and certain individual patient considerations may necessitate waived counts to preserve a patient’s life or limb. Documenting the rationale for waived counts and for variation in standard practice provides a record of the occurrence and an alert to subsequent caregivers that the patient may be at an increased risk for an RSI.

**Recommendation X**

**Policies and procedures for the prevention of RSIs and unretrieved device fragments should be developed, reviewed periodically, revised as necessary, and readily available in the practice setting.**

Policies and procedures establish authority, responsibility, and accountability. Policies and procedures assist in the development of patient safety, quality assessment, and quality improvement (QI) activities. They also serve as operational guidelines that are used to minimize patient risk factors, standardize practice, direct staff members, and establish guidelines for continuous performance improvement activities. Best practices are subject to change with the emergence of new evidence and the advent of new technologies; therefore, periodic review and revision of the health care organization’s policy is needed.

X.a. A multidisciplinary team should establish a policy and procedure for prevention of RSIs. These policies and procedures should include, but not be limited to,

- items to be counted;
- directions for performing counts (eg, sequence, item grouping);
- waived count procedures in which baseline and/or subsequent counts may be exempt;
- alternative or additional safety measures for special circumstances;
- use of adjunct technology;
measures necessary to reduce the risk of unretrieved device fragments including, but not limited to,

use of the medical device in accordance with its labeled indications and the manufacturer's
instructions for use, especially during insertion and removal,

inspection of the medical device before use for damage during shipment or storage, as well as any
out-of-box defects that could increase the likelihood of fragmentation during a procedure,

inspection of the medical device immediately after removal from the patient for any signs of
breakage or fragmentation, and

retention of any damaged medical device to assist with the manufacturer's analysis of the event;

the multidisciplinary team actions and procedures for count discrepancy reconciliation;

when radiographic screening should be used in accounting for surgical items;

documentation and reporting procedures for removal of RSIs; and

competency validation.

All perioperative team members should be committed to and involved in establishing meaningful
policies and procedures related to the prevention of RSIs. Detailed, clear, and concise policies
provide consistent, standardized direction for the team. In situations with increased risk for RSIs,
radiographic screening has been identified as an excellent method for improving early
identification.  

X.a.1. Policies and procedures should meet the requirements of regulatory and accrediting agencies.

X.a.2. A policy and procedure for reporting product packaging defects to manufacturers should be
established.

X.a.3. Policies and procedures related to the use of adjunct technology should be based on the
manufacturer's written instructions for use.

X.a.4. If intraoperative imaging is not available, the health care organization should have a policy
and procedure describing actions necessary and communication required between referring
and receiving organizations.

X.b. Based on risk analysis, the health care organization should establish policies that define when
additional measures for prevention of RSIs must be performed or when they may be waived (eg,
trauma, cystoscopy, ophthalmology).

Even in the smallest of incisions, the risk exists for RSIs. 3 The size of a pediatric patient may
dictate a correspondingly small incision that would make retention of an instrument in the
surgical wound unlikely; however, RSIs can occur in the smallest of incisions. 3 Careful
consideration should be given when establishing a policy for waived counts for the pediatric
patient because it is difficult to determine whether there is no risk of an RSI.

Some situations that have been identified as potentially contributing to the risk for RSI include,

the emergent nature of a procedure; 3, 6, 3

in unexpected change in the procedure; 2

patient obesity; 3, 2, 7, 4, 18, 44, 45

multiple surgical teams;

shift changes; 2
pressure to increase throughput (ie, reduce operating time); and staff member inexperience.

X.c. Policies and procedures should include RSI prevention measures for organ procurement procedures.

Counted items that are sent with the donated organ(s) increase the risk for RSIs for the organ recipient. Counted sharps and instruments that are retained in the donor may contribute to inventory loss or injury to other health care workers. Counted items left in the OR or procedure room may increase the risk of inaccuracy in subsequent procedure counts or create sharps injury hazards for personnel.

**Recommendation XI**

**A quality assurance/performance improvement process should be in place to evaluate the incidence and risks of RSIs and to improve patient safety.**

Quality and performance improvement functions may ensure that organizations design processes well and systematically monitor, analyze, and improve outcomes. Continuous QI opportunities arise from documented and structured quality processes and measures that can define and resolve problems.

XI.a. A multiphase, multidisciplinary process improvement program should be implemented, including, but not limited to,

- ongoing risk assessment and review (eg, failure mode effect analysis);
- policy design and review;
- a review of published evidence, internal data collection, and data analysis; and
- plans for the ongoing monitoring and analysis of processes, near misses, and adverse events related to the prevention of RSIs.

A comprehensive QI program may identify opportunities for minimizing the risk of RSI events.

XI.b. A critical investigation should be conducted regarding any adverse event or near miss related to RSIs.

Error and near miss reporting are the first steps to addressing error reduction. The distraction-prone environment of the perioperative practice setting makes it more likely that errors can be made during routine tasks, including surgical counts. Errors can be divided into two categories: those at the human interface in a complex system (ie, active), and those representing a failed system design (ie, latent). There are a number of analysis methods (eg, root cause analysis, appreciative inquiry) available to health care organizations that may be used to conduct a critical investigation of adverse events.

XI.b.1. Multidisciplinary teams should be involved in the review process and address any changes in policy that can improve patient safety.

XI.c. Reporting mechanisms for adverse events and near misses related to RSIs should be established.

Many states require public reporting when these events occur. Federal and state agencies, accrediting bodies, third-party payers, and professional associations consider RSIs a sentinel event or "never event," which should be reported and investigated.

XI.c.1. Events that necessitate reopening a wound to retrieve an RSI should be reported in
compliance with health care organizational policy, as well as local, state, and federal regulatory agencies.

XI.d. Health care organizations should value learning and respond to errors with a focus on process improvement rather than individual blame.69

Systematic performance measures (ie, indicators) and/or priority areas are identified as opportunities for improvement based on the functions and processes of the perioperative episode.51,89-91 Each perioperative team member has an ethical obligation to perform his or her role and responsibilities with appropriate competence and the highest level of personal integrity.31

XI.d.1. Errors should be evaluated in such a manner that contributing factors are first reviewed and then accountability is determined in relation to actions.

Continuous QI opportunities arise from documented and structured quality processes and measures that can define and resolve problems.

XI.d.2. Personnel should identify and respond to opportunities for improvement.

To evaluate the quality of patient care and formulate plans for corrective action, it is necessary to maintain a system of evaluation.

Glossary

Baseline "A set of critical observations or data used for comparison or a control." (Source: Association for the Advancement of Medical Instrumentation. Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities; ANSI/AAMI ST79:2006. Arlington, VA: Association for the Advancement of Medical Instrumentation; 2006:54-111.)

Gossypiboma Surgical sponge or towel unintentionally retained in the body following surgery. Synonym: Textiloma.

Instruments Surgical tools or devices designed to perform a specific function, such as cutting, dissecting, grasping, holding, retracting, or suturing.

Minimally invasive surgery Surgical procedures performed through one or more small incisions using endoscopic instruments, radiographic and magnetic resonance imaging, computer-assisted devices, robotics, and other emerging technologies.

Miscellaneous items In relation to items on the sterile field that require counting, this may include vessel clip bars, vessel loops, umbilical and hernia tapes, vascular inserts, electrosurgery scratch pads, trocar sealing caps, and any other small items that have the potential for being retained in a surgical wound.

Near miss An occurrence that could have resulted in an accident, injury, or illness but did not by chance, skillful management, or timely intervention. "Any process variation that did not affect the outcome (for the patient or personnel), but for which a recurrence carries a significant chance of a serious adverse outcome. Such a near miss falls within the scope of the definition of a sentinel event, but those outside the scope of sentinel events that are subject to review by the Joint Commission under its Sentinel Event Policy." (Source: Glossary. In: Hospital Accreditation Standards. Oak Brook Terrace, IL: Joint Commission on Accreditation of Healthcare Organizations; 2002:331, 345, 351, 354, 360.)
Radio frequency identification (RFID) A system that transmits the identity (in the form of a unique serial number) of an object wirelessly using radio waves.

Root cause analysis A retrospective approach to error analysis that focuses on failures of system design as related to common root causes of adverse events. "A process for identifying the basic or causal factors that underlie variation in performance, including the occurrence or a sentinel event. A root cause analysis focuses primarily on systems and processes, not individual performance. It progresses from special causes in clinical processes to common causes in organizational processes and identifies potential improvements in processes or systems that would tend to decrease the likelihood of such events in the future, or determines, after analysis that no such improvement opportunities exist." (Source: Sentinel events. In: Hospital Accreditation Standards. Oak Brook Terrace, IL: Joint Commission on Accreditation of Healthcare Organizations; 2002:51-52.)

Sentinel event "An unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof. Serious injury specifically includes loss of limb or function. The phrase 'or the risk thereof' includes any process variation for which a recurrence would carry a significant chance of a serious adverse outcome. Such events are called 'sentinel' because they signal the need for immediate investigation and response." (Source: Official accreditation policies and procedures. In: Hospital Accreditation Standards. Oak Brook Terrace, IL: Joint Commission on Accreditation of Healthcare Organizations; 2002:48-49.)

Sharps Items with edges or points capable of cutting or puncturing through other items. In the context of surgery, items include, but are not limited to, suture needles, scalpel blades, hypodermic needles, electrosurgical needles and blades, instruments with sharp edges or points, and safety pins.

Sponges Soft goods (eg, gauze pads, cottonoids, peanuts, dissectors, tonsil/laparotomy sponges) used to absorb fluids, protect tissues, or apply pressure or traction.

Waived count Surgical procedures in which accurate accounting for sponges, instruments, and miscellaneous items is determined to be unachievable or in situations in which the time required to perform the count may present an unacceptable delay in patient care (eg, trauma procedures, anterior-posterior spinal procedures).

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