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PREVENTING RETAINED SURGICAL ITEMS

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Objectives

After viewing the video and reading this study guide participants will be able to:

* Discuss the role of a multidisciplinary committee in establishing standardized practices for accounting for all surgical items.
* Describe the items that may become a retained surgical item.
* List three common strategies used to account for surgical items.
* Describe the situations where retained surgical items are more likely to occur.
* Discuss the role of adjunct technologies in the prevention of retained surgical items.

Overview

Perioperative personnel are dedicated to providing quality care to patients undergoing surgical interventions. Establishing a consistent multidisciplinary approach and employing standardized transparent, verifiable, and reliable practices to account for all surgical items used during a procedure will lessen the potential for patient harm as a result of retention of a surgical item. The Institute of Medicine has identified several goals to achieve a better health care system; avoiding injuries from the care that is intended to help patients is one of the goals. It is estimated that about 1,500 events of retained surgical item(s) occur annually in the United States.¹ Common strategies that have been used to account for all surgical items include, standardized procedures combined with manual counting, enhanced communication, multidisciplinary teamwork, radiological confirmation, and the use of adjunct technology.

A retained item might be a sponge, towel or other textile referred to as “soft goods,” an instrument, sharp, or other miscellaneous small item. A standardized count procedure follows the same sequence each time the count is conducted. This study guide is intended to provide guidance for reducing the risk of retained surgical items (RSIs) in patients undergoing surgical and other invasive procedures.
The Role of Human Error
The retention of a surgical item following surgery is the result of a human and/or organizational (ie, process) error. There are many ways of defining error. Reason’s definition of error is the failure of planned actions to achieve their desired goal. Reason’s human error study showed that errors may involve some kind of deviation from routine practice. Reason writes that errors can be human or organizational in nature and that various organizational and human factors combine to create an accident (Figure 1). Whether we use the terms error, slip, lapse, mistake, accident, or failure, the connotation is the same in this study guide. Errors can be reduced by improving the quality and delivery of the necessary information within the workplace.

Preventable Occurrence
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 a retained surgical item a sentinel event or a “never event.” Newly established payment guidelines indicate that health care organizations and providers will no longer be reimbursed for additional care provided as result of a “never event.” Results from a study conducted by Greenberg et al showed that the occurrence rates of retained surgical items are 45% for sponges, 34% for instruments, and 21% for needles. Another study by Lincourt revealed occurrence rates at 52% for sponges and 43% for instruments. Greenberg reported that discrepancies in the counting process occurred approximately once in every eight procedures. Greenberg also reported that counts involving a change in personnel were three times as likely to involve a discrepancy as those where the personnel remained the same.

Figure 1. Stages in the development of an organisational accident
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Additional situations identified as potentially contributing to the risk for RSIs include:

- multiple major procedures performed at the same time;
- emergency procedures;
- an unexpected change in procedure;
- patient obesity;
- shift change;
- pressure to increase throughput (ie, reduce operating time); or
- staff member inexperience.

Incidences of retained surgical items can attract critical press coverage and may result in litigation against the surgical team. It is rarely productive to blame perioperative personnel for errors as blame implies delinquency. Exhortations and sanctions against perioperative personnel are inappropriate because the individual did not choose to err in the first place. Nevertheless, the consequences of retained surgical item(s) are devastating for the patient and perioperative team members.

**Consequences For the Patient**

When a surgical item is retained in a patient, he or she generally will exhibit a septic course which may include any of the following:

- abscess or granuloma formation,
- small bowel fistulae formation,
- obstruction, visceral perforation,
- sepsis, and
- death.

The patient may experience acute symptoms or may not experience symptoms until months or years after the original surgical intervention. Any item used during the surgery has the potential to become a retained item and the risk of retention exists with even the smallest of incisions. Sponges predominate among malpractice claims because they are often detected on postoperative imaging and more likely to lead to clinical sequelae and legal action.

**Strategies**

The potential exists for inaccurate counts whether using manual count practices or using an adjunct technology. Perioperative personnel should thoroughly understand risk reduction strategies and be willing to adopt these strategies. Several strategies that have been used successfully to decrease the incidence of retained surgical items 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). The potential risk for retention of an item is unpredictable; therefore, it is best to account for all items opened and used in a procedure. A standardized process of accounting may decrease the incidence of retained surgical items. A multi-disciplinary team should be responsible for drafting policies and procedures applicable to the health care 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.

**Using a Multidisciplinary Approach**

All team members are responsible for the prevention of retained surgical items. A multi-disciplinary team should establish a consistent approach for preventing retained surgical items during all surgical or invasive procedures. There are multiple aspects to this approach. The first involves a multi-disciplinary team within the facility establishing written policies for preventing retained surgical items. After the policies have been written, perioperative staff members should become thoroughly acquainted with the policies and demonstrate competence to implement them on a consistent basis.
In addition, surgeons and first assistants should:

- be actively engaged in implementing safe practices that support prevention of retained surgical items;
- use only radiopaque surgical items;
- communicate placement of surgical items in the wound;
- acknowledge awareness of the start of the count process; and
- perform a methodical wound exploration at initiation of the closing counts.

The anesthesia care provider should:

- maintain situational awareness that supports the prevention of retained surgical items;
- plan anesthetic milestone actions so that these actions do not pressure the perioperative team to perform insufficient counting practices;
- not use counted items; and
- 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.

**Standardized Process for Counting**

The RN circulator and the scrub person should perform standardized procedures when accounting for all surgical items opened and used during a procedure. A standardized process of accounting may decrease the incidence of retained surgical items.

A standardized count procedure is one that follows the same sequence each time. This can assist in achieving accuracy, efficiency, and continuity among perioperative team members. The count sequence should be in a logical progression each time (e.g., from large to small item size, from proximal to distal from the wound). In other words, from the wound toward the sterile back table.

A count may be requested by any member of the perioperative team. The RN circulator should initiate the count with the scrub person, document the count reconciliation, and report any count discrepancy.

Unnecessary activity should be eliminated during the counting process to enable the scrub and circulating team members to focus on the task at hand. Loud music, phone calls, additional items to the surgical field, or other patient care activities can distract team members and increases the risk of an incorrect count.

All items opened and used during a procedure should be accounted for at the end of the procedure. Although a retained item is most likely left in the abdomen or pelvis, an item can be left anywhere there is an incision large enough to contain an item. The health care organization should give careful consideration when establishing a policy allowing waived counts, especially for the pediatric patient, because it is difficult to determine whether there is no risk of a retained item in a pediatric patient.
**Documenting the Count**

Count documentation can be kept on a count sheet, whiteboard, or other system identified by the facility policy. Any perioperative team member who assists the surgical team by opening sterile items, such as extra sutures or radiopaque sponges, on the sterile field should

- count the items with the scrub person;
- add the counted items to the count documentation; and
- promptly inform the RN circulator about what was added.

**The Count Process**

Soft goods should be counted audibly by two individuals, one of whom is an RN circulator. The package band should be broken by the scrub person and discarded so that the soft goods can be separated and fully visualized by both the scrub person and the RN circulator. Counted soft goods should never be cut or altered in any way.

Initial counts of radiopaque soft goods should be performed and recorded for all surgical procedures to establish a baseline for subsequent counts. Counts should be conducted at established time frames specific to the procedure. Following are examples of these time frames.

- Before the procedure
- When adding new items to the field
- Before closure of a cavity within a cavity (eg, uterus)
- When wound closure begins
- At skin closure at the conclusion of the procedure
- Whenever the RN circulator or scrub person are permanently relieved

Deliberate and consistent application of standardized procedures is critical in preventing retained surgical items.

Radiopaque sponges should not be used as postoperative wound dressings and non-radiopaque dressing material should not be opened on the field until the final count is conducted.

Towels have sometimes been used in a wound for retraction and, when left behind, have resulted in patient injury. All soft goods used in the wound should be radiopaque.

When soft goods are intentionally left in the wound as therapeutic packing, and the patient leaves the OR with this packing in place, the number and type of items should be documented by the perioperative RN in the medical record. If it is unknown how many items are left in the wound, the medical record should reflect that the count was incorrect. When the patient returns to the OR for a subsequent procedure, the number and type of items removed should be documented in the medical record.

**Handling Sponges Discarded From the Sterile Field**

After counted soft goods are discarded from the sterile field, they should be placed in a pocketed sponge bag or similar system to facilitate counting and to prevent wet sponges from dripping on the floor. Counted soft goods should remain in the procedure room until the procedure is finished and the counts are completed and reconciled. Personnel handling discarded soft goods should use appropriate personal protective equipment.

**Management of Sharps**

Sharps should be counted for all procedures to establish a baseline for subsequent counts. Sharps include scalpels, needles, and other miscellaneous items which may not be radiopaque and may be unintentionally retained in the surgical wound. Again, deliberate, consistent application and adherence to standardized procedures for counting is necessary to prevent the retention of items. Needles may account for up to 21% of retained surgical items. Even small needles left in the patient may cause injury; however, needles smaller than 10 mm may be difficult to visualize radiographically.
Figure 2. Description of Discrepancies.³
a. Object being counted.
b. Type of Discrepancy.
Examples of miscellaneous items that should be counted include, but are not limited to:

- defogger solution bottles, caps, or accessories;
- 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.

**Counting Sharps**

The counting procedure for sharps and miscellaneous items should be performed during the same time frames as soft goods, including:

- before the procedure,
- when adding new items 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, and
- anytime the RN circulator or scrub person is permanently relieved.

The accounting procedure for sharps and miscellaneous items should be conducted in a logical progression, for example, from the surgical site to the back table to off the field.

**Counting Needles**

There are some specific strategies that should be employed when counting needles. If the suture package contains multiple needles, the number of needles should be verified by the scrub person when the package is opened. Empty suture packages should not be used to rectify a discrepancy in a closing needle count as the actual number of needles may not be the same as the number of empty packages.

The scrub person should assess the condition of sharps or other items and verify that they are intact when returned from the sterile field.

Breakage or separation of parts can occur during procedures, so it is necessary to verify that all broken or separated parts are present or accounted for when they are returned from the operative site.

Used sharps should be kept in a puncture-resistant container to minimize the risk for accidental needlestick injury and to assist in counting at the conclusion of the procedure. Sharps should not be discarded until the final count has been reconciled. Sharps should be disposed of at the end of the procedure using the same containment policy for biohazardous waste.

**Instruments**

Instrument counts also are a proactive injury prevention strategy. Instruments should be counted for all procedures in which the likelihood exists that an instrument could be retained, including during minimally invasive procedures.

Counting instruments begins when they are assembled for sterilization. Instruments should be counted at this time, but this count is not considered the initial or first count. Preprinted count sheets are used to record the counted instruments. Subsequent instrument counts should be performed:

- before the procedure,
- when new instruments are added to the field,
- at wound closure or at the end of the procedure, and
- at the time of permanent relief of the RN circulator or scrub person, although it may not be possible to see all items at that time.

The health care organization’s policies should clearly define circumstances in which the instrument count may be waived. There also may be procedures in which accurate instrument counts may not be achievable or practical. Examples may include emergency trauma or extremely complex procedures with unusually large numbers of instruments (e.g., anterior-posterior spinal procedures).
How To Count Instruments
Instruments should be counted audibly and viewed concurrently by two individuals, one of whom should be the RN circulator. The counts are conducted in the same sequence each time and in a logical progression. It is important that individual pieces of assembled instruments are accounted for and documented on the count sheet. Individual parts may become loose and fall into the wound or fall off the sterile field.

Occasionally an instrument will break during usage, so it is important to verify that all broken parts are accounted for. Serious adverse events can occur with retained or unretrieved instrument fragments. If the count is unresolved or fragments are not retrieved, the circumstances should be documented in the patient’s medical record and the patient should be informed. Occasionally device fragments may be intentionally left in the wound if it is determined that it would present a greater risk for the patient to retrieve them. Depending on the situation, an incident report may need to be completed.

One way to simplify instrument counts is to remove excess instruments from sets. Standardization of instrument sets to contain the minimum number and variety of instruments also can be effective.

Managing Discrepancies
When a discrepancy in the count is identified, the surgical team should rapidly intervene. The RN circulator should inform the surgeon and receive verbal acknowledgement and immediately begin a visual search surrounding the surgical field. Closure of the wound should be stopped and the scrub person and surgeon should visually search the sterile field. If the missing item is not recovered, intraoperative imaging should be performed to rule out a retained item. The radiograph should be taken before final closure of the wound if the patient’s condition permits. However, if the patient’s condition is unstable, a radiograph should be taken as soon as possible in the next phase of care. There may be circumstances in which the surgeon determines that it is not in the best interest of the patient to perform an intraoperative radiograph to locate a retained item.

Progressive radiological techniques are recommended for successful identification of retained items. This may include multiple portable views, fluoroscopy, or computerized tomography. Intraoperative imaging should be read by a radiologist and the results communicated directly to the surgeon and followed by read back confirmation from the surgeon. After all attempts to locate a missing item have failed and the count remains unresolved, the unresolved count should be documented in the operating room record and the patient informed.
Policy
The health care organization should have a policy for prevention of retained surgical items which includes the process of counting and defines circumstances for waived counts. The policy should define circumstances in which a radiograph is indicated and include a needle size limit criteria where radiography will effectively assist in identifying retained needles. Needles 10 mm or smaller may not be consistently visible on a radiograph. Documentation criteria should be included in the policy.

Adjunct Technology
Health care organizations may decide to use one of the rapidly emerging adjunct technologies as an extra measure of safety to supplement the manual count procedure. Perioperative personnel and physicians should be part of the product selection committee to evaluate purchase of adjunct technology to determine the most suitable application in their setting.

There are technologies available to track soft goods and allow timely detection of retained sponges even when the manual count may be considered correct. These systems use a variety of technologies, such as radio-frequency identification (RFID) or bar coding to track soft goods. Adjunct technologies for accounting of needles and instruments are on the horizon.

Orientation, Education, and Competency Validation
Perioperative personnel should receive initial orientation, ongoing education, and competency validation in the performance of standardized measures to prevent retained items. Personnel should know the corrective actions that should be implemented when a process failure occurs. If adjunct technologies are employed in the facility, personnel should receive education and training on each system and demonstrate competence.

Critical Investigation
Measures taken for the prevention of retained items should be documented in the patient’s medical record. Documentation of nursing activities is considered sound professional practice and demonstrates that all reasonable efforts were made to protect the patient’s safety.

A critical investigation should be conducted regarding any adverse event or near-miss related to retained items. Reporting mechanisms for adverse events and near misses related to retained items should be established and followed based on local, state, and federal regulatory agencies.

Quality Assurance
A quality assurance improvement process should be in place to evaluate the incidence and risks of retained items. Health care organizations should value learning and respond to errors with a focus on process improvement rather than individual blame.

Summary
Establishing a consistent multidisciplinary approach for preventing retained surgical items is a primary injury prevention strategy. All perioperative team members are responsible for the prevention of retained items. Health care organizations are responsible for employing standardized, transparent, verifiable, and reliable practices to account for all surgical items used during a procedure and for developing policies for prevention of retained items. 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 to lessen the potential for retained items.
REFERENCES


SUGGESTED READING/RESOURCES


1. Which of the following might be included in standardized procedures used to account for surgical items during an invasive procedure?
   a. Radiological confirmation
   b. Complete and accurate counting
   c. Adjunct technology
   d. All of the above

2. A standardized count procedure means
   a. counting whenever the surgeon asks for the count.
   b. following the same sequence of counting each time.
   c. counting for selected procedures identified by the RN circulator.
   d. following the directions given by the charge nurse.

3. The risk for a retained surgical item can occur when
   a. New employees are assisting during major abdominal procedures.
   b. Shift changes take place during a minor procedure.
   c. Multiple procedures are being performed at the same time.
   d. The patient is obese.
   e. All of the above

4. Any item used during a surgical procedure has the potential to become a retained item with even the smallest of incisions.
   a. True
   b. False

5. Which of the following strategies represents the best approach for preventing retained surgical items?
   a. Using music as a calming influence
   b. Implementing multidisciplinary teamwork and enhanced communication
   c. Eliminating manual counts and relying on adjunct technology
   d. Obtaining an x-ray whenever the abdominal cavity is opened

6. Surgeons and first assistants should be part of the multidisciplinary team responsible for prevention of retained item(s) and be actively engaged in safe practices. Which of the following actions by the surgeon supports prevention of retained item(s)?
   a. Communicate placement of surgical items in the wound
   b. Perform a methodical wound exploration at initiation of the closing count
   c. Use radiopaque surgical items
   d. All of the above

7. The RN circulator and scrub person should perform a standardized count procedure each time the count is performed. A standardized count procedure.
   a. assists in achieving accuracy, efficiency, and continuity among perioperative team members.
   b. should be conducted in the same sequence each time as defined by the health care organization.
   c. should be conducted in a logical progression (eg, large to small item size, proximal to distal from the wound).
   d. all of the above.
8. Instruments should be accounted for
   a. When sets are assembled for sterilization
   b. When the likelihood exists that an instrument could be retained
   c. During minimally invasive procedures
   d. All of the above.

9. When counting banded surgical sponges, the package band should be broken and discarded before counting so that the sponges can be
   a. recycled and sent to a third world country
   b. separated and visualized during the count
   c. returned to the manufacturer
   d. discarded and removed from the room

10. Soft goods may be intentionally left in the wound as therapeutic packing and the actual number of soft goods may be unknown. Documentation in the medical record should reflect that the count was
    a. correct
    b. incorrect

11. Needles that are inadvertently left in a wound
    a. will only cause patient injury if they are larger than 20mm
    b. may be difficult to visualize radiographically
    c. will not cause the patient injury if less than 10mm
    d. can always be visualized with fluoroscopy

12. The counting procedure for sharps and miscellaneous items should be performed at the same time that soft goods are counted.
    a. True
    b. False

13. When counting needles in a multiple needle suture pack
    a. it is safe to assume that the package count is correct.
    b. only the scrub person is responsible for counting the needles.
    c. the scrub person should verify the number of needles when the package is opened.
    d. the empty suture package may be used to reconcile a discrepancy in the count.

14. Waived instrument counts should be determined by
    a. the complexity of the procedure.
    b. the orders of the surgeon.
    c. the health care organization’s policy.
    d. none of the above.

15. When a discrepancy in the count is identified
    a. the surgeon should be informed and provide verbal acknowledgement.
    b. wound closure should be stopped if the patient’s condition permits.
    c. the scrub person should assist with visual inspection of the area surrounding the sterile field.
    d. all of the above
12. D
13. C
14. C
15. A
16. B
17. B
18. B
19. D
20. D
21. C
22. C
23. D
24. B
25. A
26. E
27. B
28. A
29. C
30. D

ANSWER KEY
PREVENTING RETAINED SURGICAL ITEMS