

## Retained Surgical Items: Causation and Prevention

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### Background

A retained surgical item (RSI) is a surgical patient safety problem that occurs because of ineffective practices and communication strategies, in the context of a complex work environment with multiple stressors and problematic systems and equipment (for additional details, please see the related primer on [Retained Surgical Items: Definition and Epidemiology](#)). To prevent RSIs, attention must be directed to changing systems of care rather than focusing on correcting individual behavior. The patient safety goal is to systematically curate surgical item management practices and improve the exchange of knowledge and information across multiple healthcare providers in any patient care situation that may involve an RSI. Each RSI case is essentially a result of human error (or device failure) in a complex and high-risk environment. Applying the Reason “[Swiss cheese](#)” model of error propagation can be informative in understanding the complexity of RSI causation.<sup>1</sup> In the operating room (OR) or procedural area, each slice of Swiss cheese represents a group of practitioners or entities with professional practices that are employed to defend against a surgical item being retained in a patient.

There are three primary defenders –nurses (including surgical technologists acting in the scrub person position), surgeons and anesthesiologists – whose actions can prevent retention. Additional slices of cheese include two secondary defenders – manufacturers/distributors of surgical products and radiologists/radiology technologists – whose products and actions don’t directly prevent retention but when correctly involved can mitigate patient harm. The holes in each defender’s slice of cheese represent active and latent factors or failure modes that may become active at any time, place, or situation. Active factors are usually apparent and expected but when latent factor holes “line up”, an error in one defense mechanism fails to be recognized and stopped, allowing the hazard to propagate through all layers. An RSI is rarely due to the failure of one individual or defender but usually results from multiple errors or acts of omission or commission by multiple people.

**Table 1** illustrates multiple possible latent factors related to a true case example of a retained 4x4 surgical sponge. Surgical sponges have radiopaque markers. In this case, the sponge was used during a heart operation and because of multiple errors, it wasn’t removed as intended. During the case, the

anesthesiologist placed devices on the skin and inserted a central venous line for monitoring. The nursing team called the sponge count “correct” at the end of the case because they “counted” twenty 4x4 surgical sponges. However, when a second package of 4x4 surgical sponges was added in the middle of the operation, which actually contained eleven sponges instead of ten, the nursing team did not separate the sponges so did not catch this manufacturing error. There were actually twenty-one sponges in the case that needed to be accounted for. The surgeon did not routinely perform a wound examination before closing the chest, doing so only if told the count was “incorrect,” so they did not discover that there was an extra sponge by the heart. The patient left the OR to recover in the intensive care unit (ICU), as usual. The anesthesiologist looked at the postoperative chest x-ray to confirm that there was no pneumothorax from the line they had placed but did not “see” the retained sponge because they thought the sponge radiopaque markers were just wires from electrode monitoring leads. The surgeon looked at the chest x-ray and focused on the lung fields because they wanted to see if the chest tube was placed correctly and did not “see” any abnormalities. Later that evening, when all ICU radiographic images were reviewed per protocol, the reviewing radiologist recognized a radiopaque marker in the mediastinum as a retained sponge. The radiologist had difficulty determining who to call because the x-ray requisition was incomplete but finally, the surgeon was notified and a team assembled to take the patient back to the OR (with family consent) to remove the sponge.

**Table 1. Possible Latent Factors Contributing to a Retained Surgical Sponge**

<b>Defender Slice of cheese</b>	<b>Possible Failure Modes or Latent Factors  (“holes in the slice of cheese”)</b>	<b>Example</b>
Manufacturers/ Distributors of products	<ul style="list-style-type: none"> <li>• Incorrect number of sponges in a package</li> <li>• Defective or missing radiopaque markers or drapes that contain confounding radiopaque components</li> <li>• Poorly manufactured plastic sponge holder pockets</li> <li>• Usability characteristics of tools or devices incompatible with the OR</li> </ul>	Ten 4x4 surgical sponges (gauze sponges with a radiopaque marker) are supposed to be in each pack by industry standards. The sponges are packaged and sold by weight, not by the number of sponges. When each package of sponges is added to the field the sponges are to be individually separated and counted. Nursing staff frequently find packs with 9 or 11 sponges and by policy these “bad packs” of sponges are not to be used.

## Anesthesiologists

- Throw dressing sponges in waste receptacles intended for surgical sponges
- Provide packages of sharps or sponges without shared information to nurses

After inserting a central line, a chest x-ray is ordered and examined to make sure there are no line insertion complications (e.g. pneumothorax, retained guidewire, malposition of the line).

## Surgeons

- Don't routinely examine the surgical wound before closing
- Use uncounted items intra-corporally
- Overestimate their ability to interpret x-ray images accurately
- Value speed and efficiency over caution and safety, given time constraints

During performance of the heart operation, the surgeon used 4x4 sponges to absorb blood around the coronary arteries. They may perform a "sweep" of the wound but usually rely more on nurses to "count" the sponges and tell them if something is missing. They frequently close the chest before the completion of counts because of infection concerns. Surgeons are not content experts in x-ray image interpretation.

Nurses/Surg  
Techs

- No standardized counting method, allowing practice variation
- No leadership authority or accountability to establish a single standard
- Value speed and efficiency over caution and safety, given time constraints in executing duties
- Too many items to safely count under most OR conditions and no alternative management practice
- Variable experience and expertise of staff working in same case

At the initial count, the staff separate the individual sponges in the manufacturer's pack of surgical sponges and count ten sponges. In the middle of the case, more sponges are needed, so a new package is opened but they don't take the time to separate the sponges. In that moment, they assumed that any fresh, unopened pack of sponges would have ten, and it was a busy case, so "it should be ok". They do not know that the sponges are packaged and sold by weight and have actually never been counted.

Radiologists

- Information exchange protocols and call back systems are ineffective
- Lack of knowledge about radiographic appearance of surgical items
- Inadequate technical support in intraoperative radiography
- Poor image transmission

On the postoperative chest x-ray taken to check the position of the central line, the radiologist interprets the curvy radiopaque marker of the retained sponge correctly but has trouble getting the information to the surgical team. Radiologists often don't know exactly what the metallic density or radiopaque object is, but they are expected to call out the existence of the abnormality.

## Processes to Identify RSIs

### Wound examination

Team members have a joint and shared responsibility to prevent retention and are expected to use their specific professional practices. For example, surgeons and anesthesia care providers are required to remove any items not intended to remain in the patient, and to accomplish this task by routinely performing a wound examination or field scan before completing the operation.<sup>2</sup> Nurses and surgical technologists perform multiple surgical counts at specified times, to aid in recognizing missing items and to control inventory used during a procedure. Surgeons do not perform counts and nurses do not perform wound examinations, not because they cannot do so, but because they are not content experts in each other's professional practices. Reliable practices performed with expertise and strong communication among OR team members are needed. With the recognition that retained guidewires, sheaths and catheters occur after interventional vascular, cardiac and radiological procedures in sites other than ORs, proceduralists (not just surgeons) must develop standardized processes to account for all tools and device parts that they use and consider, where possible, incorporating additional skilled personnel to help ensure accountability. Successful practices originating in the OR can be shared with other clinical teams and settings to accelerate improvement.

### Surgical counts

The performance of surgical counts by two people is a time-honored practice in the current OR environment. The Association of periOperative Registered Nurses (AORN) has guidelines on the importance of how and when surgical items are counted, and how count results are communicated and acted upon (**Table 2**).<sup>3</sup>

#### **Table 2. Surgical Count Processes**

Surgical Count	A process involving two people who look at items together; one person manually separates each item, and they audibly count the number of items (“see, separate and say”). For a surgical count performed in the OR, at least one of the two people must be a registered nurse. Surgical counts are performed during any procedure in which an incision is made or a wound is created, and surgical items are used. The surgical count is a defined process with multiple, uniformly practiced steps to identify any packaging errors and to monitor the number of items used during the operation or procedure.
Correct Final Count	At the end of the operation, the number of items counted into the case equals the number of items counted out. This process includes the management of items that may not have been specifically “counted” but which must be accounted for, such as surgical devices.
Incorrect Final Count	At the final count, either too many or too few of a specific class of item (e.g., sponge, sharps, small miscellaneous items, instruments) is identified and the count of those items is unable to be reconciled.

In a review of forty-six confirmed administrative penalty cases from a harm-based state reporting system, the final sponge count was called “correct” (which could not have been true) in 40 of the 46 (87%) retained sponge cases.<sup>4</sup> There must have been some problem with the practice of counting in these cases. In five cases, four of which involved retention of OR towels, no counts at all were performed. In all 46 cases, the surgeon had a faulty practice as well, because their “wound examination” failed to discover the sponge before the patient left the OR. In only one case where manual counting alone was used, the final sponge count was correctly called “incorrect”. In this case, secondary actions were taken to try to find the missing lap pad (e.g., repeating the wound exam, re-counting the sponges, searching the room, taking x-rays) but these actions failed, and the patient was taken out of the OR. The retained lap pad was visible on the intraoperative images but there was no requirement, in the setting of an unreconciled incorrect count, for intraoperative images to be read by a radiologist, who is the content expert in radiologic image interpretation.

These findings suggest that some surgical count practices do not reliably detect errors, as illustrated in the case of surgical sponges shown in Table 3.

**Table 3. Reliability of Surgical Count Practices, Illustrated by Retained Surgical Sponge Case**

	TRUTH (sponge in patient)	TRUTH (NO sponge in patient)
TEST: counting sponges abnormal (sponge count called incorrect)	RNs call sponge count incorrect Sponge in patient <b>TRUE Positive</b> Incorrect Count Retention Case	RNs call sponge count incorrect NO sponge in patient <b>FALSE Positive</b> Miscount
TEST: counting sponges normal (sponge count called correct)	RNs call sponge count correct Sponge in patient <b>FALSE Negative</b> Correct Count Retention Case	RNs call sponge count correct NO sponge in patient <b>TRUE Negative</b>

The sponge “count” can be considered a test, the results of which can be verified by actual circumstances. A false negative count (i.e., the sponge count is called correct but there is a retained sponge) is the most common scenario in retained surgical sponge cases. At the end of the operation, everyone thinks that all sponges have been accounted for, but in truth, there is a sponge still in the patient. This is the most dangerous scenario because everyone thinks the patient is safe (based on the false negative test result) but days, weeks, months or even years later, the retained sponge becomes manifest.

True positive counts, in which the sponge count is called incorrect and the patient leaves the OR with a retained sponge, are not common. In these cases, counting identified a problem but communication failed. OR team members failed to share information with each other to make informed decisions, to obtain necessary additional studies (e.g., intraoperative x-rays), or to communicate effectively with other stakeholders such as radiologists. While “incorrect sponge counts” have been identified as causal in most retained sponge cases, this reference to “incorrect counts” is a post hoc conclusion that the counts documented in these cases (i.e., usually correct counts) were wrong. These cases should be viewed as false negative counts.

False positive counts, in which the sponge count is called incorrect and additional actions are taken in the OR (e.g., x-rays, searching, recounting) to reconcile the count, occur frequently. These events may be considered “near miss events” (often referred to as “miscounts”) and require valuable OR time to reconcile incorrect counts that usually result from human counting errors.<sup>5</sup> When miscount rates are high in an OR, they can become “the norm.” This problem is called normalization of deviance and may drive unhealthy cultural responses (e.g., “this happens all the time”).<sup>6</sup> Frequent miscounts can influence the responses and reactive behaviors of all personnel when count deviations occur.

These observations are specific to surgical sponge management, but the principles are equally applicable to the management of any of the classes of surgical items that are managed with a “counting” practice. For example, false positive counts are exceedingly common in the management of suture needles.<sup>7</sup> This is a practice problem related to how large numbers (in some cases, more than 100) of different-sized needles are safely passed back and forth between a scrub person and surgeon. Other needle management challenges include efforts to avoid dropping a needle in the patient or on the surgical field, losing track of the needles, and preventing needlestick injury to either party.

While sponge counts are a time-honored preventive measure, they are heavily dependent on human performance and are thus subject to human error. In attempts to improve upon the manual practice of counting sponges, at least three technological adjuncts have been invented, but these approaches also depend on human performance and are subject to device failure. These innovations include a [3D matrix/barcode label-based sponge counting system](#), a radiofrequency detection system that detects sponges containing a radiofrequency tag by using an electronic pad to scan the patient and a handheld scanner to interrogate the OR, and a number of [radiofrequency identification systems](#) (RFID) that count and detect sponges that contain an RFID chip, sensor or label.<sup>8,9,10</sup> These mutually exclusive systems are considered [adjuncts](#) so must be used in addition to manual surgical sponge counts. All surgical sponges must also contain a radiopaque barium marker, which is identifiable by x-ray, should the manual or electronic count fail. To date, there are no studies comparing the effectiveness of these systems against one another in the same OR settings, so hospital purchasers make choices based on their preferences or the preferences of their surgical staff. On the horizon are artificial intelligence (AI)-driven sponge and blood management devices.<sup>11</sup>

At the time of this writing, no new technological devices have been introduced to facilitate intraoperative counting of clinical instruments. An intra-corporeal magnetic device recently became available to assist in the removal of sharps or small, miscellaneous metal items (e.g., screws) once they have been identified by x-ray.<sup>12</sup> For other items, manual counting practices are still in force. In one study, acquisition of [technological count solutions](#) alone failed to improve RSI rates in the Veterans Health Administration due to the persistence of problematic practices and communication issues. In the 46 administrative penalty retained sponge cases there were two cases of retained bar-code/device counted lap pads. In both cases, the final sponge counts were documented as correct. The errors in practice were identified to be in the human/machine interface where the humans either misinterpreted or did not believe information coming from the device. Comprehensive, multi-modal, team-based approaches that address both technology and clinician practices appear to lead to sustainable reductions in RSI rates<sup>13,14</sup> so clinician practices, leadership, and communication issues still must be addressed in all efforts to prevent RSIs.

## RSI Prevention Approaches

Modern operating and procedure rooms are complex environments where many surgical items, including broken parts or pieces of items, can be retained. There is not enough time, or enough people, to reliably count every item, so different strategies must be developed and employed to account for surgical items used in operations and procedures. The most important result is to ensure there is no surgical item left inside a patient that can be expected to cause harm. While counting may be a means of inventory control, other methodologies may be employed to ensure that everything that can and should be removed from a patient is removed. Mandatory x-rays can be used in lieu of counting instruments, although this strategy increases cumulative radiation exposure, not just for the patient but also for OR staff. Another option, in cases where many instruments and equipment for implantation are used, and it is not feasible to “count” everything, is to use a “time out” before implantation begins. This is a “hard stop” where the surgeon purposefully examines the wound to ensure no instruments or trial devices are within the wound, and the scrub person and circulating nurse concurrently examine the trays and surgical field to confirm that all equipment has been returned and agree (or not) that nothing remains inside the patient. The goal here is not to know “how many” instruments are involved but to determine with visual and tactile skills that nothing is left in the wound. These techniques, along with use of visual pattern recognition and simple adjuncts and devices to aid in separating small miscellaneous items or sharps, are used to identify if error has occurred in the management of these “too numerous to count” surgical items.

Retention of broken parts or pieces of devices is common, given the very large number of different devices and tools used in ORs. Fragments are usually removed, when possible, but the decision to remove a retained fragment is based on the clinician weighing the risk of harm from leaving the fragment where it is versus the risk of harm from trying to retrieve the fragment. Unretrieved device fragments (UDFs) usually result from operator errors in using the device, manufacturer defects, or use of worn and end-of-life equipment. Broken devices and any saved parts should be sequestered for examination. When defective devices are identified, the FDA Safety Information and [MedWatch Adverse Event Reporting System](#) should be notified. National reports of events are collated and made public with follow-up to device manufacturers on safety and design, occasionally leading to market recalls. A disclosure discussion is held with the patient to discuss the existence and nature of the UDF; the patient is included in the decision to remove the fragment or not. Any potential for injury from the UDF, and any tests or treatments to be avoided or obtained, should also be discussed.

When an RSI is suspected, the clinical team must carefully consider the potential consequences of not immediately searching for and removing the RSI. Retained sponges may cause sterile mass effects, leading to obstruction, or may become infected, leading to abscess formation or sepsis. Retained instruments, sharps or small miscellaneous items may embolize, migrate within tissues, lead to thrombosis, site infection or perforation, depending on the item and where it is located. When it is determined after discovery of an RSI that the risk of retention exceeds the risk of removal, the patient must undergo a second operation, which is considered a “harm,” no matter the duration or complexity of that operation.

It is important to remember that RSIs occur because of human error within complex systems. Creating safer environments for human work should reduce opportunities for error. Implementing system changes in

processes of care requires attention to inter-professional culture differences and ways of sharing knowledge and information between clinical teams. For example, surgeons, nurses, radiologists, and anesthesiologists have different employment relationships with hospitals and need different peer-learning systems to improve their knowledge and correct their behavior. Hospitals, health systems, and ambulatory care surgical sites often develop site-specific or systemwide actions and training programs for employees. Multiple options are worthy of consideration.

## Conclusion

There are four straightforward prevention strategies for healthcare organizations to consider in their efforts to prevent RSIs:

1. Develop systemwide multi-stakeholder policies and procedures that provide guidance and direction for all providers of care. Traditional policies are usually directed at hospital employees, but effective multi-stakeholder policies and procedures involve all team members. Better policies contain guideline-based and up-to-date recommendations and explain the rationale for those recommendations and procedures. Ambiguous content is minimized to optimize consistent implementation across settings of care and to provide clear guidance.
2. Provide education and training regarding safe practices and safe communication strategies within the system of care, as this education and training is not part of general professional licensure.
3. Implement audits, tracking, and reviews of care deviations at each hospital or surgical site, rather than relying on external agencies or systems, so all providers of care are held accountable for their actions and decisions.
4. Site-specific usability analyses and comparative effectiveness studies of new innovations and technological advances are important to determine whether the devices under consideration are likely to be helpful at that site, given that site's culture, case mix, and workflows.

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