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Retained Surgical Items: Definition and Epidemiology.

January 4, 2024
Romano PS, Gibbs VC. Retained Surgical Items: Definition and Epidemiology. PSNet [internet]. 2024.
https://psnet.ahrq.gov/primer/retained-surgical-items-definition-and-epidemiology

Background

Prudent medical practice and federal and state laws require that any surgical item not intended to remain inside a patient be removed. When a surgical item is not removed, it is referenced as a **retained surgical item (RSI)**. Surgical items are supplies and devices used in or around a surgical or procedural site, wound, or incision that are used to aid in the performance of an operation or procedure, to provide exposure or coverage, or to absorb blood and other body fluids. These items are NOT “foreign” bodies or objects; they are supplies or devices that the hospital or facility purchased and were intentionally used by the operating room (OR) staff in the delivery of care. By contrast, foreign bodies or objects refer to external items that an individual may ingest, insert, aspirate, or be shot or stabbed with. Examples include ingested batteries, dentures, safety pins, screws and other sharp objects, inserted sex toys, bullets, shrapnel, and polymer projectiles. Surgical intervention may be needed to remove a retained foreign object (RFO) or retained foreign body (RFB) that is found within the body.

Retention of a surgical item refers to possessing, keeping, or holding onto it; this word implies that the surgical item was not intended to remain in the patient. For example, when reducing and repairing a fracture using plates or screws, the final construct is not considered to be “retained hardware”. The term “retained hardware” would only be used if some piece or part of the construct was supposed to be removed but was not. Therefore, the term “RSI” does not require a modifier, such as inadvertent, unintended, or accidental. If an item such as wound packing or a wound vacuum system or a vascular clamp is intentionally placed for treatment or therapy and intended to temporarily remain in a patient after the procedure, the preferred terminology is “therapeutic packing” or placement. If that therapeutic pack is not removed as intended, then it should be described as a “retained surgical pack” rather than as “unintentional retention of an intentionally retained pack.”

With the above considerations in mind, the term “retained surgical item (RSI)” is clearly preferred over older terms such as RFO, RFB, inadvertent RFO or RFB, or unintentional RFO or RFB. Although RSI is also an abbreviation for the anesthesia procedure, “rapid sequence induction,” confusion is unlikely given the context for using these terms. Clarity of usage will improve reporting, optimize coding, and enhance search

engine functionality to provide better information. An RFO or RFB is not the result of medical error, whereas an RSI is a multi-stakeholder patient safety problem and possibly an act of medical negligence. Proper application of the terms RSI and RFO/RFB will identify different elements of causation and different preventive strategies in examining cases.

Taxonomy

RSIs are classified into two groups. **Group I** includes four (4) classes of surgical items that comprise a traditional “surgical count” performed by operating room (OR) staff: surgical sponges and surgical towels, sharps, small miscellaneous items (SMI), and instruments. **Group II** includes dressings and drape towels, devices used during operations and procedures, and device fragments that result from breakage or separation of a device. This group also includes multi-component implant systems. These group II items are not usually managed with a “surgical count”. The table below provides detailed examples from each group.

Group I	
Surgical sponges	Soft items made of white (bleached) cotton, woven fabric or gauze that contain x-ray detectable markers and are used within surgical wounds. Surgical sponges include but are not limited to laparotomy pads (18”x18”), mini laps (12”x12”), baby laps (4”x18”), radiopaque 4”x4” or 4”x8” sponges, tonsil or round sponges, peanut or “cigarette” sponges, and neurosurgical patties.
Surgical towels	Large (16”x26”) woven cotton towels used in the OR and procedure areas. Surgical towels ALWAYS have X-ray detectable (radiopaque) markers. Only white (bleached) surgical towels are used intra-corporally (i.e., inside a patient), and must be counted.
Sharps	Metallic, pointed or cutting objects of various sizes that include but are not limited to suture needles, scalpel blades, hypodermic needles, and hooked knife blades.
Small miscellaneous items (SMI)	Other objects used during surgical procedures that are often single use, often not radiopaque, may be composed of multiple parts, and may include but are not limited to electrosurgical scratch pads, electrocautery tips, vessel loops, rubber shods, suture booties, umbilical tapes, laparoscopic or thoracoscopic ports, disposable instrument inserts, cotton-tip applicators, marking pens, suture reels, screws, nails, safety pins, endoscopic clip appliers, bulldog clamps, vascular inserts, hemostatic materials, nasal suction bulbs, bulb syringes, and visceral ”fish” retainers.
Instruments	Surgical tools designed to perform specific functions such as cutting, dissecting, grasping, holding, suturing or retracting. These items are usually stored and sterilized in surgical trays and individually may have multiple parts. They are usually metallic and radiopaque. Examples include, but are not limited to clamps, needle holders, multi-component retractors, malleable/ribbon retractors, screwdrivers, knife handles, and scissors.

Group II	
Dressings	Soft items such as gauze sponges or rolls, ribbon packing, nasal packs and other packing material, prep swabs, iodoform gauze, nonadherent pads, and polyurethane foam sponges for vacuum-assisted wound care. These soft goods are usually applied at the end of a procedure to cover or provide hemostasis in a wound. They are intended to be changed or removed at another site by personnel other than an OR nurse or surgical technologist. They are not considered part of a surgical count because they are managed outside the domain of OR staff.
Drape Towels	Drape towels are usually blue, green or an unbleached natural color, are made of coarser grade cotton, and are multi-functional. They are primarily used as drapes, wipes or covers. They do not contain radiopaque markers, are not to be placed inside patients, and are not counted.
Devices	Devices are any type of equipment or tools that have designated functions used during a procedure that may have electronic or mechanical component parts. Devices include items such as staplers, drains, catheter insertion sets, needle localization sets, vessel sealing apparatus, and stone retrieval kits.
Device fragments	Device fragments are broken parts or pieces of tools or devices. Examples include a piece of a drill bit, a broken tip or part of an instrument, a broken part of a catheter or drain, a fragment of a stent, or the tip of a guidewire.
Implant Systems	Instrumentation and individual components arranged on multiple preset trays that are required for reconstructive bone and joint surgery, and certain audiologic and cardiovascular device implantations. These implant systems are frequently loaned from a vendor for a specific case or procedure and are referred to as “loaner trays or instrumentation.” A single system may be composed of multiple trays, each holding parts such as instruments, sizers, trials, inserts and liners used to measure and prepare the implantation site. The specific non-biological implantable devices, which are also part of the systems, are then opened and inserted to create the final surgical construct.
Trial devices, inserts, or sizer component parts	Surgical tools used to measure and prepare a site for the insertion of a compatible, non-biological, implantable device. These surgical tools are often multiple, arranged on pre-designed trays, made of plastic or dense polymer, and may not be radiopaque.

A patient with a retained device, needle, sponge, instrument, dressing or SMI is generally considered to have experienced a “never event”, a safety event that is never supposed to happen. All RSI cases are usually required to be reported to internal hospital risk management and patient safety incident reporting systems. Some RSI cases qualify as reportable adverse events [called serious reportable events (SRE) by the National Quality Forum (NQF) or sentinel events by The Joint Commission (TJC)], triggering notification to external entities. There are three general entities for external reporting:[1] (1) mandatory reporting to state

licensing or public health authorities; (2) voluntary reporting to Patient Safety Organizations (PSOs), collaborations authorized under the Patient Safety and Quality Improvement Act of 2005; and (3) voluntary reporting to regulatory, accreditation, or certification agencies, such as The Joint Commission. All entities agree that an item is retained if found in a patient “after surgery”. However, the precise definitions of “after surgery” or “after surgery ends” differ somewhat.

Most states that require mandatory event reporting, the American Hospital Association Coding Clinic, and thus the Centers for Medicare & Medicaid Services (CMS) follow the NQF SRE 2011 guidelines, which state that surgery ends: “(1) after all incisions or procedural access routes have been closed in their entirety, (2) devices have been removed, (3) final surgical counts have concluded and any discrepancies resolved, and (4) the patient has been taken from the operating room.” A vaginal birth ends when the mother is in the immediate recovery period (1-2 hours post birth). These conditions are closely analogous to traditional OR record designations for: procedure start time (incision/cut time), procedure finish time (closed time), and “out of OR” time. In other words, “after surgery ends” corresponds to the period after “out of OR,” NOT the period after incisional closure, because the operation isn’t over until the patient leaves the OR.

Part 3 of the above definition is particularly important because of how surgical counts are performed and any discrepancies are resolved. In some cases, the surgical team is still looking for an item that they know is missing, but they have exhausted the ability to find it in the OR. For example, if plain radiographs have not been helpful, the team may decide to get computed tomography (CT) images, or they may transfer the patient to the intensive care unit (ICU), where additional assistance for patient safety and monitoring is available. In these cases, any items discovered through subsequent imaging would not be considered retained or reportable because known discrepancies had not yet been resolved, and in fact, the team was using best practices to solve the problem.

In contrast to NQF, TJC opines that “after surgery” includes any time after completion of the wound skin closure, even if the patient is still in the OR under anesthesia. This definition is not accepted by the Association of periOperative Registered Nurses (AORN) or the American College of Surgeons (ACS). Indeed, many healthcare facilities use the NQF definition while others use the TJC definition for reporting, but all follow the NQF definition for ICD-10-CM (International Classification of Diseases, 10th Revision, Clinical Modification) coding and reimbursement for care. Clearly, using one definition vs the other will yield a difference in the number of RSI events.

Epidemiology

Not all RSIs are required to be externally reported, which influences the reported incidence of RSI cases. Specifically, “unretrieved device fragments (UDF)” are not usually considered SREs or sentinel events, so they are rarely reported to external systems. These items are unretrieved because a clinical determination has been made by the provider that the risk of removing the object exceeds the risk of leaving it where it is. In these cases, there is still internal organizational reporting where the organization (1) discloses to the patient the presence of the unretrieved device or device fragment and (2) keeps a record of cases to identify trends and patterns (for example, by type of procedure, by type of retained item, by manufacturer, by practitioner) that may highlight opportunities for improvement. In addition, surgical drains and guidewires

(most commonly in central veins) are devices that are not counted but may be retained during insertion or may break upon removal. These occurrences are considered device retention events (i.e., retained device fragments) and may require an operation or procedure for removal, if the risk of removal is less than the risk of retention. Incorrect counts of surgical needles are common and frequently remain unresolved, with little available information about the frequency of actual retention of suture needles. Therefore, careful examination of what RSI are being discussed in RSI estimates is warranted.

With the above caveats in mind, the incidence of RSIs has been estimated as 1.3 per 10,000 surgical procedures, according to a systematic review of 21 incidence studies. These rates vary somewhat based on whether the data originate from external reporting systems or from internal (facility reporting) sources and what the system reporting rules are with specificity to what types of surgical items are required to be reported.

For example, data from one of the best state reporting systems provides information about the relative distribution of RSI cases. California started public reporting of all RSI events in 2007 with possible administrative penalties assessed after investigation of confirmed events. In an evaluation conducted by Verna Gibbs, MD (email communication, September 2024), the 79 cases that received administrative penalties from 2007-2011 were distributed as follows:

- 46 cases (58%) involved surgical sponges or towels.
    - 31 lap pads, 11 radiopaque textile (4x4) sponges, and 4 towels
    - 16/46 (35%) of these cases came from obstetric or gynecology areas.
- 0 cases involved sharps (indicating that needles/sharps either are not retained or were not reported, because they were not retrieved and were not considered to cause harm).
- 24 cases (30%) involved SMI and device fragments.
- 9 cases (11%) involved instruments.
    - 7/9 cases involved one type of instrument – a malleable/ribbon retractor.

Retained sponges are the most frequently reported surgical item to cause patient harm because these cases require a second operation for sponge removal, which is considered harm. Increased appreciation of the problem of retained vaginal sponges and other items (e.g., vaginal packing) left behind after spontaneous vaginal births, as well as the frequent retention of lap pads after cesarean births, has brought increased recognition to these areas as opportunities for improvement. UDFs are often the most frequently reported to internal facility reporting systems (with drill bits lodged in bone as the most common type of UDF), but these events are rarely reported to external systems. Instruments are very rarely retained even though hundreds of instruments are opened and used during some operations. Needles are the most frequently miscounted surgical item, but their relative contribution to the problem of RSIs is unclear. Individual facilities and healthcare entities have reported improvement in the incidence of specific types of RSI cases, such as retained surgical sponges, but it is unclear whether this incidence has decreased over time nationally and whether the finding is generalizable to all types of RSI.

Known risk factors for RSIs, according to a 2014 meta-analysis of three studies, include intraoperative blood loss greater than 500 mL; duration of operation; more than one sub-procedure; failure to perform surgical counts; involvement of more than one surgical team; and unexpected intraoperative factors or

events. The occurrence of any safety variance, and specifically an incorrect count at any time during the procedure, has been repeatedly associated with elevated RSI risk. Obesity may be a risk factor specifically among patients who have an abdominopelvic operation. These observations suggest that there are opportunities for practice improvements in the environments where procedural and surgical care is provided.

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