Prevention of retained surgical items
BY SHARON MCNAMARA RN, MS, CNOR, CST

Retained surgical items are considered a preventable error, creating a strong culture of safety that supports patient advocacy and team collaboration. Effective communication and respect for each other’s role and skill set is required to promote optimal outcomes for the patient. Each individual provider on the team must be responsible, accountable, and present to the process of preventing retained surgical items, and prepared for the shared decision making that is necessary in providing safe patient care. This alert will outline the important components of:

- What to count
- When to count
- How to count
- Count discrepancies
- Intentional retention

Retained surgical items (RSI) is also one of the major issues at the forefront of the surgical patient safety movement. RSIs can result in post surgical complications, reoperation and/or death for the patient. Several national organizations have relayed the following:

- **The Joint Commission** categorizes RSI as a “sentinel event” that requires a defect analysis. RSI is on the National Quality Forum's list of serious reportable events and is one of the Center for Medicare & Medicaid Services' “never events,” identified as one of the hospital-acquired conditions that is preventable.

- **The Institute of Medicine** has six goals to achieve improved healthcare systems, one of which is preventing injuries that result from care – including prevention of RSI. "Healthcare 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."
The Council on Surgical and Perioperative Safety's Safe Surgery Principle 6 endorses standardized processes of care to prevent the retention of foreign bodies during surgery.6 The American College of Surgeons' statement on the prevention of retained foreign bodies after surgery recommends, “Prevention of foreign body retention requires good communication among perioperative personnel and the consistent application of reliable and standardized processes of care.”6

The Association of periOperative Registered Nurses has recently revised and updated the Recommended Practice (RP): Prevention of Retained Surgical Items (previously RP: Sponge, Sharps, and Instruments Counts).4 Recommendation I advocates, “A consistent multidisciplinary approach for preventing RSIs should be used during all surgical and invasive procedures.”4

The Veterans Health Administration7 and Institute for Clinical Systems Improvement8 policies require that the surgical team apply a standard approach to the prevention of unanticipated retained items. In addition to standardized procedures, multidisciplinary teamwork and communication, counting procedures (both manual and adjunct), radiologic verification, documentation, policy and procedure development, and measures for investigation of count discrepancies should be considered.

**What to count?**

**Sponges**
- Radiopaque sponges, laparotomy packs, towels, peanuts, kitners, dissectors, cottonoids, tonsil sponges, dental rolls
- Radiopaque surgical sponges and soft goods should not be cut, altered in any way or used for dressing
- Each sponge should be separated and counted individually to verify accuracy

**Sharps**
- Needles, scalpels, blades, hypodermic needles, electrosurgery active electrode blades/needles, safety pins, drill bits, saw blades

**Instruments**
- Instruments are counted on all procedures in which the likelihood exists that an instrument could be retained
- Instruments are counted in sets; each set should have an itemized count sheet with documentation of count by person assembling the set (this does not constitute the initial count in the OR)
- Individual pieces of instruments (blades, sheathes, suction tips, wing nuts) should be accounted for separately and documented
- Inspect returned instruments for breakage or separation of parts

**Miscellaneous items**
- Electrosurgery scratch pads, endostapler reload cartridges, laparotomy sponge rings, Raney clips, trocar sealing caps, umbilical and hernia tapes, vessel loops, vascular inserts, vessel clip bars, suture reels, shods, catheter introducers/sheaths

**How to count**
- Initial count and all counts require separation of sponge material and needles.4-7
- The circulating RN and the scrub person will count out loud

**When to count**
- Before the procedure to establish the initial or baseline count.4-7 This includes laparoscopic procedures where there is potential to convert to an open procedure.4,9,11
- When new items are added to the sterile field.4-7
- Before closure of a cavity within a cavity (uterus).4-7
- When wound closure begins.4-7
- At skin closure (final count).4-7
- At the time of permanent relief of the scrub person or the registered circulating nurse (direct visualization of all items may not be possible).4,3,8
- Any time a member of the surgical team expresses concern about the accuracy of the count process.7
- Incidents when sponge, sharp or instrument counts may be waived should be clearly defined in policy and procedure and established by the healthcare organization.4,9

**Sponges, sharps, instruments**

**Sponges and sharps**
• Counts should be performed using a logical standardized sequence every time. The facility policy should define the sequence. An example would be: start at the sterile field, then Mayo stand, move to the back table and then off the field.

• Before closure of the surgical site, the surgeon should announce closure and perform a methodical wound exploration.

• During count process there should be no distractions, interruptions or staff changes.

• Adjunct technologies may be used to supplement manual count procedures, currently available: bar code, radio-frequency, and radiofrequency identification (RFID) technology.
  − Bar code technology has a unique matrix bar code affixed to each item; the items are scanned as they are added and removed from the sterile field with a hand held reader. Research demonstrates this method identified more count discrepancies (missing sponges) than traditional counting but cannot detect a missing sponge.
  − Radio-frequency technology entails a radio-frequency chip sewn into the item and a wand connected to a console is passed over the patient. This system counts and detects sponges and the console signals with an audible and visual alarm. Research demonstrates this technology detected 100% of sponges in the chest and abdomen of cadavers.
  − RFID technology counts and detects sponges via a chip sewn into the item. This system is seen affixed to a large bin into which sponges when discarded count and identify the sponge material.

• No sponges, needles or instruments should be removed from the operating room before closure of the wound is complete.

Count discrepancies

• The RN circulator has the ethical responsibility to notify the perioperative team immediately on note of a discrepancy (number and type of item missing) and he/she should receive verbal acknowledgement from the surgeon and team members. This facilitates multiple actions to be taken by the sterile team members (inspecting the incision, drapes, Mayo stand) and unsterile team (inspecting the floor, kick buckets, linen and garbage).

• If it is safe for the patient, wound closure should be suspended until the discrepancy is resolved or, if radiographs are required, there is no need to reopen the patient. This may prevent having to report the incident to regulatory agencies or accrediting bodies.

• If the item is not found, at this point a radiograph will be ordered. Effective communication with the radiology team is important so that the tech taking the x-ray and the radiologist reading it have a clear understanding of what they are looking for and where in the body they will image.

• Reporting the radiograph results should be by direct report, be timely, and include a read-back verbal confirmation.

• Radiographs may be waived if the patient is unstable or the item, such as a small needle, would not be visible. Policy should outline these circumstances including specifying what types of needles require radiograph and who should read the film.

• The count is repeated and verified.

Intentional retention

• Sponges/lap packs/tapes can be used for packing and intentionally retained as part of therapy. Policies and procedures to standardize processes for:
  − When and how to communicate about these intentionally retained items
  − What and how to document
  − The plan for removal
  − Confirmation with the surgeon

• Removal procedure: radiopaque sponges that are removed do not become part of the count for the removal procedure. They need to be isolated and identified as being from the original
procedure. A cross check with the documentation from the original procedure should validate the correct number of sponges is being retrieved.

- The surgeon should perform a methodical wound exploration and possibly order a radiograph to assure retrieval of all items.
- The count is documented as reconciled.
- The patient should be informed of any items purposely left in the wound and the plan for retrieval. This includes retained fragments of instruments, needles, etc. and policy should state who is responsible for informing the patient. Transparency is greatly valued in a culture of safety.

Procedures, documentation, quality monitoring, and orientation

- Policies and procedures for the prevention of retained surgical items should be developed, reviewed periodically, revised to reflect evidence-based practice as necessary, and readily available in the practice setting. Having clear policies available for staff to follow reduces individual interpretation and supports safe patient care.
- Defining in policy what is the “end of the surgical procedure” is important for reporting purposes and may vary by state.
- Documentation should include results of the surgical item count, notification of the team members, any instruments or items intentionally retained, and actions taken if there were count discrepancies.
- Inclusion of prevention of retained surgical items should be included in orientation of team members and competency to perform the varied processes validated.
- Surgical count competency should be validated yearly or after variation in practices have been eliminated. Use of a variety of methods is recommended: pre and post test on content, demonstration and return demonstration to validate technique and policy compliance, real time auditing of the process which provides opportunities for coaching to reinforce new and updated processes.
- Quality monitoring through rounds/audits/observations should be conducted to validate compliance with best practice.

Additional risk reduction strategies

- Teamwork: Collaboration with all members of the surgical team to establish meaningful policies, procedures, and tools related to counting processes and the commitment of team members to preventing retained surgical items is paramount. This includes buy in by the surgeons and collaboration with anesthesia.
- Use of containment devices for sharps provides protection from needle stick injuries, allows clear visualization of sharps, and prevents miscounts.
- Use of a whiteboard to document the number and type of sponges, sharps, and miscellaneous items that allows all practitioners in the room to see the count.
- Use of a standardized, preformatted documentation record/count sheet. Memory alone should never be relied on.
- Use of pocketed sponge bags to place sponges to be counted. They allow for visibility and separation of each sponge/pack.
- Creation of an educational board for the radiology team with common retained items on it to use as a comparison could facilitate more effective communication between the perioperative and radiology teams in the event of a retained item.
- Implementation of a “time out” for counting.
- Develop a standardized communication method such as SBAR.
- Decrease the number of instruments in sets and develop organized set up that mirrors the count sheet to create a standard and efficient process for the instrument processing team and the OR team.
- Develop a count reconciliation checklist to assist with standardized process in a retained surgical item event.

Retained surgical items are considered a preventable occurrence. There are many issues that arise based on such an occurrence and may include:

- **State reporting** – many states require public reporting when these events occur.
- **No pay** – federal and state agencies, accrediting bodies, third party payers, and professional associations consider an RSI a sentinel or “never event.” Healthcare organizations and providers may not be reimbursed for additional care provided as a result of these “never events.”
- **Victims** – most importantly, there are victims caught in the fallout. The patient may experience extended length of stay, reoperation, long term pain and disability, even death. The practitioners involved are often devastated as they feel responsible for the error and the complications experienced by the patient.
- **Reputation** – the organization could see their reputation tarnished through media coverage or public reporting, both of which could affect the bottom line when patients make a different choice for their healthcare.
TechnologyBytes

BY ANN GAFFEY RN, MSN, CPHRM, DFASHRM

Electronic health record implementation in hospitals and physician office practices: Understanding the meaningful use incentive program

The Health Information Technology for Economic and Clinical Health (HITECH) Act provisions of the American Recovery and Reinvestment Act of 2009 included billions of dollars in incentive money for eligible hospitals and healthcare providers to adopt and become “meaningful users” of electronic health records (EHR)/electronic medical records (EMR) and to improve health information technology in our healthcare system. There are both Medicare and Medicaid incentive programs, and some providers may qualify for both.

The adoption of EHR technology has become explosive in the past two years, but there is much more to accomplish. While 91% of hospitals surveyed by the Healthcare Information and Management Systems Society (HIMSS) (n=5337) have at least a very basic system in place (for example, electronic record keeping capability in lab, radiology, and pharmacy), only 1.2% have achieved a fully paperless environment (HIMSS Analytics Database, 2012). On the physician practice side of adoption, EMR/EHR system use among office-based physicians increased from 18% in 2001 to 57% in preliminary 2011 estimates (see graphic below).

Adoption of EMR/EHR systems by office-based physicians has increased


Source: CDC/NCHS, National Ambulatory Medical Care Summary, 2011.

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What is the meaningful use program?
The intent of this program is for eligible hospitals and providers to use certified EHR technology in a meaningful manner, and that the certified technology is connected in a way that provides for the electronic exchange of health information to improve the quality of care. The key to understanding is knowing what facilities and individuals are eligible to participate (thus the “eligible provider” and “eligible hospital” language), what is considered to be certified technology, and what these providers need to do to be considered meaningful users.

Determining eligibility
Who is eligible, and for which program – Medicare, Medicaid, or both? On the hospital side, for eligibility under the Medicare EHR Incentive Program, it must be a:

- “Subsection (d) hospital” in the 50 states or DC that are paid under the Inpatient Prospective Payment System
- Critical Access Hospital (CAH), or
- Medicare Advantage Hospital.

To be eligible under the Medicaid EHR Incentive Program, it must be a(n):

- Acute care hospital (including critical access and cancer hospitals) with at least 10% Medicaid patient volume, or
- Children’s hospital (with no Medicaid patient volume requirements)(CMS).

On the provider side, Eligibility Requirements for Professionals (EPs) are based on individual practitioner status, not necessarily an entire group of practitioners. Only one incentive payment per year is available, regardless of the number of practices or locations at which he or she provides services. EPs under the Medicare EHR Incentive Program include doctors of medicine or osteopathy, doctors of dental surgery or dental medicine, doctors of podiatry, doctors of optometry, and chiropractors. Hospital-based eligible professionals are not eligible for incentive payments. EPs under the Medicaid EHR Incentive Program include physicians (primarily doctors of medicine and doctors of osteopathy), nurse practitioners, certified nurse-midwives, dentists, and physician assistants who furnish services in a Federally Qualified Health Center or Rural Health Clinic that is led by a physician assistant. The incentive for EPs under the Medicare EHR Incentive Program include doctors of medicine or osteopathy, doctors of dental surgery or dental medicine, doctors of podiatry, doctors of optometry, and chiropractors. Hospital-based eligible professionals are not eligible for incentive payments. EPs under the Medicaid EHR Incentive Program include physicians (primarily doctors of medicine and doctors of osteopathy), nurse practitioners, certified nurse-midwives, dentists, and physician assistants who furnish services in a Federally Qualified Health Center or Rural Health Clinic that is led by a physician assistant. The incentive for EPs under the Medicare EHR Incentive Program include doctors of medicine or osteopathy, doctors of dental surgery or dental medicine, doctors of podiatry, doctors of optometry, and chiropractors.

Employing certified technology
Certified technology standards, implementation specifications, and certification criteria have been developed and adopted by Health and Human Services. The technology being used must be tested and certified by an Office of the National Coordinator Authorized Testing and Certification Body in order for a provider to qualify for EHR incentive payments. One question that comes up from time to time is from physicians who have been using a specific EHR in their office for many years – can they still use this technology and quality for the incentives? Only if the EHR vendor took the steps needed to obtain certification, and the physician’s office has upgraded to that version.

The last step of the incentive program that must be achieved to receive the first incentive payment is to meaningfully use the technology, and then attest to CMS about the use. There are three stages of compliance, and Stage 1 Meaningful Use criteria are currently being attested to, which will be the case through 2013. For eligible professionals, there are a total of 25 meaningful use objectives. To qualify for an incentive payment, 20 of these 25 objectives must be met. For eligible hospitals and CAHs, there are a total of 24 meaningful use objectives. To qualify for an incentive payment, 19 of these 24 objectives must be met. An example of a meaningful use objective for EPs is that they must maintain an active medication list for more than 80% of all unique patients seen, and have at least one entry recorded as structured data in the EHR (or an indication that the patient is not currently prescribed any medication). An example of a meaningful use objective for an eligible hospital is to provide more than 50% of all patients of the inpatient or emergency departments of the eligible hospital who request an electronic copy of their health information, an electronic copy of the health information (including diagnostic test results, problem list, medication lists, medication allergies, discharge summary, procedures) within three business days upon request.

The good news is that the use of electronic health records is growing, incentive money is being paid to early adopters ($2.6 billion paid out as of end of 2011), and we are beginning to see some of the advantages of the ability to exchange health information between medical group providers, system hospitals, and more. With this burst of technology, however, we are also seeing some of the risks that come with the electronic documentation process, in systems that in essence are millions of line of computer code.

Physicians often consult with colleagues informally to get quick, limited advice on a patient. Depending on the circumstances, however, the “curbside consultant” can be held to a formal doctor-patient relationship with the patient, opening the door to potential malpractice liability. A recent case illustrates the risk.

A woman in her late thirties had a total abdominal hysterectomy and right salpingo-oophorectomy. During the operation, her gynecologist saw the balloon of the Foley catheter in her bladder and realized he had accidentally created a rent in the bladder wall.

He consulted with a urologist, who was preparing for an operation next door, on how best to repair the rent. After taking a quick look at it, the urologist advised him on a two-layer closure and the thickness of the suture bites. After finishing the repair, the gynecologist tested for leaks with saline stained with methylene blue. The repair held, but the dye demonstrated a previously unnoticed separate laceration of the bladder. The gynecologist went next door to consult again with the urologist, who was now in the middle of his own operation. This time the urologist recommended using figure-of-eight sutures, not doing another dye test, and keeping the Foley catheter in. The gynecologist did just that.

The repair of the second laceration did not hold, and the patient suffered a vesicovaginal fistula, infections, and scarring. Another urologist surgically closed the fistula. The patient reports having continued pelvic and bladder pain, plus abdominal and intestinal problems.

She sued the gynecologist for malpractice; later she added the urologist to the claim as well. The urologist moved for summary judgment because the statute of limitations had expired before the patient added him as a defendant. To get around this, the plaintiff’s lawyer had to claim the urologist had concealed his involvement with the patient’s care, which if true would have tolled (suspended) the statute of limitations. But the urologist did not write a note in the chart (the consultation note ended up helping him because it caused the statute of limitations to start running and the plaintiff allowed it to run out, but this is not typical). His defense would have been helped by the gynecologist’s testimony that he did not rely on the urologist’s advice in making his treatment decisions.

In this case, the urologist probably would have been found to have a duty of care to the patient. He looked at the bladder laceration in person. He gave detailed patient-specific treatment advice, such as how deep the sutures should be. He was consulted twice, and he dictated a note that was placed in the patient’s chart (the consultation note ended up helping him because it caused the statute of limitations to start running and the plaintiff allowed it to run out, but this is not typical). His defense would have been helped by the gynecologist’s testimony that he did not rely on the urologist’s advice in making his treatment decisions.

Informal consultations are beneficial overall for the practice of medicine, but they must be solicited and given with care. The most important way for physicians to avoid being sued for asking for or providing a curbside consultation is to ensure the clinical situation is appropriate for the type of limited-information, general advice that curbside consultations should entail. If the advice would depend on details of the clinical circumstances, on a clinical assessment or judgment that the consultant would be in a better position to make, there are two or more confounding variables, or a very detailed review of the patient’s history and physical is needed, a formal consultation should be performed. In addition, if the treating physician contacts the consultant a second time on the same patient, a formal consultation should be requested.

When a curbside consultation is appropriate, the physician should clarify that this is what he is providing, keep it simple, do not bill the patient (preferably do not even learn the patient’s name), do not write a note in the chart (keeping a personal record of the question and advice is always advisable but probably unrealistic for most), and ask the requesting physician not to write about the curbside consultation or put the consultant’s name in the chart. If the requesting physician feels a need to document the curbside consultation in the chart because of his reliance on the advice, a formal consultation would be preferable.

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