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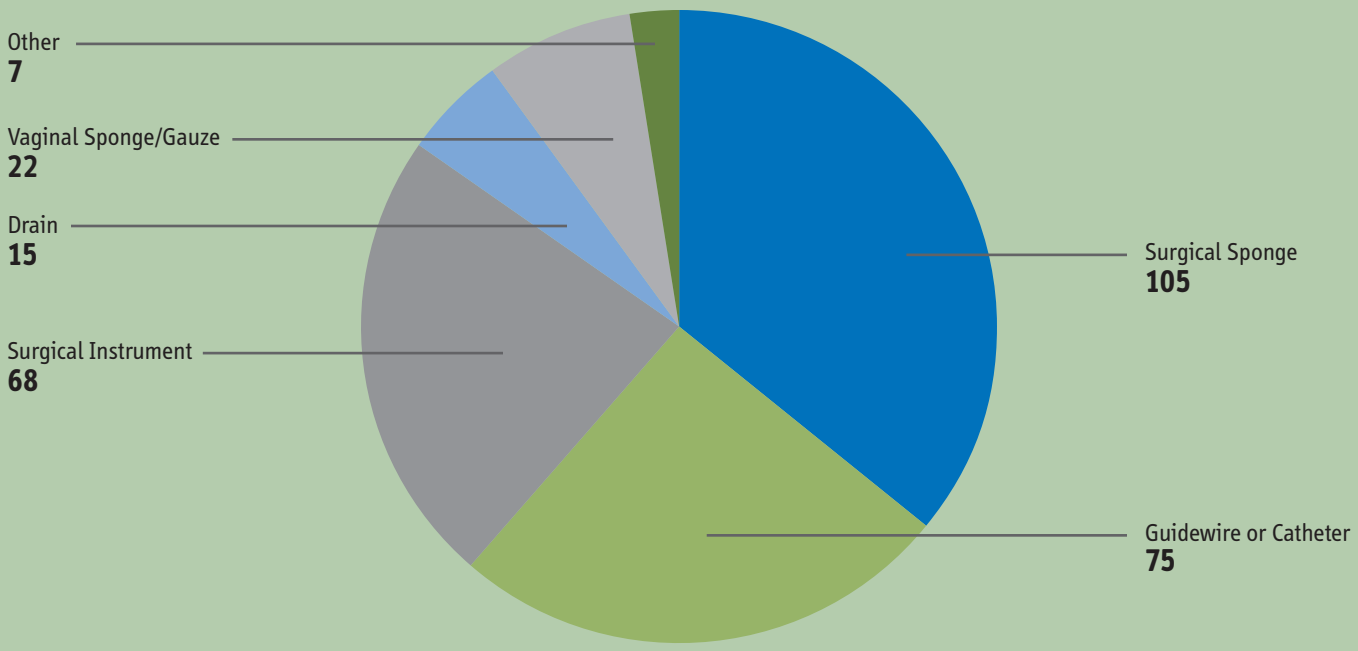
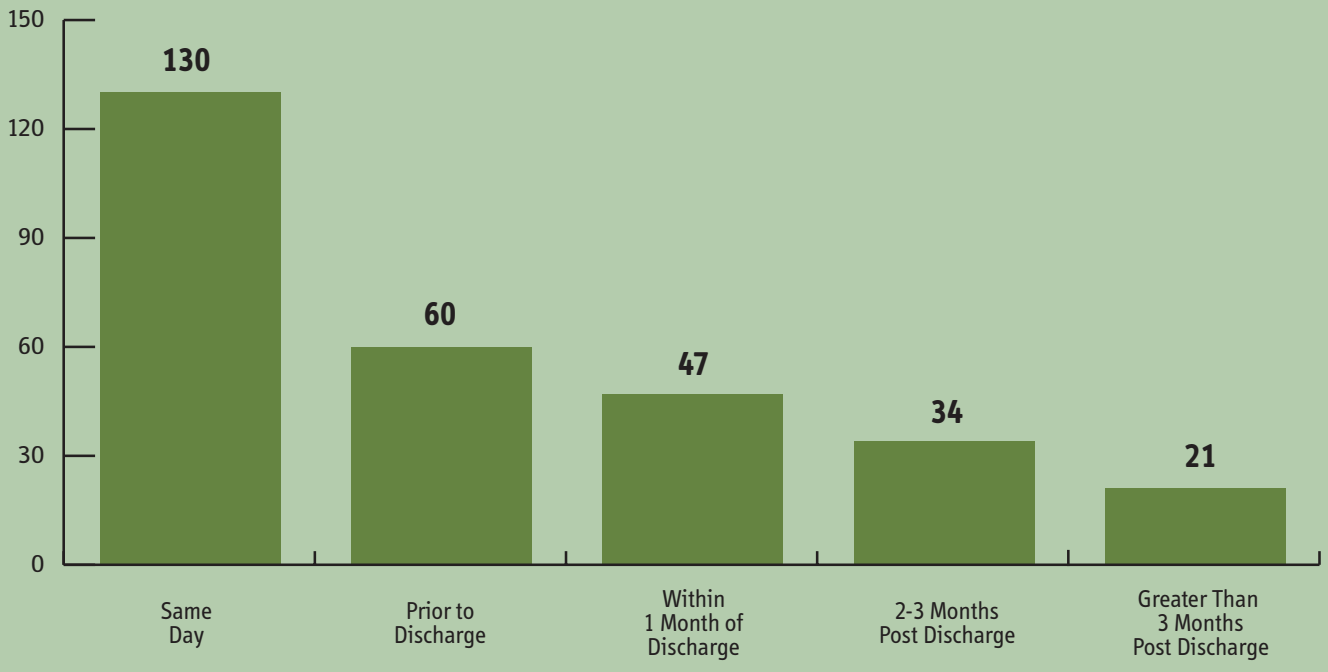


Number or Reported Occurrences by Length of Time Between Procedure and Discovery of Retained Foreign Object, NYPORTS, 2008-2009



Did We Lose Something?

Unintentionally Retained Foreign Objects Reported to the New York State Patient Occurrence and Reporting Tracking System

INTRODUCTION

Have you heard the story of the man who had a surgical clamp in his belly that was discovered when the airport metal detector sounded? The fact is that most occurrences of unintentionally retained foreign objects are much less dramatic, and are usually found using medical radiology, not the Transportation Security Administration's scanners!

Unintentionally retained foreign objects are problematic for at least two reasons. First, they can cause patient harm. Fibrous objects such as sponges illicit a reaction from the body's immune system. They can also lead to infection, abscess, obstruction, and pseudotumors. Nonfibrous objects may also be a source of infection, as well as perforation, impairment of function, pain, etc. The second problem is the resource issue. Retained foreign objects are "never events," and additional medical costs incurred when retrieving the object or treating the complications associated with the object will not be reimbursed by many insurance plans, including Medicare and Medicaid. The systems that facilities have put into place to prevent retained sponges and surgical instruments are also costly in terms of equipment and time, so we want the systems to work efficiently and effectively. Occurrences of retained foreign objects that are reported to the New York State Patient Occurrence and Reporting Tracking System (NYPORTS) are sentinel events of a system that sometimes doesn't work. This report provides statistics about the occurrences of retained foreign objects reported to NYPORTS and highlights risk reductions strategies implemented by facilities following occurrences.

There were 292 NYPORTS reports of unintentionally retained foreign object (NYPORTS reporting code 913) in 2008 and 2009. There were an additional 118 reports of equipment failure resulting in a retained foreign object (reporting codes 937 and 938).[1] Overall, 65% of the reported occurrences were discovered prior to discharge of the patient. About one quarter of patients had a medical complication associated with the retained objects, and just over half required a return to the operating room or other procedures to remove the object.

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[1] *Retained foreign objects due to equipment failure do not require a Root Cause Analysis in NYPORTS, and will not be the focus of this report. The majority of equipment failures involved retained tips of instruments or needles. Of the 119 occurrences reported, 52 involved additional procedures to remove the object and 65 were left in the patient.*

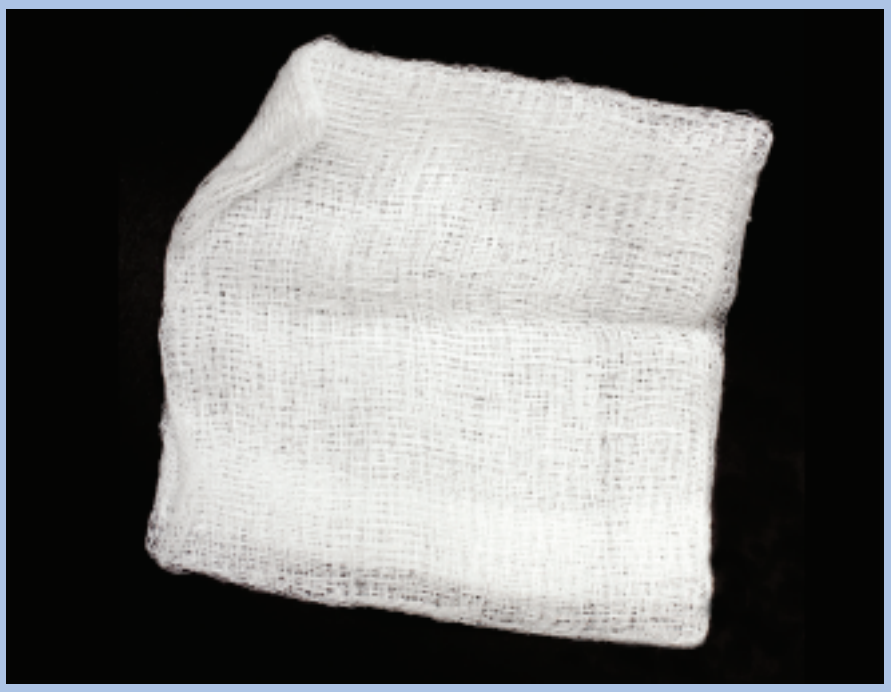
Did We Lose Something? *(continued)*

SPONGES, LAP PADS AND GAUZE

Fibrous objects accounted for a little under half (43%) of the reported retained objects. This included 105 occurrences involving surgical sponges or laparotomy pads, 22 involving sponges or gauze retained in the vagina following vaginal delivery, and 2 instances of retained wound packing. Patients with retained fibrous objects were more likely to experience complications (33%, compared to 13% of patients with nonfibrous objects). Patients with retained fibrous objects were also more likely to have the object discovered after discharge (43%, compared to 29% of patients with nonfibrous objects). These patterns are likely related; a fibrous object is more likely to cause an infection or abscess, and a sponge is then found when the patient undergoes imaging or surgery for the associated symptoms. One quarter of the retained fibrous objects were discovered after imaging or surgery related to symptoms of the retained object, compared to 12% of the nonfibrous objects.

VAGINAL SPONGES RETAINED AFTER CHILDBIRTH

Case 1 ***"30-year-old female underwent a normal spontaneous vaginal delivery. First degree lacerations encountered and repaired. On day 35 post partum, the patient returned to the OB clinic with complaints of lower back pain and a white vaginal discharge with a foul order for 1 week. The patient stated she removed a 4x4 piece of gauze from her vagina the previous evening, which she brought with her. Specimens sent to pathology.***



Antibiotics prescribed with follow up in one week in the gyn clinic.

In addition to identifying interruptions to normal work flow as a contributing cause, the findings of this Root Cause Analysis (RCA) include the need to standardize sponge and needle counts by 2 persons at the close of all vaginal deliveries and to utilize tailed, radio-opaque sponges rather than unmarked 4x4 gauze. The literature suggests implementation of these measures will lesson the risk of a similar event in the future, particularly in a situation where normal work flow is interrupted."

The 22 instances of retained sponges or gauze following vaginal delivery are of particular concern due to the frequently mentioned lack of a count policy for vaginal births. In the majority of instances, the facility reported that there was no policy for wound sweep or counting sponges or gauze pads used during vaginal delivery and subsequent repair of episiotomy or tearing. Since the sponge or gauze is used to dam the flow of blood, it may be placed higher in the vagina and not be visible following the suturing. Risk reduction strategies reported by facilities generally included implementing a count procedure and wound sweep policy for all vaginal births as well as documenting the count or wound sweep. As reported in the example above, a few facilities implemented stronger risk reduction strategies, such as changing available supplies by replacing gauze, which are easily mistaken for blot clots, with larger sponges with tails that remain outside the vagina. Policies and procedures are also needed to spell-out the process to follow when the count is off, for example, use of radio-opaque sponges implies x-ray follow-up as needed. One facility reported that they extended the use of their newly adapted radiofrequency detection system to the Labor and

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Delivery Unit. Thirteen of the 22 occurrences resulted in reported symptoms, with one mother requiring re-admission for treatment of post-partum infection. Seven mothers presented to the emergency department due to symptoms and eleven mothers were prescribed antibiotics. For more information on vaginal count policies for vaginal deliveries, see the American Congress of Obstetricians and Gynecologists Committee opinion no. 464: Patient Safety in the Surgical Environment, *Obstet Gynecol.* 2010 Sep;116 (3):786-90.

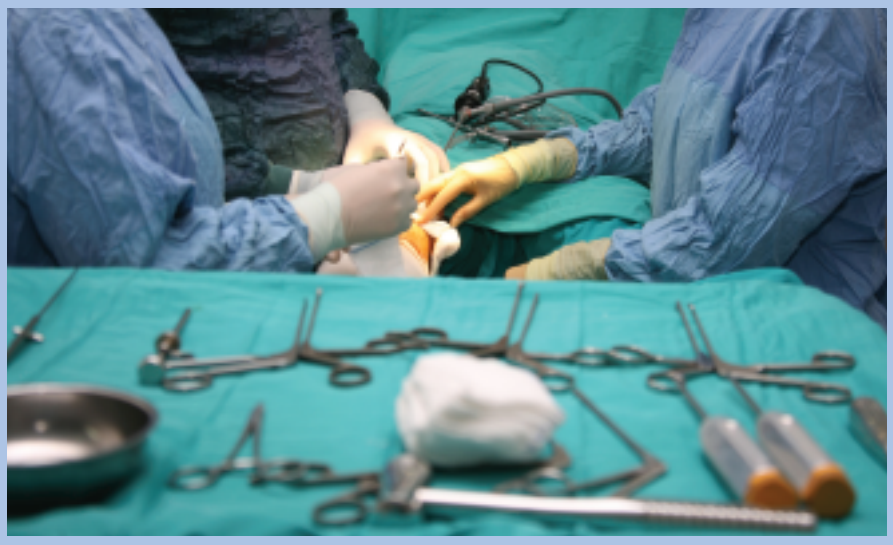
Root cause analysis findings related to counts of retained surgical sponges

Occurrence	*Number*	*Percent*
Count reported "correct"	**50**	**48%**
Item was still in patient	6	6%
Uncounted addition to surgical field or other inadequate documentation	5	5%
Other type of failure to follow procedure	6	6%
Unable to determine what aspect of count failed	33	31%
Count reported "incorrect"	**48**	**46%**
Closure proceeded anyway, clinical reasons cited	8	8%
Closure proceeded anyway, no clinical reason given	16	15%
Closure completed before count completed	6	6%
Second count correct, mistaken belief that item was found	3	3%
Search for item failure	15	14%
Other and unknown	**7**	**7%**
Total	**105**	**100%**

SURGICAL SPONGES

The lack of a count policy following vaginal delivery is in sharp contrast to surgical procedures, for which there are well established guidelines to: 1) follow a procedure for counting all items in surgical field; 2) perform a sweep of the wound; 3) use only radio-opaque sponges; 4) follow a procedure for resolving discrepancies and 5) document all counts (Joint Commission *Perspective on Patient Safety*, March 2006, Volume 6 Issue 3 page 11).

The occurrence of retained surgical sponges are split approximately 50/50 between those where the count of the sponges was reported as correct and those where it was reported as incorrect. The literature confirms the New York experience (see Egorova NN et al, *Annals of Surgery* 2008 Jan; 247(1):13-8 and Greenberg CC et al *Annals of Surgery* 2008 Aug;248(2):337-41). Most of the instances where the count was reported as correct, the root cause analysis team was unable to determine the root causes of the retained sponge, which is likely related to the delayed discovery of these sponges; 20 of the 33 (60%) were found more than one week after discharge. Among the occurrences where the sponge count was incorrect, the root causes were associated with the procedures used to resolve discrepancies or with operating room culture of complacency regarding incorrect counts. Two recurrent issues were closing the surgical site before the x-ray results were available and, the lack of communication between the surgical team and radiology



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Did We Lose Something? *(continued)*

service. For example, in several instances, the x-ray quality was too poor to rule out a retained object or the x-ray field was not broad enough, but ineffective communication lead the surgical team to believe that the x-ray results were negative rather than inconclusive. **Including the suspicion of a retained foreign object as the reason for the x-ray is an important risk reduction strategy.**

Another issue that was identified in several occurrences was inconsistency in policy and procedures in specialty surgical areas of the facility. As reported in the example below, the facility had revised the policy regarding resolution of incorrect counts in the main OR, but the revised policy had not been implemented in the labor and delivery OR.

Root cause analysis findings related to imaging to detect retained surgical sponges

	Initial Count			
	Correct Number	Percent	Incorrect Number	Percent
Imaging not used	40	80%	5	10%
Object not radio-opaque	2	4%	1	2%
Object not appreciated on x-ray	3	6%	6	13%
Object detected on x-ray	5	10%	24	50%
Object not in field of x-ray			6	13%
Poor quality x-ray			6	13%

Case 2 ***"This 29-year-old pregnant patient underwent an elective Cesarean section at term. The surgery was uncomplicated, but one lap pad was unaccounted for during the final count. While the patient remained in the OR, a portable x-ray was ordered and obtained. The lap pad was identified on x-ray and the patient's incision was re-opened and the lap pad removed without incident.***

On initial review of this case and the Labor and Delivery OR count policy in use, opportunities for improvement within the policy were identified. Specific areas included appropriate counting methods, communication, and escalation of the chain of command. Upon further investigation, however, it was learned that the facility's Main OR, which shares its policies with the Labor and Delivery OR, had recently revised their count policy as a result of the identification of several of the same issues that were found to be problematic in the analysis of this case.

The RCA Team carefully reviewed the revised OR policy. They agreed that each area identified as being in need of improvement was captured and appropriately addressed within the revised OR policy.

As a result, focus shifted from revising the current Labor and Delivery policy, to identifying why the Labor and Delivery OR had not received this update and to ensuring that, going forward, the OB OR consistently receives the updated policies from the Main OR in a timely manner so that the OB staff may be appropriately educated and the most current policy applied."

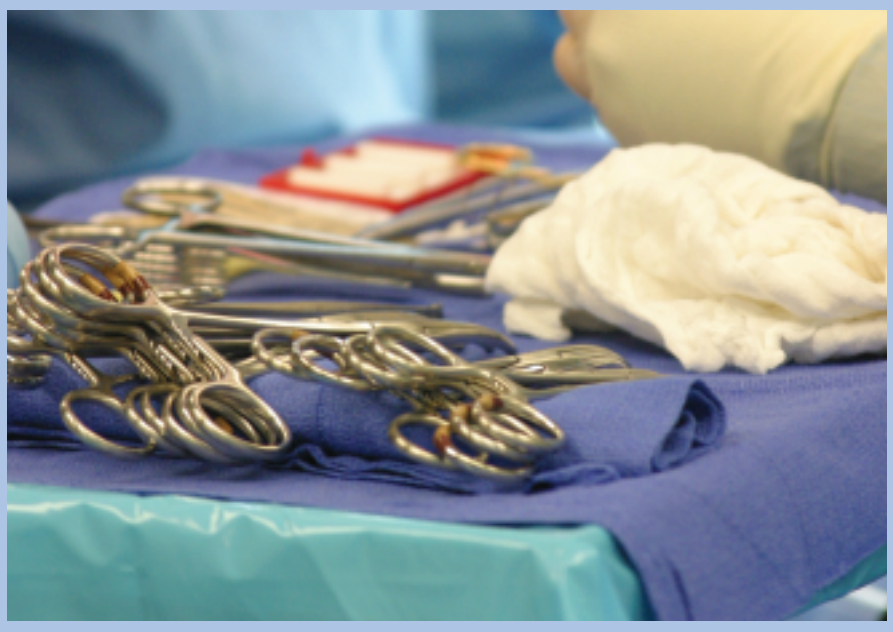
SURGICAL INSTRUMENTS

There were 83 occurrences of retained needles, surgical instruments, or parts of instruments or equipment. The root causes for these occurrences are as diverse as the types of objects that were retained. Some patterns could be identified, however.

Type of surgical instruments reported as retained foreign objects

Type of Object	*Number of Occurrences*
Drain or drain fragment	15
Needle	10
Retractor	7
Clamp	6
Fragment drill bit	5
Stent	4
Clip	2
Fragment needle	1
Other whole object	16
Other fragment	17

- Nine of the reported occurrences involved a retained foreign object in the vagina following hysterectomy or other gynecological surgery or procedure. As with the retained gauze following episiotomy or laceration repair subsequent to childbirth, the root causes of many of these occurrences was lack of a count policy or procedure related to vaginal sponges or instruments. Often, the Root Cause Analysis team found that the object in question was not included on the count sheet, reminding us that all instruments that have the possibility of being placed in the body should be included in the count. In addition to these vaginal occurrences, ten other occurrences related to objects not being on the count sheet were reported, including three retractors or retractor parts, three orthopedic trial components, two guide pins, an esophageal dilator, and a suture passer.



- Retention of post-surgical drains or drain fragments was often related to accidentally catching the drain tip with a stitch. Subsequently, force was used in removal of the drain, resulting in breakage or retention of the drain tip. Because drain removal is often assigned to residents, supervision regarding proper technique was often cited by the Root Cause Analysis teams.
- Nine occurrences were reported to involve equipment failure or breakage. Although such events are typically reported in NYPORTS as equipment failure (reporting code 937 or 938), these events were reported as retained foreign objects due to the delayed recognition of the breakage. These events involved needles, drill bits, drains (discussed above), angioplasty balloons, and a gastric band. A common theme was lack of inspection of the object after use.
- Six of the occurrences involving fragments were associated with equipment that was cut or modified during the procedure. Several were related to equipment, such as tubes or stents, that were cut to size during the procedure, which in turn lead to the inability to do an adequate visual examination at the conclusion of the procedure. The example described on the next page illustrates the difficultly that modification may cause. This example involved cutting off a tail

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that is designed to remain outside the open cavity. Also playing a role in the occurrence were issues related to hand-off, other communication, and documentation; all recurrent themes in patient safety.

Case 3 ***"The case began but as the procedure progressed, the surgeons encountered difficulty in reaching the distal posterior margin of the tumor. The surgeons made the decision to change the procedure to an abdominoperineal resection due to the difficulty in visualizing the margin of the tumor. The surgeon called for a FISH retractor, which was not on the back table, since this instrument is not usually called for during the planned procedure. The FISH retractor is a flat piece of vinyl material with a retainer ring attached to it. The retainer ring is intended to stay outside the patient's body and is used to "pull" the retractor out of the abdomen prior to closing. The ring also signals that the retractor is in the patient's body, since it remains outside the patient.***

The circulator obtained the retractor, opened it and placed it on the sterile field, but did not document it on the instrument count sheet. When the surgeon was ready for the retractor, the scrub tech wet the retractor and handed it to the surgeon who then cut the retainer ring off the instrument. His intention in doing so was to use the ring to pull the sigmoid colon down. At this point, the altered retractor was not discarded, but the remainder was placed in the belly to hold back the bowel while the wound closure began.

The scrub tech and circulator were both replaced by other staff during the surgery, but there was no verbal communication regarding the use of the FISH retractor. The relief circulator and scrub tech do the first closing count, but there is no count of the FISH as it does not appear on the instrument count sheet. The final instrument count on the abdomen is done by relief Scrub tech and circulator, but no FISH retractor is counted as it does not appear on the instrument count sheet. The surgery is completed and the patient is sent to PACU in stable condition.

Six days post op, the patient had developed abdominal distention and signs of an ileus. An abdominal x-ray was done which revealed a foreign body in the intra-abdominal cavity. The patient was taken to the OR for an exploratory lap and the FISH retractor was found and removed."

CATHETERS AND GUIDEWIRES

Guidewires and catheters were the most commonly reported nonsurgical retained objects, with 80 occurrences reported in 2008 and 2009. About half of these occurrences were retained *complete* central line guidewires, and half were guidewire or catheter *fragments*. Often, the retained guidewire or fragment was immediately recognized by the proceduralist. More problematic were the occurrences where there was a delayed recognition of the object. As with the retained sponges, one commonly cited issue was poor quality communication between the procedural team and radiology service, related in the event below.

Case 4 ***"A retained foreign body in the right common femoral vein and subcutaneous tissue was identified in this patient subsequent to an unsuccessful attempt in placing a central line in the right groin. Upon removing the guidewire from the right groin, the Resident observed the tip of the wire was partially denuded, missing some of the outer metal coiled covering of the wire. According to the Resident, the x-ray of the pelvis was ordered with the intention of ruling out a foreign body in the right groin. This information was not in the medical record or the clinical history for the chest and pelvis x-ray.***

According to the Radiology Resident and Radiologist, they were

not aware there was an attempt in placing a central catheter in the right groin. When the preliminary reading did not identify a foreign body, the Resident thought there was no foreign body and no further action was necessary.

This case was due to a combination of human error, a delay in recognition of the retained foreign body and system issues, including communication and documentation issues. In addition, an opportunity for improvement was identified, specifically, the need to document the proctored procedures performed by third year Residents such as central line catheter insertions."

In this example, the resident noted that the wire was not intact, but failing to inspect the guidewire, catheter, drain or other equipment when it is removed from the body was a frequently reported cause of delayed recognition in instances of equipment failure or breakage. Following these occurrences as well as occurrences where the entire wire was left in after line insertion, several facilities decided to add removal and inspection of the guidewire to their central line insertion checklists, following the same rational for counting of surgical instruments. This strategy could be particularly helpful in facilities where a large proportion of central lines are inserted by residents, since inexperience in line insertion was also frequently cited as a contributing factor for retained guidewires.

The nature of these retained objects meant that a large proportion of the patients needed additional procedures, often interventional radiology or vascular surgery, but few patients had medical complications resulting from retained wires or catheters. Most problematic were the handful of instances where the catheter tip was sheared off during epidural anesthesia administration. The patients with retained epidural catheter tips usually needed follow-up with neurology or neurosurgery.

CONCLUSIONS

Given the large number of operative and invasive procedures performed in New York State each year, retained foreign objects are a rare complication, but they have been a source of significant patient harm in a few instances. This summary of root cause analysis reports submitted to NYPORTS shows that, like most serious safety events, retained foreign objects are often due to multiple related failures that cascade through the system. For all types of occurrences, lack of effective communication with respect to radiology was frequently mentioned as a root cause. Opportunities for improved communication were identified for both the procedural team, in terms of providing indication for the films, and the radiology service, in terms of communication regarding issues such as film quality, x-ray field, and need for clinical correlation of findings. For surgical occurrences, communication within the operating room or procedural suite was also frequently mentioned, particularly related to incorrect counts and to counting items entered onto the sterile field, especially during shift changes. Communication tools, such as Situation-Background-Assessment-Recommendation (SBAR), documentation tools such as checklists and white boards, and technological advancements, such as radiofrequency identification systems for surgical sponges, will continue to lower the risk of retained objects, but none of these strategies will replace the need for continuously maintaining and improving a culture of safety – i.e. open communication whenever any question arises.

NEW YORK STATE DEPARTMENT OF HEALTH
Office of Health Systems Management
Hedley Park Place, 6th Floor
433 River Street
Troy, NY 12180