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PATIENT SAFETY INITIATIVE
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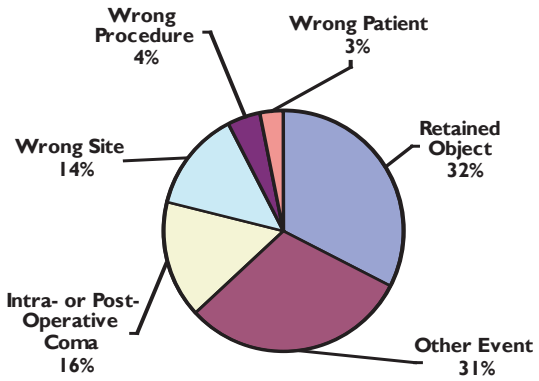
Patient Safety Initiative Update

- The first annual report for the Department of Health and Senior Services (Department) patient safety activities was released in October. That report, **Patient Safety Initiative: 2005 Summary Report**, describes the activities of the Patient Safety Initiative during 2005. It also presents a summary of events reported and related hospital analyses for that period including root cause and impact for the patient. Special emphasis is given to the most frequently reported events: falls, pressure ulcers and surgical events.
- The Health Care Administration Board approved the patient safety rules for initial publication at their October 19, 2006 meeting. Those regulations describe the requirements for each health care facility to have a patient safety plan and committee as well as the requirements for mandatory reporting of serious preventable events. The rules will be effective for different types of health care facilities following a phase-in time table based on adoption of the rules:
  - ❖ *Upon adoption:* rehabilitation, general, psychiatric and special hospitals;
  - ❖ *Six months after adoption:* ambulatory care, home health care and hospice;
  - ❖ *One year after adoption:* assisted living, comprehensive personal care homes, long-term care, adult and pediatric day health, residential health care.
- A new **instructions manual** for hospital reporting of significant events was released in early November. The changes focus primarily on clarifications of the existing instructions. For example, the root cause analysis (RCA) section has been reformatted to provide examples and to make the requirements more clear. Several changes in the reporting categories were made in order to be consistent with the proposed regulations. These changes in reporting include: special categories for new and reprocessed single-use devices; exclusion of reporting on pressure ulcers which developed as a result of underlying vascular etiology; extension in time frame for impact of surgical post-operative death or post-operative coma from 12 hours to 24 hours after surgery. The new instructions manual is effective on January 1, 2007.
- The last of three groups of hospitals finished the Falls Collaborative Workshop in September. Teams representing 51 hospitals participated in the two-session workshop designed to discuss the national perspective on fall prevention. Hospitals were successful in initiating quality improvement projects designed to prevent falls.

Overview: Retained Objects

The incidence of unintentionally retained objects during surgery is estimated to be one in 1,500 operations.[1] Reports of retained objects constitute 4% of all reports received by the New Jersey Patient Safety Initiative and are the most common surgical event reported as shown in Figure 1.

Figure 1: Frequency of Types of Surgical Events



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Also in this issue:

It is important to note that the New Jersey Patient Safety Initiative codes reports of retained objects resulting from broken instruments or supplies as device failures. This includes events related to broken catheters, bone hooks, laser tips and orthopedic hardware.

Similar to the findings from national studies,[1] the majority of retained objects reported to the Patient Safety Initiative are surgical pads and sponges. Retained pads and sponges are known as gossypiboma, derived from gossypium (Latin: "cotton") and boma (Swahili: "place of concealment"). Complications resulting from a retained sponge include pain, infection, granulomatous response with abscess development, fistula formation and/or intestinal obstruction.[2] Other types of retained objects, such as clamps, needles and retractors, may cause organ damage, bowel perforation, sepsis and severe pain.

The most commonly identified causes of retained objects are the rapid pace of emergency procedures, unexpected changes in the operation, and high patient body mass index (BMI).[1] Under these conditions, staff may be rushed, distracted, or may need to introduce new equipment during the surgical procedure, disrupting the standard counting process.

Surgeons and operating room teams routinely rely on sponge and instrument counts as a means to prevent retained objects.[3] The Association of periOperative Registered Nurses (AORN) recommends four separate counts of surgical sponges and supplies: the first before the procedure begins, the second before closure of a cavity within a cavity, the third before wound closure begins, and a final count during skin closure.[4] They also recommend counts when the OR team is relieved.

Use of these recommendations, however, is not universal or standardized and is often modified according to individual hospital policy.[3]

Reasons for a Falsely Correct Count

A recent study published in the *New England Journal of Medicine* found that in nearly 90% of cases of retained foreign objects, the counting procedure showed that all equipment and supplies were accounted for.[1] Reasons for a falsely correct count when objects are actually missing include staff fatigue, distractions, interruptions and the use of relief teams.

Three days after an exploratory laporatomy that involved multiple emergency blood transfusions, several surgeons and relief OR teams, a KUB was ordered to differentiate a post-operative ileus from an obstruction. At surgery, a sponge was removed.

Introduction of equipment and supplies during surgery but not communicated to the circulating nurse and therefore not added to the count sheet may also result in a retained object with a "correct" count.

Patient underwent an emergency exploratory laporatomy with lysis of adhesions and detorsion of a small bowel volvulus. Three weeks later he complained of abdominal pain and a CT scan showed a foreign object. At surgery a "Fish®" bowel protector was removed. This object was called for at the end of the case and not added to the count sheet.

Response to an Incorrect Count

If 90% of the cases of retained objects involve falsely correct counts, that leaves 10% where the counts did not match. Why was the object not removed for these patients? In some of the cases, surgery must be ended in order to immediately stabilize the patient. But in the other cases, the issue may be a culture where the inequities of power between surgical team members did not allow challenging a count or the violation of operating room protocols. In one study of medical malpractice claims, incorrect sponge counts were accepted prior to closure either due to the surgeon dismissing the count without re-exploring the wound, or to the nursing staff allowing the incorrect count to be accepted.[5]

The needle count was incorrect at the end of a coronary artery bypass surgery (CABG). Although the surgeon did not believe the count was truly incorrect, an intra-operative x-ray was taken. The surgeon completed the procedure and moved the patient to the recovery area before he had the result. Later that day, the patient was taken back to the OR and the retained needle was removed.

In the cases reported to the Department, some of the factors are physician refusal to believe the count, removing the patient from the OR before the x-ray result is obtained, incorrect reading of the x-ray by a

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non-radiologist and the radiologist only reporting on the absence of the object noted on the requisition and not the additional one seen.

At final count a needle was missing and could not be found. An intra-operative x-ray was ordered and the requisition read "rule-out lost needle." The radiologist called the OR and reported directly to the surgeon that there was no needle. When the final report was received, it was noted that there was a retained object. The patient was taken to the OR and a sponge was removed.

Procedures Outside OR

Lack of standard procedures and policies regarding post-operative notes and count sheets for procedures performed outside the main operating room may lead to an increased risk of retained objects. Sponge and needle counts are routine for cesarean deliveries but not for vaginal deliveries. Similarly, intra-cardiac devices (ICD) are implanted in the Cardiac Catheterization Lab and central lines are placed in patients on the units and on the floors. Preventing retained guidewires is the goal since detection after insertion may be difficult.[6]

Two months after implant of a pacemaker, the patient was readmitted for an infected surgical pocket. The pocket was opened and a 4x4 gauze sponge removed. There was no count procedure in the Cardiac Catheterization Lab.

In General

Some hospitals are investigating an emerging technology that involves electronically tagging all equipment and supplies. Retained objects can then be detected by a wand that is passed over the patient. Such technology may be an efficient way to reduce the retention of foreign objects. It is not, however, a cure-all. Technology and established procedures are only effective in reducing medical errors when all members of the treatment team understand the importance of and compliance with hospital policies. This in turn requires that hospital policies are appropriate and serve to promote safety and quality improvement.

Overview: Lost Surgical Specimens

The Department has received a few reports of lost surgical specimens and, while this represents a very small percentage of the total number of reports, the potential harm to the patient is significant.

The path of the surgical specimen from generation in the OR to documentation of the final reading and diagnosis in the medical record is a long one with many steps. The pre-analytic phase includes the specimen generation, collection, labeling, recording, storing and transport to the pathology laboratory's receiving unit. The analytic portion includes the lab's documentation of receipt, preparation and staining of the tissue, reading the slide and rendering a diagnosis, documenting the reading and diagnosis and transmitting this to the patient's chart.

Errors can occur at every step of this process and are not rare. One article estimates that pre-analytic errors may occur in as many as 6% of cases.[7] The resulting consequences may be minor and have no harmful impact for the patient. If a specimen is labeled with the wrong day, that error is unlikely to cause the patient harm. The impact may be catastrophic if the wrong patient's name is on the label or if the specimen is lost prior to diagnosis.

During the planned surgery for a buccal cyst, the surgeon decided to remove a small nodule on the tongue that "he knew" was benign and placed it on a piece of gauze. At the end of the case, the gauze with the nodule could not be found.

The Association of periOperative Registered Nurses (AORN) recommends immediately placing the specimen in a labeled container to secure it as one of the steps to decrease the likelihood of losing it.[4]

Hospitals and other health care facilities are encouraged to analyze their own process for specimen handling before there is a significant incident that impacts their patients' care. One hospital that did so in response to a lost specimen found multiple points in the process that were vulnerable to failure. By implementing a rapid cycle improvement strategy, Plan-Do-Study-Act (PDSA),[8] they were able to significantly improve their process.

Second Looks: Retained Objects and Lost Specimens

In this issue, we extend the Overview sections on retained objects and lost specimens to examine reports to the Patient Safety Initiative and hospitals' responses to these events. Retained objects and lost specimens have potentially catastrophic results for the patient. In the interest of sharing this information and decreasing the probability of a similar incident happening at your facility, we invite you to take a "Second Look" at your facility with these events in mind.

1. *Ten days after a long, complicated gastrointestinal surgery, the patient complained of abdominal pain and was taken back to the OR where a lap pad was removed. The first surgery had required multiple nursing relief teams. Towards the end of the procedure, the surgeons were rushing to get the patient off the table and expressed the need for speed to the nurses as they were doing the final counts.*

Comment: The use of counts to reduce the incidence of retained foreign objects is clearly not always sufficient. Hospitals are continuously focusing on promoting effective communication and implementing procedures that help prevent human error. After their analysis of this event, this hospital implemented the use of wall boards and began addressing the issues of clear communication and the culture of mutual respect at a systems level. Use of wall boards with clear plastic bags in the count procedure may serve as an additional visual cue and thus reduce the likelihood of a miscount.

2. *The surgeon placed the cervical cone biopsy specimen on a piece of gauze; the assistant surgeon placed the gauze on the sterile OR table where they both later examined it and left it on the table. The nurse then retrieved a specimen cup from the cabinet and at the end of the procedure the cup was sent to the laboratory. Five hours later, after the patient had been discharged from the facility, the lab called stating that the cup was empty.*

Comment: During its investigation, the hospital found that cup had not been prepared in advance and was very small; so small, in fact, that the label completely covered the cup making visualization of any contents very difficult. They also examined the entire process, as Slavin[8] has suggested, and found that there were several "points" of vulnerability for failure. As a result of this analysis, the hospital assigned one staff person to transport specimens to the lab on a scheduled basis, provided larger specimen cups, and required the surgeon and the nurse to visually confirm the container's contents. To insure that these actions are implemented, the hospital is monitoring them by direct observation and reviewing the documentation tools.

3. *A suture reel was missing at the end of a 7-hour procedure that was complicated by extensive hemorrhage and required surgeons from three specialties to scrub in. The x-ray technician took the intra-operative film to the radiologist and then called the OR to report "no reel seen." One month later the patient presented to her physician's office complaining of flank pain. A CT scan showed an abdominal abscess and lap sponges; two sponges were removed at an exploratory laporatomy. The radiologist's final report after the initial surgery had noted the presence of the sponges.*

Comment: The Department has received more than one report where only the lack of the queried object and not the presence of another foreign body was communicated to the surgeon. During their RCA investigation, this hospital found that there was no standard protocol for reporting intra-operative x-ray results and immediately required direct radiologist to surgeon communication. As discussed in the June 2006 issue of *Patient Safety Updates*, the incomplete or delayed communication of imaging results can cause harm to the patient. Perhaps adding the inclusive phrase "any foreign body/object" to the requisition, in addition to the missing object, will decrease incomplete reporting.

4. *Two weeks after a femoral line was inserted at the bedside the patient was readmitted for shortness of breath. After several chest x-rays, whose interpretation was difficult because of multiple leadwires on the chest, a foreign body was detected and the guidewire was removed from the subclavian vein.*

Comment: Insertion of central lines is a common occurrence in the acute care setting and often takes place outside of the main OR where procedures offer some protection from retained objects. The Department

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Second Looks (cont.)

has received several reports of retained guidewires that required the patient involved to undergo an additional procedure for removal. Because the guidewire comes with the catheter and is not separately introduced, as a retractor is during surgery, it is more likely to be overlooked after the successful insertion of the line. During the RCA process, the hospital decided to require a post-operative note, based on those done after major cases, that specifically documents the removal of the guidewire.

Adopting procedures designed for patient safety from the main operating room to all other locations where invasive procedures are formed will decrease the incidence of retained sponges, pads, "peanuts" and instruments.

In Conclusion

A "blame free" culture that rewards staff for reporting risks and taking responsibility for mistakes does not mean that staff is not held accountable. Retained objects and lost surgical specimens are frequently the result of miscommunication and failure to follow standard protocols. Hospitals should actively monitor compliance with their existing policies and examine their process improvement opportunities. A multifaceted approach to error prevention can reduce or eliminate the prevalence of retained objects with their associated complications and the incidence of lost surgical specimens.

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