PATIENT SAFETY ALERT

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# RETAINED FOREIGN OBJECTS

Retained foreign objects or failure to remove items during a procedure or surgery, such as surgical instruments, sponges, or other items, continue to be a patient safety issue. According to The Joint Commission, unintended retention of foreign objects ranked fourth on its list of sentinel events identified by type in 2008.

A foreign body left inside a patient can have catastrophic results. Consider this, only 6% of retained foreign objects were discovered within one day of surgery. In fact, the average number of days to discovery is approximately 21 days post-surgery. (Berger and Saunders, 2008)

Berger and Saunders (2008) also found that 59% of patients who had a retained foreign object were readmitted to the hospital or had a prolonged length of stay; 69% required a second surgery to remove the retained object; nearly 50% developed sepsis or infection; and, 15% developed a fistula or had a small bowel obstruction.

In the United States, mortality rates from unintended retention of foreign objects are as high as 11% to 35%, and surgical items are left in approximately 1,500 people per year. About 54% were left in the abdomen or pelvis, 29% in the vagina, 7% in the thorax, and the remainder were found elsewhere. (Joint Commission Perspectives on Patient Safety, March 2006).

An unintended retained foreign object is a preventable error. "The redundancy of surgical counts, combined with the interruptions and distractions occurring in perioperative care settings, places counting practice at risk for error" (AORN, July 2006). The combination of human error and systems issues have been studied for many years; the cause is usually multifaceted.

The risk of foreign body retention during surgery is: increased nine-fold during emergency surgeries; increased four-fold with unplanned changes in surgical procedures; doubled when involving more than one surgical team in a surgical procedure; increased when there is greater blood loss during the procedure (Gawande et al. 2003; Berger and Saunders, 2008).

It is, therefore, important for the surgical team to understand the risk factors that can contribute to increased potential for a retained foreign object. The surgical team members should cross-check and cross-monitor each other to assure that the OR team has not drifted from the established process of instrument and sponge count, both pre-procedure and before wound closure, and especially during high risk situations.

An unintended retained foreign object is a serious patient safety concern. It is also a "*Never Event*" that may negatively impact hospital reimbursement.

**When in a procedure or operating room:**

**How often do you count during a procedure? Do you know your facility's policies and procedures on what to do if the count is not accurate?**

**See page 4 for tips on how to prevent an unintentional retained foreign object during a procedure/surgery and what you should do if the count is not accurate.**

# Case Study #1

A 60 year old male was admitted for chest pain, diagnosed with an acute myocardial infarction and underwent a cardiac catheterization. Following the procedure, he was transferred to another facility, and underwent a coronary artery bypass graft (CABG).

During the course of the procedure a discrepancy was identified with the surgical count. The discrepancy was communicated to the surgeons and a post operative x-ray was obtained but was read as negative. Although the surgeon recalled reviewing the x-ray as being negative, the findings were not documented by him but by the nursing staff.

Although the count was communicated as being incorrect to the surgeons after the x-ray, the patient was closed after a second search of the body cavity, the garbage and the OR floor. A follow up x-ray was obtained in the post anesthesia care unit, but there was no indication regarding the possibility of a retained sponge or foreign object on the request.

The assisting surgeon left before the final count and claimed that he was not notified of the discrepancy and therefore never looked for a foreign object when reviewing post-operative films.

A pre-discharge chest x-ray was completed. The patient appeared to recover well from the surgery and was discharged home.

The x-ray film was read after the patient was discharged. The finding described an opaque object, but the finding was not communicated to the surgeons.

For a period of 10 months after the surgery, the patient was seen at the clinic with complaints of pain. stiffness upon arm movements, and chest pain.

Thereafter, he traveled out of the country and consulted with a physician. An x-ray was obtained which revealed a foreign body in the pleural cavity.

He subsequently underwent a left thoracotomy which led to a surgically induced cracked rib for the removal of the sponge.

At the time of the procedure a chest abscess was noted. He remained hospitalized for 8 days, treated with antibiotics and discharged home.

### *Outcome:*

The patient claimed that as a result of the second surgery, he suffered from constant pain and developed regional pain syndrome.

Plaintiff's attorney alleged that the retained foreign object caused the patient to have continuous pain, develop an infection, and resulted in an avoidable second surgery.

## *A settlement of $500,000 was reached by HHC*

## LESSONS LEARNED

- All team members including the attending surgeon should be present for surgical counts in the operating room.
- The decision by a practitioner to leave the operating room prior to the completion of the surgical count does not relieve the practitioner of his or her accountability to the patient if a foreign object is retained as a result of a surgical procedure.
- Complete information, including the possibility of a surgical count discrepancy, should be included on post operative radiology requests when there is a concern of a discrepancy.
- Results of radiological studies obtained at any point in the patient's care that reveal a potentially retained foreign object should be communicated to the attending physician or surgical team immediately.

## Case Study #2

A 56 year old man was admitted for benign prostatic hypertrophy and an outlet obstruction. He underwent a flexible cystoscopy and an open supra pubic prostatectomy.

Postoperatively, while in the post anesthesia care unit, his abdomen became distended and he complained of back pain with no drainage noted from the supra pubic tube.

A sonogram was performed which noted fluid in the abdomen. He was returned to the Operating Room after the initial surgery to rule out a bladder perforation. A perforation was noted and the bladder was repaired.

During the initial and subsequent surgeries (supra pubic prostatectomy and exploratory surgery) a Masson-Judd retractor was used by the surgical team.

Although the retractor was neither counted nor documented on the count sheets during the surgeries, the instrument and sponge counts were both reported and recorded as being correct.

On postoperative day number 4, the patient developed shortness of breath, fever and tachycardia with a change in his mental status. He was transferred to the ICU. While in the ICU a portable chest and abdominal x-ray was performed, which showed a foreign body in the pelvic region.

An abdominal/pelvic CT scan was performed. It confirmed a foreign body, possibly a thumb screw from a retractor in the hemi pelvis. In addition, free fluid was noted in the pelvic region.

His condition continued to deteriorate and he developed severe septic shock.

He was returned to the operating room for exploration and the extraction of the foreign body. A retractor screw was found to be lodged in the peritoneum during the explorative procedure.

### *Outcome :*

Plaintiff's attorney alleged that a portion of the surgical instrument was left in the patient unintentionally during the flexible cystoscopy and open supra pubic prostatectomy surgery. The unintentional foreign object required the patient to undergo a laparotomy to remove the object.

Postoperatively, the patient developed an infection and his condition deteriorated and he subsequently died.

***A settlement of $750,000 was reached by HHC***

## LESSONS LEARNED

- All equipment used during surgery should be visually inspected before and after removal from the patient for any signs of breakage or fragmentation.
- Surgical instrument counts must be performed (pre, intra, and post procedure) as part of the standard for all operative procedures.

**The Joint Commission Resources suggest the following steps to mitigate the occurrence of retained objects:**

- Auditing of operative/procedural records to ensure required counts are completed and documented
- Reviewing policies and procedures to ensure they are consistent with current practice and ensuring current practice is consistent with policies and procedures
- Conducting random "real time" observations of staff to monitor compliance with safe practice
- Ensuring that initial and ongoing competencies are assessed regularly
- Using "near miss" incidents as learning experiences for staff

# Tips in the Prevention of Unintentional Retained Foreign Objects in Surgery

## Setting the Standard

Each facility should have a standardized counting policy and procedure for sponges, sharps, and instruments that are in compliance with national standards.

## Steps in Preventing Retained Foreign Objects in Surgery

***(The American College of Surgeons 2005; Berger and Saunders; AORN 2007; U.S. Food and Drug Administration 2008)***

- Audible counting by two healthcare workers, including at least one RN. Specify responsible team members.
- Inspect devices prior to use and immediately upon removal from the patient for any signs of breakage or fragmentation.
- Timing of counts:
  - At baseline

    Count prepackaged sponges and instrument sets:

    a. Verify counts printed on outside of package before use

    b. Match preprinted count sheets to standardized instrument sets
  - After any updates, such as when instruments are added
  - At change of staff (during handover)
  - Prior to start of wound closure

    If there are any discrepancies with the count:

    a. Notify the surgeon immediately, so that a methodical wound exploration can be done before closure

    b. Thoroughly search OR area (floor, garbage, etc.)

    c. Consider a portable x-ray scanner (reading of x-ray should be done by a radiologist)
  - At end of procedure (skin closure)
- Use radiopaque (x-ray detectable) sponges and towels within the surgical wound

  Radiopaque sponges should not be cut because of embedded indicators
- Assure effective communication and teamwork among perioperative team members

  Assess staff fatigue, especially lengthy and emergent cases (Campione 2009)
- Thoroughly document surgical counts, including:
  - Timing and number of counts, results obtained, and surgeon notification
  - Personnel involved in count
  - Instruments or sponges (wound packing) intentionally remaining within the patient
  - All actions taken and efforts made when discrepancies occur
  - Rationale if count is skipped, e.g., emergency case

**In conclusion, unintentional retained foreign objects are preventable. Effective teamwork and communication, as well as adherence to facility policies and procedures are key to preventing unintentional retained foreign objects in surgery.**

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