Patient Safety Tip of the Week

August 19, 2014

Some More Lessons Learned on Retained Surgical Items

Just when you think you've learned everything about retained surgical items/retained foreign objects you get surprised by some new lessons learned.

Among the most recent CDPH (California Department of Public Health) release of RCA's and plans of correction were another 4 cases of retained foreign objects. Three were in ob/gyn procedures. That should not be surprising since a substantial proportion of retained surgical items have been reported in Ob/Gyn procedures and vaginal deliveries (Stiller 2010). The Minnesota Hospital Association and ICSI also have focused on Ob/Gyn procedures in their efforts to prevent retained foreign objects. The fourth retained foreign object case was related to a pacemaker insertion.

The cases (CDPH CA00268068), (CDPH CA0029845B), (CDPH CA00309249), (CDPH CA00180867, CA00180956) had many of the factors previously identified as contributing to retained surgical items (eg. conversion to open procedure, transitioning of OR staff during the procedure, etc.) and reinforced many of the important recommendations we've discussed in our prior columns. The latter include fundamentals of the "count", use of white boards and "count bags", ensuring attention of all and avoiding distractions during the count, good communication between staff, the methodical wound exam, and the importance of auditing to ensure all components of your policies are carried out.

Three of the cases involved surgical sponges or lap packs, which are the most commonly retained foreign objects. But what caught our eye was a case with another unusual retained surgical item and the system implications it had in its lessons learned. You'll recall in our Patient Safety Tips of the Week for June 12, 2012 "Lessons Learned from the CDPH: Retained Foreign Bodies" and November 5, 2013 "Joint Commission Sentinel Event Alert: Unintended Retained Foreign Objects" we noted several **unusual items found as retained foreign bodies** (a blue towel, a cautery tip, a Kerlix bandage, a piece of labeling tape from a surgical instrument, and a fish-shaped soft flexible viscera retainer).

The case with the unusual retained surgical item (CDPH CA00268068) began as a laparoscopic supracervical hysterectomy. The surgical counts for sponges, instruments, sharps and needles were "correct" as done by the scrub person and RN circulator. The patient was discharged. Approximately a year and a half later examination because of post-intercourse bleeding and pain revealed a circular piece of metal attached to the patient's cervix. This was removed by the physician and confirmed to be a KOH Cup™. The KOH Cup™ is a device intended to improve safety during certain procedures. Used in combination with a uterine manipulator, the KOH Cup™ enhances traction capabilities, enabling greater access and visualization of critical anatomic structures and helps prevent damage to such adjacent structures.

Though the hospital at the time of the original surgery did have a policy regarding what to do if an instrument was discovered to be missing, apparently neither the surgical team nor sterile processing department noted that the KOH Cup™ was missing and did not initiate attempts to find it. At the time the KOH Cup™ was apparently not considered separately from the uterine manipulator.

The hospital subsequently began attaching the KOH Cup™ to the uterine manipulator with a suture. It also added the KOH Cup™ to its list of surgical instruments separate from the uterine manipulator. The hospital also added a "red rule" to ensure that all foreign objects placed into the vaginal cavity have a "tail" that is visible from the outside and that all items placed into the vaginal cavity are announced by the surgeon and entered onto the instrument count white board. It also included discussion and documentation during the post-case debriefing that the surgeon has examined the patient for all items and removed them (see also our July 22, 2014 Patient Safety Tip of the Week "More on Operating Room Briefings and Debriefings").

The hospital also developed a policy and procedure on "Missing Instruments/Parts, Procedure for Locating". They did inservicing of all appropriate staff and initiated an audit program for surgical counts and specifically for KOH cups.

Though the KOH Cup™ was another unusual retained surgical item, we were actually most interested in the role that SPD staff and central supply might play in patient safety initiatives to prevent retained surgical items. In fact, we found one such case where they actually did just that with a missing KOH Cup™ (FDA 2014). That case was begun as a laparoscopic assisted vaginal hysterectomy, using a KOH Cup™ and uterine manipulator. When the case was converted to an open total abdominal hysterectomy the surgeon removed the uterine manipulator and the laparoscopic instruments were passed on by staff and a new instrument tray opened for the TAH. The case was completed without problems. The next day the central supply supervisor called OR staff noting that the KOH Cup™ was missing from the instrument set and another had been ordered. Staff were confident the missing KOH Cup™ had not been discarded and subsequently contacted the surgeon, who examined the patient and found and removed the missing KOH Cup™.

We suspect that many facilities likely simply consider such instances an inventory or logistical problem. We wonder how many would ask the question "Could that missing item still be inside the patient?". It's another great example we can use when we go department to department telling them "patient safety is everyone's job".

What does your facility do when an instrument or other object is missing from a tray or set after a procedure?

We've already done several columns on retained surgical items (listed below). We encourage you to read them because they contain a wealth of information on the topic.

Our prior columns on retained surgical items/retained foreign objects

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- June 12, 2012 "Lessons Learned from the CDPH: Retained Foreign Bodies"
- November 2012 "More on Retained Surgical Items"
- January 8, 2013 "More Lessons Learned on Retained Surgical Items"
- November 5, 2013 "Joint Commission Sentinel Event Alert: Unintended Retained Foreign Objects"

References:

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Minnesota Hospital Association. Eliminating Retained Foreign Objects (Safe Count and Safe Account Programs). http://www.mnhospitals.org/patient-safety/current-safety-quality-initiatives/retained-foreign-objects

ICSI (Institute for Clinical Systems Improvement). Prevention of Unintentionally Retained Foreign Objects During Vaginal Deliveries. Revision date: January 2012 https://www.icsi.org/guidelines__more/catalog_guidelines_and_more/catalog_guidelines/catalog_patient_safetyreliability_guidelines/rfo/

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FDA. MAUDE Adverse Event Report: COOPER SURGICAL KOH CUP VAGINAL FORNICES DELINEATORS UTERINE MANIPULATOR. Page Last Updated: 07/31/2014 http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/Detail.CFM?MDRFOI__ID=1298303