Project Submission:
2009 Delaware Valley Patient Safety Award

THOMAS JEFFERSON UNIVERSITY HOSPITAL

"Using RFID Detection to Prevent Retained Surgical Sponges"

THE HEALTH CARE IMPROVEMENT FOUNDATION

Building Partnerships For Better Health Care

2009 Patient Safety Award Nomination Abstract

TITLE: Using RFID Detection to Prevent Retained Surgical Sponges

ABSTRACT:

Retained surgical sponges remain a serious healthcare risk. Studies suggest a rate of 1 event per 5,000 to 10,000 cases (with the Agency for Healthcare Research and Quality[1] suggesting the higher limit). Despite adopting published guidelines for reduction, our experience was within this range.

Technological alternatives for reducing this error include embedded electronic indicators in each sponge and tools for reducing the error rate of traditional sponge counting. Thorough investigation of available resources revealed that the use of embedded indicators was both more efficient and more likely to eliminate retained sponges, and a pilot program was designed. Surgical sponges containing passive Radio Frequency Identification ("RFID") chips were selected as the methodology of choice after intensive technical and clinical review complicated by their new and untried nature.

The project required both education of all stakeholders and achievement of support for the concept among users initially unconvinced of the need to change practice. Delivery of product for pilot use was achieved after overcoming major production and supply chain problems, and adoption was achieved with a concerted effort by the vendor, Supply Chain Management and Perioperative Nursing. All radioopaque sponges were replaced with identical substitutes containing RFID chips, and use of detection wands implemented for all cases formerly requiring radioopaque sponges.

Since adoption of this system almost 1 year ago, 3 retained sponges have been detected prior to wound closure and none has been closed in a wound.

GOAL

- No unintentionally retained surgical sponges

BASELINE DATA

Our hospital has experienced at least one retained surgical sponge per year from 2003 to 2008.

---

[1] http://www.ahrq.gov/clinic/ptsafety/chap22.htm (accessed July 20, 2009)

INTERVENTION

After evaluation of available systems for improving accuracy of surgical sponge counts, radiofrequency identification ("RFID") of sponges was selected as the methodology of choice and RF Surgical Systems of Bellevue, Washington was selected as the vendor. Surgical sponges with embedded passive RFID chips in addition to radio-opaque markers were adopted for all cases in which radio-opaque sponges were previously used. RFID-tagged sponges are detectable by passing an antenna ("wand") that emits a low-power, low frequency signal over each patient at the completion of the procedure. Retained sponges are identified by audible and visible alerts triggered in the control console by reflected signal from the RFID chip.

The manufacturer's recommended process for detection was added to current sponge count methodology, and comprehensive education including hands-on use of the devices was provided to the medical and nursing staffs by the vendor.

Conversion of sponges was completed in early October 2008 and the use of RFID detection was then instituted.

RESULTS

No surgical sponges were retained in any patient having a surgical procedure at our hospital since implementation of RFID detection in October 2008. Three potentially retained sponges were detected prior to wound closure despite reportedly normal manual sponge counts. All were retrieved with neither harm nor potential harm to the patients. Acceptance of the process by surgeons and hospital staff has been easy to achieve, and no resistance has been encountered.

POTENTIAL FOR ADOPTION BY OTHER PENNSYLVANIA HOSPITALS

The RF Surgical Systems devices and associated surgical sponges with embedded RFID chips are now distributed by Cardinal Health and are readily available for purchase and adoption by Pennsylvania hospitals. Our policy and procedure document for counting of surgical sponges (appendix 1) may be emulated for rapid implementation.

APPENDIX

- Policy and procedure document for counting and RFID detection of surgical sponges

- RFID detection system usage detail

POLICY & PROCEDURES FOR SPONGE COUNTING AND RFID DETECTION

Purposes: To protect patients from unintentional retention of foreign objects used during surgery, including all objects placed entirely within the confines of a natural or surgically created cavity whether or not they are visible to the surgeon after placement. To assure inventory control of all instrumentation utilized during surgery. To define the indications for use of externally detectable sponges containing radio-opaque markers and radio frequency identification ("RFID") chips. To prevent nonproductive use of RFID wands.

1. Only items that are radiographically detectable may be used on a surgical field containing an open incision. Sponges containing radio-opaque markers will be used exclusively whenever an incision or other route of surgical access into which a surgical sponge might reasonably be placed during the course of the procedure is created, whether or not such placement is planned. All sponges containing radio-opaque markers will also contain RFID chips unless the sponge size and style in question is not available with an embedded chip.

2. When procedures in which only a joint space, the paranasal sinuses, digestive tract, respiratory tract, or peritoneal, retroperitoneal, thoracic, or pelvic cavities have been entered are completed endoscopically, and/or no incision is made for other than passage of an endoscope and associated instrumentation, sponge and instrument counts do not need to be performed. This also applies to procedures in which a cutaneous or mucosal incision in made but no subcutaneous or submucosal cavity is created or entered, e.g. circumcision, dental extraction.

3. Sponges containing radio-opaque markers and RFID chips will be immediately available in all operating rooms and will be used should an urgent event (e.g. bleeding) necessitate creation or enlargement of an incision for manual access.

4. All counts are done aloud by both the scrub and circulating nurse participating and with eye contact and the name of the item being counted. All items are separated during the count so that each participant can see the individual item as well as each x-ray detectable strip. The names of the persons performing the count must be documented on the operative record.

5. All items should be counted:
    - Prior to the incision to determine a baseline
    - Any time the scrub or circulating nurse is relieved
    - At the closure of a cavity
    - At the beginning of closure
    - At skin closure or the end of the procedure

6. Any items that are added to the sterile field are to be counted and documented. No item can be exchanged for another once the case has begun.

7. Only sponges that contain the standard multiple identified on the package are to be used. Any deviations should be removed from the sterile field, secured in a bag, labeled "not

counted" and initialed. The bag is retained in the room isolated from the field and treated as uncounted.

8. Suture needles should be initially counted according to the number listed on the package and verified by the scrub and circulating nurse when the package is opened.

9. Any sharps broken during the procedure must be accounted for in its entirety.

10. Once the procedure is started no trash or linen should be removed from the room until the final count has been performed.

11. If a surgical wound is to be packed using x-ray detectable sponges with a notation on the operative record of the number of the items. No x-ray detectable sponges should be used as dressings. When the sponges are removed and the incision closed, they should be isolated from the other counted sponges and the number verified with the other operative record.

12. It is the expectation that every effort will be made to complete counts prior to the incision, even in the event of an emergency.

13. A final count is to be done even if the count could not be performed at the beginning of the procedure. This should be documented on the event report.

14. X-rays are to be done for the following:
    - To verify that packed sponges have been removed.
    - To verify that all items have been removed during an emergency and unable to count
    - To verify when a patient is transferred from another facility with counted items in place.
    - To verify an incorrect count.

    Note: If the item is found and removed a second x-ray is to be performed to verify the item was removed.

    Note: At no time can the surgeon refuse to do an x-ray, although if the patient is unstable the x-ray can be performed at the next level of care and the results called to the charge nurse.

15. To verify a correct count the RF surgical detecting system will be used on all cases in which RF tracking sponges are utilized. *
16. The RF tracking system is to be used at the time of an incorrect count and/or at the end of the procedure.
17. The RF tracking system DOES NOT replace the verbal/ visual sponge count.
18. The use of the RF surgical detecting system will be documented on the operative record.
19. A routine x-ray will be done, at the discretion of the surgeon, at the end of the procedure, on all patients that are considered to be in the following high risk categories:
    - Cases with more than 50 lap sponges opened.
    - Patients with a high BMI (>60 BMI or >400 pounds).
    - Any unexpected change in the operation.
    - Any emergency procedure.

*See RF Surgical Tracking System Procedure

RFID SURGICAL SPONGE DETECTION SYSTEM USE

Purpose: To assure the accurate accountability of all sponges within the surgical area during surgery. To protect the patient from unintentional retention of a foreign object during surgery.

Steps in Procedure

1. To verify a correct count the RF surgical detecting system will be used on **all cases that the RF tracking sponges are utilized.**

The circulating nurse will:

- open the sterile package containing the wand.
- turn the RF console "on" until the patient leaves the room. If the console is turned "off" this will disable the wand and require that it be replaced. Keep other RF devices and keys away from the scan area.
- plug the RF wand into the front of the console.
  a) green light on the front of the console indicates that the wand is ready for use.
  b) make appropriate modifications to temporary pacemaker setting. Scan only when pacemaker is in non demand mode.
  c) calibrate the wand when it is held above the patient.
  d) verify that the system is operational by having the scrub person scan a tagged sponge before placing the wand over the patient.

2. Each scanning procedure includes a vertical and horizontal scan. (see appendix 1).

A)Vertical Scan

i) the surgeon or designee is responsible for positioning the wand as close as possible to the incision and parallel to patient's body. Move wand distally from position 1 to position 2.

ii)Continue scanning through numeric sequence, at a rate of 3 seconds per pass. Passes 3-4-5-6 are performed with wand positioned on lateral sides of torso, parallel to

Points to be Emphasized

The RF surgical detecting system DOES NOT replace the verbal/ visual sponge count.

NOTE: the time the RF wand is plugged into the console. There is a 24 hour time limit from when the wand is first plugged in until the wand must be replaced. The RF wand can be unplugged at any time within the 24 hour time limit.

If the presence of an item is identified by the RF wand, explore the cavity or incision and then repeat the scanning procedure until no item is detected.

The patient and all linen and waste containers will be scanned according to the RF detect scanning procedure to locate the missing items to resolve an incorrect count and if the device did not detect the item in the cavity or incision.

the body.

iii) Final pass will return wand from position 6 back to starting position 1.

B) Horizontal Scan

i) The surgeon or designee places the wand on lateral side of torso, parallel to body at position 1. Move wand in arc to opposite lateral torso from position 1 to position 2.

ii) continue scanning through numeric sequence, at a rate of 3 seconds per pass.

iii) final pass will from position 6 back to starting position 1.

The circulating nurse will document in the Perioperative record the results of the RF detection system.