Prevention of Retained Foreign Objects

Jane Kennedy RN, BSN, MBA, CNOR
Senior Consultant
Cardinal Health
Objectives

• Discuss the impact, consequences, and contributing factors of retained foreign objects (RFO)

• Identify new technologies available to support clinical practice related to count procedures

• Discuss RFO technology selection process considerations
What is the strangest thing you have seen left in a patient?
Where have RFO’s been found???

Most common body cavity:
- Abdomen
- Pelvis

Reported cases:
- Vagina
- Thorax
- Spinal Canal
- Face
- Brain
- Extremities
Common Retained Objects

- Sponges, laps, towels (most common - 70%)
- Cottonoids, peanut sponges, dissectors
- Needles
- Instruments
- Cautery scratch pads
- Guidewires
- Device tips
- Vessel loops
- Suture Boots
- Packaging components – activation prevention parts
- Potentially anything on the sterile field can be left behind
Makin it Real

• 88% of cases that had an RFO had a documented correct surgical counts
  - 70% of RFOs are sponges.
• Legal settlements - $250,000 average, up to $10,000,000 (January 2008 – Macon, GA)
• 1 in 5,500 procedures – some sources document as high as 1 in 1,500 procedures
• RFO is the most common adverse surgical event reported
• Evolving public reporting (access to) of these events
Impact of RFO on Patient Outcomes

- Repeat Surgeries
- Prolonged Hospitalization
- Hospital Readmission
- Sepsis/Bowel Perforations/Organ Damage/Infection/Acute Pain
- Potential Disability
- Unnecessary pain and Suffering
- Death

**Mortality rates – reported from 11 to 35%**
Impact of RFO on Institutions

- Public Relations and Reputation – Institution, Surgeon, Nursing Staff
- Loss of credibility as an institution
- Recent Reimbursement Rulings
- Insurance Implications to Institution/Surgeon/Nursing Staff
- State Licensing – Reporting Obligations
- Lawsuits - $750 Million to $1.4 Billion Annually
Why is This an Issue?

Medicare Says It Won’t Cover Hospital Errors

By ROBERT PEAR
Published: August 19, 2007

- WASHINGTON, Aug. 18 — In a significant policy change, Bush administration officials say that Medicare will no longer pay the extra costs of treating preventable errors, injuries and infections that occur in hospitals, a move they say could save lives and millions of dollars… Medicare says it will not pay for the treatment of “serious preventable events” like leaving a sponge or other object in a patient during surgery and providing a patient with incompatible blood or blood products.
Contributing Factors of a Retained Object

- **Procedural**
  - Unexpected change in procedures
  - Emergency/Trauma cases
  - Patients with high BMI

- **Operational / Process**
  - Standardized procedures are not followed
  - Staff experiences distractions
    - Interruptions by Anesthesiologist / Surgeons requests
    - Interruptions by phone calls, alarms, etc
  - Staff is “rushed” to reconcile at the end of surgery
  - Shift transitions: 8-9 hours for 1 surgery – 2 mandatory 15 minute breaks and lunch break for scrub / circulating nurse
    - The more often a count is performed, the greater the chance for error!
Counting Protocols

• Sponge counting protocols:
  – Date to the 1940’s
  – Have utilized racks, carousels, mats and plastic bags

• AORN protocols:
  – Were established in 1976 – Recommended guidelines
  – Policies and procedures are developed by hospitals based on their interpretation of the recommendations
  – Policies vary from facility to facility
  – Not everyone requires counts on ALL items for ALL procedures

• More & more items are being added to count protocols but sponges still remain the #1 item left behind – 70%
Professional Organizations Guidelines

- Association of Operating Room Nurses (AORN)
- The Joint Commission (JCAHO)
- American College of Surgeons (ACS)
- Institute for Clinical Systems Improvement (ICSI)
- Veterans Health Administration (VHA)
Typical Count Technology Used Today

- Supplies are managed by Materials Management with bar code technology but Nursing has different technology available…

Whiteboards

Handwritten Notes
Whiteboarding

All currently available new technology is intended to supplement manual counts, not replace them.
New Technology

Current Solutions

- Bar Coding Technology- Computer assisted counting using serialized data matrix bar-coded product
  - SurgiCount Medical
- RF (Radio Frequency) Technology- Non-serialized RF detection
  - RF Surgical
- RFID (Radio Frequency Identification) Technology- Computer assisted counting and detection using serialized RFID product
  - ClearCount Medical
SurgiCount Medical Safety-Sponge™ System

- The Safety Sponge System™ consists of
  - Individually and uniquely bar-coded (data matrix) surgical sponges.
  - Hand held line of sight scanners.
  - Printing and documentation through SurgiCount printers or interface capabilities with your ORIS
  - Desktop Database

- Scan and count sponges **in** at the beginning and **out** at the end of surgery
  - Unique identification code for each tag
  - Doesn’t allow double counting of the same sponge
Using the SurgiCount System

- During the sponge “count in” process, simply scan IN the sponges.
- Each product has a unique identification code, so every product is identified, counted and documented in the system at the start of the procedure.
  - Due to the unique id code, no sponge can be “double counted.”
  - The unique id code allows each product to be categorized as a gauze sponge, lap sponge or towel.
- During the sponge “count out” process, simply scan OUT the sponges.
  - If a sponge hasn’t been counted “in”, the system won’t let you count it “out”.
  - If a sponge has already been counted out, the system won’t let you accidentally count it out twice.
  - You can manually override the system, however, it is indicated in the record that a manual override was performed.
- At the end of the procedure simply print out the count report or upload to your ORIS system and documentation can be permanently added to the patient chart / surgical record.
RF Surgical™ RF Detection System

• The RF Surgical™ RF Detection System consists of:
  – A handheld scanning wand connected to a compact, self-calibrating console
  – Micro passive RF tags which are embedded in a variety of surgical gauze, sponges and towels.

• Using the system
  – Used in conjunction with manual counting procedures
  – When the system is activated and the wand is passed over a patient, an audible and visual alert would signal the presence of any retained object fitted with a tag.
ClearCount Medical SmartSponge® System

- The SmartSponge® System consists of:
  - SmartBucket™ with SmartWand™
    - The SmartBucket™ records and stores your counts with computer assistance to establish your initial baseline and final counts
    - The SmartWand™ can be used to perform a patient scan. Convenient LEDs on the handle, as well as audible and visual indicators on the SmartBucket, will alert the user if any sponges are detected during the scan.
  - SmartSponges™
    - Small, passive Radiofrequency Identification (RFID) tag securely embedded in each sponge and towel.
  - SmartTag™
    - The SmartTag™ is used to provide the user with notification that the scan is proceeding properly, eliminating the possibility of user error.
- The only FDA cleared RFID system to integrate both counting and detection
SmartSponge® System - SmartBucket™

This product, its design and use are protected by several U.S. Patents.
Selection Considerations

- Ease of use and integration into the operation room environment
- RFO incidence avoidance
- Cost effectiveness
Ease of Use and Integration into the OR

• **Is the practice safe?**
  - Computer assisted counting (SurgiCount and ClearCount)
    - Proven safe in Harvard and Mayo Clinic studies
  - RF Surgical
    - Adverse event report: Chips falling off product (2008)

• **Is the practice simple?**
  - Computer assisted counting (SurgiCount and ClearCount)
    - Utilizes widely used technology
    - Well tolerated by staff
    - Used in more procedures than all other sponge technologies
  - RF Surgical
    - Inconsistent results with wand articulation directions

• **Is there support and education provided to OR staff?**
  - Education for staff including CEU program for SurgiCount
  - RF Surgical and ClearCount
RFO Incidence Avoidance

• Does the solution provide documentation?
  Computer assisted counting (SurgiCount and ClearCount)
  – SurgiCount has Citadel™ file manager
  RF Surgical
  – No documentation, just a “beep”

• Does the practice comply with AORN recommended practices?
  Computer assisted counting (SurgiCount and ClearCount)
  – Validates AORN Recommended Practices
  – Repeatable practice
  RF Surgical
  – Reduced incentive to count accurately

• Is the solution supported by Evidence-based Outcomes?
  SurgiCount
  – SurgiCount software tracks sponges, patients, personnel, etc.
  – Numerous studies on effectiveness including Harvard Brigham and Women’s Hospital and Mayo
  RF Surgical
  – False positives from badges, keys, etc
  – No unique ID
  – No aggregate information
Cost Effectiveness

- **SurgiCount**
  $12-15 per procedure
- **ClearCount**
  $25-30 per procedure
- **RF Surgical**
  $20-25 per procedure
  *(approx. $15-20 per procedure if reusable wand is utilized)*

*incremental supply costs*
Recap

What we have learned:
- Incidence and impact of RFO on patient outcomes
- Impact and consequences of RFO on hospitals
- Contributing factors of RFO
- Sources of RFO
- New technology to aid in the prevention of RFO
- Important considerations when selecting a RFO prevention solution
The solution a hospital chooses for prevention of retained foreign objects should support the current AORN recommended practices and also be adopted across all surgical procedures in order to create a universal standard of enhanced care.
A Bit of Humor to Close