What Have We Learned On The Way To ZERO?

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Time to Coordinate Efforts in Surgical Patient Safety

1. The Wrongs
2. Surgical Fires
3. Retained Surgical Items

Retained Surgical Items

- New preferred term rather than RFO
- Foreign Objects include swallowed pennies, pins, shrapnel, bullets
- Surgical Items are the tools and materiel that we use in procedures to heal not to harm
- It’s a surgical patient safety problem
Four Classes of Items

1. Soft Goods
   a) Sponges
   b) Towels
2. Miscellaneous Small Items and Unretrieved Device Fragments
3. Sharps/Needles
4. Instruments

NQF Required Reporting

Serious Reportable Events (SRE) 2011 Update

<table>
<thead>
<tr>
<th>Event</th>
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<tbody>
<tr>
<td>Unintended retention of a foreign object in a patient after surgery or other invasive procedure</td>
</tr>
<tr>
<td>Applicable Settings:</td>
</tr>
<tr>
<td>- Hospitals</td>
</tr>
<tr>
<td>- Outpatient/Office-based Surgery</td>
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<tr>
<td>- Ambulatory Practice Settings/Office-based Practices</td>
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<tr>
<td>- Long-term Care/Skilled Nursing Facilities</td>
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<tr>
<th>Additional Specifications</th>
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<tr>
<td>Includes medical or surgical items intentionally placed by provider(s) that are unintentionally left in place</td>
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<tr>
<td>Retains:</td>
</tr>
<tr>
<td>a) objects present prior to surgery or other invasive procedure that are intentionally left in place;</td>
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<tr>
<td>b) objects intentionally implanted as part of a planned intervention;</td>
</tr>
<tr>
<td>c) objects not present prior to surgery/procedure that are unintentionally left in place</td>
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<td>c) objects not present prior to surgery/procedure that are intentionally left in when the risk of removal exceeds the risk of retention (such as microneedles, broken screws)</td>
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<table>
<thead>
<tr>
<th>Implementation Guidance</th>
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<tbody>
<tr>
<td>This event is intended to capture:</td>
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<tr>
<td>- Occurrences of unintended retention of objects at any point after the surgery/procedure.</td>
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<tr>
<td>- Includes:</td>
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<tr>
<td>- Objects that are left behind in the healthcare setting (post-anesthesia recovery unit, surgical suite, emergency department, patient bedside) and regardless of whether the object is to be removed.</td>
</tr>
<tr>
<td>- Unintentionally retained objects (including such things as wound packing material, sponges, catheter tips, trocars, guide wires) in all applicable settings</td>
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</table>

When is it Retained?

- After all incisions have been closed in their entirety
- Devices have been removed
- Final surgical counts have concluded
- Patient has been taken from the operating/procedure room

http://www.qualityforum.org/projects/hacs_and_sres.aspx
**Incidence 2012**

STILL > ZERO

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**Recently in California**

- Fresno Surgical Hospital
- LAC+USC
- Mission Hospital Regional Med Ctr
- Scripps Memorial
- Sutter Solano
- Torrance Memorial
- Ventura County Med Ctr

December 2011

14 Hospitals cited with Administrative Penalties. Vary from $25,000 to $100,000.

7 of the 14 related to retained surgical items

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**Recently in California**

- Kaiser San Diego
- Kaiser SF
- Keck Hosp of USC
- Mad River Community
- Motion Picture and TV Hospital

June 2012

13 Hospitals cited with Administrative Penalties. Totaling $825,000

5 of the 13 related to retained surgical items

4 soft goods, 1 SMI

$300,000 fines
Why do they occur?

• Focus has been on “risk assessment”, attempts to identify case or patient characteristics that will predict retention
• More insightful to look at personnel and environmental characteristics
• It’s us not the patient!
• It’s a system problem

Miscellaneous Small Items

• Small Miscellaneous Items and Unretrieved Device Fragments (UDFs)
• Increasingly reported
  + 70% of retained items in the Minnesota Hospital Association reports
  + 50% of items from the California Dept of Public Health
  + Majority of items from California Hospital Patient Safety Organization voluntary reporting system
  + Probably the second most common item other places (e.g. Pennsylvania, VA reports)
    • have been “bundled” in the instrument category

Device Fragments

• Unretrieved Device Fragments (UDF) can lead to serious adverse events
• US FDA notification Jan 2008
• Local tissue reaction, infection, perforation, obstruction, emboli
• CDRH receives ~1000 adverse event reports a year related to UDFs

http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices
Small Items/Fragments

- Two Types of Case based on LOCATION of event
  
  I. OR CASES
    - radiopaque items
    - non-radiopaque items
  
  II. Non-OR CASES

Essential causes

OR CASES
Assuming Surgeon USES the device correctly
  1) Manufacturer defects
  2) Worn and Used equipment
    - Drill bits imbedded in bone
  3) New Unfamiliar Devices
    - Multiple separable parts
    - Non-radiopaque pieces
  - Surgical Technologist is Content Expert

Surgical Technologists

- Content experts on materiel
  - Check condition of all items passed and returned on the field
  - Requires knowledge about instruments, tools, surgical items
  - Standardized back table
  - Must speak up and question if something is amiss
Surgical Technologists

- Consider
  - Certification of Technologists, education and curriculum development
  - Separate inservices where ST review all equipment, devices
  - Instrument tray/specialty materiel review with SPD
  - “See something, say something”

Retained Device Fragments

II. NON-OR CASES
1) Intravascular
   - Everywhere: cardiology, radiology, anesthesiology, ICU
   - Guidewires, catheters, sheaths, introducers
2) Interstitial
   - Subcutaneous space, breast tissue
   - Insertion Technique

Removal is desired

- MRI procedures problematic
- Magnetic fields can cause movement, migration
- Radiofrequency fields cause heating
Disclosure vs. reporting

- Retained small item but clinical decision NOT to remove.
- Impossible to retrieve
- ?? can cause harm
- DISCLOSE TO THE PATIENT
- Discuss about reporting

Engage with OR leadership to hone multistakeholder prevention strategies

OR Engagement

- Communication and Practice problems with the THREE major stakeholders
  1. Surgeons
  2. Nurses
  3. Radiologists

Elements of Causation

Applying Swiss Cheese Model of Sir James Reason BMJ 2000;320:768

LATENT FACTOR

DEFENSES

Hazard:

COMMUNICATION

Counts: NURSES

X-ray: RADIOLOGISTS

OR PRACTICES

Leakage:
Communication

• It’s what is right not who is right
  - Between nurses and surgeons
    • “We’re missing a sponge” “OK, let’s re-explore the wound!”
    • “Dr. Is this a good time for lunch relief?”
  - Between nurses and scrub techs
    • “Separate each raytex so we can make sure we have 10”
    • “Let’s verify the sponge holders before you take permanent relief”
  - Between surgeons
    • “Make sure you check behind the heart for any raytex before you close”
    • “Let’s do our wound exam and look for sponges”

OR Practices

• What we do and how we manage our work
  We = Multiple Stakeholders
  - Anesthesiologists: 4X4 management, coordinated reversal from anesthesia
  - Surgeons: use only radiopaque items, perform a wound exploration
  - Nurses: surgical item accounting process
  - Scrub Techs: organize field, know equipment
  - Radiologists/Technologists: film quality, review
  - Risk Managers/Administrators: resources

Practice Issues

• Variable counting processes exist throughout an OR - no standardization, little transparency, counting in unit of issue
• Frequent confirmation bias between scrub and circulator
• Loss of situational awareness and missing events that occur outside the scrub or circulator’s locus of control
• Normalization of deviance
• Retained sponge cases have occurred when low numbers of sponges (<20 sponges) have been used or in any size wound - it’s not about counting!
NoThing Left Behind

- Multistakeholder project
- Work with any hospital
- Adoption of simple principles and if needed, technological adjuncts
- Engage in research studies to define best practices
- Develop an evidence base to inform policies and procedures that can be systematically applied

What I see is …..

- Lots of practice variation within OR
- Focus on “counting”
- Massaging the policy
- Adding steps that aren’t part of natural work flow
- Reliance on Memory - “don’t forget to….”
- Not seeing how people have set themselves up for failure
- Risk management trumps patient safety

Findings

- 80% of retained sponge cases occur in the setting of a CORRECT COUNT
  - Problems with OR practices
- If noise, distractions etc. disrupt the practice of counting it’s not a very reliable practice
- Very few reports specifically discuss THE PRACTICE but rather external factors around the practice
Findings

• 20% occur in the setting of an INCORRECT COUNT
  ➢ Problems with knowledge and communication
• X-rays not called for, misread, wrong views, “negative”
• Incorrect count not reported, nurse manager never informed, no process for finding items or going to next step

SPONGE ACCOUNTING SYSTEM

Monitoring “Sponge Traffic”

• Nurses use a standardized process to put sponges in hanging plastic holders and document the counts on a wall-mounted dry erase board in every OR
• Surgeons perform a methodical wound exam in every case and before leaving the OR - verify with the nurses that all the sponges (used and unused) are in the holders.

NLB Policy & Practice

http://www.nothingleftbehind.org
**Zero for at Least a Year**

- **2005**: 5
- **2006**: 2
- **2007**: 3
- **2008**: 3
- **2009**: 2
- **2010**: 1
- **2011**: 0

Policy review, revisions, reinforcement

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**NoThing Left Behind: Retained Sponges in Participating Hospitals**

<table>
<thead>
<tr>
<th>Year</th>
<th>Pre-Implementation</th>
<th>Post-Implementation</th>
</tr>
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<tbody>
<tr>
<td>2008</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>2009</td>
<td>12</td>
<td>4</td>
</tr>
<tr>
<td>2010</td>
<td>24</td>
<td>7</td>
</tr>
<tr>
<td>2011</td>
<td>36</td>
<td>10</td>
</tr>
</tbody>
</table>

Collective Experience Pre: 70 Retained Sponges --> 18 Post

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**Sponge Management**

- **Policy**
- **Process**
- **Practice**

- Safe Care
- Standardized Care
- Customized Care

- Computer Assisted Sponge Counting
- Sponge Tagging System
- Smart Sponge System
- FFC/Infection Control

- SCRUB
- PDA
- Trolley

- Pre-Op: Tag sponge
- Intra-Op: Track sponge
- Post-Op: Return sponge

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Nurses use a standardized process to put sponges in hanging plastic holders and document the counts on a wall-mounted dry erase board in every OR.

Surgeons perform a methodical wound exam in every case and before leaving the OR - verify with the nurses that **all** the sponges (used and unused) are in the holders.

**Trust but Verify**

**EASY AS 1-2-3**

1. **WHERE ARE THE SPOONGES?**
2. **WHERE ARE THE SPOONGES?**
3. **WHERE ARE THE SPOONGES?**
**NOT business as usual**

- Practice change for nurses and surgeons, accounts for sponges
- Visible, transparent system
- Different process for use of sponge holders (not counters), dry erase board data for all to see
- “Show me” step proves that “the count is correct”

**Surgeon Essence**

- Perform a methodical wound exam in every case
- If you’re told of a missing sponge, stop closing the wound and look again
- At the end of every case say “show me” and look at the sponge holders and see that there are no empty pockets
Nursing Essence

• In every case where an incision is made and surgical sponges are used, the sponges MUST be accounted for
• Work with free sponges ONLY in multiples of TEN
• At the IN count the most important element is to SEPARATE the sponges
• At the FINAL count all the sponges (used and unused) must be in the sponge holders

NURSES EASY AS 1,2,3

Always Multiples of 10

• Only one system for staff to manage
• Ten sponges no matter if laps or raytex
• Running total count on board; easy math; easily see how many are out
• Ten pockets in holder means only one sponge per pocket
• Final count has no empty pockets, easy visual
• Show me step proves no sponges are in the patient!
No Empty Pockets!

Biohazard Waste Disposal

- Hanging sponge holder full of bloody sponges can be disposed of in RED biohazard bags
- This removes sponges from the room so they can't confound subsequent cases

Case
Radiology Guidelines

- Region of Interest specifics
- Instructions for radiology techs to take correct images
- Information to help get it right

Incorrect Count CheckList

- Visible in every OR
- Levels the playing field
- Knowledge and Communication so all team members can do the right thing
- It’s what is right not who is right… remember?

Use it Anywhere

- Sponge ACCOUNTing should be in place ANYWHERE surgical sponges are used and there is an incision or wound
  - Labor and Delivery Rooms
  - OB Operating Rooms
  - Cardiology procedure rooms
  - Radiology suites where incisions are made
Surgical Safety CheckList

There is NO excuse

Time to Coordinate Efforts to Prevent Retained Surgical Items

There is NO excuse

SAFER SURGERY
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