Points of Confusion with The Players and The Policies

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Professor of Surgery UCSF
Staff Surgeon, SFVAMC

www.nothingleftbehind.org

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Congratulations and thank you to these participating hospitals:

El Centro Regional Medical Center
Kerns Hospital San Diego
Palomar Medical Center
Peninsula Memorial Healthcare District
Peninsula Hospital
Rady Children’s Hospital – San Diego
Scripps Encinitas Hospital
Scripps Memorial Hospital Encinitas
Scripps Memorial Hospital La Jolla
Scripps Mercy Hospital
Scripps Mercy Hospital Chula Vista
Sharp Chula Vista Medical Center
Sharp CommuniCare Hospital and Healthcare Center
Sharp Coronado Hospital
Sharp De Gaspari Hospital
Sharp Mary Birch Hospital for Women & Newborns
Sharp Memorial Hospital
Tri-City Medical Center
Ud Kiry San Diego Healthcare System
WeHa Hospital of Chula Vista

To learn more about Patient Safety First... a California Partnership for Health, visit nhfca.org/psf.

Special Thanks to: Julia Slininger RN, Jenna Fischer, Alicia Munoz, Dominique Diaz
What is an RSI?

• It’s not Rapid Sequence Induction
• It’s Retained Surgical Item as the preferred term (not RFO or RFB or iRFB or uRFO)
• 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
Retained Foreign Body

A 37-YEAR-OLD MAN PRESENTED TO THE EMERGENCY DEPARTMENT WITH PROXIMATE BLEEDING, ABDOMINAL PAIN, AND AN ALTERED MENTAL STATUS. ON PHYSICAL EXAMINATION, HE WAS FOUND TO BE ICteric, with a BP OF 76/80 mm Hg, a pulse of 130 beats per minute, and an oxygen saturation of 98%. Abdominal examination revealed a mass and the presence of peritoneal signs. There was no evidence of trauma. A foreign body was found on rectal examination but was not visible. Once the patient was hemodynamically stable, plain film radiography of the abdomen was performed, and an empty bottle was seen in the rectosigmoid colon. Laparotomy revealed a glass bottle of beer lodged in the sigmoid colon, with multiple associated perforations in the mesosigmoid colon. The bottle was extracted, and Hartmann’s procedure was performed. The patient was treated with broad-spectrum antibiotics and analgesics and underwent colorectal reconstruction, after which the recovery was uneventful.
A 68-year-old woman presented with a 4-year history of vague pelvic and back pain. Her endometrial hysterectomy specimen did not show any evidence of cancer. A CT scan of the abdomen showed an 8-cm pelvic mass. Because of concern about metastatic carcinoma, she underwent exploratory laparoscopy, which revealed extensive adhesions of the lower abdomen and a yellow, dense mass involving the rectovaginal pouch of Douglas (Panel A). Attempts to dissect the mass led to its rupture, revealing necrotic tissue that was suggestive of a dermoid cyst. However, on aspiration of the contents, an old sponge was identified and removed. The term for a left-behind surgical sponge is gossypiboma, derived from the Latin gossypium (cotton) and the Greek ibous (place of contamination). The patient had an uneventful recovery and was discharged 2 days later.
AHRQ PSI #5 and #21

Retained Surgical Item or Unretrieved Device Fragment Count
technical specifications

Patient Safety Indicators #5 (PSI #5)
AHRQ Quality Indicators™, Version 4.5, May 2013
Provider-Level Indicator
Type of Score: Count
Only Secondary diagnosis
Denominator - All medical /surgical discharges

Patient Safety Indicator #21
Area Level Indicator
Principal or secondary diagnosis
Denominator – Population of county of patient or hospital location
Four Classes of Items

1. Soft Goods
   a) Surgical Sponges*
   b) Surgical Towels*
   c) Dressing sponges, Towels, Packs, Prep Swabs, Gauze pledgets

2. Small Miscellaneous Items (SMI)
   includes parts of instruments

3. Sharps/Needles

4. Instruments (the whole instrument)

*cotton soft goods that contain a radiopaque marker for X-ray detection
Retained Surgical Items
# Documentation

<table>
<thead>
<tr>
<th>Final Count</th>
<th>CORRECT</th>
<th>INCORRECT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sponge</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Needle/Sharps</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Instruments</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Small Misc Items</td>
<td>X</td>
<td></td>
</tr>
</tbody>
</table>
Unretrieved Device Fragments

- Unretrieved Device Fragments (UDFs)
- “Official” FDA nomenclature, not “bits and pieces”
- Broken parts or pieces of devices and surgical items
- These are the items where the “risk of retrieval > risk of retention” mantra is frequently invoked
Device Fragments

- can lead to serious adverse events
- US FDA notification Jan 2008
- Local tissue reaction, infection, thrombosis, perforation, obstruction, emboli
- Center for Devices and Radiological Health (CDRH) receives ~1000 adverse event reports a year related to UDFs

http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/TipsandArticlesonDeviceSafety/ucm070187.htm
ECRI’s Top 10

Emergency Care Research Institute

- #7 Retained devices and unretrieved fragments
- Second most common RSI
WHEN IS AN ITEM CONSIDERED “RETAINED”?
National Quality Forum

- Originator of “never event” term
- 2011 Consensus document of all SRE
- NQF guides federal, state, public, AHRQ, American Hospital Association Coding Clinic interpretations

http://www.qualityforum.org/projects/hacs_and_sres.aspx
AHRQ PSI #5 and #21

AHRQ QI™ Version 4.5, Patient Safety Indicators #5, Technical Specifications,
Retained Surgical Item or Unretrieved Device Fragment Count
www.qualityindicators.ahrq.gov

Retained Surgical Item or Unretrieved Device Fragment Count
Technical Specifications

Patient Safety Indicators #5 (PSI #5)
AHRQ Quality Indicators™, Version 4.5, May 2013
Provider-Level Indicator
Type of Score: Count

ICD-9-CM Retained surgical item or unretrieved device fragment diagnosis codes:

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>9984</td>
<td>FB LEFT DURING PROCEDURE</td>
<td>E8714</td>
<td>POSTENDOSCOPY FORGN BODY</td>
</tr>
<tr>
<td>9987</td>
<td>POSTOP FORGN SUBST REACT</td>
<td>E8715</td>
<td>POSTCATHETER FORGN BODY</td>
</tr>
<tr>
<td>E8710</td>
<td>POST-SURGICAL FORGN BODY</td>
<td>E8716</td>
<td>FB POST HEART CATHETER</td>
</tr>
<tr>
<td>E8711</td>
<td>POSTINFUSION FOREIGN BDY</td>
<td>E8717</td>
<td>GB POST-CATHETER REMOVAL</td>
</tr>
<tr>
<td>E8712</td>
<td>POSTPERFUSION FORGN BODY</td>
<td>E8718</td>
<td>POST-OP FOREIGN BODY NEC</td>
</tr>
<tr>
<td>E8713</td>
<td>POSTINJECTION FORGN BODY</td>
<td>E8719</td>
<td>POST-OP FOREIGN BODY NOS</td>
</tr>
</tbody>
</table>
## NQF Required Reporting

### Serious Reportable Events (SRE) 2011 Update

<table>
<thead>
<tr>
<th>Event</th>
<th>Additional Specifications</th>
<th>Implementation Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Unintended retention of a foreign object in a patient after surgery or other invasive procedure</td>
<td>• <strong>Includes</strong> medical or surgical items intentionally placed by provider(s) that are unintentionally left in place</td>
<td><strong>This event is intended to capture:</strong></td>
</tr>
<tr>
<td>• <strong>Applicable Settings:</strong></td>
<td>• <strong>Excludes:</strong></td>
<td>– Occurrences of unintended retention of objects at any point after the surgery/procedure ends regardless of setting (post anesthesia recovery unit, surgical suite, emergency department, patient bedside) and regardless of whether the object is to be removed after discovery</td>
</tr>
<tr>
<td>– Hospitals</td>
<td>a) objects present prior to surgery or other invasive procedure that are intentionally left in place;</td>
<td>– Unintentionally retained objects (including such things as wound packing material, sponges, catheter tips, trocars, guide wires) in all applicable settings</td>
</tr>
<tr>
<td>– Outpatient/Office-based Surgery Centers</td>
<td>b) objects intentionally implanted as part of a planned intervention and;</td>
<td></td>
</tr>
<tr>
<td>– Ambulatory Practice Settings/Office-based Practices</td>
<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>
<td></td>
</tr>
<tr>
<td>– Long-term Care/Skilled Nursing Facilities</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
When is it retained?

- A surgical item is considered to be retained if it is found in the patient:
  - AFTER SURGERY
  - AFTER THE SURGERY/PROCEDURE ENDS

- When is it after surgery?
After surgery is.....

- 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
When is it Retained?

- After surgery
- After surgery is NOT wound closure
- After surgery is “out of OR”
- So everybody has to work together to make sure we get any surgical tools not intended to remain out of the patient before leaving the OR
But…

WHAT ABOUT THE JOINT COMMISSION?
Sentinel Event - Retained foreign object after surgery

Sometimes a needle or screw will break leaving a fragment behind. Is this a reviewable sentinel event?

What about a retained sponge following vaginal delivery?

When, exactly, is “after surgery?”

Why was this particular point in the process selected as the definition of “after surgery?”

Sentinel Event - Retained foreign object after surgery

Q: Sometimes a needle or screw will break leaving a fragment behind. Is this a reviewable sentinel event?

A: In some cases, a broken needle or screw fragment is recognized at the time of surgery and a clinical judgment is made to leave the fragment in the patient. That decision is based on an assessment of the relative risks of leaving it in versus removing it. It would therefore not be considered an unintentionally retained foreign object.

Sentinel Event - Retained foreign object after surgery

Q: What about a retained sponge following vaginal delivery?

A: A retained sponge after a vaginal delivery is a reviewable sentinel event. The new language in the definition of reviewable sentinel events is, “Unintended retention of a foreign object in a patient after surgery or other procedure.” Note that it says “other procedure” not “other invasive procedure.” Vaginal delivery in the hospital is not an “invasive” procedure, but it is a procedure. More to the point, a retained sponge in this circumstance is indicative of the same underlying systemic problems that could cause other “retained foreign body” situations.

Sentinel Event - Retained foreign object after surgery

Q: When, exactly, is “after surgery?”

A: “After surgery” is any time after completion of the skin closure; even if the patient is still in the OR under anesthesia.

Sentinel Event - Retained foreign object after surgery

Q: Why was this particular point in the process selected as the definition of “after surgery?”

A: The decision to define “after surgery” as the completion of skin closure was based on the premise that a failure to identify and correct an unintended retention of a foreign object prior to that point in the procedure represents a significant system failure, which requires analysis and redesign. It also places the patient at additional risk by virtue of extending the surgical procedure and time under anesthesia.

Can’t find what you are looking for?
Ask your own question?

http://www.jointcommission.org/about/JointCommissionFaqs.aspx?CategoryId=11#498
When is it retained?

Preventing unintended retained foreign objects

The unintended retention of foreign objects (URFOs) – also called retained surgical items (RSIs) – after invasive procedures can cause death, and surviving patients may sustain both physical and emotional harm, depending on the type of object retained and the length of time it is retained. There may be an extended timeframe between occurrence and detection of an URFO. Retained foreign objects are most commonly detected immediately post-procedure; by X-ray; during routine follow-up visits; or from the patient’s report of pain or discomfort.

URFOs refer to any item or foreign object related to any operative or invasive procedure that is left inside a patient. Objects most commonly left behind after a procedure are:

http://www.jointcommission.org/sea_issue_51/
TJC Sentinel Events

• Does not speak directly to the issue!
• Voluntary Reporting to TJC
• Consider RSI a reviewable sentinel event
• Organizations are expected to respond to sentinel events as outlined in the standards and elements of performance (EP)
Requirements

• EP 5 Leaders create procedures to respond to system failures
• EP 7 Leaders define sentinel event
• EP 8 Organization conducts RCAs
• EP 9 Leaders have support systems for staff involved in event
• EP 21/22 Patient Disclosure happens
Previously said after surgery was wound closure

http://www.jcrinc.com/foreign-objects-retained-after-surgery
So

• What should we do?
• Is there any work on a consensus definition between the two organizations?

......... Not that I know of
Guidance

• TJC interprets after surgery to be wound closure….. With strange and impractical reasoning I must say because it creates the risk of “premature case closure”

• Joint Commission Resources took down their website on the issue

• What to do? Use the NQF definition

• Define in your hospital policy what you are going to adhere to and then follow it.
Retained Surgical Item

• A surgical tool or material that is found in the patient after the patient is out of the OR or procedure area.

• This means that staff are using best practices to make sure they get the items out of the patient.

• Doing the right thing shouldn’t be thought of as a sentinel event, therefore follow NQF not TJC.
HOW FREQUENTLY DO THESE EVENTS OCCUR?
and what is retained and where?
October 2013

The Joint Commission
Sentinel Event Alert

A complimentary publication of
The Joint Commission
Issue 51, October 17, 2013

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http://www.jointcommission.org/sea_issue_51/
TJC Sentinel Events

Events, risk factors and root causes
From 2005 to 2012, 772 incidents of URFOs were reported to The Joint Commission’s Sentinel Event database.* Sixteen deaths resulted from these incidents. About 95 percent of these incidents resulted in additional care and/or an extended hospital stay. In hospital settings, these incidents occurred in operating rooms, labor and delivery areas, as well as ambulatory surgery centers and other areas where invasive procedures are performed (e.g., cath lab, GI lab, interventional radiology, emergency department).

8 years
= 96.5 events per year ~ 100/year
50 states; 2 RSI events/year/state
CDPH reports from 10/25/2007 – 10/24/2013 (7 years) where hospitals received administrative penalties of $25,000 - $100,000

75 Retained Surgical Item cases

43 cases involving Soft Goods

28 laps; 12 raytex; 3 towels (1 ROT)

23 cases of Small Miscellaneous Items and UDFs

9 cases of a retained Instrument

(56% are visceral retractors)
California AP events

• 7 years of public reporting currently includes cases from only 5 years - 2007 - 2011

• 75 reports = 15 cases/year
  ➤ 43 cases (57%) soft goods
    • 11/43 (26%) Ob 7 > Gyn 4 cases
    • 28 laps; 12 raytex; 3 towels
  ➤ 23 cases (31%) SMI+UDFs
  ➤ 9 cases (12%) instruments
  ➤ 0 cases sharps
CDPH 2011

- FOIA request by CHPSO
- 114 releasable reports
  - 52 (46%) no information
  - 8 not RSI cases + no info = 53%
  - 26 (23%) soft goods
  - 19 (17%) UDFs
  - 7 (6%) SMI + UDFs = 23%
  - 2 retained sharps (1 needle/1 blade)
  - 0 instruments
CDPH 2011- drill down

- 23 cases
  - 8 lap pads, 8 raytex, 1 towel, 2 vag packs, 4 other types of sponges
  - 11 (48%) retained in abdomen/abd wall
  - 9 (39%) retained in the vagina
  - 3 other sites (pacemaker pocket, back)
  - 13 cases (57%) were OB/GYN procedures
  - 2 cases involved Technology Adjuncts
UHC 2011
University Health Consortium
• 100 academic medical centers
• 428 RSI* reports
  ➡ 171 (40%) UDFs
  ➡ 137 (32%) soft goods
  ➡ 77 (18%) Instruments (I doubt this! more likely SMI’s + Instruments) + UDFs = 58%
  ➡ 43 (10%) sharps

*TJC definition

Williams, JACS May (online) 2014
UHC subset 2011

- 824 surgical sponge “events”
  - 13 (1.57%) retained using NQF definition
- 811 (98%) are miscounts!
- 40 hospitals in PSO
  - 1/3 hospitals had issue with retention but every hospital has problems with miscounts
Findings

- Sponges are the most frequently retained items that cause clinical patient harm
  - The most common site is the abdomen then vagina
  - OB/GYN cases especially C-Sxns are important
- SMIs and UDFs are the second most commonly retained items
- Needles are most frequently miscounted item but infrequently retained
- Instruments are very uncommonly retained
  - Most common is a visceral retractor
When Reporting

• State what the problem is
  ➤ Retained Surgical Item (RSI), Unretrieved Device Fragment (UDF)

• Specify the Class of Item
  ➤ Soft Good, Sharp/Needle, Instrument, Misc Item - includes parts of instruments

• Specify WHAT the item is
  ➤ Raytex 4x4 sponge, malleable retractor, 4x4 dressing sponge, 13 mm needle

• Details of the item and retention events
HOW IS MY HOSPITAL DOING IN COMPARISON TO OTHERS?
<table>
<thead>
<tr>
<th>Hospital Name</th>
<th>County</th>
<th>Foreign body left during procedure</th>
</tr>
</thead>
<tbody>
<tr>
<td>National average rate (2009)</td>
<td></td>
<td>155</td>
</tr>
<tr>
<td>Statewide number of adverse events (2011)</td>
<td></td>
<td>38</td>
</tr>
<tr>
<td>Statewide average rate (2011)</td>
<td></td>
<td>NA</td>
</tr>
<tr>
<td>Atlanticare Regional Medical Center - Mainland</td>
<td>Atlantic</td>
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<tr>
<td>Atlanticare Regional Medical Center - City</td>
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<td>0</td>
</tr>
<tr>
<td>Shore Medical Center</td>
<td>Atlantic</td>
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<tr>
<td>Bergen Regional Medical Center</td>
<td>Bergen</td>
<td>0</td>
</tr>
<tr>
<td>Englewood Hospital and Medical Center</td>
<td>Bergen</td>
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</tr>
<tr>
<td>Hackensack University Medical Center</td>
<td>Bergen</td>
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</tr>
<tr>
<td>Holy Name Medical Center</td>
<td>Bergen</td>
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<tr>
<td>Valley Hospital</td>
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<tr>
<td>Virtua-Memorial Hospital Burlington Cty.</td>
<td>Burlington</td>
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</tr>
<tr>
<td>Virtua-West Jersey Hospital Marlton</td>
<td>Burlington</td>
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</tr>
<tr>
<td>Lourdes Medical Center of Burlington Cty.</td>
<td>Burlington</td>
<td>1</td>
</tr>
</tbody>
</table>

Reported by volume

https://web.doh.state.nj.us/apps2/hpr/psi.aspx
Outcomes measures include errors, accidents, and injuries that this hospital has publicly reported.

<table>
<thead>
<tr>
<th>Measure</th>
<th>Hospital’s Score</th>
<th>Worst Performing Hospital</th>
<th>Avg. Performing Hospital</th>
<th>Best Performing Hospital</th>
<th>Data Source</th>
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</thead>
<tbody>
<tr>
<td>Foreign Object Retained After Surgery</td>
<td>0.000</td>
<td>0.358</td>
<td>0.03</td>
<td>0</td>
<td>CMS Hospital Compare</td>
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<tr>
<td>Air Embolism</td>
<td>0.000</td>
<td>0.098</td>
<td>0.00</td>
<td>0</td>
<td>CMS Hospital Compare</td>
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<tr>
<td>Pressure Ulcer - Stages 3 and 4</td>
<td>0.000</td>
<td>0.894</td>
<td>0.10</td>
<td>0</td>
<td>CMS Hospital Compare</td>
</tr>
</tbody>
</table>
AHRQ PSI #5 and #21

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Only Secondary diagnosis
Denominator - All medical /surgical discharges

Patient Safety Indicator #21
Area Level Indicator
Principal or secondary diagnosis)
Denominator – Population of county of patient or hospital location
<table>
<thead>
<tr>
<th>PATIENT SAFETY INDICATORS (PSIs)</th>
<th>INDICATOR COUNTS</th>
<th>OBSERVED RATES*</th>
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<tbody>
<tr>
<td></td>
<td>2007</td>
<td>2011</td>
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<tr>
<td>PSI #21  Foreign Body Left During Procedure</td>
<td>374</td>
<td>346</td>
</tr>
<tr>
<td>PSI #22  Iatrogenic Pneumothorax</td>
<td>1,658</td>
<td>1,464</td>
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<tr>
<td>PSI #23  Central Venous Catheter-Related Blood Stream Infection</td>
<td>5,405</td>
<td>2,480</td>
</tr>
<tr>
<td>PSI #24  Postoperative Wound Dehiscence</td>
<td>451</td>
<td>375</td>
</tr>
<tr>
<td>PSI #25  Accidental Puncture or Laceration</td>
<td>9,423</td>
<td>8,212</td>
</tr>
<tr>
<td>PSI #26  Transfusion Reaction</td>
<td>17</td>
<td>33</td>
</tr>
<tr>
<td>PSI #27  Postoperative Hemorrhage or Hematoma</td>
<td>3,663</td>
<td>3,456</td>
</tr>
</tbody>
</table>

* PSI observed rates per 100,000 population.
<table>
<thead>
<tr>
<th>Year</th>
<th>Cases</th>
</tr>
</thead>
<tbody>
<tr>
<td>2007</td>
<td>374</td>
</tr>
<tr>
<td>2008</td>
<td>375</td>
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<tr>
<td>2009</td>
<td>334</td>
</tr>
<tr>
<td>2010</td>
<td>332</td>
</tr>
<tr>
<td>2011</td>
<td>346</td>
</tr>
</tbody>
</table>

Remember we asked for the 2011 cases? – only 114 were releasable and of those 53% were uninformative
California Rate by County

Patient Safety Indicators: Statewide and County Trends, 2007-2011
Five-Year Average Observed Hospitalization Rate

PSI #21  Foreign Body Left During Procedure

Source: Office of Statewide Health Planning and Development, Patient Discharge Data, 2007-2011
Agency for Healthcare Research and Quality, Patient Safety Indicators, Version 4.4
Patient Safety Indicators: Statewide and County Trends, 2007-2011
Annual Observed Hospitalization Rate
PSI #21  Foreign Body Left During Procedure

<table>
<thead>
<tr>
<th>Year</th>
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<tbody>
<tr>
<td>2007</td>
<td>-</td>
<td>1.4</td>
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<tr>
<td>2008</td>
<td>5.9</td>
<td>1.4</td>
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<td>2009</td>
<td>7.9</td>
<td>1.2</td>
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<tr>
<td>2010</td>
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<td>1.2</td>
</tr>
<tr>
<td>2011</td>
<td>3.8</td>
<td>1.2</td>
</tr>
</tbody>
</table>

Source: Office of Statewide Health Planning and Development, Patient Discharge Data, 2007-2011
Agency for Healthcare Research and Quality, Patient Safety Indicators, Version 4.4
Individual hospital

- Current reports DO NOT separate RSI and UDFs
- RSI are most certainly a never event. These are completely preventable
- It is less clear about UDFs
- Retained sponges cause the most harm and should be eliminated
- Six sigma performance is ~1/300,000 cases
Disclosure vs. Reporting

- Retained small item or device fragment but clinical decision NOT to remove
- Impossible to retrieve
- Unlikely to cause harm
- **Disclose to the patient**
- Discuss about reporting


R.I. hospital fined $300,000 for leaving drill bit in patient's head

October 27, 2010
by **Brendon Nafziger**, DOTmed News Associate Editor

A Rhode Island hospital was fined $300,000 by the state for leaving a broken drill bit in a patient’s head for two days following brain surgery, according to state officials, and local media also report a separate case at the hospital where forceps were left in a patient for three months after surgery.

**ENGAGE WITH OR LEADERSHIP TO HONE MULTI STAKEHOLDER PREVENTION STRATEGIES**
Sentinel Event - Retained foreign object after surgery

Q: Sometimes a needle or screw will break leaving a fragment behind. Is this a reviewable sentinel event?

A: In some cases, a broken needle or screw fragment is recognized at the time of surgery and a clinical judgment is made to leave the fragment in the patient. That decision is based on an assessment of the relative risks of leaving it in versus removing it. It would therefore not be considered an unintentionally retained foreign object.

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Sentinel Event - Retained foreign object after surgery

Q: Why was this particular point in the process selected as the definition of “after surgery?”

A: The decision to define “after surgery” as the completion of skin closure was based on the premise that a failure to identify and correct an unintentional retention of a foreign object prior to that point in the procedure represents a significant system failure, which requires analysis and redesign. It also places the patient at additional risk by virtue of extending the surgical procedure and time under anesthesia.
### NQF Required Reporting

#### Serious Reportable Events (SRE) 2011 Update

<table>
<thead>
<tr>
<th>Event</th>
<th>Additional Specifications</th>
<th>Implementation Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Unintended retention of a foreign object in a patient after surgery</td>
<td>• Includes medical or surgical items intentionally placed by provider(s) that are unintentionally left in place</td>
<td>This event is intended to capture:</td>
</tr>
<tr>
<td>or other invasive procedure</td>
<td>• Excludes:</td>
<td>- Occurrences of unintended retention of objects at any point after the surgery/procedure ends regardless of setting (post anesthesia recovery unit, surgical suite, emergency department, patient bedside) and regardless of whether the object is to be removed after discovery</td>
</tr>
<tr>
<td>• Applicable Settings:</td>
<td>a) objects present prior to surgery or other invasive procedure that are intentionally left in place;</td>
<td>- Unintentionally retained objects (including such things as wound packing material, sponges, catheter tips, trocars, guide wires) in all applicable settings</td>
</tr>
<tr>
<td>- Hospitals</td>
<td>b) objects intentionally implanted as part of a planned intervention and;</td>
<td></td>
</tr>
<tr>
<td>- Outpatient/Office-based Surgery Centers</td>
<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>
<td></td>
</tr>
<tr>
<td>- Ambulatory Practice Settings/Office-based Practices</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Long-term Care/ Skilled Nursing Facilities</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Position Statement: Adverse Events Which Include Retained Foreign Objects – Retained Fragments From A Broken Needle Or Screw

From Kathleen Billingsley, Deputy Director, Center for Health Care Quality, California Department of Public Health, Position Statement, March 30, 2010:

Adverse events which include retained foreign objects are defined in the Health and Safety Code (HSC). Specifically, HSC Section 1279.1 (b) (1) (D) states, “Retention of a foreign object in a patient after surgery or other procedure, excluding objects intentionally implanted as part of a planned intervention and objects present prior to surgery that are intentionally retained.”

In some surgical procedures, fragments from a broken needle or screw may be retained within the patient. The physician makes a clinical judgment at the time of surgery to leave the fragment within the patient as the relative risks outweigh the removal of the foreign object.

The California Department of Public Health’s (CDPH) determines that this is a reportable adverse event. CDPH requires facilities to report even these types of retained objects wherein the physician makes a clinical decision to retain the object; however, the CDPH may not issue a deficient practice relative to an adverse event.

Billingsley, Kathleen (CDPH-L&C)
Recommendations

• So the NQF does not consider the unretrieved device fragments a SRE so probably not required to report
• Except in California – you must report
• Voluntarily report to MedSun system
• Even if there is no requirement to report, should DISCLOSE to the patient and should conduct an RCA
• To inform the patient have to have info
When device breaks

- Collect all available parts
- Sequester them – do NOT throw them away
- Consider getting an x-ray of site
- Obtain information about the item e.g. model #, lot and serial number
- Save an unbroken item for comparison with damaged goods
- Complete an incident report
- Report to MedSun
**Med Sun**

- The FDA Safety Information and Adverse Event Reporting Program
- Report on the FDA’s MedWatch website
  
  
  ➤ Select “Report a Serious Medical Product Problem Online”
  
  ➤ Select “Health Professional” or “Consumer/Patient” on the right side of the page to begin the report
Patient Disclosure

1. Advise patients of the existence and nature of the UDF to include the following information:
   1. material composition of the UDF,
   2. the measurement/size of the fragment,
   3. location,
   4. x-rays findings with interpretation,
   5. potential for injury e.g. migration, infection, embolization, thrombosis and
   6. any procedures or treatments to be avoided or to be obtained
Why do RSI occur?

- Efforts traditionally focused on vigilance and everyone looked at events as “special cause”
- Around 2003 moved to “risk assessment”, attempts to identify case or patient characteristics that will predict retention
- Now just beginning to look at personnel and environmental characteristics – not the patient, the PROVIDERS
- All along it’s been a system problem treated as a problem of individuals or as a complication rather than as a patient safety problem
Elements of Causation

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

DEFENSES

LATENT FACTORS

Losses

“Counts”: NURSES

Xray: RADIOLOGISTS

Exploration: SURGEONS

Hazards

MANUFACTURERS

COMMUNICATION

OR PRACTICES

Retained Surgical Item
Error recognition

• Each slice of cheese represents a defense and a source of error
• If the defense of one fails then the hazard propagates to the next
• Nurses and Surgeons are the primary defenders
• The humans are the only ones that are going to be able to recognize the errors
Elements of Causation

Applying Swiss Cheese Model of Sir James Reason

BMJ, 2000;320:768

Exploration: SURGEONS
"Counts": NURSES
Xray: RADIOLOGISTS

DEFENSES

LATENT FACTORS

Hazards
MANUFACTURERS

RETAINED SURGICAL ITEM

COMMUNICATION
OR PRACTICES
Communication

- Is not just talking
- It’s the exchange of knowledge and information
- Patient safety problems frequently have communication failures
- How information is exchanged (or not)
- Interested in the how not the who
The Owl Syndrome

- Focusing on who
- Anytime you see initials it signals an emphasis on who
- Who did rather than how did
- Remnants of a blame and shame culture
Communication

• It’s **what** is right not who is right
  ➤ Between nurses and surgeons
    • “We’re missing a sponge” “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/Technicians: film quality, timely review, appropriate images
Pandora’s Box
A lot of Variation

<table>
<thead>
<tr>
<th>Method</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Use the hanging counter bags for raytex and count in 10's</td>
<td>4</td>
</tr>
<tr>
<td>Use the hanging counter bags for laps by breaking center divider and count in 5's</td>
<td>4</td>
</tr>
<tr>
<td>Collect in kick bucket and count 10 by hanging blue tags over edge of bucket</td>
<td>2</td>
</tr>
<tr>
<td>All sponges only in multiples of 10</td>
<td>2</td>
</tr>
<tr>
<td>In the unit of issue</td>
<td>2</td>
</tr>
<tr>
<td>Use the RFID system (Clearcount)</td>
<td>1</td>
</tr>
<tr>
<td>Collect sponges in groups of 5 and secure in clear plastic bag and put on floor</td>
<td>1</td>
</tr>
<tr>
<td>Collect sponges in groups of 10 and secure in clear plastic bag and put on floor</td>
<td>1</td>
</tr>
<tr>
<td>Lay sponges out on drape or flat surface and count with scrub</td>
<td>1</td>
</tr>
<tr>
<td>Collect in kick bucket and count 10 by pointing with ring forceps</td>
<td>1</td>
</tr>
<tr>
<td>Collect in kick bucket and count 5 by hanging blue tags over edge of bucket</td>
<td>1</td>
</tr>
<tr>
<td>Collect in kick bucket and count 5 by hanging over fingers</td>
<td>1</td>
</tr>
<tr>
<td>Use the RFID system (Clearcount) with counter bags</td>
<td>0</td>
</tr>
<tr>
<td>Use the wand system (RF Surgical) only on selected cases.</td>
<td>0</td>
</tr>
<tr>
<td>Use the wand system (RF Surgical) with a manual count on every case</td>
<td>0</td>
</tr>
<tr>
<td>Use the wand system (RF Surgical) with one of the manual count practices above</td>
<td>0</td>
</tr>
<tr>
<td>Use the bar code device (Surgicount) with kick buckets and counter bags</td>
<td>0</td>
</tr>
<tr>
<td>Use the bar code device (Surgicount) with kick buckets</td>
<td>0</td>
</tr>
<tr>
<td>Collect sponges and put some in hanging counter bags</td>
<td>0</td>
</tr>
</tbody>
</table>
This process involves the use of plastic hanging blue-backed sponge-holders which each contain 5 pouches. Each pouch has a thin center-divider which separates each pouch into 2 pockets. One sponge per pocket means that each holder can accommodate 10 sponges. We recommend that each holder always be set up to hold 10 sponges be they laparotomy pads or raytex and different types of sponges should not be mixed within one holder. The sponge holders are held on racks mounted to IV poles. A wall-mounted dry erase board to record operative information and the IN counts should be easily visible in each room. This process should be standardized for use throughout all operating rooms to provide consistency in all types of operative cases.

The single most important element in the use of the hanging sponge-holders is to make sure that the final count is taken when ALL the sponges that have been opened during the case (used and unused) have been placed in the holders. The surgeon and nurse can then visually verify that all sponges have been accounted for and none remain in the patient.

1. Use blue-backed sponge holders on all cases that use surgical sponges. Add laps and raytex in groups of 10. At the IN count "see, memorize and say" individual sponges within each pack.
2. Hang the holders on the special racks attached to designated IV poles. Use a separate holder for each sponge type e.g. one for laps, one for raytex.
3. Used sponges coming from the operative field should be placed into a CLEAR plastic bag-lined receptacle (e.g. kick buckets or ring stands).
4. Take each used sponge from the receptacle. Make sure you have only one sponge. Open it up to its full length and then fold it up into an oval. Place one (1) sponge per pocket, two (2) sponges per pouch, ten (10) sponges per holder.
5. Put the first sponge in the LAST pocket in the bottom of the holder. Load the holder horizontally from the bottom row to the top row, filling first the bottom two pockets and continuing upwards. This process (going from the bottom to the top) will make visual determination of the filled holder easier to see from the OR table. Once a holder is full with 10 sponges, visual confirmation with the scrub person should occur before hanging the next empty holder.
6. Place the folded sponge inside the pocket with the blue tag or stripe visible but not dangling out. The blue stripe must be visible because this is what differentiates a sponge with a radiograph from a gauze dressing. Place another sponge in the other pocket in the other side of the pouch. Periodically throughout the case put the used sponges in the holder. Keep the kick buckets empty.
7. At the time of the final count, ALL sponges MUST be in the sponge holders and the final verification must be taken by two people viewing the sponge holders. There should be NO EMPTY POCKETS.
8. Keep a running total of the sponges added to the surgical field on the dry erase board using the same format that is used to count needles. The last number should always be the total number of sponges opened during the case.
9. At a permanent change of relief, the number of sponges in the holders should be physically reviewed using visual and audible communication between the circulating nurses changing positions before the relieved nurse departs the OR.
10. Sponge holders should remain hanging in their racks from the IV poles. At the completion of the case the holders can be disposed of in a锐 be hazardous bag thus removing all the sponges from the case so there will be "nothing left behind" to confound the counts on a subsequent case.

10 LAPS / 10 RAYTEX / 10 POCKETS / 10 STEPS...
Don't Just “Swish or Sweep”, perform a Methodical Wound Examination (MWE)

The goal is to get all the sponges OUT so they can be accounted for

1. A methodical exploration of the operative wound must be conducted prior to closure in every operation. The space to be closed must be carefully examined. Special focus should be given to closure of a cavity within a cavity (i.e., heart, major vessel, stomach, bladder, uterus, and vagina). Surgeons should strive to SEE and TOUCH during the exploration whenever possible; reliance on only one element of sensory perception is usually insufficient. Before closing, the surgeon should first make a best effort to remove all sponges, then the nurse and scrub person will count them and feedback to the surgeon if all have been accounted for.

2. The general process is to look and feel in the recesses of the wound and examine under fatty protuberances and soft-tissue appendages. Unless clinically contraindicated for a specific patient, the following steps should be taken for procedures performed in the abdomen or pelvis.
   a. Examine all four quadrants of the abdomen with attention to:
      i. Lifting the transverse colon
      ii. Checking above/around the liver and above/around the spleen
      iii. Examining within and between loops of bowel
      iv. Inspecting anywhere a retractor or retractor blades were placed
   b. Examine the pelvis
      i. Look behind the bladder, uterus (if present) and around the upper rectum.
   c. The vagina should be examined if it was entered or explored as part of the procedure.

3. Unless clinically contraindicated for a specific patient, the following general steps should be taken for procedures performed in the mediastinum or thorax.
   a. In a mediastinal procedure, if the mediastinal pleura were opened, examine the ipsilateral pleural cavity.
   b. In a cardiac procedure, elevate the apex of the heart and examine the retrocardiac space. Examine the transverse sinus to the right and left of the aorta and pulmonary artery.
   c. In a thoracic procedure, examine the thoracic cavity with attention to the thoracic apex and base of the lungs, paravertebral sulcus, and inferior recesses of the diaphragm. Place a hand or finger behind the lung and palpate from apex to base.

FINAL COUNT

SHOW ME
Radiology Guidelines

- Missing Surgical Item (MSI) guidelines
- Region of Interest specified images
- Instructions for radiology techs to take correct images
- Information to help get it right

MISSING SURGICAL ITEM (MSI) – Radiographic Exams

Upon identification of a missing surgical item, the Surgeon or Nurse will order STAT X-Rays for the specific region of interest (ROI) as listed below. The Radiology Technologist can use this guidelines for planning optimal image quality.

<table>
<thead>
<tr>
<th>Exam</th>
<th>Views</th>
<th>ROI</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>MSI Cranium</td>
<td>AP &amp; Lateral (2V)</td>
<td>Top of Skull to below Mandible and bilateral skin borders.</td>
<td>Include Face and Neck if ENT surgery</td>
</tr>
<tr>
<td>MSI Chest</td>
<td>AP &amp; Oblique (2V)</td>
<td>Apices to Costophrenic Angles (CPA) and bilateral skin borders.</td>
<td>This may require more than one film for the AP projection. The Oblique may be a single 14x17 of the ROI</td>
</tr>
<tr>
<td>MSI Abdomen/Pelvis</td>
<td>AP &amp; Oblique (2V)</td>
<td>Diaphragm to Pubis and bilateral skin borders.</td>
<td>This may require more than one film for the AP projection. The Oblique may be a single 14x17 of the ROI</td>
</tr>
<tr>
<td>MSI Vagina</td>
<td>AP &amp; Inlet (2V)</td>
<td>Inferior gluteus to above crest and bilateral skin borders.</td>
<td>Inlet: Place 14x17 vertical with 25 degree caudal angulation. Special attention needed to avoid grid cut-off</td>
</tr>
<tr>
<td>MSI Extremity</td>
<td>AP &amp; Lateral</td>
<td>Include above and below ROI and bilateral skin borders.</td>
<td>Use large films. Order must be specific to ROI: LUE or LLR RUE or RLE</td>
</tr>
</tbody>
</table>

Most portable units have a maximum kVp of 90 – 120 and maximum mAs of 320. The x-ray source must be set at the safest distance to preserve the sterile field. Because of these limitations adequate images may be impossible to obtain in the morbidity obese patient. Image quality should be discussed with a radiologist.
Which is it?

A Communication or Practice Problem

The Joint Commission
Sentinel Event Alert

A complimentary publication of
The Joint Commission

Issue 51, October 17, 2013

Preventing unintended retained foreign objects

The unintended retention of foreign objects (URFOs) – also called retained surgical items (RSIs) – after invasive procedures can cause death, and surviving patients may sustain both physical and emotional harm, depending on the type of object retained and the length of time it is retained. There may be an extended time frame between occurrence and detection of an URFO. Retained foreign objects are most commonly detected immediately post-procedure; by X-ray; during routine follow-up visits; or from the patient’s report of pain or discomfort.

URFOs refer to any item or foreign object related to any operative or invasive procedure that is left inside a patient. Objects most commonly left behind after a procedure are:
Three types of Retained Sponge Case:

1. No Count Retention Case
2. Correct Count Retention Case
3. Incorrect Count Retention Case
No Count Case

• Cardiology cath labs (pacemakers)
• Radiology procedure rooms where NON-percutaneous procedures are performed (e.g. porta-caths, infusion pumps)
• Normal procedure in labor and delivery birthing rooms

NLB Vernacular
Correct Count Case

• Terminology relates to the count at the end of the case NOT what was the count looking back at the event

• So a CCRC is a case of an RSI where the counts were called “correct” at the final count

• These are practice problems

NLB Vernacular
Findings

• 80% of retained sponge cases occur in the setting of a CORRECT COUNT
  ➔ Problems with OR practices
• Very few reports specifically discuss THE PRACTICE but rather external factors around the practice
• If noise or distractions disrupt the practice of counting it’s not a very reliable practice
Incorrect Count Case

- At the final count for the case there was an incorrect count. Something was missing yet the patient left the OR with the item inside of them
- Involvement of other stakeholders
- Usually acts of omission
- Problems with knowledge and communication
Findings

• 20% of cases occur in the setting of an INCORRECT COUNT
  ➤ Problems with knowledge and communication

• X-rays not called for, no radiologist input, wrong views, images called “negative”

• Incorrect count not reported, nurse manager never informed, no process for finding items or going to next step to make sure no harm
The California Story

Reports from 10/25/2007 – 10/24/2013

75 Retained Surgical Item cases

43 Soft Goods

27 laps; 12 raytex; 39 CCRC (91%)

1 lap; ICRC

3 towels NCRC

So if you think the “counts are correct” what is the nurse going to “speak up” about? It’s not a problem with communication as much as it’s a problem with the PRACTICES being used
Findings from NLB series

- 10% are NO COUNT cases
  - Usually vaginal births or pacemakers

- 70% of retained sponge cases occur in the setting of a CORRECT COUNT;
  - Problems with OR practices e.g. variable practices or having a fragile one that isn’t very reliable

- 20% occur in the setting of an INCORRECT COUNT
  - Problems with knowledge and communication usually with radiology
In March 2010 pt underwent laparoscopic cholecystectomy converted to open for gangrenous cholecystitis. 2 hour operation, counts correct. Post/op pt had bleeding, hemorrhagic shock and NEXT MORNING was taken back to OR for re-exploration and hemostasis of some liver and gallbladder fossa vessels. Counts called correct. Pt had ICU stay and eventually discharged. Pt returned to hospital 5 times with c/o chest pain, headache and hematuria. Last visit admitted with chest pain and had ? type of Xray (could be chest or abdomen) showing retained lap pad in RUQ with abscess. Returned to OR for removal.

Lap pad retained in second operation. No details of how “counts” are performed. No one knows when or how error in counting occurred.

Call to Action

1. CDPH citation focused on following count policy and the education of staff on AORN counting, doing audits and using “plastic bags” and observe each other counting.
2. No analysis of a specific practice
3. No analysis of other stakeholder actions e.g. surgeon MWE, radiologist

Pearl of Wisdom
In 2010 patient underwent uncomplicated C-section (?elective or emergent). Counts correct at end of case. Mother and infant went home. Seven weeks later mother returned to ED with left lower abdominal mass and wound infection. CT scan obtained which showed retained lap pad and abscess.

Pt taken to OR and found to have jejunal and sigmoid colon perforation in area of lap pad adhesion. Pt underwent small bowel and sigmoid colon resection. Did well.

Counts were performed during operation. No details of how “counts” are performed. No one knew where error occurred.

CCRC Ob/Gyn - Pelvis

**Story**

1. CDPH citation and hospital focused on following count policy and the counting of sponges and how many counts to perform. Staff education, observations and audits etc., etc
2. No analysis of a specific practice
3. No analysis of actions of other stakeholder e.g. surgeon MWE

**Call to Action**

**Pearl of Wisdom**
In 2010 patient underwent uncomplicated CABG for ? Indications. Counts called correct. Some time post/op pt underwent CXR which showed “opacities” and then underwent CT which showed retained (probable) raytex.

Pt taken to OR for thoracotomy and removal of raytex in pericardial space. Did well.

No details of how “counts” are performed. No one knows when or how raytex retained.

1. CDPH citation focused on hospital plans to use dry erase board to record counts, plastic hanging pocketed panels, RF sponges and crew resource management training.
2. No analysis of a specific practice
3. No analysis of other stakeholders e.g. surgeon MWE, radiologist
CCRC Small Case

Story

In 2010 patient underwent ACL repair for ACL insufficiency. 3 cm incision for operation. 10 (likely) raytex 4x4’s used during the case. MD practice to put anesthetic soaked sponge in wound while reviewing knee function. Counts called correct at end of case. 2 months later patient returned to MD office with a lump in knee. Xray showed retained raytex. Pt elected to go to another hospital for sponge removal.

Staff knew MD put sponge in wound. No details of how “counts” are performed. No one knows when or how error in counting occurred or why sponge wasn’t removed. Was only 3cm incision so didn’t “think” had to really “count”.

Call to Action

1. CDPH citation focused on following count policy which stated that raytex should not be used as dressing or as packing. (this wasn’t packing however because intent was never to leave in wound)
2. Action was to have ST and RN both initial count sheet
3. No analysis of a specific practice
4. No analysis of other stakeholder actions e.g. surgeon MWE

Pearl of Wisdom
17 yo primagravidia has normal vaginal birth. 10 dressing sponges opened during birth. Mother and baby discharged home. 4 weeks later mother seen in MD office with foul vaginal odor and discharge. Mild fever. Has stopped breast feeding infant and has no energy. MD examines vagina and removes old fetid sponge. Non radiopaque sponge use presents a problem in event physical exam not performed and if x-ray obtained. Ultrasound might not be informative. No details of how “counts” were performed. Likely not counted but recorded as correct. No one knows when or how error occurred.

Call to Action

1. RCA focused on following count policy and the education of staff on AORN counting.
2. No analysis of a specific practice
3. No analysis of other stakeholder actions e.g. obstetrician MWE

Pearl of Wisdom
Have an action plan

- NCRC have to get a PRACTICE
- CCRC have to change PRACTICE
  - Design ways to improve the process: SAS, RFAS
    - Decrease number of steps
    - Increase reliability of individual steps
  - Get a whole new process: SSS²;
- ICRC have to address COMMUNICATION
  - Use an Incorrect FINAL count report
  - ASSIGN RESPONSIBILITY for follow-up
  - Move beyond the role of the RN circulator
  - Engage radiology, surgery providers
Hierarchy of Actions

High impact
- Leadership involvement
- Simplify process and remove unnecessary steps
- Standardize equipment
- Evaluate forcing functions

Intermediate impact
- Checklist/cognitive aid
- Staffing workload
- Redundancy
- Enhanced documentation/communication/Readback
- Visual cueing

Low impact
- Education, training, form a committee to analyze, revise policy
Hierarchy of Actions

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Sponge Counts

1. Count before start of case
2. Count at cavity closure
3. Count when new sponges added
4. Count at fascial closure
5. Count at skin closure
6. Count when all sponges off field = FINAL COUNT
1. 6 step process

1. Count at start of case  95%
2. Count at cavity closure  99%
3. Count when add sponges 98%
4. Count at fascial closure  99%
5. Count at skin closure  90%
6. Count when all sponges off field 95%
   (FINAL COUNT)

OVERALL reliability?
Not the Average, Take the Product of the Probabilities

1. Count at start of case  95%
2. Count at cavity closure  99%
3. Count when add sponges  98%
4. Count at fascial closure  99%
5. Count at skin closure  90%
6. Count when all sponges off field (FINAL COUNT)  95%

OVERALL reliability = 78%
1. Reduce # of steps

1. Count b4 start of case 95%
2. Count at cavity closure 99%
3. Count when add sponges 98%
4. Count at fascial closure 99%
5. **Count at skin closure 90%**
6. Count when all sponges off field = FINAL COUNT 95%

**OVERALL 78%**

---

1. Count b4 start of case 95%
2. Count at cavity closure 99%
3. Count when add sponges 98%
4. Count at fascial closure 99%
5. Count when all sponges off field = FINAL COUNT 95%

**OVERALL 87%**
1. Reduce # of steps

1. Count b4 start of case 95%
2. Count at cavity closure 99%
3. Count when add sponges 98%
4. Count at fascial closure 99%
5. Count at skin closure 90%
6. Count when all sponges off field = FINAL COUNT 95%

OVERALL 78%
What usually happens?

• Sponge left in kick bucket
  ➤ RN going to empty kick buckets
  ➤ RN going to put countbags in red bags

• Add-a-step actions
  ➤ Add another count!
  ➤ Have MD tell the RN whenever “tucks”
  ➤ RN write on DEB; erase DEB when out
  ➤ Put a clamp on end of sponge; or on drape
  ➤ Put rings on sponges, and count the rings!
Standardization

• Develop and implement a standardized process for the management of surgical sponges
• Every case, every OR, every time
• Make it simple and easy to use
• Everyone has to use it the same way
• REDUCE VARIATION…….. DECREASE COMPLEXITY

STOP JUGGLING!
# 2. Improve Reliability

<p>| | |</p>
<table>
<thead>
<tr>
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<th></th>
</tr>
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</tr>
<tr>
<td>6.</td>
<td>Count when all sponges off field = FINAL COUNT</td>
</tr>
</tbody>
</table>

1. Count b4 start of case

At the IN count the critical step is to SEPARATE the sponges when doing the 3S’s

At the final count all sponges (used and unused) MUST be in the holders

5. Count at skin closure | 90% |

6. Count when all sponges off field = FINAL COUNT
2. Improve Reliability

1. Count b4 start of case 95%
2. Count at cavity closure 99%
3. Count when add sponges 98%
4. Count at fascial closure 99%
5. Count at skin closure 90%
6. Count when all sponges off field = FINAL COUNT 95%

OVERALL 78% 5%
Simplify and↑ Reliability

1. Count b4 start of case 95%
2. Count at cavity closure 99%
3. Count when add sponges 98%
4. Count at fascial closure 99%
5. Count at skin closure 90%
6. Count when all sponges off field = FINAL COUNT 95%

OVERALL 78%

1. Count b4 start of case 98%
2. Count at cavity closure 99%
3. Count when add sponges 98%
4. Count at fascial closure 99%
5. Count when all sponges off field = FINAL COUNT 98%

OVERALL 92%

14%
Change Practice

• Rewriting the policy or adding a step to an existing policy is unlikely to prevent recurrence and actually decreases reliability

• Problem is with error prone, non-verifiable practices

• This includes the addition of a new technology adjunct, is this just another add-a-step or a whole new process? Is it a hole in a slice of cheese or a new slice?
Most “Count” Policies

• Have non-directive language
• Have add-a-step actions
• Unclear Small Miscellaneous Item part
• No specific practice for sponge mgmnt
• Should use names for specific counts
• Not multi-stakeholder; when they are
• Surgeon actions not in surgeon domain
• No Radiology or Anesthesiology guidelines
Non-directive language

• “Counts will be performed in all cases where there is a chance of retention”
  ➤ Who decides on the chance of retention?

• Counts will be performed in all cases where surgical sponges are used and an incision is made or a wound exists
AORN Practices

- These are RECOMMENDED practices - ultimately up to the hospital to decide
- Multi-disciplinary
  - Accountability beyond the RN Circulator
  - Guidelines for
    - Surgeons, scrub techs, anesthesiologists, radiologists
- Addresses problems with device fragments and small misc items
# Count Confusion

<table>
<thead>
<tr>
<th>Count</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>IN: initial, added IN</td>
<td>1st</td>
</tr>
<tr>
<td>OUT: Closing</td>
<td>2nd</td>
</tr>
<tr>
<td>OUT: FINAL</td>
<td>3rd</td>
</tr>
</tbody>
</table>

Using numbers, 1\textsuperscript{st}, 2\textsuperscript{nd}, 3\textsuperscript{rd} is confusing and poor communication. What is the 4\textsuperscript{th} or 5\textsuperscript{th} count? Anyone can call for a count anytime so how do you “record” the 6\textsuperscript{th} or other interim counts?
AORN Counts

1. Before the procedure to establish a baseline and identify manufacturing packaging errors and when new items are added to the field
2. Before closure of a cavity within a cavity
3. When wound closure begins
4. At skin closure at the end of the procedure or at the end of the procedure when counted items are no longer in use (ie, final count)
5. Time of permanent relief of either the scrub or circ although direct visualization of all items may not be possible
4th count is a problem!

4. At skin closure at the end of the procedure or at the end of the procedure when counted items are no longer in use (i.e., final count)

► Has an “or” statement – requires a choice e.g. is skin closure the end of the procedure or is the end when items are not in use?

► What is a “final count”?

► Implies there is a 1st (at skin closure) and a 2nd (at the end of the procedure) which are both parts of the 4th count
Better would be:

• Perform a count at skin closure
• Perform a count at the end of the procedure when counted items are no longer in use (ie. Final count)

This however changes a 5 count practice to a 6 count practice……. without demonstrable advantage
Count Confusion

• No wonder there are problems with just counting!
• Nurse A’s 2\textsuperscript{nd} count is Nurse B’s 1\textsuperscript{st} final count or maybe not……
• This is a good example of where communication problems contribute to retention
Sponge ACCOUNTing

• Sponge ACCOUNTing uses words for each of the 3 primary counts

• The FINAL COUNT is defined:
  at the FINAL COUNT all the sponges (the used and unused) must be in the sponge holders

• IN, CLOSING, FINAL counts each have defined actions so there is less ambiguity
Closing Count

• Surgeon performs a methodical wound exam to get all the sponges out

• Nurses perform two person accounting practice between field, table and holders
  ➤ Give surgeon closing suture while you continue count
  ➤ Respond back to surgeon “We think the count is correct; We think we’ve got all the sponges” (or NOT!)

• Keep on the field some sponges to use for closing.
At the FINAL Count:

- All the sponges (used and unused) MUST be in the sponge holders
- Before MD leaves the OR they say “show me”; or you say “let me show you”
- Each pocket should be full - 10 sponges per holder.
- Team based verification
Instruments

• Retention is not related to the number of instruments – it’s related to how and when the instrument is used
• Use standardized count sheets which are first completed in SPD
• Instruments should be recorded in one place
• X-rays in lieu of an instrument count can work IF the radiologists know that is what the xray is being used for
POLICY
NoThing Left Behind®:
Prevention of Retained Surgical Items Multistakeholder Policy

PRACTICE
WHERE ARE THE SPONGES?
ALL SPONGES (used and unused) ARE HERE
SPONGE ACCOUNTING

http://www.nothingleftbehind.org
Be Careful

• Not a Chinese menu – take some from Column A and some from Column B
• Policy must have internal consistency
• What is outlined in Part A must agree with actions in Part B
• Look at the NLB Policy in totality
What are we doing?

• Goal is the optimal allocation of effort. Danger is wasting effort on things that won’t improve quality of care or truly prevent patient harm.

• Measures that are reliable and valid
  - reliable enough to reflect the impact of what we do
  - meaningful enough to spend time and effort on = validity
Elements of Causation

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

LATENT FACTORS

DEFENSES

Hazes

MANUFACTURERS

Exploration: SURGEONS

Counts: NURSES

Xray: RADIOLOGISTS

COMMUNICATION

OR PRACTICES

Retained Surgical Item
Surgeon’s Role

• Is active not reactive
• The surgeon puts the items in the patient, decides what is intended to remain, has to order and direct taking of x-rays, communicates with peer MD, is the one who has to remove any items and has to disclose any events to the patient
Surgeon’s Role

• The surgeon strives to perform a methodical wound exam in every case as the first step before wound closure

• The surgeon creates an OR environment that encourages the exchange of knowledge and information

• Has to be part of the change effort
Don’t Just “Swish or Sweep”, perform a Methodical Wound Examination (MWE)

The goal is to get all the sponges OUT so they can be accounted for

A methodical exploration of the operative wound must be conducted prior to closure in every operation. The space to be closed must be carefully examined. Special focus should be given to closure of a cavity within a cavity (i.e., heart, major vessel, stomach, bladder, uterus, and vagina). Surgeons should strive to SEE and TOUCH during the exploration whenever possible; reliance on only one element of sensory perception is usually insufficient. Before closing, the surgeon should first make a best effort to remove all sponges, then the nurse and scrub person will count them and feedback to the surgeon if all have been accounted for.

1. The general process is to look and feel in the recesses of the wound and examine under fatty protuberances and soft-tissue appendages. Unless clinically contraindicated for a specific patient, the following steps should be taken for procedures performed in the abdomen or pelvis.
   a. Examine all four quadrants of the abdomen with attention to:
      i. Lifting the transverse colon
      ii. Checking above/around the liver and above/around the spleen
      iii. Examining within and between loops of bowel
      iv. Inspecting anywhere a retractor or retractor blades were placed
   b. Examine the pelvis.
      i. Look behind the bladder, uterus (if present) and around the upper rectum.
      c. The vagina should be examined if it was entered or explored as part of the procedure.

2. Unless clinically contraindicated for a specific patient, the following general steps should be taken for procedures performed in the mediastinum or thorax.
   a. In a mediastinal procedure, if the mediastinal pleura were opened, examine the ipsilateral pleural cavity.
   b. In a cardiac procedure, elevate the apex of the heart and examine the retrocardiac space. Examine the transverse sinus to the right and left of the aorta and pulmonary artery.
   c. In a thoracic procedure, examine the thoracic cavity with attention to the thoracic apex and base of the lungs, paravertebral sulcus, and inferior recesses of the diaphragm. Place a hand or finger behind the lung and palpate from apex to base.
Surgeon/MD Issues

• “We haven’t had a retained sponge here”… “it was only a vaginal sponge”…why are we wasting (time, money, effort) on this?

• MDs must be active participants in efforts to prevent RSI. They have “skin in the game”.

• We are not wasting time, money or effort; this is a good use of available resources.
Change Strategy

• A tool to help in the development of a case for change
• The formula for change
• C = (DVF) > (greater than) R
• Change can come about when Data (dissatisfaction) x Vision x First Steps > Resistance

Dannemiller and Jacobs 1992
Data

- 80% of retained sponge cases have occurred in the setting of a correct count
- We have had 5 cases of retained surgical sponges in the last 2 years
- The total outlay of liability coverage has been in excess of 1 million dollars
Vision

• A retained sponge must be removed with another operation and that causes patient harm. As healthcare providers we try to heal not harm

• We want our OR to be considered the safest, the best place to have an operation
First Steps

• Find a surgeon champion, a nurse champion and a radiology champion to engage in the process change

• Discuss with leadership their unequivocal support to push forward when the pushback starts

• Define needed resources and make sure they are available
Resistance

- I haven’t ever had a retained sponge so why do I have to change my practice?
- Why are you wasting our time?
- I’m a radiology technologist so I’m not a member of the OR team
- If I do that it will increase my liability
- How much is this going to cost my patient?
Message

• We are going to find ways to make this practice change work here at xxxx
• Not being asked to evaluate the practice
• Not being asked if you like it or are just “trying it on” like a pair of pants
• Use our collective brainpower and will to figure out how to effect change
Important Points

• It’s a Retained Surgical Item
• Which is a Surgical Patient Safety Problem
• These involve faulty Communication and OR Practices
• Multi-stakeholder involvement
• Therefore they are SYSTEM problems NOT easily remediated by individual action
Important Points

• Physicians and Nurses are the primary defenders – can prevent event

• Radiologists are secondary defenders – mitigate harm

• The safety rules and standardized practices apply to everyone

• It’s people that make an OR, birthing room, procedural area safe
System Problems

• Failure of leadership involvement
• Surgeon fears and lack of engagement
• Everyone really wants to keep doing the same thing and believe outcomes will be different
• Persistent belief in the superiority of “counting” and personal excellence, miss “systemness”
• Risky group behaviors trump safety, dysfunctional consensus building
• Failure of managers to train, perform audits and competency assessments and embrace reporting
Perspective

• The biggest resistance to change will come from within
• Everyone will tell you however it comes from without…
• And it does
Thank You

For sharing lessons learned and having the courage to effect change
For taking the time in your day to attend this presentation
To the Patient Safety First Collaborative and
To our patients ……. who endure
SAFER SURGERY

www.nothingleftbehind.org