Retained Surgical Items

Understanding Failure Modes Generates Behavior Change

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Patient Safety First...
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HOSPITALS

Why Should People Jump?

Burning Platform
BECAUSE.....
RSI are considered to be NEVER EVENTS and the Incidence is
STILL > ZERO
The California Story

Reviewed CDPH reports from 10/25/2007 – 8/5/2013 where hospitals received administrative penalties of $25,000 - $100,000

74 Retained Surgical Item cases
43 cases involving Soft Goods
28 laps; 12 raytex; 3 towels (1 ROT)
23 cases of Small Miscellaneous Items
8 cases of a retained Instrument (50% are visceral retractors)
Learning from “Intelligent Failures” – Prevention of RSI
Intelligent Failures

• When failures occur – events and close calls – they are analyzed and studied so learning can take place.

• The information from these analyses is disseminated and shared.
Surgical Patient Safety

Establish a structure of safe surgical care

Safe surgical care is care without unintended HARM

harm to the patient (and by direct extension if we harm patients we also suffer and are personally harmed)
Prevent error

- Not error free care, because as humans we will err
- We try to prevent surgical error by understanding the human factors that lead to error and change the environments in which we work
- And when error occurs - recognize it, report it and share learnings from the event
Mitigate injury

• Important to mitigate the level or degree of injury if error does occur
• Ultimately the goal is to optimize human performance
Learning from “Intelligent Failures” – Prevention of RSI

1. Small Miscellaneous Items (SMIs)
Small Miscellaneous Items

- Small Miscellaneous Items and Unretrieved Device Fragments (UDFs) are frequently retained
- 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
SMI Data Project

• Collaboration with CHPSO
• Reports are Patient Safety Work Product
  ➤ Confidential
  ➤ Privileged
  ➤ Deidentified

• Illinois, Michigan, Missouri, Nebraska, North Carolina, California, Tennessee participated – ended October 2012
• Together with data from NLB sources there are 105 cases
Retained Items

2.5 foot plastic drape
stapler head in rectum
ring band sizer for heart valve sizing
blade extender
tip of Bullard laryngoscope
3.5 cm piece of lumbar drain catheter
retractor blade
metal portion of Heart String device
2-4mm drill bits x 10 cases
4 cm portion of fetal scalp electrode
piece of Weck cell sphere
endoscopic anti-fog solution bottle
Breakaway part of lami bolt
Portion of uterine manipulator

2.5 cm temporary neck pin
1x8" xeroform gauze
Raney clips
electrocautery tip
8x5mm metal screw cap
Piece of screwdriver head
patellar protector
piece of Rhotan dissector
Suture sleeve of AICD lead
5mm tip of right angle clamp
plastic tip of bipolar device
Steinman pin
Part from Capio device
Nasal suction bulb
Interesting Findings

• Needles are the most frequently miscounted items in the OR yet very few reports of retained needles

• Under-reporting of retention or just miscounted?

• Sponges still predominate as most problematic RSI

• There are always interesting stories
Two Types of Case based on LOCATION of event

I. OR CASES
   a. Radiopaque items
   b. Non-Radiopaque items

II. Non-OR CASES
OR Cases

- Radiopaque Items
  - Screws, bolts, parts of retractors
  - Wires, baskets
  - Drill bits, metallic fragments
  - Stapler heads, suction tips

NLB Vernacular
Radiopaque Items

- Identify early if something is missing
- Usually will be the scrub person
  - the circulating nurse is out of the field
  - the surgeon is focused on operation
  - discovery in SPD is too late
- Obtain an intraoperative x-ray
- Usually can find and retrieve these items
- Recognition is key
OR Cases

- Non-Radiopaque Items
- Plastic trocars, vessel loops,
- Rubber stoppers, flanges, eye protectors
- Tips from tunneling devices
- Pieces of wood

NLB Vernacular
OR Cases

- Non-Radiopaque Items
- Plastic trocars, vessel loops,
- Rubber stoppers, flanges, eye protectors
- Tips from tunneling devices
- Pieces of wood
Non- Radiopaque Items

• Identify early if something is missing
• Usually will be the scrub person
  ➣ the circulating nurse is out of the field
  ➣ the surgeon is focused on operation
  ➣ discovery in SPD is too late
• Obtain an intraoperative x-ray - why?
• Make a plan for further post-operative studies e.g. CT scan
• Report the incorrect final item count
Scrub Position

• 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

NLB Vernacular
Standardize Tables

• Reduce variation on how STs set up and maintain back tables
• Aids with discovery of a missing item
• Everything in its place
• Not “my table”
• Beyond counting
Non-OR Cases

1) Intravascular
   ➤ Everywhere: cardiology, radiology, anesthesiology, ICU
   ➤ Guidewires, catheters, sheaths, introducers

2) Interstitial
   ➤ Subcutaneous space, breast tissue
   ➤ Catheter parts, broken drains, wires

NLB Vernacular
Guidewires

• Interventional Radiology can successfully remove these >90% of the time IF recognized and removed early

• Late discovery leads to fibrous adherence
Removal is desired

- MRI procedures problematic
- Magnetic fields can cause movement, migration
- Radiofrequency fields cause heating
Retention Prevention

- At least for Guidewires:
- Prevention
  ➤ Proceduralist competency and expertise
    • Training and experience
  ➤ CLABSI protocol has last element on checklist:
    • Guidewire is IN THE KIT
- Mitigation of Harm:
  ➤ Immediate Post-procedure CXR
2) Interstitial

- Subcutaneous space
- Insertion and removal techniques lead to retention
- Post-removal inspection of device is key
Why do they occur?

• Catheter and guide wire fractures that result in UDFs can be caused by these inappropriate techniques:
  • withdrawing a catheter through or over a needle
  • shaping a device to conform to the patient’s anatomy when the device wasn’t designed to be reshaped
Why do they occur?

• using undue force and torque (rotational force) on insertion or withdrawal
• improperly manipulating a catheter using devices that are too small or too large
• using a device for an off-label purpose
Essential causes

A. Provider errors and mistakes in use of the device
   ➤ This is the most common finding

B. Provider uses the device correctly but there is a problem with the device
   ➤ 1) Manufacturer defects
   ➤ 2) Worn and Used equipment
   ➤ 3) New Unfamiliar Devices
      • Multiple separable parts
      • Non-radiopaque pieces of a multi-part device
Essential causes

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Learning from “Intelligent Failures” – Prevention of RSI

1. Small Miscellaneous Items (SMIs)
2. Unretrieved Device Fragments (UDFs)
Device Fragments

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

http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/TipsandArticlesonDeviceSafety/ucm070187.htm
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
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

2. Report to MedSun
Learning from “Intelligent Failures” – Prevention of RSI

1. Small Miscellaneous Items (SMIs)
2. Unretrieved Device Fragments (UDFs)
3. Towels
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(50% are visceral retractors)
Small bowel resection

- Uncomplicated case
- Folded blue towel placed over the bowel to protect from injury during fascial closure
- Scrub passed the towel, usual surgeon practice
- Operation completed
- Counts called correct
Retained Towel

- Towels are drapes NOT dressings
  - Different grade & quality of cotton, blue dye
- No xray marker
- Not included in the count
- Change practice e.g. use a super-size sponge
  - or
- Purchase dressing quality white towels with an xray detectable marker
- Include in count when towels added to the field

Camazine, Contemp Surg 2005;61:398
Only use x-ray detectable white cotton disposables in the wound
- Order white x-ray detectable towels if you use in-wound towels

Don’t cut or alter sponges

Strive for a safe sponge:wound size ratio
- e.g. big sponge/small wound
Radiopaque Towels (ROTs)

White fine weave towel with radiopaque (RO) marker
Additional Info

• White ROTs are in packs of 4 or 6
• Add to field in “unit of issue”, write on dry erase board, account for them at the end of the case
• They don’t go in pockets of the holders
• Use green or blue drape towels as drapes, don’t “count” them
Standard Practice

- Record on the dry erase board after the towels are opened, counted and placed on the field.
- At the final count have 4 white RO Towels on the back table, easily visible for everyone to see that they have been accounted for.
Don’t use as drapes

- Don’t use white ROTs as drape towels (use the blue or green as usual).
- If an xray is needed during the case the radiopaque markers on the towels will confound image interpretation
- White towels as drapes will cause glare from OR lights -> MD eye strain
Special usage

- In CT/Vascular cases, some MDs like to use a white towel as a background when sewing with fine suture. This makes it easier to see the blue or black suture.
- OK to use a white ROT.
- Have a package available. Open it, count it, use it, remove it,
- ACCOUNT for it!
Wound Exam

• Surgeon has to perform a methodical wound exam in every case
• Not a “swish or a sweep”
• The point of the exam is to get the surgical items out so the nurses can count them
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.
      ii. 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.
   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
Learning from “Intelligent Failures” – Prevention of RSI

1. Small Miscellaneous Items (SMIs)
2. Unretrieved Device Fragments (UDFs)
3. Towels
4. Sponges
The New Easy as 1-2-3

• The 3 most important things to do to prevent retained surgical sponges
  ➤ 1. SEPARATE the sponges – on the IN and on the OUT
  ➤ 2. Surgeons have to actually look during the MWE
  ➤ 3. Get all the sponges in one place to make sure they are all ACCOUNTED for
Retained Sponge

• Most common retained surgical item that requires a re-operation
• Detection can be difficult and remote from the initial operation
• The sponge must be removed
• Primary problem is faulty OR practices
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

In Count

Operation

3 S’s:
See, Separate, and Say

Closing Count

Kick Bucket Ring Stand

Final Count

Correct

Correct: Found the Sponge

Missing Sponge

Alert

Incorrect: Didn’t find the Sponge

RN Verify

SCRUB

MD Verify

RN Look in Trash

MD Surgeon

RN Administration

MD Patient

MD Radiologist Verify

X-Rays AP Oblique
Resistance

• Think you can just take “parts” of the practice and expect to get the same outcome (which is ZERO)
• Think the practice is about “counting”
• Greatest resistance is with “Unit of Issue”
  ➤ THE unit of issue is only in multiples of ten
  ➤ Now you can actually know “how many”
Wrong Thinking

• Staff think can keep working in 5’s for laps and 10’s for raytex

• Put the sponges in “unit of issue” in the HBBPSH

  ➔ PROBLEM

• Running two separate systems of counts and two separate systems of sponge “counter bags”

• Counting the sponges where they “lay”
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
• Haven’t yet had a case of 10 retained sponges!
Other Side of the Moon

- Overly concerned with the “add a pack” to get 10. Treating as a major obstacle…….. It’s NOT
- 1 pack of laps may cost $1.25
- Switch out the custom packs and use what you get, try other size sponges
- surprisingly is abrasion free…….. once you do it
Small Case? A Solution

• In small cases think don’t need 10 laps?

• Want clean sponges at the end of the case?

• Put a few in the pockets at the beginning of the case
Process Elements

All free sponges are managed in multiples of 10. The RN and ST “see, SEPARATE & say” for all IN counts. The counts are written on a white board in a standardized format which is the same in all rooms. Sponges are SEPARATED and placed in hanging blue-backed plastic sponge holders (HBBPSH) starting with the bottom pocket and moving horizontally up. At the CLOSING count there is a “pauze for the gauze” where the surgeon does a methodical wound exam before asking for closing suture and the RN and ST perform a closing count. At the FINAL COUNT there is a “show me” step where the RN and surgeon look at the hanging holders to VERIFY there are NO EMPTY POCKETS.
NURSES

USE PLASTIC HANGING SPONGE-HOLDERS FOR LAPS AND RAYTEX

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, SEPARATE 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 bucket or ring stand).
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 pockets; 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 radiographic marker 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 red biohazard 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...
The Vagina

• Retained vaginal sponges after normal births
• Inserting non-radiopaque items into the vagina
  ➤ After gyn procedures esp laparoscopic
• Retained vaginal packs
  ➤ Dressing management plan
• Retained perineal prep swabs
  ➤ Anatomy deficits for foley insertion
Emergency Cases

- C-sxns are urgent/emergent BUT they are known and expected
- OB/ORs teams “do these all the time” so NOT novel
- Expectation is that experienced personnel are available
- Rooms are set up and ready to go
Emergency Cases

• The default is that you WILL BE able to use the practice

• It takes on average 1 sec per sponge to count IN therefore it takes ~10-15 seconds to count in 10 sponges

• Move the sponges out of the kick buckets into the holders

• Even if there is a plan to get an xray continue to put the sponges in the holders throughout the case
All eggs in X-ray basket

Misread x-ray
**MSI Imaging Guidelines**

- **Region of Interest specifics**
- **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 these 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><strong>MSI Cranium</strong></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><strong>MSI Chest</strong></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><strong>MSI Abdomen/Pelvis</strong></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><strong>MSI Vagina</strong></td>
<td>AP &amp; Inlet (2V)</td>
<td>Inferior gluteus to above crest and bilateral skin borders. Inlet must show the pelvic ring.</td>
<td>Inlet: Place 14x17 vertical with 25 degree caudal angulation. Special attention needed to avoid grid cut-off</td>
</tr>
<tr>
<td><strong>MSI Spine</strong></td>
<td>AP/PA &amp; Lateral</td>
<td>C-spine: Neck T-spine: Chest L-spine: Abdomen</td>
<td>C-spine: 11x14 T-spine: 14x17 L-spine: 14x17</td>
</tr>
<tr>
<td><strong>MSI Extremity</strong></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 RLR</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 morbidly obese patient. Image quality should be discussed with a radiologist.
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?
Case
“Because I Didn’t Have To”

- As in – no one made me do it

- As in – I know how to count 10 raytex and I don’t need to use the “counters” to do it
Yes you do! ...

- Even if there are only 10 sponges
- We know you know how to count...
- You are using the holders to PROVE where the sponges are, not to count them!
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 OR managers to train, perform audits and competency assessments and embrace reporting
The New Easy as 1-2-3

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Only works if you use it
Perspective

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