





NoThing Left Behind® 

What Have We Learned On The Way To ZERO?


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**Patient Safety First...
 a California Partnership for Health** 

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



Event	Additional Specifications	Implementation Guidance
<ul style="list-style-type: none"> • Unintended retention of a foreign object in a patient after surgery or other invasive procedure • Applicable Settings: <ul style="list-style-type: none"> - Hospitals - Outpatient/Office-based Surgery Centers - Ambulatory Practice Settings/Office-based Practices - Long-term Care/Skilled Nursing Facilities 	<ul style="list-style-type: none"> • Includes medical or surgical items intentionally placed by provider(s) that are unintentionally left in place <ul style="list-style-type: none"> • Excludes: <ol style="list-style-type: none"> a) objects present prior to surgery or other invasive procedure that are intentionally left in place; b) objects intentionally implanted as part of a planned intervention and; 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) 	<p>This event is intended to capture:</p> <ul style="list-style-type: none"> - 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 - Unintentionally retained objects (including such things as wound packing material, sponges, catheter tips, trocars, guide wires) in all applicable settings

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

Recently in California



CDPH Issues \$850,000 in Penalties to California Hospitals

Date: 09/20/11
Number: 11-02


December 2011




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

7 of the 14 related to retained surgical items

1. Fresno Surgical Hospital
2. LAC+USC
3. Mission Hospital Regional Med Ctr
4. Scripps Memorial
5. Sutter Solano
6. Torrance Memorial
7. Ventura County Med Ctr

Recently in California



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

1. Kaiser San Diego
2. Kaiser SF
3. Keck Hosp of USC
4. Mad River Community
5. Motion Picture and TV Hospital

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/Alerts>

Small Items/Fragments



- Two Types of Case based on LOCATION of event

- I. OR CASES
 - radiopaque items
 - non-radiopaque items
- II. Non-OR CASES

NLB Vernacular

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

NLB Vernacular

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

NLB Vernacular

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"

NLB Vernacular

Retained Device Fragments



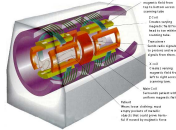
II. NON-OR CASES

- 1) Intravascular
 - ➔ Everywhere: cardiology, radiology, anesthesiology, ICU
 - ➔ Guidewires, catheters, sheaths, introducers
 - 2) Interstitial
 - ➔ Subcutaneous space, breast tissue
- Insertion Technique

Removal is desired



CRITICAL WARNING: AVOID METALS IN MRI
Within the metallic cones of an MRI scanner, the patient is surrounded by two electromagnetic coils and the components of a transmitter.



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

Disclosure vs. reporting



<http://www.ohsu.edu/portal/portal.cfm?nav=14438>

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



October 27, 2010

By [Shonda Nafziger](#), DOD Med 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 foreign matter left in a patient for three months after surgery.

- 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



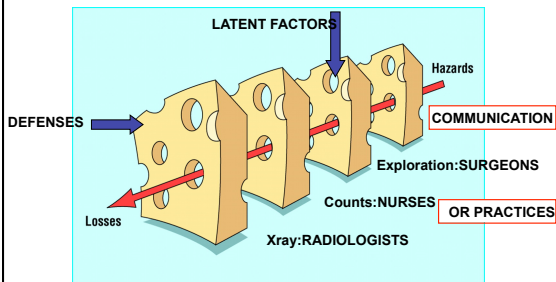
- Communication and Practice problems with the THREE major stakeholders

- ➔ 1. Surgeons
- ➔ 2. Nurses
- ➔ 3. Radiologists

Elements of Causation



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



Communication



• It's what is right not who is right

- Between nurses and surgeons
 - "We're missing a sponge" "OK, Lets 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
- Xrays 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.



50 lap pads accounted for

[NoThing Left Behind]

NLB Policy & Practice

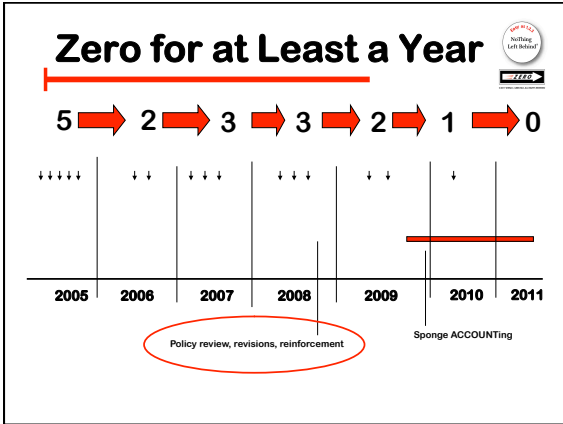


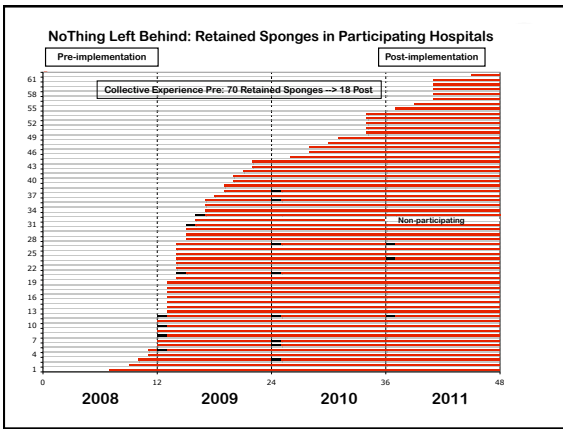
POLICY
NoThing Left Behind®:
Prevention of Retained Surgical
Items Multistakeholder Policy

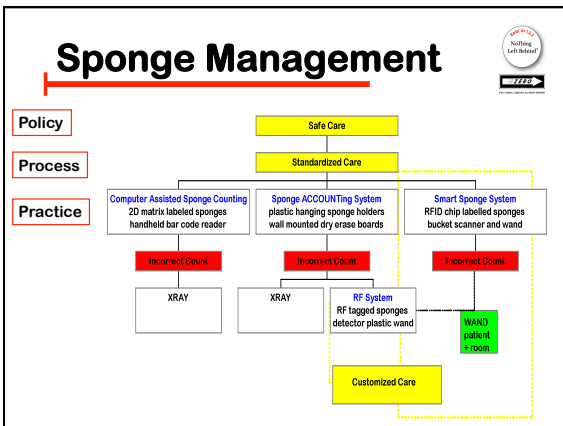
PRACTICE
WHERE ARE THE SPONGES?
ALL SPONGES
(used and unused)
ARE HERE

SPONGE ACCOUNTING

<http://www.nothingleftbehind.org>

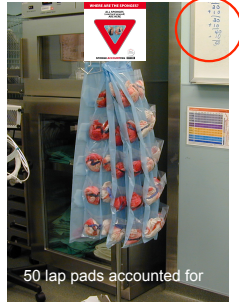




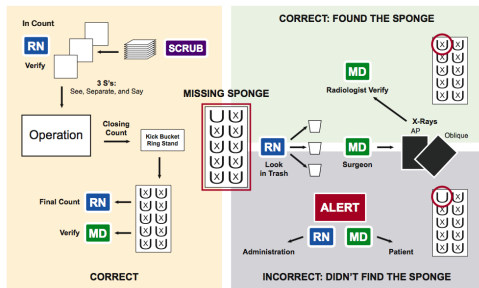


SPONGE ACCOUNTING SYSTEM *Monitoring "Sponge Traffic"*

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Trust but Verify



EASY AS 1-2-3

1.

SPONGE ACCOUNTING

3.

YIELD AND TAKE TIME TO RECTIFY AN INCORRECT COUNT
INCORRECT COUNT TRACK

2.

WHERE ARE THE SPONGES?
EASY AS

<p>1</p> <p>IN COUNT(S) ALWAYS</p> <p>CHECK SPONGES</p> <p>...for packaging errors.</p>	<p>2</p> <p>CLOSING COUNT TAKE A</p> <p>WOUND EXAM</p> <p>...to perform the Methodical Wound Exam.</p>	<p>3</p> <p>FINAL COUNT SAY</p> <p>SHOW ME</p> <p>...that ALL sponges are in the holders.</p>
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SPONGE ACCOUNTING

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

SURGEONS EASY AS 1,2,3

SPONGE ACCOUNTING PROCESS

1 CHECK SPONGES
IN COUNT(S)
Only use any identifiable sponges on wounds.
Don't fill them. Avoid use of small sponges in large cavities.

2 PAUSE THE GAUZE
CLOSING COUNT
Perform a methodical wound exam (MWE), to get all the sponges out. **CALL OUT** "I think all the sponges are out" THEN wait for closing advice.

3 SHOW ME
FINAL COUNT
Before you close the WOUND, look at the sponge holders to verify you are full. Then describe to support. → MWE was performed and sponges were accounted for.

PAUSE THE GAUZE
CLOSING COUNT
Methodical Wound Examination (MWE)
Don't just "Swish or Sweep"
The counting step on a wound must be completed prior to closure in every operation. The goal is to track the number of sponges used. Special focus should be given to closure of cavity with a cavity (i.e. head, thigh, neck, stomach, bladder, neck, and pelvis). Surgeons should check the SEE AND TOUCH technique when possible, utilizing only one element of sensory perception to verify sufficient. The surgeon should never rely solely on removal of sponges or the visual account for count.

The general process to look and feel in the creases of the wound and examine under early preincision and soft tissue approximation.
This is usually completed for a specific cavity. The following steps should be taken for procedure performed in the dissection of cavities. These steps should be performed before removing stationary or table-mounted drapes.

- Examine all four quadrants of the pad cover with attention to:
 1. Missing sponges within the pad.
 2. Missing sponges within the pad.
 3. Examine within and between tops of drapes.
 4. Missing sponges within the pad.
 5. Missing sponges within the pad.
- Look behind the backrest area if present and around the upper member.
- The angle should be maintained if one cannot see around a part of the member.

Unless clinically contraindicated for a specific patient, the following general steps should be taken for procedure performed in the dissection of cavities.

- In a methodical procedure, if the individual above were opened, examine the ipsilateral internal cavity.
- In a similar procedure, above the apex of the head and examine the suboccipital space.
- Examine the posterior view to the right and left of the area and posterior view.
- In a similar procedure, examine the anterior view of the abdomen from the umbilicus and anterior of the knee, posterior view of the abdomen, anterior view of the hip, then a head or large body in the upper extremities to the groin.

3 SHOW ME
FINAL COUNT
GET TO **KNOWLEDGE**

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



Surgical Safety Checklist



To: Surgeons, Anesthesiologists & CRNAs,
OR Nurses & Scrub Techs



GO LIVE: Friday, October 9, 2010
ALL TEAM MEMBERS ADD ALL SECTIONS

REQUIRED ACTIONS

1. Patient Identification

When the surgeons, anesthesiologist, OR nurse/scrub tech

Where: Prior to an OR procedure

2. Site, Side, and Procedure

When: Must be called by the ANESTHESIOLOGIST who must be present in the OR. The "Time Out" occurs before the anesthesia. OR questions must not have to be answered but must be in the room.

Where: "Time Out" must be performed **and** **before** the anesthesia is ready. The surgeon will not be present **until** the "Time Out" is completed.

3. Medication Review

When: Any medication, including IV, anesthesia drugs

Where: At the completion of the case

SEE THE NEW SVCA SURGICAL PATIENT SAFETY CHECKLIST (SVCA MTT TOOL)

Time	Surgeon	Anesthesiologist	OR Nurse/Scrub Tech
1. Patient Identification	<input type="checkbox"/> Yes	<input type="checkbox"/> Yes	<input type="checkbox"/> Yes
2. Site, Side, and Procedure	<input type="checkbox"/> Yes	<input type="checkbox"/> Yes	<input type="checkbox"/> Yes
3. Medication Review	<input type="checkbox"/> Yes	<input type="checkbox"/> Yes	<input type="checkbox"/> Yes

Patient Safety First... a California Partnership for Health



Time to Coordinate Efforts to Prevent Retained Surgical Items

There is NO excuse

SAFER SURGERY

Verna C. Gibbs M.D.



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