NoThing Left Behind®

What Have We Learned On The Way To ZERO?

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www.nothingleftbehind.org

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 Unretreived Device Fragments
3. Sharps/Needles
4. Instruments

NQF Required Reporting

Serious Reportable Events (SRE) 2011 Update

Event	Additional Specifications	Implementation Guidance
• Unintended retention of a foreign object in a patient after surgery or other invasive procedure • **Applicable Settings:** – Hospitals – Outpatient/Office-based Surgery Centers – Ambulatory Practice Settings/ Office-based Practices – Long-term Care/ Skilled Nursing Facilities	• **Includes** medical or surgical items intentionally placed by provider(s) that are unintentionally left in place • **Excludes:** 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)	**This event is intended to capture:** – 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

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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

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

Recently in California

August 2012

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

5 of the 13 related to retained surgical items

2 raytex, 2 lap pads, 1 towel

$275,000 fines

1. Kaiser SSF
2. St. Agnes
3. St Francis
4. Simi Valley
5. UC Irvine

Recently in California

December 2012

12 Hospitals cited with Administrative Penalties. Totaling $785,000

4 of the 12 related to retained surgical items

4 soft goods; 1 xeroform gauze, 2 laps, 1 raytex

$250,000 fines

1. Kaiser San Rafael
2. Methodist of Southern CA
3. Mission Hospital Orange County
4. Orange Coast Memorial

Why do they occur?

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

Miscellaneous Small Items

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

Device Fragments

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

http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices

Small Items/Fragments

- Two Types of Case based on LOCATION of event

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

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

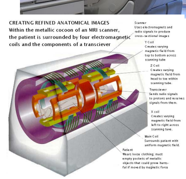
II. NON-OR CASES

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

2) Interstitial
   - Subcutaneous space, breast tissue

- Insertion Technique

Removal is desired

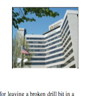


- MRI procedures problematic
- Magnetic fields can cause movement, migration
- Radiofrequency fields cause heating

Disclosure vs. reporting

http://www.dotmed.com/legal/print/story.html?nid=14628

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.

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

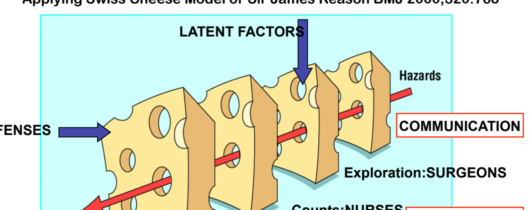
Engage with OR leadership to hone multistakeholder prevention strategies

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 <u>what</u> 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 occured 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

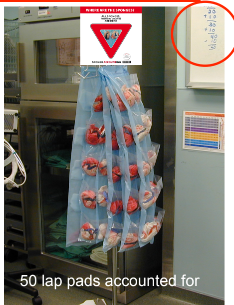
Findings

- 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.



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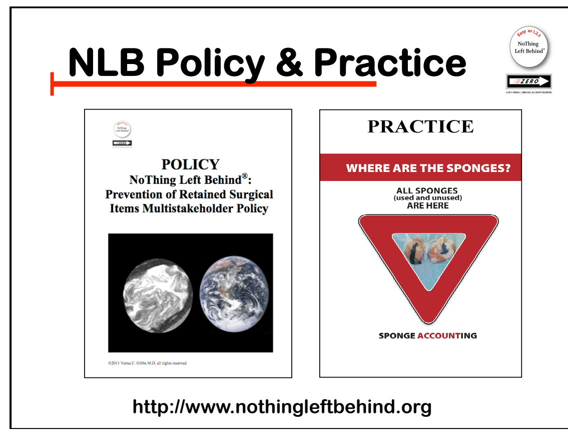
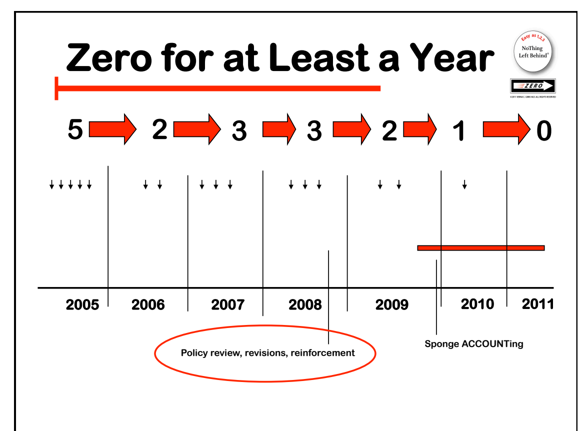
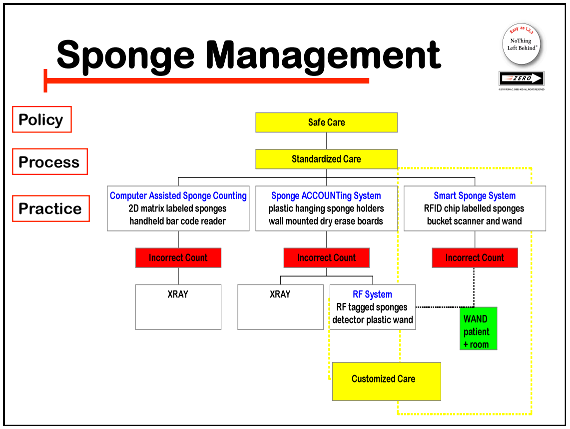
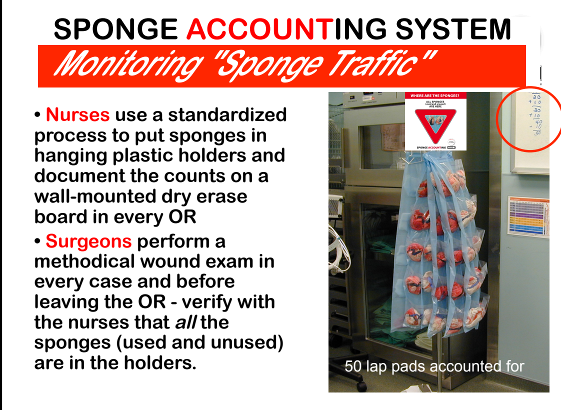
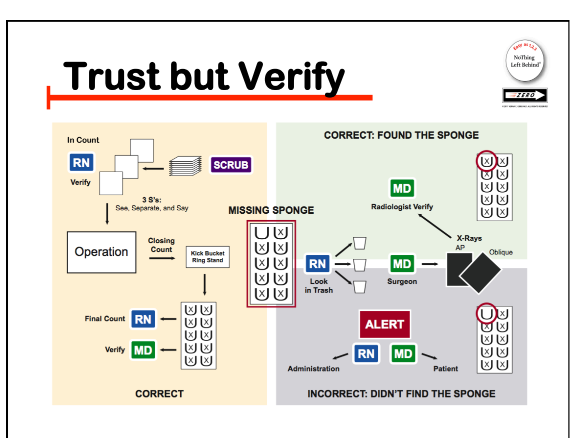

NLB Policy & Practice
POLICY
NoThing Left Behind®:
Prevention of Retained Surgical
Items Multistakeholder Policy
PRACTICE
WHERE ARE THE SPONGES?
ALL SPONGES
(used and unused)
ARE HERE
SPONGE ACCOUNTING
http://www.nothingleftbehind.org


Zero for at Least a Year
5 2 3 3 2 1 0
2005
2006
2007
2008
2009
2010
2011
Policy review, revisions, reinforcement
Sponge ACCOUNTing

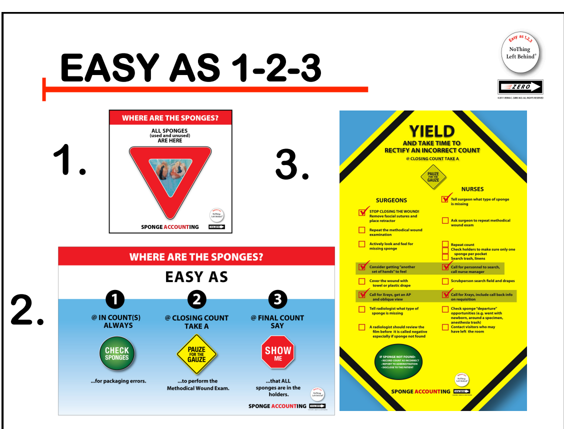
Hospitals here….


Sponge Management
Policy
Process
Practice
Safe Care
Standardized Care
Computer Assisted Sponge Counting
2D matrix labeled sponges
handheld bar code reader
Sponge ACCOUNTing System
plastic hanging sponge holders
wall mounted dry erase boards
Smart Sponge System
RFID chip labelled sponges
bucket scanner and wand
Incorrect Count
Incorrect Count
Incorrect Count
XRAY
XRAY
RF System
RF tagged sponges
detector plastic wand
WAND
patient
+ room
Customized Care


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


Trust but Verify
In Count
RN
Verify
SCRUB
3 S's:
See, Separate, and Say
Operation
Closing Count
Kick Bucket Ring Stand
Final Count
RN
Verify
MD
CORRECT
MISSING SPONGE
CORRECT: FOUND THE SPONGE
MD
Radiologist Verify
X-Rays
AP
Oblique
RN
Look in Trash
MD
Surgeon
ALERT
RN
MD
Administration
Patient
INCORRECT: DIDN'T FIND THE SPONGE

EASY AS 1-2-3



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 xray detectable sponges or towels. Don't alter them. Avoid use of small sponges in large cavities.

2 PAUZE FOR 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 ask for closing suture.

3 SHOW ME — FINAL COUNT: Before you leave the OR, look at the sponge holders to verify they are full. Then dictate in op report "a MWE was performed and sponges were accounted for."

CLOSING COUNT — Methodical Wound Examination (MWE)

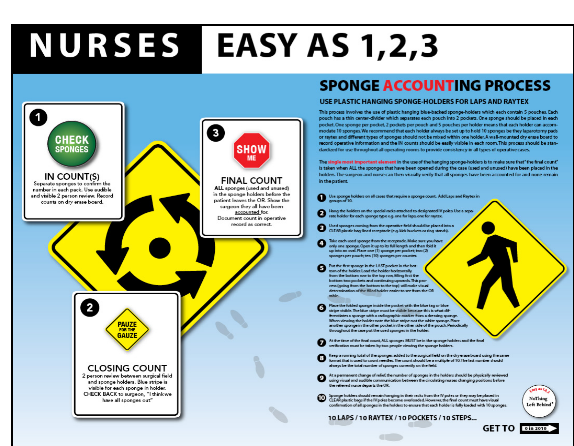
Don't just "Swish or Sweep"

FINAL COUNT

GET TO

Nursing Essence

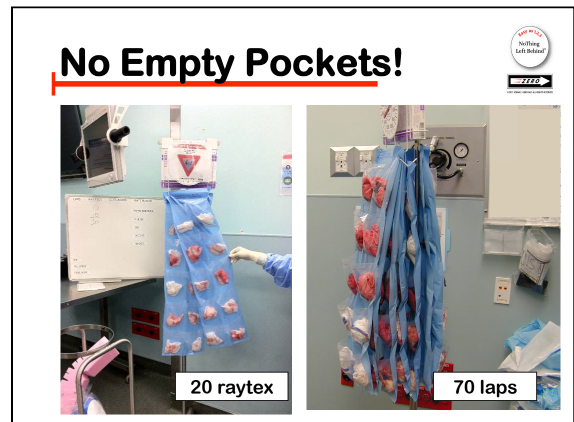
- In every case where an incision is made and surgical sponges are used, the sponges MUST be accounted for
- Work with free sponges ONLY in multiples of TEN
- At the IN count the most important element is to SEPARATE the sponges
- At the FINAL count all the sponges (used and unused) must be in the sponge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



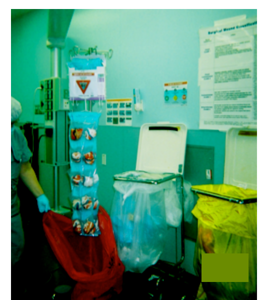
Always Multiples of 10

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

No Empty Pockets!



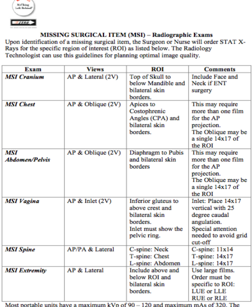
Biohazard Waste Disposal



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

Case

Radiology Guidelines



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.

Exam	Views	ROI	Comments
MSI Cranium	AP & Lateral (2V)	Top of Skull to below Mandible and bilateral skin borders.	Include Face and Neck if ENT surgery
MSI Chest	AP & Oblique (2V)	Apices to Costophrenic Angles (CPA) and bilateral skin borders.	This may require more than one film for the AP projection. The Oblique may be a single 14x17 of the ROI
MSI Abdomen/Pelvis	AP & Oblique (2V)	Diaphragm to Pubis and bilateral skin borders	This may require more than one film for the AP projection. The Oblique may be a single 14x17 of the ROI
MSI Vagina	AP & Inlet (2V)	Inferior gluteus to above crest and bilateral skin borders. Inlet must show the pelvic ring.	Inlet: Place 14x17 vertical with 25 degree caudal angulation. Special attention needed to avoid grid cut-off
MSI Spine	AP/PA & Lateral	C-spine: Neck T-spine: Chest L-spine: Abdomen	C-spine: 11x14 T-spine: 14x17 L-spine: 14x17
MSI Extremity	AP & Lateral	Include above and below ROI and bilateral skin borders.	Use large films. Order must be specific to ROI: LUE or LLE RUE or RLE

Most portable units have a maximum kVp of 90 – 120 and maximum mAs of 320. The xray 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.

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

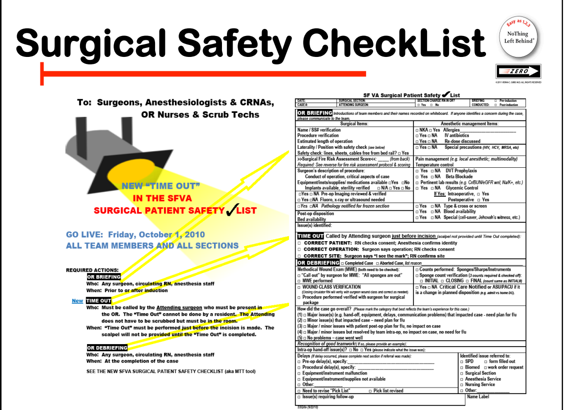
Incorrect Count CheckList

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

Use it Anywhere

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

Surgical Safety CheckList



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

NEW "TIME OUT"
IN THE SFVA
SURGICAL PATIENT SAFETY ✓LIST

GO LIVE: Friday, October 1, 2010
ALL TEAM MEMBERS AND ALL SECTIONS

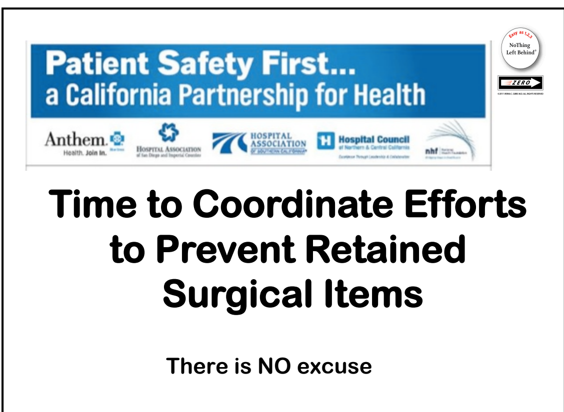
REQUIRED ACTIONS:

OR BRIEFING
Who: Any surgeon, circulating RN, anesthesia staff
When: Prior to or after induction

New **TIME OUT**
Who: Must be called by the Attending surgeon who must be present in the OR. The "Time Out" cannot be done by a resident. The Attending does not have to be scrubbed but must be in the room.
When: "Time Out" must be performed just before the incision is made. The scalpel will not be provided until the "Time Out" is completed.

OR DEBRIEFING
Who: Any surgeon, circulating RN, anesthesia staff
When: At the completion of the case

SEE THE NEW SFVA SURGICAL PATIENT SAFETY CHECKLIST (aka MTT tool)



Time to Coordinate Efforts to Prevent Retained Surgical Items

There is NO excuse