Open Mike: Questions and Answers on the Prevention of RSI

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www.nothingleftbehind.org

FREE Webinar Series

July – December 2014

• 6 monthly 1.5 hour sessions
• Prevention of RSI topics
• Policy & Practices
• L&D, ASC, Peds
• Needles, UDFs, SMIs
• Packing protocols
BECAUSE.....
RSI are considered to be NEVER EVENTS and the Incidence is 
STILL > ZERO
Four Classes of Items

1. Soft Goods
   a) Surgical Sponges
   b) Towels
   c) Dressings, Packs and Prep Swabs

2. Small Miscellaneous Items (SMI)
   includes parts of instruments
   Unretrieved Device Fragments (UDF)
   “risk of retrieval > risk of retention” items

3. Sharps/Needles

4. Instruments (the whole instrument)

Retained Surgical Items
WHEN IS AN ITEM RETAINED?
and therefore required to be reported

NQF Required Reporting
Serious Reportable Events (SRE) 2011 Update

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When is it retained?

• A surgical item is considered to be retained if it is found in the patient AFTER SURGERY

• 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

http://www.qualityforum.org/projects/hacs_and_sres.aspx
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?
When is it retained?

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.1 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?
  - Define in your 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
- 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

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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

The California Story

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
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 > Gyn 4 cases
    • 28 laps; 12 raytex; 3 towels
  ➤ 23 cases (31%) SMI
  ➤ 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

• 26 hospitals had soft goods cases but actually there were 27 patients because 1 hospital had 2 patients each with a retained sponge
• 2 of the 26 hospitals had AP (so already “counted”)
• 2 cases sponges were Not Retained*
• So there are 23 cases

* NQF definition

CDPH 2011- drill down

• 23 cases
  ➤ 8 lap pads, 8 raytex, 1 towel, 2 vag packs, 4 other types of sponges
  ➤ 11 retained in abdomen/abd wall
  ➤ 9 retained in the vagina
  ➤ 3 other sites (pacemaker pocket, back)
  ➤ 13 cases (57%) were OB/GYN procedures
  ➤ 2 cases involved Technology Adjuncts

NLB Vernacular
UHC 2011

- 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 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
Sponges are the most frequently retained items that cause clinical patient harm
   The most common site is the abdomen, then the VAGINA
SMIs and UDFs are the second most commonly retained items
   These should be reported and disclosed to patient
Needles are the most frequently miscounted items
Instruments are very uncommonly retained
   When retained the most common is a visceral retractor

RSI occur because of multi-stakeholder PRACTICE problems

The reason to address the problem isn’t just because of retention.
It’s because there are practice problems with surgical item management in procedures
DO UDF’S HAVE TO BE REPORTED?
Do we have to get an X-ray?

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/TipsandArticlesonDeviceSafety/ucm070187.htm
ECRI’s Top 10

- #7 Retained devices and unretrieved fragments

TJC Recommendations

“not an unintentionally retained foreign object

http://www.jointcommission.org/about/JointCommissionFaqs.aspx?CategoryId=11#498
### NQF Required Reporting

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### California Rules

**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 when 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)
So

- What should we do?
- Is there any work on a consensus definition?

......... Yes, CDPH is reviewing

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
- 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

What to do?

• A 9mm needle was unaccounted for at the end of an open heart operation
• Do we have to disclose to the patient?
• Do we have to report this event to CDPH
Answer

• This is an incorrect sharps final count
• Where is the needle? If you do not know with certainty then it could be in the patient….
• MD should disclose to the patient
• Show them the needle, give them options

Answer

• Get a CT scan with 4-5mm cuts
• If + you know where the needle is
• If – you know the needle isn’t in the patient (you don’t necessarily know where it is)
• No CT? You do not know it’s not in the patient so report to CDPH
• Do NOT charge the patient for the CT
But

- Do you offer a CT even when an x-ray is negative?
- Depends….. What kind of x-rays
- Who read the x-rays, where were they taken, how many views
- What are the characteristics of the missing object

The reason to address the problem isn’t just because of retention.
It’s because there are practice problems with surgical item management in procedures
WHAT ABOUT FOREIGN OBJECTS LEFT IN THE VAGINA? WHAT GETS LEFT BEHIND AND WHAT DO WE HAVE TO COUNT?

The Vagina

- Second most common site for sponge retention
  - Usually after vaginal birth
- Have a reliable sponge management practice used in L&D
The Vagina

• Most common site of retained packing
• Use only radiopaque material
  ➔ Can be discovered with x-ray
• The packing is considered a dressing
• Strong handoff practices to ensure removal
  ➔ 1) MD order
  ➔ 2) RN handoff
  ➔ 3) Inform the patient

The Vagina

• Panoply of retained SMI after laparoscopic hysterectomy
  ➔ Asepto bulbs, RUMI rings, cervical manipulators, olive tips, jellied gloves
• Practice problem with Surgeon in how to close the vaginal cuff
• Use something that can be transparently missed and therefore 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

Laparoscopic removal of retained raytex sponge

NLB Practice & Policy

PRACTICE
WHERE ARE THE SPONGES?

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

http://www.nothingleftbehind.org
Sponge Management

Policy

Process

Practice

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.
Only works if you use it

WHERE CAN I BUY THE SAS?

Next
You can’t

- The sponge holders and racks are available from any surgical distributor
- You use standard issue surgical sponges
- Follow defined multi-stakeholder practices outlined in manual
- There is also a video on the practice
- www.nothingleftbehind.org

Sponge Holders

- Have heard them called different things:
  - Counter bags
  - Sponge bags
  - Sponge Counters
  - Sponge Trees
  - Hanging shoe-bag counters
- NLB uses sponge holders because all they do is hold the sponges so everyone can see them
“Bagged” Sponges

Bag vs Holder

- Even if they are labeled “counter bags” or “sponge bags” we call them holders in SA
- Can you tell how many sponges?
- Which is more reliable?
Line buckets with clear bags

- Unused Sponge in White Bag
- Bloody Sponge in Red Bag
- Clear Plastic Bag

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
WHAT IS BEST PRACTICE REGARDING THE ADDITION OF SPONGES ON THE DRY ERASE BOARD?

No Hieroglyphics

1) Running total superscript format
   10 10 10
   10 20 30 40
2) Vertical summation
   10
   10
   20
   10
   10
   30
WHY ARE MULTIPLES OF TEN REQUIRED? LAP PADS COME IN PACKS OF FIVE?

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

- Ten pockets in holder will always have one sponge/pocket
- What does 5 empty pockets mean?
  - Forgot to add one pack of laps to count?
  - Really had 15 out?
  - Or……

The California Story

Reports from 10/25/2007 – 8/5/2013

74 Retained Surgical Item cases

- 43 Soft Goods
  - 28 laps; 12 raytex; 3 towels
  - 2 cases 5 retained sponges

How did this happen?

\[ 5 + 5 + 5 + 5 + 5 + 5 + 5 \]
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
• surprisingly is abrasion free…… once you do it
WHAT IS THE DIFFERENCE BETWEEN THE CLOSING COUNT AND THE FINAL COUNT?

Count Confusion

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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>OUT: Closing</td>
<td></td>
<td></td>
<td></td>
</tr>
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<td>OUT: FINAL</td>
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Using numbers, 1st, 2nd, 3rd is confusing and poor communication. What is the 4th or 5th count? Anyone can call for a count anytime so how do you “record” the 6th or other interim counts? You usually don’t….. Hence confusion.
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 (ie, 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 communication problems with just counting!
• Nurse A’s 2nd count is Nurse B’s 1st final count or maybe not…….
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. How many?
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

Next

IF WE THROW OFF ALL THE SPONGES WHAT ARE WE SUPPOSED TO USE FOR CLEANING THE PATIENT AFTER SURGERY?
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

Next

TJC TALKS MORE ABOUT COMMUNICATION PROBLEMS BUT YOU SPEAK ABOUT PRACTICE PROBLEMS – WHICH IS IT?
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
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

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
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

NLB Vernacular

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
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

Next

INSTRUMENT COUNTS
Seven points

1. Retained instruments are very rare
2. Use SPD specific count sheets
3. Track instruments in ONE place
4. MD MWE + ST review at closing count
5. Mandatory X-ray “in lieu” of count
6. See NoThing Left Behind policy
7. Reduce #’s of items on instrument trays

NLB Practice & Policy

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SAFE SURGERY

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