“LOSE A SPONGE LATELY?”

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C & S CONSULTING
Dr. Wesp is a paid consultant of RF Surgical Systems, Inc.
OUTLINE

1. WHAT IS THE DATA?

2. WHY DOES IT MATTER?

3. WHAT IS AVAILABLE?

4. A CMO’S PERSPECTIVE
GOSSYPHIBOMA

SURGICAL SPONGES UNINTENTIONALLY LEFT INSIDE A PATIENT DURING A SURGICAL PROCEDURE

**Incidence**
- Exact incidence under-reported
- Incidence between 1/100 – 1/7,000 procedures
- ~1,500-2,000 cases of RFI occur annually in US

**Variable time to Discovery**
- Mean of 21 days to detection
- 26% remain undetected for ≥60 days
- 40% discovered within 1 year
- 50% identified ≥5 years post surgery

Sources: Whang et al. Amer J Roen, 2009
COMMON RETAINED SURGICAL SPONGES

RSS – SPONGES, GAUZE & TOWELS

- Most common is 4X4 Raytec
- 2nd most common is Lap pad
- Reports of OR towels, tonsil, peanuts, etc. are rare:

  OR Towels  Tonsil sponge  Peanut  Cottonids

- Discovery - 50% after 5 years
  - Mass and or pain
  - Erosion - fistula, intestinal, obstruction
RETAINED SPONGES CAN OCCUR FOR VARIOUS REASONS

ERRARE HUMANUM EST (TO ERR IS HUMAN)

AORN HFMEA*
Frequency of Causes of Potential Failures in Sponge Management

- Circulator unable to see from location: 4%
- Surgeon continues to close wound: 5%
- Time Pressure (13%) + Emergency (5%): 18%
- Distraction: 21%
- Multitasking: 18%
- Not Following Procedures (Systemic Breakdown): 14%

Top Causes: 81%


AORN Recommendation VII (2010): Practice for Adjunct Technology to prevent RSI

“Perioperative staff members may consider the use of adjunct technologies to supplement manual count procedures”
WHY YOU CAN’T COUNT ON SPONGE COUNTS ALONE

DESPITE THEIR FREQUENT USE, MANUAL COUNTING & X-RAYS DO NOT PROVIDE DEFINITIVE PROOF AGAINST SPONGE RETENTION

Manual sponge counting alone does not prevent RSS

Historically, the primary intervention for preventing RSS has been manual counting

Counting identifies a retained item **77%** of the time when one is present

Nearly **88%** of all RSS occur when sponge counts are thought to be correct

1. Egorova et al. JACS, 2008
2. Gawande et al. NEJM, 2003
WHY YOU CAN’T COUNT ON XRAY

DESPITE THEIR FREQUENT USE, X-RAYS DO NOT PROVIDE DEFINITIVE PROOF AGAINST SPONGE RETENTION

X-Rays do not prevent RSS

- Recommended practices in the event of a miscount include intraoperative X-Rays\(^1\)
- Multiple X-Rays are required to cover the entire abdomen
- Patient exposed to unnecessary radiation & anesthesia time
- X-Rays identify a retained item 67% of the time when present\(^2\)
- Average cost of an X-Ray to address sponge miscounts: $286\(^3\)

1. AORN, 2014
2. Cima et al. NEJM, 2003
3. Williams et al. JACS, 2014
THE HIGH PRICE OF RSIs

THERE IS NEED FOR IMPROVEMENT

In a closed-case series of medical malpractice claims, RFOs in the vagina comprised approximately 27% of cases.¹

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RETIRED SURGICAL SPONGES: PATIENT SAFETY RISK

DESPITE INDUSTRY SPONSORED AWARENESS ATTEMPTS, SURGICAL SPONGES ARE STILL UNINTENTIONALLY LEFT INSIDE PATIENTS

**A Never Event, which must be prevented**

Retained Surgical Items (RSI) occur 39 times per week in the US

RSIs occur at a rate of 1 in every 5,500 surgical procedures

Retained Surgical Sponges are a Never Event

Mortality related to RSIs ranges from 11 – 35%

69% of retained surgical items are surgical sponges (RSS)

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RETAI NED FO REIGN OBJE CT = NEVER EVENT CLASSIFICATION

29 Events listed by the National Quality Forum (NQF)

Table. Never Events, 2011

The National Quality Forum’s Health Care "Never Events" (2011 Revision)

Surgical events

Surgery or other invasive procedure performed on the wrong body part

Surgery or other invasive procedure performed on the wrong patient

Wrong surgical or other invasive procedure performed on a patient

Unintended retention of a foreign object in a patient after surgery or other procedure

Source: www.nothingleftbehind.org
"Organizations should research the potential of using assistive technologies to supplement manual counting procedures and methodical wound exploration”

“Retained vaginal sponge is a reviewable sentinel event and is reportable as a breach in quality and patient safety”
REPUTATION OF HOSPITAL

PATIENT SAFETY IS A VITAL COMPONENT OF A HOSPITAL’S BRAND

“The damage to a hospital’s reputation from publicity surrounding a retained sponge is harder to calculate in dollar figures, but it is surely considerable”

- A-F letter grades issued, based on methodology that includes RSI
- RSI comprises 6% of total score

“It is very clear that for a hospital institution, community reputation is critically important to their branding, to their image, and they will respond if that information is transparent”

THE HIGH PRICE OF RSIs

A LEGAL PERSPECTIVE

From Law Firm’s Website:

“The solution to this widespread problem is diligent tracking procedures on the part of surgical teams along with the use of technological systems to detect items remaining in the body”

“No one should think negatively of medical malpractice cases, especially when it comes to RSI. Only when hospitals have to pay for their mistakes, will they make the extra effort to ensure that these adverse never events never occur”

Source: www.detlinglaw.com; March 2013
A COSTLY PROBLEM ON MANY LEVELS

RSS RESULT IN COSTLY RE-OPERATIVE EXPENSES, LEGAL BATTLES AND A COMPROMISED HOSPITAL REPUTATION

### Procedure Costs Considerations

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<td>10,000</td>
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### Legal Cost Considerations

| Average malpractice legal defense cost: | $43,258
| Average malpractice settlement cost:   | $327,726

**Surgical site Infections occur in 43% of RSS cases**

Average cost of SSI per patient: $25,543

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1. CMS-1390-P, 2008
2. J Law, Medicine & Ethics, 2012
THE INEFFICIENCY PROBLEM

MISCOUNTS CREATE INEFFICIENCY, WHICH CAN BE VERY COSTLY TO A HOSPITAL SYSTEM

Misscounts waste time

Sponge miscount rate:
1 out of every 150 procedures\(^1,2\)

Average OR time per miscount:
20 minutes\(^1,3\)

OR time is expensive

Avg. Cost of OR Time (per minute)

\$62\(^3\)

Procedure Volume | Probable Miscounts | Wasted OR Time | Financial Impact
---|---|---|---
10,000 | 67 | 1,333 minutes | \$82,667

2. Rupp et al. JACS, 2012
OUTLINE

1. WHAT IS THE DATA?

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2009 Systematic Review

Factors that could help minimize RSIs:
(1) Knowledge of risk factors
(2) Use of modern technology
(3) Improved perioperative patient processing systems
ADJUNCT TECHNOLOGY RECOMMENDATIONS

ORGANIZATIONS SHOULD RESEARCH THE POTENTIAL OF USING TECHNOLOGY TO SUPPLEMENT MANUAL COUNTING

Joint Commission calls for hospitals to address problem of objects left in surgical patients

Recommendation VII: Practice for Adjunct Technology to prevent RSI

“Perioperative staff members may consider the use of adjunct technologies to supplement manual count procedures”

Recommendations to prevent the retention of sponges, sharps, instruments

[ST-51] Statement on the prevention of retained foreign bodies after surgery
There are 3 FDA cleared companies offering adjunct technologies with confirmed hospital users:

1) SurgiCount Medical - Safety Sponge System  
   – Manual Scanning of Barcodes

2) ClearCount Medical – SmartSponge System  
   – High Frequency, RFID Technology

3) RF Surgical Systems- RF Assure® Detection  
   – Low Frequency, RF Detection Technology
BARCODE SPONGE COUNTING

SURGICOUNT MEDICAL (STRYKER)

- Ability to digitally count each sponge
- Requires a line of site
- Studies demonstrated improved ID of misplaced & miscounted sponges
- No in-vivo detection capability
- Could increase time spent counting

1. Williams et al. JACS, 2014
Background

- Evaluation of a computer-assisted method for counting sponges using a barcode system
- N = 298 (1/2 Barcode)

Key Takeaways

- Unable to determine if barcode could decrease retained sponge rate – small sample size
- Barcode system appeared to introduce new technical difficulties to counting process
- Abandoned in 5 of 150 procedures due to time constraints
- N = 33 sponges misplaced
  - 30 sponges found in trash, under drapes, on floor
  - 3 sponges found retained inside of patient

Source: Greenberg et al. Annals of Surgery • Volume 247, Number 4, April 2008
<table>
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<tr>
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<th>SurgiCount</th>
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<tr>
<td>N</td>
<td>148</td>
<td>150</td>
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<tr>
<td>Time =</td>
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<td>5.3 min</td>
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<tr>
<td>(per procedure)</td>
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“The bar-code system improved the ability of the surgical team to recognize discrepancies in the sponge count, but did not change the amount of time required to resolve discrepancies or the likelihood of requiring an x-ray to resolve a discrepancy.”

- Greenberg et al.
CIMA ET AL. JCAHO 2011

LARGE PROSPECTIVE RANDOMIZED EFFICACY STUDY

**Background**

- Evaluation to improve counting performance using barcode
- Primary endpoint: prevention of sponge RSIs at 18 months
- N = 87,404

**Key Takeaways**

- No RSIs were reported
- No work flow disruptions or increases in case duration
- Staff satisfaction acceptable, with a high degree of trust in system
- The barcode system proved to be a **reliable system** that improves patient safety
- **Study did not reduce X-Rays**
  - Mayo Clinic is one of the few US care providers using Intraoperative Imaging for **all open procedures**

Source: Cima et al. JCAHO • Volume 37, Number 2, February 2011
HIGH FREQUENCY RFID SYSTEM

CLEARCOUNT MEDICAL (STRYKER) – NO LONGER COMMERCIALLY AVAILABLE

• Provides sponge detection & identification
  – Wand & Bucket system

• Uses high frequency RF signal, which is compromised in the presence of fluid & metals

• Information on accuracy & effectiveness is limited

• Clinical feasibility study involving only 8 patients found detection accuracy to be 100%¹

1. Williams et al. JACS, 2014
THE RF SURGICAL SOLUTION

RF ASSURE DETECTION TECHNOLOGY USES A LOW-ENERGY RADIO FREQUENCY DESIGN TO DELIVER DETECTION OF MISPLACED SURGICAL SPONGES

- **Patient safety**
  Minimizes RSS for optimum patient safety & quality of care\(^1\)

- **Essential efficiency**
  Reduces unnecessary X-rays & sponge count related delays\(^2\)

- **Cost effective**
  Prevents repeat procedures, legal settlements & reimbursement losses associated with RSS\(^2\)

- **Proven performance**
  Clinically validated OR performance and compatibility\(^1,2,3,4\)

- **Complete compliance**
  Adheres to AORN, JCAHO & ACS recommended practices

\(^1\) Rupp et al. JACS, 2012
\(^2\) Williams et al. JACS, 2014
\(^3\) Steelman. Amer J Surg, 2011
THE RF ASSURE CONSOLE

THE RF ASSURE DETECTION SYSTEM - 3 EASY TO USE COMPONENTS

RF Assure Console
ConformPlusII Body Scanner
Blair-Port Wand

- User-friendly interface delivers fast feedback with minimal distraction
- Generates a unique confirmation number for essential recordkeeping and compliance
- Small footprint saves space in the OR environment
CONFORMPLUS II DETECTION MAT

THE RF ASSURE DETECTION SYSTEM - 3 EASY TO USE COMPONENTS

- Hands-free scanning for in-vivo sponge detection
- Scans for retained surgical sponges in 15 seconds
- Conforms to pressure ulcer reduction and relief standards (AORN)
ENABLES CONSISTENCY WITH OR WORKFLOW

CONFORMPLUS II ANTENNA ARRAY BODY SCANNER
THE BLAIR-PORT WAND

THE RF ASSURE DETECTION SYSTEM - 3 EASY TO USE COMPONENTS

- Quickly locates missing sponges in linen and trash bins and around sterile field
- Offers extended detection range in cardiac, trauma and bariatric cases when used with the Mat
- Reusable with sterile drape for reduced waste
RF ASSURE TECHNOLOGY – L&D APPLICATION

RF ASSURE DELIVERY SYSTEM

DESIGNED FOR LABOR & DELIVERY

• Non-intrusive design enables post-delivery vaginal scan
• Scans for angle and depth of the birthing canal
• Dual scanning capability
  - Birthing canal
  - Surrounding area
• Slim profile, portable
• Easy to use and clean
Focus on Labor & Delivery

- 69% of all RFBs
- 7% had >1
- 54% in abdomen
- **22% in vagina**
- 7% in thorax

-Gawande, 2003, NEJM
VERISPHERE

RF ASSURE DELIVERY SYSTEM – EVOLVED FOR LABOR & DELIVERY

- Designed for L&D – Vaginal Deliveries
- Eliminates the need to move the scanner in a pattern to achieve proper alignment with the RF Tag
- Merges functions of Blair-Port® Wand and ConformPlus™ Mat into single, portable scanner
The RF Detection System detected a sponge in ONE case in which the counts were reported as correct (1 / 2,285)

The RF Detection System help rectify in 35 cases with incorrect counts

No true RSIs occurred during the study period

No False Negatives, No False Positives reported during study period

**Conclusion:**

The incorporation of the RFDS resulted in the prevention of a surgical sponge (1 / 2,285) not detected by manual counting protocols and assisted in the resolution of 35 surgical sponge miscounts
Sensitivity of Detection of Radiofrequency Surgical Sponges: A Prospective, Cross-over Study

840 complete patient data points:
- True Positives: 619 (There were no false-positives)
- True Negatives: 221 (There were no incorrectly identified false readings)
- 100% sensitivity
- 100% specificity

404 morbidly obese subjects:
- 100% sensitivity
- 100% specificity

**Conclusion:** The sensitivity and specificity of RF sponge technology are much higher than published reports of surgical counts or published findings of intraoperative radiographs for retained sponges.
PROCEDURAL TIME SAVINGS

RF ASSURE DETECTION SYSTEM PROVIDES REDUCTION IN OR TIME

Williams et al., 2014
J Am Coll Surg

RSS Reduction (2010-2012)

Manual Counting

RF Technology

16 minutes shorter

“The data showed that over a 2-year period, OR time for RF users was on average about 16 minutes shorter”
- Williams et al.

• Resolving a count discrepancy, including radiography when the count cannot be reconciled, can take 13\textsuperscript{1} to 23\textsuperscript{2} minutes

• Would have resulted in average savings of $1,000 per case

2. Josephs, Patient Safety Presentation, St. Vincent Hospital, Worcester, MA
COST EFFECTIVENESS

COST SAVINGS & COST AVOIDANCE VS RF ASSURE IMPLEMENTATION COST

Williams et al., 2014
J Am Coll Surg

- Implementation cost offset by RF Technology’s efficiency
  - Decreased use of radiography & OR time
- Cost Savings & Cost Avoidance over implementation cost

1. Williams et al. JACS, 2014
LECTURE OUTLINE

1. RETAINED SURGICAL SPONGES – INCIDENCE & CAUSE

2. INSTITUTIONAL & STAKEHOLDER IMPACT OF RSS

3. ADJUNCTION TECHNOLOGIES AVAILABLE

4. CASE STUDY – A CMO’S PERSPECTIVE
St. Joseph Health is a $4.6 billion, integrated Catholic healthcare delivery system sponsored by the St. Joseph Health Ministry. We provide a full range of care facilities including acute care hospitals, home health agencies, hospice care, outpatient services, skilled nursing facilities, community clinics, and physician organizations throughout California, Texas and New Mexico. Our 24,000 dedicated employees strive daily to provide perfect care while building the healthiest communities and ensuring every encounter is sacred. SJHS is committed to maintaining a continuum of care that matches the diverse needs of the communities we serve.
KEYS TO SUCCESSFUL IMPLEMENTATION

8 SIMPLE RULES FOR GETTING IT DONE!

1. Engage
2. Define the Problem
3. Make it Personal
4. Present Data
5. Use the Literature
6. Integrate
7. Lobby
8. Don’t Give Up!
Dear Senior Leader,

Elimination of wrong-site procedures and retained foreign bodies are two of St. Joseph Health System’s Perfect Care goals. Numerous evidenced-based strategies have been identified to mitigate wrong-site and retained foreign bodies, including implementation of a Safe Surgery Checklist. The purpose of this letter is to provide background information, the tool, and outline ministry expectations and the senior leader’s role with implementation and sustainability.

The New England Journal of Medicine published an evidenced-based article in January, 2009, on the use of a standardized checklist for surgical processes. The goal of the checklist is to facilitate team dialogue to optimize communications, prevent complications, and reduce medical costs related to errors. It enables consistency in safety for patients and introduces (or maintains) a culture that values excellence. The rate of death was 1.5% before the checklist was introduced and declined to 0.8% afterward (P=0.003). Inpatient complications occurred in 11% of patients at baseline and in 7% of patients after introduction of the checklist. The outcomes were compelling, and shared with the SJHS Perfect Care Steering Committee; Quality Committee of the Board; Physician Leadership Team and the OR Leadership Group who recommended this strategy be adopted throughout SJHS.
Retained sponges – Discovery via X-Ray

Photos courtesy of Dr. Boyd, MHUHC
ROOT CAUSE ANALYSIS

WHY ARE RETAINED SPONGES HAPPENING IN OUR INSTITUTION?

- Count process not followed ($N = 7$)
- Device not included in count ($N = 3$)
- Staff change out/handoff during case ($N = 3$)
- Device: failure, parts disconnect ($N = 2$)
- X-ray quality (full field) / reading (delay) ($N = 2$)
- Staff knowledge (inexperienced, student, device components) ($N = 3$)
**Sponge Management**

**Policy**

- Computer Assisted Sponge Counting
  - 2D matrix labeled sponge
  - handheld bar code reader

**Process**

- Safe Care

**Practice**

- Standardized Care
  - Sponge ACCOUNTing System
    - plastic hanging sponge holder
    - wall mounted dry erase board
  - RFID Sponge Systems
    - RFID chip labelled sponge
    - bucket scanner and wand

**Incorrect Count**

- XRAY
- XRAY
- RF System
  - RF tagged sponge
  - detector plastic wand

**Customized Care**

**WAND**
- patient
- + room
• Engage OR staff and physicians in *solution development*
• Conduct a *gap analysis* of all count policies
• Develop *minimum standard* SJHS Count policy
  – *Ensure consistency* - based on evidence/best practice/learnings
• Re-evaluate technology for sponge counting and detection
  – Bar coding, RF, RFID
• Consider a *risk assessment* of commonly used equipment
  – Non-fixed equipment that could pose a risk for RFB
• Review and incorporate *recommendations* from key professional organizations
• Evaluate Medical Staff Rules and Regulations as it pertains to OR practices
• Evaluate and codify a *process* for physician and staff education of new equipment
• *Clarify* the definition of RFB
• Conduct an overall *Risk Assessment* of ministry OR’s
QUESTIONS & ANSWERS
RF SURGICAL systems

RFSurg.com