Unintended Retained Foreign Objects: The Mayo Story

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We were trying to understand the problem of RFOs.
Our initial focus

• Know our data

• Review our policies and procedures
  • Unify and make internally consistent
  • Clarify, explain, and improve with staff input
  • Constant education, auditing, and re-education

• Standardize and educate
  • When to count
  • Who is suppose to count
  • What to count
  • What to do (or not do) when others are counting
True RFOs (N=34)

Figure 3: Breakdown of Items Retained in Surgery

<table>
<thead>
<tr>
<th>Item</th>
<th>Quantity</th>
<th>Cum %</th>
<th>% of Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sponges</td>
<td>23</td>
<td>68%</td>
<td>68%</td>
</tr>
<tr>
<td>Instruments</td>
<td>8</td>
<td>91%</td>
<td>24%</td>
</tr>
<tr>
<td>Needles</td>
<td>3</td>
<td>100%</td>
<td>9%</td>
</tr>
</tbody>
</table>

Time Period: 2003-2006
### Site of RFOs

<table>
<thead>
<tr>
<th>Site</th>
<th>Sponge</th>
<th>Needle</th>
<th>Instrument</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abdomen/pelvis</td>
<td>11</td>
<td>3</td>
<td>1</td>
</tr>
<tr>
<td>Thoracic cavity/mediastinum</td>
<td>4</td>
<td>-</td>
<td>4</td>
</tr>
<tr>
<td>Head and neck</td>
<td>2</td>
<td>-</td>
<td>1</td>
</tr>
<tr>
<td>Cranium</td>
<td>1</td>
<td>-</td>
<td>1</td>
</tr>
<tr>
<td>Joint space</td>
<td>1</td>
<td>-</td>
<td>1</td>
</tr>
<tr>
<td>Soft tissue</td>
<td>1</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Obstretical/vagina</td>
<td>2</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Oropharynx</td>
<td>1</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>23</strong></td>
<td><strong>3</strong></td>
<td><strong>8</strong></td>
</tr>
</tbody>
</table>

Types of sponges retained: 7 ray-tecs, 11 laparotomy sponges, 1 cottonoid/peanut sponge, 4 unable to determine from record

Type of instruments retained: portion of vascular stent, shunt, device marker, malleable retractor, bulldog clamp, aneurysm clip, drill bit, pedicle marker
## Characteristics of RFO events

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>All (N = 68)</th>
<th>Near Miss (N = 34)</th>
<th>RFO (N = 34)</th>
<th>p-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age – yr</td>
<td>62.5 ± 19.3</td>
<td>67.6 ± 14.2</td>
<td>57.6 ± 22.5</td>
<td>0.033</td>
</tr>
<tr>
<td>Female Sex – no./Total no. (%)</td>
<td>25/68 (37%)</td>
<td>11/34 (32%)</td>
<td>14/34 (41.2%)</td>
<td>-</td>
</tr>
<tr>
<td>Count of Sponges and Instruments performed no./total no. (%)</td>
<td>65/68 (95.6%)</td>
<td>34/34 (100%)</td>
<td>31/34 (91.2%)</td>
<td>-</td>
</tr>
<tr>
<td>Counts considered correct</td>
<td>26/68 (38.2%)</td>
<td>3/34 (14.7%) §</td>
<td>21/34 (61.8%)</td>
<td>-</td>
</tr>
<tr>
<td>Body-mass Index #</td>
<td>29.0 ± 6.8</td>
<td>28.1 ± 5.2</td>
<td>29.9 ± 8.1</td>
<td>0.285</td>
</tr>
<tr>
<td>Duration of operation – min</td>
<td>345.6 ± 120.2</td>
<td>342.8 ± 82.7</td>
<td>348.3 ± 148.7</td>
<td>0.85</td>
</tr>
<tr>
<td>Estimated volume of blood lost - ml</td>
<td>480.8 ± 430.6</td>
<td>416.2 ± 317.3</td>
<td>468.1 ± 486.2</td>
<td>0.788</td>
</tr>
<tr>
<td>Blood loss of &gt; 500 ml or patient on autotransfusion – no./total no. (%)</td>
<td>32/68 (47.1%)</td>
<td>18/34 (52.9%)</td>
<td>14/34 (41.1%)</td>
<td>-</td>
</tr>
<tr>
<td>Operations performed on emergency basis</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>-</td>
</tr>
<tr>
<td>Operations performed after hours – no./total no. (%)</td>
<td>32/68 (47.1%)</td>
<td>18/34 (52.9%)</td>
<td>14/34 (41.1%)</td>
<td>-</td>
</tr>
<tr>
<td>Unexpected change in operation</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>-</td>
</tr>
<tr>
<td>&gt; 1 Surgical team involved- no./total no. (%)</td>
<td>6/68 (8.8%)</td>
<td>4/34 (11.8%)</td>
<td>2/34 (5.9%)</td>
<td>-</td>
</tr>
</tbody>
</table>

*+ values are means ± standard deviations;  
# Body Mass Index (BMI) is weight of patient in kilograms divided by square of the height in meters  
§ In 3 cases formal counting was not done as there was no existing policy for counts for those specific procedures. In these cases, the team in the OR believed that there was a discrepancy despite having a correct count at the end of the procedure  
¤ Operations that were started before 6 a.m. or completed after 4 p.m.
Root Cause Analysis of RFOs

• No association with the risk factors noted in the literature

• No association with personnel “shift” changes

• Most common factors associated with RFOs events at MCR
  • Failure to consistently follow standard operating room counting policies including proper documentation of the counts
  • Failure of communication between operating team members
Cardiac surgery case

- 45 minutes spent looking for a needle
- All policy and procedures followed
- No needle could be found
- Sponge count correct
“Tipping Point”

• Counting in the OR is a process
  • It can be standardized
  • Staff can be educated
  • Performance can be monitored
  • Feedback can be provided and performance can be “improved”
  • Unfortunately it was a flawed process

• Counting was not the primary problem

• Communication and team performance were the fundamental problems that needed to be addressed
Changing the Focus

• We started a conversation about how we communicate in the OR

• Leadership looked at how we addressed problems in the OR

• We re-focused our efforts towards
  • Promoting open and standardized communication
  • Recognize the contribution of all team members in the conduct and success of the operation

• Shift from a “team of experts” to an “expert team”
Time Lines for the Three-Phase Project

Phase I
Formation of Multidisciplinary Team
Defect Analysis and Policy Review

Phase 2
Awareness and Communication

Phase 3
Monitoring and Control

See Figure 3 for details.

Phase II: Awareness and Communication Plan, 2007

- All-staff meeting focused on RFO
- Simulation Center Video on “Perfect Counting Process”
- Correction process demonstration
- All-staff presentation on “Impact of Teamwork and Communication in OR”
- All-staff presentation on “High Reliable Surgical Teams”

Jan  Feb  Mar  Apr  May  Jun  Jul  Aug  Sep  Oct  Nov  Dec
Improved from ~ 14 days to ~ 70 days
Days Between Events

URFO Events: February 2009 – November 2013

Improved from ~ 70 days to ~ 170 days

Average Days Between Events

Date of Event:
- 2-9-2009
- 5-9-2009
- 8-9-2009
- 11-9-2009
- 2-9-2010
- 5-9-2010
- 8-9-2010
- 11-9-2010
- 2-9-2011
- 5-9-2011
- 8-9-2011
- 11-9-2011
- 2-9-2012
- 5-9-2012
- 8-9-2012
- 11-9-2012
- 2-9-2013
- 5-9-2013
- 8-9-2013
- 11-9-2013

Days Between Events:
- 0
- 20
- 40
- 60
- 80
- 100
- 120
- 140
- 160
- 180
- 200
- 220
- 240
- 260
- 280
- 300
- 320
- 340
- 360
- 380
- 400

Question Mark
Reduction Efforts

• Know your data
  • What is the real problem?
  • Does everyone agree that is the problem?
  • Does everyone know the data?

• Review the policies and processes
  • What are people suppose to be doing?
  • Are people really doing what they are suppose to be or say they are doing?
    • Policies are one thing... practice is another
    • Continually measure and improve

• Engagement
  • Leadership (institutional, surgical, nursing) and staff interacting in a bidirectional fashion

• A “new” way of thinking and doing
Summary

• Counting in the OR is not as simple as we all make it out to be.

• It is not the responsibility of a single person or a small group of people. It is the responsibility of the entire team.

• Individual and team communication skills are a fundamental safety skill-set that profoundly influences numerous other processes during the operation that contribute to a successful outcome.
How Did We Get Here?

• Policies
• White Boards
• Speak-Up (tucked items)
• Specific Steps in the Count Policy
• “Conscientious Count Campaign”
• Human Factors Expert Observations
• Adjunct Technology
Count Process

For every surgical patient, we will follow the steps:

**Count IN**
1. SCAN sponge material master tag
2. Manual COUNT sponges, instruments, sharps

**Tucked Items**
Must be verbalized, acknowledged & documented on white board

**Count OUT**
1. Manual COUNT of sponges, instruments & sharps
2. SCAN sponge material individual tags in groups of 2 towels, 5 laps & 10 raytec
3. BAG sponge material in groups of 2 towels, 5 laps & 10 raytec

**Pause Before Closure**
1. Everyone STOPS
2. VERIFY sponge, instrument, sharps counts with manual COUNT & white board
3. SCAN out sponge materials
4. “Team Agrees”

**Final Count**
1. Everyone STOPS
2. VERIFY counts of closure material with manual COUNT & white board
3. SCAN out all sponge material and CLOSE case report
4. “Team Agrees”
5. Open and apply dressing/pull drapes
Financial Implications

- Cost per Case: ~ $13 per procedure
- Cost per Year: ~ $780,000 per year
- Increased Patient Safety & Outcome
- Savings by Reduced Number of Events
Leadership Role

• Support Need for Change
• Select Section Champions (Change Agents)
• Promote Innovative Thinking
• Fiscal Responsibility
The Sponges

- Unique label
  - Data matrix code
  - ID number
- Virtually impossible to remove label
- If cannot scan, can manually enter into the counter
Technology

• Data-Matrix Coded Products
  • 2 Year investigation and implementation process

• Two Trials
  • Modifications After Each
Modifications

- Screen shots
  - Reduced # of information fields
  - Scan to enter data i/o typing data

- Tags
  - Originally on midline of sponge
  - Offset 6 mm towards side of sponge
Training and Support

• On-site Support from the company (1 per specialty with a pager)

• Daily Updates
  • Tips & Tricks
  • User Suggestions
  • Q & A

• Evaluation of Implementation

• Ongoing Support
Training and Support

- Announced Change Coming (D-5)
- Articles in Fact Sheet (D-4)
- Information / Example of Scanner (D-3)
- Trained Super-Users (D-2)
- Train All Staff / Skill Check-Off (D-1)
- D-Day! Monday, February 2, 2009
Sponge Counter and Software

- Color touch-screen
- 10 hour battery life
- Modifiable user settings
- Audible & visual cues
- Hand-held or hands-free modes
Count Out

COUNT OUT

IN   OUT   LEFT

18x18  5    3    2

Volume: HIGH

Battery: 98%
Lessons We Learned

• Requires Paradigm Shift in Thought
• No Single Panacea
• Continuous Attention
  • Daily Reminder: RFO Board #
• Ongoing Support
  • Shared Reports of Events or “Near Miss” stories
Number of Days Without a Retained Foreign Object...

107
Future Goals

• Tracking Instruments
• Tracking Sharps