Employment of Root Cause Analysis and Lean Techniques to Improve Communication of Surgical Retained Foreign Objects

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What surgeons leave behind costs some patients dearly

Two victims discuss surgical items that were left in their bodies and how it has affected their daily lives since. An expert talks about how retained sponges happen, and a new technology to help ensure patient’s safety.

Peter Eisler, USA TODAY 8:28 a.m. EST March 8, 2013

More than a dozen times a day, doctors sew up patients with sponges and other supplies mistakenly left inside. The mistake costs some victims their lives.

USA Today March 8, 2013
Introduction

- Surgical retained foreign objects (RFOs) remain a source of patient morbidity and mortality, despite decades of proactive work to eliminate their occurrence. Most recently, RFOs have been considered “never” events by the Centers for Medicare and Medicaid Services (CMS), with no provider payments for related expenses and as Sentinel Events by The Joint Commission.
- Root Cause Analysis (RCA) is a long-established technique to understand the causative factors in an untoward event, with the goal of complete elimination. Although often considered a self-contained quality system, RCA has its foundation in both traditional quality techniques such as the Plan-Do-Study-Act (PDSA) cycle and Lean healthcare methods.
- This exhibit will demonstrate the application of Lean methodology within the framework of Root Cause to eliminate RFOs.

Retained Foreign Objects (RFOs)

- Surgical RFOs are a preventable cause of morbidity and mortality
- Estimates of incidence range from 1 in every 1,000 abdominal operations to 1 in every 18,000 inpatient operations
- Substantial risk factors for RFOs include high Body Mass Index (BMI), emergency surgery, multiple surgical procedures, multiple surgical/nursing teams, prolonged surgery and unplanned change in operative strategy
Common Surgical RFOs

- Soft goods, such as sponges and towels
- Device components or fragments (such as broken parts of instruments), stapler components, parts of laparoscopic trocars, guidewires, catheters, and pieces of drains
- Needles and other sharps
- Instruments, most commonly malleable retractors

"URFOs refer to any item or foreign object related to any operative or invasive procedure that is left inside a patient"*


Lap Sponge: Right Lower Quadrant
The Most Common Root Causes of RFOs Voluntarily Reported to The Joint Commission

- The absence of policies and procedures
- Failure to comply with existing policies and procedures
- Failure in communication with physicians
- Failure of staff to communicate relevant patient information
- Inadequate or incomplete education of staff

The Joint Commission, Sentinel Event Alert. Issue 51: October 17, 2011

RFOs: Considered Fully Preventable

The National Quality Forum: RFO as a Required Reportable Event

Agency of Healthcare Research and Quality: RFO as a “Never Event”

http://www.qualityforum.org

http://www.ahrq.gov
RFOs: Errors in Practice and Communication


Root Cause Analysis (RCA)

- Devised in the 1950s by the National Aeronautics and Space Administration (NASA)
- A factor is considered a root cause if removal from the process prevents the final undesirable event from recurring
- A (direct) causal factor is one that affects an event's outcome and may decrease the likelihood of recurrence, but can’t prevent it entirely
- RCA is typically employed after an event has occurred, but it is potentially useful to predict potential adverse events even before they occur and therefore avoid poor outcomes

RCA: Basic Elements

- Systematic
- Multidisciplinary team effort with strong leadership
- No “blame or shame”
- Simplest or lower cost solution preferred
- Solutions by consensus and “achievable”
- Evaluate sequence of events/timeline
- Ask “why?” multiple times
- Iterative and continuous process with verification of success
- Eliminate barriers
- Potential to transform reactive to forward-looking culture

RCA Process Evaluation

- Human factors
- Environment
- Equipment
- Information/communication
- Training
- Policy and procedure
- Cultural barriers
RCA Processes

RCA and Lean

- RCA employs techniques that are common to other quality methodologies, including Lean
- Lean methodology was adapted from the Toyota Production System (TPS)
- Lean philosophy: Produce only what is needed, when it is needed, with no waste
- Lean approach requires determination of value added for each step in the process
- Standardization is an essential Lean component
Lean Applications to Healthcare

- Focus on value as defined by the customer
- Empower all in a blameless environment
- Align service quality, timing and location (Just in Time = JIT)
- Prevent waste (Muda)
- Error proof processes
- Level work loads (Heijunka)
- Standardize and sustain work
- Strive for continuous flow (people, supplies, equipment, information, processes) rather than batches

What is Waste?

Anything the customer does not perceive as value

- Defects
- Overproduction
- Waiting
- Neglect of Human Talent
- Transportation
- Inventory
- Motion
- Excess Processing

D.O.W.N.T.I.M.E. Goal = Zero Waste
Common Tools for Process Visualization: Spaghetti and Fishbone Diagrams

Spaghetti Diagram
Useful for documentation of flow

Fishbone Diagram
Useful for evaluation of causation

The RFO RCA Process

- Request for RCA can originate from anyone
- RCA convenes all stakeholders. For RFO:
  - Surgery: nursing, assistants, surgeons, trainees, perioperative personnel
  - Radiology: operations, technologists, radiologists
  - Information Technology/PACS
  - Risk management
- Policies and processes evaluated for areas of “risk”
  - Current procedures and pathways mapped including responsibilities and flow of people, information. Emphasis on why the current state exists
  - Unclear steps, inefficient methods or “breakdown points” identified with interventions mapped and standardization planned
  - Educational scope and methodology planned
RFO Process:
Evaluation of the Root Causes

- Commercially available electronic data search/aggregator used to identify radiologic procedures with RFO codes
- Expected exam information gathered
  - STAT order with ordering caregiver, history
  - Accession number (RIS/PACS exam identifier)
  - Attending radiologist (code assigned)
  - Report
- Exam report evaluation
  - Presence/absence of foreign body
  - Documentation of conversation with surgeon including name, date and time

RFO : 6 Month Data Collection

<table>
<thead>
<tr>
<th># Exams for FB</th>
<th>#/% Ordered “Stat”</th>
<th>#/% with Adequate hx</th>
<th>#/% with Report Documentation</th>
<th>#/% Exams with FB</th>
<th>#/% FB with Report Documentation</th>
</tr>
</thead>
<tbody>
<tr>
<td>374</td>
<td>91/24%</td>
<td>36/10%</td>
<td>63/17%</td>
<td>12/3%</td>
<td>2/17%</td>
</tr>
</tbody>
</table>

Further evaluation and interventions needed
RFO Exams: When do They Occur?

Are we staffed adequately?
- Technologists
- Radiologists
Are we adequately equipped?
The RFO RCA Process: Results

- Exam frequently not ordered as “STAT” with interpretation
- STAT RFO exam indistinguishable from other STAT studies on the PACS work list
- Suspected RFO type typically not listed
- Type of surgery, reason for request and expected RFO location not listed
- Appropriate radiologist not always notified of exam in timely manner
- Ordering surgeon contact information not always available and may no longer be in the operating room
- Surgeon may already have “closed” the patient prior to receipt of report
- Radiologist may not document RFO communication in report
- Report may not be signed in a timely manner

RFO Evaluation Process: Communication Lapses as Root Causes

- Communication of need for exam and location
- Communication of exam type and urgency
- Communication of reason for exam
- Communication of surgical procedure, suspected RFO type and anatomic location
- Communication of ordering surgeon and contact information
- Communication of pending exam to radiologist
- Communication of results from radiologist to surgeon

What could go wrong? The Need to Standardize
RFO: Historic Communication
Flow of Information

Potential danger points addressed:
✓ Technologist unaware of request for exam
✓ Radiologist unaware of request for review in PACS
✓ Radiologist unaware of type/location of suspected RFO
✓ Radiologist can’t locate ordering surgeon
✓ Patient “closed” prior to report receipt
✓ Radiologist does not include documentation in report

The RFO RCA Process: Policy and Procedure Revisions

- Radiology RFO procedure codes were introduced September, 2012
  - Must be ordered “stat” with history including suspected RFO or reason for exam if not suspected, type and site of surgery, surgeon, pager/extension. Exam to be ordered before needed for causes that are predictable to assure prompt imaging
- IT solutions including display of RFO code, exam to top of PACS work list
- Technologist to notify appropriate reading area/radiologist of exam verbally and document in PACS
- Surgeon to remain available for results reporting and avoid “closing” the patient
- Radiologist’s role is to immediately contact the Attending Surgeon/Proceduralist, at the extension/pager provided to communicate the radiograph findings, or make a recommendation for additional imaging
- All communication to be documented in templated, final report with method, date, time and recipient
- Electronic, “pop-up” communication field to be instituted for redundancy
Communication: The Order

What’s missing?
- “STAT” designation
- Type of RFO
- Type of Surgery
- OR location
- Contact information

Revision of the EMR Order:
Required Fields

- Exam type
- STAT designation
- Specific RFO Code
- Procedure and OR
- Surgical team members
- RFO trigger
- Suspected location
- Suspected RFO type
- Surgeon pager (autopage function)
RFO: PACS Work List Revision

- RFO studies identified by exam type, previously just as “STAT"
- RFO studies to the “top” of the work list: prioritized
- Educational effort for faculty, trainees

Communication: The Report

What’s missing?
- Evidence of direct reporting
- Who was contacted?
- How were they contacted?
- When were they contacted?
Standard and electronic communication

**Templatting the Report**

**RFO : Concurrent Interventions**

- Repeated education of faculty/trainees/radiology and surgery personnel: in person, electronic, M & M presentations and by policy publication
- Compliance of individuals provided to section chiefs/program director, with ongoing review of radiologist and surgeon adherence to policy
- Continued noncompliance dealt with by VC/CQO radiology, surgical section chiefs, program directors as an opportunity to raise awareness and improve patient care
Data Summary: Documentation of Communication*

- Baseline data
  - 63/374 (17%)
- After intervention 1
  - 58/95 (61%)
- After intervention 2
  - 79/95 (83%)
- After intervention 3
  - 89/101 (88%)
- Currently
  - 93%: Review is continuous!

* Spans several RCAs

Conclusions

- Surgical retained foreign objects remain a stubborn quality issue, despite significant publicity and external oversight
- Root cause analysis is a time proven amalgam of methods that can successfully uncover and solve multifactorial process issues that result in RFOs
- Root cause analysis utilizes techniques that are common in other quality improvement methodology, including Lean
- Consistent application of Lean principles, including involvement of all stakeholders, lack of blame, striving to decreasing waste, and standardization of policies and processes to sustain improvements can provide successful solutions to avoid RFOs
Suggested Readings