THE UNIVERSITY OF CHICAGO MEDICINE

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

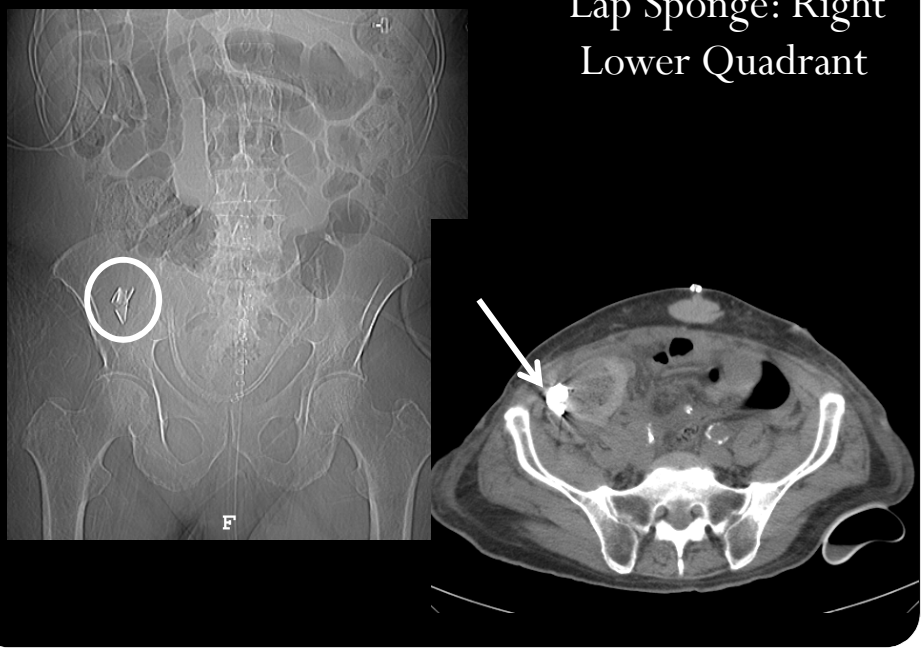
Common Surgical RFOs

- 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"*

*The Joint Commission, Sentinel Event Alert. Issue 51: October 17, 2013

Lap Sponge: Right Lower Quadrant



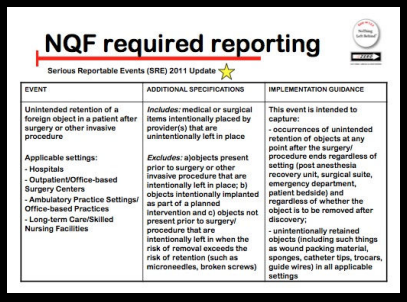
The Most Common Root Causes of RFOs Voluntarily Reported to The Joint Commission

- 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, 2013

RFOs: Considered Fully Preventable

The National Quality Forum: RFO as a Required Reportable Event



NQF required reporting

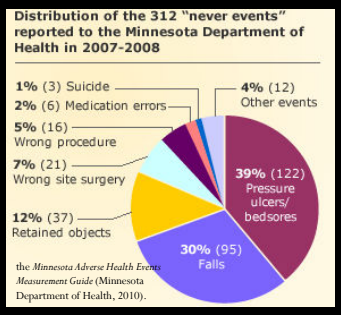
Serious Reportable Events (SRE) 2011 Update

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

NATIONAL QUALITY FORUM

http: www.qualityforum.org

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

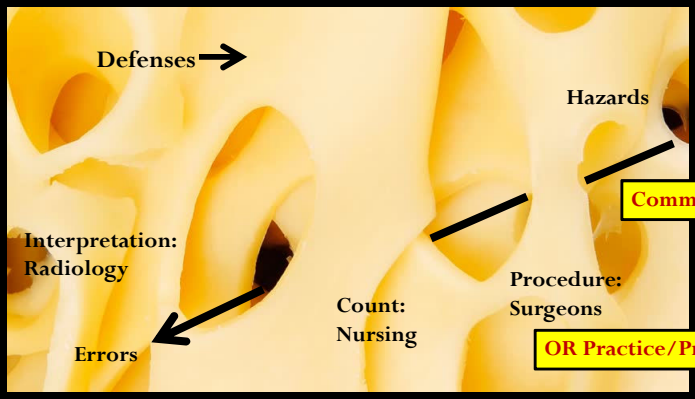


the *Minnesota Adverse Health Events Measurement Guide* (Minnesota Department of Health, 2010).

AHRQ Agency for Healthcare Research and Quality
Advancing Excellence in Health Care www.ahrq.gov

http: www.ahrq.gov

RFOs: Errors in Practice and Communication



After Reason J. *Human Error: Models and Management*. BMJ 2000; 320: 768-770.

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

http://www.hq.nasa.gov/office/codeq/rca/rootcauseppt.pdf

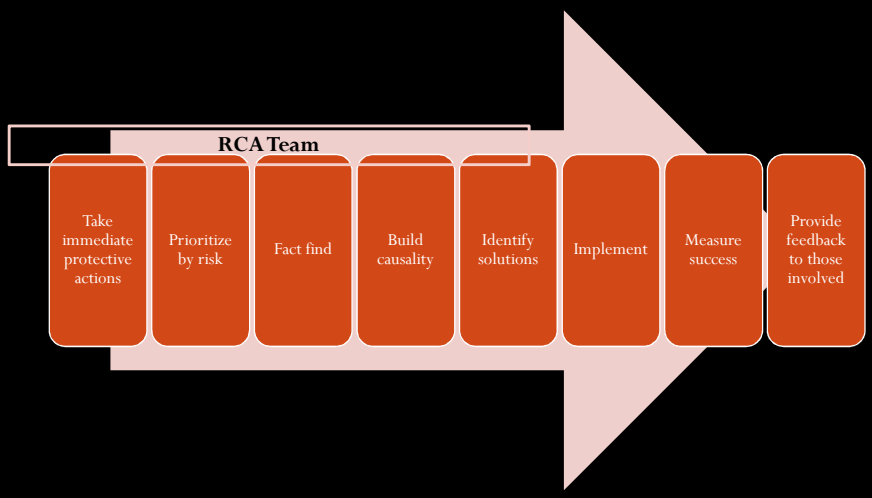
RCA: Basic Elements

- 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

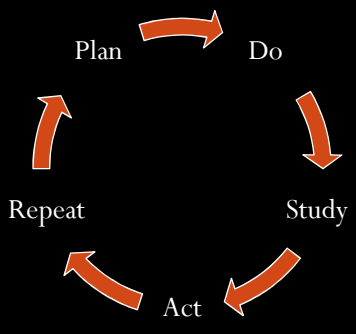
- Focus on value as defined by the customer
- Empower all in a blameless environment
- Align service quality, timing and location (Just in Time = JIT)
- Prevent waste (Muda)
- Error proof processes
- Level work loads (Heijunka)
- Standardize and sustain work
- Strive for continuous flow (people, supplies,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

What is Waste?

Anything the customer does not perceive as value

- **D**efects
- **O**verproduction
- **W**aiting
- **N**eglect of Human Talent
- **T**ransportation
- **I**nventory
- **M**otion
- **E**xcess Processing

D.O.W.N.T.I.M.E.

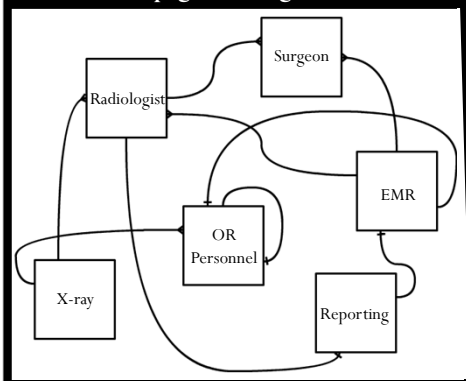


Goal = Zero Waste

Common Tools for Process Visualization: Spaghetti and Fishbone Diagrams

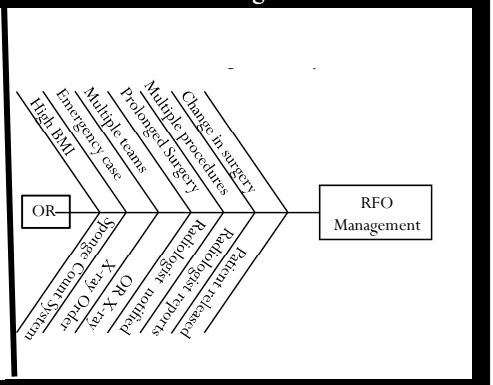
Useful for documentation of flow

Spaghetti Diagram



Useful for evaluation of causation

Fishbone Diagram



DM Paushter 2015

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

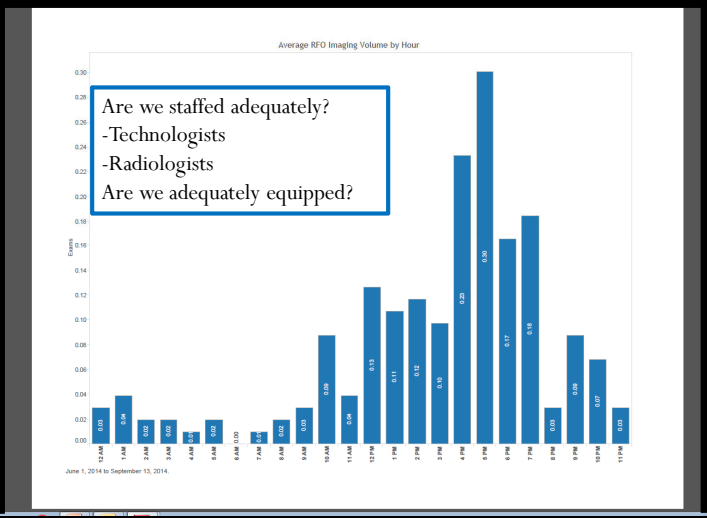
- Commercially available electronic data search/aggregator used to identify radiologic procedures with RFO codes
- Expected exam information gathered
  - STAT order with ordering caregiver, history
  - Accession number (RIS/PACS exam identifier)
  - Attending radiologist (code assigned)
  - Report
-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

RFO : 6 Month Data Collection

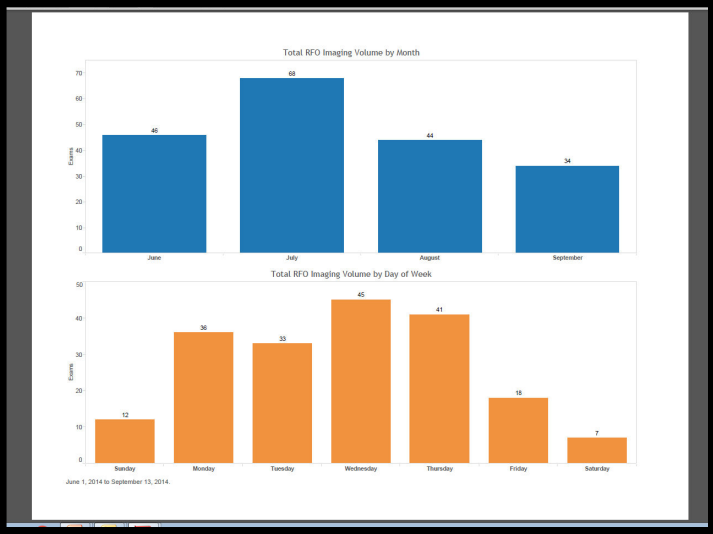
# Exams for FB	#/% Ordered "Stat"	#/% with Adequate hx	#/% with Report Documentation	#/% Exams with FB	#/% FB with Report Documentation
374	91/24%	36/10%	63/17%	12/3%	2/17%

Further evaluation and interventions needed

RFO Exams: When do They Occur?



RFO Exams: When do They Occur?



The RFO RCA Process: Results

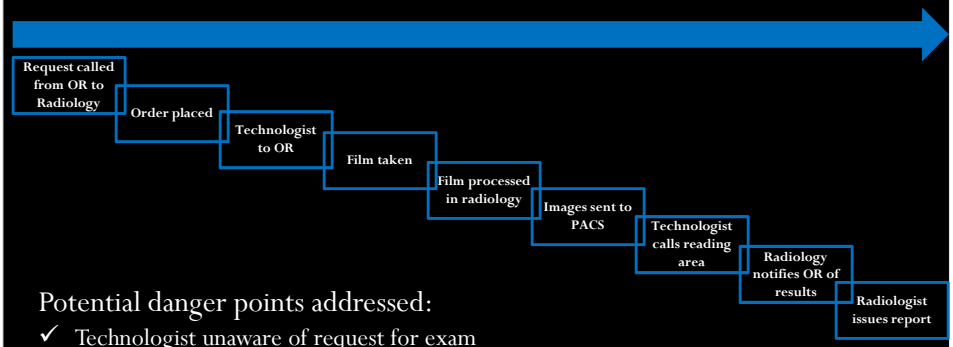
- Exam frequently not ordered as "STAT" with interpretation
- STAT RFO exam indistinguishable from other STAT studies on the PACS work list
- Suspected RFO type typically not listed
- Type of surgery, reason for request and expected RFO location not listed
- Appropriate radiologist not always notified 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

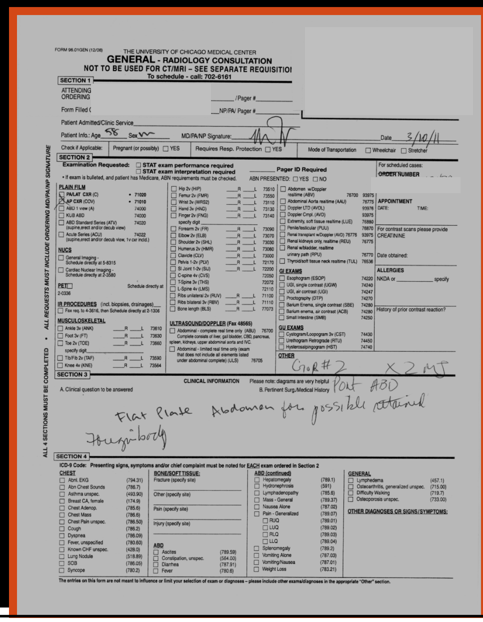
DM Paushter, 2015

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



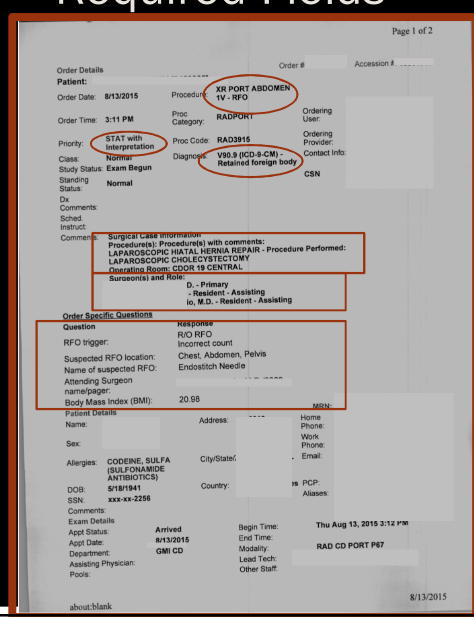
Revision of the EMR Order: Required Fields

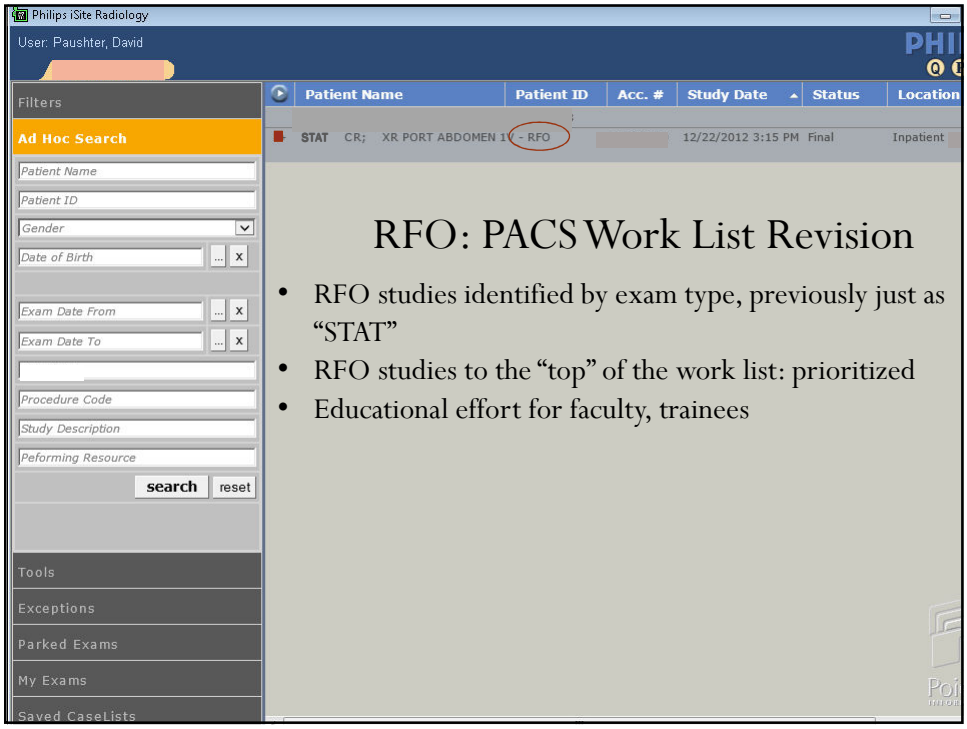
Exam type

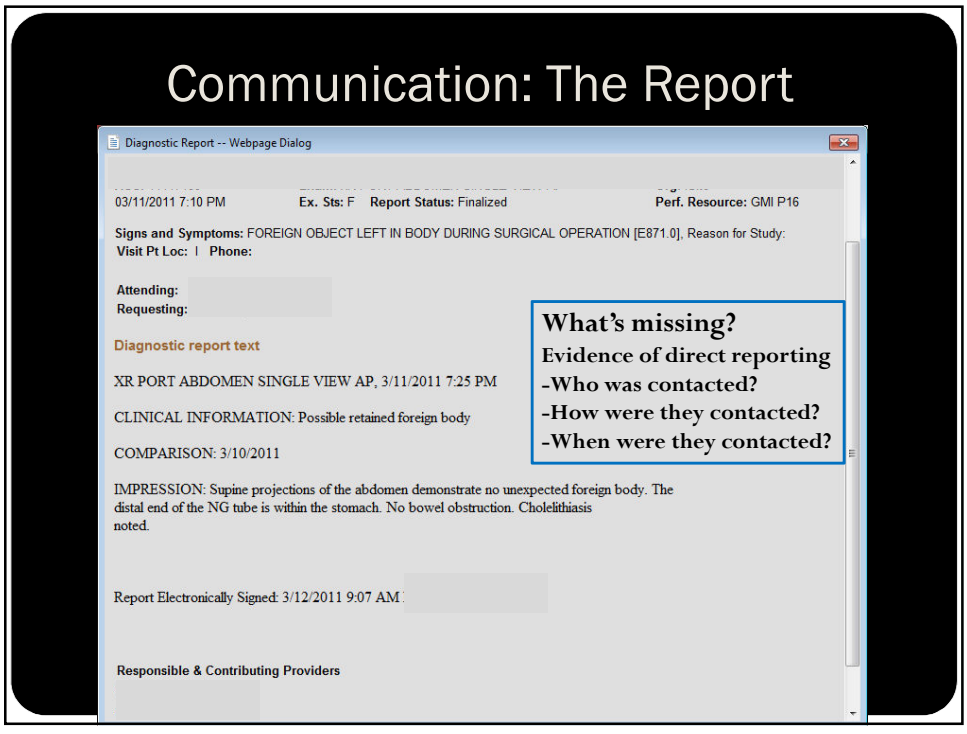
STAT designation
Specific RFO Code

Procedure and OR
Surgical team members

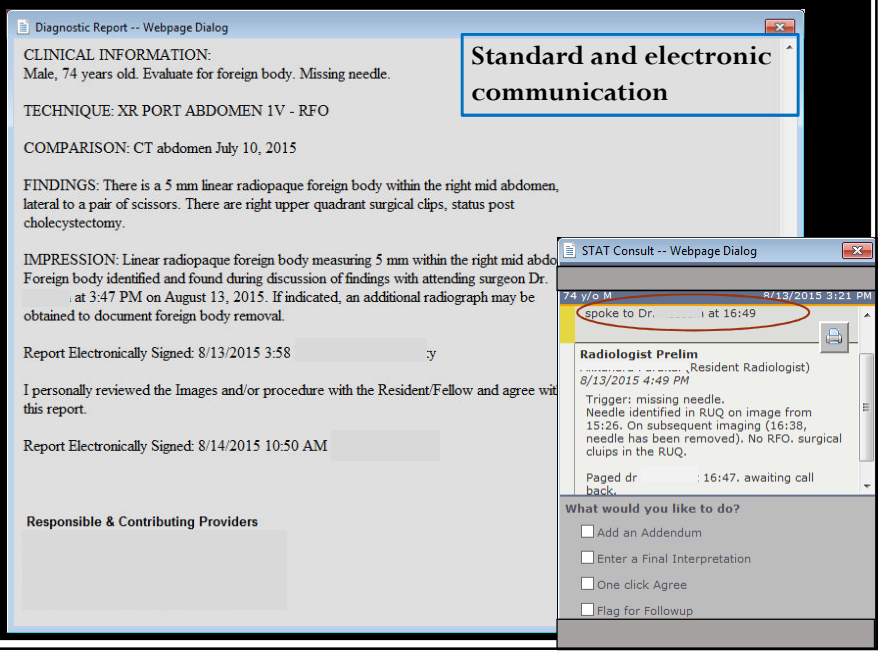
RFO trigger
Suspected location
Suspected RFO type
Surgeon pager
(autopage function)




Philips iSite Radiology
User: Paushter, David
Filters
Ad Hoc Search
Patient Name
Patient ID
Gender
Date of Birth
Exam Date From
Exam Date To
Procedure Code
Study Description
Peforming Resource
search
reset
Tools
Exceptions
Parked Exams
My Exams
Saved CaseLists
Patient Name
Patient ID
Acc. #
Study Date
Status
Location
STAT CR; XR PORT ABDOMEN 1 - RFO
12/22/2012 3:15 PM Final
Inpatient
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
Diagnostic Report -- Webpage Dialog
03/11/2011 7:10 PM
Ex. Sts: F
Report Status: Finalized
Perf. Resource: GMI P16
Signs and Symptoms: FOREIGN OBJECT LEFT IN BODY DURING SURGICAL OPERATION [E871.0], Reason for Study:
Visit Pt Loc: I Phone:
Attending:
Requesting:
Diagnostic report text
XR PORT ABDOMEN SINGLE VIEW AP, 3/11/2011 7:25 PM
CLINICAL INFORMATION: Possible retained foreign body
COMPARISON: 3/10/2011
IMPRESSION: Supine projections of the abdomen demonstrate no unexpected foreign body. The distal end of the NG tube is within the stomach. No bowel obstruction. Cholelithiasis noted.
Report Electronically Signed: 3/12/2011 9:07 AM
Responsible & Contributing Providers
What's missing?
Evidence of direct reporting
-Who was contacted?
-How were they contacted?
-When were they contacted?

Templating the Report

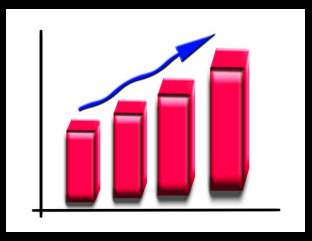


RFO : Concurrent Interventions

- 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 intervention1
  - 58/95 **(61%)**
- After intervention 2
  - 79/95 **(83%)**
- After intervention 3
  - 89/101 **(88%)**
- Currently
  - **93%: Review is continuous!**



* Spans several RCAs

17

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

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