Executive Leaders' Role in Root Cause Analysis

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Learning Objectives

Understand the importance of a Root Cause Analysis (RCA)

Learn how the executive's role increases RCA effectiveness

Review Virginia Mason's RCA process in response to adverse events

Review the importance of executive leadership in promoting accountability

Today's Outline

1. Introduce a Case Study
2. What is Root Cause Analysis (RCA)
3. Why RCA is Important
4. RCA Process Steps
5. RCA as Part of Virginia Mason Patient Safety Alert System
6. Back to the Case Study & Role of Executive Leader
7. Lessons Learned

Case Study: Retained Foreign Object (RFO)

Introduce a Case Study

- 84 year old surgical patient
- Patient complained of shortness of breath post-operatively
- Assessment indicated suspicion for a retained surgical sponge
- Re-operation with removal of a sponge a few days later
- No RFOs at Virginia Mason since 2012 with 50,000+ operations
  - → *Industry research says hospitals average one RFO per year*
  - → *RFO is reportable to DOH*

Our Next Step:
Use RCA to study and prevent future RFOs

What is Root Cause Analysis?

A structured problem-solving technique that results in one or more corrective actions to prevent reoccurrence of an event

- Techniques involve an evidence-based understanding of the fundamental causes of error and the event
- A key management role for correcting serious deviations of outcomes from expectations
- Time/resource intensive, e.g. days-to-weeks

The goal of a Root Cause Analysis is a *Root Solution*

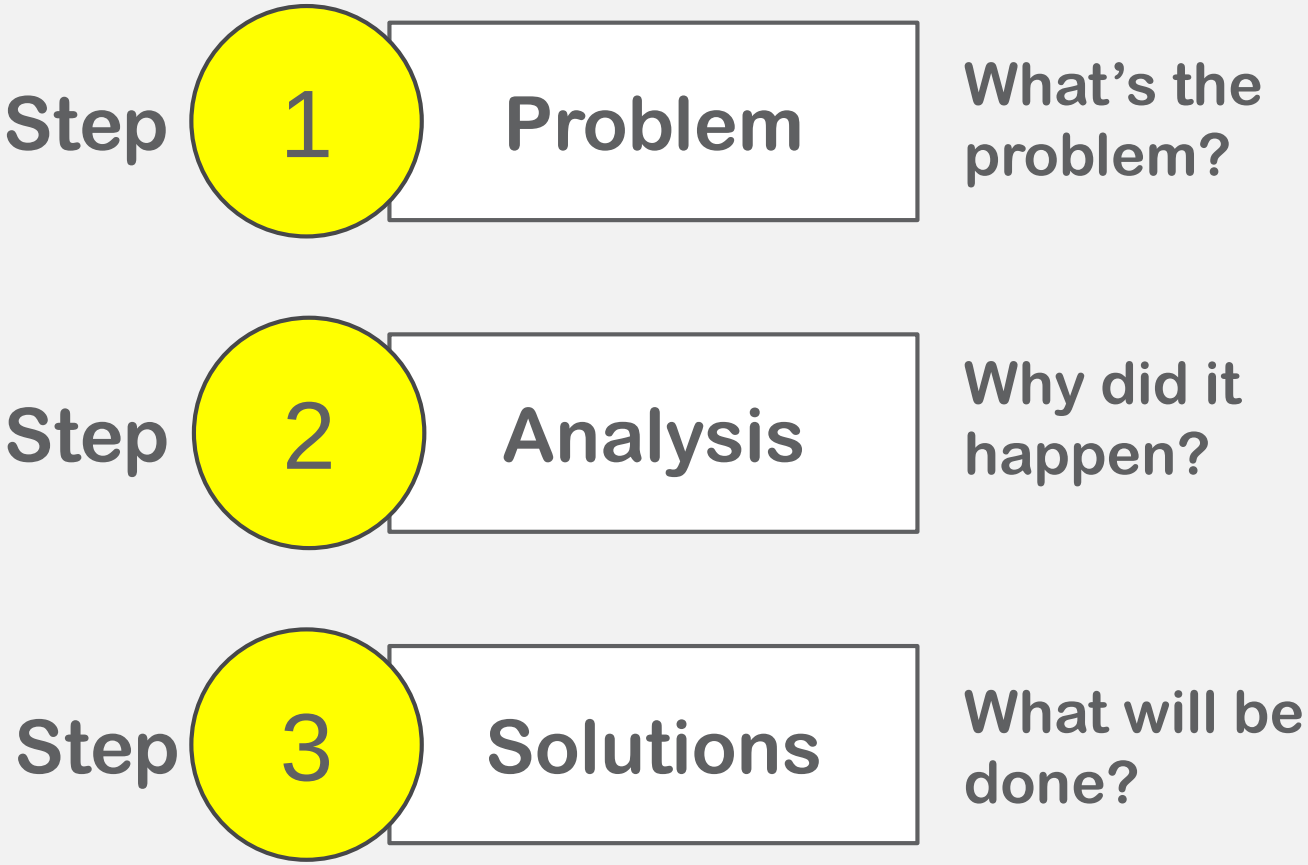
- What happened?
- Why did it happen?
- What can you do to prevent it from happening again?

Why is Root Cause Analysis Important?

A process to solve and prevent serious events from happening in the future

- *Patient Satisfaction & Trust*
- *Risk Mitigation*

RCA Three Meeting Model



Step 1: State the Problem

RCA Process Steps

What = Problem(s)

When = Date/time/different, unusual, unique

Where = Facility/site/tasks being performed

Impact to Goals = Specific to goals of safety

Frequency = Effect of re-occurrence

Step 2: Analysis

Why Why Why Why Why.....

- Conduct Interviews
- Research Evidence Based Practice
- Perform Gap Analysis
- Complete Cause and Effect Diagram
  - What sequence of events led to the problem?
  - What conditions allowed the problem to occur?

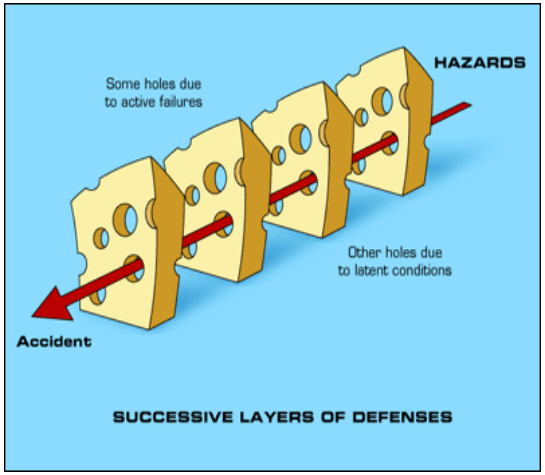
Step 3: Solutions -Corrective Action Plans

RCA Process Steps

- What can you do to prevent the problem from happening again?
- Establish corrective action plan
  - How will the corrective actions be implemented?
  - Who will be responsible for them?
  - Risks of implementation of solutions?
- Failure mode and effects analysis (FMEA)
- Process Improvement

Root Cause Analysis Process

- RCA reveals shortcomings embedded in standards, expectations, procedures, processes, and behaviors.
- Shortcomings are the "holes in the Swiss Cheese" all of which aligned and resulted in the event
- Holes in the Swiss Cheese must be fixed to prevent event from happening again



Best-Practice RCA

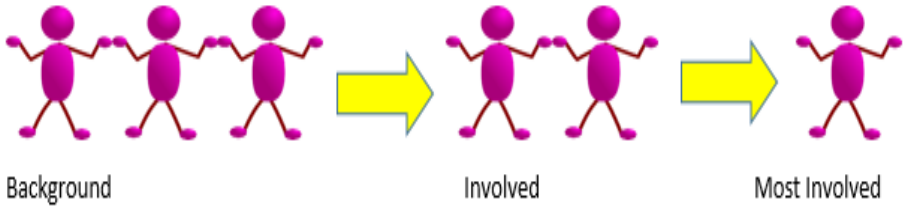
- Root Cause Analysts trained in RCA techniques
- Executive Owner & Operational leader own and lead
- Scope for event investigation
- Conduct 1:1 fact finding interviews
- Use appropriate analytical tools
- Understand failure modes
- Corrective Actions to Prevent Reoccurrence (CATPR) with single person accountability and operational ownership
- Robust safety alert/lessons learned process

Best-Practice RCA

Use a three meeting model - rapid response to safety events

- Meeting 1: Identify Problem-Review the situation and gather facts
- Meeting 2: Analysis-Establish Root Cause using analytical tools
- Meeting 3: Solution-Establish corrective action plan
  - Corrective Actions to Prevent Reoccurrence (CATPR) with single person accountability and operational ownership
  - RAMS-Reasonable, Achievable, Measureable, & Sustainable

Interviews



Try to Capture:

- Relevant facts, chronology of events
- Potential deviations of standard work/processes
- Other interesting information
- Questions for the next interview (based on what was learned from previous interview)

Following the Interview you should be able to:

- Identify defects (slices of Swiss Cheese) that contributed to the event
- Where did steps in process deviate or vary from expectations
- Identify whether errors or deviations were skill, rule or knowledge based
- Identify the individual deviation
- Identify the system failures (what system issues contributed to the individual choices)

Key Points on Verification

Don't drive the review of the event from a desk.

- *Go to the site where the event occurred*

Conduct pertinent literature review:

- *Identifies and clarifies standards of care*
- *Opportunity to benchmark lessons learned from other organizations*
- *Ideas for alternative corrective actions published elsewhere*
- *Regulatory Agencies (e.g. Joint Commission, DOH, etc.) will be more convinced you have been "thorough and credible"*

Determine Sequence of Events

- Establish a timeline of activities leading up to the event
- Keep focused on documenting facts, people involved, actions taken, surrounding environment
- Be factual without passing judgement
- Qualify, Validate, and Verify Information

End State should look like this:

The Virginia Mason Patient Safety System

Patient Safety System at Virginia Mason

Protecting Patients

Engaging Staff

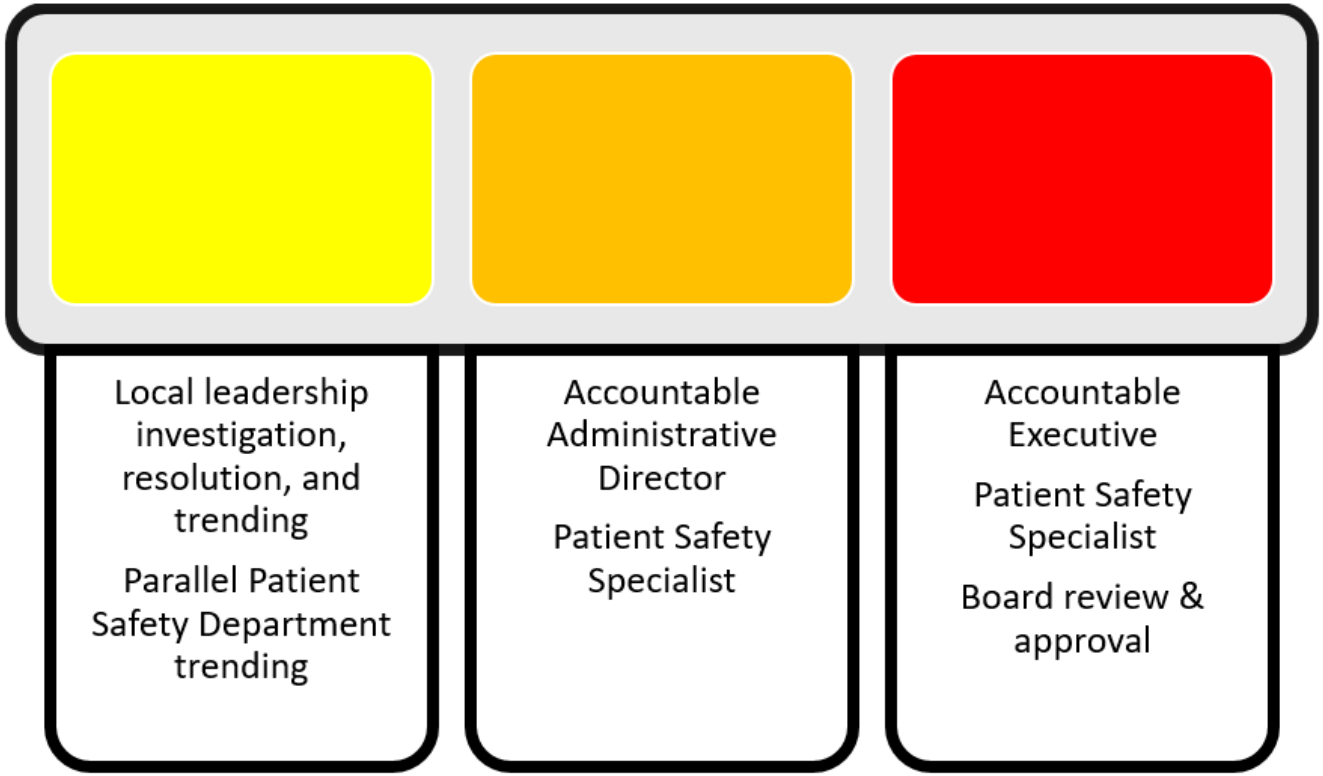
Saving Costs

- Focused on doing what is best for patients
- Employees learn that it is their duty to report anything that has caused harm or could cause harm to a patient
- PSAs support the organization's culture of safety
- Patient safety events are categorized into areas of severity

Patient Safety System at Virginia Mason

Severity of Adverse Event

PSA Categories



Process Flow

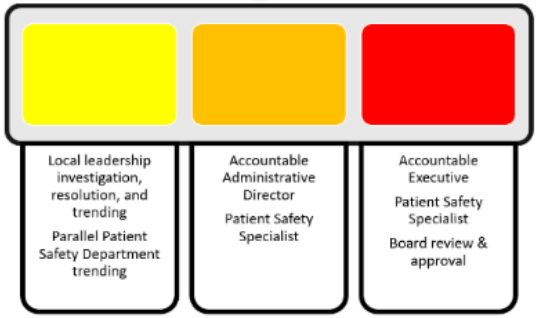
Severity of Adverse Event

Categorization of issue

Escalation of Red events to Execs

RCA

Board approval for closure



Red PSA Resolution Team
(Root Cause Analysis Process)

Serious Safety Event

Executive Leader Role

Accountable Executive
RCA Sponsor

Responsibilities:

- Establish urgency
- Ensure stabilization of patient and team
- Lead the Red PSA process
- Establish priorities and allocate resources
- Remove roadblocks
- Communicate status to other senior leaders
- Approves Root Cause and Root Solution
- Reports event to board members

Executive Leader Role

Accountable Executive
RCA Sponsor

Action Plan:

1. **Attend huddle**
   within two hours of being notified of red PSA
2. **Review details of the event**
   Safety Specialist completes Patient Harm Event 1st meeting form
3. **Establish investigation process**
   identify who will be interviewed and who is on the RCA team
4. **Lead 2nd and 3rd PSA meetings**
   participate in RCA and discuss corrective actions
5. **Final approval of Corrective Action Plan (CAP)**
   accountability – metrics – completion date - sustainability

RED: Patient Safety Alert RCA Pathway

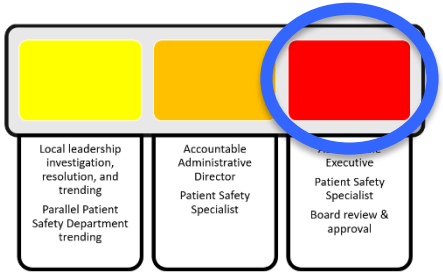
Day of incident/ Confirmed RED

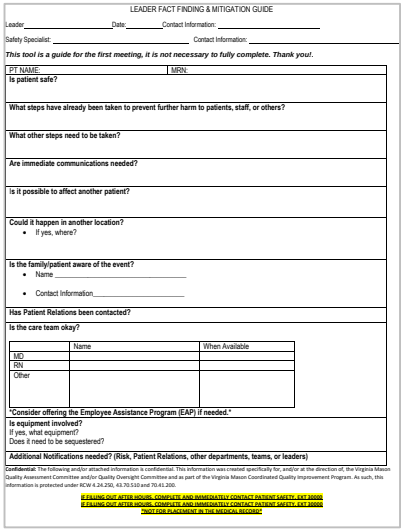
- ✓ Protect Patient
- ✓ Preserve evidence
- ✓ Fact Finding
- ✓ Patient Safety Specialist (PSS) sets up process

Within 2 Hours of Notification

Huddle at Accountable Exec. Office –

- ✓ Confirm Initial Severity
- ✓ Review Facts
- ✓ Determine RCA Team
- ✓ Determine the tasks to be completed for investigation (i.e. interviews/review chart)
- ✓ Determine next Cause Analysis/CAP meeting
- ✓ Signals Dir./AD/VP/Chief
- ✓ Thanks Reporter
- ✓ PSS Facilitates and takes notes





LEADER FACT FINDING & MITIGATION GUIDE

Leader:_____Date:_____Contact Information: _____

Safety Specialist: _____ Contact Information: _____

This tool is a guide for the first meeting, it is not necessary to fully complete. Thank you!.

PT NAME: MRN:

Is patient safe?

What steps have already been taken to prevent further harm to patients, staff, or others?

What other steps need to be taken?

Are immediate communications needed?

Is it possible to affect another patient?

Could it happen in another location?
- If yes, where?

Is the family/patient aware of the event?
- Name _____
- Contact Information_____

Has Patient Relations been contacted?

Is the care team okay?

	Name	When Available
MD		
RN		
Other		

Consider offering the Employee Assistance Program (EAP) if needed.

Is equipment involved?
If yes, what equipment?
Does it need to be sequestered?

Additional Notifications needed? (Risk, Patient Relations, other departments, teams, or leaders)

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IF FILING OUT AFTER HOURS, COMPLETE AND IMMEDIATELY CONTACT PATIENT SAFETY, EXT 30009.
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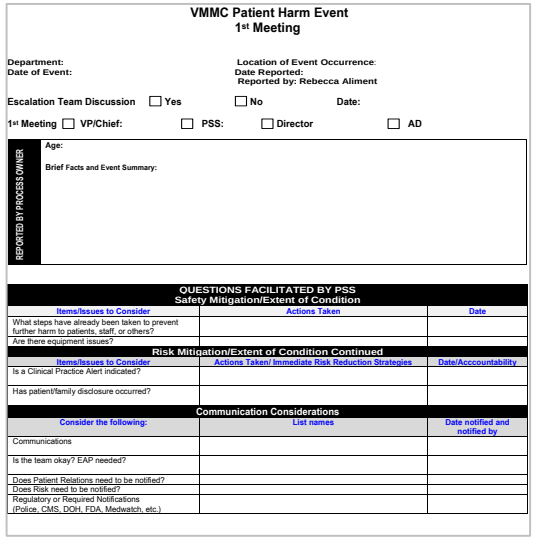
NOT FOR PLACEMENT IN THE MEDICAL RECORD!



VMMC Patient Harm Event
1st Meeting

Department:
Date of Event:

Location of Event Occurrence:
Date Reported:
Reported by: Rebecca Aliment

Escalation Team Discussion ☐ Yes ☐ No Date:

1st Meeting ☐ VP/Chief: ☐ PSS: ☐ Director ☐ AD

REPORTED BY/PROCESS OWNER

Age:

Brief Facts and Event Summary:

QUESTIONS FACILITATED BY PSS
Safety Mitigation/Extent of Condition

Items/Issues to Consider	Actions Taken	Date
What steps have already been taken to prevent further harm to patients, staff, or others?		
Are there equipment issues?		

Risk Mitigation/Extent of Condition Continued

Items/Issues to Consider	Actions Taken/ Immediate Risk Reduction Strategies	Date/Acccountability
Is a Clinical Practice Alert indicated?		
Has patient/family disclosure occurred?		

Communication Considerations

Consider the following:	List names	Date notified and notified by
Communications		
Is the team okay? EAP needed?		
Does Patient Relations need to be notified?		
Does Risk need to be notified?		
Regulatory or Required Notifications (Police, CMS, DOH, FDA, Medwatch, etc.)		

VMApplause! Care. Collaborate. Inspire.

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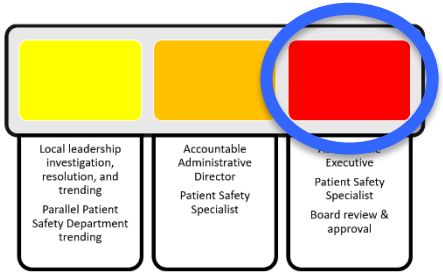
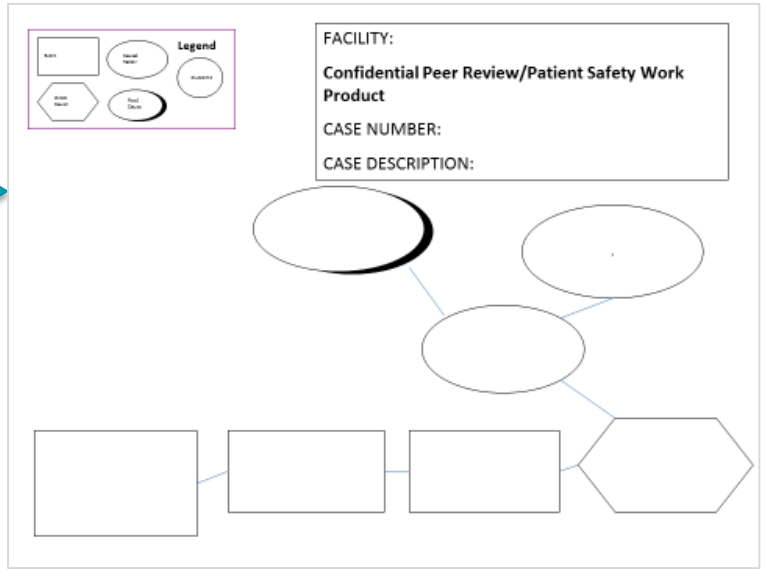
Red PSA RCA Pathway



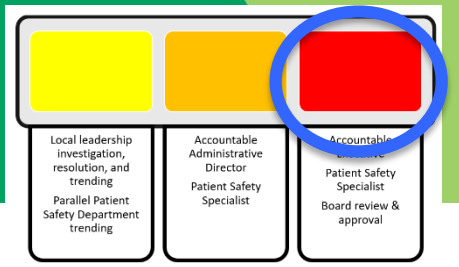
Patient Safety Specialist (PSS)

- ✓ Investigate,
- ✓ interview,
- ✓ determine sequence of events
- ✓ Facilitates RCA 3 Meetings

Determine Analysis Tool-i.e. Event and Causal Factor



Red PSA RCA Pathway



< 19 days Post DOI

Meeting #2 – Causes
- ✓ Agree on facts and proximate causes
- ✓ Build consensus for possible root causes

If unable to agree on Root Cause schedule 3rd Meeting

Meeting #3- Corrections
- ✓ Confirm root causes
- ✓ Finalize Corrective Action Plan
  - ✓ Ownership determined, timeline & metrics
  - ✓ Reporter updated

< 26 Days from DOI

Deploy CAPS

If Root Cause Agreed on complete objectives in 3rd Meeting

RCA 2nd / 3rd Meeting Agenda DRAFT

Participants:

-Accountable Leader (if unable to attend a communication plan is made to update Accountable Leader)
-RCA Team Lead (AD or Dir. Where patient event occurred)
-RCA Analysist (PSS)
-Stake Holders/Subject Matter Experts (staff from dept. of where occurred; effected dept.; medical staff leadership)
-Reporter (if applicable)

Agenda Item	Responsible Role	Tool To Use	Time to Allow
Set Ground Rules	RCA Team Lead/RCA Analysist RCA Team Role Review	Respect for People RCA Team Role	5
Review Investigation Tool and Analytical tool – Clarify information and issues	RCA Analysist	Investigation Tool Analytical Tool used Interview results	10
Identify and Finalize Root Cause(s)	Team	Root Cause Effectiveness Tool	15
IF ROOT CAUSES NOT	**IDENTIFIED**	**DO NOT PROCEED -**	**SCHEDULE 3rd MEETING**
Develop CAPs that are: **Reasonable** **Achievable** **Measureable** **Sustainable**	Team	CAP Effectiveness Tool	5
CAP assigned with Implementation metrics	RCA Team Lead/RCA Analysist	CAP Tool	10
Communication Plan for Progress of Implementation Developed and Agreed Upon	RCA Team Lead/RCA Analysist	Huddle or SharePoint	5
Lessons Learned Developed	Team	Lesson Learned Template	5
Date of KPO 60 day Report Out	RCA Team Lead	Outlook Calendar Invite	5

CAP= Reasonable
Achievable
Measurable
Sustainable

PSS to meet with PS Dept. Dir. to evaluate Root Cause and CAPs

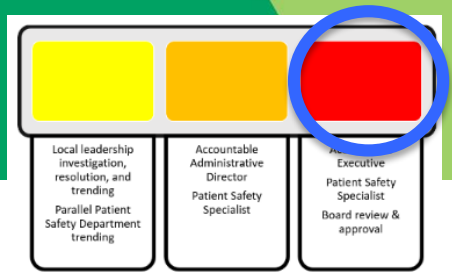
Red PSA RCA Pathway

Developing CAP Framing Form

PSA: **Severity: Red/ Orange/Yellow** **Exec. /Leader:**

1. What Needs to be completed, and by when?	2. Why is the CAP important?
3. What factors may make this CAP complex?	4. What biases or mental valleys may we, or other influencers or decision-makers have?
5. What quantitative or qualitative data should we gather and analyze prior to CAP form Finalization?	6. What constraints exist for this CAP(s)?
7. Whose support is essential to making this CAP Successful? Why?	8. What's unknown that needs to be explored further prior to finalizing CAP?
9. What stakeholder groups do we need to consult with before finalizing CAP? (Stakeholder perspectives tool)	10. What else needs to be considered to prepare for our discussions with decision-makers and/or stakeholders of CAP?

Red PSA RCA Pathway



Patient Safety Specialist (PSS)

< 28 Days from DOI

- ✓Weekly update with Accountable Exec. Owner
- ✓On status of CAPs, as needed

Monitor implementation of CAPs

< 60 days from DOI

- ✓ CAPs are fully implemented
- ✓ Report on progress to Accountable Exec. Owner monthly

< 100 days from DOI

- ✓ RED PSA is presented to QOC for closure
- ✓ PSA Pointers- Lesson's Learned Disseminated

Key Takeaways

Lessons Learned

- Engage your workforce as inspectors obsessed with patient safety
- Drive your culture with respectful behaviors, stories, & celebrations
- Determine how to sort & prioritize your events and be stewards of your resources
- Define roles & responsibilities for those involved in the RCA process

Retained Surgical Sponge

Back to the Case Study

- Retained surgical sponge required our patient to have an unnecessary operation, delayed recovery and potential loss of trust
- Incidence was reported to the Department of Health

Step 1: State (define) the Problem

Retained foreign object (surgical sponge) on a patient who underwent an abdominal surgical procedure

Step 2: Analysis-Collect the Data

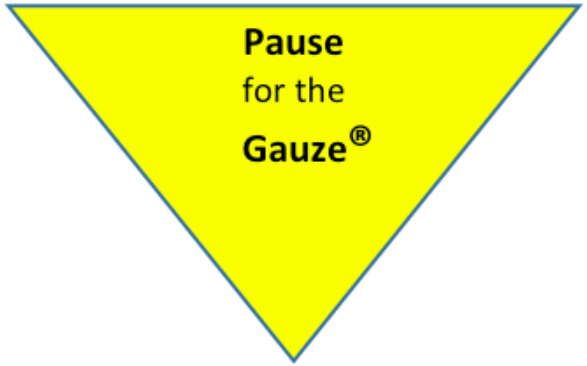
RCA Process Steps

1. Multidisciplinary team formed:

- Surgeon, Anesthesiologist, Radiologist, Surgical Resident, Surgical Tech, Circulator RN, Director of OR

2. External environmental scan of industry best practice

- Study "no item left behind" initiative
- Pause for the Gauze
- Review of DOH, TJC standards
- Count bags
- Separation of sponges from dressings
- Use of devices



3. Standard Work review

- Counting method, count boards, separation of sponges and dressing

4. Role of radiologist in final clearance

- Role of surgeon; resident teaching; anesthesia implications

Step 2: Identify Possible Causal Factors

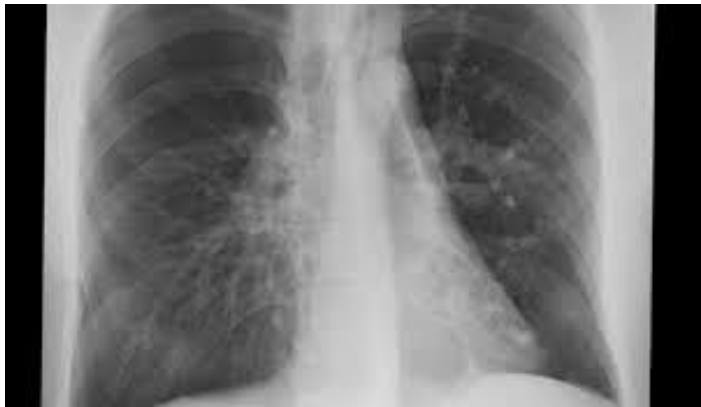
RCA Process Steps

What sequence of events led to the problem?

- Use of count bag and deviation from standard process
- Dressing placed on mayo stand in proximity to sponges
- Count process

What conditions allowed the problem to occur?

- Saturday surgery
- Radiology image review and confirmation- white noise on image
- Timing of the radiology confirmation
- Resident expertise



Step 2: Identify the Root Cause

What is the real reason the problem occurred?

- **Sponge count methods varied**
  - → Sponge count process (bags, ST and RN collaboration, OR board usage)
  - → Complacency of team
  - → Dressings placed on mayo stand which contributed to wrong case count
- **Surgical resident focused on reading the post op x-ray for retained instrument but not sponges**
- **Radiologists do not receive clinical information on the patient**
  - → White noise on the radiology image - no opportunity for radiologist to confirm reading
  - → Timing of the confirmation was after the patient left the OR

Step 3: Solutions - Corrective Action Plan

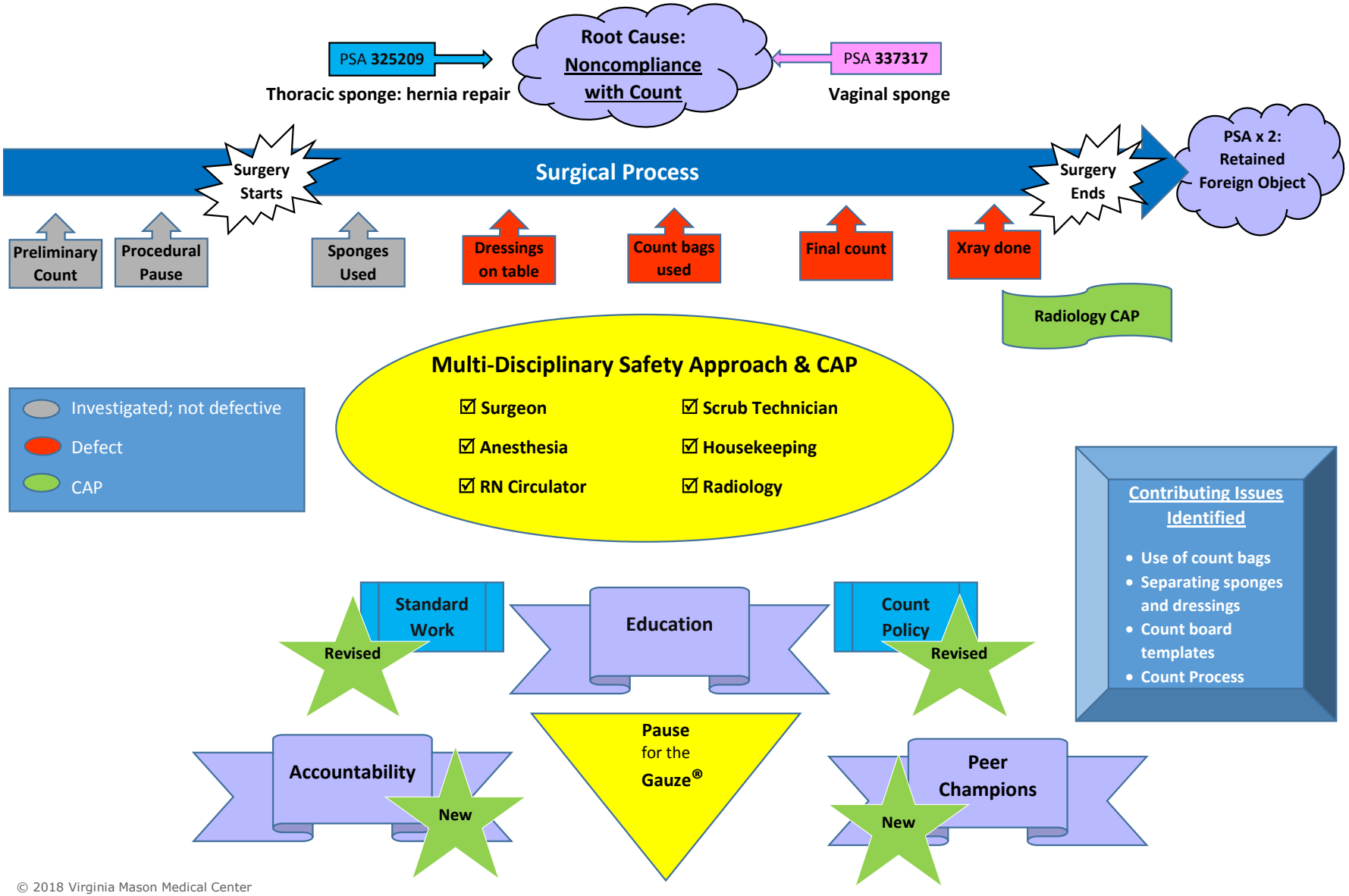
What can you do to prevent the problem from happening again?

RCA Process Steps

Our Corrective Action Plan:

1. **Resident education and training**
   How to read images for retained instruments and sponges
2. **Standard process for sponge counts and dressings**
   Re-education of entire OR team; audits 6 months; accountability
3. **Establish role of radiologist**
   Stat radiology confirmation before patient leaves OR
   Phone consult to review tubes, drains, hardware
4. **Pause for the Gauze initiative**

Retained Foreign Object Root Cause



Ending to Our Case Study

One month after discharge from the hospital…

84 year old patient returned to Alaska and back to work as a lumberjack

Lessons Learned

Our Journey at Virginia Mason: Culture of Safety

- Role of executive leader to promote active participation
- Time at the site of care to see the process
- Multidisciplinary team approach to RCA (residents, front line team members, etc.)
- Maintain Rigor: presentation to Board, implementation of CAP, audits and coaching

The Power of RCA Tools and Process

- Fishbone
- Causal factors charts
- Common cause analysis
- Study of industry best practices

Impact on the team when something goes wrong

Resources:

National Patient Safety Foundation:

- RCA2 Improving Root Cause Analyses and Actions to Prevent Harm; Second online publication, Version 2, January 2016.

Healthcare Performance Improvement (HPI):

- SEC & SSER Patient Safety Measurement System for Healthcare-HPI White Paper Series-Rev. 2-May 2011

American Society Healthcare Risk Management (ASHRM):

- White Paper Series: Serious Safety Events
  Root Cause Analysis Playbook