Partnership for Patient Care
Safety Forum II Workshop:
The Road to Achieving RCA Best Practice

Maureen Ann Frye, MSN, BC, CRNP, CPPS, CPHQ
Abington Jefferson Health
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Introduction, Disclaimer and Confidentiality Statement
Patient Safety Event

- G1 P0 mom laboring without event.
- Epidural and a peripheral line running on one Pump.
- Patient progressing well
- New nurse at bedside, first day off orientation. Comes on duty and assigned care of patient
- Bedside shift report given.
- Few minutes into shift, the pump alerts “air in line”
- Nurse resolves the issue
- 2 hrs. later it is discovered that the epidural line is connected to the peripheral infusion. The hub for the epidural is not connected to anything.
What do you want to know?
What do you need to know?

• Was there harm to mother or infant?
• What happened?
• Why did it happen?
• How did it happen?
• Who was involved?
• What is supposed to happen?

Risk vs. Severity Based?
The Goal

• Identify the causal (or basic) factor(s) underlying the variation in performance
• Find the fundamental reason(s) for why a failure or adverse situation occurred

• Use of ‘failures’ vs. errors
Evolution of Cause Analysis Theory and Expectations

Safety I theory
- the historical basis for RCAs
- reactive

Fair and Just Culture
- handling the individual vs. the system to avoid blame, promote reporting, learning and improved safety culture

Safety II theory
- study of positive deviance

Complexity theory
- understanding complex adaptive systems

High reliability theory
- Anticipation & Resilience

RCA2 (NPSF)

Requirements, Regulations And Public Expectation:

• Sentinel events
  Severity based - thorough & credible

• “Never” Events (SREs)

• Serious Events
  (MCARE in PA)
Getting to *Zero Harm* through Lessons Learned from Events of Harm

**Zero Harm and Suffering**
Relationship-Based and Mindful Management of the System

**Reliability Science**
Knowledge and understanding of human error and human performance in complex systems

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**Leadership**
Reinforce & Build Accountability for performance expectations and Find & Fix system problems

**Behaviors**
*of Individuals & Groups*

**The Patient**
8:05-8:20A
Evolution of Cause Analysis Theory and Expectations

Safety I theory
- the historical basis for RCAs
- reactive

Fair and Just Culture
- how we handle the individual vs. the system to promote reporting, learning and improved safety culture

Safety II theory
- a new perspective

Complexity theory
- confounding new dimension

High reliability theory
- Anticipation & Resilience

Requirements, Regulations And Public Expectation:
- Sentinel events
  *Severity based - thorough & credible*
- “Never” Events (SREs)
- Serious Events
- (MCARE in PA)
## Crosswalk – A Guide to TJC Sentinel Events and NQF Serious Reportable Events ("NeverEvents")

Abington Jefferson Health

<table>
<thead>
<tr>
<th>Category</th>
<th>Sentinel Event Language</th>
<th>NQF &quot;Serious Reportable Events&quot; &quot;NEVER EVENTS&quot; which include some CMS Hospital Acquired Conditions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Suicide or Attempted Suicide</td>
<td>Suicide of any patient receiving care, treatment, services in a staffed around-the-clock care setting or within 72 hrs. of discharge</td>
<td>Patient suicide, attempted suicide or self-harm that results in serious injury while being cared for in a healthcare setting</td>
</tr>
<tr>
<td>Discharge to wrong unauthorized person</td>
<td>Discharge of an infant to the wrong family</td>
<td>Discharge or release of a patient/resident of any age, who is unable to make decisions, to another person instead of the authorized person</td>
</tr>
<tr>
<td>Abduction</td>
<td>Abduction of any pt. receiving care, treatment, services</td>
<td>Abduction of a patient/resident of any age</td>
</tr>
<tr>
<td>Unanticipated deaths: Maternal-Child</td>
<td>Unanticipated death of a full-term infant</td>
<td>Death or serious injury of a neonate associated with labor or delivery in a low risk pregnancy</td>
</tr>
<tr>
<td></td>
<td>Any intrapartum (re: the birth process) maternal death</td>
<td>Maternal death or serious injury associated with labor or delivery in a low risk pregnancy while being cared for in a healthcare setting</td>
</tr>
<tr>
<td></td>
<td>Severe maternal morbidity (not primarily related to the natural course of the patient’s illness or underlying condition) when it reaches a patient and results in any of the following: Permanent harm or severe temporary harm</td>
<td></td>
</tr>
<tr>
<td>Elopement</td>
<td>Any elopement (unauthorized departure) of a pt. from a staffed around-the-clock care setting (including ED), leading to death, permanent harm, or severe temporary harm to the patient</td>
<td>Patient death or serious injury associated with patient elopement</td>
</tr>
<tr>
<td>Blood transfusion reactions/harm</td>
<td>Hemolytic transfusion reaction involving administration of blood/blood products having major blood group incompatibilities (ABO, Rh, other blood groups)</td>
<td>Patient death or serious injury associated with the unsafe administration of blood products</td>
</tr>
<tr>
<td>Rape, assault, homicide of patient</td>
<td>Rape, assault (leading to death, permanent harm, or severe temporary harm), or homicide of any patient receiving care, treatment, and services while on site at the hospital</td>
<td>Sexual abuse/assault on a patient or staff member within or on the grounds of a healthcare setting</td>
</tr>
<tr>
<td>Wrong site, patient or type of surgery/procedure</td>
<td>Invasive procedure, including surgery, on the wrong patient, at the wrong site, or that is the wrong (unintended) procedure</td>
<td>Surgery/invasive procedure on the wrong site</td>
</tr>
<tr>
<td>Retained foreign object</td>
<td>Unintended retention of a foreign object in a patient after an invasive procedure, including surgery</td>
<td>Unintended retention of a foreign object in a patient after surgery or other invasive procedure</td>
</tr>
<tr>
<td>Post op death</td>
<td></td>
<td>Intraoperative or immediately post-operative death in a ASA Class 1 patient</td>
</tr>
<tr>
<td>Hyperbilirubinemia</td>
<td>Severe neonatal hyperbilirubinemia (bilirubin &gt;= 25 mg/dl)</td>
<td></td>
</tr>
<tr>
<td>Prolonged fluoroscopy</td>
<td>Prolonged fluoroscopy with cumulative dose &gt;1,500 rads to a single field or any delivery of radiation to the wrong body region or &lt;2% above the planned radiotherapy dose</td>
<td></td>
</tr>
</tbody>
</table>
Identifying Causal Factors: Event Case Study

Goal of the RCA process
1. What happened?
2. Why did it happen?
3. What can be done to prevent it from happening again?

Interviews:
- Who to interview?

Structured Questioning to remove bias/blind spots
- Comprehensive System Analysis
  - Scope and Triggering Questions

5 “Why’s” or Fishbone Diagram

Developing the timeline and/or process map
Structured Interviewing
to Identify the
Causal / Contributory Factors

Team Exercise

Individual Factors

System Factors
Identifying the Causal Factor(s)

Writing the Causal Statement: Practice and Consensus

<table>
<thead>
<tr>
<th>CAUSE</th>
<th>Something</th>
</tr>
</thead>
<tbody>
<tr>
<td>EFFECT</td>
<td>Leads to Something</td>
</tr>
<tr>
<td>EVENT</td>
<td>Which increases the likelihood that the adverse will occur</td>
</tr>
</tbody>
</table>

- Team Composition
- Fact Based
- Peer Review Protections
- System Analysis focus
- Tools to aid: Fishbone diagram, process map, timeline

6/21/2020 8:20-9:00A
“If we change the CAUSE because we have a problem with it, we can reduce the EFFECT of that cause and, in fact, prevent the next EVENT”
Causal Statement 1:
Unannounced / unevaluated change from yellow epidural tubing resulted in loss of situational awareness of the difference between peripheral and epidural lines leading the nurse to attach the cleared 'air in line' tubing into the peripheral line.

Causal Statement 2:
Use of one alaris pump to manage a two infusions (one high alert) introduced the risk of inadvertent IV line confusion that resulted in the epidural infusion being attached to the peripheral line.

Causal Statement 3:
Failure to trace IV lines when managing infusions created the risk that 2 lines could be easily interchanged resulting in the epidural line being attached to the peripheral line and not to the epidural site hub.

Causal Statement 4:
Failure of the anesthesiologist to attach the yellow “EPIDURAL LINE” alert flag onto the tubing created a lost visual cue signaling the epidural vs. the peripheral line resulting in the epidural infusion being inadvertently attached to the peripheral line.

Causal Statement 5:
Lack of supervision and use of less experienced nurses created a situation of IV line mismanagement resulting in a medication administration error.
Getting to the Strongest Action Plans

(Risk Reduction Strategies)
Product Substitution and Change Process

Creating the **Clinical Expert Group**

**Product Substitution or Change**

**Clinical Expert Group Analysis and Action**

- **Product that needs substitution or change:**
- **Manufacturer:**
- **Product description:**
- **Statement of:**

**Details on what and how this product is used:**

**Key specifications to consider:**

**Reason:**

**Current inventory on the shelf/Anticipated date of run out:**

[ ] [ ]

**Notification:**

**Clinical Assessment and Surveillance in:**

[ ] [ ] [ ]

**Substitution Change Affect:**

[ ] [ ] [ ]

**End user report provided:**

[ ] [ ]

**Product Substitution or Change:**

**Medical Product Analysis and Clinical Safety:**

**Manufacturer, Name, Key Specifications:**

**Benefits:**

**Communication Plan:**

**End user comments:**

**Monitoring Plan:**

**Legend for Clinical Risk Assessment**

**Communication Need / Message**

<table>
<thead>
<tr>
<th>Audience</th>
<th>Method</th>
<th>By whom</th>
<th>By when</th>
</tr>
</thead>
</table>

**Action Plan**

| [ ] [ ] [ ] [ ] [ ] [ ] |

**Monitoring:**

**Clinical Safety Risk Criteria / Definition**

- [ ] [ ] [ ] [ ] [ ] [ ]

**Clinical Safety Risk Criteria / Definition**

- [ ] [ ] [ ] [ ] [ ] [ ]
Embedding “Safety First in Every Decision” into our Leadership Behaviors for Reliability

Leadership for Reliability in Patient Safety and Patient Experience:
A CROSSWALK AND ALIGNMENT MODEL
Simplifying Cause Analysis:
One Organization’s Approach - Abington Jefferson Health

Abington Hospital
- 570 beds
- 33,000+ admissions
- 100,000+ emergency room visits
- 13,000+ surgical procedures
- 700 active members of the Medical Staff
- 5000 Employees
- $750 million in revenue
- 45% market share in primary service area
- 2010 – AH State Baldrige award

Lansdale Hospital
- 120 beds
- 5,500 admissions
- 28,000 emergency room visits
- 4,500 surgical procedures
- 128 active members of the Medical Staff
- 900 employees
- $85 million in revenue
Root Cause Analyses - Time and Resources

- Takes between 40-90 hours to complete
- Involves interviews, chart reviews, data collection, literature searches and meetings with experts/leaders to determine the causal factors and create action plans.
- FY17: we conducted 30+ RCAs with 4 Safety/Quality Specialists
RCA$^2$ and its impact

*We had to find a more systematic approach!*

Reviewed the document against TJC Sentinel Event Criteria, NQF Never Event Criteria, PA DOH MCARE criteria and our journey to reliability using SSE methodology

- Identified the requirements that must be in place and spent ~8 months in redesign

- Renamed our approach “Comprehensive System Analysis”
- Created a scalable, user friendly and reliable tool
- Conducted Cause Analyst training for internal consistency, accountability and evidence
- Deployed the model in March 2017
Key components of our model

• Avoidance of the words Root Cause Analysis as a title
  • Rather, Comprehensive Systematic Analysis (CSA)
    • Focus remains on systems/processes
    • Humans often fail due to underlying system/process problems
    • Fair/Just Culture Performance Management Decision Guide remains our leadership tool to manage individual performance and is outside the scope of our CSA

• Created a flow chart and a scalable approach
  • Use a checklist to track/modify the scope of the investigation
Comprehensive System Analysis (CSA)  
A Scalable Approach to Thorough and Credible Cause Analyses at AJH

Event of Interest (EOI) identified: An event which caused harm or the risk thereof which warrants further investigation

Initiate BASIC INVESTIGATION (BI)
- Obtain initial case details
  - Chart review
  - Interview leadership/Staff
- Begin scalable CSA Checklist
  - Forms: SWAT, mortality review form, chain of custody form, basic investigation catalogue, ACA form

Initiate protected documentation repository w/ standard naming convention (BI01.05.17.Fall.MAF)

Present event at next “Create a Reliable Day” Unit Briefing
Notify Hospital Leadership and PSO based on known harm or severe risk thereof

If Known or Unknown Harm?
  - Yes
  - Is this a precursor event or does it carry some risk of harm or concern?
    - No
    - No further action is needed. Investigation is closed.
    - Yes
    - Minor Event (precursor)
      - No
      - Yes
      - Major Event
        - Yes
        - Major Event Investigation (MEI)
          - Change folder name to MEI
        - No
        - Minor Event
          - Yes
          - Minor Event Investigation (Minor EI)
            - Change folder name to Minor EI
          - No
          - No further action is needed. Investigation is closed.
        - No
        - Sentinel Event
          - Initiate Sentinel Event Investigation (SEI)
            - Change folder name to SEI

See Page 2
See Page 3
See Page 4
Sentinel Event Investigation

Key Requirement: 45 business days from date of sentinel event determination to action plan development

**INTERVIEWS**
- Interview involved individuals, those proximate to the event and others, as needed
- Scan notes into protected document repository

**TIMELINE OF EVENT**
- Using chart review and interview data, construct a timeline of the events

**LITERATURE REVIEW**
- Conduct or initiate literature review related to the event.

**POLICY REVIEW**
- Collect and Review relevant organizational policies for analysis

**SYSTEM AND PROCESS INQUIRY**
- Incorporate systematic inquiry to elicit blind spots or areas where causal or contributory factors may be identified.

**CAUSAL AND CONTRIBUTORY FACTOR IDENTIFICATION**
- Facilitate meeting with stakeholders and content expert
- Review timeline
- Review identified causal and contributory factors that may be involved
- Share literature/best evidence
- Discuss/achieve consensus on causal/contributory factors

**APPROVAL OF ACTION PLAN**
- Review with CPSO/Director for cross check and approval
- Action Owner approval and sign off

**ACTION PLAN DEVELOPMENT**
- Consensus on causal factors and development of strongest corrective actions and timeframe
- Focus is on System/Process Factors

**ACCOUNTABILITY**
- Tracking to Action Plan Completion Phase begins.
- Consider Event-Based QAPI project assignment.
- Outcome Metrics: Days from SE identification to Action Plan Development <45 days

**LEADERSHIP PRESENTATIONS**
- Sentinel Events must be presented to Pt Safety Committee/Patient Safety Governance

**INVESTIGATION CLOSED**
Major Event Investigation

Requirement: 60 business days from date of major event determination to action plan development

INTERVIEWS
- Interview involved individuals, those proximate to the event and others, as needed
- Scan notes into protected document repository

Resources: Forms: Interview form

TIMELINE OF EVENT
- Using chart review and interview data, construct a timeline of the events

Resources: Forms: Process Map, Timeline Tools

LITERATURE REVIEW
- Conduct or initiate literature review related to the event.

Resources: Librarian, ECRI, Casarett, PA Patient Safety Authority, Internet / evidence-based references

POLICY REVIEW
- Collect and review relevant organizational policies for analysis

Resources: Intranet-based Policy repository

SYSTEM AND PROCESS INQUIRY
- Incorporate systematic inquiry to elicit blind spots or areas where causal or contributory factors may be identified.

Resources: CSA Scope and Triggering Questions (reference and documentation tool)

CAUSAL AND CONTRIBUTORY FACTOR IDENTIFICATION
- Facilitate meeting with stakeholders and content expert
- Review timeline
- Review identified causal and contributory factors that may be involved
- Share literature/best evidence
- Discuss/achieve consensus on causal/contributory factors

Resources:
- 5 Whys, Fishbone Diagram, Event Causation and Action Plan form, CSA Score and Triggering Question reference

APPROVAL OF ACTION PLAN
- Review with MPSQI/Director for cross check and approval
- Action Owner approval and sign off

ACTION PLAN DEVELOPMENT
- Consensus on causal factors and development of strongest corrective actions and timeframe
- Focus is on System/Process Factors

Resources:
- Action Hierarchy, Event Causation and Action Plan form, Tracking of Action Items Log

ACTION PLAN DEVELOPMENT

ACCOUNTABILITY
- Update and track action plan progress in Tracking Log and schedule for Regular Review

INVESTIGATION CLOSED
Tracking to Action Plan Completion Phase begins. Consider Event-based QAPI project assignment.
Outcome Metrics:
- Days from ME identification to Action Plan Development <60 days
- Serious Safety Event Rate
- Days since Last Serious Safety Event

LEADERSHIP PRESENTATIONS
- Major Events can be presented to Pt Safety Committee/Patient Safety Governance as time permits. Serious Safety Events MUST be presented and SBAR shared on the Intranet
**Minor Event Investigation**

**Goal:** 90 business days from date of minor event determination to action plan development

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**INTERVIEWS**
- Interview involved individuals, those proximate to the event and others.
- Scan notes into protected document repository.

**Resources:** Forms: Interview form, SWAT or ACA form.

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**SYSTEM AND PROCESS SCAN**
- Scan the scope and triggering questions at a high level to ensure systematic identification of potential blind spots or improvement opportunities.

**Resources:** CSA Scope and Triggering Questions (reference and documentation tool).

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**ACTION PLAN DEVELOPMENT**
- Local or team based action plans as needed.
- Plans can be incorporated into existing improvement teams if pertinent.

**Resources:** Action Hierarchy, Document repository/tracking form.

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**APPARENT CAUSE ANALYSIS**
- Debriefing/briefing with local leader or content expert as needed.
- Review identified apparent causal factors.

**Resources:** ACA form, CSA Scope and Triggering Question reference.

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**INVESTIGATION CLOSED**

**Add to Annual Risk/Hazard Analysis Document**
Key components of our model

• Avoidance of the words Root Cause Analysis as a title
  • Rather, Comprehensive Systematic Analysis
    • Focus remains on systems/processes
    • Humans often fail due to underlying system/process problems
    • PMDG remains a tool for unsafe behavioral choices and is outside the scope of our CSA

• Flow chart and scalability
  • Using a checklist to increase/modify the scope of investigation

• Weekly reconciliation with risk and regulatory for consensus.
Key components of our model

• Avoidance of the words Root Cause Analysis as a title
  • Rather, Comprehensive Systematic Analysis
    • Focus remains on systems/processes
    • Humans often fail due to underlying system/process problems
    • PMDG remains a tool for unsafe behavioral choices and is outside the scope of our CSA

• Flow chart and scalability
  • Using a checklist to increase/modify the scope of investigation

• Reconciliation with risk and regulatory for consensus.

• Tools for guiding the investigation
  • Scope and Triggering Questions to identify blind spots to causal/contributory factors

• Tracking “heat map” for progress and escalation to leadership
<table>
<thead>
<tr>
<th>Project/Folder</th>
<th>Issue</th>
<th>Issue Owner</th>
<th>CSA Action Plan Status</th>
<th>Due Date</th>
<th>Resolution Date</th>
<th>Logged By</th>
<th>Department</th>
</tr>
</thead>
<tbody>
<tr>
<td>MEL Fall with non displaced humeral head fracture</td>
<td>Staff lack of understanding of effects of concurrent use of medications with potential to have cognitive altering effects</td>
<td>Marylou Kurilla, Annmarie Chavarria</td>
<td></td>
<td>07/27/17</td>
<td>N/A</td>
<td>Fahy, Jeannine</td>
<td>Nursing</td>
</tr>
<tr>
<td>SEI Ureteral Injury During Laparoscopic Low Anterior Resection</td>
<td>Provider failed to utilize ureteral stents to mitigate risk of ureteral injury, despite this being a known complication for procedure</td>
<td>Kirtin, Dr Orlando</td>
<td></td>
<td>08/17/17</td>
<td>08/17/17</td>
<td>Fahy, Jeannine</td>
<td>Surgery</td>
</tr>
<tr>
<td>MEL Fall with non displaced humeral head fracture</td>
<td>Lack of decision support for administration of pre-procedural sedation to geriatric patients.</td>
<td>Schneider, Doron</td>
<td></td>
<td>08/31/17</td>
<td>N/A</td>
<td>Fahy, Jeannine</td>
<td>Center for Safety and Quality</td>
</tr>
<tr>
<td>SEI Endometrial Biopsy Without Follow Up</td>
<td>There is no documentation of communication between pathologist and AHP staff.</td>
<td>Mackey, Amy</td>
<td></td>
<td>09/01/17</td>
<td>N/A</td>
<td>Fahy, Jeannine</td>
<td>OB GYN</td>
</tr>
<tr>
<td>SEI Endometrial Biopsy Without Follow Up</td>
<td>There is no decision support page/algorithm available for Pap Smear follow up.</td>
<td>Schneider, Doron</td>
<td></td>
<td>09/01/17</td>
<td>N/A</td>
<td>Fahy, Jeannine</td>
<td>Center for Safety and Quality</td>
</tr>
<tr>
<td>SEI Endometrial Biopsy Without Follow Up</td>
<td>Initial pathologist requested results of D&amp;C; however, the results went to a different pathologist.</td>
<td>Auerbach, Herbert</td>
<td></td>
<td>09/01/17</td>
<td>N/A</td>
<td>Fahy, Jeannine</td>
<td>Pathology</td>
</tr>
<tr>
<td>SEI Verapamil ordered and administered to incorrect patient</td>
<td>Review Intern Manual for details about what information to provide when giving orders (i.e., always giving last name, not just first name)</td>
<td>IM Chiefs</td>
<td></td>
<td>09/15/17</td>
<td>N/A</td>
<td>Fahy, Jeannine</td>
<td>Internal Medicine Residency Program</td>
</tr>
<tr>
<td>SEI Verapamil ordered and administered to incorrect patient</td>
<td>Ensure pharmacists use a standardized form for note taking of orders. Enforce the following in pharmacy: use of modify function to edit orders, always having all medications in view when working in EHR, asking providers for their last name, always checking patient names and medication reconciliation when verifying orders.</td>
<td>Shawn Parekh, Michele Sheaffer, Robert A Waite</td>
<td></td>
<td>09/15/17</td>
<td>N/A</td>
<td>Fahy, Jeannine</td>
<td>Pharmacy</td>
</tr>
<tr>
<td>SEI Verapamil ordered and administered to incorrect patient</td>
<td>Create a “Could This Happen to You” about this event and include cultural sensitivity information for Nurses Notes</td>
<td>MoSachern, Alyssa</td>
<td></td>
<td>09/15/17</td>
<td>N/A</td>
<td>Fahy, Jeannine</td>
<td>Nursing</td>
</tr>
<tr>
<td>MEL Delay in Cryptococcosis Treatment</td>
<td>The process for notifying providers about abnormal results is fractured and difficult to navigate.</td>
<td>Schneider, Doron</td>
<td></td>
<td>09/20/17</td>
<td>N/A</td>
<td>Fahy, Jeannine</td>
<td>Center for Safety and Quality</td>
</tr>
</tbody>
</table>
Sharing, Learnings, Questions and Take-Aways
Thank you!

For additional information, contact

Maureen Ann Frye, MSN, BC, CRNP, CPPS, CPHQ  
Director, John J. Kelly Institute for Patient Safety and Quality  
Abington Jefferson Health  
1200 Old York Road  
Abington PA  19001

215-481-4510  
Maureen.frye@jefferson.edu