Practical Tools for the High Reliability Journey

Root Cause Analysis (RCA)
Failure Mode Effects Analysis (FMEA)

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Objectives

• Identify the limitations of traditional improvement activities for sustainable change in a complex organization.

• Describe how to apply the tools of Root Cause Analysis (RCA) and Failure Mode Effects Analysis (FMEA) to obtain sustainable, reliable results.
The need for new tools....

“Our Age of Anxiety is, in great part, the result of trying to do today’s job with yesterday’s tools and yesterday’s concepts”

Marshall McLuhan (Canadian Philosopher /sociologist 1911-1980)

The Medium is the Massage: An Inventory of Effects by Marshall McLuhan & Quentin Fiore, Bantam Books, New York, 1967
Why? It’s a complex world……..

Characteristics:
• Unpredictable/Chaotic
• Emergent conditions
• Rapid Change
• Inter related parts that cannot be easily separated
• No easy answers

Tools need to focus on reliability:
• Prevention
• Resilience
• Adaptability
• Tools that look at the “whole”
• Deference to expertise
• Collaboration
• System issues/root causes

Dekker, Cilliers, & Hofmyer, 2011
Why? ZERO Harm requires new thinking/methods

• “When you design for zero, you surface different ideas and approaches that if you’re only designing for 90 percent, may not materialize. It’s about purposefully aiming for a higher level of performance.” Thomas Priselac, Cedars Sinai Medical Center

• How much harm are you willing to tolerate? How many falls? How many CAUTI’s???
A New Paradigm in Improvement

Yesterday’s Thinking
• Control
• Hindsight
• Reduce problem to parts (complicated)
• Disciplinary silos
• Individuals are the source of errors
• Change the individual

Today’s Thinking
• Adaptability
• Foresight
• Consider problem as a whole (complexity)
• Disciplinary collaboration
• Individuals are the source of solutions
• Change the system

Woods, et. al., 2012
What are the challenges faced with old models of improvement tools?

- Punitive
- Don’t account for human factors
- Reactive not proactive
- Focus on individual not system
- Strong interventions lacking
- Sources of bias not recognized
- DON’T LEAD TO SUSTAINABLE OUTCOMES AND ZERO HARM

Braaten, 2016
New Tools (RCA and FMEA)
System Solutions and Proactivity= High Reliability

• System level solution
• Collaborative
• Anticipate problems and fix prior to implementation
• Strong interventions that consider human factors
• Involve frontline staff in solutions
Root Cause Analysis (RCA)
Fix the Problem at the Root

• **Definition**: Systematic process to assess the underlying beliefs and practice that result in a failure

• **End product**: Identify the root cause or causes that if removed would have prevented the failure

National Patient Safety Foundation, 2015
Basic Elements of RCA Investigation

WHAT happened

HOW it happened

WHY it happened

Unsafe Acts

Human Behaviour

Contributory Factors

Solution Development & Review of effectiveness (recurrence of PSI)

‘WHO did it’ is not the objective

National Patient Safety Agency,
http://www.nrsl.npsa.nhs.uk/resources/collections/root-cause-analysis/rca-training
Human Error is the beginning of the investigation not the end…

• Human error is a symptom of the problem, not the problem

• Look deeper for the second story
  – Ask “why” 5 times

• Understand work at the “frontline”
Steps to an RCA

1. Is it an RCA?
2. Gather information/Map process
3. Assemble Team
4. Identify Root Causes
5. Identify Actions
6. Measure success
7. Disseminate findings

Braaten, 2016
Step 1: Is it an RCA??

**Yes**

- **Sentinel Events**
  - Adverse event led to death or injury
- **Aggregated Reviews**
  - Falls
  - Pressure ulcers
  - Med errors
- **Near misses or close calls with the potential for severe outcomes**
  - Potential for severe outcomes

**No**

- **Criminal Acts**
  - Thefts
  - Abuse
  - Impairment
- **Reckless Behavior**
  - Drug diversion
  - Refusing to follow a policy

National Patient Safety Foundation, 2015
Step 2: Gathering Information

• Interview one person at a time
  – Who to interview

• Safe Environment
  – Seek to learn not to judge

• Ask what happened?
  – not WHO did it

• Ask about context
  – Processes, equipment, human resources, leadership, communication, human factors, policies

Local Rationality: Put yourself in their shoes
• “Why did it make sense at the time?”

Braaten, 2016; Dekker, 2016
### The Interview Guide

#### The Interview Guide

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**Nursing Excellence Advocacy Team (NEAT) Worksheet: CRASH - PROPERTY OF NEAT**

**CONFIDENTIAL INFORMATION FOR QUALITY IMPROVEMENT**

**DO NOT SHARE OR PLACE IN EMPLOYEE FILE**

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**Standard of care issue and date of event:**

**Introduction:** I would like to talk to you about _______ event. The purpose is to learn and improve care as a hospital system.

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<table>
<thead>
<tr>
<th>What happened from your perspective?</th>
</tr>
</thead>
<tbody>
<tr>
<td>What factors influenced your action or decision?</td>
</tr>
<tr>
<td>What do you think should have or was supposed to happen?</td>
</tr>
<tr>
<td>Do you think others could make the same mistake?</td>
</tr>
<tr>
<td>What solutions do you suggest to prevent this from happening again at CRASH?</td>
</tr>
<tr>
<td>Do you need any support?</td>
</tr>
</tbody>
</table>

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If you think of something else, please call. We will circle back with you for feedback after we discuss the event and solution at the next NEAT meeting.

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**Learning and healing; not punishing**

**Avoiding bias**

**Involving the person in the solution assisting with decreasing second victim distress**

**Support**

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Centura Health, 2017
Remember the Second Victim

- Second victims are healthcare providers involved in an unanticipated adverse patient event or medical error that causes injury who then become traumatized by the event

- Consequences: Dropping out or Staying with guilt

- Thriving: learning from the mistake and making a difference for the future (RCA)

Scott, 2011
Step 3: Assemble the Team

• 4-6 participants
• At least one expert in the subject matter
• An individual who is not an expert
• Front line staff familiar with the subject matter
• A patient advocate or a patient
• Avoid staff directly involved in the event to avoid bias

National Patient Safety Foundation, 2015
Step 4: Searching for Root Causes

- Ask Why and What until all questions are answered
- A root cause needs a cause and effect
- A root cause only starts with human behavior, **not ends**
- Violation of policy is not a root cause. Why?
- Would the root cause (if fixed) correct the problem?

National Patient Safety Foundation, 2015; Vidyasager, 2015
Human Factors Checklist

✓ Lack of Communication
✓ Assumptions
✓ Complacency
✓ Lack of Knowledge
✓ Distraction
✓ Lack of Teamwork
✓ Fatigue

✓ Lack of Resources
✓ Rushing-Go Fever
✓ Lack of Assertiveness
✓ Confirmation bias
✓ Stress
✓ Lack of Situational Awareness
✓ Normalization of deviance

Adapted from The Dirty Dozen
Ask Why 5 Times to find the Root Cause

Why?
• Event: A patient on a mental health hold was allowed to elope from the hospital

Why?
• He was wearing civilian clothes and was let out the door by an employee who thought he was a visitor.

Why?
• His clothes had not been secured and he got dressed.

Why?
• He was not being monitored in the secure portion of the department

Why?
• The department is lacking enough secure beds for the demand (ROOT CAUSE)
Avoiding the bias: The perils of judging human behavior

• **Hindsight bias**—”Knew it all along”
• **Outcome bias**—judge people more harshly based on outcome
• **Confirmation bias**—look for facts that confirm beliefs

Dekker, 2016
Steps 5: Identify Effective Actions

- **Strong** – mistake proofing; taking away an error prone product
  - Forcing the correct way and placing a barrier to the incorrect

- **Weak** - education
  - “be more careful”

Caroll, 2011
Step 6: Measure Success

• Actions need to have measurable criteria as outcomes
Step 7: Disseminate Findings

• Interventions are made stronger with education and support
• Staff
• Leadership
• Hospital board

Braaten, 2016
Key Points for a Highly Reliable RCA: Did it...?

• Invest in strong interventions that will lead to lasting change?

• Identify all system issues that led to the human error?

• Ask 5 Whys to get to root cause?

• Assure that solutions are associated with strong timelines and follow up?

• Recognize and discuss sources of bias affecting the RCA process?

• Provide healing and resolution to staff?
Failure Mode Effects Analysis (FMEA)

• "Accidents do not occur because people gamble and lose, they occur because people do not believe that the accident that is about to occur is at all possible."
  James Reason, Human Error

• FMEA
  – Anticipation of error- Ask “what is the worst that can happen?”
  – Mitigate the failure before it occurs
  – Identify our processes to detect failure before the failure progresses

Success begins with failure

Reason, 2000; IHI
Steps to an Effective FMEA

- Choice an appropriate process
- Form the team
- List every step in the process
- Identify how each step could fail
- Score each failure mode by likelihood, severity, detection
- Calculate the risk number
- Prioritize actions by high risk
- Create strong interventions to mitigate failure modes with highest risk

Bilys, 2016; IHI
Step 1: Identify a Process

- Must be a process with identifiable steps
- New processes
  - Surgical procedures
- Existing processes
  - Fall prevention
  - Suicide attempt prevention in high risk patients
- Not in response to an event
  - Hunting for “failure” modes

Bilys, 2016
Step 2: Form the Team

- Multidisciplinary
- Must be knowledgeable of the process at the frontline
- Need to set up adequate time

Bilys, 2016
Step 3: Map the Process

Suicidal patient in ED

Remove all potentially dangerous items

Completely undress patient and place in hospital gown with no ties

Secure all belonging and inventory

Place in room with visual monitoring

Maintain 15 minute checks and continuous line of sight

Visitors must be escorted in and out of room

Re-check room and patient after visits from visitors or other staff
Step 4: Analyze each step for potential for failure, effect of failure, and potential for occurrence

<table>
<thead>
<tr>
<th>Step</th>
<th>Step</th>
<th>Failure Mode</th>
<th>Effect of failure</th>
<th>Failure Cause</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Remove all potentially dangerous objects from room</td>
<td>Items left in room such as chairs, Mayo stand, phones allowed to be kept with patient</td>
<td>Could use object to harm self or others</td>
<td>Staff not following a consistent protocol</td>
</tr>
</tbody>
</table>
## Step 5: Scoring

<table>
<thead>
<tr>
<th>Category</th>
<th>A What is the likelihood the failure will occur?</th>
<th>B If the failure occurs, how likely will we know it occurred?</th>
<th>C Severity on the patient</th>
</tr>
</thead>
<tbody>
<tr>
<td>Score</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>≥ 1 In 150k</td>
<td>Almost Certain</td>
<td>Did Not Reach Patient, Near Miss</td>
</tr>
<tr>
<td>2</td>
<td>1 In 150k</td>
<td>Very High</td>
<td>Reached Patient, No Harm</td>
</tr>
<tr>
<td>3</td>
<td>1 In 15000</td>
<td>High</td>
<td>Reached Patient, Emotional Distress Or Inconvenient</td>
</tr>
<tr>
<td>4</td>
<td>1 In 2000</td>
<td>Moderately High</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>1 In 400</td>
<td>Moderate</td>
<td>Additional Treatment</td>
</tr>
<tr>
<td>6</td>
<td>1 In 80</td>
<td>Low</td>
<td>Temporary Harm, Bodily or Psychological</td>
</tr>
<tr>
<td>7</td>
<td>1 In 20</td>
<td>Very Low</td>
<td>Permanent Harm</td>
</tr>
<tr>
<td>8</td>
<td>1 In 8</td>
<td>Remote</td>
<td></td>
</tr>
<tr>
<td>9</td>
<td>1 In 3</td>
<td>Very Remote</td>
<td>Severe Permanent Harm</td>
</tr>
<tr>
<td>10</td>
<td>≤ 1 In 2</td>
<td>Absolute Uncertainty</td>
<td>Death</td>
</tr>
</tbody>
</table>
Step 6: Calculate the Risk Score

<table>
<thead>
<tr>
<th>Current controls to prevent or detect failure</th>
<th>A (Likelihood to Occur)</th>
<th>B (Likelihood of Detection)</th>
<th>C (Severity (Potential Harm))</th>
<th>Calculate Risk Priority Number (RPN) = A x B x C</th>
</tr>
</thead>
<tbody>
<tr>
<td>Few</td>
<td>10</td>
<td>8</td>
<td>5</td>
<td>400</td>
</tr>
</tbody>
</table>

A x B x C = Risk score
## Step 7: Select High Risk Processes for Mitigation of Risk

<table>
<thead>
<tr>
<th>Step #</th>
<th>High Risk Area</th>
<th>Failure Mode</th>
<th>Mitigation</th>
<th>Measure of success</th>
<th>When complete</th>
<th>Who is responsible</th>
</tr>
</thead>
</table>
| 2      | All high risk items removed from room | Visitors or staff may bring items back into room | • The room will be checked after the visitor and/or staff has left the room.  
• Reminder on door  
• Checklist created | Audit of checklist completed at end of shift | 7 days | Suzanne and Ron |
Step 8: Select Effective Interventions

### Rank Order of Error Reduction Strategies

- **Less Error**
  - Forcing functions and constraints
  - Automation and computerization
  - Standardization and protocols
  - Checklists and double check systems
  - Rules and policies
  - Education / Information
  - Be more careful, be vigilant

- **More Error**

### Problem Table

<table>
<thead>
<tr>
<th>Problem</th>
<th>Weak</th>
<th>Intermediate</th>
<th>Strong</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Infusing antibiotics too fast</strong></td>
<td>Training sent out to all staff on</td>
<td>Require staff to double check rate prior to infusion</td>
<td>Hard limits on pumps that don’t allow infusion above a certain rate</td>
</tr>
<tr>
<td></td>
<td>appropriate rates</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Tube feeding hooked up through an IV line</strong></td>
<td>Label tubing “For Enteral Use Only”</td>
<td>Alert pops up on computer screen “For Enteral Use only”</td>
<td>Incompatible connections. Can only be connected to the correct tube or site</td>
</tr>
</tbody>
</table>

Caroll, 2011; Braaten, 2016
Summary

• RCA and FMEA are tools that assist us use HRO principles to cope in a complex world
  – Proactive
  – Multidisciplinary
  – Fixes system issues
  – Looks at processes from the frontline view
  – Focus on strong interventions and follow up
References/Resources


References/Resources


Institute of Healthcare Improvement (IHI). Failure modes and Effects Analysis retrieved from http://www.ihi.org/resources/Pages/Tools/FailureModesandEffectsAnalysisTool


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