Practical Tools for the High Reliability Journey
Root Cause Analysis (RCA)
Failure Mode Effects Analysis (FMEA)

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STTI 28th International Nursing Research Congress
Dublin, Ireland
July 28, 2017
2:30 P.M. – 3:45 P.M.

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Conflict of Interest

- The presenter for this presentation has disclosed no conflict of interest related to this topic.

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.

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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

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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

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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 ???

Aim for ZERO HARM

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May, 2013

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**

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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
- <u>DON'T LEAD TO SUSTAINABLE OUTCOMES AND ZERO HARM</u>

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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
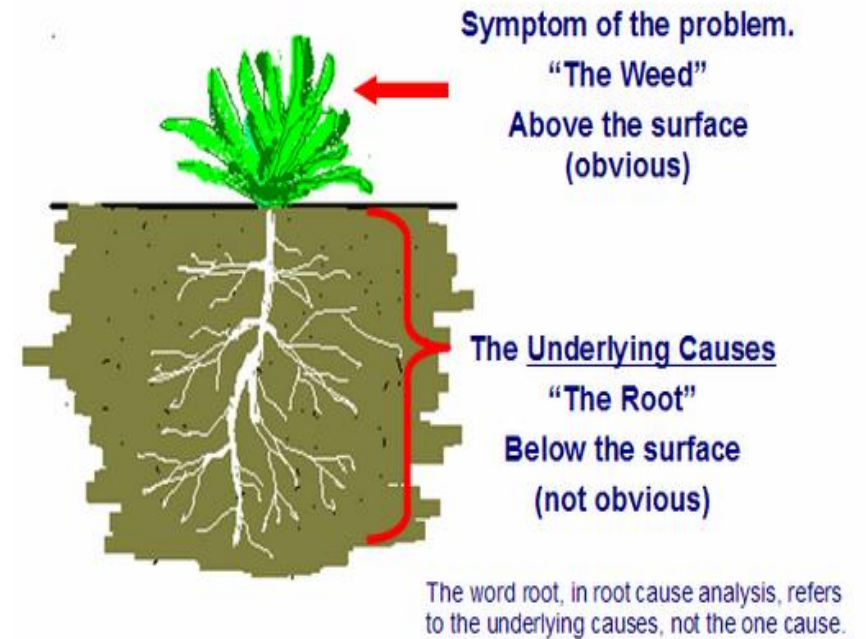- Involve frontline staff in solutions

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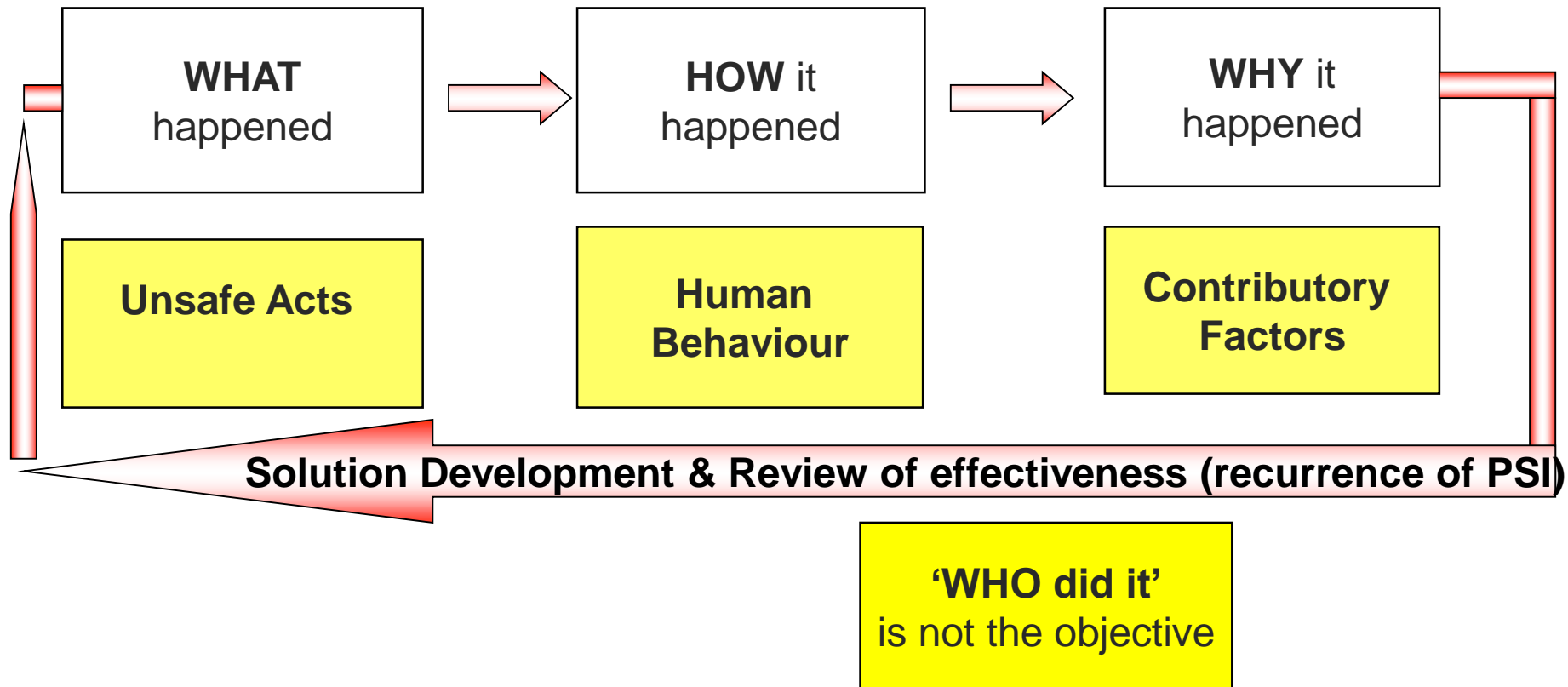
Root Cause Analysis(RCA)
Fix the Problem at the Root

- **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

Root Cause Analysis Basics

Symptom of the problem.
"The Weed"
Above the surface
(obvious)

The Underlying Causes
"The Root"
Below the surface
(not obvious)

The word root, in root cause analysis, refers to the underlying causes, not the one cause.

National Patient Safety Foundation, 2015

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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)
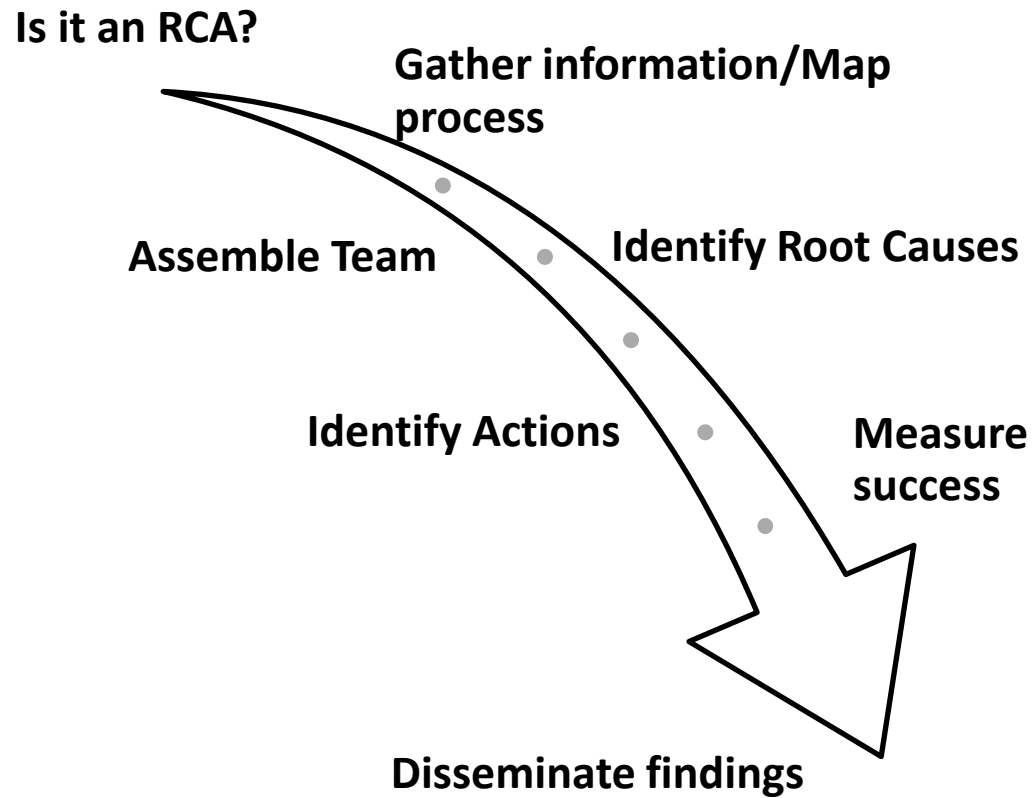
'WHO did it' is not the objective

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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"

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Woods, et. al., 2012

Steps to an RCA

Is it an RCA?

Gather information/Map process

Assemble Team

Identify Root Causes

Identify Actions

Measure success

Disseminate findings

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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

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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

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)

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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

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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

MY TRAIN OF THOUGHT... HAS DERAILED

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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)**
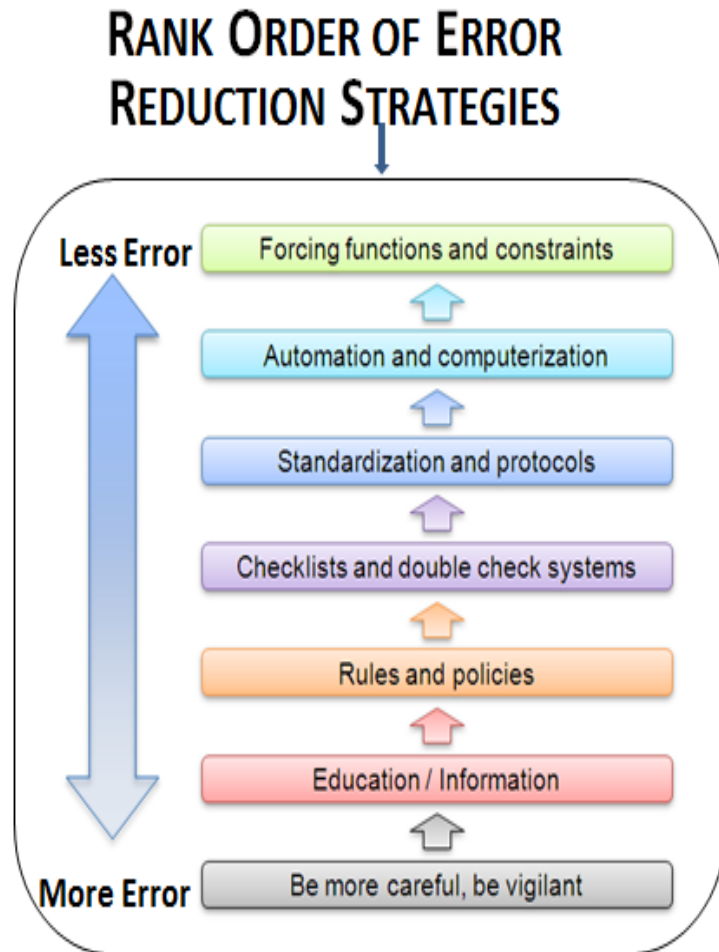
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Braaten, 2016

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

PEOPLE GENERALLY SEE WHAT THEY LOOK FOR AND HEAR WHAT THEY LISTEN FOR

HARPER LEE, TO KILL A MOCKING BIRD

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Dekker, 2016

Steps 5: Identify Effective Actions

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

- **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"

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Caroll, 2011

Step 6: Measure Success

- Actions need to have measurable criteria as outcomes

Structure
- Physical environment

Process
- Protocols, policies, procedures

Outcomes
- Big picture indicators

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Donabedian, 2005
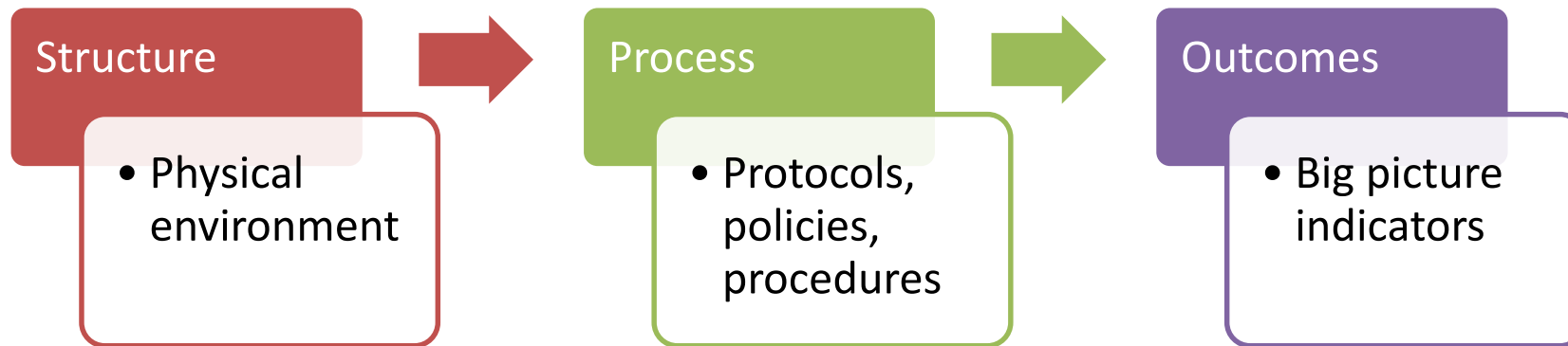
Step 7: Disseminate Findings

- 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?

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Braaten, 2016

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

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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

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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

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Bilys, 2016

Step 2: Form the Team

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

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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

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Step 4: Analyze each step for potential for failure, effect of failure, and potential for occurrence
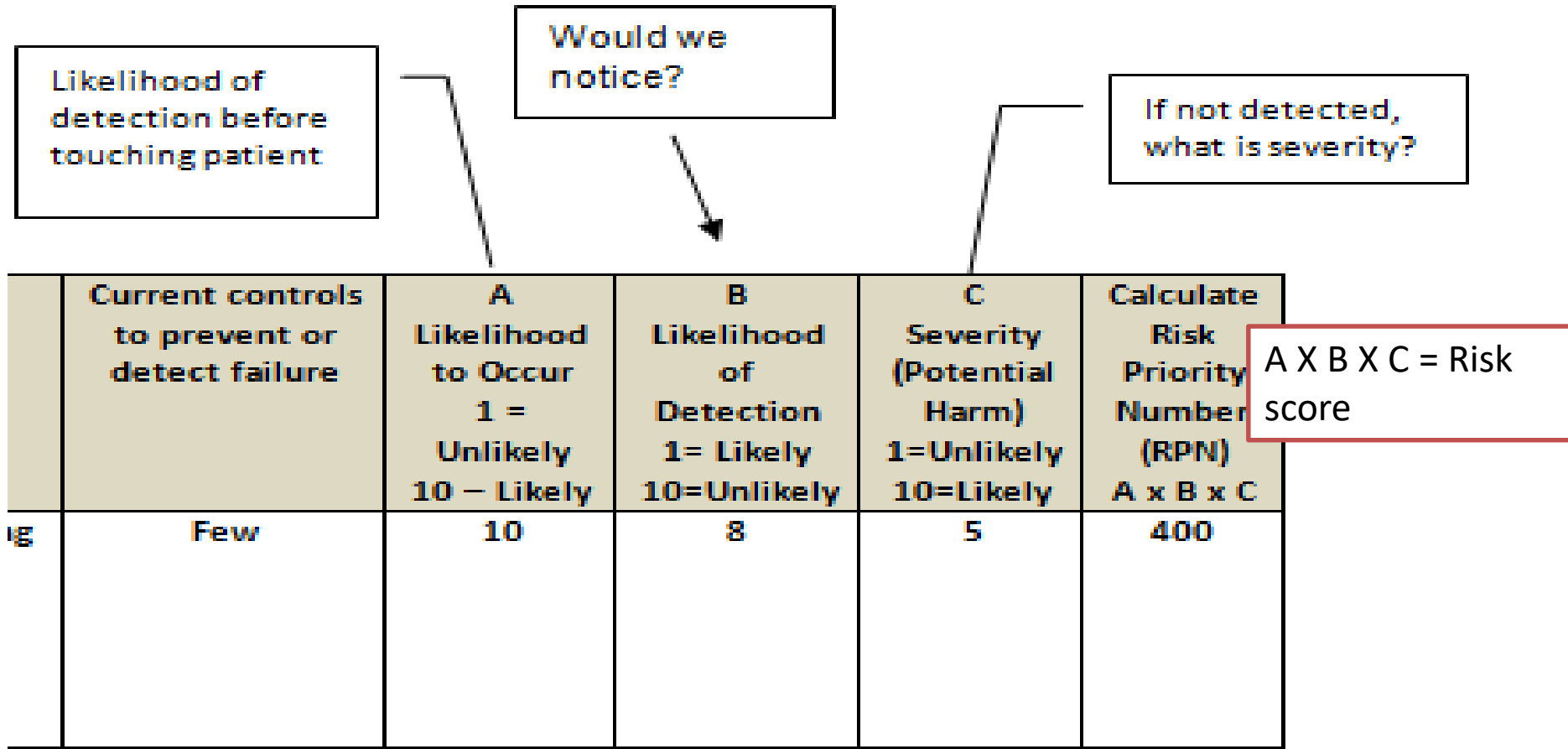
Step	Step	Failure Mode What could go wrong?	Effect of failure What would happen to the patient?	Failure Cause Why would the failure happen?
1.	Remove all potentially dangerous objects from room	Items left in room such as chairs, Mayo stand, phones allowed to be kept with patient	Could use object to harm self or others	Staff not following a consistent protocol

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Step 5: Scoring

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

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Step 6: Calculate the Risk Score

Likelihood of detection before touching patient

Would we notice?

If not detected, what is severity?

A X B X C = Risk score

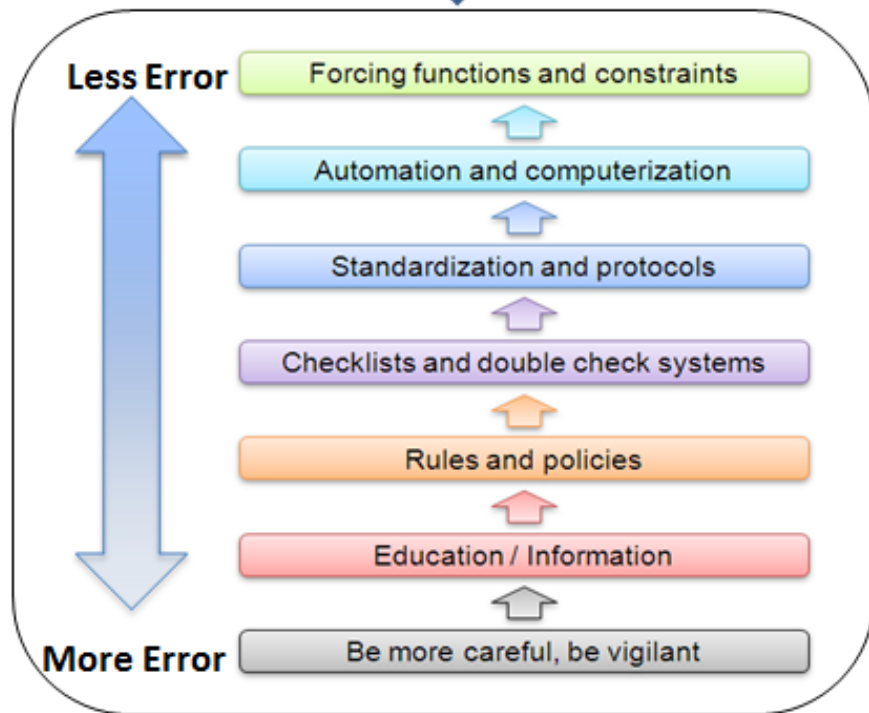|	Current controls to prevent or detect failure	A Likelihood to Occur 1 = Unlikely 10 – Likely	B Likelihood of Detection 1= Likely 10=Unlikely	C Severity (Potential Harm) 1=Unlikely 10=Likely	Calculate Risk Priority Number (RPN) A x B x C
ng	Few	10	8	5	400

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Step 7: Select High Risk Processes for Mitigation of Risk

Step #	High Risk Area	Failure Mode	Mitigation	Measure of success	When complete	Who is responsible
2 RPN-200	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

Centura Health, 2017

Step 8: Select Effective Interventions

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More Error

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

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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

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