National Conference in Patient safety

Workshop:

Root Cause Analysis (RCA) and Failure Mode and Effect Analysis (FMEA)

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Disclaimer:
PRESENTING AUTHORS HAVE NO RELATIONSHIPS TO DISCLOSE

Objectives

<u>By the end of this workshop, the participant shall be able to :</u>

1. Explain what is meant by the terms Route Cause Analysis and Mode Failure and Effect Analysis
2. Describe the use of each term in health care environments
3. Explain the difference in the utilization between the two terms
4. Apply this knowledge in simulated practice in advance to application into clinical practice (use the NHS as a model option)

RCA: What is it?

- Root cause analysis is a systematic process used to address problems or non-conformance to identify the source of the problem
- A root cause is the underlying breakdown or failure of a process which, when resolved, prevents the problem from reoccurring
- In health care, a problem often has more than one cause

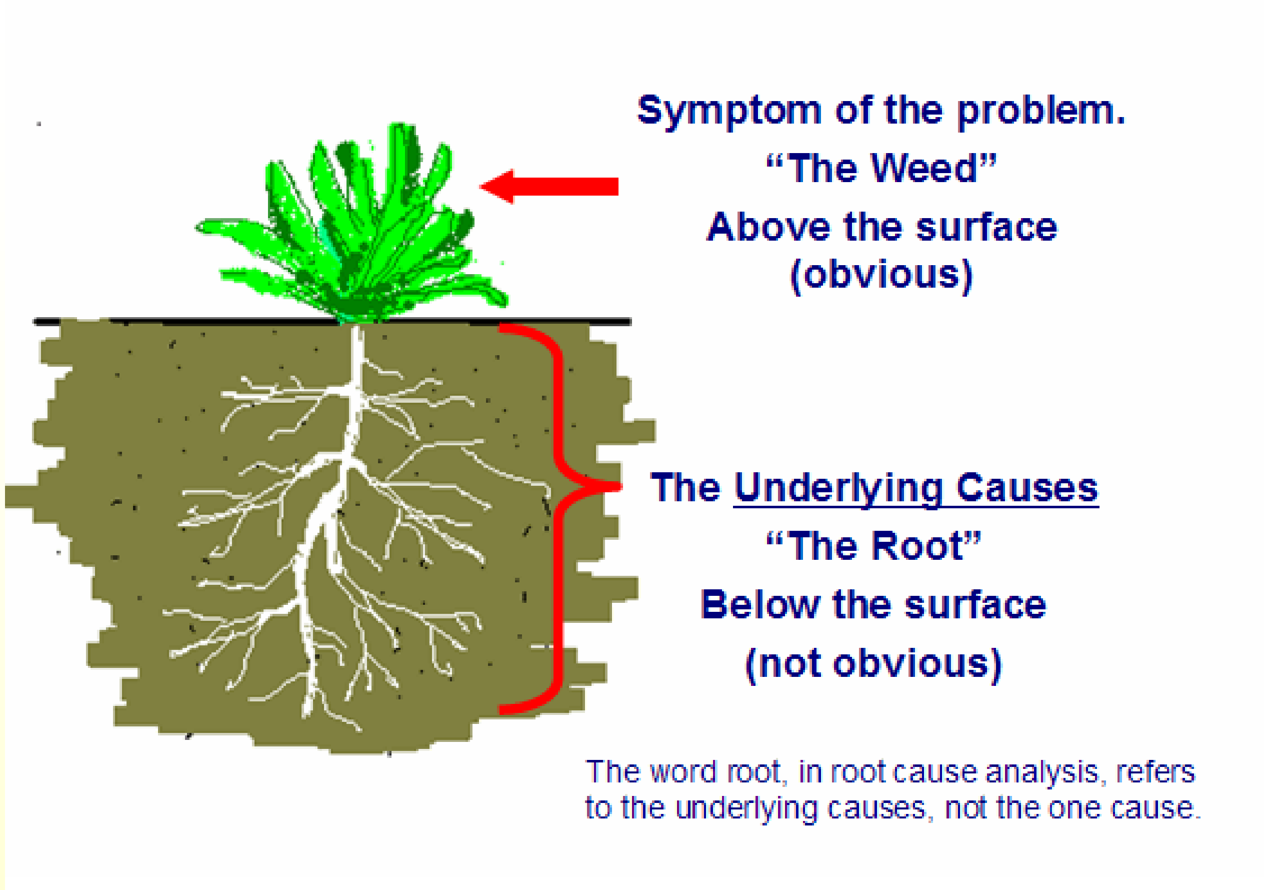
RCA is a retrospective investigation

What is a ROOT CAUSE?

= A fundamental contributory factor

- One which had the greatest impact on the system failure.
- One which, if resolved, will minimise the likelihood of recurrence both locally and across the organisation.

('Treat the illness not the symptoms')



An important aspect of RCA is the use of a systematic approach to examine errors, removing the focus on individuals in the process of analyzing the situation

Process of RCA

- All factors that lead to errors should be examined in order to meet the ultimate goal of identifying ways or system defenses to prevent repetition of the error

Form a Team to investigate by asking:

What happened?

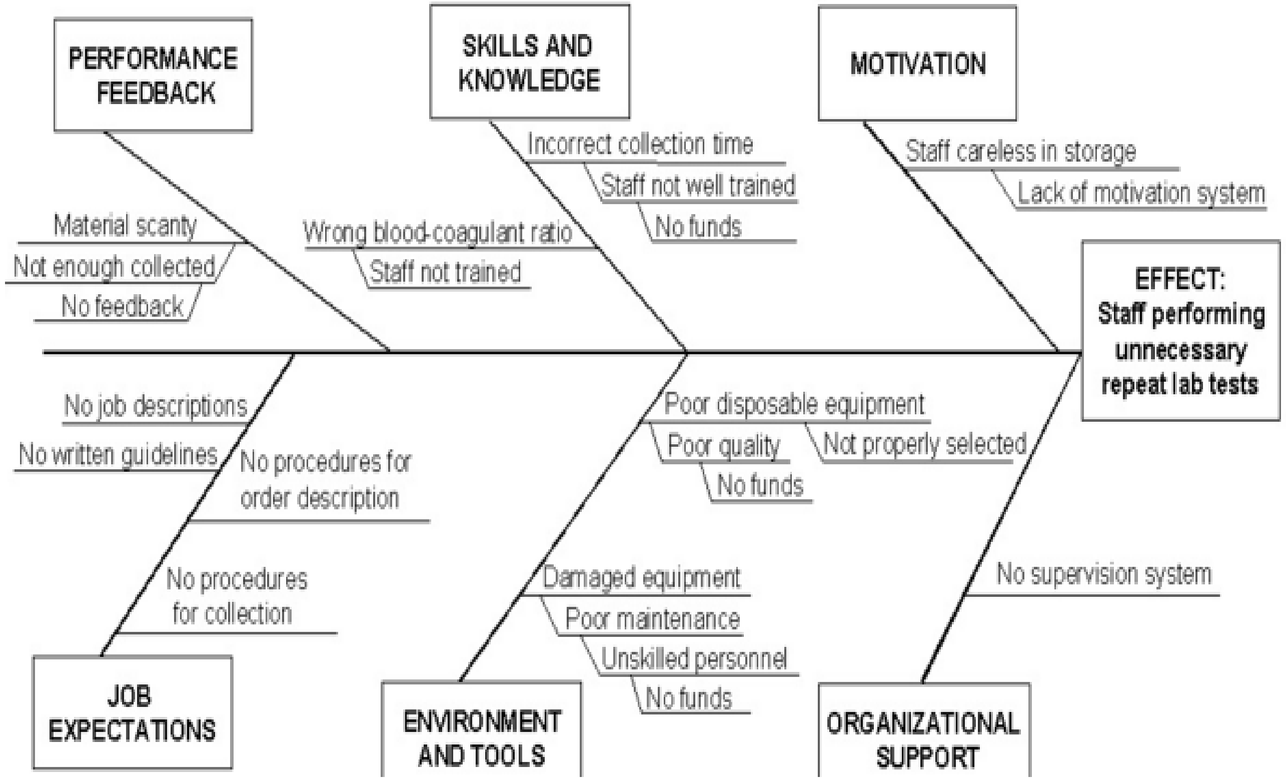
How did it happen?

Why did it happen

What should be done to prevent it from happening again?

The “5 Whys” technique

- Examine breakdown in the process by asking five or more whys to drill down to the “root cause”
- CAUTION: avoid a premature answer
- Use cause-and-effect diagram (such as a fishbone diagram) to visualize the relevant issues: people, processes, materials, environment, and management issues related to the event



The RCA Investigation Process

Getting Started

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Gathering and Mapping the Information

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Identifying Care and Service Delivery Problems

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Analysing the Information - Identifying Contributory Factors and Root causes

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Generating Recommendations and Solutions

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Implementing Solutions

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Writing the Report

Source:

NHS
National Patient Safety Agency

Detection Factors

Stage of detection	✓
• During proactive risk assessment, prior to opening, a new or changed service	
• At pre-admission patient assessment	
• Immediately prior to care/treatment	
• During direct care/treatment	
• During continued care by third party agency	
• Post-care/treatment	

How was the incident detected	✓
□ By checklist	
□ Via clinical assessment/observations - staff identifying a change in patient's condition	
□ Via a test/investigation - staff identifying a change in patient's condition	
□ Via general observation - by staff (heard noise, found patient on floor etc)	
□ Via general observation - by the patient/carer/relative/friend	
□ Via general observation - by another patient	
□ Via a cry for help - from patient/carer/relative/friend/other patient	
□ By a subjective feeling/symptom reported by the patient	
□ Via Care-staff walkaround	
□ Via Management walkaround	
□ By a monitor	
□ By an alarm	
□ By patient buzzer / call bell system	
□ By a change in a system or machine function	
□ By a change in the environment	
□ By a count (e.g. Swab count, head count etc)	
□ By a query	
□ By audit	
□ By a review	
□ By Incident trend	
□ By locally shared learning	
□ By nationally shared learning	
□ From research / evidence	
□ By complaint or claim	
□ By an associated incident (e.g. Patient misidentification)	
□ By notification from an external agency (e.g. Police, Coroner, Media)	
□ Other	

NHS
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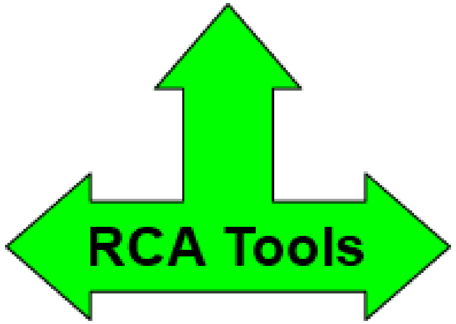
Contributory Factors

Contributory factors framework

Fishbone diagram



Run chart

Contributory Factors Framework

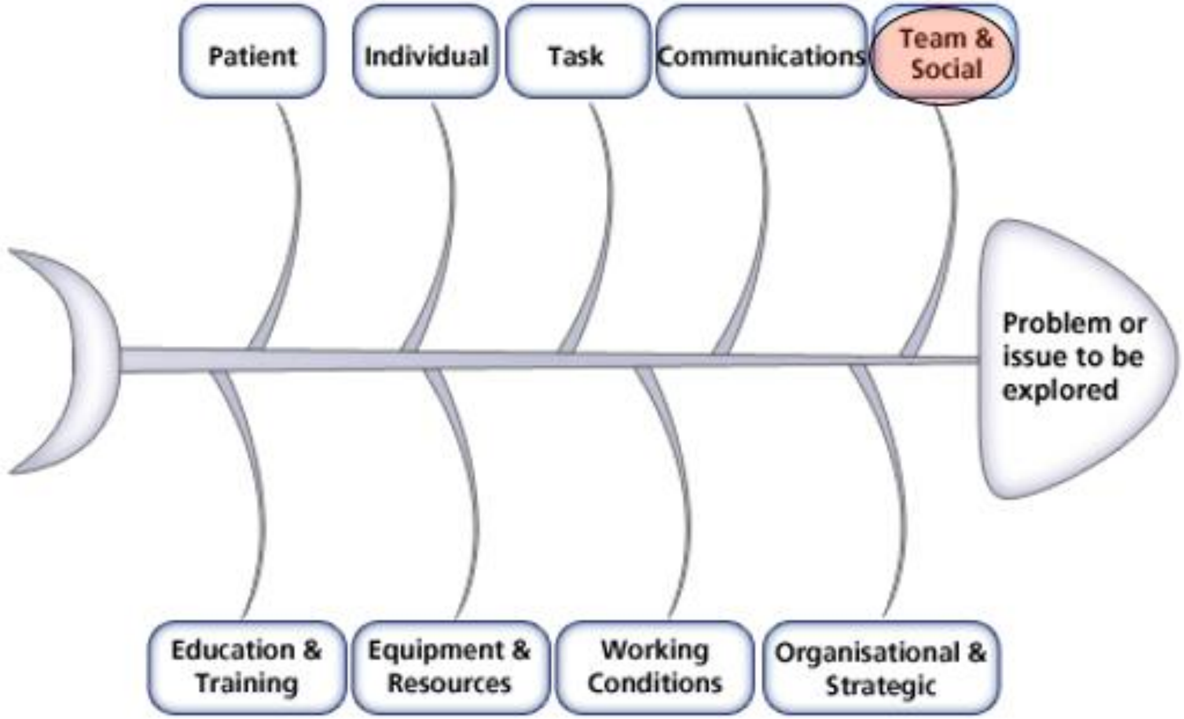
Detailed list of contributory factors collected from incident investigation in Healthcare Settings

- Patient factors
- Individual staff factors
- Task factors
- Communication factors
- Team & social factors
- Education & training factors
- Equipment & resource factors
- Working conditions/environment factors
- Organisational & strategic factors

Team & Social factors

Contributory factors - NPSA framework

The key part of the analysis is to identify the contributory factors lying behind each problem. The NPSA's CFF has categories and components relating to exploring incidents. Click each category to find out more.



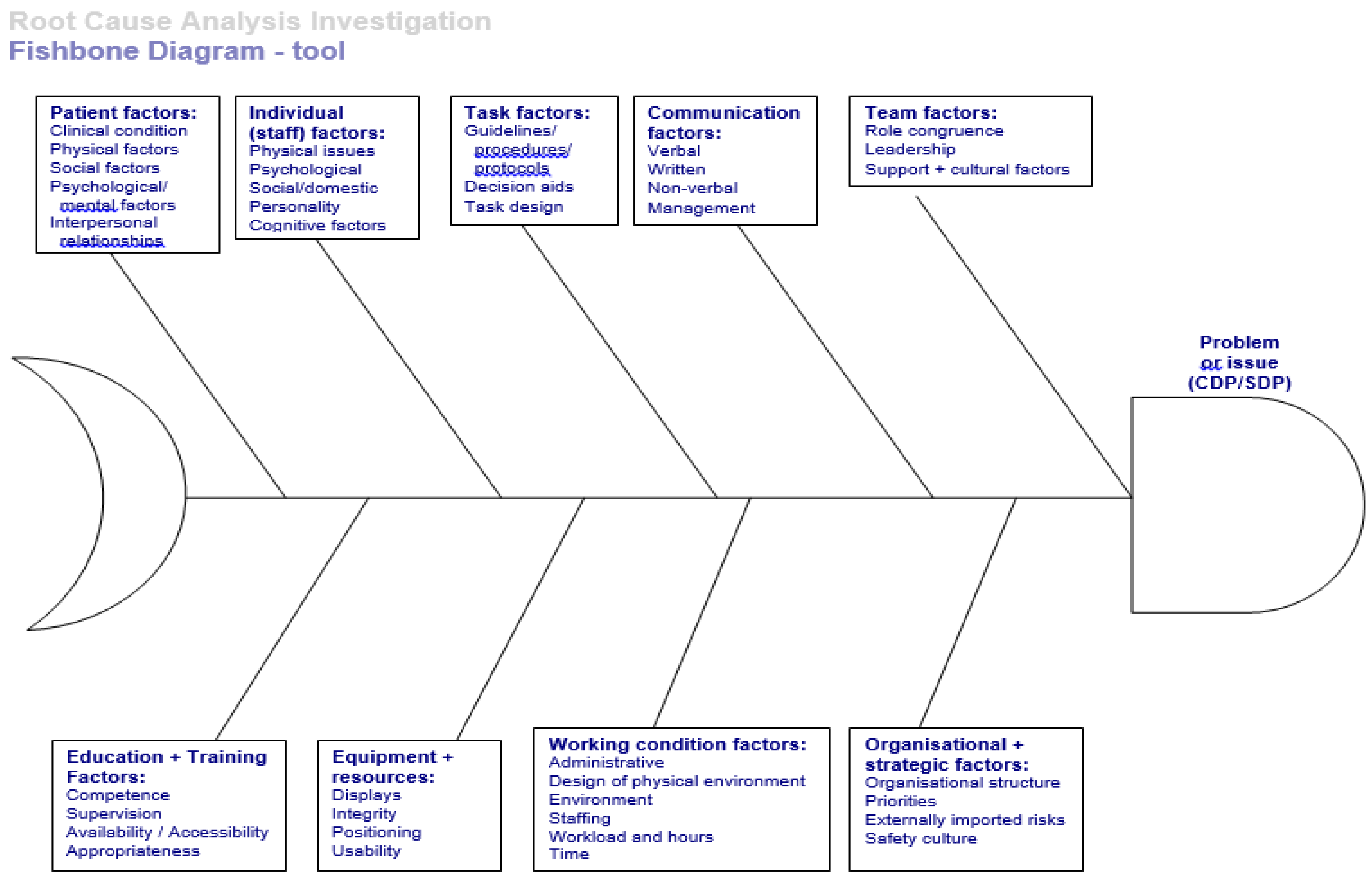
Team and social factors are grouped into three types:

- Role congruence
- Leadership
- **Support and cultural factors.**

Example: Multi-disciplinary team rarely met and the weekly Directorate meeting was for doctors only.

Content from National Patient Safety Agency material
http://www.nationalarchives.gov.uk/doc/open-government-licence/version/2/

Fish Bone Diagram



Change Analysis Tool

Root Cause Analysis Investigation - tools

Change Analysis

Normal / Accepted Procedure	Actual Procedure at time of Incident	Was there a change (Y/N)	If yes, what was the CDP/SDP that contributed to the incident

CDP: Care Delivery Problem; SPD: Service Delivery Problem

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Barriers Analysis Tool

National Patient Safety Agency

Root Cause Analysis Investigation tools

Barrier Analysis

Activity:						
Hazard(s)	Barriers / controls / defences already in place	Failsafe attributes • Strong • Medium • Weak	Improve barriers by:	Additional barriers required?	Cost implications	Responsibility • Individual • Manager • Trust

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RCA & ‘Drilling Down’ - to identify Root Causes

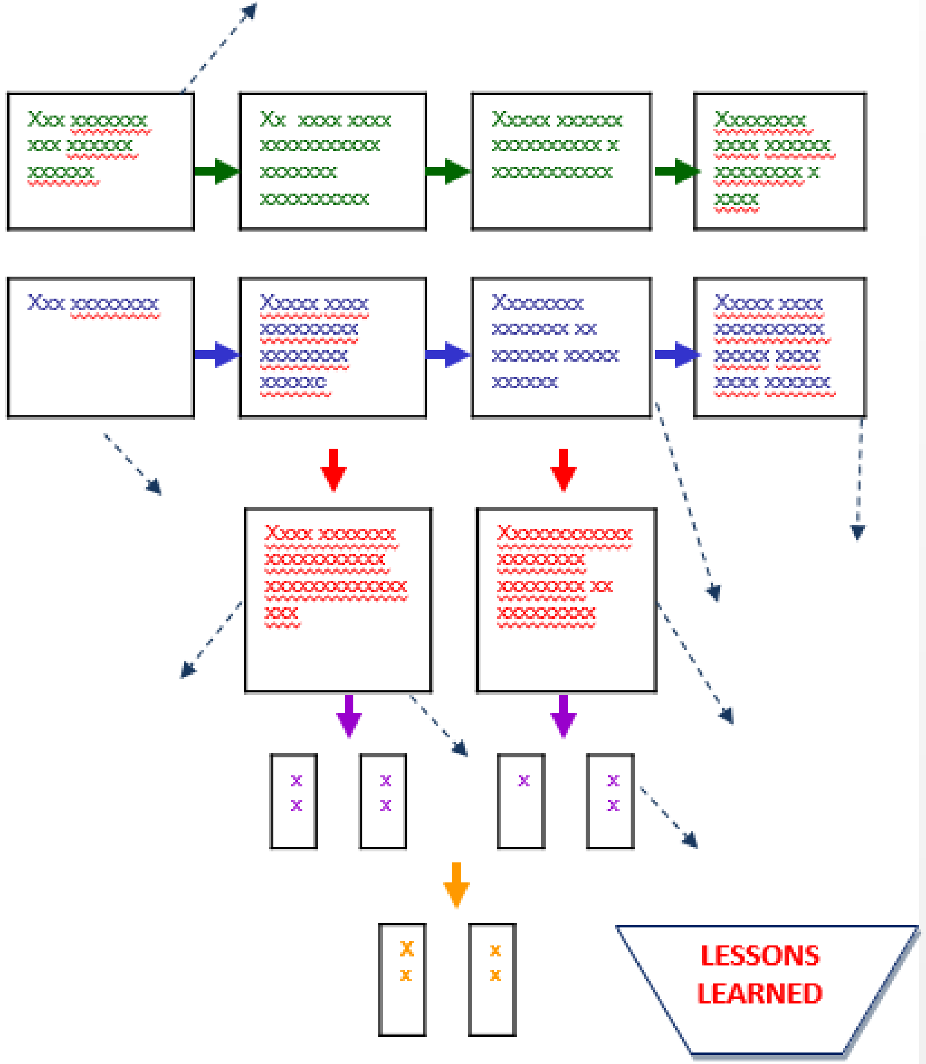
B. What should have happened
Policy / Guidelines / Acceptable practice

A. What actually happened
The patient’s journey

1. Care & Service Delivery Problems
Variations from acceptable practice
(Actions, Errors and Omissions)

2. Contributory Factors
Influencing factors contributing to breach (+SRK)

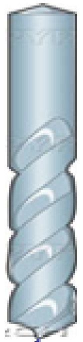
3. Root Cause(s)
Fundamental contributory factors
(Need to identify and treat the illness, not the symptoms)



'Pareto effect' or '80/20' rule:

80% of undesired behaviour will be related to 20% of causes

Drilling Down to find Root Causes



Drill down to at least ➔ this level before considering solutions

Drill down to here ➚ if at all possible

1. CDPs + SDPs - Unsafe Acts & Unsafe conditions

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2. Contributory Factors *(Proximate causes)* - Process Issues

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3. Root Causes - *(Causal factors)* Systemic Issues

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Root Causes - Leadership Issues

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Root Causes - Societal Issues

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Root Causes - Economy Issues

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Failure Mode and Effect Analysis

- A ‘prospective’ process
- Proactive; to PREVENT occurrence of failures
- A systematic method of identifying and preventing product and process failures before they occur
- Ddoes not require a specific case or adverse event
- Rather, a high-risk process is chosen for study, and an interdisciplinary

A team asks: ***“What can go wrong with this process and how can we prevent failures?”***

Case

- 72-year-old patient admitted to your hospital with findings of an acute abdomen requiring surgery. The patient is a smoker, with Type 2 diabetes and an admission blood sugar of 465, but no evidence of DKA. She normally takes an oral hypoglycemic to control her diabetes and an ACE inhibitor for high blood pressure but no other medications. She is taken to the OR emergently, where surgery seems to go well, and post-operatively is admitted to the ICU. Subsequently, her blood glucose ranges from 260 to 370 and is “controlled” with sliding scale insulin. Unfortunately, within 18 hours of surgery she suffers an MI and develops a postoperative wound infection 4 days after surgery. She eventually dies from sepsis.

Discuss how RCA and FMEA could be demonstrated in this scenario

Case-contd

RCA:

Causal factors: lack of use of a beta-blocker preoperatively and lack of use of IV insulin to lower her blood sugars to the 80–110 range

FMEA:

An interdisciplinary team asks the question (before any incident happens): “What can go wrong with this process and how can we prevent failures?”

The team decides to conduct an FMEA on controlling blood sugar in the ICU or administering beta-blockers perioperatively to patients who are appropriate candidates

http://www.the-hospitalist.org/

Possible Findings of FMEA

- A significant risk encountered in achieving tight glucose control in the range of 80–110 includes hypoglycemia
- Common pitfalls of insulin administration include administration and calculation errors that can result in 10-fold differences in doses of insulin
- If an inadequate amount of solution is flushed through to prime the tubing, the patient may receive saline rather than insulin for a few hours, resulting in higher-than-expected glucose levels and titration of insulin to higher doses
- The result would then be an unexpectedly low glucose several hours later
- Other details of administration, such as type of IV tubing used and how the IV tubing is primed, can greatly affect the amount of insulin delivered to the patient and thus the glucose levels

✓ The advantages of FMEA include its focus on system design rather than on a single incident such as in RCA

✓ By focusing on systems and processes, the learning and changes implemented are likely to impact a larger number of patients

Group Work

- Each group will be required to think of a specific problem, and develop a RCA technique to arrive at the root cause