Root Cause Analysis

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Root Cause Analysis

- Because the surest way to correct failure is to first determine the cause...
Root Cause Analysis

- Because the surest way to correct failure is to first determine the cause...
- Ask yourself, how much confidence do you have in a corrective action if the cause is unknown?
Compensative vs. Corrective

- Consider a common electronic device failure: your computer freezes and will not respond to user input.
- Compensative Action: Reboot.
- Corrective Action: Software update that fixes the bug that causes system failure.
- Are your corrective actions compensative or corrective?
Root Cause Analysis

- A *systematic* approach used to find the root causes of an adverse event and...
Root Cause Analysis

A *systematic* approach used to find the root causes of an adverse event and to deliver a root cause analysis report containing:
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1) the problem, failure, or adverse event;
2) the methods used for determining causes;
3) all probable causes with likelihood for each cause (i.e., probability that cause contributed to the adverse event); and
4) the evidence for reported causes and likelihoods.
Root Cause Analysis—Initiation

- There are multiple RCA systems or processes with differing strengths and weaknesses.
- Towards choosing which method to utilize; first characterize the problem, failure, or adverse event—i.e., define the problem!
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Towards choosing which method to utilize; first characterize the problem, failure, or adverse event—i.e., define the problem!

Assume that complaints are insufficient for defining the problem. Investigation is necessary to characterize problems in a quantitative and/or factual manner.
Consider the Baxter Dialyzer (AX, AF, and A series) recalled in October, 2001.

Which “statement of the problem” is most likely to lead to a rapid determination of cause for the adverse events?
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Which “statement of the problem” is most likely to lead to a rapid determination of cause for the adverse events?

“Eleven deaths a few hours after dialysis at different clinical facilities with the same brand of dialyzer, all manufactured at the Ronneby, Sweden plant.”
Consider the Baxter Dialyzer (AX, AF, and A series) recalled in October, 2001.

Which “statement of the problem” is most likely to lead to a rapid determination of cause for the adverse events?

“Eleven deaths from apparent respiratory failure, a few hours after dialysis at different clinical facilities with the same brand of dialyzer, all manufactured at the Ronneby, Sweden plant.”
Root Cause Analysis-Example

- Consider the Baxter Dialyzer (AX, AF, and A series) recalled in October, 2001.
- Which “statement of the problem” is most likely to lead to a rapid determination of cause for the adverse events?

  “Eleven deaths from apparent respiratory failure with frothy substance in lung capillaries, a few hours after dialysis at different clinical facilities with the same brand of dialyzer, all manufactured at the Ronneby, Sweden plant.”
Root Cause Analysis—Methods

- For adverse events: Forensic Engineering, Fault Tree Analysis.
- For user errors: Comparative Re-enactment, Change Analysis.
- For device failures: Failure Mode Analysis, Common Cause Analysis.
- For repeatable problems: Scientific Method.
- For unrepeatable events: Consider all correlations as potentially causative.
Root Cause Analysis-Example

- After the first eleven deaths, the associated batches of Baxter Dialyzers were recalled and assessed. No defects were identified and product was released.

- If no “causes” are found then the likelihood is 0% that the Baxter Dialyzer is faulty.
Root Cause Analysis-Example

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- If no “causes” are found then the likelihood is 0% that the Baxter Dialyzer is faulty.
- 40 more patients died of respiratory distress a few hours after dialysis.
Root Cause Analysis—Methods

Need to consider all aspects of device manufacture and usage.

- Design
- Materials
- Suppliers
- Components
- Assembly
- Cleaning
- Sterilization
- Packing
- Shipping
- Storage
- Implantation
- Users/Usage
- Monitoring
- Interference
- All Others
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Root Cause Analysis—Results

- All possible causes need to be identified.
- A likelihood for each cause needs to be assigned based on the probability that the problem resulted from said cause.
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- A likelihood for each cause needs to be assigned based on the probability that the problem resulted from said cause.
- Causes can be a combination of causes, a combination of factors, and a combination of causes and factors.
- Statistical analysis is warranted.
FDA inspection of Baxter Dialyzers found unknown liquid substance in cartridges.

Substance was later identified as a processing fluid containing perfluorocarbon (PF5070), a substance with unknown toxicity at that time.

Rabbits given a similar dosage of PF5070 died of respiratory failure with a frothy substance in their lung capillaries.
What is the likelihood that residual PF5070 in dialyzers was the cause of death for the 50+ patients (4 in U.S.) who died suddenly from respiratory failure after dialysis?
Root Cause Analysis-Example

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99.9%
By Definition: Quality System Failed

- A quality system ensures that a device performs as intended (i.e., as per the label).

![Snake Oil Ad](image-url)
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If a device does not perform as intended then the quality system failed.
By Definition: Quality System Failed

- A quality system ensures that a device performs as intended (i.e., as per the label).
- If a device does not perform as intended then the quality system failed.
- After finding the *cause* of device failure, find the *cause* of quality system failure.
- Corrective actions are needed for the quality system too.
Questions?