Learning from Risk Management
Integrating Root Cause Analysis and Failure Mode & Effect Analysis into Your Compliance Program

Health Care Compliance Association
2005 Compliance Institute

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Program Objectives

- Understand why humans make mistakes and why systems fail
- Describe the Root Cause Analysis and Failure Mode and Effect Analysis techniques
- Identify when to use these tools in the compliance setting
- Understand why these tools can enhance your compliance program effectiveness
People Make Mistakes…

- Information
- Equipment / Tools
- Process Design
- Job / Tasks
- Qualifications
- Perception of Risk
- Environment
- Culture
- Supervision
- Communication
Systems Fail…

- Human Factors
- Barriers and Safeguards
- Ability to identify failures before they become critical
- Ability to limit the effect of failure
Compliance Systems Fail…

- Complex processes
- Complex rules
- Many hand-off’s along the way
- Technology systems provide only partial answers
- Retrospective monitoring
What others have learned…

- Understanding where the system fails is key to effective corrective action.
- Approach to failures requires more than "name-blame-train", requires understanding of human factors.
- Risk Management tools such as Root Cause Analysis and Failure Mode and Effects Analysis are effective for all types of real and potential losses.
  - Banking, aerospace, transportation, automotive, nuclear energy, military, etc.
Domino Theory

- Frank Bird – 1974
  - Mishaps are the result of a series of errors
Error Theory

James Reason - 1990

- Active Failures (sharp end)
  - At first glance appear to be the “cause” of the failure

- Latent Failures (blunt end)
  - Failures away from the “event”
  - Examples: poorly written policies, incorrect data, poor hiring practices, ineffective supervision, etc.
“Swiss Cheese” Model

- Barriers or safeguards protect the system
  - Culture
  - Oversight and Supervision
  - Policies and Procedures
  - Education and Training
  - Monitoring
  - HR Processes
  - Vigilance and Memory
  - Communication

- Formal and Informal barriers
- Safeguards are rarely perfect (holes in the cheese)
- When the holes line up – system failure
Where “Latent” Failures May Occur

- Charles Perrow:
  - Design
  - Equipment
  - Procedures
  - Operations
  - Supplies and Materials
  - Environment

- Charles Vincent
  - Institution
  - Organization and Management
  - Work environment
  - Team
  - Individual
  - Task
  - Patient
Human Error

- **Skill-based errors**
  - Often failures of memory, not paying attention to what you are doing

- **Decision errors**
  - Typically failures of training, incomplete or misinterpreted information

- **Perception errors**
  - “Best Guess” errors often due to incomplete information and personal bias
At-Risk Behavior

- Routine Violations
  - “Everyone does it”
  - Policies no one follows
  - Incentive for violation greater than consequence

- Unintended At-Risk Behavior
  - No perception of risk

- Reckless Behavior
  - Willful and intentional
  - Manage through disciplinary action
Root Cause Analysis

- Process designed for investigation
- Understand not only “what” and “how” but “WHY”
- Series of probing “why” questions
- Understanding Root Cause allows you to develop effective recommendations for correction and prevent reoccurrence
RCA Process

- Assemble a team
  - Participants
  - Witnesses
  - Experts (IT, HR, Clinicians, Coders, etc.)
  - Organizational Leaders
- Chart the sequence of events
  - Identify causal factors
  - Understand cause and effect
RCA Process

- Identify the root causes
  - Understand why each causal factor existed
  - Most occurrences will have multiple causal factors and each causal factor will have multiple root causes.

- Generate Recommendations for Correction
  - JCAHO offers a good tool for summarizing your RCA
Failure Mode & Effects Analysis

- Developed by the US Military in 1949
- Used effectively in many industries
- July 1, 2001 JCAHO implemented new standards in support of error reduction programs, identified FMEA as technique
- Differs from RCA in that it is a pro-active technique
- FMEA is rigorous and detailed process
FMEA Process

- Define the process
  - High-risk, High-vulnerability
  - Review internal and external data
- Gather multi-disciplinary team
  - Subject matter experts, staff, multiple viewpoints, non-expert
- Break process into sub-processes
  - Identify sub-processes that are most problematic
FMEA Process

- Flow-chart each sub-process
- Identify how each step in the sub-process could fail (Failure Modes)
- Identify what would likely happen if the failure occurred (Failure Effect)
- Find your “Risk Priority Number”
- Rank failures by risk priority
- Identify causes of failures (RCA)
- Recommendations for re-design and corrective actions
Risk Priority Number

- **Probability of Occurrence**
  - What are the chances this will fail?
  - 1-10 score, 10 being very likely will fail

- **Severity of Failure**
  - How serious would this failure be?
  - 1-10 score, 10 being very serious or catastrophic

- **Difficulty of Detection**
  - What are the chances this failure would be detected before it is too late to fix?
  - 1-10 score, 10 being very difficult to detect

- **Multiply scores to get RPN**
  - In the case of ties, add scores also
Example

- Process: Advance Beneficiary Notice
- Sub-Process: Outpatient registration screening for medical necessity
- Failure Modes:
  - Physician does not provide diagnostic information
  - LCD, NCD and LMRP not available to registration staff
  - Registration staff can not interpret LCD, NCD and LMRP information
  - Unable to read physician order
  - Etc…
Example

- **RPN:**
  - **Failure Mode:** Physician does not provide Diagnostic Info.
    - Probability of Occurrence – 7 (pretty likely)
    - Severity of Failure – 3 (not particular severe)
    - Detectability – 2 (likely to detect)
  - \( 7 \times 3 \times 2 = 42 \)
Example

■ RPN:
  ■ Failure Mode: Registration staff can’t interpret LMRP, LCD, NCD.
    ■ Probability of Occurrence – 7 (pretty likely)
    ■ Severity of Failure – 6 (severe)
    ■ Detectability – 4 (likely to detect)
  ■ 7 X 6 X 4 = 168
■ Conduct RCA (abbreviated)
■ Corrective Action
Tips For Incorporation

- Pick your processes carefully
  - RCA
    - Significant compliance failures
    - Reoccurrence would have significant consequences
    - Use to investigate trends
  - FMEA
    - New processes
    - Redesigned processes
    - Deleting programs or services
Tips…

- Involve Others
  - Experts
  - Line staff
  - Executives (who can approve resources)
  - People in the chain
Tips…

- Participate in your organizations risk management program
  - RM’s are well versed in RCA and FMEA
  - Methods, forms, tools, resources may already be available in your facility
  - Understand barriers as they exist in your organization
  - Participate in the next RCA or FMEA
Tips...

- Tag on to evaluations currently being considered in your organization
  - Look at the potential compliance failures
  - For example, if your organization is looking at medication delivery in the ED, you may want to look at safe guards to ensure you are not billing for self-administered medications.
Tips…

- It’s a way of thinking
  - When conducting your investigations consider the human factors and latent failures – you don’t always need the RCA forms to get to the root cause.
  - When considering a new service/process, think about the sub-processes and how each might fail. Build your safe guards for the most likely and/or most severe failures.
Tips…

Learn More

- VA National Center for Patient Safety: [www.patientsafety.gov](http://www.patientsafety.gov)
- JCAHO: [www.jcaho.org](http://www.jcaho.org)
- Agency for Healthcare Research and Quality: [www.ahrq.gov/qual/errorsix.htm](http://www.ahrq.gov/qual/errorsix.htm)
- FDA Patient Safety News: [www.fda.gov/cdrh/psn](http://www.fda.gov/cdrh/psn)