

**Failure Mode Effects and
Analysis**
FMEA, FMECA or RCA
How do you know?

**Rossa, Rossa & Associates
and
Associated Surveys for
Healthcare**

Presented
by
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Rossa, Rossa & Associates
 Bridging the Gap Between
 Quality and Success



FMEA Objectives
 Participants will be able to:

Increase knowledge of the basic concepts involved
 in failure modes effect analysis and the tools used to
 conduct these activities *WHY?*

Determine internal and external
reporting requirements *WHAT?*

Explain FMEA techniques
 (preparing for the analysis through risk
 assessment/corrective actions) *HOW?*

Factors that contribute to success
 to FMEA projects *TRENDS to REPLICATE*

WHY FMEA?
Why Risk Assessment?
Proactive rather than reactive

**Involves knowledgeable customer
 focused team finding solutions**

**Prioritization of Performance
 Improvement efforts**

**Compliance with Joint Commission
 Standards**

Why Individuals Don't Report

- Why are errors not reported:
 - May get fired
 - May get reported to the board
 - May get someone in trouble
 - Will get put on a team to resolve issue
 - Don't want (or have time for) all the paper work and follow-up

Why Facilities Don't Get Involved

- Costly
- Too much time – to accomplish
- Not enough time – always putting fires out
- Recession
- Lay offs
- External pressures towards other priorities

FMEA Limitations

Limitation of FMEA:

1. *lot of detail about the failure of individual components,*
2. *does not take combinations of failures into account.*

FMEA Limitations

As with other numerical methods figures are best derived from either:

- 1. actual measurement or*
- 2. controlled experiments.*
- 3. If these are not available, then estimates should be treated with appropriate caution.*

WHAT is FMEA?

A systematic, proactive method for evaluating a process to:

- identify where and how it might fail
- assess the relative impact of different failures.

Provides information to use in identifying the parts of the process most in need of change, Prioritization.

HOW does FMEA Process Work?

- **Failure Modes**
(What could go wrong?)
- **Failure Causes**
(Why would failure happen?)
- **Failure Effects Analysis**
(What would be the consequence of each failure?)

What Does this Mean?

Severity x Occurrence x Detection = Risk Priority

Severity = potential effect of the failure

Occurrence = likelihood that the failure will occur

Detection = likelihood of problem detection before it reaches the patient

Example Severity/Harm Scale

Rating	Description	Criteria
1	Very Low or None	Minor Nuisance
2	Low or Minor	Operable but reduced performance
3	Moderate or Significant	Gradual performance deterioration
4	High	Loss of function
5	Very High or Catastrophic	Safety related catastrophic failures resulting in harm

Example Occurrence Scale

Rating	Classification	Example
10	Very High	Inevitable Failure
8	High	Repeated Failures
6	Moderate	Occasional Failures
3	Low	Few Failures
1	Remote	Failure Unlikely

Using FMEAs & RPNs

- Select a process to improve
- Define FMEA process and scope
- Obtain materials about process
- Recruit knowledgeable customer focused team
- Identify failure modes and causes
- Calculate RPNs
- Evaluate results
- Use RPNs to plan improvement efforts

Add Criticality

- **Criticality**
 - can be applied both to failure modes and to effects
 - allows prioritization of remedial actions (rank order)

failure mode criticality simply put is to likelihood that it will occur in a given period (such as 12 months).

Criticality

- **Criticality of a failure effect (loss of utilities) is the likelihood of that effect occurring due to any failure mode (car hits utility pole taking out all facility's power)**
 - How would that effect your facility?
 - Emergency Management or Utility Management
- **Criticality may be further refined by also taking into account any other items which are considered to be important, such as severity of failure or chance of injury to a patient.**

Detection = likelihood of problem detection before it reaches the patient

Acronyms

FMECA (Failure Mode, Effects and Criticality Analysis)

FMEA (Failure Mode, Effects and Analysis)

HFMEA (Healthcare Failure Mode Effectiveness Analysis)

Using TRENDS to REPLICATE

- Performance Improvement and Criticality
- Other Links from professional organizations
- References
- Joint Commission
 - National Patient Safety Goals
 - Priority Focus Areas
 - Clinical Service Groups
- Institute for Healthcare Improvement
- CMS and Core Measures
- Physician Peer Issues

Where to Start Risk Analysis

1. Choose a Topic
2. Establish a PI Team
3. Set up a Process Flow Diagram
4. Decide what effects of failure might be on the remainder of the process
5. Decide on interventions to lower the criticality index

**Root Cause Analysis
(RCA) Process**

- Root Cause Analysis for “After the Fact”
- Sentinel Events
- Tracing or Tracking Errors (process referred to by the Swiss Cheese Effect)
- Many others

**FMEA and the RCA Process
Similarities**

Focus on systems issues
Develop flow charts
Actions and outcome measures developed
Scoring matrix (severity/probability)
Use of Triage/Triggering questions, cause & effect diagram, brainstorming
Interdisciplinary Team

**FMEA and the RCA Process
Differences**

Develop Flow Diagram
Focus on systems issues
Actions and outcome measures developed
Scoring matrix (severity/probability)
Use of Triage/Triggering questions, cause & effect diagram, brainstorming
Interdisciplinary Team

FMEA and the RCA Process
Differences (cont'd)

Process vs. chronological flow diagram
Prospective (what if) analysis
Choose topic for evaluation
Include detectability and criticality in evaluation
Emphasis on testing intervention

Example: Hand Hygiene
Main Causes of Failure to Clean Hands
(across all participating hospitals)

- Ineffective placement of dispensers or sinks
- Hand hygiene compliance data are not collected or reported accurately or frequently
- Lack of accountability and just-in-time coaching
- Safety culture does not stress hand hygiene at all levels
- Ineffective or insufficient education

<http://www.centerfortransforminghealthcare.org/projects>

Example: Hand Hygiene (Cont'd)
Main Causes of Failure to Clean Hands
(across all participating hospitals)

- Hands full
- Wearing gloves interferes with process
- Perception that hand hygiene is not needed if wearing gloves
- Health care workers forget
- Distractions

<http://www.centerfortransforminghealthcare.org/projects>

Links

Tools & Resources

- Interactive FMEA Tool from the Institute for Healthcare Improvement
[\[http://www.IHI.org/ihi/workspace/tools/fmea/\]](http://www.IHI.org/ihi/workspace/tools/fmea/)
- Examining Risk Numbers in FMEA
[\[http://www.reliasoft.com/newsletter/2q2003/rpns.htm\]](http://www.reliasoft.com/newsletter/2q2003/rpns.htm) FMEA\Critical Tests Results Institute for Healthcare
- **Criticality:** Improvement Failure Modes and Effects Analysis Tool Process Data Report.htm

Links/References

Association of Practitioners for Infection Control www.apic.org

Patient Safety & Quality Healthcare e-Newsletter
www.psqh.com/forms/psqhnews.shtml

World Health Organization
<http://www.who.int>

Behavioral Health References

- The latest issue of *BHC News* is now available at Joint Commission.
- Executive Director
- New BHC team ready to serve you
- Resources:
 - Annual Behavioral Health Care Conference
 - Free chapter updates
 - Social media links
- *BHC News* online contact us or follow this link:

http://www.jointcommission.org/Accreditation/Programs/BehavioralHealthCare/BHCNews/issue_03_09.htm

Joint Commission

- **All other areas are also available by logging on to www.jointcommission.org**
- **Center for Transforming Healthcare tackling safety, quality problems**
- **Revised 2010 NPSGs**

Healthcare Staffing Certification References

Briefings on HCSS Certification scheduled for October 1 and October 20 Attendees receive free copies of the Health Care Staffing Certification Manual, the Certification Handbook, and the Review Process Guide

Not-yet-certified health care staffing firms are invited to attend a free briefing on The Joint Commission's Health Care Staffing Services Certification Program. Attendees will learn about the benefits of Joint Commission certification and the process of becoming certified. The briefings include an opportunity to talk directly with Joint Commission staff about the application process, standards, on-site review and pricing. The briefings will be held:

October 20, 9 to noon, Florida Hospital, Winter Park, Fla. , Others coming soon

To register, go to www.jointcommission.org/HCSbriefings.htm.

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CMS/CDC References

- CMS online tools at www.medicare.gov.
 - Restraints
 - Medication administration
 - Others
- Center for Disease Control (CDC) at www.cdc.gov
 - Handwashing !!!!!

General References

New Resource for Talking About Health Care Quality RWJ Robert Wood Johnson Foundation
[New Resource Provides Building Blocks for Presentations on Health Care Quality and Reform](#)
 As the debate around health reform continues, it is important that all of our audiences understand what works and doesn't work about health care in America. This new interactive resource will help users effectively communicate the problem facing America today and offers stories and ideas from people working to improve the quality of health care.
Talking About Quality is a bank of 150 ready-to-use slides that includes statistics, charts, graphics and messages, as well as audio clips from people on the front lines of health care. Users can easily download slides for use in their own presentations or create custom slideshows on www.rwjf.org using *My Presentation Builder*.
 These slides will be updated on a regular basis with the most recent research and statistics.

General References

- Susan Mellott, RN, CPHQ, PhD (Mellott & Associates) offers a longer program with CEUs. Susan provided input including the next example.
- Jackie Webster, LMSW-AP, Behavioral Health input
- Peter Rossa, RN, CPHQ, PhD general and environmental issues

Sample Failure Mode, Effects, and Criticality Analysis for a Hypothetical Medication Use Process in the

Process	Pharmacy	Dispense	OR	Transfer	Sterile Field	Administer	Patient
Potential Failure Mode	Look-alike drugs; Multiple Concentrations	Wrong drug; Wrong Concentration		Switched drugs; Contamination		Wrong Drug; Wrong Dose	
Potential Effect on Patients	Potentially serious, if dispensed	Potentially serious, if administered		Potentially serious, if administered		Potentially serious, depending on drug	
Likelihood of reaching patient	Low	Medium		High		High	
Criticality of Failure mode	Low	Medium		High		High	
Root causes	Open formulary ambiguous labels	Alphabetical storage; Ambiguous labels		Unnecessarily complex process; Approved procedure not consistently followed		No means of verifying any dose after transfer to sterile field	
Strategies	P&T Committee review design of formulary content and process	Reassign storage system - introduce bar coding		Simplify procedure; Eliminate open vessels for IV drug; Monitor drug storage		No action needed; Risk minimized earlier in process	



Acknowledgments

- Texas Healthcare Quality Association
 - TAHQ Board
 - TAHQ Educational Committee
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- Mellott & Associates

QUESTIONS?
