The Role of Failure Mode and Effects Analysis in Health Care

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In this article...

Take an in-depth look at how health care organizations can use a tool designed to predict risks in complicated processes even before the process occurs.

Failure mode and effects analysis (FMEA) is a systematic and team-based process designed to evaluate risk and reliability and has been used in the manufacturing industry for the past 50 years.

It was first used by the military in 1949[1] and later popularized by NASA in the 1960s. The Ford Motor Co. later adopted FMEA as a way to reduce risk in its manufacturing processes.[2]

The term "mode" refers to the way a product or process might fail, while "effects" refer to the consequences of the failure on the product or process. It is an inductive method designed to recognize and evaluate the potential failure of a product or process, the effects of that failure, and the actions that should be taken to reduce or eliminate the potential failure.[3]

FMEA can be characterized as a risk and reliability tool for management. FMEA is part of a larger group of Human Reliability Analysis (HRA) tools. Melinda Lyons and others provided a comprehensive review and listed 35 tools described in the literature that have been used to assess human reliability (see Appendix A).[4] They classified these HRA tools into five categories based on how an individual HRA tool is used:

1. Data collection.
2. Task description.
3. Task simulation.
4. Human error identification and analysis.
5. Human error quantification.

FMEA falls in the fourth category.

The use of FMEA in health care appeared as a risk management tool in the early 1990s when the Institute of Safe Medication Practices became interested in using it to reduce medication errors.[5]

Since then, FMEA has been used in a variety of areas such as in IV drug administration,[6] fall prevention[7] and the administration of chemotherapy.[8] Each of these examples represents complex processes comprising multiple steps that could ultimately result in the failure the process.

James Reason, MD, suggested that failure of a given process results from the latent (hidden) errors that are embedded in any given process.[9] Latent errors are difficult to discover unless that process is dissected and evaluated based on each step in the process. In the manufacturing world the production of a widget requires multiple manufacturing steps that could result in a defective widget.

Similarly in health care, administrative and clinical management processes can be quite complex and include multiple steps that could result in failure. FMEA is designed to dissect a particular process into its individual steps, isolate the potential steps that could cause the problem, assign a specific risk level to each abnormal step, analyze the risk potential for the process, and assign an action plan to correct the problem.

FMEA can be divided into three major subtypes linked to:

1. Systems and subsystems.
2. The design of a product or service.
3. The implementation of the product or service.

The pertinent questions that might be asked are:

- What is the difference between FMEA and root cause analysis (RCA)?
- Does the use of RCA not achieve the same goal as FMEA?

The two tools are similar in the sense that both attempt to determine the causes of failure. However, FMEA attempts to determine the cause of failure before the product or service is put into operation (proactive), while RCA evaluates the causes of failure after the failure has occurred (reactive).[10]

To further define the FMEA process, Dev Raheja suggested that the following questions should be asked by the risk assessment team.[11]

1. What are the steps in the process?
2. What can go wrong in each step of the process? (failure mode)
3. Why would it go wrong? (cause)

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4. What are the consequences? (effects)
5. How frequently would this event or failure likely occur? (occurrence)
6. If anything is going to go wrong, how early can it be detected? (detection)
7. How severe can the possible harm be? (severity)
8. How would one mitigate the harm? (action)

Questions 5, 6 and 7 require some type of scoring methodology. For health care, R. Dan Reid provided three specific scoring methods based on a 10-point scale that addressed the domains as:

- Occurrence (5)
- Detection (6)
- Severity (7)[2]

We modified Reid's scoring table to include Six Sigma designations to provide additional insight into the

Table 1: Severity, occurrence or detection table

Rating	Failure probability	Defects/million opportunities	Yield (no defects) %	Six Sigma Designation
10	Very high	>500,000	50%	1.5
9	Very high	308,000	69.2%	2.0
8	High	135,000	86.5%	2.6
7	High	54,800	94.5%	3.1
6	Moderate	13,900	98.6%	3.7
5	Moderate	2,550	99.7%	4.3
4	Moderate	480	99.95%	4.8
3	Low	70	99.99%	5.3
2	Very low	8	99.999%	5.8
1	Remote	3.4	99.9997%	6.0

scoring criteria (Table 1). Note that by placing the defect rate next to the yield rate (no defects), even with a 98 percent no defect rate, Reid suggests that the failure probability is still at a level considered to be moderate in severity.

At this level (98 percent without defects) the Sigma designation is 3.7. Most manufacturing companies are functioning at a 4.5 to 5.0 Sigma level, a low to very low risk of an occurrence happening.

By comparison, most health care processes that function in a 98 percent defect-free environment would be considered quite acceptable, yet for a manufacturing company this defect-free level would represent moderate risk.

The scoring scale (1 to 10) for a FMEA is based on how significant the impact would be if the potential failure were to occur.[2] The definition that is assigned to each of the 10 numerical values on the scale is based on which scale is used and the criteria that an organization creates for each category.

For example, when using the severity scale the definitions might range from "no effect," score of 1, to "could cause death," score of 10. For the occurrence category, the definitions might range from "remote," score of 1, to "occurrence very high," score of 10. And finally, for the detection category, the definitions might range from "will detect," score of 1, to "unable to detect," score of 10.

So, how can we use this information to quantify the risk of a particular process?

Reid describes the concept of risk prevention number (RPN), which is the product of the severity score, the occurrence score and the detection score (RPN = S x O x D).[2]

Reid notes that the lower the RPN, the lower the chance of failure. The range of possible RPN scores is 1 to 1,000. The higher the RPN, the greater is the risk.

Thomas Carbone and Donald Tippett, extended the concept of FMEA by creating a Risk FMEA process (RFMEA) to project development, which is a method to identify, quantify, and remove/reduce risk for the project during its design, development and deployment.[12] Martha Riehle, RN, and others provided a clear example of FMEA scoring using the RPN for medication dosing.[6]

VA version

In 2002 the Department of Veterans Affairs developed a hybrid version of FMEA called Health Care Failure Mode Effect Analysis (HFMEA™).[13]

This VA hybrid tool consists of using an interdisciplinary team to study the process prospectively, create process and subprocess flow diagrams, identify mode and failure mode causes, establish a hazard scoring matrix (sometimes referred to as a risk score), create a decision tree algorithm to identify system vulnerabilities, develop outcome measures, and institute specific organizational action plans.

Joseph DeRosier and others developed the HFMEA model by incorporating the components of FMEA and two other tools, developed by the Food and Drug Administration to protect the food supply from biological and chemical contamination, the Hazards Analysis and Critical Control Point (HACCP). They incorporated the important components of each into a comparative table.[13]

HFMEA consists of a five-step process using a multidisciplinary team:

STEP 1 Define the high-risk area or process.

STEP 2 Assemble the team.

STEP 2 Graphically describe the process.

STEP 4 Conduct a hazard analysis.

STEP 5 Develop action plans and outcome measures.

There are two primary differences between FMEA and HFMEA. HFMEA includes a hazard scoring matrix and decision tree that are not present in FMEA. In addition, DeRosier significantly modified three other components of FMEA for use in the HFMEA process. These included modification of the severity and probability definitions, the actions and outcomes component, and the responsible person and management concurrence component.

Although FMEA is being used more extensively in health care, there are important organizational considerations that need to be evaluated before using FMEA.

Since FMEA requires a large investment in time and personnel, a positive return on investment should be considered before instituting any FMEA-related project.

For example, Robert Weinstein and others used the Veterans Administration's HFMEA methodology to evaluate the sterilization of surgical instruments and noted that an eight-member HFMEA team spent a total of 26.5 hours in 19 meetings to complete the HFMEA process, resulting in the total of 212 person-hours.

The director and selected members of the team spent an additional 40+ hours after the work of the team was completed in editing the results of the project.[14] Assuming direct and indirect costs of $100/hour of time (probably a low number depending on the type of health care organization and its location), this project cost Weinstein's organization about $25,000.

However, if the process of FMEA eliminates the potential for a large liability or malpractice action filed against the organization, the benefit would far outweigh the potential litigation, liability or settlement costs.

This type of analysis does not even include the potential issues of human suffering and death. The use of FMEA should be considered if a failure is likely to occur, if failure is unlikely to be detected using routine surveillance techniques, or if failure is likely to cause severe harm.

Because FMEA is time intensive and laborious, there is an ongoing effort to simplify and automate the process in order to provide organizations with better tools to use FMEA in a more efficient and cost effective way.[15] In addition, since a FMEA process generally is established to evaluate systems or complex processes, the FMEA team usually comprises people from multiple disciplines. Therefore, it is important to consider the coordination of the team's activities, communication with senior leaders, managing the potential political issues, and understanding and considering the impact on the key stakeholders, in addition to the financial implications.

A successful FMEA process can only occur when the FMEA team is led by a trained and experienced facilitator and operates under team rules and processes.

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References:

1. United States Military Procedure MIL-P-1629, Procedures for Performing a Failure Mode, Effects and Criticality Analysis (November 9, 1949).
2. Reid RD. FMEA – something old, something new. 2005. *Quality Progress.* May 2005, pp. 90-93.
3. *Dailmer-Chrysler, Ford Motor Co, and General Motors, Potential Failure Mode and Effect Analysis (FMEA) Reference Manual*, Automotive Industry Action Group. 2001.
4. Lyons M, Adams S, Woloshynowch M, Vincent C. Human reliability analysis in healthcare: A review of techniques. *International J Risk and Safety in Medicine*, 16:223-237, 2004.
5. Cohen MR, Davis NM, Senders J. Failure mode and effects analysis: A novel approach to avoiding dangerous medication errors and accidents. *Hosp Pharm* 29(4):319-24, April 1994.
6. Riehle MA, Bergeron, Hyrkas K. Improving process white changing practice: FMEA and medication administration. *Nursing Management.* 39(2):28-33, Feb. 2008.
7. Weeks SK, Bijkersma F, Hubbartt E, and others. Failure mode and effects analysis: a search for ways of preventing patients from falling. *Am J Nurs.* 104(4):72A-72D, April 2004.
8. Sheridan-Leos N, Schulmeister L, Hartranft S. Failure mode and effects analysis: a technique to prevent chemotherapy errors. *Clin J Oncol Nurs.* 10(3):393-98, June 2006.
9. Reason J. Human error: models and management. 2000. Brit Med J. 320(7287):768-70, March 18, 2000.
10. Senders JW. FMEA and RCA: the mantras of modern risk management. *Qual Saf Health Care*, 13(4);249-250, Aug. 2004.
11. Raheja D. Delivering reliability in the healthcare system. Contained in the *IEEE Reliability Society Annual Technology Report*, 2008.
12. Carbone TA, Tippett DD. Project risk management using the project risk FMEA. *Engineering Management Journal*; 16(4): 28-35, Dec. 2004.

13. DeRosier J, Stalhandske E, Bagian JP, Nudell T. Using health care failure mode and effect analysis: the VA National Center for Patient Safety's Prospective Risk Analysis System. 2002. *The Joint Commission Journal on Quality Improvement*. 28(5):248-67, May 2002.

14. Linkin DR, et al. Applicability of healthcare failure mode and effects analysis to health care epidemiology evaluation of the sterilization and use of surgical instruments. *Clin Infect Dis*, 41(7): 1014-19, Oct. 1, 2005.

15. Papadopoulos Y, Parker D, Grante C. Automating the failure modes and effects analysis of safety critical systems. 2004. Eighth IEEE International Symposium on High Assurance Systems Engineering. Computer Society.

Appendix A

1. Accident Evolution Barrier Function Model (AEB)
2. Absolute Probability Judgment (APJ)
3. A Technique for Human Error Analysis (ATHEANA)
4. Barrier Analysis (BA)
5. Change Analysis (CA)
6. Critical Decision Method (CDM)
7. Cognitive Event Tree System (COGENT)
8. Cognitive Reliability and Error Analysis Method (CREAM)
9. Cognitive Task Analysis CTA)
10. Error of Commission Analysis (EOCA)
11. Event Tree Analysis (ETA)
12. Failure Mode Effects Analysis (FMEA)
13. Framework Assessing Notorious Contributing Influences for Error (FRANCIE)
14. Fault Tree Analysis (FTA)
15. Generic Error Modeling System (GEMS)
16. Hazard and Operability Analysis (HAZOP)
17. Human Cognitive Reliability (HCR)
18. Human Error Assessment and Reduction Technique (HEART)
19. Human Reliability Management System (HRMS)
20. Hierarchical Task Analysis (HTA)
21. Influence Diagrams Analysis (IDA)
22. Management Oversight Risk Tree (MORT)
23. Paired Comparisons (PC)
24. Petri-nets
25. Systematic Human Error Reduction and Prediction Approach (HHERPA)
26. Success Likelihood Index Methodology-Multi-Attribute Utility Decomposition (SLIM-MAUD)
27. Skill Rule Knowledge Framework (SRK)
28. Sneak Analysis
29. Task Analysis
30. Tecnica Empirica Stima Errori Operatori (TESEO)
31. Technique for Human Error Assessment (THEA)
32. Technique for Human Error Rate Prediction (THERP)
33. Time-line Analysis
34. Technique for the Retrospective Analysis of Cognitive Errors (TraceR)
35. Work Safety Analysis (WSA)

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