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FMEA: Preventing a Failure Before Any Harm Is Done

By Dr. Deborah L. Smith

FMEA (Failure Mode and Effects Analysis) is a proactive tool, technique and quality method that enables the identification and prevention of process or product errors before they occur. Within healthcare, the goal is to avoid adverse events that could potentially cause harm to patients, families, employees or others in the patient care setting.

As a tool embedded within Six Sigma methodology, FMEA can help identify and eliminate concerns early in the development of a process or new service delivery. It is a systematic way to examine a process prospectively for possible ways in which failure can occur, and then to redesign the processes so that the new model eliminates the possibility of failure. Properly executed, FMEA can assist in improving overall satisfaction and safety levels. There are many ways to evaluate the safety and quality of healthcare services, but when trying to design a safe care environment, a proactive approach is far preferable to a reactive approach.

Further Definitions of FMEA

FMEA evolved as a process tool used by the United States military as early as 1949, but application in healthcare didn't occur until the early 1990s, around the time Six Sigma began to emerge as a viable process improvement methodology.

One of several reliability evaluation and design analysis tools, FMEA also can be defined as:

- A problem prevention tool used to identify weak areas of the process and develop plans to prevent their occurrence.
- A semi-quantitative, inductive bottom-up approach executed by a team.
- A tool being recommended for Joint Commission on Accreditation of Healthcare Organizations (JCAHO) Standard LD.5.2.
- A structured approach to identify the ways in which a process can fail to meet critical customer requirement.
- A way to estimate the risk of specific causes with regard to these failures.
- A method for evaluating the current control plan for preventing failures from occurring.
- A prioritization process for actions that should be taken to improve the situation.

Why Do a FMEA?

Historically, healthcare has performed root cause analysis after sentinel events, medical errors or when a mistake occurs. With the added focus on safety and error reduction, however, it is important to analyze information from a prospective point of view to see what could go wrong before the adverse event occurs. Examining the entire process and support systems involved in the specific events – and not just the recurrence of the event – requires rigor and proven methodologies.

Here are some potential targets for a FMEA application:

- New processes being designed
- Existing processes being changed
- Carry-over processes for use in new applications or new environments
- After completing a problem-solving study (to prevent recurrence)
- When preliminary understanding of the processes is available (for a Process FMEA)
- After system functions are defined, but before specific hardware is selected (for a System

FMEA as a Six Sigma DMAIC Project Tool

- Assessment tool for diagnosis to opportunity
- Prevention tool for high level risk – define scope and process being studied
- JCAHO Standard Req. L.D. 5.2 (www.jcaho.com)
- Preventive tool
- Reduce risk of sentinel events
- Reduce high risk of medical care system error
- Never too late to start FMEA

FMEA)
- After product functions are defined, but before the design is approved and released to manufacturing (for a Design FMEA)

Preparing and Updating the FMEA

- The responsible Process Owner leads the FMEA team.
- The team approach to preparing FMEA is recommended.
- The responsible Process Owner is expected to involve multi-disciplinary representatives from all affected activities. Team members should include subject matter experts and advisors as appropriate.
- Each Process Owner is responsible for keeping the FMEA updated.

Roles and Responsibilities

The FMEA team members will have various responsibilities. In healthcare, the terms multi-disciplinary or collaboration teams are used to refer to members from different departments or professions. Leaders must lay the groundwork conducive to improvement for the team initiative, with empowerment to make the changes and recommendations for change, plus time to do the work.

The FMEA team should not exceed 6 to 10 people, although this may depend on the process stage. Each team should have a leader and/or facilitator, record keeper or scribe, time keeper and a champion. In the data gathering or sensing stage, extensive voice of the customer may be required. During the FMEA design meeting, however, the team must have members knowledgeable about the process or subject matter. It is advisable to include facilitators with skills in team dynamics and rapid decision-making. Ground rules help define the scope and provide parameters to work within.

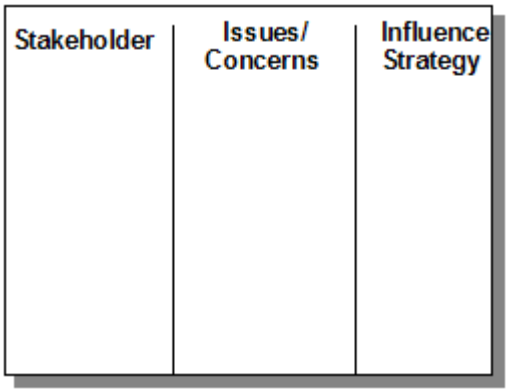
The team should consider questions such as: What will success look like? What is the timeline? The FMEA provides the metrics or control plan. The goal of the preparation is to have a complete understanding of the process you are analyzing. What are the steps? What are its inputs and outputs? How are they related?

Techniques for Accelerating Change

While Six Sigma is based on solid principles and well-founded data, without departmental or organizational acceptance of change, Six Sigma solutions and tools such as FMEA may not be effective. Teams may decide to use change management tools such as CAP (Change Acceleration Process) to help build support and facilitate rapid improvement. Careful planning, communication, participation and ensuring that senior leaders are well-informed throughout the process will greatly increase the chance for a smoother implementation.

Approach the FMEA process with a clear understanding of the challenges, an effective approach to overcome those challenges, and a plan to demonstrate a solid track record of results. To gain leadership support, clearly define the value and return on investment for required resources.

Supporting FMEA Using Influence Strategy – Once key stakeholders are known and their political, technical or cultural attitudes have been discussed (and verified), the task is to build an effective strategy for influencing them to strengthen, or at a minimum, maintain their level of support. This simple tool helps the team assess stakeholder issues and concerns, identifying and creating a strategy for those who must be "moved" to a higher level of support.



Benefits of FMEA

Here are the benefits of FEMA:

- Captures the collective knowledge of a team
- Improves the quality, reliability, and safety of the process
- Logical, structured process for identifying process areas of concern
- Reduces process development time, cost
- Documents and tracks risk reduction activities
- Helps to identify Critical-To-Quality characteristics (CTQs)
- Provides historical records; establishes baseline
- Helps increase customer satisfaction and safety

FMEA reduces time spent considering potential problems with a design concept, and keeps crucial elements of the project from slipping through the cracks. As each FMEA is updated with unanticipated failure modes, it becomes the baseline for the next generation design. Reduction in process development time can come from increased ability to carry structured information forward from project to project, and this can drive repeatability and reproducibility across the system.

Types of FMEA

Process FMEA: Used to analyze transactional processes. Focus is on failure to produce intended requirement, a defect. Failure modes may stem from causes identified.

System FMEA: A specific category of Design FMEA used to analyze systems and subsystems in the early concept and design stages. Focuses on potential failure modes associated with the functionality of a system caused by design.

Design FMEA: Used to analyze component designs. Focuses on potential failure modes associated with the functionality of a component caused by design. Failure modes may be derived from causes identified in the System FMEA.

Other:

- FMECA (Failure Mode, Effects, Criticality Analysis): Considers every possible failure mode and its effect on the product/service. Goes a step above FMEA and considers the criticality of the effect and actions, which must be taken to compensate for this effect. (critical = loss of life/product).
- A d-FMEA evaluates how a product can fail, and likelihood that the proposed design process will anticipate and prevent the problem.
- A p-FMEA evaluates how a process can fail, and the likelihood that the proposed control will anticipate and prevent the problem.

Summary: FMEA Requires Teamwork

A cause creates a failure mode and a failure mode creates an effect on the customer. Each team member must understand the process, sub-processes and interrelations. If people are confused in this phase, the process reflects confusion. FMEA requires teamwork: gathering information, making evaluations and implementing changes with accountability. Combining Six Sigma, change management and FMEA you can achieve:

- Better quality and clinical outcomes
- Safer environment for patients, families and employees
- Greater efficiency and reduced costs
- Stronger leadership capabilities
- Increased revenue and market share
- Optimized technology and workflow

Understanding how to use the right process or facilitation tool at the right time in healthcare can help providers move quality up, costs down and variability out. And that leads to preventing one failure before it harms one individual.

About the Author: ***Dr. Deborah L. Smith*** *joined GE Healthcare in 2001. She has more than 30 years of experience in clinical and operational healthcare, experience in process design and performance improvement, organizational development and change management. She was a faculty member at the University of Charleston and West Virginia State College, and served on the adjunct faculty at West Virginia University's School of Medicine. Dr. Smith is currently Six Sigma product leader for GE's Performance Solutions group, and leads educational offerings including the Master Black Belt Leader for Healthcare program. Her academic credentials are in healthcare, business and education with a doctorate in healthcare management, masters in human resource management and associate degree in radiologic technology. She can be reached at deborah.smith@med.ge.com.*

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