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Strategies and Tips for

Maximizing Failure Mode & Effect Analysis

in Your Organization

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Strategies and Tips for Maximizing Failure Mode & Effect Analysis in Your Organization

The prevention and reduction of errors in the provision of healthcare have captured the increased attention of policymakers, providers and the public over the past ten years. As research into patient safety has become more sophisticated and the healthcare community has embraced fields of study outside of healthcare, a shift in thinking about how errors occur has provided new ways to approach possible solutions.

Patient safety is, arguably, a traditional risk management concept viewed in a contemporary format. One definition of healthcare is about loss control, whether human loss or financial loss, and has been at the foundation of every successful risk management program since the inception of risk management. Risk assessment and risk treatment tools used by risk managers have evolved over time and include both reactive and proactive measures. As new thinking, strategies, tools, and practices have been launched, risk managers have eagerly accepted these changes in their commitment to reducing risk in healthcare organizations.

For example, there are various techniques used in industry and aerospace for conducting proactive risk assessment. These risk assessment techniques have recently become recognized for their relevance to healthcare. The most widely known tool that incorporates methods for identifying failure modes and their causes is one developed and used in the aerospace industry since the mid-1960's – Failure Mode and Effect Analysis (FMEA).[1]

Applied to healthcare, FMEA is one patient safety tool that provides risk managers the opportunity to "get ahead of the curve" and favorably impact the patient care environment. The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) is a leading driver behind the use of FMEA. In 2001, the JCAHO revised its accreditation standards to include a requirement that healthcare organizations perform, annually, at least one proactive risk assessment on a high-risk process. While the standard, LD 5.2[2] , does not mandate that a specific proactive risk assessment methodology be used, such as FMEA, it does outline a generic process for identifying and addressing failure modes in healthcare processes.

Introducing FMEA

This paper will refer to FMEA and HFMEA™ (Healthcare Failure Mode Effect Analysis) interchangeably. HFMEA™ refers to the terminology developed specifically for use in healthcare by the Veterans Administration National Center for Patient Safety (VA NCPS)

[1] The Basics of FMEA; R. McDermott, R. Mikulak, M. Beauregard; 1996; p. 3

[2] JCAHO 2002 Hospital Accreditation Standard, LD 5.2, p.200-201

with assistance from the Tenet HealthSystem. The paper will not teach you how to conduct an FMEA or HFMEA ™ but instead will take you through the steps of risk assessment and provide a framework for understanding.

This paper will describe how to use proactive risk assessment for patient safety, when to use it, and who should be involved in its application. It will also explore concerns about evidentiary protection and discoverability. Lastly, this paper will provide risk management tips from risk managers in the field who are facilitating failure mode analyses.

The VA NCPS extensively reviewed several proactive risk assessment tools before determining that the application of such tools in healthcare required some modification. As such, the VA NCPS has modified the concepts of FMEA and deployed the techniques and tools in all of its 163 healthcare centers. The new tool was named HFMEA™. The American Hospital Association has recently mailed a package of HFMEA™ materials to every hospital CEO in the country. The package includes video and CD instruction and worksheets on the use and application of HFMEA™ . The materials in the kit are intended to be shared with risk managers and others in the organization responsible for patient safety.

Traditionally, failure mode refers to a weakness or vulnerability in any part of a process or a chain of events that has the potential to cause a safety problem. Failure occurs when a process begins to produce something you don't want. HFMEA™ looks at a process, as is typically done in healthcare where FMEA, traditionally used in industry to assist in the recognition and identification of potential failure modes, looks at a device or component. In either application, the use allows for a proactive examination of what could go wrong and the opportunity to fix it before failure. As used in healthcare, both are adaptations of previously prescribed methodologies that, while used predominantly in certain fields in the past, are not specific to any particular application. Both FMEA and HFMEA ™ can be used to meet the intent of the JCAHO standard for proactive risk assessment. They are consistent with, but not necessarily inclusive of, the requirements of the standard.

What Does FMEA mean for Risk Managers?

Risk managers are experienced and knowledgeable about investigating medical errors and developing strategies and deploying tools to improve patient safety. FMEA is another tool in the box of effective risk management strategies to understand and reduce medical errors. Where the advent of sentinel event reporting and performing of root cause analysis bolsters the tenet of "learning from our mistakes," FMEA assists risk managers and others in driving change before it can do harm by forecasting potential failures and proactively applying loss control techniques to those potential failures. To do this, risk managers and others in an organization must conduct an in-depth analysis of a process in order to assess and modify it to reduce the potential for harm.

FMEA - Getting Started

What follows is an overview of one particular method of proactive risk assessment - FMEA.

Select a High-Risk Process

Strategy: Develop a list of high-risk processes in your organization. From the list, select one or more processes (or sub-processes) for which to perform an FMEA. Processes that have variable input, are complex, non-standardized, heavily dependent on human intervention, performed under tight or loose time constraints, tightly coupled and hierarchical (not team oriented) are all candidates for consideration.

Risk Management Tips:

- In identifying processes for proactive risk assessment, consider incident reports, loss experience / claims data, worker's compensation reports, the literature, or anything that even intuitively, warrants analysis. Consider, also, those accidents that have high severity or occur with great frequency. Catastrophic events are sentinel events and any of the Sentinel Event Alerts issued by the JCAHO may yield opportunities for possible analysis.
- Keep a "parking lot" list of your ideas for possible analysis.
- While the JCAHO standard requires that at least one proactive risk assessment be performed each year, your organization may benefit from conducting as many as possible given limits on organizational resources.
- Be realistic about the scope of the high-risk process or sub-process you identify for risk assessment – start small so that you and your team are not overwhelmed. Don't look for problems that don't exist.
- Get support from senior leadership.

Assemble a Team

Strategy: The team should consist of a multidisciplinary group of people, including physicians, who regularly perform the activity identified as high-risk. While the size of the team can vary depending on the number of people involved in a process, be prudent by including those with hands-on experience, and keep the team small. Other important members of the team include a subject matter expert, a leader, and a facilitator who understands the FMEA process. It is also important to include a neutral party — a person who is not intimately familiar with the process but whose perspective will be helpful to thinking outside of the box.

Risk Management Tips:

- The role of the risk manager may be multifaceted. The risk manager may be the leader, the facilitator or the content expert. It is advisable, though, that the risk manager avoids being the leader and the facilitator concurrently in order to manage the workload.
- A subject matter expert is a person who owns or plays a major role in the process chosen for assessment.
- A leader is a person who has experience with guiding a team and who will lead the team to ensure risk reduction is completed.
- A facilitator is a person who is trained to understand team dynamics, is knowledgeable about the FMEA process, and can advise the leader throughout the assessment. A good facilitator is important to open communication.
- It is important for team members to know what they will gain from the experience. Involve them in developing a schedule and give them ownership.
- There are many good resources to learn more about creating high performing teams. One to consider is The Team Handbook by Scholtes, Joiner, and Striebel.

Diagram the Process

Strategy: Once the team has agreed upon the process to examine, map the process by using flowcharting or cause and effect diagramming techniques that are understood in the organization. Identify the "way things were intended to work" and the "way things are actually working".

Risk Management Tips:

- Do your homework – conduct literature searches on the topic for risk assessment. Identify best practices, review / refer to internal procedures and policies, and look outside your organization for information.
- There are many good resources to learn more about flowcharting, cause and effect diagramming and other mapping techniques. One to consider is The Memory Jogger by Brassard and Ritter.
- Use Post-it™ notes or self-adhesive index cards to track the steps. Use a wall or whiteboard to post the notes (representing the steps in the process) to create a visual representation of the process being assessed.
- Invite the team to visit the worksite and observe the process.

Identify the potential failure modes

Strategy: Identify the steps in the process where there is, or may be, undesirable variation. The gap between the ideal and the reality are often the first failure modes identified. A process can have multiple failure modes and each failure mode can have multiple possible effects. In reviewing each step in the process, the following questions should be addressed:

1. What could fail with this step? (Ie: failure modes)
2. Why would this failure occur? (Ie: causes)
3. What could happen if this failure occurred? (Ie: effects)

Risk Management Tips:

- Code (number, letter, color) each step in the process. Include sub-processes.
- Allowing for ample team discussion is an effective way for the team to identify failure modes. As a quality improvement tool, brainstorming has certain rules that should be followed to maximize its effectiveness and assure full participation by all.

[3] JCAHO Journal on Quality Improvement; May 2002 Journal, Volume 28, Number 5; page 254.

Assess failure modes and identify causes

Strategy: Fundamental risk assessment is grounded in identification and measurement of risk. Measuring, or ranking, risk is facilitated by using a pre-determined methodology that is understood and consistently applied in an organization. To mitigate risk, you must understand the frequency and severity of that risk.

HFMEA™ uses a simplified tool, the Hazard Scoring Matrix™, to assess risk. The Matrix applies hazard analysis principles that factor in the severity and probability of the potential failure mode occurring. The severity score is a "measure of the potential effect of the failure mode." The Matrix defines degrees of severity as: catastrophic, major, moderate, and minor. Degrees of probability are defined as frequent, occasional, uncommon, and remote.[3]

In the industry model of FMEA, each failure is assigned a risk priority number (RPN) based on the likelihood of occurrence (OC), the severity if it occurred (SV), and the likelihood of detection (DT). RPN = OC x SV x DT.

When ranking risk, other factors can be considered. The JCAHO is not specific as to how to prioritize the failure modes for further analysis and action, but expects some sort of ranking so that limited resources will be applied in the most useful manner.

Risk Management Tips:

- Keep track of definitions that are used for rating risk and use them consistently.
- Use a common nomenclature when describing, discussing, and applying the rating tool.
- Consider a catastrophic event to be nearly the same as a sentinel event.
- Keep the scale simple.

Conduct a root cause analysis (RCA) on the most critical failure modes

Strategy: Failures with the highest score are those that should be focused on first. The team should look at the potential root causes of the highly scored failure by asking the following questions:

1. Why might the failure occur?
2. When might the failure occur?
3. What might cause the failure to occur? (Ie: steps in the process)
4. Where might the failure occur?

It is important to note the differences between root cause analysis and FMEA/HFMEA ™. Both have the goal to reduce patient harm, involve identifying conditions that lead to harm, and are team activities. However, they are distinct in that FMEA/HFMEA™ is proactive, focuses on an entire process and asks "what if?" The root cause analysis is reactive, focuses on the actual failure, is clarified by hindsight, prone to fear and resistance, and asks "why?" It may be helpful to use RCA as part of the FMEA process when it is necessary to analyze failure modes that do not have immediately evident actionable causes. To reduce risk, it's important to understand the root causes of the failure

Redesign the process

Strategy: Use mapping techniques such as flowcharts, fishbone, and cause and effect diagrams and as much discussion as needed to identify and design the new process. Actions for the team to consider in the redesign of the process include:

1. Determine if a step in the process should be eliminated, controlled, transferred, or accepted.
2. Identify an action or countermeasure for the failure mode that would reduce future risk
3. Choose a person to complete the action.
4. Identify the process or approach to reduce the risk.

Risk Management Tips:

- As the process is redesigned, apply principles of patient safety such as reducing reliance on memory; incorporating the use of checklists and protocols; incorporating redundancy; improving information access; reducing hand-offs; standardizing procedures, displays and layouts; using forcing functions, and simplifying procedures.
- Take a break then come back to perform another FMEA on the redesigned process before widespread implementation.
- Conduct a literature review to identify any recommended risk reduction strategies that have already been successfully implemented.
- Pilot test the redesigned process before widespread implementation.

Identify and implement measures of effectiveness

Strategy: After the new process is implemented and staff is trained in the new process, the new process needs to be measured to see if it is improved.

Risk Management Tips:

- Conduct audits. Interviewing or reconvening members of the team performing the new process is critical to measure effectiveness.
- Provide feedback to the team. Doing so can be an effective incentive for team members to continue to participate in proactive risk assessment.
- Observe the new process and map it to compare it to the ideal.
- Employ project management software.
- Depending on the risk manager's responsibilities, decide if the ongoing monitoring of the new process may be more appropriately handled by PI personnel so quality indicators can be used to measure improvement.

Implement a strategy of maintaining the effectiveness of the redesigned process over time.

Strategy: Measure the process again.

Risk Management Tip:

- Periodically check in with team members.

Protecting the Process

As with root cause analysis, the potential use of an FMEA generated document by a plaintiff in a legal action alleging medical malpractice is of great concern to many risk managers. The concern is, perhaps, heightened because FMEA proactively identifies potential failures and assigns a hazard score or risk priority number. To the extent that identified potential failures are not addressed (or not addressed well) and there is a later mishap involving that particular failure point, a previously existing FMEA could provide potent evidence for a plaintiff in a medical malpractice case (provided that the FMEA is subject to discovery and is admissible in court). Obviously, such a result would have a chilling effect on an organization's future use of FMEA for proactive risk assessment.

Risk managers can mitigate the potential discovery of FMEA and other sources of organizational analysis by following procedures under state laws that permit limited discovery protections for work product related to peer review or quality improvement. Under most states' law, these peer review or quality improvement protections are provided to promote the important public policy that furthers organizational self-evaluation of medical errors and systems improvement. In addition, some organizations perform FMEA at the direction of legal counsel, thereby creating attorney-client privilege.

Although some states provide limited protection for work products related to peer review or quality improvement, this protection under the patchwork of state laws is subject to judicial interpretation and balancing of a plaintiff's interest in discovery versus the public policy interest promoted by the peer review or quality improvement statute.

Currently, there are limited federal statutes promoting the public policy interests that further peer review and quality improvement activities in healthcare organizations. However, the Patient Safety and Quality Improvement Act (S. 2590), recently introduced in the Senate, seeks legal protections for information submitted voluntarily to patient safety improvement organizations that are designed solely for quality improvement and patient safety. It also seeks to create incentives for voluntary reporting systems that are non-punitive and promote learning. A "near" companion bill introduced in the U.S. House of Representatives (H.R. 4889) also states that if an organization believes it qualifies as a patient safety organization, under S. 2590, it can self-qualify to the Agency for Healthcare Research and Quality (AHRQ).

Risk Management Tips:

- Peer review and quality improvement evidentiary protections vary from state to state and are further interpreted by state courts. It is imperative to seek initial and ongoing competent legal review of your organization's procedure for maintaining the confidentiality of FMEA documents.
- Have the team chartered by the process improvement (PI) committee and the work performed under the auspices of the quality committee or, if applicable, under direction of legal counsel.
- Evidentiary protections provided under state law should never be assumed. For example, it is possible that through the conduct of an organization or individual, that a court would consider an evidentiary privilege "waived" by a defendant, thus allowing peer review analysis such as a FMEA to come into evidence in a malpractice trial.
- Consider limiting distribution of work product to avoid inadvertently waiving privilege. One way to limit distribution of FMEA work product is to bifurcate analytical work product (limited distribution) from written recommendations and implementation plans that receive wider internal distribution.
- Until such protections can be assured at either the state or national level, providing a "disclaimer" or "intent statement" on a FMEA is recommended. Again, consult your organization's counsel.
- Cite every page of a FMEA work product as "confidential" and with a statement of the intended privilege, whether it is a peer review privilege, quality improvement privilege, or attorney-client privilege. Consult legal counsel to select the appropriate citation.

As more proscriptive and refined approaches to understanding how errors occur in the healthcare environment are identified, risk managers appreciate that the FMEA process has the potential to provide a useful framework to enhance patient safety. Proactive risk assessment promotes decisions being made based upon the collection and analysis of data in the quest to proactively reduce potential harm to patients. Adopting a new approach can take time and will require patience, yet applying failure mode analysis can yield numerous opportunities for improving patient safety

Sharpening the Tool: How to Optimize FMEA

In getting started…

1. Seek support from senior leadership.
2. Seek out a trained facilitator or get training in facilitation. A good facilitator is important to open communication.
3. Help team members figure out what they will gain from the experience, involve them in developing a schedule, and give them ownership.
4. Look for best practices already identified for the process being assessed.

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