The Basics of Healthcare Failure Mode and Effect Analysis

Videoconference Course
Presented by

VA National Center for Patient Safety

Course Title **The Basics of Healthcare Failure Mode and Effect Analysis**

Course Length 2 hours

Course Description

The purpose of this course is to help VA Patient Safety Managers understand and carry out analysis using Healthcare Failure Mode and Effect Analysis (FMEA) techniques in accordance with the revised standards issued by the Joint Commission on the Accreditation of Healthcare Organizations (L.D.5.2. Select high risk process for proactive risk assessment). Participants will learn through instruction and practice the steps involved in carrying out a successful proactive risk assessment using Healthcare FMEA. In addition, we will discuss how to choose an appropriate topic for evaluation

Course Objectives

By the end of the course, participants will:

- Understand the purpose of Healthcare FMEA
- Have a conceptual understanding of the steps of the Healthcare FMEA process
- Know how to choose an appropriate topic for analysis
- Be able to successfully address the JCAHO 2001 proactive risk assessment standard

Target Audience

VA patient safety managers and other interested healthcare professionals at VA facilities nationwide

Course Delivery

VHA Video teleconference broadcast from Ann Arbor, Michigan

Dates

August 27, 2001	8:45am-11:00am (EDT)
August 28, 2001	8:45am-11:00am and 1:45pm-4:00pm (EDT)
August 29, 2001	8:45am-11:00am (EDT)

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Healthcare Failure Modes and Effects Analysis (HFMEA)

JCAHO Standard LD.5.2 requires facilities to select at least one high-risk process for proactive risk assessment each year. This selection is to be based, in part, on information published periodically by the JCAHO that identifies the most frequently occurring types of sentinel events. The National Center for Patient Safety will also identify patient safety events and high risk processes that may be selected for this annual risk assessment.

Healthcare Failure Modes and Effects Analysis (HFMEA) has been designed by the VA National Center for Patient Safety (NCPS) specifically for healthcare. HFMEA streamlines the hazard analysis steps found in the traditional Failure Modes and Effects Analysis (FMEA) process by combining the detectability and criticality steps of the traditional FMEA into an algorithm presented as a Decision Tree. It also replaces calculation of the risk priority number (RPN) with a hazard score that is read directly from the Hazard Matrix Table. This table was developed by NCPS specifically for this purpose.

Healthcare FMEA Steps

STEP 1 Define the HFMEA Topic

Define the topic of the Healthcare FMEA along with a clear definition of the process to be studied. See Figure 1.

STEP 2 Assemble the Team

The team is to be multidisciplinary including Subject Matter Expert(s) and an advisor. See Figure 1.

STEP 3 Graphically Describe the Process

A. Develop and verify the flow diagram (this is a process vs. chronological diagram).

B. Consecutively number each process step identified in the process flow diagram.

(Hint: It is very important that all process and sub-process steps be identified before proceeding.)

STEP 4 Conduct a Hazard Analysis

A. List all possible/potential failure modes under the sub-processes identified in HFMEA Step 3. Consecutively number these failure modes (i.e. 1a(1), 1a(2)…3e(4), etc.). Transfer the failure modes to the HFMEA Worksheet, Line 2. See Figure 2.

(Hint: This is the step in the process where the expertise and experience of the team really pays off. Use various methods including the NCPS triage/triggering questions, brainstorming, and cause and effect diagramming to identify potential failure modes.)

B. Determine the Severity and Probability of the potential failure mode and record these on Lines 4 and 5 of HFMEA Worksheet. Look up the Hazard Score on the Hazard Score Matrix and record this number on Line 6 of the HFMEA Worksheet. See Figures 3, 4,and 5.

C. Go to the HFMEA Decision Tree. Use the Decision Tree to determine if the failure mode warrants further action. Record the action to "Proceed" or to "Stop" on the HFMEA Worksheet, Line 7. If the action is to "Stop" proceed to the next sub-process identified in Step 4B. (Note: if the score is 8 or higher, document the rationale for any "Stop" decisions.). See Figure 6.

D. List all of the failure mode causes for each failure mode where the decision is to "Proceed" and record them on the HFMEA Worksheet, Line 3.

(Hint: Each failure mode may have multiple failure mode causes. Failure modes include anything that could go wrong that would prevent the sub-process step from being carried out. For example: if logging onto a laptop computer is the process step, possible failure modes are not being able to log in and delayed login. Possible failure mode causes would include the computer not being available, no power, no log in ID for the operator, etc.)

STEP 5 Actions and Outcome Measures

(Hint: Place the control measure in the process at earliest feasible point. Multiple control measures can be placed in the process to control a single hazard. A control measure can be used more than one time in the process. Solicit input from the process owners if they are not represented on the team. Try to simulate any recommended process change to test them before facility-wide implementation.)

C. Identify outcome measures that will be used to analyze and test the redesigned process.

D. Identify a single, responsible individual by title to complete the recommended action.

E. Indicate whether top management has concurred with the recommended action.

Definitions:

Effective Control Measure – A barrier that eliminates or substantially reduces the likelihood of a hazardous event occurring.

Healthcare Failure Mode & Effect Analysis (HFMEA) - (1)A prospective assessment that identifies and improves steps in a process thereby reasonably ensuring a safe and clinically desirable outcome. (2)A systematic approach to identify and prevent product and process problems before they occur.

Hazard Analysis - The process of collecting and evaluating information on hazards associated with the selected process. The purpose of the hazard analysis is to develop a list of hazards that are of such significance that they are reasonably likely to cause injury or illness if not effectively controlled.

Failure Mode - Different ways that a process or sub-process can fail to provide the anticipated result.

Probability – See the Probability Rating Scale, Figure 3.

Figure 1. Healthcare FMEA Process Steps 1 and 2

Step 1. Select the process you want to examine. Define the scope (Be specific and include a clear definition of the process or product to be studied).

This FMEA is focused on _____

_____

_____

_____

_____

_____

Step 2. Assemble the Team

FMEA Number_____

Date Started _____ Date Completed_____

Team Members 1._____ 4._____

2._____ 5._____

3._____ 6._____

Team Leader _____

Are all affected areas represented? YES NO

Are different levels and types of knowledge represented on the team? YES NO

Who will take minutes and maintain records? _____

Figure 2. Healthcare FMEA Worksheet

Step 4	1	**Process Step**					
	2	**Potential Failure Mode**					
	3	**Potential Cause(s)**					
	4	**Severity**					
	5	**Probability**					
	6	**Hazard Score**					
	7	**Decision (Proceed or Stop)** ***(Note: If the score is 8 or higher and the decision is to "Stop," document the rationale for this decision)***					
Step 5	8	**Action (Eliminate, Control, or Accept)**					
	9	**Description of Action**					
	10	**Outcome Measure**					
	11	**Person Responsible**					
	12	**Management concurrence (yes or no)**					

Figure 3. Severity Rating

Catastrophic Event *(Traditional FMEA Rating of 10 - Failure could cause death or injury)*	**Major Event** *(Traditional FMEA Rating of 7 – Failure causes a high degree of customer dissatisfaction.)*
Patient Outcome: Death or major permanent loss of function (sensory, motor, physiologic, or intellectual), suicide, rape, hemolytic transfusion reaction, Surgery/procedure on the wrong patient or wrong body part, infant abduction or infant discharge to the wrong family **Visitor Outcome:** Death; **or** hospitalization of 3 or more. **Staff Outcome:** * A death or hospitalization of 3 or more staff **Equipment or facility:** **Damage equal to or more than $250,000 **Fire**: Any fire that grows larger than an incipient	**Patient Outcome:** Permanent lessening of bodily functioning (sensory, motor, physiologic, or intellectual), disfigurement, surgical intervention required, increased length of stay for 3 or more patients, increased level of care for 3 or more patients **Visitor Outcome:** Hospitalization of 1 or 2 visitors **Staff Outcome:** Hospitalization of 1 or 2 staff **or** 3 or more staff experiencing lost time or restricted duty injuries or illnesses **Equipment or facility:** **Damage equal to or more than $100,000 **Fire:** Not Applicable – See Moderate and Catastrophic
Moderate Event *(Traditional FMEA Rating of "4" – Failure can be overcome with modifications to the process or product, but there is minor performance loss.)*	**Minor Event** *(Traditional FMEA Rating of "1"– Failure would not be noticeable to the customer and would not affect delivery of the service or product.)*
Patient Outcome: Increased length of stay **or** increased level of care for 1 or 2 patients **Visitor Outcome:** Evaluation **and** treatment for 1 or 2 visitors (less than hospitalization) **Staff Outcome:** Medical expenses, lost	**Patients Outcome:** No injury, nor increased length of stay nor increased level of care **Visitor Outcome:** Evaluated and no treatment required **or** refused treatment **Staff Outcome:** First aid treatment only with no lost time, nor restricted duty injuries

Figure 4. Probability Rating

Frequent - Likely to occur immediately or within a short period (may happen several times in one year)

Occasional - Probably will occur (may happen several times in 1 to 2 years)

Uncommon - Possible to occur (may happen sometime in 2 to 5 years)

Remote - Unlikely to occur (may happen sometime in 5 to 30 years)

Figure 5. Hazard Scoring Matrix

Probability	Severity of Effect			
	Catastrophic	**Major**	**Moderate**	**Minor**
Frequent	**16**	**12**	**8**	**4**
Occasional	**12**	**9**	**6**	**3**
Uncommon	**8**	**6**	**4**	**2**
Remote	**4**	**3**	**2**	**1**

How to Use This Matrix:

(1) Determine the Severity and Probability of the Hazard based upon the definitions included with this matrix. (NOTE: These definitions are the same as those used in the Root Cause Analysis Safety Assessment Code.)

Figure 6. Decision Tree