The Basics of Healthcare Failure Mode and Effect Analysis

Videoconference Course presented by
VA National Center for Patient Safety
What is Failure Mode and Effect Analysis?

Failure Mode and Effect Analysis (FMEA) is a systematic method of identifying and preventing product and process problems before they occur.
Why Use FMEA?

- Aimed at prevention of tragedy
- Doesn’t require previous bad experience or close call
- Makes system more robust
- Fault tolerant
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
Do you take actions to prevent yourself from being late to work? Yes or No

Do you “take the shortcut” when you see traffic building up in a familiar place? Yes or No

Do you try to distinguish “big problems” from “little problems”? Yes or No

Do you see the possibility of eliminating some problems, but need a better way to show that to people? Yes or No
Your answers indicate that you are already applying some of the principles of Failure Mode and Effect Analysis (FMEA) to prevent problems in day-to-day life.
Who uses FMEA?

- Engineers worldwide in:
  - Aviation
  - Nuclear power
  - Aerospace
  - Chemical process industries
  - Automotive industries

- Has been around for over 30 years
- Goal has been, and remains today, to prevent accidents from occurring
Historically…

- Accident prevention has not been a primary focus of hospital medicine.
- Misguided reliance on “faultless” performance by healthcare professionals.
- Hospital systems were not designed to prevent or absorb errors; they just reactively changed and were not typically proactive.
If FMEA were utilized, the following vulnerabilities might have been recognized and prevented:

- Major medical center power failure
- MRI Incident – ferromagnetic objects
- Bed rail and vail bed entrapment
- Medical gas usage
JCAHO Standard LD.5.2
Effective July 2001

Leaders ensure that an ongoing, proactive program for identifying risks to patient safety and reducing medical/health care errors is defined and implemented.
The organization seeks to reduce the risk of sentinel events and medical/health care system error-related occurrences by conducting its own proactive risk assessment activities and by using available information about sentinel events known to occur in health care organizations that provide similar care and services. This effort is undertaken so that processes, functions and services can be designed or redesigned to prevent such occurrences in the organization.
Intent of LD.5.2 (continued)

Proactive identification and management of potential risks to patient safety have the obvious advantage of preventing adverse occurrences, rather than simply reacting when they occur. This approach also avoids the barriers to understanding created by hindsight bias and the fear of disclosure, embarrassment, blame, and punishment that can arise in the wake of an actual event.
JCAHO Standard LD.5.2

- Identify and prioritize high-risk processes
- Annually, select at least one high-risk process
- Identify potential “failure modes”
- For each “failure mode,” identify the possible effects
- For the most critical effects, conduct a root cause analysis
JCAHO Standard LD.5.2

- Redesign the process to minimize the risk of that failure mode or to protect patients from its effects
- Test and implement the redesigned process
- Identify and implement measures of effectiveness
- Implement a strategy for maintaining the effectiveness of the redesigned process over time
Healthcare FMEA Definitions

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.
Effective Control Measure:
A barrier that eliminates or substantially reduces the likelihood of a hazardous event occurring.
Healthcare FMEA Definitions

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.
Healthcare FMEA Definitions

Failure Mode:
Different ways that a process or subprocess can fail to provide the anticipated result.
HFMEA and the RCA Process

Similarities

- Interdisciplinary Team
- 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

Differences

- Process vs. chronological flow diagram
- Prospective (what if) analysis
- Choose topic for evaluation
- Include detectability and criticality in evaluation
- Emphasis on testing intervention
HFMEA Points Out System/Process Vulnerabilities

A → B → C

Identified process issue; focus for intervention
Reason’s Model of Accidents

DEFENSES
- VHA Pol/Proc
- VAMC Pol/Proc
- Professional
- Team
- Individual
- Environmental

TRIGGERS
- Lack of Procedures
- Punitive Policies
- Mixed Messages
- Sporadic Training
- Attention Distractions
- Deferred Maintenance
- Clumsy Technology

Patient

Accident
Process Design & Organizational Change

- **Process Re-Design**
  - Redundancy
  - Usability Testing
  - Simplification
  - Fail-safe designs
  - Reduce Reliance on Memory & Vigilance
  - Simplify
  - Standardize
  - Checklists
  - Forcing Functions
  - Eliminate Look and Sound-alikes
  - Simulate
  - Looser coupling of systems

- **Organizational**
  - Increase Constructive Feedback and Direct Communication
  - Teamwork
  - Drive Out Fear
  - Leadership Commitment
The Healthcare Failure Modes and Effects Process

Step 1 - Define the Topic
Step 2 - Assemble the Team
Step 3 - Graphically Describe the Process
Step 4 - Conduct the Analysis
Step 5 - Identify Actions and Outcome Measures
Healthcare FMEA Process

STEP 1

Define the Scope of the HFMEA along with a clear definition of the process to be studied.
STEP 2

Assemble the Team – Multidisciplinary team with Subject Matter Expert(s) plus advisor
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.
C. If the process is complex identify the area of the process to focus on (manageable bite)
STEP 3 - Graphically Describe the Process

D. Identify all sub processes under each block of this flow diagram. Consecutively letter these sub-steps.

E. Create a flow diagram composed of the sub processes.
Healthcare FMEA Process

STEP 4 - Conduct a Hazard Analysis

A. List Failure Modes
B. Determine Severity & Probability
C. Use the Decision Tree
D. List all Failure Mode Causes
STEP 5 - Actions and Outcome Measures

A. Decide to “Eliminate,” “Control,” or “Accept” the failure mode cause.

B. Describe an action for each failure mode cause that will eliminate or control it.

C. Identify outcome measures that will be used to analyze and test the re-designed process.
STEP 5 - Actions and Outcome Measures

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

E. Indicate whether top management has concurred with the recommended actions.
Forms & Tools

- Forms
- Worksheets
- Hazard Scoring Matrix
- Decision Tree
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 HFMEA 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?____________________________
## HFMEA Subprocess step name and title

<table>
<thead>
<tr>
<th>HFMEA Step 4 - Hazard Analysis</th>
<th>HFMEA Step 5 - Identify Actions and Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Failure Mode: First Evaluate failure mode before determining potential causes</td>
<td>Potential Causes</td>
</tr>
<tr>
<td>--------------------------------</td>
<td>---------------------------------------------</td>
</tr>
<tr>
<td></td>
<td>Severity</td>
</tr>
</tbody>
</table>
HFMEA Decision Tree

The HFMEA Decision Tree...

Does this hazard involve a sufficient likelihood of occurrence and severity to warrant that it be controlled? (e.g. Hazard Score of 8 or higher)

Is this a single point weakness in the process? (e.g. failure will result in system failure) (Criticality)

Does an Effective Control Measure exist for the identified hazard?

Is the hazard so obvious and readily apparent that a control measure is not warranted? (Detectability)

STOP

NO

YES

PROCEED TO HFMEA STEP 5
1. Does this hazard involve a sufficient likelihood of occurrence and severity to warrant that it be controlled? (e.g. Hazard Score of 8 or higher)
2. Is this a single point weakness in the process? (e.g. failure will result in system failure) (Criticality)

YES

NO
HFMEA Decision Tree

3. Does an Effective Control Measure exist for the identified hazard?

- YES
- STOP

- NO
4. Is the hazard so obvious and readily apparent that a control measure is not warranted? *(Detectability)*
## Hazard Analysis

### SEVERITY RATING:

<table>
<thead>
<tr>
<th>Catastrophic Event</th>
<th>Major Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>(Traditional FMEA Rating of 10 - Failure could cause death or injury)</td>
<td>(Traditional FMEA Rating of 7 - Failure causes a high degree of customer dissatisfaction.)</td>
</tr>
</tbody>
</table>

**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
# Hazard Analysis

**SEVERITY RATING:**

<table>
<thead>
<tr>
<th>Moderate Event</th>
<th>Minor Event</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>(Traditional FMEA Rating of “4” – Failure can be overcome with modifications to the process or product, but there is minor performance loss.)</em></td>
<td><em>(Traditional FMEA Rating of “1” – Failure would not be noticeable to the customer and would not affect delivery of the service or product.)</em></td>
</tr>
</tbody>
</table>

### 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 time or restricted duty injuries or illness for 1 or 2 staff

### Equipment or facility:
- **Damage more than $10,000 but less than $100,000**

### Fire:
- Incipient stage† or smaller

### 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 nor illnesses

### Equipment or facility:
- **Damage less than $10,000 or loss of any utility‡ without adverse patient outcome (e.g. power, natural gas, electricity, water, communications, transport, heat/air conditioning).**

### Fire:
- Not Applicable – See Moderate and Catastrophic
Hazard Analysis

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)
HFMEA Hazard Scoring Matrix

<table>
<thead>
<tr>
<th>Probability</th>
<th>Severity</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Catastrophic</td>
</tr>
<tr>
<td>Frequent</td>
<td>16</td>
</tr>
<tr>
<td>Occasional</td>
<td>12</td>
</tr>
<tr>
<td>Uncommon</td>
<td>8</td>
</tr>
<tr>
<td>Remote</td>
<td>4</td>
</tr>
</tbody>
</table>
Example - Driving to Work

- Decided to perform FMEA on driving to work.
- Want to include the processes associated with this activity.
- Meant as an illustrative example by walking through the steps.
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 HFMEA 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?____________________________
Step 3A. Gather information about how the process works – describe it graphically.

Teaching Example

Wake Up → Get dressed → Start the car → Drive the car → Park the car → Walk into work
Teaching Example

Step 3B. Consecutively number each process

1. Wake Up
2. Get dressed
3. Start the car
4. Drive the car
5. Park the car
6. Walk into work
Teaching Example

Step 3C. If process is complex, choose area to focus on.

1. Wake Up
2. Get dressed
3. Start the car
4. Drive the car
5. Park the car
6. Walk into work

Scope
Teaching Example

Step 3D. If necessary, list sub-process steps and consecutively number.

1. Wake Up
   - 1A. Hit snooze on alarm
   - 1B. Again, hit snooze on alarm
   - 1C. Get out of bed
   - 1D. Find fuzzy slippers

2. Get dressed
   - 2A. Get coffee
   - 2B. Take shower
   - 2C. Find clean clothes
   - 2D. Find shoes

3. Start the car
   - 3A. Find keys
   - 3B. Find wallet
   - 3C. Look for bag
   - 3D. Look for coffee
   - 3E. Shovel out car

4. Drive the car
   - 4A. Coffee in cupholder
   - 4B. Bagel on seat
   - 4C. Listen to traffic report
   - 4D. Choose route

5. Park the car
   - 5A. Notice and take exit
   - 5B. Negotiate turn
   - 5C. Find spot
   - 5D. Get car to turn off

6. Walk into work
   - 6A. Collect bag, coffee, bagel
   - 6B. Close and lock doors
   - 6C. Begin walking
   - 6D. Return for keys
Teaching Example

Step 3D. Wake up (Sub-process flow diagram)

1A. Hit snooze button
1B. Again, hit snooze button
1C. Get out of bed
1D. Look for fuzzy slippers
Step 4A. List all failure modes.

1A. Hit snooze button
1B. Again, hit snooze button
1C. Get out of bed
1D. Look for fuzzy slippers

Failure Modes
1A(1) Turn off alarm
1A(2) Unplug Alarm
1A(3) Break alarm clock
## HFMEA Worksheet, Step 4A

### Hit Snooze Button - 1A

<table>
<thead>
<tr>
<th>Failure Mode: First Evaluate failure mode before determining potential causes</th>
<th>Potential Causes</th>
<th>Scoring</th>
<th>Decision Tree Analysis</th>
<th>HFMEA Step 5 - Identify Actions and Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Severity</td>
<td>Probability</td>
<td>Haz Score</td>
</tr>
<tr>
<td>1A(1)</td>
<td>Turn off alarm</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- **HFMEA Step 4 - Hazard Analysis**
  - Failure Mode: First Evaluate failure mode before determining potential causes
  - Potential Causes
  - Scoring
  - Decision Tree Analysis
  - Action Type (Control, Accept, Eliminate)
  - Actions or Rationale for Stopping
  - Outcome Measure
  - Person Responsible
  - Management Concurrency

- **HFMEA Step 5 - Identify Actions and Outcomes**
  - Actions or Rationale for Stopping
  - Outcome Measure
  - Person Responsible
  - Management Concurrency
## HFMEA Worksheet

### HFMEA Step 4 - Hazard Analysis

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<tbody>
<tr>
<td>First Evaluate failure mode before determining potential causes</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>1A(1) Turn off alarm</th>
</tr>
</thead>
</table>

### HFMEA Step 5 - Identify Actions and Outcomes

<table>
<thead>
<tr>
<th>Scoring</th>
<th>Decision Tree Analysis</th>
<th>Action Type (Control, Accept, Eliminate)</th>
<th>Actions or Rationale for Stopping</th>
<th>Outcome Measure</th>
<th>Person Responsible</th>
<th>Management Concurrence</th>
</tr>
</thead>
</table>

- **Severity**
- **Probability**
- **Haz Score**
- **Single Point Weakness?**
- **Existing Control Measure?**
- **Detectability**
- **Proceed?**
Step 4B. Determine the Severity and Probability of each potential cause. This will lead you to the Hazard Matrix Score.

**SEVERITY RATING:**

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**Fire:** Not Applicable – See Moderate and Catastrophic
Step 4: Hazard Analysis

Step 4. Determine the Severity and Probability of each potential cause. This will lead you to the Hazard Matrix Score.

**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)
HFMEA Hazard Scoring Matrix

<table>
<thead>
<tr>
<th>Probability</th>
<th>Severe</th>
<th>Major</th>
<th>Moderate</th>
<th>Minor</th>
</tr>
</thead>
<tbody>
<tr>
<td>Frequent</td>
<td>16</td>
<td>12</td>
<td>8</td>
<td>4</td>
</tr>
<tr>
<td>Occasional</td>
<td>12</td>
<td>9</td>
<td>6</td>
<td>3</td>
</tr>
<tr>
<td>Uncommon</td>
<td>8</td>
<td>6</td>
<td>4</td>
<td>2</td>
</tr>
<tr>
<td>Remote</td>
<td>4</td>
<td>3</td>
<td>2</td>
<td>1</td>
</tr>
</tbody>
</table>
Step 4: HFMEA Decision Tree

1. Does this hazard involve a sufficient likelihood of occurrence and severity to warrant that it be controlled? (e.g. Hazard Score of 8 or higher)

  YES

  NO
Step 4: HFMEA Decision Tree

2. Is this a single point weakness in the process? (e.g. failure will result in system failure) (Criticality)

- YES
- NO
Step 4: HFMEA Decision Tree

3. Does an Effective Control Measure exist for the identified hazard?

   YES
   
   STOP

   NO
   
   YES
Step 4: HFMEA Decision Tree

4. Is the hazard so obvious and readily apparent that a control measure is not warranted? (Detectability)

- NO
  - PROCEED

- YES
  - STOP
## HFMEA Worksheet, Steps 4B & 4C

### Hit Snooze Button - 1A

<table>
<thead>
<tr>
<th>Failure Mode: First Evaluate failure mode before determining potential causes</th>
<th>Potential Causes</th>
<th>HFMEA Step 4 - Hazard Analysis</th>
<th>HFMEA Step 5 - Identify Actions and Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Severity</strong></td>
<td><strong>Probability</strong></td>
<td><strong>Haz Score</strong></td>
<td><strong>Decision Tree Analysis</strong></td>
</tr>
<tr>
<td>Major</td>
<td>Occasional</td>
<td>9</td>
<td>N</td>
</tr>
<tr>
<td>1A(1) Turn off alarm</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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### HFMEA Step 4 - Hazard Analysis
- Severity: Major, Occasional
- Probability: Occasional
- Haz Score: 9
- Decision Tree Analysis: Proceed?
- Action Type: Control, Accept, Eliminate
- Actions or Rationale for Stopping
- Outcome Measure
- Person Responsible
- Management Concurrence
## HFMEA Worksheet, Step 5

### Hit Snooze Button - 1A

<table>
<thead>
<tr>
<th>Failure Mode:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Turn off alarm</td>
</tr>
</tbody>
</table>

#### HFMEA Step 4 - Hazard Analysis

<table>
<thead>
<tr>
<th>Potential Causes</th>
<th>Scoring</th>
<th>Decision Tree Analysis</th>
<th>HFMEA Step 5 - Identify Actions and Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Severity</td>
<td>Probability</td>
<td>Hazard Score</td>
</tr>
<tr>
<td>1A(1)</td>
<td>major</td>
<td>occasional</td>
<td>9</td>
</tr>
<tr>
<td>1A(1)a</td>
<td>major</td>
<td>occasional</td>
<td>9</td>
</tr>
</tbody>
</table>

**Notes:**
- **Severity:** major, occasional
- **Probability:** major, occasional
- **Hazard Score:** 9
- **Existing Control Measure?** N, N
- **Detectability:** Y
- **Proceed?**
- **Action Type:** Eliminate
- **Actions or Rationale for Stopping:**
  - Purchase new clock
  - Purchase by certain date xx/xx/xx
- **Outcome Measure:**
  - YOU
  - Yes
Step 3A. Gather information about how the process works – describe it graphically.

HFMEA PSA Example

- PSA test ordered
- Draw sample
- Analyze sample
- Report to physician
- Result filed (CPRS)
Step 3B. Consecutively number each process step.

1. PSA test ordered
2. Draw sample
3. Analyze sample
4. Report to physician
5. Result filed (CPRS)
HFMEA PSA Example

Step 3C. If process is complex, choose area to focus on.

1. PSA test ordered
2. Draw sample
3. Analyze sample
4. Report to physician
5. Result filed (CPRS)
Step 3D. If necessary, list sub-process steps and consecutively number.

1. PSA test ordered
   - A. Order written
   - B. Entered in CPRS
   - C. Received in lab

2. Draw sample
   - A. ID patient
   - B. Select proper tube/equip.
   - C. Draw blood
   - D. Label blood

3. Analyze sample
   - A. Review order
   - B. Centrifuge Specimen
   - C. Verify Calibration
   - D. Run QC
   - E. Run sample
   - F. Report result
   - G. Enter in CPRS

4. Report to physician
   - A. Report received

5. Result filed (CPRS)
   - A. Telephone
   - B. Visit set up
   - C. Result given
Step 3E. Analyze Sample (Sub-process flow diagram)

3A. Review order
3B. Centrifuge specimen
3C. Verify calibration
3D. Run QC
3E. Run sample
3F. Report result
3G. Enter in CPRS
Step 4A. Hazard Analysis: List potential failure modes for each process step.

**HFMEA PSA Example**

- **Failure Mode:** 1. Wrong test ordered
  2. Order not received

- **Failure Mode:** 1. Equip. broken
  2. Wrong speed
  3. Specimen not clotted
  4. No power
  5. Wrong test tube

- **Failure Mode:** 1. Instr not calibrated
  2. Bad calibration stored

- **Failure Mode:** 1. QC results unacceptable

- **Failure Mode:** 1. Mechanical error
  2. Tech error

- **Failure Mode:** 1. Computer crash
  2. Result entered for wrong pt.
  3. Computer transcription error
  4. Result not entered
  5. Result mis-read by tech

Scope
HFMEA PSA Example

Step 4B,C, D. Determine hazard score and list all the potential causes for each potential failure mode.

| Failure Mode: First Evaluate failure mode before determining potential causes | Potential Causes | Scoring | Decision Tree Analysis | HFMEA Step 5 - Identify Actions and Outcomes |
|---|---|---|---|---|---|
| | | Severity | Probability | Hazard Score | Single Point Weakness? | Existing Control Measure? | Detectability | Proceed? | Action Type (Control, Accept, Eliminate) | Actions or Rationale for Stopping | Outcome Measure | Person Responsible | Management Concurrence |
| 3F(1) Computer Crash | | Major | Occasional | 9 | N | N | Y | | | | |
| 3F(1)a Virus | | Major | Occasional | 9 | N | N | Y | | Control | Purchase and install virus protection software | Software installed | Chief IRM | Y |
| 3F(1)b Old equipment | | Moderate | Remote | 2 | Y | Y | | N/A | Ongoing/continuous program to replace existing equipment | | |
| 3F(1)c Software license expired | | Moderate | Occasional | 6 | Y | Y | | N/A | All software licenses are reviewed annually | | | | |
Step 4: HFMEA Decision Tree

1. Does this hazard involve a sufficient likelihood of occurrence and severity to warrant that it be controlled? (e.g. Hazard Score of 8 or higher)

   YES
   NO
Step 4: HFMEA Decision Tree

2. Is this a single point weakness in the process?
   (e.g. failure will result in system failure)
   (Criticality)

YES

NO
Step 4: HFMEA Decision Tree

3. Does an Effective Control Measure exist for the identified hazard?

- YES
- STOP

- NO
Step 4: HFMEA Decision Tree

4. Is the hazard so obvious and readily apparent that a control measure is not warranted? (Detectability)

- NO → PROCEED
- YES → STOP
HFMEA PSA Example

Step 4B,C, D. Determine hazard score and list all the potential causes for each potential failure mode.

<table>
<thead>
<tr>
<th>Failure Mode: First Evaluate failure mode before determining potential causes</th>
<th>Potential Causes</th>
<th>HFMEA Step 4 - Hazard Analysis</th>
<th>Decision Tree Analysis</th>
<th>HFMEA Step 5 - Identify Actions and Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>3F(1) Computer Crash</td>
<td></td>
<td>Scoring</td>
<td>Decision Type (Control, Accept, Eliminate)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Severity</td>
<td>Probability</td>
<td>Haz Score</td>
</tr>
<tr>
<td></td>
<td>Major</td>
<td>Occasional</td>
<td>9</td>
<td>N</td>
</tr>
<tr>
<td>3F(1)a Virus</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Major</td>
<td>Occasional</td>
<td>9</td>
<td>N</td>
</tr>
<tr>
<td>3F(1)b Old equipment</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Moderate</td>
<td>Remote</td>
<td>2</td>
<td>Y</td>
</tr>
<tr>
<td>3F(1)c Software license expired</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Moderate</td>
<td>Occasional</td>
<td>6</td>
<td>Y</td>
</tr>
</tbody>
</table>
### HFMEA PSA Example

**HFMEA Step 4 - Hazard Analysis**

<table>
<thead>
<tr>
<th>Failure Mode: First Evaluate failure mode before determining potential causes</th>
<th>Potential Causes</th>
<th>Scoring</th>
<th>Decision Tree Analysis</th>
<th>Action Type (Control, Accept, Eliminate)</th>
<th>Actions or Rationale for Stopping</th>
<th>Outcome Measure</th>
<th>Person Responsible</th>
<th>Management Concurrence</th>
</tr>
</thead>
<tbody>
<tr>
<td>3F(5)</td>
<td>Tech mis-reads results</td>
<td>Moderate</td>
<td>frequent</td>
<td>8</td>
<td>N</td>
<td>N</td>
<td>Y</td>
<td></td>
</tr>
<tr>
<td>3F(5)a</td>
<td>Tech fatigue</td>
<td>Moderate</td>
<td>frequent</td>
<td>8</td>
<td>Y</td>
<td>N</td>
<td></td>
<td>N/A</td>
</tr>
<tr>
<td>3F(5)b</td>
<td>Too busy</td>
<td>Moderate</td>
<td>frequent</td>
<td>8</td>
<td>N</td>
<td>N</td>
<td>Y</td>
<td>Control</td>
</tr>
<tr>
<td>3F(5)c</td>
<td>Poor lighting</td>
<td>Moderate</td>
<td>remote</td>
<td>2</td>
<td>N</td>
<td>Y</td>
<td>N</td>
<td>N/A</td>
</tr>
<tr>
<td>3F(5)d</td>
<td>Confusing readout on PSA instrument</td>
<td>Moderate</td>
<td>frequent</td>
<td>8</td>
<td>N</td>
<td>N</td>
<td>Y</td>
<td>Eliminate</td>
</tr>
</tbody>
</table>

**HFMEA Step 5 - Identify Actions and Outcomes**

<table>
<thead>
<tr>
<th>Report Result - 3F</th>
</tr>
</thead>
</table>

*Note: The table above includes the scoring system for severity, probability, hazard score, single point weakness, existing control measure, detectability, proceed decision, action type, actions or rationale for stopping, outcome measure, and person responsible for management concurrence.*
Let’s work on another example that takes place in a healthcare setting using the Healthcare FMEA Process…
Step 3A. Gather information about how the process works – describe it graphically.

- Process Step
  - Medication ordered (CPRS)

- Process Step
  - Auto electronic transfer to Pharmacy package

- Process Step
  - Pharmacy fills script; sends to floor

- Process Step
  - Nurse administers
Step 3B. Consecutively number each process step.

1. Medication ordered (CPRS)
2. Auto electronic transfer to Pharmacy package
3. Pharmacy fills script; sends to floor
4. Nurse administers
Step 3C. If the process is complex, choose an area to focus on.

1. Medication ordered (CPRS)

2. Auto electronic transfer to Pharmacy package

3. Pharmacy fills script; sends to floor

4. Nurse administers

Scope
HFMEA BCMA Example

Steps 3D. Identify all sub-processes under each block. Consecutively letter these sub-steps.

1. Medication ordered (CPRS)
   - A-Dummy terminal
   - B-PC’s

2. Auto electronic transfer to Pharmacy package
   - Sub-processes:
     - A-Check drug allergies
     - B-Check drug interactions
     - C-Check proper dosages
     - D--Orders Labs
     - E-order sent to auto dispensing

3. Pharmacy fills script; sends to floor
   - Sub-processes:
     - A-Automatically fills orders checked
     - B-Drugs pulled and script filled
     - C-Med cart filled
     - D-Cart sent to floor

4. Nurse administers
   - Sub-processes:
     - A-Log on to laptop
     - B-Medcart
     - C-Medications scanned
     - D-Patient band scanned
     - E-Medication given to patient
     - F-Patient record updated
Steps 3D. Identify all sub-processes under each block. Consecutively letter these sub-steps.

1. Medication ordered (CPRS)
   - A-Dummy terminal
   - B-PC’s

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   - Sub-processes:
     - A-Log on to laptop
     - B-Medcart
     - C-Medications scanned
     - D-Patient band scanned
     - E-Medication given to patient
     - F-Patient record updated
HFMEA BCMA Example

Steps 3E. Create a flow diagram composed of the sub-processes.

1. Log onto laptop
2. Get med cart
3. Scan meds
4. Scan patient band
5. Give med
6. Update record

4A 4B 4C 4D 4E 4F

Log onto laptop → Get med cart → Scan meds

**4A**
- Failure Modes:
  1. Laptop missing
  2. Network down
  3. No battery power
  4. CPRS not functioning
  5. Forget password
  6. Pharmacy pkg down
  7. RF system not working
  8. Server off line/down

**4B**
- Failure Modes:
  1. Med cart not there
  2. Filled incorrectly
  3. Expired meds
  4. Wrong cart

**4C**
- Failure Modes:
  1. Medication missing from cart
  2. Scanner/laptop missing
  3. No power for laptop
  4. Barcode label missing
  5. Barcode label not readable
  6. No power for scanner

**HFMEA BCMA Example**

**Scan patient band (4D)**
- Failure Modes:
  1. Wrong ID
  2. Band missing
  3. Band not readable
  4. Patient not there

**Give med (4E)**
- Failure Modes:
  1. Patient won’t/can’t take med

**Update record (4F)**
- Failure Modes:
  1. Cannot update record

- **4A. Log onto laptop**
  - Failure Modes:
    1. Laptop unavailable
    2. No battery power
    3. Network down
    4. CPRS not functioning
    5. Forget password
    6. Pharmacy pkg down
    7. RF system not working
    8. Server off line/down

- **4B. Get med cart**
  - Failure Modes:
    1. Med cart not there
    2. Filled incorrectly
    3. Expired meds
    4. Wrong cart

- **4C. Scan meds**
  - Failure Modes:
    1. Medication missing from cart
    2. Scanner/laptop missing
    3. No power for laptop
    4. Barcode label missing
    5. Barcode label not readable
    6. No power for scanner
Step 4. List all the potential causes for each potential failure mode.

### HFMEA BCMA Example

<table>
<thead>
<tr>
<th>Potential Causes</th>
<th>Sev</th>
<th>Prob</th>
<th>Haz Score</th>
<th>Single Point Weakness?</th>
<th>Existing Control Measure?</th>
<th>Detectability</th>
<th>Proceed?</th>
<th>Action Type (Control, Accept, Eliminate)</th>
<th>Actions or Rationale for Stopping</th>
<th>Outcome Measure</th>
<th>Person Responsible</th>
<th>Management Concurrence</th>
</tr>
</thead>
<tbody>
<tr>
<td>4A(1) Laptop unavailable</td>
<td>Moderate</td>
<td>Occasional</td>
<td>6</td>
<td>Y</td>
<td>N</td>
<td>N</td>
<td>Y</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4A(1)a Theft</td>
<td>Moderate</td>
<td>Occasional</td>
<td>6</td>
<td>Y</td>
<td>N</td>
<td>N</td>
<td>Y</td>
<td></td>
<td>Control</td>
<td>Buy backup</td>
<td>Total downtime is less than or equal to 15 minutes</td>
<td>Chief IRM</td>
</tr>
<tr>
<td>4A(2)b Locked in an office</td>
<td>Moderate</td>
<td>Occasional</td>
<td>6</td>
<td>Y</td>
<td>N</td>
<td>N</td>
<td>Y</td>
<td></td>
<td>Control</td>
<td>Call for IRM help</td>
<td>Total downtime is less than or equal to 15 minutes</td>
<td>Chief IRM</td>
</tr>
</tbody>
</table>
HFMEA BCMA Example

Step 4. List all the potential causes for each potential failure mode.

<table>
<thead>
<tr>
<th>Failure Mode:</th>
</tr>
</thead>
<tbody>
<tr>
<td>First Evaluate failure mode before determining potential causes</td>
</tr>
</tbody>
</table>

### Log onto Laptop - 4A

<table>
<thead>
<tr>
<th>Potential Causes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Battery failure</td>
</tr>
<tr>
<td>Battery not charged up</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
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<tr>
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<td>Probability</td>
<td>Haz Score</td>
<td>Single Point Weakness</td>
<td>Existing Control Measure</td>
<td>Detectability</td>
<td>Proceed?</td>
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<td>N</td>
<td>N</td>
<td>Y</td>
</tr>
<tr>
<td>Moderate</td>
<td>Occasional</td>
<td>6</td>
<td>Y</td>
<td>N</td>
<td>N</td>
<td>Y</td>
</tr>
</tbody>
</table>
Summarize Today’s Discussion

- Extension of what we’re currently doing
- Fully complies with JCAHO 2001 standards
- VHA NCPS providing training and forms
- Additional examples in Fall
- Need to do only one in fiscal year 2002
- Request feedback and suggestions