Healthcare Failure Mode and Effect Analysis (HFMEA) Proactive Risk Assessment

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Why conduct proactive risk assessments?
- Reduces likelihood of patient harm
- No previous bad experience or close call
- Creates robust and fault tolerant systems
- The Joint Commission

Objectives
- Understand the purpose of HFMEA proactive risk assessment
- Provide a conceptual understanding of the HFMEA process steps
- Understand how to choose an appropriate analysis topic
- Apply the HFMEA steps

Proactive Risk Assessment Models
- Failure Mode Effect Analysis (FMEA)
- Operational Risk Management (ORM)
- Hazard Analysis and Critical Control Point (HACCP)
- Healthcare Failure Mode Effect Analysis (HFMEA)

Joint Commission Standard LD.04.04.05
The hospital has an organizationwide, integrated patient safety program within its performance improvement activities.

Element of Performance A10:
At least every 18 months, the hospital selects one high-risk process and conducts a proactive risk assessment. (See also LD.04.04.03, EP 3)
Who uses proactive risk assessment?
• Aviation
• Nuclear power
• Aerospace
• Chemical process industries
• Automotive industries
• Food processing
• HEALTHCARE!

Failure Mode Effect Analysis
• Choose team, choose topic, and flow diagram the process
• Identify failure modes and failure mode effects
• Calculate a risk priority number (RPN) for each failure mode and effect (severity, occurrence, detection on scale of 1-10)
• Team chooses RPN cut-off point identifying what requires corrective action
• Develop interventions for high-risk failure modes
• Re-calculate the RPN to see if action (on paper) is successful (on paper) in reducing hazard/vulnerability below the cut-off

Hazard Analysis and Critical Control Point (HACCP)
(1) Conduct a hazard analysis
(2) Identify critical control points
(3) Establish critical limits
(4) Develop monitoring procedures
(5) Devise corrective actions
(6) Design verification procedures, and
(7) Ensure appropriate record-keeping and documentation procedures

Failure Mode Effect Analysis
• Used for process and product analysis
• Definitions for Severity, Detection and Occurrence not healthcare specific
• Occurrence rating, harder to score using a 10 point scale
• Severity rating, almost all healthcare scores were a 10 (failure could injure the customer or employee)
Healthcare Failure Mode Effect Analysis

- Developed by VA National Center for Patient Safety
- Combines pieces of FMEA, HACCP, and RCA
- Failure modes, causes
- Severity, Probability, Detectability & Decision Tree

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.

HFMEA Components

<table>
<thead>
<tr>
<th>Concepts Employed</th>
<th>HFMEA</th>
<th>FMEA</th>
<th>HACCP</th>
<th>RCA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Team membership</td>
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<tr>
<td>Diagramming</td>
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<td>Process</td>
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<td>Failure Modes &amp;</td>
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<tr>
<td>Causes</td>
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<td>Hazard Score</td>
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<td>Matrix</td>
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<td>Severity &amp;</td>
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<td>(RCA)</td>
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<td>Probability</td>
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<td>Definitions</td>
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<td>(RCA)</td>
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<tr>
<td>Actions &amp; Outcomes</td>
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<td>Responsible Person</td>
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<td>(RCA)</td>
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<td>&amp; Management</td>
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<td>concurrence</td>
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<td>Testing Action</td>
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</tbody>
</table>

VA NCPS HFMEA process

- In use since 2001
- Used nationally & internationally
- Used for coordinated national VA surgical instrument and device reprocessing analysis in 2007

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 sub-process can fail to provide the anticipated result.

Failure Mode is “what” could go wrong.
Failure Mode Cause is “why” it would go wrong.
Healthcare FMEA Definitions

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

HFMEA may be applied to a wide range of topics:
- Reporting lab results
- Completing medical records
- Prevention of aspiration pneumonia
- Blood transfusion administration
- Colorectal cancer screening
- Alarms in LTC and extended care
- Code Blue team response
- Reprocessing medical devices

The Healthcare Failure Mode Effect Analysis Process Steps

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

Worked with a large healthcare system to proactively:
- Analyze their plan to simultaneously roll out smart pumps across the entire healthcare system
- Impact of relocating the air ambulance home base from a city center airport to suburban airport

Healthcare FMEA Process

STEP 1 – Define the Topic
Define the HFMEA topic to be analyzed
- Review Incident Reports for trends
- Rely on personal experience and institutional memory
- Quality Assessment data

Topic should be:
- Reasonable in scope (typically 5 to 6 primary process steps)
- NOT presented as a problem statement!
  - Ensuring correct site surgery not preventing incorrect surgery
Refining a topic
• Initially: Performing “diagnostic testing”
• Then: Performing “AN INPATIENT diagnostic test”
• Further narrowing: Performing an “inpatient IMAGING diagnostic test”
• Leading to final: Performing an “inpatient MRI diagnostic test for Trauma Orthopaedics patients”

Healthcare FMEA Process

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:

________________________________________________________________________
________________________________________________________________________
________________________________________________________________________
________________________________________________________________________
________________________________________________________________________
________________________________________________________________________
________________________________________________________________________
________________________________________________________________________

Healthcare FMEA Process

Step 2. Assemble the Team

HFMEA Number

Date Started
Date Completed

Team Members

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?

Healthcare FMEA Process STEP 3 - Graphically Describe the Process

A. Develop and Verify the Flow Diagram

✓ Construct using an easel, flip chart and post it notes or project electronically to keep group focused/engaged

STEP 2 - Assemble multidisciplinary team

• Suggest 6 to 12 members
• Process experts & individuals naive to the process
• Individual with “leadership” skills
• Someone who can serve as the recorder
• Have more than one subject matter expert

Make sure that members understand role as liaison to Department/Service

STEP 3 - Graphically Describe the Process

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)
✓ Complete a preliminary/draft process flow diagram prior to meeting with the group.
✓ After completing the process diagram visit the work area and observe the process. Take the whole team, if possible. Verify that you have it right!

Healthcare FMEA Process

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. Identify Failure Mode Causes
Step 4: Hazard Analysis

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

SEVERITY RATING:

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

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Step 4: Hazard Analysis

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

SEVERITY RATING:

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

<table>
<thead>
<tr>
<th>Patient Outcome:</th>
<th>Increased length of stay or increased level of care for 1 or 2 patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Visitor Outcome:</td>
<td>Evaluation and treatment for 1 or 2 visitors (less than hospitalization)</td>
</tr>
<tr>
<td>Staff Outcome:</td>
<td>Medical expenses, lost time or restricted duty injuries or illness for 1 or 2 staff</td>
</tr>
<tr>
<td>Equipment or facility:</td>
<td><strong>Damage more than $10,000 but less than $100,000</strong></td>
</tr>
<tr>
<td>Fire:</td>
<td>Incipient stage‡ or smaller</td>
</tr>
<tr>
<td>Patients Outcome:</td>
<td>No injury, nor increased length of stay nor increased level of care</td>
</tr>
<tr>
<td>Visitor Outcome:</td>
<td>Evaluated and no treatment required or refused treatment</td>
</tr>
<tr>
<td>Staff Outcome:</td>
<td>First aid treatment only with no lost time, nor restricted duty injuries nor illnesses</td>
</tr>
<tr>
<td>Equipment or facility:</td>
<td><strong>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).</strong></td>
</tr>
<tr>
<td>Fire:</td>
<td>Not Applicable – See Moderate and Catastrophic</td>
</tr>
</tbody>
</table>
Step 4: Hazard Analysis

Step 4B. 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>Severity</th>
<th>Catastrophic (4)</th>
<th>Major (3)</th>
<th>Moderate (2)</th>
<th>Minor (1)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Frequent (4)</td>
<td>16</td>
<td>12</td>
<td>8</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>Occasional (3)</td>
<td>12</td>
<td>9</td>
<td>6</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>Uncommon (2)</td>
<td>8</td>
<td>6</td>
<td>4</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Remote (1)</td>
<td>4</td>
<td>3</td>
<td>2</td>
<td>1</td>
<td></td>
</tr>
</tbody>
</table>

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## HFMEA Worksheet, Step 4

### HFMEA Step 4 - Hazard Analysis

<table>
<thead>
<tr>
<th>Potential Causes</th>
<th>Severity</th>
<th>Probability</th>
<th>Haz. Score</th>
<th>Decision Tree Analysis</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Action Type (Control, Accept, Eliminate)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Actions or Rationale for Stopping</td>
</tr>
</tbody>
</table>

### HFMEA Step 5 - Identify Actions and Outcomes

<table>
<thead>
<tr>
<th>Action</th>
<th>Outcome Measure</th>
<th>Person Responsible</th>
<th>Management Concurrence</th>
</tr>
</thead>
</table>

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**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
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 → Is this a single point weakness in the process? (failure will result in system failure) (Criticality)

Yes → Does an Effective Control Measure exist for the identified hazard?

Yes → Stop

No → Is the hazard so obvious and readily apparent that a control measure is not warranted? (Detectability)

Yes → Stop

No → Proceed to HFMEA Step 5
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 \hspace{2cm} NO

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Step 4: HFMEA Decision Tree

   NO

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

   YES \hspace{2cm} NO \hspace{2cm} STOP

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Step 4C: HFMEA Decision Tree

   YES

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

   YES \hspace{2cm} STOP

   NO

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Single Point Weakness (criticality)

A single point weakness is a step in the process that is so critical that its failure will result in system failure or in an adverse event.

Example: momentary interruption of the power supply that would result in loss of IT data (if battery back up is not provided).

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Effective Control Measure

An effective control measure serves as a barrier that eliminates or substantially reduces the likelihood of a hazardous event occurring.

Example: anesthesiology machine prevents misconnection of medical gases through the use of pin indexing and connectors that have different threads.

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**Effective Control Measure**

- BCMA
- Free flow protection built into medication pumps
- Read-back or repeat-back on all verbal medication orders
- Only radiopaque sponges used in the OR

**Detectability**

- RF chips used on all surgical instruments and the patient is “wanded” prior to closing
- Syringes containing narcotics in locked syringe pumps are labeled so content name and concentration are visible even when the door is locked
- Regulators are not provided on medical air gas outlets in patient sleeping rooms

**Step 4: HFMEA Decision Tree**

- 4. Is the hazard so obvious and readily apparent that a control measure is not warranted? (Detectability)
  - YES: Proceed to worksheet Step 5
  - NO: STOP

**HFMEA Process Steps**

- **Step 4 – Analyze Failure Modes and Causes**
  - Use the HFMEA Worksheet as a cognitive aid and forcing function for the team.
  - Use the HFMEA Decision Tree to triage modes and causes.
  - Evaluate Failure Modes before identifying any Failure Mode Causes

**Detectability**

Detectability is how likely it is that the system failure or hazard will be detected by staff before it causes harm or interrupts completion of the required task or procedure.

Example (Not Detectable): Drug library updates are pushed to the smart pumps daily but the nurse isn’t aware if the library has been updated.

**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.
HFMEA 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.

Teaching Example

- Getting to work on time
Step 3A

Gather information about how the process works – describe it graphically.

1. Wake Up
2. Get dressed
3. Start the car
4. Drive the car
5. Park the car
6. Walk into work
Consecutively number each process step

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

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 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
Step 3E
Create a flow diagram composed of the subprocess steps

1A  1B  1C  1D
Hit snooze button → Again, hit snooze button → Get out of bed → Look for slippers
## HFMEA Worksheet

### HFMEA Subprocess step name and title

<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></td>
<td></td>
<td>Scoring</td>
<td>Decision Tree Analysis</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Severity</td>
<td>Probability</td>
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HFMEA Worksheet

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HFMEA Worksheet

Sub-process description

Failure mode description

Sub-process step number 1A + failure mode Number (1)

Sub-process number 1A + Failure Mode number (1) + Cause identifier (a)

Failure Mode Cause description

Time Saver

1A(1)

Turn off alarm

1A(1)a

Missed snooze button

This space should left blank unless Failure Mode score was “stop”; insert rational here.

HFMEA Step 4 - Hazard Analysis

HFMEA Step 5 - Identify Actions and Outcomes

Scoring

Decision Tree Analysis

Action Type (Control, Accept, Eliminate)

Actions or Rationale for Stopping

Outcome Measure

Person Responsible

Management Concurrency

Sub-process number 1A + failure mode Number (1)

Severity

Probability

Haz Score

Single Point Weakness?

Existing Control Measure?

Detectability

Proceed?

Scoring

Major

Occasional

9

N

Y

Eliminate

Purchase new clock

Purchase by certain date xx/xx/xx

YOU

Yes
Teaching Example

Step 4A. List all failure modes.

1A
- Hit snooze button

Failure Modes
- 1A(1) Turn off alarm
- 1A(2) Unplug alarm
- 1A(3) Break alarm clock

1B
- Again, hit snooze button

Failure Modes
- 1B(1) Turn off alarm
- 1B(2) Unplug alarm
- 1B(3) Break alarm clock

1C
- Get out of bed

Failure Modes
- 1C(1) Don’t get out of bed
- 1C(2) Out of bed on wrong side

1D
- Look for slippers

Failure Modes
- 1D(1) Don’t find slippers
- 1D(2) Find wrong slippers
**Subprocess Step: 1A Hit Snooze Button**

| Failure Mode: First Evaluate failure mode before determining potential causes | Potential Causes | Severity | Probability | Haz Score | Single Point Weakness? | Examine Control Measure? | Detectability | Proceed? | Action Type (Control, Accept, Eliminate) | Actions or Rationale for Stopping | Outcome Measure | Person Responsible | Management Concurrence |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **1A(1)** Turn off alarm | | | | | | | | | | | | | | |
Step 4: Hazard Analysis

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

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**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
### HFMEA Hazard Scoring Matrix

<table>
<thead>
<tr>
<th>Probability</th>
<th>Catastrophic</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

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Step 4C: HFMEA Decision Tree

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

   YES → STOP
   NO

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Step 4: HFMEA™ Decision Tree

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

   NO
   YES

   NO → STOP

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Decision Tree – Control Measure

Q. What is an effective control measure?
A. Serves as a barrier that eliminates or substantially reduces the likelihood of a hazardous event occurring. For example, an anesthesiology machine may prevent cross connection of medical gases through the use of pin indexing and connectors that have different threads.

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Decision Tree – Single Point Weakness (criticality)

Q. What is a single point weakness?
A. The step in the process is so critical that its failure will result in system failure or in an adverse event. For example, momentary interruption of the power supply that would result in loss of EMR or MAR data.

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Step 4: HFMEA Decision Tree

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

   NO
   Proceed to Step 5

   YES → STOP

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Decision Tree – Detectable

Q. What would be an example of a detectable hazard?
A. Must be so visible and obvious that it will be discovered before it interferes with completion of task and activity. As part of the Bar Code Medication Administration contingency plan, information is backed up to certain computers every hour from the server. However, there is no message received and no way to confirm that this has actually occurred. Thus, this lacks detectability and represents a vulnerability.
## HFMEA Worksheet, Step 4

### 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></td>
<td></td>
<td>Scoring</td>
<td>Decision Tree Analysis</td>
</tr>
<tr>
<td>Major Occasional</td>
<td>Occasional</td>
<td>9</td>
<td>N N Y</td>
</tr>
</tbody>
</table>

| 1A(1) Turn off alarm | | | | | | | |

---

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**HFMEA Worksheet, Steps 4B, C & D**

### Hit Snooze Button - 1A

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

#### Scoring
- **Severity**: Major, Occasional
- **Probability**: 9
- **Haz Score**: Major, Occasional
- **Single Point Weakness?**: N
- **Existing Controls**: N
- **Detectability**: Y

#### Decision Tree Analysis
- **Proceed?**: Y

#### Action Type (Control, Accept, Eliminate)
- Actions or Rationale for Stopping
- Outcome Measure

#### Person Responsible

#### Management Concurrency

<table>
<thead>
<tr>
<th></th>
<th>Action Type</th>
<th>Person Responsible</th>
<th>Management Concurrency</th>
</tr>
</thead>
<tbody>
<tr>
<td>1A(1)</td>
<td>Missed snooze button</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
## Action Hierarchy

| Stronger Actions | Architectural/physical plant changes  
|                  | New devices with usability testing before purchasing  
|                  | Engineering control or interlock (forcing functions)  
|                  | Simplify the process and remove unnecessary steps  
|                  | Standardize on equipment on process or caremaps  
|                  | Tangible involvement and action by leadership in support of patient safety  
| Intermediate Actions | Redundancy  
|                     | Increase in staffing/decrease in workload  
|                     | Software enhancements/modifications  
|                     | Eliminate/reduce distractions (sterile medical environment)  
|                     | High Fidelity Simulation based training  
|                     | Checklist/cognitive aid  
|                     | Eliminate look and sound-alikes  
|                     | Readback/Repeatback  
|                     | Enhanced documentation/communication  
| Weaker Actions | Double checks  
|                 | Warnings and labels  
|                 | New procedure/memorandum/policy  
|                 | Training  
|                 | Additional study/analysis  

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## HFMEA Worksheet, Steps 4B, C & D

### Hit Snooze Button - 1A

<table>
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<td><strong>Failure Mode:</strong></td>
<td><strong>Scoring</strong></td>
<td><strong>Decision Tree Analysis</strong></td>
</tr>
<tr>
<td>First Evaluate failure mode before determining potential causes</td>
<td>Severity</td>
<td>Probability</td>
</tr>
<tr>
<td>1A(1) Turn off alarm</td>
<td>Major</td>
<td>Occasional</td>
</tr>
<tr>
<td>1A(1)a Missed snooze button</td>
<td>Major</td>
<td>Occasional</td>
</tr>
</tbody>
</table>
HFMEA PSA Example

Step 3A. Gather information about how the process works – describe it graphically.

Process Steps

- PSA test ordered
- Draw sample
- Analyze sample
- Report to physician
- Result filed (CPRS)
HFMEA PSA Example

Step 3B. Consecutively number each process step.

Process Steps

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

5 to 6 primary process steps
Step 3D. If necessary, list sub-process steps and consecutively number.

HFMEA PSA Example

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

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

3. Analyze sample
   Sub-processes:
   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
   Sub-processes:
   A. Report received

5. Result filed (CPRS)
   Sub-processes:
   A. Telephone
   B. Visit set up
   C. Result given

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HFMEA PSA Example

Step 3E. Analyze Sample (Sub-process flow diagram)

Sub-process Steps

3A  3B  3C  3D  3E  3F
Review order  Centrifuge specimen  Verify calibration  Run QC  Run sample  Report result

3G  Enter in CPRS

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Step 4A. Hazard Analysis: List potential failure modes for each process step.

**HFMEA PSA Example**

- **3A**
  - Review order
  - Failure Mode:
    1. Wrong test ordered
    2. Order not received

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

- **3C**
  - Verify calibration
  - Failure Mode:
    1. Instr not calibrated
    2. Bad calibration stored

- **3D**
  - Run QC
  - Failure Mode:
    1. QC results unacceptable

- **3E**
  - Run Sample
  - Failure Mode:
    1. Mechanical error
    2. Tech error

- **3F**
  - Report result
  - Failure Mode:
    1. Computer freezes/crashes
    2. Result entered for wrong pt.
    3. Computer transcription error
    4. Result not entered
    5. Result mis-read by tech

- **3G**
  - Record result (EMR)

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HFMEA PSA Example

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

<table>
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</tr>
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<tbody>
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</table>

<table>
<thead>
<tr>
<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 Concurrency</th>
</tr>
</thead>
<tbody>
<tr>
<td>3F(1) Computer Freezes/ Crashes</td>
<td>Major</td>
<td>Occasional 9</td>
<td>N</td>
<td>N</td>
<td>Y</td>
<td>Control</td>
<td>Purchase &amp; Install virus protection software</td>
</tr>
<tr>
<td>3F(1)a Computer attached by virus</td>
<td>Major</td>
<td>Occasional 9</td>
<td>N</td>
<td>N</td>
<td>Y</td>
<td>Control</td>
<td></td>
</tr>
<tr>
<td>3F(1)b Older hardware cannot handle new OS</td>
<td>Moderate</td>
<td>Remote 2</td>
<td>Y</td>
<td>Y</td>
<td>N</td>
<td>N/A</td>
<td>Replacement equipment purchased &amp; available</td>
</tr>
<tr>
<td>3F(1)c Virus Protection software license expired</td>
<td>Moderate</td>
<td>Occasional 6</td>
<td>Y</td>
<td>Y</td>
<td>N</td>
<td>N/A</td>
<td>Software licenses reviewed automatically</td>
</tr>
</tbody>
</table>
### HFMEA PSA Example

#### HFMEA Step 4 - Hazard Analysis

<table>
<thead>
<tr>
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<th>Scoring</th>
<th>Decision Tree Analysis</th>
<th>HFMEA Step 5 - Identify Actions and Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>3F(5) Tech mis-reads results</strong></td>
<td><strong>Severity</strong></td>
<td><strong>Probability</strong></td>
<td><strong>Scoring</strong></td>
<td><strong>Decision Tree Analysis</strong></td>
</tr>
<tr>
<td>Moderate</td>
<td>frequent</td>
<td>8</td>
<td>N N Y</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>3F(5)a Tech fatigue due to double shifts</strong></td>
<td>Moderate</td>
<td>frequent</td>
<td>8</td>
<td>Y</td>
</tr>
<tr>
<td><strong>3F(5)b Workload exceeds staffing level</strong></td>
<td>Moderate</td>
<td>frequent</td>
<td>8</td>
<td>N N Y</td>
</tr>
<tr>
<td><strong>3F(5)c Insufficient lighting level to read display</strong></td>
<td>Moderate</td>
<td>remote</td>
<td>2</td>
<td>N</td>
</tr>
</tbody>
</table>

**Report Result - 3F**

**HFMEA Step 4 - Hazard Analysis**

- **Failure Mode:** First Evaluate failure mode before determining potential causes
- **Potential Causes:**  
  - 3F(5) Tech mis-reads results
  - 3F(5)a Tech fatigue due to double shifts
  - 3F(5)b Workload exceeds staffing level
  - 3F(5)c Insufficient lighting level to read display

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

- **Action Type:** (Control, Accept, Eliminate)
- **Actions or Rationale for Stopping**
- **Outcome Measure**
- **Person Responsible**
- **Management Concurrence**

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HFMEA Exercise

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:

The process of placing the correct contact lense on the left eye
HFMEA Exercise

Saline
Who is on the proactive risk assessment team?

- Multidisciplinary members
- Subject matter experts
- Individual naïve to the process
- One individual serves as a team leader
- One as a team recorder

How long does it take to complete a proactive risk assessment?

It depends upon the:
- Scope of the process or sub-process that is examined
- Skill of the team advisor
- Commitment of the team members to work effectively, and their team skills
- Based upon our experience with RCAs, we have found that as teams become more skilled and facile, the time decreases and the quality of the product increases.

Are there any common pitfalls in conducting proactive risk assessment and how can they be avoided?

- Avoid trying to solve world hunger with your team
- Focus in on a manageable part of the process
- Select the right people for the team
- Choose a leader for the team comfortable in managing a group process
- Set a timeline

Tips continued...

- Present failure modes as a problem statement that needs to be corrected
- When doing the process flow diagram ensure the team is diagramming the process steps that actually occur and not the ideal process.
Tips continued...
- After the team develops the process diagram, have some team members visit the work area to observe staff performing the process to verify that their assumptions are correct.
- Follow the numbering and lettering format for the process and sub process diagrams. This is essential to keep the team organized when they move on to identifying failure modes!

Tips continued...
- Remember to conduct the hazard analysis on the failure mode before identifying failure mode causes. This will prevent you wasting time identifying and assessing causes that don’t need to be addressed.

Additional Examples of HFMEA Processes
- Transferring the Bariatric Patient from Bed to Wheelchair
- Timely Delivery of Antimicrobial Therapy for Septic Patients in the PICU
- Blood Specimen Labeling in the ER by Outside Practitioners
- Assessment and Treatment of Complex Wounds in Continuing Care Facilities
- Labeling Lab Specimens