Healthcare Failure Modes and Affects Analysis (HFMEA)

Guidebook

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Contents

Introduction and General Overview

Objective

The objective of this guidebook is to provide Patient Safety Managers (PSMs) and Patient Safety Officers (PSOs) with an understanding of the fundamental steps of conducting Healthcare Failure Mode and Effect Analysis (HFMEA).

Background

The ability to proactively identify and account for potential vulnerabilities is a fundamental aspect of high reliability and the delivery of safe patient care. Failure Mode and Effect Analysis (FMEA) is one of the most widely adopted techniques for conducting a proactive risk assessment. FMEA is a systematic process used to help identify product and process problems before they occur (Mikulak, McDermott, & Beauregard 2008). The FMEA process may be used to define, identify, and eliminate known or potential failures, problems, or errors in a system, design, process, or service line. The VA National Center for Patient Safety (NCPS) adopted and modified FMEA for use in the healthcare environment in 2001, incorporating concepts from other quality and safety tools (e.g., Root Cause Analysis (RCA), Hazard Analysis and Critical Control Point (HACCP). The tool was named Healthcare Failure Mode and Effects Analysis (HFMEA) and is uniquely suited to proactive risk assessment of healthcare processes.

Why HFMEA?

HFMEA is a healthcare focused tool for proactive risk assessment. Unlike RCA, HFMEA is *prospective*, considering possible risks before they occur. HFMEA has its origin in FMEA methods taken from manufacturing, however, HFMEA has key differences. For example, the processes for assigning severity and probability, actions and outcomes, and lines of responsibility and accountability are present in FMEA but were substantially modified in the HFMEA process. HFMEA adds a decision tree algorithm and borrows the hazard scoring matrix from the RCA process.

NCPS requires facilities to complete at least one proactive risk assessment every 12 months. However, The Joint Commission (TJC) requires facilities to select one high risk process and conduct a proactive risk assessment every 18 months, at a minimum to comply with the Hospital

Accreditation Program requirements (The Joint Commission, 2017). The HFMEA process, when successfully implemented, meets the requirement.

***Note:** The facility should submit the completed Healthcare Failure Mode and Effect Analysis (HFMEA) or proactive risk assessment (PRA) as soon as possible, but no later than 3 months after analysis completion, onto the NCPS intranet site* http://vaww.ncps.med.va.gov/Dialogue/HFMEATopics/submit.asp.

TJC outlines several key strategies for effective proactive risk assessment, all of which are incorporated in the HFMEA process. These include describing a chosen process, identifying ways in which a process might fail, describing the effects of potential failures on patient safety, prioritizing potential process failures, determining why such potential failures could occur, redesigning processes and/or underlying systems, and testing and monitoring redesigned processes (The Joint Commission, 2017). For the most critical risks, proactive risk assessments allow participants to develop a plan to identify probable causes, redesign the process, and test changes to confirm desired outcomes (The Joint Commission, 2017). HFMEA was originally developed for potential risks to patient safety but is also an effective technique to consider issues of timeliness, efficiency, effectiveness, patient-centeredness, or other healthcare system priorities. HFMEA is intended for users of all skill levels to identify important problems and high-yield solutions.

HFMEA Steps

The 5-steps to a successful HFMEA are described below.

1. Define the topic with a clear definition of the process to be studied.
2. Assemble a multidisciplinary team that includes subject matter experts (SME), an advisor, a recorder, and a team leader. A multidisciplinary team ensures relevant knowledge is available and various viewpoints are considered.
3. Graphically describe the process. Team members will develop and verify a diagram of the process flow, which is the *Process Flow Diagram.* Each step in the process is numbered, sub-processes are identified, and areas within the process that need attention are identified.
4. Conduct a hazard analysis and list all possible/potential failure modes under the sub-processes identified in step 3. The team will determine the probability and severity of

the failure modes, determine their potential causes when warranted, and consider each one using the HFMEA decision tree.

5. Develop actions and outcome measures that will eliminate or control each failure mode.

Define the Topic

The first step in conducting an HFMEA is to identify and define the topic to be analyzed. The topic should represent a high-risk and/or vulnerable area and needs to include a clear definition of the process to be studied. This section provides guidance on identifying a suitable topic, which includes examples to assist in the selection of a topic that is within an appropriate scope.

1.1 HFMEA Project Types

The following list represents one way to initiate conceptualizing systems within healthcare facilities.

- **System** – Analyze system-wide functions that can impact patient safety, *i.e.* delays with diagnosis and treatment.
- **Design** – Focus on initial design processes using systems thinking and a multidisciplinary approach.
- **Process –** Consider processes such as medication administration and discharge planning.
- **Service –** Standardize services when variability of a product or service performance poses a patient safety risk.
- **Software** – Assess electronic health record (EHR) software vulnerabilities.

1.2 Identifying Potential HFMEA Topics

There are many sources available to help the team identify topics to analyze. For example, the ECRI Institute publishes an annual list of the "Top 10 Patient Safety Concerns," which highlights potential risks across the continuum of care (2019); this list may help identify high priority topics or concerns. Topics may also be identified using the following list of sources:

- Topics may be identified during the RCA process

- Review and/or trending of patient safety event reports or other event reporting systems
- Review of readmission and patient advocate data
- Solicit ideas from leaders and staff about hazards which are likely to cause injury or illness if they are not effectively controlled
- Evaluate risks with new or existing products, processes, and systems that have a potential to fail (Preferably, this is done prior to implementation of a new product, process, or system)
- Review TJC sentinel event list
- Consider vulnerabilities reported via other channels

1.3 Determining the Scope of the HFMEA Topic

After the topic is identified, consider the following strategies to further investigate whether the appropriate scope was identified. The team should define clear boundaries for the process to be examined. The complexity of the process and the availability of the team members should be considered. For example, if the process is facility-wide, the team may choose to focus on high priority or high-risk areas. If the process is complex or lengthy, the team may choose to focus on one or more of the process steps (See Chapter 3 for additional information). The subject matter experts may be helpful in refining the scope.

1.4 Writing a Topic Statement

Drafting the topic statement is a straightforward process. After identifying a potential scope, PSMs can gather facts, data, and material about the scope to include consideration of events that have occurred at other facilities. The topic statement should include a description of the topic being analyzed and the scope of what will be covered. Consider the following guidelines when drafting a topic statement:

- The topic statement should describe what process is being analyzed
- The topic statement should describe the boundaries or scope of what will be analyzed
- The topic statement should be clear, definitive, concise, and leave no room for misinterpretation
- The topic statement should be brief, consisting of one or two sentences

Examples of effective topic statements are included below.

> **Example 1:**
>> *"Medication error prevention specifically related to pharmacy assigned medication administration times."*
>
> **Example 2:**
>> *"Cleaning of non-critical reusable medical equipment and high touch surfaces in in-patient care areas."*
>
> **Example 3:**
>> *"Handoff of mental health patients from admission to arrival on acute care."*

Assemble the Team

The composition of the team should be multidisciplinary and the number of people on a team depends on the scope of the process being reviewed (QAPI, 2013). There should be at least one representative from each employee group involved in the process. For example, if the HFMEA is aimed at the process of assessing residents in a Community Living Center for fall risk and protecting those residents found to be at a high risk, the team should include clinical staff such as representatives from Nursing (RN and LPN or CNA), Medicine, Environmental Management Services, Physical Medicine and Rehabilitation Services, and Behavioral Health Services.

2.1 Advisor

Typically, the facility PSM serves as the team's advisor. The primary responsibilities of the advisor are to define the project topic and scope, assemble the project team, orient team members to the process, and provide consultation to the team throughout the process. The advisor should provide the team with a clear vision of the task. The advisor initiates the process and works with hospital leadership to gain support and escalate issues as necessary. Understanding the HFMEA requirements is an important characteristic of an effective advisor. Specific responsibilities of the advisor include:

- Identifying the high-vulnerability topic/process (in consultation with the Medical Center Director)
- Obtaining leadership support to ensure the topic aligns with leadership goals
- Assembling a multi-disciplinary team with subject matter experts (and individuals who are unfamiliar with the process)
- Completing the charter memo and obtaining Director concurrence
- Requesting supervisor support for team member participation
- Providing orientation/overview of the HFMEA process to team members
- Supporting the team with ongoing consultation

2.2 Team Leader

The advisor appoints the team leader and ensures a clear understanding of the processes being reviewed. The team leader guides the team and serves as the project manager. It is important that the team leader understand the HFMEA process and can facilitate the team, as needed. The team leader's responsibilities include:

- Arranging meeting times and location
- Setting and maintaining ground rules for meetings
- Keeping the team on task and within the timeline
- Using the HFMEA tools and cognitive aides developed by NCPS
- Facilitating the use of materials *(e.g.*, flipcharts and sticky notes) for flowcharts and diagrams
- Summarizing the work completed and identifying next steps
- Writing the final HFMEA summary for leadership review
- Consulting with the advisor

2.3 Subject Matter Experts

Subject matter experts (SME) are staff who have immediate experience with the process being analyzed or who bring additional knowledge, experience, or points of view that will benefit the team. Including SMEs who are involved directly in the process being analyzed helps the team to understand the process steps (as planned and as actually carried out). If possible, SMEs should be included from multiple shifts to gain a true perspective of topic being analyzed. The experiences of staff working during the day may be much different than what happens during the evening and night shifts (QAPI, 2013). The staff selected to serve as the SME team members should have day-to-day responsibilities for completing one or more steps in the process under analysis. Effective SME team members:

- Have personal knowledge of what happens in the process, including differences between work as performed and as planned
- Are vital to the project success
- Must be allowed a flexible schedule to participate fully in team meetings and work required outside of recurring team meetings

Team participation can be demanding, and supervisors must be made aware of the time commitment when they are selecting individuals to serve on the team.

2.4 Recorder

The recorder is responsible for documentation during the working sessions, taking minutes, and distributing the information to the team. The recorder is responsible for:

- Updating flip charts, worksheets, and process flow diagrams throughout the working sessions and between meetings
- Notating the process flow diagram and documenting the hazard analysis decisions
- Recording the actions and outcome measures
- Using the HFMEA numbering scheme
- Recording any necessary information
- Assisting the team leader to stay on the timeline

2.5 HFMEA Cover Sheet

The cover sheet is used to record the administrative information about the HFMEA. Administrative information includes the topic statement, dates started and completed, team members and designations, and other information. When completing the topic sheet, teams should include the following information:

- The final topic statement
- A list of all team members, their position titles, and contact information
- Designation of team leader and team recorder
- Self-certification that all affected areas of the process being examined are represented on the team
- Self-certification that members at various levels within the organization with different types of knowledge are included on the team
- Annotation of the official date the HFMEA was started and the date it was completed

An example of the HFMEA Cover Sheets are shown in Appendix A & B.

Graphically Describe the Process

After the topic is defined the team will create a graphical representation of the process being examined. The goal of graphically describing the process being examined is to break the entire process into small pieces, arrange them in a logical order, and construct a process flow diagram that the team will use to build the analysis. The team will identify the main process steps, sub-process steps, and assemble them in sequential order. To begin the graphic description of the process, it is important to have several resources available to the team. Important resources may include individuals who are SMEs, relevant policies, standard operating procedures, and any resource that provides guidance to the team to help identify each step in the process being analyzed.

3.1 Constructing the Graphic Picture of the Process Flow Diagram

As the SMEs describe how the process is accomplished, the team will begin mapping each of the main steps in the process being evaluated. Unlike event diagrams used for the RCA process, the HFMEA process flow diagram follows the premise of what is *routinely* done during the process being reviewed. Consecutively number the main processes as shown in Figure 1.

Figure 1. Process Flow Diagram
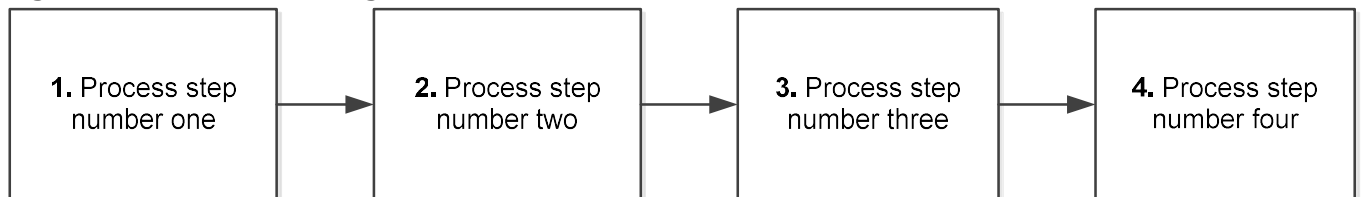
3.2 Identify the Subprocesses

Identify all sub-processes under each block of the main flow diagram. Consecutively, letter these sub-steps (*e.g.* 1a, 1b…3e, etc.). Sub process boxes will begin with the same whole number as the main process and each subsequent sub process box with have incremental letters after the whole number (1a, 1b, 1c, 1d, etc.…) as shown in Figure 2. Once the process flow diagram is completed, visit the area to observe the process and validate if the diagram is correct. If it is not, adjust it to reflect what was observed. A process flow diagram for a blood specimen draw and subsequent process steps are shown in Appendix C and D.

Figure 2. Main Process Steps with Sub-Processes

1. Process step number one	**2.** Process step number two	**3.** Process step number three	**4.** Process step number four
1A. Sub-process step description	**2A.** Sub-process step description	**3A.** Sub-process step description	**4A.** Sub-process step description
1B. Sub-process step description	**2B.** Sub-process step description	**3B.** Sub-process step description	**4B.** Sub-process step description
	2C. Sub-process step description	**3C.** Sub-process step description	**4C.** Sub-process step description
	2D. Sub-process step description		

3.3 Narrowing the Process/Scope

Refining the process and limiting the scope may be necessary if the team determines the process is too large or complex to be feasible. In these cases, the next step is to select the specific parts of the process the team will focus on. This helps to narrow the scope of the HFMEA. The team captures the subprocesses selected by drawing a circle or oval around the column to be evaluated as shown in Figure 3.

Figure 3. Refining the Scope
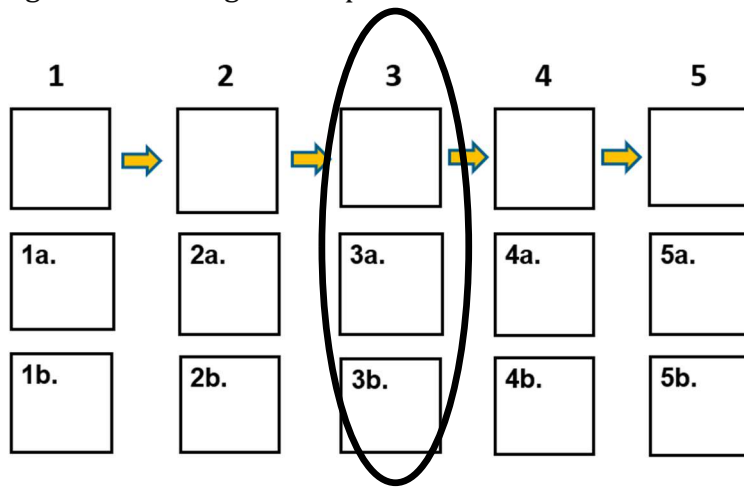
3.4 Tips

1) If the process is complex with numerous steps, narrow the scope by selecting a step that has high impact or importance to the project. This will help make the project manageable.
2) Unlike event diagrams used for the RCA process, the HFMEA process flow diagram follows the premise of what is *routinely* done during the process being reviewed.
3) Once the process flow diagram is completed, visit the area to observe the process and validate if the diagram is correct. If it is not, adjust it to reflect what was observed.

Pitfall: Limiting the description to what happened on a specific day. Remember, the description must reflect what is *routinely* done.

Conduct a Hazard Analysis

Hazard analysis is 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 or vulnerabilities that are of such significance that they are reasonably likely to cause injury or illness if they are not effectively controlled. This chapter will describe the concepts of failure mode, failure mode cause, the hazard matrix, the decision tree, the numbering scheme, and the worksheet and how they are used to conduct and document a hazard analysis.

4.1 Failure Modes and Failure Mode Causes

A **failure mode** is defined as one of the various ways that a process step or subprocess step can fail to accomplish its intended purpose. For example, for the subprocess step of identifying a patient for specimen collection, potential failure modes would include: (1) Patient not identified by using two identifiers, (2) Patient consent form not completed, and (3) Pre-procedure timeout not completed. Failure modes describe <u>what</u> could go wrong or <u>how</u> the process could fail. A failure mode may be unique to a single sub-process step or it may apply to multiple subprocess steps. The risk could be different depending on which part of the process it occurs in.

A **failure mode cause** is defined as the reason why a potential failure mode might occur. A single failure mode will typically have more than one potential cause. For the example failure mode, *Patient not identified by using two identifiers* that was previously described*,* potential causes would include: (1) Lack of a written policy requiring the use of two identifiers for specimen collection, (2) Lack of staff training on the use of two identifiers, and (3) Patient is not able to provide two identifiers. Failure mode causes describe <u>why</u> something might go wrong or what vulnerabilities could cause the failure mode to occur. See Appendix E & F for examples.

4.2 HFMEA Hazard Analysis Sequence

The general sequence of events is described below:

1. Identify and list the potential failure modes for each subprocess step within the overall process.
2. Assign a hazard score to each failure mode using the HFMEA Hazard Matrix (severity and probability).

3. Use the HFMEA Decision Tree to determine if each failure mode warrants further attention.

4. Identify and list the potential failure mode causes for each failure mode that warrants further attention (based on the HFMEA Decision Tree).

5. Assign a hazard score to each failure mode cause using the HFMEA Hazard Matrix and use the HFMEA Decision Tree to determine if each failure mode cause warrants actions and outcome measures.

The hazard analysis process helps the team determine potential failure modes and failure mode causes significant enough to develop actions and outcome measures.

4.2.1 Identify and list all possible potential failure modes

The first step in the hazard analysis is to systematically list all potential failure modes for each process step and subprocess step within the process. Starting with the first subprocess step, the team should brainstorm what potential failure modes would prevent each subprocess step from succeeding. As failure modes are identified, they should be numbered in accordance with the overall numbering sequence (*e.g.,* 1a(1), 1a(2)…3(e)1, 3e(2)…). The team should utilize various sources and tools to help determine how each process step might fail. It is common for teams to discover one or more failure modes for each subprocess step. Failure modes may involve many facets such as process, technology, information, human factors, product quality, or anything else that may cause a process to fail. Failure modes may include several types of human errors. Human errors include slips (errors in execution), lapses (omissions or failure to execute a task), and mistakes (decision-based errors, or when the intended action does not result in the intended result). Appendix E provides an example of how failure modes may be listed below their associated subprocess steps.

4.2.2 Assign a severity and probability to each failure mode

When the team has identified the potential failure modes for each subprocess step, the next step is to begin the analysis of each failure mode. The analysis starts by assigning a hazard score to the failure mode.

The four possible severity ratings are Catastrophic (4), Major (3), Moderate (2), and Minor (1). The four probability ratings are Frequent (4), Occasional (3), Uncommon (2), and Remote (1). Definitions of each severity and probability rating are shown in Tables 1 and 2, respectively. A

hazard score is assigned to each failure mode by reviewing the severity and probability definitions then selecting the appropriate severity rating and probability rating using the HFMEA Hazard Matrix, which is shown in Table 3.

Table 1. HFMEA Severity Ratings. Use this table to assign a severity rating when determining the hazard score of a failure mode or failure mode cause.

	Patient Outcome	Visitor Outcome	Staff Outcome	Equipment or Facility
Catastrophic Event (4)	[a, b] Death, major permanent loss of function, suicide, rape, hemolytic transfusion reaction, surgery or procedure on the wrong patient or wrong body part	Death; **or** hospitalization of 3 or more visitors	A death **or** hospitalization of 3 or more staff	Damage equal to or more than $250,000. Any fire that grows larger than an incipient stage
Major Event (3)	[a] Permanent lessening of bodily function, disfigurement, surgical intervention, increased length of stay or level of care for 3 or more patients	Hospitalization of 1-2 visitors	Hospitalization of 1-2 staff, 3 or more staff with lost time or restricted duty injuries/illnesses	[c] Damage equal to or more than $100,000.
Moderate Event (2)	Increased length of stay **or** increased level of care for 1 or 2 patients	Evaluation **and** treatment for 1-2 visitors (less than hospitalization)	Medical expenses, lost time or restricted duty injuries or illness for 1-2 staff	Damage more than $10,000 but less than $100,000. A fire at incipient stage or smaller
Minor Event (1)	No injury, nor increased length of stay nor increased level of care	Visitor evaluated (no treatment or treatment refused)	First aid only (no lost time, restricted duty injuries or illnesses)	[c, d] Damage less than $10,000. Loss of utility system with no adverse outcome.

[a] Loss of function to include sensory, motor, physiologic, or intellectual function.

[b] Also includes infant abduction or infant discharge to the wrong family.

[c] Fire events are not applicable for Major and Minor categorizations. They will be categorized as Major or Moderate Events.

[d] E.g., power, natural gas, electricity, water, communications, transport, heat/air conditioning.

About severity ratings: When assigning a severity rating, the team should consider a reasonable "worst case" scenario. The severity of each failure mode can be stretched to extremely severe or extremely minimal consequences; therefore, keeping the assessment focused on reasonable "worst case" scenarios is useful in promoting consistent assessment by the team and focusing on practical and realistic issues.

Table 2. HFMEA Probability Ratings. Use this table to assign a probability rating when determining the hazard score of a failure mode or failure mode cause.

HFMEA Probability Ratings
Frequent Event (4) Likely to occur immediately or within a short period (may happen several times in one year)
Occasional Event (3) Probably will occur (may happen several times in 1 to 2 years)
Uncommon Event (2) Possible to occur (may happen sometime in 2 to 5 years)
Remote Event (1) Unlikely to occur (may happen sometime in 5 to 30 years

Table 3. HFMEA Hazard Matrix. Use this matrix to select a hazard score based on the assigned severity and probability of a failure mode or failure mode cause.

HFMEA Hazard Matrix					
		Severity of Effect			
		Minor (1)	Moderate (2)	Major (3)	Catastrophic (4)
Probability	Frequent (4)	4	8	12	16
	Occasional (3)	3	6	9	12
	Uncommon (2)	2	4	6	8
	Remote (1)	1	2	3	4

Using the Hazard Matrix. Using the hazard matrix is a straightforward process. The steps are described below.

1. Determine the severity rating using the definitions in Table 1.
2. Determine the probability ratings using the definitions in Table 2.
3. Look up the corresponding hazard score on the hazard matrix (where the chosen severity and probability categories intersect).

4.2.3 Use the HFMEA Decision Tree to determine if further action is warranted for each failure mode.

Assigning a hazard score for each failure mode is only a part of the analysis. The next step is to triage the item using the HFMEA Decision Tree. The decision tree is an algorithm that will prioritize each respective failure mode or failure mode cause and inform the HFMEA team if further action is warranted.

The decision tree is one of the key components distinguishing HFMEA from traditional Failure Mode and Effect Analysis (FMEA). The decision tree concept is borrowed from Hazard Analysis and Critical Control Point (HACCP), which is a risk assessment tool developed by the FDA and used in the food industry (Wallace 2014; DeRosier *et al.,* 2002). It provides supplementary logic and introduces three important decision points: *criticality, absence of effective control measures,* and *lack of detectability*. These decision points are treated as yes or no questions used to guide the team's decisions. When used correctly, the decision tree is a powerful tool to quickly identify which potential failures will be addressed. The following definitions are the basis of using the HFMEA Decision Tree:

Single Point Weakness (Criticality) – A single point weakness measures whether the entire system will fail if an individual part or step of the process fails.

If a step in the process is so critical that its failure would result in a system failure or adverse event, it is considered a single point weakness. For example, a momentary power interruption can be viewed as a single point weakness for many processes that are reliant on electricity. The absence of a specimen label poses a single point weakness for many processes involving laboratory specimens. There may be more than one single point weakness in a single process or there may be none.

Effective Control Measure – An effective control measure is an existing barrier that eliminates or substantially reduces the likelihood of a hazardous event from occurring.

Identifying whether an effective control measure is already in place requires knowledge of the process being analyzed. Effective control measures may come in many forms, including but not limited to checklists, system interlocks, redundancies, and mechanical or electronic forcing functions. For example, the pin indexing standard for medical gases is an effective control measure that physically prevents medical gases from being inadvertently interconnected. A bar code system that forces the reconciliation of the correct patient and specimen may be an effective control measure under the right circumstances. Care should be taken to consider the strength of existing control measures. Weaker actions such as documentation, training, or double checks do not constitute effective control measures.

Obvious Hazard (Detectability) – An obvious hazard is something obvious enough that it will be discovered before the failure occurs or before the effect of the failure results in a system failure or adverse event.

Obvious hazards may often incorporate visual information, warning indicators, or other mental cues that are clear and evident to the user. For example, temperature alarms in lab specimen storage areas may provide auditory alarms and send electronic warning messages if the temperature goes out of range. This type of indicator would be clear and evident to staff and allow them to take preventative measures. The sole presence of an alarm does not make something detectable. For processes involving alarms, teams should consider whether the alarms are distinguishable in their context of use and if they provide enough information to the appropriate personnel. Alarms are not the only source of detectability. Obvious hazards may include any scenario that is highly unlikely to go unnoticed by the users prior to failure or harm.

Using the HFMEA Decision Tree

The decision tree is shown in Figure 4. It is used to assess both failure modes and failure mode causes. For failure modes, the decision tree determines if the team must identify potential causes of the failure or not. For failure mode causes, the decision tree will determine if the team must determine actions and outcome measures for each respective cause.

Figure 4. HFMEA Decision Tree. Use the decision tree to help the team determine if further action is warranted for each failure mode and failure mode cause.
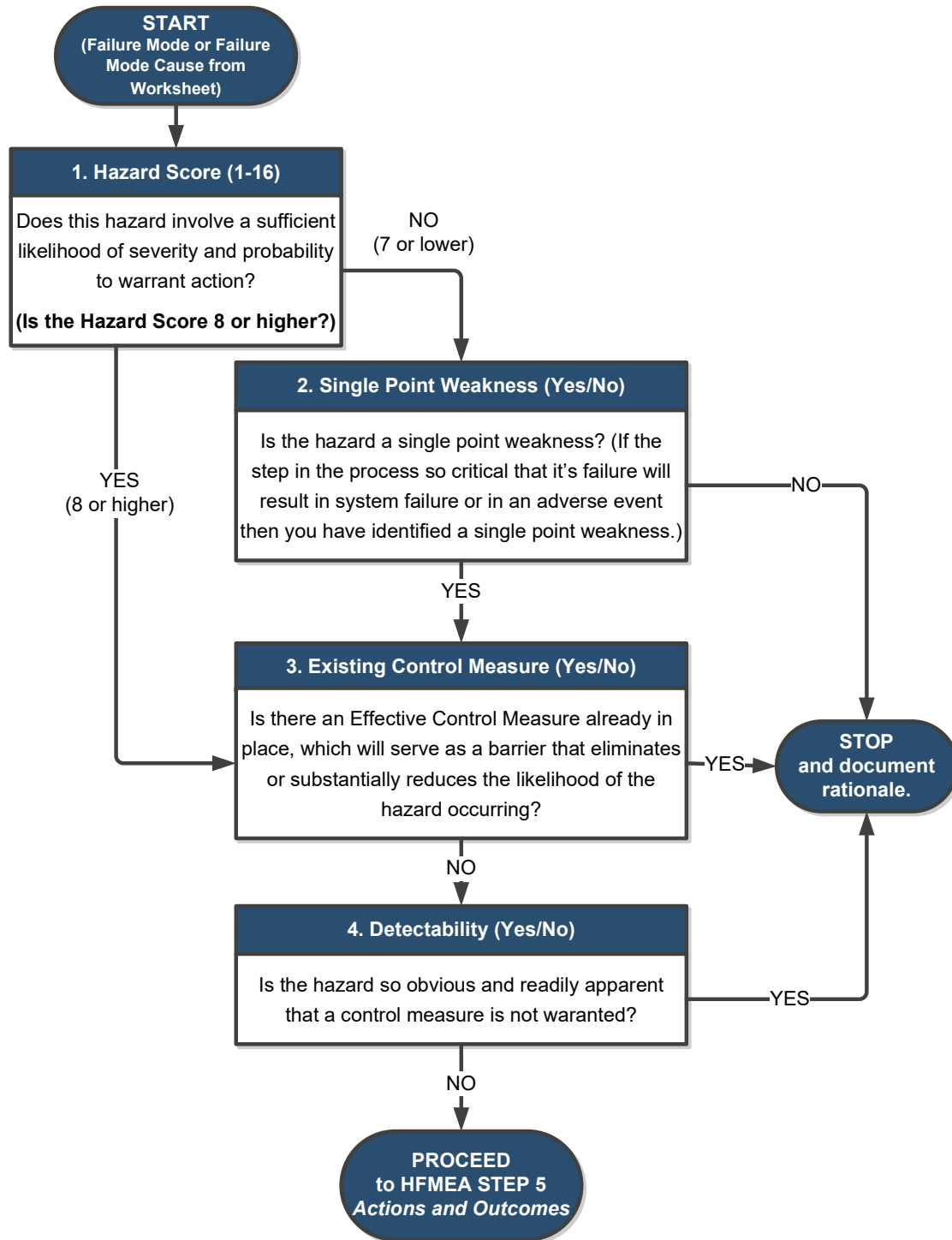
The decision tree should be used after assigning a hazard score to a failure mode or failure mode cause. The hazard score answers the first decision point of the decision tree.

To use the decision tree, the team will discuss the responses to a series of three to four questions. The first question determines if the hazard involves enough likelihood of severity and probability to warrant action. Was the hazard score 8 or higher on the hazard matrix? The decision tree will then indicate which questions should be answered and in what order based on a YES/NO response at each decision point. The series of questions will direct the team to one of two possible end points and will inform the team if they will (1) PROCEED and develop actions and outcome measures for a hazard, or if they may (2) STOP, document their rationale, and focus their attention elsewhere. Having a copy of the decision tree diagram available during the working sessions will make the process clearer for the team.

Of note, the decision tree directs the team to a different route for items with hazard scores above or below a value of 8. Even if the hazard score is 7 or lower, the team will still be asked to assess for single point weakness (criticality). If a hazard score is 8 or higher, the hazard is deemed dangerous enough that it should be further analyzed even if it is not a single point weakness. In the latter case, the team will skip the single point weakness (criticality) decision point and move to reviewing existing control measures as indicated in the decision tree diagram.

The next feature observed in the decision tree is that there are two automatic "STOP" questions. If a failure has an effective existing control measure in place or is deemed detectible, the team should "STOP" and focus their attention on other failures. Whenever the team chooses to "STOP," they should document that decision in the HFMEA worksheet and briefly describe the effective control measure in the justification.

By the end of the decision tree, the team will have systematically determined if the failure should be addressed. After each failure mode and failure mode cause has undergone a decision tree analysis, the team will have a curated list of failures and potential causes for which solutions will be created in *HFMEA Step 5 – Actions and Outcome Measures*.

Actions and Outcome Measures

Once the team has identified one or more potential failure mode causes that warrant action, the next step is to identify the type of action to take, identify specific actions to implement, assign the actions to individuals, and determine the outcome measures to assess the effectiveness of the actions.

5.1 Action Types

There are three action types in the HFMEA process for the team to choose. The team will decide whether to eliminate, control, or accept the failure mode causes identified. The action types are described below.

- **Eliminate -** to prevent all future occurrences by removing the failure point.
- **Control -** to minimize all future occurrences by implementing mitigating factors.
- **Accept -** to acknowledge and accept known risks.

The most effective option is to eliminate the failure mode cause or failure point, which may require one or more strong actions. If the failure mode cause cannot be eliminated, the best option may be to control the failure mode cause by using one or more actions. Sometimes the team may decide to accept a failure mode cause if there are no remedies available.

Teams will select an action type for each failure mode potential cause that scores to PROCEED and document it on the worksheet. If the team chooses to accept the failure mode cause, a brief rationale is required on the worksheet.

Teams will develop specific actions and outcome measures to minimize or prevent the identified causes from happening. The team will ensure the actions are directly linked to the failure mode causes and the outcome measures are linked to the actions. Ordinarily, it is best not to rely solely on actions that place an extra burden on a person's memory (*e.g.*, training or written policy).

Ideally, the team should identify actions that are physical rather than procedural (*e.g.*, keypad lock versus a "do not enter" sign) and permanent rather than temporary. It is useful for teams to ask the process owners and managers responsible for implementing the actions how they would fix the problem or identify strategies that have or have not worked in the past.

5.2 Pilot Testing

Actions have a better chance of success if they are pilot-tested or process changes are simulated before being implemented facility-wide. Consider starting the pilot on the unit with the most willing volunteers who may be able to identify the gaps in the process. Ask staff and patients what worked well and what could be done to improve the new process. Build time for pilot testing into the overall action plan and the outcome measures time frame.

5.3 Action Strength

HFMEA action strengths are different than the action types (eliminate, control, accept). Understanding action strength is important to ensure the desired outcome. The team should strive to develop at least one strong or intermediate action for each failure mode cause. However, weak actions are sometimes necessary to complete the steps in the process. Weak actions can be used as a complement to intermediate and strong actions. For example, training and policy changes may accompany a change in process or equipment.

Actions are classified into three levels of strength, based on their presumed level of effectiveness (Table 4).

- **Stronger Actions** – Stronger actions aim to permanently remove an identified vulnerability by reducing reliance on human memory, and emphasizing permanent, physical or architectural changes, interlocks, simplification, or standardization.
- **Intermediate Actions –** Intermediate actions are intended to increase detectability, prevent, or minimize recurrence of events (*e.g.* checklists, cognitive aids, improved communication, system redundancies, or software configuration).
- **Weaker Actions** – Weaker actions are highly dependent on human memory. These actions may be used to complement stronger and intermediate actions (*e.g.* analysis, policy and procedure, or training).

Table 4. Actions Listed by Strength Category

Hierarchy of Actions	
Stronger Actions	• Architectural/physical plant changes • New device with usability testing before purchasing • Engineering control or interlock (forcing functions) • Simplify the process and remove unnecessary steps • Standardize on equipment or process or care maps • Tangible involvement and actions by leadership in support of patient safety • High Reliability training (perpetual, including simulation, competency evaluation, staff off patient care, leadership sanctioned)
Intermediate Actions	• Increase in staffing/decrease in workload • Software enhancement/modifications • Eliminate/reduce distractions (sterile medical environment) • Checklist/cognitive aid • Eliminate look sound alike • Read back • Enhanced documentation/communication • Redundancy • Training using simulation
Weaker Actions	• Double checks • Warnings and labels • New procedure/memorandum/policy • Training • Additional study/analysis

5.4 Outcome Measures

Once an action has been identified for implementation, it is important to measure whether it was effective and if any unintended consequences occurred. The best outcome measures cover a realistic timeframe and take urgency into account, sample a reasonable number of situations that are similar or related to the event, and are specific and quantifiable (numerators, denominators, thresholds, rates, etc.). Outcome measures should measure if the action was effective.

Because some events occur less frequently than others, event frequency may dictate the scope of the outcome measure. For example, it is difficult to demonstrate if a certain action will reduce the actual number of incorrect surgeries or inpatient suicide attempts if such events rarely occur. However, it is easy to show that actions like using the five-step *Ensuring Correct Surgery* process or doing rigorous contraband searches on locked units will help ensure safe patient

care through elimination of specific vulnerabilities such as misidentification revealed during the pre-surgical period or potential weapons discovered and removed during the admission process.

SMEs may be able to help identify outcome measures. They can be asked questions like, "How would you know if an action made a difference or not?" and "How would you measure it?" SMEs have ideas about data already being collected or how data may be collected more efficiently. Ideas may be different than customary auditing procedures or medical record review processes. SMEs also bring experience-based ideas about what can be measured through observation or follow-up interviews. Additionally, they may be able to direct what needs to be required for a document review (and where to find it).

Always consider the processes and measures which are already in place for outcome measurement. This will help to maximize existing opportunities instead of creating new or duplicate work. For example, if a leadership team already conduct walking rounds consider adding an additional observation related to the outcome measure developed by the team. If medical records of interest are already being audited or reviewed, ask if additional questions related to the outcome measure can be added. Consider observing the process over a defined period. For example, random observation of nurses administering medications using Bar Code Medication Administration (BCMA) over 6 months can be implemented. Use the observation as a time to discover gaps or barriers in the process and to praise staff for correctly implementing a new procedure.

Outcome measures provide confirmation that an action accomplished what it was intended to accomplish. A well-designed outcome measure will highlight the overall effectiveness of the action.

Consider whether the outcome measures identified meet the criteria listed.

- Outcome measures show the *effectiveness* of the action not *completion* of the action. *For example, if a new fall assessment tool is implemented, the outcome should measure falls or fall rates and not the percentage of staff trained to use the assessment tool.*
- The outcome measure should be quantifiable.

- The sampling strategy should be specific and include a time frame for the measurement. *For example, a random sample of 15 charts per quarter will be reviewed for four consecutive quarters.*
- The performance threshold identified should be reasonable and attainable.

Glossary

Action Type – Is the course of action the HFMEA team recommends resolving a failure mode or a potential cause. There are three action types; eliminate, control, and accept. Eliminate means to remove the failure mode or failure mode cause. Control means to decrease the likelihood that a failure will occur, or to put measures in place to reduce the severity if the failure does occur. Accept means that there may be no reasonable action available, or the benefits out weight the risks of a specific situation.

Adverse Event - An untoward incident, therapeutic misadventure, iatrogenic injury, or other unintended harm directly associated with care or services provided within the jurisdiction of the VHA. Examples of adverse events include, but are not limited to, patient falls, administration of the wrong medication, failure to make a timely diagnosis, procedural errors or complications, and missing patient events.

Close Call – An event or situation that could have resulted in an adverse event but did not, either by chance or through intervention. Such events have also been referred to as near miss events or potential events. An example of a close call would be a surgical or other procedure almost performed on the wrong patient due to lapses in verification of patient identification but caught prior to the procedure.

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

Event Diagram – A chronological diagram of the series of events leading up to an adverse incident or close call. Event diagrams are used in RCA. They are not used in HFMEA.

Failure Mode -Different ways that a process or sub-process can fail to provide the anticipated result (i.e., what could go wrong)

Failure Mode Cause – Different reasons as to why a process or sub-process would fail to provide the anticipated result (i.e., why it would go wrong).

Hazard Analysis - A hazard analysis is the process of collecting and evaluating information on hazards associated with the selected process. The purpose of 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.

Hazard Score- A score used to help prioritize failure modes and failure mode causes. The hazard score is determined by assigning severity and probability ratings to a hazard and looking up the result on the HFMEA Hazard Matrix. The hazard score replaces the risk priority number (RPN) used in traditional FMEA.

Healthcare Failure Mode and Effect Analysis (HFMEA) - (1) A prospective assessment that identifies and improves steps in a health care 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 Decision Tree - An algorithm used to prioritize each respective failure mode or failure mode cause and inform the HFMEA team if further action is warranted.

HFMEA Hazard Scoring Matrix – A matrix used to assign a Hazard Score to a failure mode or failure mode cause. The HFMEA Hazard Scoring Matrix incorporates the severity and probability ratings of the potential hazard. The higher the score, the greater the potential risk.

HFMEA Worksheet - The HFMEA Worksheet is used for Steps 4 and 5 to document the analysis, actions, and outcome measures for each failure mode and failure mode cause. The worksheet is designed to document one failure mode and its associated causes.

Management Concurrence- An indicator that Medical Center leadership (most often the Medical Center Director) has agreed or concurred with the HFMEA team's findings and the proposed action plan.

Obvious Hazard (Detectability) – An obvious hazard is something obvious enough that it will be discovered before the failure occurs or before the effect of the failure results in a system failure or adverse event.

Outcome Measures: Evaluation of the results of an activity, process, or program. Outcome measure thresholds are calculated by dividing (numerator) by the number of times the event or error could have occurred (denominator).

Probability Rating- A pre-defined rating scale used to estimate the frequency that hazardous or potentially hazardous events are likely to occur. Available probability ratings are Frequent, Occasional, Uncommon, and Remote.

Process Flow Diagram – A graphic picture that describes a healthcare process as a series of process steps and sub-process steps arranged in sequential order. Each process step and sub-process step in the process flow diagram is numbered and areas within the process that need attention are identified.

Process Step –The main, high level, tasks that are routinely carried out in order to complete the process being evaluated by the HFMEA team. Process steps are further broken down into their individual detailed components (sub-process steps).

Responsible Person- The specific individual who has been identified by the HFMEA team, and approved by leadership, to complete a specific HFMEA action or monitor an outcome measure.

Root Cause Analysis (RCA) - RCA is a specific type of focused review, is interdisciplinary in nature, and is used to learn from and respond to safety-related issues. The analysis focuses primarily on systems and processes rather than individual performance. The analysis identifies changes and expectations that could be made in systems and processes, through either redesign or development of new processes, and systems that would improve performance and reduce the risk of the adverse event or close call recurrence.

Severity Rating- A pre-defined rating scale used to characterize consequences the of a potential hazard if it were to occur. The rating scale incorporates the actual or anticipated impact

to a patient, visitor, staff, equipment, and the facility. Available Severity Ratings include Catastrophic, Major, Minor, Moderate, and Minor.

Single Point Weakness – An indicator of whether the entire system will fail if an individual part of the process fails. A single point of weakness is a part of a system that, if it fails, will stop the entire system from working.

Sub-Process Step – Detailed specific tasks that are routinely carried out in order to complete the higher-level process steps. A process step (high level) should typically consist of two or more sub-process steps (detailed) that describe the exact sequence of tasks to be carried out.

Appendix A. Cover Sheet Showing HFMEA 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, product, system, or equipment to be studied). Narrowing the scope or focus is important because of human factors that could contribute to the process or system vulnerabilities. Examples include communication errors, inadequate training, staffing concerns, shift and shift change issues, and other barriers such as unclear rules, policies, and/or procedures.

This HFMEA Focus

_____

_____

_____

_____

Step 2. Assemble the Team

HFMEA™ Name / Number: HFMEA SUBJECT 2019 (Use the current year as the number)

Date Started   _____

Date
Completed: _____

Note: NCPS requires facilities to complete one high risk HFMEA every 12 months, which includes implementation of actions and outcome measures.

Team Members - The multidisciplinary team should include members from each service involved in the process and at least one or more that are unfamiliar with the process. Members who are not familiar with the process will be able to ask the "why" questions that will allow the team to detail the process steps. List the individuals below, along with their name, title, phone number, and email.

1. _____
2. _____
3. _____
4. _____
5. _____
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? _____

Appendix B. Completed Cover Sheet Showing HFMEA Process Steps 1 and 2

Note: *Names and contact information in this example are fictitious.*

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 Focus

The purpose or focus of this HFMEA is to evaluate whether this VHA facility has the capability of handling emergency blood transfusions outside of normal business hours, specifically on weekends.

Step 2. Assemble the Team

HFMEA Name / Number: Emergency Medical Response / 2019

Date Started: March 7, 2019
Date Completed: Jun 28, 2019

Team Members - The team should include members who are involved in the process and at least one or more who are unfamiliar with the process.

1. Peter Flowers, MSN, BSN, RN Clinical Coordinator Inpatient Floors, peter.flowers@va.gov x27337
2. Janet Bean, MHA Administrative Officer of the Day, janet.bean@va.gov x25332
3. Henry Jello, MSN, RN, Emergency Medicine Service, henry.jello@va.gov x29266
4. Tanya, Map, MSN, RN, Outpatient Clinics, tanya.map@va.gov x38225
5. Timothy Kandal, Chief Technologist Radiology, timothy.kagal@va.gov x46335
6. Peter Kleen, CRNA, Chief Nurse Anesthetist, peter.kleen@va.gov x23755
7. Betty Jenner, MD, Physician, Pathology & Lab Medicine, betty.jenner@va.gov x21566
8. Susan House, Pharm D, Pharmacy Supervisor, susan.house@va.gov x25117

Team Leader: Jeff Lamp, MD, Physician, Emergency Medicine Service pager (658)540-7100 x3325

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?

Wayne Springs, Secretary Medicine Service, wayne.springs@va.gov x23456

Appendix C. Blood Specimen Collection Process Flow Diagram Example

| 1. MD enters lab orders | → | 2. Nurse checks EHR order section every 2 hours or sooner for new orders | → | 3. Labels are automatically printed every 24 hours. New orders printed once ordered. | → | 4. Nurse/clerk collects all lab orders that are due | → | 5. Nurse verifies the patient's identity | Continued on next page → |

| 1A. MD identifies the patient | 2A. Nurse confirms the patient identify | 3A. Labels restocked by ward staff | 4A. Nurse retrieves labels from printer for specimens | 5A. Nurse verifies pt. wristband against label |

| 1B. MD assesses the patient | 2B. Nurse opens the correct record for the patient | 3B. New labels are loaded into label machine | 4B. As new orders arrive, RN checks printer for labels | 5B. Nurse IDs every patient prior to blood collection |

| 1C. MD identifies appropriate lab tests | | 3C. Printer ink cartridges are stocked on unit |

| 1D. MD enters lab/specimen order in CPRS | | 3D. Printer ink cartridges are loaded into label printer |

| | | 3E. Lab collection labels are sorted in order of draw |

Continued →

6. Nurse collects blood specimens → **7.** Nurse sends blood specimens to Pathology/Lab services

6A. Nurse identifies vein to puncture

6B. Nurse washes hands

6C. Nurse dons gloves

6D. Nurse gathers supplies and labels

6E. Nurse performs venipuncture

6F. Nurse affixes labels to specimen in front of patient

6G. Patient confirms correct info on label

6H. Specimens placed in transport containers

7A. Blood is transported immediately to avoid hemolysis

Appendix D. Subprocess for blood specimen collection

6. Nurse collects blood specimens

7. Nurse sends blood specimens to Pathology/Lab services

6A. Nurse identifies vein to puncture

7A. Blood is transported immediately to avoid hemolysis

6B. Nurse washes hands

6C. Nurse dons gloves

6D. Nurse gathers supplies and labels

6E. Nurse performs venipuncture

6F. Nurse affixes labels to specimen in front of patient

6G. Patient confirms correct info on label

6H. Specimens placed in transport containers

Appendix E. Example of Failure Modes and Potential Causes. *Note: Failure modes are shown on top (dark shaded boxes) and causes are listed below (white boxes).*

2E(1) Incorrect/incomplete or no label on specimen container	2E(2) Incorrect data entered
2E(1)a Multiple labels printed and the specimen has another patients label	**2E(2)a** Information required to be written multiple times
2E(1)b No clear process and designation of staff responsibility	**2E(2)b** Handwritten information illegible on labels
2(E)1c Labels too small to write necessary information	**2E(2)c** Distractions in work area

Appendix F. Failure Mode Process Diagram for Blood Collection Example

6.
Nurse collects blood specimens

6A. Nurse identifies vein to puncture

6B. Nurse washes hands

6C. Nurse dons gloves

6D. Nurse gathers supplies and labels

6E. Nurse performs venipuncture

6F. Nurse affixes labels to specimen in front of patient

6A(1). Nurse unable to locate antecubital vein

6B(1). No sink available

6B(2). No antimicrobial hand wash available

6C(1). Gloves are wrong size

6C(2). No gloves available

6D(1). Missing supplies

6D(2). Dropped supply with no replacement

6E(1). Unable to detect vein

6E(2). Patient uncooperative

6F(1). Label missing

6F(2). Label does not adhere to tube

6F(3). Label tears

6G. Patient confirms correct info on label

6H. Specimens placed in transport containers

6G(1). Label ink smudged/illegible

6G(2). Not enough ink on label

6G(3). Two patients with similar identifiers

6G(4). Not labeled in presence of patient

6G(5). Patient incoherent with no wristband

6H(1). Transport system down

6H(2). There is no runner

HFMEA Test Questions

1. How is HFMEA different from RCA?
   a. RCA is retroactive and HFMEA is proactive
   b. HFMEA does not consider actual events and close calls
   c. RCA is based in engineering methods while HFMEA is not
   d. RCA attempts to define event severity and probability, while HFMEA does not
   e. HFMEA relies on interdisciplinary teams while RCA does not

2. What are the 5 key steps, in order, of the HFMEA process?

   Step 1_____

   Step 2_____

   Step 3_____

   Step 4_____

   Step 5_____

3. The Joint Commission requires all accredited healthcare facilities conduct an ongoing, proactive risk assessment, at a minimum, every 18 months, to identify and assess patient safety hazards. The most critical identified risks or failure modes require which of the following actions?
   a. Identification of potential causes
   b. Process redesign
   c. Testing of changes
   d. All of the above
   e. None of the above

4. Which section of the RCA process was incorporated into the HFMEA process?
   a. Retrospective analysis of individual events
   b. Triage Questions
   c. Hazard Scoring Matrix
   d. Decision Tree Matrix
   e. Actions and Outcomes Hazard Matrix

5. The scope of the HFMEA project should be which of the following?
   a. Broad and contain undefined goals
   b. Clearly defined
   c. Narrow
   d. About a system, a design, a process, a service, or software
   e. b, c and d.

6. What type of HFMEA is focused on medication administration?
   a. Software
   b. Design
   c. Service
   c. System
   d. Process
   e. All of the above

7. What are some methods used to identify a HFMEA topic?
   a. Solicit ideas from leaders/staff about hazards which are likely to cause injury or illness if they are not effectively controlled.
   b. Evaluate risks with new or existing products, processes and systems that have a potential to fail preferably prior to implementation.
   c. Review close calls, SAC 1, and SAC 2 event trends.
   d. a and c only
   e. b and c only
   f. a, b and c

8. Once the PSM has identified a potential project scope, what should they do?
   a. Gather facts, data, and material about the scope.
   b. Rank projects with those having the least impact to reduce patient harm.
   c. Review close calls, such as SAC 4 and 5 event trends.
   d. Consider events which occurred at other facilities.
   e. a and d

9. After a topic has been defined for the HFMEA project and the scope has been narrowed, the PSM should identify which disciplines are needed and propose someone to be the
   a. Service Chief
   b. Program Manager
   c. MD
   d. RN
   e. Team leader

10. Who typically serves as the HFMEA advisor?
    a. Team Leader
    b. Subject Matter Expert
    c. Patient Safety Manager
    d. Recorder

11. The HFMEA advisor recommends a team leader and ensures that the team leader has a clear understanding of how to conduct an HFMEA and of the processes being reviewed.

    a. True
    b. False

12. The team leader's responsibilities include which of the following? (*Select all that apply*)

   a. Arranging meeting times and location
   b. Setting ground rules for meetings
   c. Keeping the team on task and within the timeline
   d. Using tools and cognitive aides developed by NCPS
   e. Completion of the HFMEA in 45 days.

13. Which of the following statements is true about assembling a multidisciplinary HFMEA team? (*Select all that apply*)

   a. There should be at least one representative from each employee group involved in the process.
   b. Consider physician involvement when needed.
   c. The team will always include the facility director.
   d. The number of people and disciplines needed on a team is dependent on the scope of the process being reviewed.

14. What must be done before the team can graphically describe the process? (*Select all that apply*)
   a. Make sure the scope of the HFMEA is defined and manageable.
   b. Ensure the team is multidisciplinary and is present.
   c. Only the subject matter experts, who understand the process, need to be present.
   d. Make sure all team members workday shift, so they can attend the meetings.

15. As the team begins to graphically describe the process, a member wants to add the process steps in random order. Choose the best response:

   a. If all of the steps are identified, random order is appropriate.
   b. Random order is fine because the steps will be placed in order later.
   c. It is okay because the team is not responsible for making sure the sequence of the steps is correct.
   d. It is best to identify the steps in sequential order as much as possible to fully understand the process.

16. Identifying and listing the sub-process steps related to the main process are optional for a HFMEA.

   a. True
   b. False

17. A team member states that the HFMEA process flow diagram is based solely on a description of what happened on a specific day. Which response to this statement is the most appropriate?

   a. This is a correct statement and it is appropriate to use an event diagram.
   b. This is not a correct statement because the process needs to show how the process is routinely done.
   c. Neither statement is correct.

18. Sub-process steps should be numbered in sequential order under the main process step.

    a. True
    b. False

19. True or False: A process flow diagram is necessary before the team can conduct the HFMEA Hazard Analysis.
    a. True
    b. False

20. What is the difference between a failure mode and a failure mode cause?
    a. A failure mode represents why a process might fail; a failure mode cause represents what can potentially go wrong.
    b. A failure mode represents what can potentially go wrong, a failure mode cause represents why it could potentially go wrong.
    c. A failure mode is part of the process flow diagram, a failure mode cause is part of the actions and outcome measures.
    d. Failure modes and failure mode causes are really the same thing.

21. What are the three concepts of the HFMEA Decision Tree?
    a. Multiple Point Weakness, System Interlocks, Frequency
    b. Success Paths, Process Variations, and Redundancies
    c. Single Point Weakness, Effective Control Measure, and Detectability
    d. Process Strengths, Fault Tolerance, and Visibility

22. Hazard Scoring and HFMEA Decision Tree Analysis are conducted on:
    a. Failure modes and failure mode causes
    b. Process steps and process sub-steps
    c. Process sub-steps and failure mode causes
    d. None of the above

23. True or False: If a failure mode scores to STOP, the team must list the failure mode causes for that failure mode.
    a. True
    b. False

24. True or False: A Process sub-step can have more than one potential failure mode?
    a. True
    b. False

25. True or False: A failure mode can have more than one potential cause?
    a. True
    b. False

26. True or False: The same failure mode cannot apply to more than one process sub-step.
    a. True
    b. False

27. What is the purpose of HFMEA Hazard Analysis? (select all that apply)
   a. To identify, collect information, and evaluate the potential hazards associated with the chosen process
   b. To develop a list of potential hazards that are of such significance that they are reasonably likely to cause an adverse event or process failure if not effectively controlled
   c. To prioritize which potential hazards that warrant dedication of facility time and resources to address.
   d. All of the above

28. A single point weakness is:
   a. An existing barrier that eliminates or substantially reduces the likelihood of a hazardous event from occurring.
   b. A step in the process so critical that its failure would result in system failure or in an adverse event.
   c. Something obvious enough that it will be discovered before the failure occurs or before the effect of the failure results in a system failure or adverse event.
   d. None of the above

29. Which of the following represent a single point weakness?
   e. An interruption of a medical system power supply
   f. Use of two forms of identification when identifying patients before specimen collection
   g. A breakdown in the cardiac telemetry arrhythmia alarm notification pathway
   h. A and C

30. What is the next step after the analysis portion of the HFMEA has been completed and the vulnerabilities have been identified?
   a. Narrow the scope
   b. Define the topic
   c. Collect data
   d. Develop actions and outcome measures.

31. Pilot testing of proposed actions and outcome measures is important for all the following *except:*
   a. successful implementation.
   b. Facility member buy-in
   c. Saving money
   d. Avoiding strong actions and quantifiable outcome measures.

32. Which actions below are considered stronger actions?
   a. Architectural/physical plant changes
   b. Training and education
   c. New devices with usability testing prior to purchase.
   d. Creating a very specific policy
   e. a. and c.

33. HFMEA Teams should consider the following actions except?
   a. Avoiding architectural/physical plant changes
   b. Human factors engineering consultation (e.g., to analyze, troubleshoot and streamline   work areas and processes, to evaluate equipment use and conduct usability testing)
   c. Forcing functions that guide processes or equipment so that it is only possible to do the correct action the first time.
   d. Tangible involvement and action by leaders in support of patient safety (e.g., greeting and closing out with RCA/HFMEA teams; patient safety related individual or team rewards; constructive feedback; town meetings; newsletters)

34. HFMEA Actions should include all of the following except?
   a. Have reasonable completion dates, the majority being completed within one year's time
   b. Contain concrete and clear directions.
   c. Vetted with the process owners
   d. Should be written in vague terms so that the responsible person can shape the HFMEA Action plan and outcome measures however they want.

HFMEA Test Question Answer Key

1. (**a**) HFMEA is *prospective*, which considers possible risks before they occur. The RCA process is retrospective and looks at events after they have occurred.

2. **Step 1** Define the HFMEA topic, **Step 2** Assemble the team, **Step 3** Visually describe the process, **Step 4** Conduct a hazard analysis, **Step 5** Develop actions and outcome measure.

3. (**d**) Failure modes require teams to identify the causes of the potential failures, redesign the process or system, and test the changes made.

4. (**c**) The Hazard Scoring Matrix from the RCA process was incorporated in the HFMEA process.

5. (**e**) The scope of HFMEA project needs to be narrow with defined goals.

6. (**e**) Due to the broad scope of the medication administration process, the HFMEA may focus on software, design, service, system, and process.

7. (**f**) The responses a, b, and c are all appropriate methods that can be used to identify a topic.

8. (**e**) Gathering facts, data, and material about the scope and considering events that occurred at other facilities are important steps.

9. (**e**) The PSM should propose a potential team leader.

10. (**c**) As the expert in the HFMEA process, the Patient Safety Manager typically serves as the advisor to the team.

11. (**a**) True – The Patient Safety Manager recommends the Team Leader and ensures the Team Leader understands the HFMEA process.

12. (**a, b, c, d**) The HFMEA does not need to be completed in 45 days. The 45-day requirement is for RCAs.

13. (**a, b, d**) The facility director is not required to be part of the HFMEA team. The team composition may be similar to the RCA team except those directly involved in the process should be included.

14. (**a, b**) All team members need to be present and should be from varied shifts, if applicable.

15. (**d**) Although answers a and b are not completely incorrect, the _best_ answer is d. The process needs to reflect the correct order of steps. Response c is not correct and may confuse the team.

16. (**b**) The subprocesses add detail, which can lead to the discovery of failure points.

17. **(b)** The HFMEA process should focus on the understanding of what is routinely done with the specific unique procedure / process being analyzed. An Event Diagram focuses on what happened on a specific day.

18. (**True**) The sequential order of the subprocesses helps the team understand and assign a hazard score.

19. (**True**) A process flow diagram provides the sub-process steps for which failure modes and failure mode causes will be uncovered and assessed during the hazard analysis. Hazard analysis will seek to uncover the potential hazards within each process sub-step.

20. **(b)** A failure mode represents <u>what</u> can potentially go wrong with the chosen process, or the different ways in which a process sub-step could fail to succeed. A failure mode cause represents a potential reason <u>why </u>a failure mode could occur.

21**. (c)** The three concepts of the HFMEA Decision Tree are Single Point Weakness, Effective Control Measure, and Detectability. These three concepts help the HFMEA team determine what to do with each potential hazard.

22. **(a)** Hazard Scoring and HFMEA Decision Tree Analysis are conducted on failure modes and failure mode causes as part of the hazard analysis to determine if the HFMEA team should proceed with each hazard or stop and move on to the next hazard.

23. (**False)** If the failure mode scores to STOP, the HFMEA <u>does not</u> need to list the potential causes for the failure mode. The HFMEA team should document their rationale for stopping on the HFMEA worksheet and proceed to the next hazard. This is intended to reduce workload and help the HFMEA teams focus on the most important hazards.

24. **(True)** There is no limit on the number of potential failure modes that can be associated with a process sub step.

25. **(True)** There is no limit for the number of potential causes that can be associated with a failure mode.

26. **(False)** HFMEA teams may encounter situations where the same failure mode is uncovered in many of their sub-process steps. This is expected. HFMEA teams should keep in mind that some of their previous analysis can be used for each instance, but the potential causes may be different for different process sub-steps.

27. **(d)** All the above are important reasons that hazard analysis is part of HFMEA.

28. **(b)** A single point weakness will stop the process from being completed as intended. In healthcare, this may result in an adverse event or failure to achieve the desired work product.

29. **(d)** Both a and c are correct. An interruption in power supply is likely to cause the entire process to fail. A breakdown in the cardiac telemetry arrhythmia alarm communication pathway will cause the entire process to fail, preventing the appropriate caregiver from acting on a potentially fatal cardiac arrhythmia. B is not a single point weakness. Using two forms of

identification is an example of redundancy. However, failure to correctly identify the patient may be viewed as a single point weakness in some contexts.

30. **(d)** The team develops actions and outcome measures.

31. **(d)** Strong actions and quantifiable outcome measures are important for change to occur.

32. **(f)** Training and policy implementation are considered weaker actions.

33. **(a)** Although architectural/physical plant changes will incur costs, they are stronger actions and should not be avoided.

34. **(d)** HFMEA Action Plans should be clearly written to avoid deviations or changes from the actions and outcome measures.

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