The authors describe the prospective risk assessment method currently being rolled out throughout the Veterans Affairs health care system.

TUTORIAL

Using Health Care Failure Mode and Effect Analysis™:
The VA National Center for Patient Safety's Prospective Risk Analysis System

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The importance of patient safety—or more specifically, protecting patients from harm incurred in medical care—is a topic of much discussion. Most reporting systems concentrate on analyzing adverse events; this means that injury has already occurred before any learning takes place. More progressive systems also concentrate on analyzing close calls, which affords the opportunity to learn from an event that did not result in a tragic outcome. Systems also exist that permit proactive evaluation of vulnerabilities before close calls occur. The engineering com-munity has used the Failure Mode and Effect Analysis (FMEA) technique to accomplish this function. FMEA focuses on processes that manufacture products and involves the calculation of a risk priority number through a three-variable equation where each variable is scored from one to ten. Medical device manufactur-ers use this process when evaluating their equipment.

Patient safety is making the transition from infancy and is entering a tumultuous adolescence, with all the resultant challenges.[1] Organizations are hiring patient safety specialists, funding is increasing

Tutorial-at-a-Glance

Background: Most patient safety reporting systems concentrate on analyzing adverse events; injury has already occurred before any learning takes place. More progressive systems also concentrate on analyzing close calls, which affords the opportunity to learn from an event that did not result in a tragic outcome. Systems also exist that permit proactive evaluation of vulnerabilities before close calls occur. The engineering community has used the Failure Mode and Effect Analysis (FMEA) technique to accomplish this function, and the Department of Veterans Affairs (VA) National Center for Patient Safety has developed a hybrid prospective risk analysis system, Health Care Failure Mode and Effect Analysis (HFMEA™).

Key aspects of the HFMEA™ process: HFMEA™ is a 5-step process that uses an interdisciplinary team to proactively evaluate a health care process. The team uses process flow diagramming, a Hazard Scoring Matrix™, and the HFMEA Decision Tree™ to identify and assess potential vulnerabilities. The HFMEA™ Worksheet is used to record the team's assessment, proposed actions, and outcome measures. HFMEA™ includes testing to ensure that the system functions effectively and new vulnerabilities have not been introduced elsewhere in the system.

The VA rollout: HFMEA™ was successfully introduced to the VA system through a series of video-conferences in August 2001. These broadcasts included a prepared training video and interactive question-and-answer sessions. To ensure a successful first year of the program, all VA facilities will focus on the same topic, with support materials from the NCPS office; the topic is a review of the contingency system for distribution of medications in the event of failure of the bar code medication administration process.

for patient safety research, and multiple conferences are being held that examine the topic. One sign of maturation is the inclusion of Joint Commission on Accreditation of Healthcare Organizations (JCAHO; Oakbrook Terrace, Ill) standards for patient safety for health care organizations seeking JCAHO accreditation. The new LD.5.2 JCAHO patient safety standard reads as follows: "Leaders ensure that an ongoing, proactive program for identifying risks to patient safety and reducing medical/health care errors is defined and implemented."[2(p LD-40),3] The intent statement clarifies that for each failure mode, a possible effect and criticality must be identified. For the most critical failure modes, facilities should identify the causes, redesign the process, and test the changes to confirm that the desired outcome is achieved.

This article describes the development of Health Care Failure Mode and Effect Analysis (HFMEA)™, its use in proactively evaluating health care processes, and its rollout within the Department of Veterans Affairs (VA) system. HFMEA™, developed by the VA National Center for Patient Safety (NCPS) with assistance from the Tenet HealthSystem (Dallas), is a hybrid prospective analysis model that combines concepts found in FMEA and Hazard Analysis and Critical Control Point (HACCP) with tools and definitions from the VA's root cause analysis (RCA)

process. HFMEA™ uses an interdisciplinary team, process and subprocess flow diagramming, failure mode and failure mode cause identification, a hazard scoring matrix, and a decision tree algorithm to identify system vulnerabilities. As part of the process, actions and outcome measures are developed, and management must concur.

Genesis of HFMEA™

NCPS developed and has implemented a patient safety program that looks at actual events and close calls to increase patient safety. The RCA process convenes multidisciplinary teams to investigate each event to determine root causes or contributing factors and then identify corrective actions and outcome measures.[4] From the inception of the VA Patient Safety Program in 1998, NCPS has recognized the need for a prospective analysis of health care processes to accomplish even more. To this end, in summer 2001, the VA examined existing models from other industries and determined that they were of limited utility for health care applications.

NCPS reviewed the FMEA system that has been successfully used in industry for many decades. When evaluating health care products or equipment, conducting a traditional FMEA is the recommended proactive risk assessment method. However, if a health

care process is being assessed, our experience is that HFMEA™ is conceptually easier to apply because of its definitions and algorithms. For example, when staff attempted to use the FMEA system to evaluate health care processes, the generic definitions used for Severity, Occurrence, and Detectability needed to be modified. In addition, when the standard definition for severity was applied to health care processes, the score was consistently identified as a 10 (failure could cause death or injury) because patient injury is likely to result when a health care process fails.

In searching for a proactive analysis tool that was developed specifically to evaluate processes, NCPS staff reviewed the HACCP system developed by the National Advisory Committee on Microbiological Criteria for Foods for the U.S. Department of Agriculture.[5] HACCP is a management system developed by the Food and Drug Administration to protect the food supply from biological and chemical contamination and from physical hazards. The HACCP system consists of seven steps: (1) conduct a hazard analysis, (2) identify critical control points, (3) establish critical limits, (4) establish monitoring procedures, (5) establish corrective actions, (6) establish verification procedures, and (7) establish record-keeping and documentation procedures.[5] HACCP incorporates the use of questions to probe for food system vulnerabilities as well as a decision tree to assist the user to identify system critical control points. HACCP did not have direct applicability to health care because of its focus on food processing and handling and because some of the probing questions do not concern health care. Defining critical control points in health care was also a significant challenge. However, the HACCP concept of a decision tree was adapted for the HFMEA™ process.

Prioritization is always a major feature in the operation of any proactive risk assessment. Fortunately, as part of the RCA process NCPS devel-

oped a Safety Assessment Code (SAC) Matrix to prioritize adverse events and close calls. In this process the severity of an event is classified as minor, moderate, major, or catastrophic, and probability is classified as remote, uncommon, occasional, or frequent. After the severity and probability are determined, the SAC Matrix is used to score (and prioritize) the event. The matrix incorporates the severity definition headings along the top horizontal row and the probability definition headings along the left column. When applied to the RCA process, the matrix scores range from 1 to 3. The Hazard Matrix uses the same definitions and concepts; however, in HFMEA™ the scores range from 1 to 16. The SAC definitions for severity and probability (occurrence) are well known by patient safety managers within the VA, and for this reason were adapted for use in HFMEA™.

To optimally meet the need in health care, a prospective risk analysis method was developed by the NCPS that includes concepts of the FMEA model from industry, the HACCP model from food safety, as well as tools and concepts that are integral to the VA's RCA program (for example, SAC and triage cards). Table 1 (below) summarizes the sources of HFMEA™ concepts. It can be argued that all the components are present in some form in all the prospective analysis models. Yet our intent is to designate the primary source for the components incorporated in the HFMEA™ model.

Table 1. HFMEA™ Components and Their Origins*

Concepts Employed	HFMEA™	FMEA	HACCP	RCA
Team membership	•	•		•
Diagramming process	•	•	•	
Failure mode and causes	•	•		
Hazard Scoring Matrix	•			•
Severity and probability definitions	•	†		•
Decision Tree	•		•	
Actions and outcomes	•	†		•
Responsible person and management concurrence	•	†		•

* HFMEA, Health Care Failure Mode and Effect Analysis; FMEA, Failure Mode and Effect Analysis; HACCP, Hazard Analysis and Critical Control Point; RCA, root cause analysis.
† Although these components are present in FMEA, they were substantially modified in the HFMEA™ model.

Key Aspects of the HFMEA™ Process

HFMEA™ is a 5-step process that uses a multidisciplinary team to proactively evaluate a health care process. The team uses process flow diagramming, a Hazard Scoring Matrix™, and the HFMEA Decision Tree™ to identify and assess potential vulnerabilities. Table 2 (right) presents a potential time line and activity plan for a team.

The HFMEA™ Worksheet (Figure 1, p 252) is used to record the team's assessment, proposed actions, and outcome measures. HFMEA™ includes testing to ensure that the system functions effectively and new vulnerabilities have not been introduced elsewhere in the system.

The HFMEA™ steps are operationally defined below. Appendix 1 (pp 259–263) presents an example of HFMEA™, focusing on prostate-specific antigen (PSA) testing. Appendix 2 (pp 264–265) provides a brief description of the steps, along with actions taken by a team working on the PSA testing example.

Step 1. Define the HFMEA™ Topic

The topic to be reviewed should be a high-risk or high-vulnerability area, to merit the investment of time and resources by the HFMEA™ team. Along these lines, JCAHO, in its intent for the standard LD.5.2, "Leaders ensure that an ongoing, proactive program for identifying risks to patient safety and reducing medical/health care errors is defined and implemented,"[2 (p LD-40)] specifies that health care organizations should use "available information about sentinel events known to occur in health care institutions that provide similar care and services . . . such selection [of the process for review] is to be based, in part, on information published periodically by the Joint Commission that identifies the most frequently occurring types of sentinel events and patient safety risk factors."[2(p LD-40),5]

Step 2. Assemble the Team

A multidisciplinary team should include subject matter expert(s), an advisor, and a team leader. A multidisciplinary team ensures that various viewpoints are considered. By having a subject matter expert, the team will gain insights into how the process is actually carried out. Conversely, having people that do not know the process encourages critical review of accepted standards and practices and identification of potential vulnerabilities that others might miss. Consider designating a team leader who has skills in group

Table 2. HFMEA™ Time Line and Team Activities*

Premeeting: Identify the topic (Step 1); select the team; notify the team (HFMEA™ Step 2). (Note: Within the VA this work is completed by the team advisor. Within the VA the advisor is the facility patient safety manager.)

1st team meeting: Diagram the process; identify subprocesses; verify the scope of work with the advisor (Step 3).

2nd team meeting: Visit the worksite(s) to observe the process; verify that all process and subprocess steps are correct (Step 3).

3rd team meeting: Brainstorm failure modes; assign individual team members to consult with process users (Step 3).

4th team meeting: Refine failure modes on the basis of user input; identify failure modes causes; assign individual team members to consult with process users for additional input (Step 3).

5th team meeting: Refine failure mode causes on the basis of user input; transfer failure modes and failure mode causes to the HFMEA™ Worksheet (Step 3); Begin the hazard analysis process by assessing each failure mode and failure mode cause (Step 4); identify corrective actions and assign follow-up responsibilities (Step 5).

6th, 7th, 8th, …nth team meetings: Continue with the hazard analysis and identification of corrective actions (Steps 4 and 5).

nth team meeting plus 1: Assign team members to follow up with the individuals charged with taking corrective action. (Note: Seeking buy-in from the individuals affected by the proposed changes is highly recommended.)

nth team meeting plus 2: Refine corrective actions based on feedback.

nth team meeting plus 3: Test the proposed changes.

nth team meeting plus 4: Meet with top management to obtain approval for all actions.

Postteam meetings: The advisor or his or her designee follows up with the responsible parties until all actions are completed.

*_HFMEA, Health Care Failure Mode and Effect Analysis; VA, Department of Veterans Affairs._

HFMEA Worksheet™

Decoding the HFMEA™ Worksheet

Worksheet for Subprocess step 1A, Hit Snooze Button

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 Concurrence
Potential Causes	Severity	Probability	Haz Score	Single Point Weakness?	Existing Control Measure?	Detectability	Proceed?					

Annotations (callout boxes):

- Subprocess description
- Subprocess Step number
- Always evaluate the failure mode first to determine if causes need to be identified.
- Failure mode number (eg, 1A1)
- **Failure Mode:** First evaluate failure mode before determining potential causes
- List failure mode, such as wrong speed for equipment
- Subprocess number + Failure Mode number + Cause identifier
- Failure Mode
- This space should be left blank, unless your hazard analysis determined a stop action. In that case, you would list the rationale for stopping.

Figure 1. *The HFMEA™ Worksheet is used to record the team's assessment, proposed actions, and outcome measures.*

processes and can make sure that the team functions effectively. The advisor acts as a consultant, helping the leader accomplish necessary tasks and stepping in as appropriate to keep the team on target.

Step 3. Graphically Describe the Process

Develop and verify the process flow diagram. To aid the team in discussing the flow diagram, consecutively number each process step (for example, 1, 2, 3. . .). Next, identify all subprocesses under each block of this flow diagram and consecutively letter these subprocess steps (that is, 1A, 1B. . . 3A, 3B. . .). Teams will find it extremely beneficial to identify all subprocess steps before proceeding with further team work. If the process is complex, identify the portion of the process or subprocess to focus on. (See Sidebar 1, right.)

Focusing on a specific part of the process will keep the team on track and allow timely completion of the project without being overwhelming. For example, one facility initially considered reviewing the entire process for medication dispensing but realized that this would be a monumental task. Instead, the facility focused on the oral medication dispensing process, resulting in a more productive and effective review that identified several system vulnerabilities.

To ensure that the team does not experience the frustration of being overwhelmed, it might be helpful to have the patient safety committee or patient safety manager identify the specific target for HFMEA™ activities. In the example (PSA testing) in Appendix 1, we identified the part of the process that is highly vulnerable and worth the team's attention—specifically, the activities related to analyzing the sample. There are many other steps associated with PSA testing that are not included in the team's efforts (for example, ordering the PSA test, drawing the sample, reporting the results to the physician, filing the results in the computerized medical record). However, this single part of the process—analyzing the sample—is complex and yields a host of potential failure modes and failure mode causes that merit remediation. NCPS's experience suggests that by narrowing the scope of the review, the team stands a better chance of a quality analysis that yields specific and effective actions.

Step 4. Conduct a Hazard Analysis

For the part of the process that the team is examining, list all possible/potential failure modes for each of

Sidebar 1. Rationale for Focusing on a Subprocess Step for HFMEA™

For example, a facility examining the discharge process for its medical center might identify the following process steps:

1. Ensuring that durable medical equipment (DME) is in place at the home
2. Confirming the schedule for home visits by appropriate clinical staff
3. Securing all needed medications prior to discharge
4. Educating the spouse or other caregiver about all aspects of the care
5. Educating the patient about the follow-up rehabilitation and care
6. Establishing an appropriate support network for the home care provider
7. Reviewing the patient's status (physical, emotional, spiritual, psychological) as appropriate, for discharge

Focusing strictly on the first process step—Step 1: Ensuring that DME is in place at home—yields the following subprocess steps:

1A. Securing the order from clinicians for the DME
1B. Reviewing the capacity of the dwelling to accommodate the equipment
1C. Identifying vendors that serve the patient's community
1D. Sending the order to the vendor
1E. Scheduling the delivery of the DME to precede the patient's arrival
1F. Receiving and setting up the DME
1G. Educating the patient's caregivers about the DME

These subprocess steps will yield sufficient opportunities for a fruitful HFMEA™ because for each subprocess step, the team will have identified potential failure modes and failure mode causes.

the subprocesses and consecutively number these failure modes (eg, 1A(1), 1A(2). . . 3E(1), 3E(2). . .). Failure modes are operationally defined as the different ways that a particular process or subprocess step can fail to accomplish its intended purpose. For example, if the subprocess step is confirming known drug allergies, failure modes would include the following: (1) not recording drug allergies and (2) incompletely capturing drug allergies. The team should use various sources and tools

to identify potential failure modes. These might include JCAHO Sentinel Event Alerts, Institute for Safe Medication Practices (ISMP) information, Food and Drug Administration databases and advisories, the NCPS Triage Cards for Root Cause Analysis™, brainstorming, and cause-and-effect diagramming.

Next, determine the severity and probability of the potential failure mode and look up the hazard score on the Hazard Scoring Matrix (Appendix 3, pp 266–267). The severity score is a measure of the potential effect of the failure mode—in other words, what would be the impact on patients or patient care if this should happen? As discussed, the severity categories include catastrophic, major, moderate, and minor, with specific operational definitions developed. The probability ratings include frequent (several times in 1 year), occasional (several times in 2 years), uncommon (sometime in 2 to 5 years), and remote (5 to 30 years).

Use the HFMEA Decision Tree™ (Figure 2, p 255) to determine whether the failure mode warrants further action on the basis of criticality, absence of effective control measures, and lack of detectability:

■ A *single point weakness (Critically)* measures whether the entire system will fail if this part of the process fails. (See Sidebar 2, right, for further discussion of this issue.)

■ An *effective control measure* eliminates or significantly reduces the likelihood of the failure occurring.

■ An *obvious hazard (Detectability)* is defined as the likelihood of detecting failure or the effect of failure before it occurs.

If the decision is to proceed for the failure mode being assessed, list all the failure mode causes for each failure mode. Each failure mode may have multiple causes. Examples of possible failure mode causes for the process step of confirming known drug allergies may include inexperienced staff, lack of competencies, failure to delineate task responsibilities, production pressures, poor support from automated systems, and lack of checklists or cognitive aids.

The HFMEA Decision Tree™ presents the steps to follow when evaluating a particular failure mode or failure mode cause. The decision tree serves as a triaging function, identifying areas where the team needs to mitigate vulnerabilities and areas not needing attention because they are not critical, they are highly detectable, or they already have an effective control measure. The goal of this process step is to focus the team's energies on only the really critical and relevant parts of the

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Sidebar 2. Decision Tree: Examples of a Single Point Weakness (Criticality), an Effective Control Measure, and an Obvious Hazard (Detectability)

Assume that your team is looking at the medical gas cylinder process. It has diagrammed the major process steps and identified subprocess steps, including "replacing empty cylinders." Further, the team has identified "connecting the incorrect gas cylinder" as the failure mode, and it then uses the decision tree to evaluate this identified vulnerability. By answering the following questions, the team will determine if it is necessary to proceed to identify failure mode causes:

■ Is this a single-point weakness?
■ Does an effective control measure already exist?
■ Is the hazard obvious?

Single point weakness (Criticality): If the formal or informal norm is to rely on the color of the cylinder to indicate the gas content, this is a single point weakness. Cylinder color can often be confused because of lighting conditions, variation in paint pigments, and chips and scratches that permit the underlying color to come through, or dirt.

Effective control measure: If your hospital does not use universal adaptors (for regulators), and all the connectors in the building have the correct pin index, the pin indexing would be an effective control measure; it would prevent the incorrect gas from being connected to the regulator.

Obvious hazard (Detectability): The primary means of identifying the gas content of a cylinder is the label. If the label is missing, this would be an obvious hazard.

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process under review. Examples of potential failure mode from the PSA example in Appendix 1 are presented in Figure 3 (p 256) and Figure 4 (p 257).

Step 5. Actions and Outcome Measures

Develop a description of action for each failure mode cause where the action is to proceed, identify outcome measures, and identify a single person responsible for completing or ensuring completion of each action. To ensure the commitment of leadership, management must concur with each recommended action. If management does not concur, the team should revise
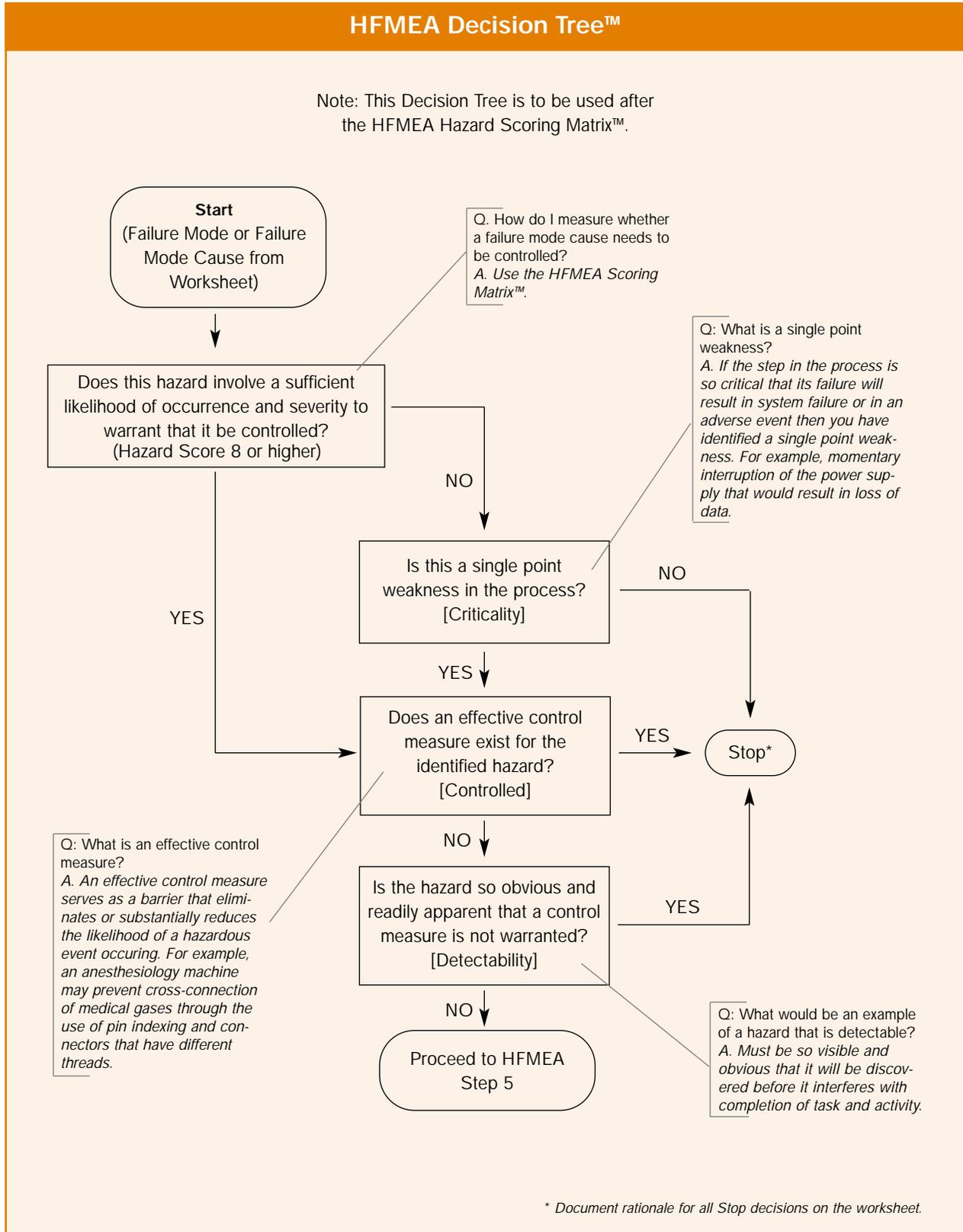
HFMEA Decision Tree™

Note: This Decision Tree is to be used after the HFMEA Hazard Scoring Matrix™.

Start
(Failure Mode or Failure Mode Cause from Worksheet)

Q. How do I measure whether a failure mode cause needs to be controlled?
A. Use the HFMEA Scoring Matrix™.

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

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

NO

YES

Is this a single point weakness in the process?
[Criticality]

NO

YES

Does an effective control measure exist for the identified hazard?
[Controlled]

YES → Stop*

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

NO

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

YES

NO

Proceed to HFMEA Step 5

Q: What would be an example of a hazard that is detectable?
A. Must be so visible and obvious that it will be discovered before it interferes with completion of task and activity.

* Document rationale for all Stop decisions on the worksheet.

Figure 2. *The HFMEA Decision Tree™ is used to determine whether the failure mode warrants further action on the basis of a lack of detection, criticality, and absence of effective control measures.*

Worksheet for Process Step 3A: Review Order

HFMEA Step 4–Hazard Analysis								
		Scoring			Decision Tree Analysis			
Failure Mode: First evaluate failure mode before determining potential causes	**Potential Causes**	Severity	Probability	Hazard Score	Single Point Weakness?	Existing Control Measure?	Detectable?	Proceed?
3A1 Wrong test ordered	⟶	Minor	Occasional	3	N			No
3A2 Order not received by lab	⟶	Moderate	Uncommon	4	Y	N	N	Yes
3A2a	Fax line busy for lab	Moderate	Remote	2	Y	N	Y	No
3A2b	Clinician doesn't fill out order	Moderate	Uncommon	4	Y	N	N	Yes

Figure 3. *This figure provides an example of a worksheet for a potential failure mode from the PSA example in Appendix 1 and its severity, probability, and resulting hazard score.*

the action. An example of an action for the failure mode cause "poor support from automated systems in confirming known drug allergies" might be "activate drug allergy module/screen in the computerized medical record and prevent transmitting prescription order unless allergy questions have been completed."

Outcome measures for these actions could include ensuring that the module has been activated and setting a date to test the system to verify that the questions have been completed prior to transmittal. A critical step of HFMEA™ includes testing to ensure that the system functions effectively and new vulnerabilities have not been introduced elsewhere in the system or in other interdependent systems.

The VA Rollout

All 163 VA medical centers were trained on the applicability and use of the HFMEA™ process in a 2-hour videoconference held in August 2001. The training included a prerecorded segment that described the HFMEA™ process and provided three examples, two of which were specific to health care. The broadcast also included a question-and-answer session. A list of frequently asked questions and their corresponding responses is provided in Table 3 (p 258).

Comments from the field following this training were positive, and additional on-site training is being conducted to reinforce the concepts and process. The prerecorded segment of the program

Worksheet for Process Step 3B: Centrifuge Specimen

Failure Mode: First evaluate failure mode before determining potential causes	Potential Causes		Scoring			Decision Tree Analysis			
			Severity	Probability	Hazard Score	Single Point Weakness?	Existing Control Measure?	Detectable?	Proceed?
HFMEA Step 4–Hazard Analysis									
3B1 Equpment broken	⟶		Moderate	Frequent	8	⟶	N	N	Yes
	3B1a	Old equipment	Moderate	Uncommon	4	Y	N	N	Yes
	3B1b	Lack of maintenance contract	Moderate	Frequent	8	⟶	N	N	Yes
3B2 Wrong Speed	⟶		Moderate	Uncommon	4	Y	Y	⟶	No
3C2 Specimen not clotted	⟶		Moderate	Frequent	8	⟶	N	N	Yes
	3B3a	Not centrifuged	Moderate	Remote	2	N	N	Y	Stop
	3B3b	Wrong antibodies	Moderate	Frequent	8	⟶	N	N	Yes

Figure 4. *This figure provides an example of a worksheet for a potential failure mode from the PSA example in Appendix 1 and its severity, probability, and resulting hazard score.*

was distributed on VHS-formatted videotapes to all facilities in September 2001 for use as an HFMEA™ team training aid.

Next Steps

The goal of NCPS is a successful HFMEA™ experience such that relevant vulnerabilities are identified

Table 3. Frequently Asked Questions*

1. Are facilities expected to conduct an HFMEA™ for an entire health care process, or can they focus on a subpart of this process?
Facilities can focus on a part of the process, especially if it is a major and complex process. Our advice would be for the patient safety committee or patient safety manager to give advance thought to the scope of the process that makes the most sense to focus on and then pursue that particular area.

2. To what extent has this been used at VA facilities?
VA facilities are just starting to use the HFMEA™ process. The program was rolled out nationally in August 2001 and training was provided to all VA Patient Safety Managers. Some stations have initiated HFMEA™ on topics of inpatient suicides, difficult intubations, and ordering and dispensing of oral liquid medication.

3. Can the process be applied to worker safety? Does the VA have plans to do so?
Yes, HFMEA™ could be used to look at process issues affecting occupational safety and health. Each facility is free to do this; however, there is not presently a requirement to do so.

4. Can you provide an example of how HFMEA™ is applied to a health care process?
Health care institutions may be driven to perform an HFMEA™ in response to the new JCAHO patient safety standards, specifically LD.5.2. According to the intent of this standard, health care institutions should use "available information about sentinel events known to occur in health care institutions that provide similar care and services. . . such selection [of the process for review] is to be based, in part, on information published periodically by the Joint Commission that identifies the most frequently occurring types of sentinel events and patient safety risk factors."

Facilities will also want to review information sources available within their facilities or health care systems that identify high risk and high-occurring vulnerabilities.

5. Who is on an HFMEA™ team?
The composition of an HFMEA™ team is similar to that of an RCA team. The VA uses a multidisciplinary team, generally made up of 6–10 individuals. At least one of the individuals on the team must be a subject matter expert. One individual serves as a team leader, and one is the team recorder. The patient safety manager serves as an advisor to the team, to keep the team on track and answer any HFMEA™ process questions that arise.

6. How long does the HFMEA™ process take?
It depends on the scope of the process or subprocess that is examined, the skill of the team advisor, and the commitment of the team members to work effectively, and their team skills. On the basis of experience with similar processes such as RCAs, we have found that as teams become more skilled and facile, the time decreases and the quality of the product increases.

7. Are there any common pitfalls in conducting HFMEA™, and what are your recommendations for avoiding them?
Focus on a manageable part of the process; it's better to have fewer actions that actually get implemented than myriad half-addressed or ignored actions. Choose a leader for the team comfortable in managing a group process. Include on your team someone who has subject matter expertise and also someone who is not familiar with the process; both provide useful perspectives. Discuss proposed process changes with those who have to implement them and make sure these people are represented on the team. Set a time line for completion of the activities, and early in the process, schedule a close-out briefing with senior management so that you'll finish in a timely fashion and gain its buy-in.

8. How are VA facilities expected to use HFMEA™?
In fiscal year 2002, each facility is expected to use the HFMEA™ process to review its bar code medication administration contingency plan. Following that, the facilities will do a least one analysis per year, on a high-risk, high-volume process.

9. How can individuals access tools used by HFMEA™?
HFMEA™ materials are available on the NCPS Web site (www.patientsafety.gov).

* HFMEA, Health Care Failure Mode and Effect Analysis; RCA, root cause analysis; VA, Department of Veterans Affairs.

and effective actions implemented. To aid in achieving this goal, NCPS distributed to all facilities additional reference materials and examples. NCPS staff is conducting numerous day-long training sessions to further reinforce HFMEA™ and in response to an identified need for additional support. This training focuses on practical examples and tips, with hands-on application of the HFMEA™ process to actual cases and the bar code medication administration (BCMA) process.

An additional next step is sharing the HFMEAs™ so that one can see the different topics that are being examined and potential vulnerabilities that may be explored. Information will be posted on the NCPS intranet, including a summary, the topic reviewed, and contact information. NCPS will not post full-text HFMEAs™ and does not anticipate including them in the database of RCAs.

Conclusions

The VA is in the early stages with the HFMEA™ process. Although initial training was provided, most facilities have waited to start until they have received the additional materials for this year's topic (BCMA

contingency plans). The VA is using a forcing function by having all facilities focus on the same topic in fiscal year 2002 (October 2001–September 30, 2002); the effectiveness of this approach remains to be seen. The utility and success are largely dependent on local leadership's buy-in and support, which requires that leadership be persuaded that HFMEA™ is worth the investment of resources. Initial response from patient safety and risk managers has been very positive, and multiple requests have been received for the training materials and presentations from non-VA health care providers.

The successes to date include developing HFMEA™, a practical proactive risk assessment model, and making this an accessible process. The training videotape with accompanying materials using actual health care examples was created in a very short timeframe, and HFMEA™ was rolled out to all facilities within 6 weeks during the summer of 2001. This material was presented at breakout sessions at the National VA and AHRQ Patient Safety Summit in September 2001 and received many strong reviews. NCPS will share further conclusions as this national experiment continues. **J**
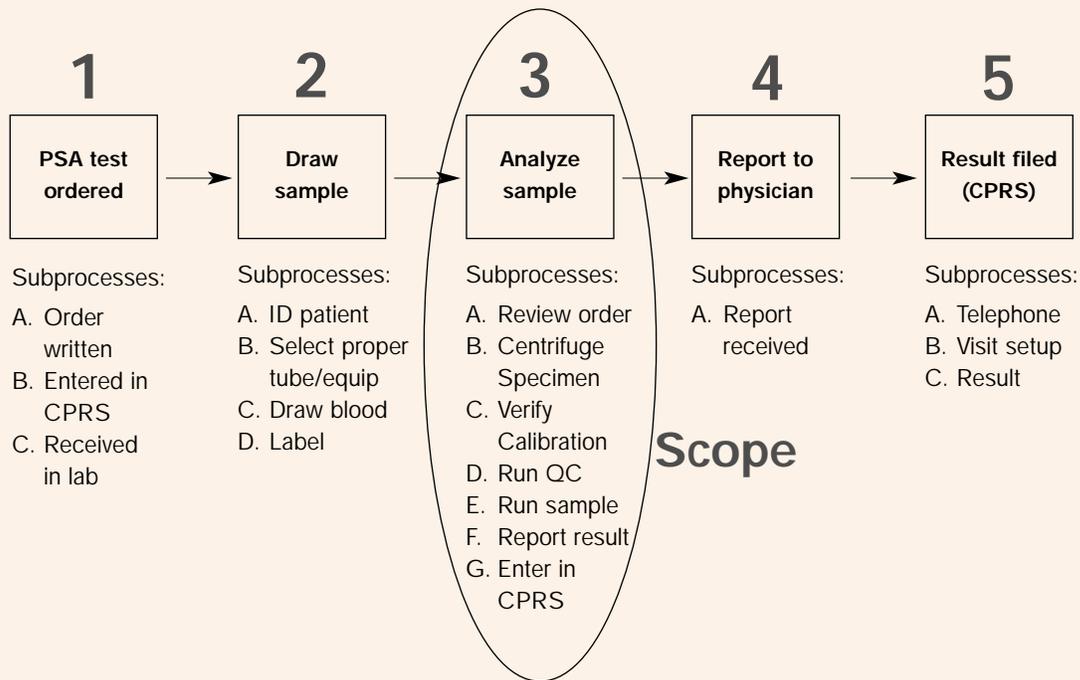
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Appendix 1. HFMEA™ Example.

This example focuses on the part of the process that is highly vulnerable and worth the team's attention–specifically, the activities of analyzing the sample. This example was also used in the HFMEA™ training video produced and distributed within the Veterans Health Administration during September 2001.
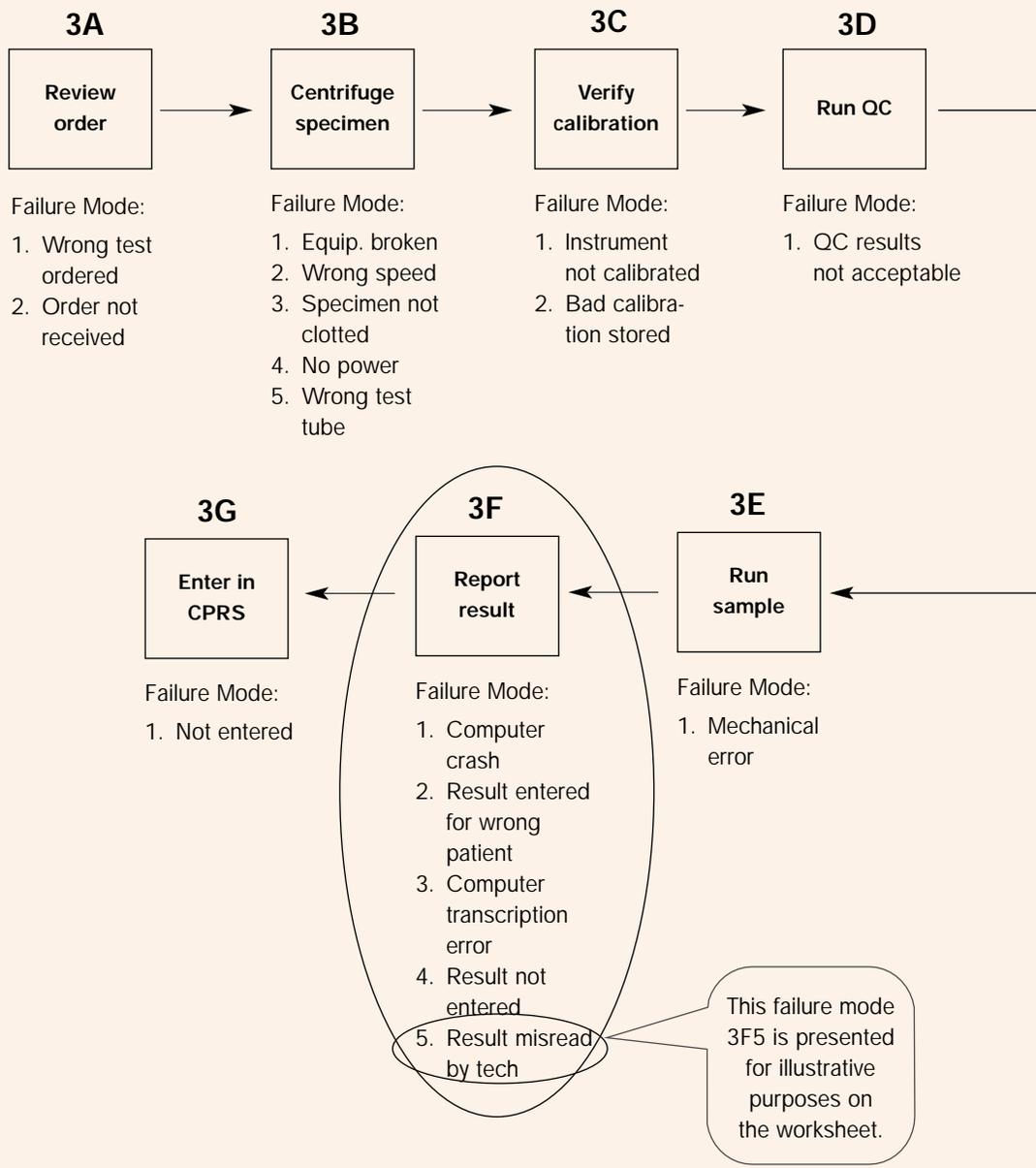
This example is based on a fictitious HFMEA™ team's review of laboratory analysis processes. The focus was directed at prostate-specific antigen (PSA) testing. For the VA, this is a high-volume process with potentially severe outcomes should the process fail. Assume that the topic (Step 1) and selecting the team (Step 2) have been accomplished. Therefore, the example starts with developing the process flowchart (Step 3). In Steps 3A through 3D the team gathers information about how the process works. The process steps are described graphically, and then they are consecutively numbered. In this example the test is ordered, the phlebotomist draws the sample, and then the sample is sent to the laboratory for analysis. The analysis is conducted, and the results are reported to the physician and recorded in the patient's medical record (in the VA this document is electronic and is part of the Computerized Patient Record System [CPRS]). Subprocess steps are then identified, listed below the process step, and consecutively lettered. QC, quality control.

1 — PSA test ordered

Subprocesses:
A. Order written
B. Entered in CPRS
C. Received in lab

2 — Draw sample

Subprocesses:
A. ID patient
B. Select proper tube/equip
C. Draw blood
D. Label

3 — Analyze sample

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

Scope

4 — Report to physician

Subprocesses:
A. Report received

5 — Result filed (CPRS)

Subprocesses:
A. Telephone
B. Visit setup
C. Result

Continued on next page

Appendix 1 *(continued)*

In steps 3E and 4A of the HFMEA™ process, the team graphically describes the subprocess steps. These subprocesses were previously described by the team and listed below the primary process step. As shown below, the subprocess steps are reconfigured into a flow diagram, enabling the team to list failure modes. The alphanumeric designation for the subprocess steps are not changed. In the PSA test example below, the team is looking at the subprocesses for Step 3 "Analyze Sample." The team then identified failure modes for each of the subprocess steps. This is done by asking what could interfere or prevent the step from successfully being completed. These failure modes are listed below the subprocess steps and sequentially numbered. Each failure mode is transferred to the HFMEA™ Worksheet (one per worksheet is recommended), and the hazard analysis is conducted.

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. Instrument not calibrated
2. Bad calibration stored

3D

Run QC

Failure Mode:

1. QC results not acceptable

3G

Enter in CPRS

Failure Mode:

1. Not entered

3F

Report result

Failure Mode:

1. Computer crash
2. Result entered for wrong patient
3. Computer transcription error
4. Result not entered
5. Result misread by tech

3E

Run sample

Failure Mode:

1. Mechanical error

This failure mode 3F5 is presented for illustrative purposes on the worksheet.

Appendix 1 *(continued)*

The HFMEA™ Worksheet has been developed to serve as a cognitive aid to the team as well as provide a convenient location to record data. The team records the subprocess step being worked on at the top and the failure mode in the lefthand column. We have incorporated an arrow in the "Potential Causes" column to help teams remember that they first need to evaluate (conduct a hazard analysis on) the failure mode before identifying failure mode causes. This is meant to be a time-saving step. If the consequences of the failure occurring do not warrant implementing corrective action, then the team can move on to the next failure mode without identifying failure mode causes.

The team transfers the failure mode (in our example, 3F5) to the HFMEA™ Worksheet. The failure mode is evaluated, and then the failure mode causes are identified and evaluated. Walking across the worksheet from left to right, the team assesses the severity and probability, using the definitions provided, uses the Hazard Scoring Matrix to obtain the hazard score, and then proceeds to the Decision Tree. If the Decision Tree indicates that the team may stop, the rationale for this is documented and the team then moves on to the next failure mode cause or to the next failure mode. In this manner the team evaluates all the process steps and subprocess steps that fall within its scope of work.

The following give some specific examples of potential failure modes from the PSA example, as well as their severity, probability, and resulting hazard scores:

Appendix 1 (continued)

Worksheet for Process Step 3F5: Result Misread by Tech

Failure Mode: First evaluate failure mode before determining potential causes	Potential Causes		Severity	Probability	Hazard Score	Single Point Weakness?	Existing Control Measure?	Detectable?	Proceed?	Action Type (Control, Accept, Eliminate) or Rationale for Stopping	Action	Outcome Measure	Person Responsible	Management Concurrence
			Scoring			Decision Tree Analysis								
3F5 Result misread by tech	→		Moderate	Frequent	8	↑	N	N	Yes					
	3F5a	Tech fatigue	Moderate	Occasional	6	Y	N	N	Yes	Control	Have a second tech confirm and initial readings when double shifts are worked	Review record every 2 weeks following double shifts. 100% compliance is expected.	Lab Supervisor	Yes
	3F5b	Too busy and distracted	Moderate	Frequent	8	↑	N	N	Yes	Control	Control access to the lab and dedicate a single phone line for all incoming calls.	Redesigned lab and phone system.	Facilities Engineering	Yes
	3F5c	Poor lighting	Moderate	Remote	2	N	N	Y	Stop	Lighting condition is obvious to user, second source is also provided.				
	3F5d	Confusing readout on PSA instrument	Moderate	Frequent	8	↑	N	N	Yes	Eliminate	Purchase new equipment	New equipment in place by XX/XX/XX	Supply Supervisor	Yes

HFMEA Step 4 - Hazard Analysis   **HFMEA Step 5 - Identify Actions and Outcomes**

Appendix 2. Health Care Failure Mode Effect Analysis (HFMEA)™ Steps

Step 1. Define the HFMEA™ Topic

Define the topic of the HFMEA™ and clearly define the process to be studied.

In our hypothetical example (see Appendix 1) the advisor had identified prostate-specific antigen (PSA) testing as the HFMEA™ team topic. Within the VA, PSA tests are a high-volume process with potentially severe outcomes should the process fail.

Step 2. Assemble the Team

The team is to be multidisciplinary including subject matter expert(s) and an advisor.

Step 3. Graphically Describe the Process

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

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

In the PSA test example the team identified five major process steps. These steps are diagrammed and numbered.

C. If the process is complex, identify the area of the process to focus on (take manageable bites).

In the example the HFMEA™ team, with the help of the advisor, identified "Analyze sample" as the process step to focus on. It was felt that this scope provided a manageable process for the team to address and was felt to be a high-risk area due to the numerous subprocess steps involved that could affect the final result.

D. Identify all subprocesses under each block of this flow diagram. Consecutively letter these subprocesses (eg, 1A, 1B. . . 3E. . .).

E. Create a flow diagram composed of the subprocesses. Consecutively letter these substeps.

(Hint: It is very important that all process and subprocess steps be identified before you proceed.)

In the PSA test example the process "Analyze sample" (Step 3) has been further refined by identifying subprocess steps. These are identified as 3A through 3G.

Step 4. Conduct a Hazard Analysis

A. List all possible/potential failure modes under the subprocesses identified in HFMEA™ Step 3. Consecutively number these failure modes (eg, 1a(1), 1a(2). . . 3e(4). . .). Transfer the failure modes to the HFMEA™ Worksheet.

(Hint: This is the step in the process where the expertise and experience of the team really pays off. Use various methods, including the NCPS triage/trigger-

ing questions, brainstorming, and cause-and-effect diagramming, to identify potential failure modes.)

For illustrative purposes we have focused on subprocess Step 3F "Report result," and failure mode 3F5 in the PSA test example. The team would evaluate all subprocess steps and failure modes.

B. Determine the severity and probability of the potential failure mode and record these on the HFMEA™ Worksheet. Look up the hazard score on the Hazard Scoring Matrix™ and record this number on the HFMEA™ Worksheet.

Refer to the HFMEA™ Worksheet in Appendix 1 for the PSA test example hazard analysis.

C. Go to the HFMEA™ Decision Tree. Use the Decision Tree to determine if the failure mode warrants further action. Record the action to proceed or to stop on the HFMEA™ Worksheet. If the action is to stop, proceed to the next subprocess identified in step 4B. (Note: If the score is 8 or higher, document the rationale for any Stop decisions.)

D. List all the failure mode causes for each failure mode where the decision is to proceed and record them on the HFMEA™ Worksheet.

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

In the example we have illustrated failure mode 3F5 and failure mode causes 3F5a through 3F5d.

E. Conduct Steps 4B and 4C on each of the potential failure mode causes.

Step 5. Actions and Outcome Measures

A. Determine whether you want to eliminate, control, or accept the failure mode cause. Record this decision on the HFMEA™ Worksheet.

B. Identify a description of action for each failure mode that will be eliminated or controlled.

(Hint: Place the control measure in the process at the earliest feasible point. Multiple control measures can be placed in the process to control a single hazard. A control measure can be used more than one

Appendix 2 *(continued)*

time in the process. Solicit input from the process owners if they are not represented on the team. Try to simulate any recommended process change to test them before facilitywide implementation.)

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

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

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

HFMEA™ Step 5 is shown on the worksheet for Process Step 3F(5) for the PSA test example (p 263).

F. Test to ensure that the system functions effectively and new vulnerabilities have not been introduced elsewhere in the system.

Appendix 3. Severity Rating Scale

Catastrophic Event *(Traditional FMEA rating of 10—Failure could cause death or injury.)*	**Major Event** *(Traditional FMEA rating of 7—Failure causes a high degree of customer dissatisfaction.)*
Patient Outcome: Death or major permanent loss of function (sensory, motor, physiologic, or intellectual), suicide, rape, hemolytic transfusion reaction, surgery/procedure on the wrong patient or wrong body part, infant abduction or infant discharge to the wrong family	**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: Death or hospitalization of 3 or more visitors	**Visitor Outcome:** Hospitalization of 1 or 2 visitors
Staff Outcome: A death or hospitalization of 3 or more staff	**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 $250,000	**Equipment or facility:** Damage equal to or more than $100,000
Fire: Any fire that grows larger than an incipient stage	**Fire:** Not applicable—See "Moderate" and "Catastrophic"
Moderate Event *(Traditional FMEA rating of 4—Failure can be overcome with modifications to the process or product, but there is minor performance loss.)*	**Minor Event** *(Traditional FMEA rating of 1—Failure would not be noticeable to the customer and would not affect delivery of the service or product.)*
Patient Outcome: Increased length of stay or increased level of care for 1 or 2 patients	**Patient Outcome:** No injury nor increased length of stay nor increased level of care
Visitor Outcome: Evaluation and treatment for 1 or 2 visitors (less than hospitalization)	**Visitor Outcome:** Evaluated and no treatment required or refused treatment
Staff Outcome: Medical expenses, lost time, or restricted-duty injuries or illness for 1 or 2 staff	**Staff Outcome:** First aid treatment only, with no lost time or restricted-duty injuries or illnesses
Equipment or facility: Damage more than $10,000 but less than $100,000	**Equipment or facility:** Damage less than $10,000 or loss of any utility without adverse patient outcome (eg, natural gas, electricity, water, communications, transport, heat/air conditioning).
Fire: Incipient stage or smaller	**Fire:** Not applicable—See "Moderate" and "Catastrophic"

Probability Rating Scale

Frequent – Likely to occur immediately or within a short period (may happen several times in 1 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).

Appendix 3 *(continued)*

HFMEA™ Hazard Scoring Matrix™

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

How to Use This Matrix:

1. Determine the severity and probability of the hazard, based on the definitions included with this matrix. (Note: These definitions are the same as those used in the Root Cause Analysis Safety Assessment Code.)
2. Look up the hazard score on the matrix.