# Chapter 9. Human Factors Informed Failure Mode and Effects Analysis

## Section 9.1. Setting the Stage

Failure Mode and Effects Analysis (FMEA) is an engineering method for proactively assessing vulnerabilities in a system before the risks cause harm. It was first used in the late 1940's by the US Armed Forces to analyze various flight control systems (Amzen, 1996), as pilot error was leading to crashes and deaths. Since, FMEA has been adapted and used in several industries including military, aerospace, automotive, plastics, food service, and more recently, in healthcare. FMEA has been promoted by several national healthcare quality and safety organizations in Canada and the United States including: the Veterans Health Administration [37], the Institute for Safe Medication Practices [38], the Institute for Safe Medication Practices Canada [39], and the Institute for Healthcare Improvement [40].

Carrying out an FMEA is a means for hospitals to satisfy accreditation standards in the US and Canada including The Joint Commission's patient safety standard LD.5.2 in the Leadership chapter of the Hospital Accreditation Manual [41] and Accreditation Canada's Required Operating Practice that hospitals conduct at least one proactive risk assessment of a high-risk process each year [42].

Many versions of the FMEA method exist across multiple industries, including Healthcare Failure Mode and Effects Anaysis HFMEA). This chapter will present a human factors informed FMEA method ($^{HF}$FMEA) tailored to proactively analyzing healthcare systems and ensuring human factors considerations are included in the process.

## Section 9.2. What is $^{HF}$FMEA?

$^{HF}$FMEA is a human factors analysis method used to identify risks within a system proactively. It is carried out by a multidisciplinary team, and can be used to assess workflows, or technology-focused processes. $^{HF}$FMEA helps you to consider:

- What can go wrong (failure mode)
- What happens if it goes wrong (effects)
- If it were to go wrong, how severe, likely, and detectable would it be (prioritizing what to focus on)
- Why could it go wrong (causes)
- What strategies could prevent it from going wrong (mitigating strategies)

The $^{HF}$FMEA aims to improve on the more traditional FMEA method by incorporating a range of human factors methods during the analysis to:

- Enable the identification of failure modes from a human factors perspective

- Take our natural human strengths and limitations into account when rating and prioritizing issues
- Identify causes from a human factors perspective
- Identify human factors informed mitigating strategies and set expectations about how much risk is likely to be mitigated given the proposed solutions

Further to incorporating human factors methods throughout the analysis, HFFMEA also supports the biomedical technology professional in ensuring critical issues surface more readily, and that resources are focused on the highest risk/highest reward issues and solutions, so the overall effort required can be optimized.

## Section 9.3. Why use HFFMEA?

HFFMEA provides a means of understanding the potential risks that exist within a system in a proactive manner, and from a human factors perspective. The ability to identify and address risks before they lead to a patient or staff safety issue is a golden opportunity to reduce actual harm.

HFFMEA can unite staff from across the organization who have different professional backgrounds and who work in different environments, by bringing them together to identify and solve problems as a group. This kind of undertaking can strengthen organizational culture and help to create a feeling of unity among staff. Involving a range of staff will serve to generate a more robust analysis and mitigating strategies than any one clinical group or unit could achieve on their own, and will help in achieving buy-in when it comes time to implement mitigating strategies identified through the analysis.

From the biomedical technology professional's perspective, completing an HFFMEA will be helpful for:

- Proactively examining and managing risks to patient safety
- Comparing the risks associated with multiple comparable technologies or processes when deciding which should be implemented e.g., for procurement
- Identifying system weaknesses that may be related to, but not directly involved in an incident
- Meeting accreditation requirements for completing at least one proactive risk assessment annually

## Section 9.4. When to use HFFMEA?

HFFMEA can be used to support several key responsibilities of a biomedical technology professional including risk management, procurement, incident management, and meeting accreditation requirements.

To manage risk proactively, a potentially problematic or high-risk process should be selected and analyzed, with any mitigating strategies identified through the analysis being implemented to prevent patient and staff harm from ever being realized. Establishing mitigating strategies before any harm is experienced is the best case scenario for patient safety and incident management.

For procurement, the processes undertaken by staff when interacting with the technologies being considered can be analyzed and compared using HFFMEA. Applying this human factors analysis tool allows the set of failure modes and proposed mitigating strategies to be compared across the possible technologies so an informed decision can be made about the level of resultant risk the healthcare organization is willing to take on.

After an incident, or a root cause analysis (RCA) (Chapter 10), HFFMEA can be applied to uncover more general system weaknesses that go beyond the failure modes that led directly to the incident. Casting your net more widely using HFFMEA can highlight other parallel and surrounding risks that would not come to light using HFRCA alone.

Many accreditation bodies require that at least one proactive risk assessment be completed by a healthcare organization annually. HFFMEA can be used to analyze a process deemed risky by the organization, or as a result of a safety incident, to fulfill this requirement.

## Section 9.5. Completing an HFFMEA

The HFFMEA process is comprised of seven steps, outlined in Figure 23. Each step will be outlined and described in this section.

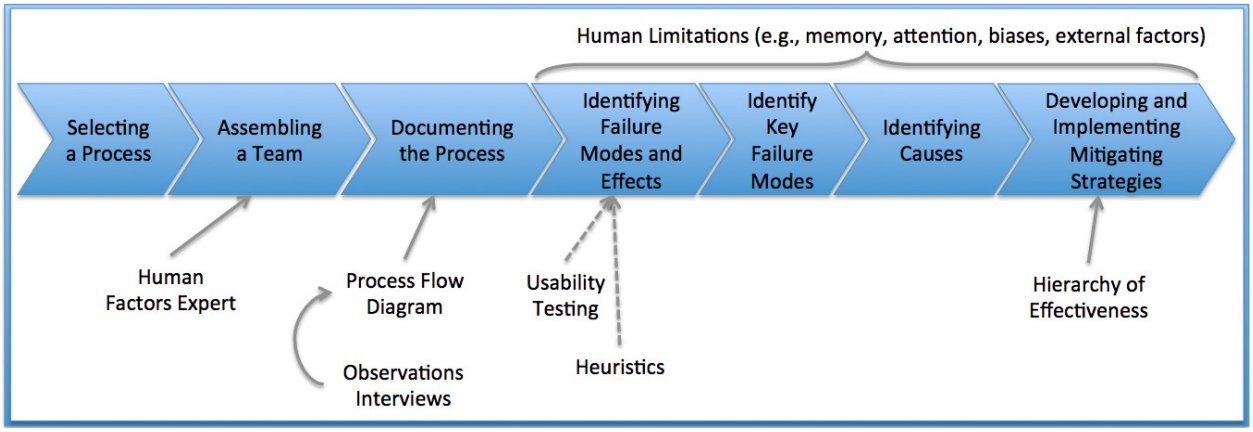


**Figure 23. The seven steps and opportunities to incorporate human factors as part of an HFFMEA**

### Section 9.5.1. Select A Process

The first, and most critical step of an HFFMEA is to select a process to analyze. In the context of this type of analysis, a process can be considered a series of tasks undertaken to

achieve a goal with a defined beginning and end. A process may be focused around a technology, or may define a series of workflow tasks required to accomplish a goal.

When choosing a process, it should be sufficiently high-risk and error prone to justify the effort involved in conducting an analysis. Comparing the residual risk associated with different technology options for procurement, and analyzing the general risks related to a critical incident usually justify an HFFMEA. To identify failure modes prospectively and independently of an incident or procurement exercise, consider reviewing incident databases from your healthcare organization or other organizations that collect incident report data like the Institute for Safe Medication Practices, FDA, ECRI Institute, Institute for Healthcare Improvement, the National Health Service (NHS) (UK), Australia Patient Safety Foundation, and reviewing guidance documents from health technology safety advocate organizations like ECRI Institute, the Association for the Advancement of Medical Instrumentation, INAHTA, and accreditation bodies like The Joint Commission. If trying to decide between two candidate processes for analysis consider the following factors, which will influence the likely success of an HFFMEA.

- Is the clinical area(s) associated with the process committed to participating? Clinical areas that have had incidents related to the process being investigated are usually willing to commit to supporting the analysis and implementing mitigating strategies.

- Is there an obvious champion on the unit(s) who will participate as part of the HFFMEA team and act as a liaison with the clinical area(s)? Having a champion from within the clinical unit is key to gaining access to the clinical area, observing the work system, and collecting artefacts in order to support an HFFMEA.

- Is the clinical area preparing to undergo a change related to the process being evaluated? If the unit is already preparing for a related change (e.g., purchasing and implementing a new device associated with the proposed process) they may be more likely to support an HFFMEA.

- Is the process pervasive across the organization (i.e., does it affect many clinical areas)? If the results of the HFFMEA will benefit many clinical areas, the effort may have a greater payoff.

- Is the process aligned with broader organizational priorities? Choosing a topic related to something the organization is actively measuring will make it easier to gain support from senior management.

#### Section 9.5.1.1 Defining the Starting and Ending Points of the Process

To support a successful HFFMEA the process scope included for analysis must be clearly defined. To do this, the starting and ending points of the process must be established, as these are the boundaries that will define the scope of the analysis. A well-defined and manageable process scope is essential to prevent the required resources and scope from escalating out of control. When defining a process scope for analysis, always lean towards too narrow a process, rather than a process that may be too broad, as there is almost no process that is too narrow for the application of HFFMEA.

#### Section 9.5.1.2 Defining Inclusion and Exclusion Criteria

To help define the process scope for an HFFMEA, consider the proposed process on a number of levels and explicitly define what will be included and excluded. Categories of information to include or exclude depend on the process under consideration, but some common ones include: Patient population, care area, technology. Table 7 provides an example of some of the variables that might be considered for inclusion/ exclusion when defining scope for the process *administering chemotherapy using an ambulatory infusion pump.*

### Section 9.5.2. Assemble a Team

Once the process, starting and ending points, and inclusion and exclusion criteria have been defined, a team must be assembled to conduct the analysis. Teams should be multidisciplinary, representing a range of knowledge, experiences, backgrounds, and perspectives. The people you choose to invite to participate on an HFFMEA team will depend on the process and scope being analyzed. As much as possible, team members should be chosen who are knowledgeable about the defined process scope, and who will think critically, and provide input, feedback, guidance, and buy-in at various stages of the HFFMEA exercise.

**Table 7. Example of variables that might be explicitly included or excluded from an HFFMEA when defining scope for the process *administering chemotherapy using an ambulatory infusion pump*.**

**Defined Process:** Administering chemotherapy with an ambulatory infusion pump

| | Included | Excluded |
|---|---|---|
| **Patient Population** | | |
| Adult | ✓ | |
| Paediatric | | ✓ |
| Clinical trials | | ✓ |
| | | |
| **Delivery Devices** | | |
| Electronic ambulatory infusion pump | ✓ | |
| Elastomeric ambulatory infusion pump | | ✓ |
| Large volume infusion pump | | ✓ |
| IV push | | ✓ |
| | | |
| **Environment** | | |
| Inpatient hospital | | ✓ |
| Outpatient hospital | ✓ | |
| Community | | ✓ |
| Home | | ✓ |
| | | |
| **Task Steps** | | |
| Ordering chemotherapy | | ✓ |
| Selecting the correct pump | | ✓ |
| Mixing chemotherapy for pump | | ✓ |
| Five rights before connecting | ✓ | |
| Connecting patient to the pump | ✓ | |
| Pump programming | ✓ | |
| Starting the pump | ✓ | |
| Pump infusing | ✓ | |
| Disconnecting the pump | ✓ | |
| | | |
| **People** | | |
| Medical oncology | | ✓ |
| Pharmacy | ✓ | |
| Nursing | ✓ | |
| Patients | | ✓ |
| Families and lay public | | ✓ |

### Section 9.5.2.1 Team Member Roles

Individual team members need to fulfill a number of different roles in order to ensure a successful project. Each HFFMEA team should include individual members who can serve as subject matter or process experts, process reviewers, and senior advisors. Additionally, some of these same team members will have to take on the roles of team leader or facilitator, scribe, and human factors expert.

### Subject Matter, or Process Experts

Subject matter or process experts are individuals who have a detailed understanding of any technologies, processes, and environments being studied. These team members will be central to mapping the process being analyzed, identifying potential risks, assessing and rating risks, and providing input when proposing and identifying the impact of mitigating strategies.

### Process Reviewers

Process reviewers are individuals who are less familiar with the process being analyzed, but who have experience and knowledge in a related field. Process reviewers are important for providing a critical review of practices and standards that are accepted by the community. Team members fulfilling this role are more likely to identify vulnerabilities that are not detected by process experts.

### Senior Advisors

Senior advisors tend to be a hospital executive, or a senior staff member, who can provide a broad organizational perspective to the team. These individuals help to facilitate access to the resources, such as people and financial support, which are needed to conduct an $^{HF}$FMEA. Senior advisors also play a key role in achieving buy-in from areas in the healthcare organization where changes will be implemented based on the mitigating strategies identified in the analysis, and for facilitating any policy changes.

### Team Leader, or Facilitator

The team leader or facilitator is a member of the team who is responsible for keeping the discussion during meetings moving and on target. The team leader should encourage participation from team members who may be more reluctant to express their ideas. The team leader should be confident, good at managing people, group dynamics, and able to facilitate group consensus building. The team leader does not have to be the same person as the project leader or coordinator.

### Scribe

The scribe is responsible for capturing the discussion and decisions made at each meeting and circulating meeting minutes to the entire team.

### Human Factors Expert

Ideally, one of the $^{HF}$FMEA team members will have human factors training. The human factors perspective for an $^{HF}$FMEA is important because human strengths and limitations are considered when identifying and rating failure modes, and when identifying

causes and recommendations. Applying a human factors lens, as described for this method, will yield additional insights for each of these HFFMEA steps. If it is not possible to include a human factors expert, a health technology professional can apply their newfound human factors lens (provided by this book and additional resources referenced in this book) to the process in order to fulfill this role and develop human factors experience. Another more cost effective option to consider is to bring in a graduate student of human factors and their advisor to help provide this perspective.

#### Section 9.5.2.2 Team Size

HFFMEA teams generally range in size from about three to eight people, but the exact number will depend on the process scope and how many stakeholders are affected by the process being analyzed. When too few team members are included in an HFFMEA, the analysis will be less robust, with the possibly of being incomplete, if relevant perspectives are not included. When too many team members are included, it can be increasingly difficult to schedule meetings, coordinate and compile team member's process work, and reach consensus.

An effective balance can be reached by tending towards a larger team, but then breaking that team into a *work team* and an *advisory team*. The work team should consist of two or three people who are responsible for conducting the detailed analysis and reporting back to the larger team. The work team should meet several times and dedicate their time to leading the hands-on work including creating diagrams, formulating the analysis and producing reports. This portion of the team can be considered the "doers". The advisory team, who make up the balance of the entire HFFMEA team, is responsible for reviewing the analysis of the work team and providing guidance and resources as required during several key meetings. This portion of the team can be considered the "enablers". Key meetings take place throughout a HFFMEA to ensure the perspectives, experience and ideas of all stakeholders are included in the analysis. In this section each of the key meetings are outlined using callout boxes to highlight their purpose and structure. The first meeting takes place once the team is selected and a process is proposed.

**Team Meeting # 1:**

**Attendees:** work and advisory teams

**Purpose:** meet and greet; review the process scope

**Estimated duration**: 1-2 hours

Once the work and advisory teams have been identified, the first meeting should focus on reviewing and getting consensus for the chosen process, starting and ending points, and the inclusion and exclusion criteria.

### Section 9.5.3. Document the Process

Once the team has been assembled and consensus has been reached on the process scope (i.e., start and end points, inclusion and exclusion criteria), the process must be documented. Documenting the process means creating a graphical representation of the steps and sub-steps required to complete your chosen process scope. Any style of graphical representation can be created, but for the purposes of this handbook a process flow diagram is recommended. To learn how to create a process flow diagram, see Chapter 6 Task Analysis.

Creating a process flow diagram is an iterative, rather than a linear, undertaking. To create a process flow diagram for an HFFMEA, first the work team members should create a diagram based on an initial understanding of what happens as part of the process. Next, any advisory team members who are also considered to be process reviewers should review this diagram. Then, the work team should go into the field to conduct observations (Chapter 4), and interviews (Chapter 5) in order to validate the process flow diagram. It is extremely important that the actual process, as opposed to the ideal process, be documented, as this will form the basis of the HFFMEA. This iterative approach of reviewing the diagram, going into the field to clarify and validate, and updating the diagram should be repeated until there are no discrepancies between the diagram and what happens in the field.

For a successful HFFMEA, it is essential that observations and interviews be conducted for a number of reasons. First, it is almost certain that going into the field will yield new information that could affect your process scope. As observations and interviews are conducted you may learn of interfacing equipment, supplies, new user groups, or different areas of the hospital, for example, which have an impact on the process being studied. In these cases your process scope may have to expand for a successful analysis. In contrast, through observations it may become evident that the original process scope chosen is too large and complex to manage with the available time and resources. In this case your process scope may have to be narrowed. Either way, any changes in process scope should be clearly defined in terms of starting/ending points, and inclusion/exclusion criteria, and also be supported by both the work and advisory teams.

In addition to re-evaluating process scope, observations and interviews are also helpful for adding detail, filling gaps in understanding, and avoiding situations where assumptions are being made about a process. Processes are almost always more detailed and complex than originally assumed, so it is important to get into the field to support the creation of an accurate diagram. Although an accurate diagram is important, it is possible to include too much detail. Knowing just how much detail to document (i.e., whether to include or exclude certain subtasks) can be a real challenge when creating a process flow diagram to support an HFFMEA. To support the creation of a diagram that is at an

appropriate level of detail, for each task and sub-task, ask yourself the question "does this task or sub-task fall within the scope of this HFFMEA". A clearly defined scope, with start and end points as well as inclusion and exclusion criteria, can go a long way in supporting this approach.

To make the process flow diagram as useful as possible for the purposes of an HFFMEA it is highly recommended that each step and sub-step be numbered to make it easier for the group to discuss individual steps throughout the analysis process. When there are different variations on the same steps of the process, each variation should be documented on the process map and labelled so that it is clear that one of the variations will take place. Labelling the variations with letters, in addition to numbers, may help to illustrate this (e.g., Sub tasks 1.2.a, 1.2.b, 1.2.c represent the three different ways that subtask 1.2 is achieved). Using swim lanes, which allow a process to be mapped to represent different clinical areas or people in a process, is also highly recommended for improved clarity.

Once the final draft of the process flow diagram has been created using the iterative approach of reviewing, going into the field, and updating the diagram, it should be shared with front line staff who are familiar with the process. Because reading a process flow diagram can be quite tedious, it is recommended that one or more meetings be set up so you can walk any reviewers through the diagram step by step. During this exercise, notes should be made directly on the diagram about any areas where changes may be required. If new information comes to light that significantly changes the process flow diagram, it is recommended further observations be conducted to validate any changes.

After any further updates have been made, the process flow diagram should be circulated among the advisory team at least a week prior to Team Meeting #2. Providing both an electronic and a paper version of the document is recommended to facilitate review and editing by team members.

**Team Meeting # 2:**

**Attendees:** work and advisory teams

**Purpose:** review process flow diagram

**Estimated Duration:** half a day

The final draft of the process flow diagram should be discussed in detail, with a member of the work team walking the group through the diagram step by step. Each team member should have a printed copy of the process flow diagram that can be used for notes and to follow along with during the session. Based on discussion during the meeting, further changes to the process flow diagram, including change in scope, are likely.

Allow ample time for this meeting, especially for a larger process scope, and consider bringing in refreshments for team members.

### Section 9.5.4. Identify Failure Modes and Effects

Once the process flow diagram has been finalized and approved by the work and advisory teams, the next step is to identify potential failure modes (FM) and effects for the defined process scope. The Veteran's Affairs National Centre for Patient Safety defines a failure mode as "different ways that a process or a sub-process can fail to provide the anticipated result" [43]. In other words, a failure mode is a description of *how* things fail. It is important to highlight that *how* things fail is different than *why* things fail. For example, when making toast, a failure mode would be *the toast burns*. Why things fail describes the cause of a failure mode. In the toast example, a possible *why* could be that the toaster darkness setting was too high. Understanding *why* things fail is important, but will be considered later on in the $^{HF}$FMEA process. The reason for this distinction is because identifying a comprehensive list of causes is extremely time consuming. The $^{HF}$FMEA method focuses the time spent identifying causes only on the most serious and important failure modes as determined through the failure mode rating process.

To facilitate the identification of failure modes, and to support the remainder of the HFFMEA method, a member of the work team should convert the final process flow diagram into a spreadsheet format. To do so, each numbered task and subtask from the process flow diagram, along with corresponding task descriptions, should be entered into rows on the spreadsheet. See Table 8 for an example of an HFFMEA spreadsheet template with process flow description steps entered into rows.

**Table 8. Example of an HFFMEA spreadsheet with process flow description information entered**

| Task # | | Failure Mode (FM) | | Effect | Scoring | | | Key Failure Mode (KFM) | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| # | Description | # | Description | | Severity (S) | Probability (P) | Hazard Score (HS) | S ≥ 3 | HS ≥ 8 | Controlled | Detectable | Single Point Weakness (SPW) | KFM ? |
| 1.0 | Check right patient | | | | | | | | | | | | |
| 2.0 | Check right drug | | | | | | | | | | | | |
| 3.0 | Check right dose | | | | | | | | | | | | |
| 4.0 | Check right route | | | | | | | | | | | | |
| 5.0 | Check right time | | | | | | | | | | | | |
| 6.0 | Attach IV tubing to patient | | | | | | | | | | | | |
| 7.0 | Turn pump on | | | | | | | | | | | | |
| 8.0 | Enter drug library | | | | | | | | | | | | |
| 9.0 | Select drug | | | | | | | | | | | | |
| ... | ... | | | | | | | | | | | | |
| ... | ... | | | | | | | | | | | | |
| ... | ... | | | | | | | | | | | | |
| ... | ... | | | | | | | | | | | | |
| ... | ... | | | | | | | | | | | | |
| ... | ... | | | | | | | | | | | | |
| ... | ... | | | | | | | | | | | | |

Once the HFFMEA spreadsheet has been initialized, the work group should meet and systematically review each task step and sub step to identify any potential failure modes. For every step and sub step, the question *how could this step or sub step go wrong* should be answered, with the answer going in the failure mode description column.

If there is more than one possible failure mode for a given task step or sub step, they should all be included. The more failure modes that can be identified and listed, the better, because when a comprehensive list is developed, the potential to reduce the risk of the failure modes identified is increased. When identifying failure modes, note that it is common for the same failure mode to be associated with different task steps and sub steps. To assist in generating a comprehensive list of failure modes, the following questions can be posed:

- How could this step or sub step be performed incorrectly?
- How could this step or sub step be performed incompletely?

- If this step or sub step is attempted correctly, what could prevent it from being completed correctly?
- What would happen if a task that is part of this step or sub step were omitted?

Including a human factors expert, or incorporating what you know about human factors when identifying failure modes, will result in a more comprehensive list of failure modes, and a more robust analysis. Consider inherent human limitations like memory, fatigue, and cognitive biases (Chapter 3).

**Table 9. Example of an HFFMEA spreadsheet with process flow description, and failure modes entered**

| Task # | | Failure Mode (FM) | | Effect | Scoring | | | Key Failure Mode (KFM) | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| # | Description | # | Description | | Severity (S) | Probability (P) | Hazard Score (HS) | S ≥ 3 | HS ≥ 8 | Controlled | Detectable | Single Point Weakness (SPW) | KFM ? |
| 1.0 | Check right patient | 1 | Right patient not checked | | | | | | | | | | |
| 2.0 | Check right drug | 2 | Right drug not checked | | | | | | | | | | |
| 3.0 | Check right dose | 3 | Right dose not checked | | | | | | | | | | |
| 4.0 | Check right route | 4 | Right route not checked | | | | | | | | | | |
| 5.0 | Check right time | 5 | Right time not checked | | | | | | | | | | |
| 6.0 | Attach IV tubing to patient | 6 | Tubing not attached to patient | | | | | | | | | | |
| 7.0 | Turn pump on | 7 | Pump is not turned on | | | | | | | | | | |
| 8.0 | Enter drug library | 8 | Do not enter drug library | | | | | | | | | | |
| 9.0 | Select drug | 9 | Drug not selected | | | | | | | | | | |
| | | 10 | Wrong drug selected | | | | | | | | | | |
| ... | ... | ... | ... | | | | | | | | | | |
| ... | ... | ... | ... | | | | | | | | | | |
| ... | ... | ... | ... | | | | | | | | | | |

It is important to reiterate that HFFMEA is a *prospective* risk analysis method, meaning that regardless of whether a failure mode has actually happened, or how unlikely it may seem, it should still be included in the spreadsheet for further consideration.

To identify the possible effects of each failure mode, the work team should think through what could happen if the failure mode occurred. When several different effects are possible, rather than listing out every possibility, include the most serious possible effects to be as conservative about the risk as possible.

When identifying effects, think about the overall goal of the process being analyzed, rather than just the most immediate effect. For example from Table 10 if the process being analyzed is *administering chemotherapy with an ambulatory infusion pump*, and a failure mode is #6, *tubing is not attached to the patient*, an immediate effect is that *the patient does not get connected to their infusion*, but in the context of the overall process goal, the effects are *medication leak*, and *the patient does not receive their chemotherapy*. Avoid taking the effect any further than this, (e.g., patient dies), because this extends beyond the goal of the process as defined (e.g., administer chemotherapy to the patient using an ambulatory infusion pump). The effect of the patient not receiving their chemotherapy (e.g., patient dies) will be captured as part of the risk rating process for the severity of the effect.

**Table 10. Example of an HFFMEA spreadsheet with process flow description, failure modes, and effects entered**

| Task # | | Failure Mode (FM) | | Effect | Scoring | | | Key Failure Mode (KFM) | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| # | Description | # | Description | | Severity (S) | Probability (P) | Hazard Score (HS) | ≥ 3 S | ≥ 8 HS | Controlled | Detectable | Single Point Weakness (SPW) | KFM ? |
| 1.0 | Check right patient | 1 | Right patient not checked | Wrong patient | | | | | | | | | |
| 2.0 | Check right drug | 2 | Right drug not checked | Wrong drug | | | | | | | | | |
| 3.0 | Check right dose | 3 | Right dose not checked | Wrong dose | | | | | | | | | |
| 4.0 | Check right route | 4 | Right route not checked | Wrong route | | | | | | | | | |
| 5.0 | Check right time | 5 | Right time not checked | Wrong time | | | | | | | | | |
| 6.0 | Attach IV tubing to patient | 6 | Tubing not attached to patient | Medication leak | | | | | | | | | |
| | | | | Patient does not receive medication | | | | | | | | | |
| 7.0 | Turn pump on | 7 | Pump is not turned on | Patient does not receive medication | | | | | | | | | |
| 8.0 | Enter drug library | 8 | Do not enter drug library | Nurse not alerted to possible wrong dose | | | | | | | | | |
| 9.0 | Select drug | 9 | Drug not selected | Pump alarm goes off | | | | | | | | | |
| | | 10 | Wrong drug selected | Patient receives wrong drug | | | | | | | | | |
| ... | ... | ... | ... | ... | | | | | | | | | |
| ... | ... | ... | ... | ... | | | | | | | | | |

Once the work team has identified as many potential failure modes, and resultant effects as possible for each step and sub step of the process, the spreadsheet should be circulated to the advisory team for review.

**Team Meeting # 3:**

**Attendees:** work and advisory teams

**Purpose:** review and expand upon potential failure modes and effects

**Estimated Duration:** 1 day

The failure modes and effects for each process step and sub step should be reviewed, discussed, and expanded upon during this meeting. The facilitator should walk the group through each step and sub-step and elicit any feedback or additional failure modes for each step. Every team member should have a printed copy of the spreadsheet and process flow diagram that can be used for notes, and to follow along with during the session. If possible, project a working copy of the spreadsheet so the entire team can see it, and have the scribe type any new or modified failure modes and effects in real time so the team can ensure the discussion is being captured accurately.

In addition to failure modes and effects, it is likely that causes will be also be brought forth. To keep this meeting on track any causes should be recorded in a separate file, or on chart paper, for future use and the facilitator should steer the group back towards the identification and review of failure modes and effects.

It is normal for further modifications to the process flow diagram to occur as a result of this meeting. Have the scribe, or another dedicated team member capture any required edits on a paper copy of the process flow diagram so they can be incorporated following the meeting.

This will be the longest meeting of the $^{HF}$FMEA, and an entire day should be scheduled, especially for a larger process scope. If it is not possible to schedule a meeting this long, plan to have several shorter meetings instead. Organize refreshments for team members, and make sure to schedule several short breaks throughout the day.

### Section 9.5.5. Rate Failure Mode Effects and Determine Key Failure Modes

A long list of failure modes and resultant effects will have been generated following Team Meeting #3. With unlimited resources, one would try to mitigate every failure mode identified, but since in reality most healthcare organizations do not have the capacity to do this, it is important to focus on fixing those failure modes that carry the highest risk. To identify which failure modes are the highest priority issues, and thus require the most attention, each failure mode and effect will be rated using risk-scoring matrices and assessed to determine if it is a key failure mode (KFM). Once the KFMs have been identified, the team can then focus on determining causes and creating mitigating strategies targeted towards these high priority issues so available resources can be used in the most efficient manner possible.

Risk-scoring matrices are rubrics that support the assignment of risk scores to each failure mode effect. In the HFFMEA framework two matrices are required to support the identification of key failure modes, a Severity-Scoring Matrix and a Probability-Scoring Matrix.

The ratings and definitions used to evaluate the severity and probability of each failure mode should be tailored to the process being analyzed, but suggested severity and probability scoring matrices are included in Table 11 as examples.

It is important that the definitions and scale chosen be appropriate and meaningful for the process scope being evaluated. For example, if several of the failure modes being considered are likely to happen daily, the definition of "Frequent" in Table 12 should be adjusted to take this into account.

The process of creating risk-scoring matrices may be most efficient if the work team develops proposed matrices and circulates them and receives comments by email, rather than meeting in person.

Once the risk-scoring matrices have been developed and approved by the work and advisory teams the work group should meet several times to assign severity and probability scores to each failure mode and effect in the HFFMEA spreadsheet. When rating severity, consider the effect of the failure mode, and when rating probability, consider the failure mode itself (Table 13).

If possible, include a human factors expert in this rating exercise because having this perspective will enable the consideration of people's inherent strengths and limitations, possibly affecting the scores assigned to different issues. Think about inherent human limitations like memory, fatigue, and cognitive biases (Chapter 3). A common pitfall when rating failure modes and effects is to assume that people should just be vigilant when it comes to a potential issue, or that they should remember to do something, but a human factors lens will help to remind the group that in reality, this is not possible.

Once the work team has rated each failure mode and effect, the HFFMEA spreadsheet should be circulated to the advisory team for review and feedback. A meeting should be scheduled for both the work and advisory teams to review and discuss the assigned severity and probability scores in person, so that any disagreements can be discussed until consensus is reached.

**Table 11. Example severity-scoring matrix**

| Severity | | |
|---|---|---|
| Rating | Description | Definition |
| 1 | Minor | Patient unlikely to be harmed |
| 2 | Moderate | Patient could be temporarily harmed |
| 3 | Severe | Patient could be permanently harmed |
| 4 | Critical | Patient could die |

**Table 12. Example probability-scoring matrix**

| Probability | | |
|---|---|---|
| Rating | Description | Definition |
| 1 | Remote | Unlikely to occur (may happen once in 5-30 years) |
| 2 | Uncommon | Possible to occur (may happen once in 2-5 years) |
| 3 | Occasional | Probable to occur (may happen more than once in 1-2 years) |
| 4 | Frequent | Likely to occur (may happen several times within the year) |

**Table 13. Severity and probability scores for each failure mode and effect**

| Task # | | Failure Mode (FM) | | Effect | Scoring | | | Key Failure Mode (KFM) | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| # | Description | # | Description | | Severity (S) | Probability (P) | Hazard Score (HS) | S ≥ 3 | HS ≥ 8 | Controlled | Detectable | Single Point Weakness (SPW) | KFM ? |
| 1.0 | Check right patient | 1 | Right patient not checked | Wrong patient | 3 | 3 | | | | | | | |
| 2.0 | Check right drug | 2 | Right drug not checked | Wrong drug | 3 | 3 | | | | | | | |
| 3.0 | Check right dose | 3 | Right dose not checked | Wrong dose | 3 | 3 | | | | | | | |
| 4.0 | Check right route | 4 | Right route not checked | Wrong route | 3 | 3 | | | | | | | |
| 5.0 | Check right time | 5 | Right time not checked | Wrong time | 2 | 4 | | | | | | | |
| 6.0 | Attach IV tubing to patient | 6 | Tubing not attached to patient | Medication leak | 1 | 2 | | | | | | | |
| | | | | Patient does not receive medication | 3 | 2 | | | | | | | |
| 7.0 | Turn pump on | 7 | Pump is not turned on | Patient does not receive medication | 3 | 1 | | | | | | | |
| 8.0 | Enter drug library | 8 | Do not enter drug library | Nurse not alerted to possible wrong dose | 3 | 4 | | | | | | | |
| 9.0 | Select drug | 9 | Drug not selected | Pump alarm goes off | 1 | 2 | | | | | | | |
| | | 10 | Wrong drug selected | Patient receives wrong drug | 3 | 2 | | | | | | | |
| ... | ... | ... | ... | ... | ... | ... | ... | ... | ... | ... | ... | ... | ... |
| ... | ... | ... | ... | ... | ... | ... | ... | ... | ... | ... | ... | ... | ... |

**Team Meeting # 4:**

**Attendees:** work and advisory teams

**Purpose:** Determine risk scoring matrices and reach consensus about severity and probability ratings for failure modes and effects

**Estimated Duration:** 3 to 4 hours

Now that the failure modes and effects have been reviewed, the work team should present the proposed risk scoring matrix for review and discussion. Any modifications to the risk scoring matrix should be made based on group consensus about the rating scale and definitions.

Severity and probability ratings will be assigned to each pair of failure modes and effects during this meeting. The facilitator should walk the group through each failure mode and the proposed scoring determined by the work group. The advisory and work teams should vote to determine whether the assigned scoring is acceptable as is. Any disagreements should be resolved through discussion to reach consensus. Every team member should have a printed copy of the HFFMEA spreadsheet with proposed scoring, as well as a copy of the risk scoring matrices for severity and probability. If possible, project a working copy of the HFFMEA spreadsheet so the entire team can see it, and have the scribe update scoring in real time.

Depending on the process scope and the number of failure modes and effects to rate, between three and four hours should be scheduled. Bring refreshments for team members if possible.

#### Section 9.5.5.1 Applying the Three Tests

Once the severity and probability of each failure mode and effect has been rated using the severity and probability rating matrices, a series of three tests are applied to determine the key failure modes. The three tests are the Severity Test, the Hazard Score Test, and Single Point Weakness Test. The tests should be applied according to the decision tree process outlined in Figure 24.

**Test 1: Severity Test**

A severity threshold is chosen by looking at the failure modes associated with each score value (or range of score values, depending on the range of your score matrices) and determining which types of failures associated with each score/score range are important to mitigate. Note that if a failure mode has multiple effects, each effect will have its own severity rating. Any failure mode and effect having a severity above or equal to the chosen threshold will automatically become a key failure mode that gets analyzed further. In Table

11, the severity threshold is 3, and so all failure modes associated with a severity rating of 3 or more are classified as KFMs.

**Table 14. Applying the severity test**

| Task # | | Failure Mode (FM) | | Effect | Scoring | | | Key Failure Mode (KFM) | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| # | Description | # | Description | | Severity (S) | Probability (P) | Hazard Score (HS) | S ≥ 3 | HS ≥ 8 | Controlled | Detectable | Single Point Weakness (SPW) | KFM ? |
| 1.0 | Check right patient | 1 | Right patient not checked | Wrong patient | 3 | 3 | | Y | | | | | Y |
| 2.0 | Check right drug | 2 | Right drug not checked | Wrong drug | 3 | 3 | | Y | | | | | Y |
| 3.0 | Check right dose | 3 | Right dose not checked | Wrong dose | 3 | 3 | | Y | | | | | Y |
| 4.0 | Check right route | 4 | Right route not checked | Wrong route | 3 | 3 | | Y | | | | | Y |
| 5.0 | Check right time | 5 | Right time not checked | Wrong time | 2 | 4 | | N | | | | | |
| 6.0 | Attach IV tubing to patient | 6 | Tubing not attached to patient | Medication leak | 1 | 2 | | N | | | | | |
| | | | | Patient does not receive medication | 3 | 2 | | Y | | | | | Y |
| 7.0 | Turn pump on | 7 | Pump is not turned on | Patient does not receive medication | 3 | 1 | | Y | | | | | Y |
| 8.0 | Enter drug library | 8 | Do not enter drug library | Nurse not alerted to possible wrong dose | 3 | 4 | | Y | | | | | Y |
| 9.0 | Select drug | 9 | Drug not selected | Pump alarm goes off | 1 | 2 | | N | | | | | |
| | | 10 | Wrong drug selected | Patient receives wrong drug | 3 | 2 | | Y | | | | | Y |
| ... | ... | ... | ... | ... | ... | ... | ... | ... | ... | ... | ... | ... | ... |
| ... | ... | ... | ... | ... | ... | ... | ... | ... | ... | ... | ... | ... | ... |

### Test 2: Hazard Score Test

To determine the hazard score of each failure mode and effect, the severity and probability scores are multiplied together. Note that if a failure mode has multiple effects, each effect will have its own hazard score. Once hazard scores have been determined, a threshold is again chosen based on of the type of failure modes associated with each hazard score. Any failure mode and effect having a hazard score above or equal to the chosen hazard threshold will be further considered, (Table 15) although it may not become a KFM.

**Table 15. Applying the hazard score test**

| Task # | | Failure Mode (FM) | | Effect | Scoring | | | Key Failure Mode (KFM) | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| # | Description | # | Description | | Severity (S) | Probability (P) | Hazard Score (HS) | HS ≥ 3 | HS ≥ 8 | Controlled | Detectable | Single Point Weakness (SPW) | KFM ? |
| 1.0 | Check right patient | 1 | Right patient not checked | Wrong patient | 3 | 3 | 9 | Y | Y | | | | Y |
| 2.0 | Check right drug | 2 | Right drug not checked | Wrong drug | 3 | 3 | 9 | Y | Y | | | | Y |
| 3.0 | Check right dose | 3 | Right dose not checked | Wrong dose | 3 | 3 | 9 | Y | Y | | | | Y |
| 4.0 | Check right route | 4 | Right route not checked | Wrong route | 3 | 3 | 9 | Y | Y | | | | Y |
| 5.0 | Check right time | 5 | Right time not checked | Wrong time | 2 | 4 | 8 | N | Y | | | | ? |
| 6.0 | Attach IV tubing to patient | 6 | Tubing not attached to patient | Medication leak | 1 | 2 | 2 | N | N | | | | |
| | | | | Patient does not receive medication | 3 | 2 | 6 | Y | N | | | | Y |
| 7.0 | Turn pump on | 7 | Pump is not turned on | Patient does not receive medication | 3 | 1 | 3 | Y | N | | | | Y |
| 8.0 | Enter drug library | 8 | Do not enter drug library | Nurse not alerted to possible wrong dose | 3 | 4 | 12 | Y | Y | | | | Y |
| 9.0 | Select drug | 9 | Drug not selected | Pump alarm goes off | 1 | 2 | 2 | N | N | | | | |
| | | 10 | Wrong drug selected | Patient receives wrong drug | 3 | 2 | 6 | Y | N | | | | Y |
| ... | ... | ... | ... | ... | ... | ... | ... | ... | ... | ... | ... | ... | ... |
| ... | ... | ... | ... | ... | ... | ... | ... | ... | ... | ... | ... | ... | ... |

For those failure modes with scores above or equal to the chosen hazard threshold, two considerations will have to be made to determine whether it is a KFM.

***Consideration 1**: Is the failure mode effectively controlled?*

An effectively controlled failure mode has an intervention that is inherent to the system that eliminates or substantially reduces the likelihood of a system failure or adverse event. For example, for the failure mode associated with process step #8 in Table 16, "Do not enter drug library", some organizations may effectively control this failure mode through the use of a bar code system that identifies the care provider each time the pump is programmed. If a quality lead on the unit follows up with staff each time the drug library is escaped, this failure mode will likely occur infrequently and only with appropriate rationale. In this case, the answer to consideration 1 is yes.

***Consideration 2**: Is the failure mode detectable?*

A detectable failure mode is considered to be an obvious hazard that is likely to be detected and mitigated, and as a result, not requiring an effective control measure.

To determine whether a failure mode is detectable, the following questions should be considered. If any of the following statements are true, the failure mode is NOT detectable and should be analyzed further:

1. There is no possible way to detect the error
2. The failure can be detected only through inspection and is not feasible or readily done
3. Error can be detected with manual inspection but there is no process in place so the detection is left to chance
4. There is a process for double-checks or detection but the process relies on vigilance and/or is applied only to a sample

Those failure modes having a hazard score above the chosen threshold and that are neither effectively controlled nor detectable, are considered KFM, and will be analyzed further.

If a failure mode has a hazard score above the chosen threshold and is either effectively controlled, detectable, or both, it will be documented but will not be analyzed further (Table 16).

**Table 16. Identifying effectively controlled and detectable failure modes**

| Task # | | Failure Mode (FM) | | Effect | Scoring | | | Key Failure Mode (KFM) | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| # | Description | # | Description | | Severity (S) | Probability (P) | Hazard Score (HS) | S ≥ 3 | HS ≥ 8 | Controlled | Detectable | Single Point Weakness (SPW) | KFM ? |
| 1.0 | Check right patient | 1 | Right patient not checked | Wrong patient | 3 | 3 | 9 | Y | Y | | | | Y |
| 2.0 | Check right drug | 2 | Right drug not checked | Wrong drug | 3 | 3 | 9 | Y | Y | | | | Y |
| 3.0 | Check right dose | 3 | Right dose not checked | Wrong dose | 3 | 3 | 9 | Y | Y | | | | Y |
| 4.0 | Check right route | 4 | Right route not checked | Wrong route | 3 | 3 | 9 | Y | Y | | | | Y |
| 5.0 | Check right time | 5 | Right time not checked | Wrong time | 2 | 4 | 4 | N | Y | Y | N | | N |
| 6.0 | Attach IV tubing to patient | 6 | Tubing not attached to patient | Medication leak | 1 | 2 | 2 | N | N | | | | |
| | | | | Patient does not receive medication | 3 | 2 | 6 | Y | N | | | | Y |
| 7.0 | Turn pump on | 7 | Pump is not turned on | Patient does not receive medication | 3 | 1 | 3 | Y | N | | | | Y |
| 8.0 | Enter drug library | 8 | Do not enter drug library | Nurse not alerted to possible wrong dose | 3 | 4 | 12 | Y | Y | | | | Y |
| 9.0 | Select drug | 9 | Drug not selected | Pump alarm goes off | 1 | 2 | 2 | N | N | | | | |
| | | 10 | Wrong drug selected | Patient receives wrong drug | 3 | 2 | 6 | Y | N | | | | Y |
| ... | ... | ... | ... | ... | ... | ... | ... | ... | ... | ... | ... | ... | ... |
| ... | ... | ... | ... | ... | ... | ... | ... | ... | ... | ... | ... | ... | ... |

### Test 3: Single Point Weakness Test

The last test to be applied is the single point weakness test. This test is applied to the failure modes with a hazard score that is less than the chosen threshold. A single point weakness is a failure that on its own would result in a system failure or an adverse event. If a failure mode is identified as a single point weakness, the same two considerations will have to be made as for the hazard-scoring test to determine whether it is a KFM.

***Consideration 1****: Is the failure mode effectively controlled?*

***Consideration 2****: Is the failure mode detectable?*

If the single point weakness is not effectively controlled or detectable, it will be considered a KFM and analyzed further.

If the single point weakness is either effectively controlled, detectable, or both, it will not be considered a key failure mode. It will be documented, but will not be analyzed further (Table 17)

**Table 17. Single point weakness test**

| Task # | | Failure Mode (FM) | | Effect | Scoring | | | Key Failure Mode (KFM) | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| # | Description | # | Description | | Severity (S) | Probability (P) | Hazard Score (HS) | ≥ 3 S | ≥ 8 HS | Controlled | Detectable | Single Point Weakness (SPW) | KFM ? |
| 1.0 | Check right patient | 1 | Right patient not checked | Wrong patient | 3 | 3 | 9 | Y | Y | | | | Y |
| 2.0 | Check right drug | 2 | Right drug not checked | Wrong drug | 3 | 3 | 9 | Y | Y | | | | Y |
| 3.0 | Check right dose | 3 | Right dose not checked | Wrong dose | 3 | 3 | 9 | Y | Y | | | | Y |
| 4.0 | Check right route | 4 | Right route not checked | Wrong route | 3 | 3 | 9 | Y | Y | | | | Y |
| 5.0 | Check right time | 5 | Right time not checked | Wrong time | 2 | 4 | 4 | N | Y | Y | N | | N |
| 6.0 | Attach IV tubing to patient | 6 | Tubing not attached to patient | Medication leak | 1 | 2 | 2 | N | N | N | Y | Y | N |
| | | | | Patient does not receive medication | 3 | 2 | 6 | Y | N | | | | Y |
| 7.0 | Turn pump on | 7 | Pump is not turned on | Patient does not receive medication | 3 | 1 | 3 | Y | N | | | | Y |
| 8.0 | Enter drug library | 8 | Do not enter drug library | Nurse not alerted to possible wrong dose | 3 | 4 | 12 | Y | Y | | | | Y |
| 9.0 | Select drug | 9 | Drug not selected | Pump alarm goes off | 1 | 2 | 2 | N | N | | | N | N |
| | | 10 | Wrong drug selected | Patient receives wrong drug | 3 | 2 | 6 | Y | N | | | | Y |
| ... | ... | ... | ... | ... | ... | ... | ... | ... | ... | ... | ... | ... | ... |
| ... | ... | ... | ... | ... | ... | ... | ... | ... | ... | ... | ... | ... | ... |

Only those failure modes and effects deemed to be KFM through this rating and ranking process will be considered going forward for the HFFMEA.

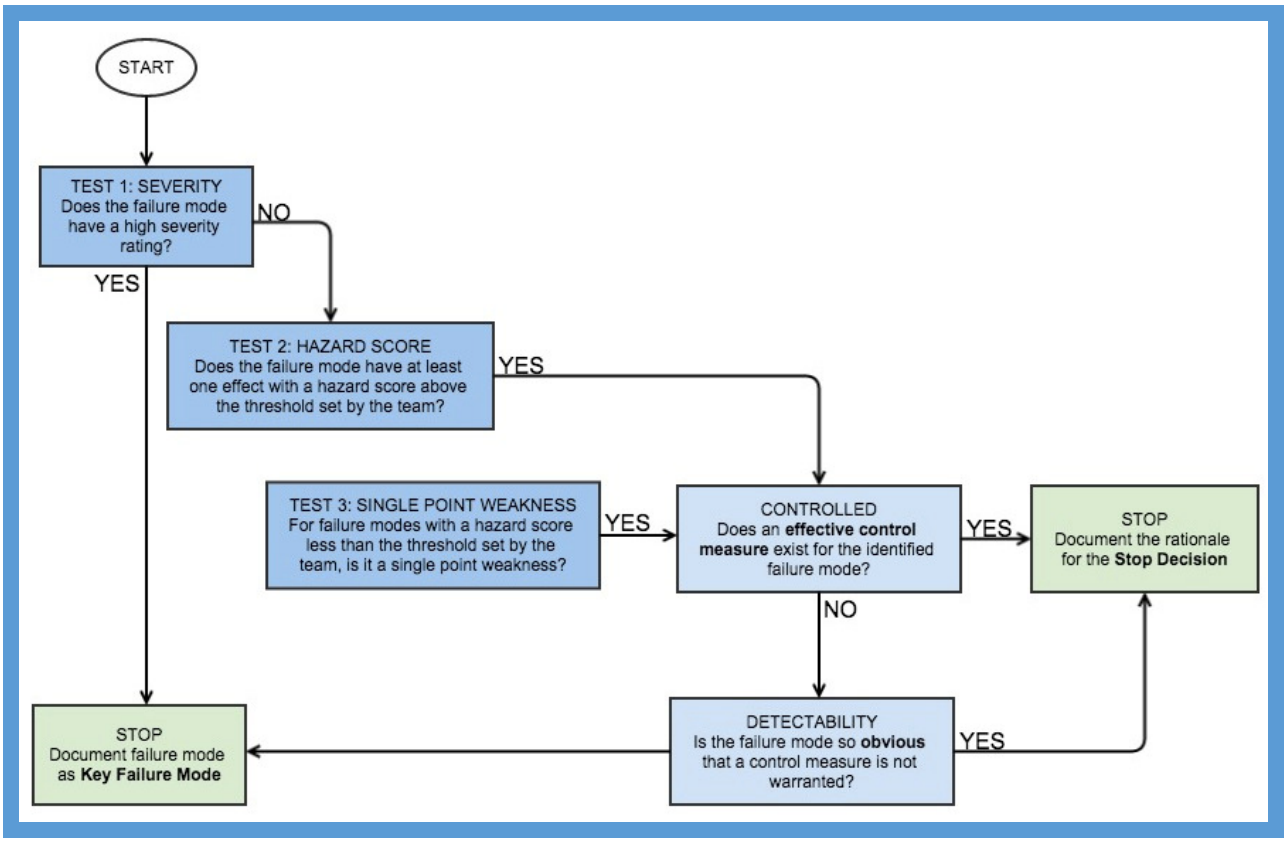


**Figure 24. Decision tree used to determine whether a failure mode is a key failure mode**

### Section 9.5.6. Identify Causes

Only those failure modes determined to be KFM will be considered for the remainder of the analysis. Once the KFMs have been identified, the work team should meet to review the KFMs and begin to identify the causes, or the *whys* behind each KFM. At this stage of the analysis, it is likely the work and advisory teams will have identified a number of causes, which should be captured in the team meeting notes. Any causes should be reviewed, and if relevant, incorporated into the analysis in the HFFMEA spreadsheet next to any of the pertinent KFM and effects.

The work team should then systematically review each KFM and effect and think about the possible causes of that failure mode. When thinking about the possible causes, or the *whys* behind each key failure mode, it is important to go beyond the first, most proximal why, because it is the root causes rather than the proximal causes that are of interest for an HFFMEA. It is important to go deeper than that first, most proximal why, because if the root causes can instead be identified and addressed, you are much more likely to address the real problem, rather than simply adding a patch to the surface of the problem. Identifying and addressing the root causes will increase the chance the risk associated with the KFM will be reduced.

Some common pitfalls to avoid when identifying causes are (1) only thinking about the human-centric causes, and (2) focusing on compliance with established protocols and procedures.

**Think Beyond the Human-Centric Causes**

We are all human and we all make mistakes. Consequently, as the work team thinks about the potential causes of each KFM, make sure to go beyond simply saying the user could perform the wrong action, and consider the underlying reasons why an incorrect action might be performed. Failing to think beyond the human-centric causes will not lead to meaningful system change as is intended for the HFFMEA. To support thinking beyond the human-centric causes continue to ask *why* after a human cause has been identified. For example, for the *administering chemotherapy with an ambulatory infusion pump* process, a cause of the failure mode *tubing not attached to the patient* might be *nurse gets distracted*. Rather than stopping here, the work team should ask why the nurse could get distracted. Perhaps in this case, each nurse is responsible for several patients who all tend to interrupt with questions about their medication. Going beyond the human-centric cause (i.e., distraction in this case) to a system-level cause (i.e., frequent interruptions by patients and high nurse workload), means that mitigating strategies can be developed to lead to meaningful system change. Perhaps if patients were given a dedicated opportunity to talk with a doctor or pharmacist prior to receiving their medications, they would have fewer questions for nurses as their infusions are being set up.

**Think Beyond Compliance with Established Protocols and Procedures**

Staff compliance issues will surface as causes to certain KFM in almost every HFFMEA, however, it is important to note that failing to comply with established protocols and procedures is rarely as a result of rebellion or ill will on the part of staff. Instead, there are almost always broader systems issues at play such as staffing levels, scheduling, unfamiliarity with protocols, unworkable protocols, differing work practices, and other work pressures that enable these deviations. When identifying causes, ensure the work team thinks beyond any compliance issues to identify those underlying system pressures so that meaningful system change can be accomplished through tailored and appropriate mitigating strategies.

When identifying causes, if the work team is unable to think beyond the human-centric or compliance focused causes, it is highly recommended other human factors methods, such as observations (Chapter 4), interviews (Chapter 5), heuristics (Chapter 7) or usability testing (Chapter 8) be used to get to the root causes of why a failure mode could occur.

Once the work team has identified causes for each KFM, the HFFMEA spreadsheet should be circulated to the advisory team for review and any feedback. A meeting with the work and advisory teams should be scheduled to review and discuss the root causes identified for each KFM.

**Team Meeting # 5:**

**Attendees:** work and advisory teams

**Purpose:** finalize root causes for each key failure mode

**Estimated Duration:** 2 to 3 hours

Root causes for each key failure mode will be reviewed, discussed, and finalized during this meeting. The facilitator should walk the group through the causes for each key failure mode. The advisory and work teams should discuss and refine causes with any disagreements being resolved through discussion to reach a consensus.

Every team member should have a printed copy of the HFFMEA spreadsheet. If possible, project a working copy of the HFFMEA spreadsheet so the entire team can see it, and have the scribe update causes in real time.

Depending on the process scope and the number of key failure modes to review, between two and three hours should be scheduled. Bring refreshments for team members if possible.

### Section 9.5.7. Develop and Implement Mitigating Strategies

The final step of an HFFMEA is to develop and implement mitigating strategies that address the root causes of the key failure modes in order to reduce the severity, or likelihood, or increase the detectability of a failure mode. Developing strategies that focus on changing the system, rather than strategies that focus on changing the person, is of the utmost importance. If mitigating strategies aim to change how a person behaves, or how they interact with the system, there may be a temporary improvement, but over time, work pressures and inherent human limitations will drive people towards their former work behaviours to allow them to meet work demands. In contrast, when mitigating strategies focus on the system, sweeping improvements can be made, rather than trying to make changes person by person. Implementing a system-level mitigating strategy means that regardless of the person, or their knowledge of policies, or their awareness or vigilance on a given day, the system is set up to guide people to perform correctly and safely.

To support the development of system-focused, rather than person-focused, mitigating strategies, as well as to compare the relative potential effectiveness of different strategies, it is highly recommended that the Hierarchy of Effectiveness (Section 3.5) be used. The Hierarchy of Effectiveness should be distributed to work and advisory team

members and a meeting should be scheduled for both groups to work together to start to develop mitigating strategies to address the root causes of the KFM.

**Team Meeting # 6:**

**Attendees:** work and advisory teams

**Purpose:** develop mitigating strategies to address root causes for each key failure mode

**Estimated Duration:** 2 to 3 hours

Ideas about how to mitigate the root causes for each key failure mode will be shared and discussed at this meeting. The facilitator should encourage a range of ideas and ensure team members consider the Hierarchy of Effectiveness when proposing and discussing strategies. A strong facilitator will be required to keep the discussion inclusive and moving forward, while still reminding team members to think about the effectiveness of proposed solutions using the Hierarchy of Effectiveness.

Every team member should have a printed copy of the HFFMEA spreadsheet. If possible, project a working copy of the HFFMEA spreadsheet so the entire team can see it, and have the scribe update ideas for mitigating strategies in real time.

Depending on the number of key failure modes, between two and three hours should be scheduled. Bring refreshments for team members if possible.

In addition to how effective a mitigating strategy is likely to be, it is also important to consider whether implementing it is feasible, given the resources available. Once the work and advisory teams have identified a number of possible mitigating strategies that are likely to be effective, the next step is to consider the required resources for proper implementation. A prioritization exercise that weighs the likely effectiveness, required resources, and available resources/feasibility for each mitigating strategy, will have to be completed by the work and advisory teams. There is no prescribed process for prioritizing the implementation strategies; however, a good guiding principle for choosing mitigating strategies is that it is more effective to implement fewer, more resource intense, mitigating strategies that will address higher risk issues than implementing many low-resource mitigating strategies that addresses lower risk issues.

To support this prioritization exercise, a copy of the HFFMEA spreadsheet with possible mitigating strategies should be circulated to the work and advisory teams for review. A meeting should be scheduled to discuss and decide upon which of the proposed strategies will be pushed forward for implementation.

**Team Meeting # 7:**

**Attendees:** work and advisory teams

**Purpose:** prioritize mitigating strategies, create implementation plans, conclude HFFMEA

**Estimated Duration:** 2 to 4 hours

The mitigating strategies put forth in Team Meeting #6 will be reviewed and prioritized based on the likely effectiveness, required resources, and available resources/ feasibility in each case. It is important to have senior advisors present at this meeting as they will have the broad organizational knowledge and authority required to decide which mitigating strategies should be implemented.

Once the group has determined which mitigating strategies to move forward with, the team should develop an implementation plan (Section 9.6, What to Do With a Completed HFFMEA).

The scribe should capture all discussion and any decision points in real-time, ideally, with any notes being projected so all team members can see them.

Depending on the number of mitigating strategies being considered, and how many are likely to move forward for implementation, between two and four hours should be scheduled. Bring refreshments for team members if possible.

Although implementation work will continue, this is the last official meeting of the HFFMEA team.

## Section 9.6. What to do with a Completed HFFMEA

As part of Team Meeting #7, once mitigating strategies have been prioritized and a decision has been made about which solutions will be implemented, a plan needs to be developed to support the successful implementation of each strategy. The plan for each strategy should outline (1) the individuals responsible for implementing the strategy, (2) the outcome measures that will be used to assess success, (3) anticipated timelines, and (4) a plan for proactively evaluating the new failure modes that are likely to be associated with the system changes made through implementing the mitigating strategy.

Each agreed upon mitigating strategy should then be implemented at the healthcare organization using the plan developed during Team Meeting #7. Although no further meetings are typically scheduled for the HFFMEA team beyond Team Meeting #7, those responsible for implementing the mitigating strategies will likely find it helpful to keep in

touch with various team members for support and guidance throughout the implementation process.

It is highly recommended that a summary document be prepared by the work team that outlines the HFFMEA process, team members, key decisions, lessons learned, and progress implementing mitigating strategies to date. This document should be circulated to the advisory team for review and approval before sharing more broadly with the healthcare organization and others. Having such a document can provide a wealth of information for future HFFMEAs and accreditation activities, and is a means of capturing how mitigating strategies came to be implemented

## Section 9.7. Limitations of HFFMEA

Prior to conducting an HFFMEA it is important to consider some of the criticisms and limitations of this method.

### Section 9.7.1. The Resources Required

Like all approaches to FMEA, the resources required to conduct an HFFMEA can be substantial. A team consisting of several professionals is required to meet regularly, and carry out a number of steps to complete an analysis. To address this challenge, the HFFMEA method aims to somewhat reduce the resources required in comparison to the more traditional FMEA methods. This is achieved by moving the failure mode ranking exercise earlier in the analysis so the bulk of the time invested by the group is spent examining those failure modes considered to be the highest risk. Further, to help control the required resources, it is highly recommended that a well-defined process scope be chosen prior to undertaking an HFFMEA.

### Section 9.7.2. Impossible to Identify Every Failure Mode

No matter how much time and effort is spent identifying failure modes, it is impossible to identify every failure mode that could occur. Healthcare systems are extremely complex in comparison to many other industries in which FMEA is used because of the variability introduced by patients and changing patient conditions, and the knowledge, experience, and mental models held by staff. Although every possible failure mode will not be uncovered using this technique, HFFMEA can be relied upon to highlight many failure modes with the potential for serious consequences that are not readily apparent prior to applying the method. If resources allow, applying other human factors methods such as heuristic evaluation (Chapter 7), and usability testing (Chapter 8) during the HFFMEA process can increase the chances of identifying as many failure modes as possible.

### Section 9.7.3. Hazard Scoring is Subjective and Only Allows for Relative Ranking

Assigning hazard scores to each failure mode is subjective, and as such, different analysis teams could assign different hazard scores to the same failure mode. Thus, hazard

scoring only allows for the relative ranking of failure modes. To make the scoring process as robust as possible, it is important that the HFFMEA team score hazards as a group, and that any disagreements are discussed until consensus is reached. The dynamics of the team should also be considered to avoid a situation where a few individuals have a strong influence on scoring. Further, the same team should score all hazards for consistency across the analysis, rather than having different team members rate different groups of failure modes. The hazard scoring process should only be used to help the HFFMEA team separate the high- and low-risk failure modes relative to each other rather than as an absolute or quantitative measure of risk at each process step.

#### Section 9.7.4. Potential for False Positives

The way in which scoring is done for a traditional FMEA means that it is possible for a high severity, low probability failure mode to yield the same risk score as a failure mode that is low severity, but high probability. This can be problematic in healthcare because when evaluating risks to patient safety, a failure mode that is unlikely, but high in severity, is likely to require more attention than a failure mode that is likely, but low in severity. Even one serious patient safety issue is still one too many, and so should be emphasized through this type of analysis. To help address this challenge, the HFFMEA makes use of a rating process that incorporates every high severity failure mode for further consideration regardless of how frequently it might happen.

#### Section 9.7.5. No Guidance for Developing Mitigating Strategies

Traditional FMEA methods do not provide any guidance for developing effective mitigating strategies to address identified failure modes. As such, it is up to the analysis team to propose solutions that will successfully prevent failure modes from occurring. Further, the actual effort required to implement a proposed mitigating strategy and the hazard score attributed to a failure mode do not always match, meaning that at times the score will indicate a need for action, but the cost and effort required are not justified by the risk. To help weigh the benefits and costs, as well as set expectations about how likely a solution is to mitigate a failure mode, the HFFMEA incorporates a hierarchy that can be used to assess a solution's likely effectiveness.

## Section 9.8. Additional Resources

Journal Articles


1. ECRI. (2004). Failure mode and effects analysis: A hands-on guide for healthcare facilities. Health Devices. 33(7); pp.233-243.

2. De Rosier J, Stalhandske E, Bagian JP, Nudell T. (2002). Using health care failure mode and effect analysis™: The VA National Centre for Patient Safety's prospective risk analysis system. Journal of Quality Improvement. 28(5); pp. 248-267.

Web Tools

1. Institute for Healthcare Improvement Failure Modes and Effects Analysis Tool. http://www.ihi.org/knowledge/Pages/Tools/FailureModesandEffectsAnalysisTool.aspx