Failure Mode and Effects Analysis (FMEA)

An Advisor's Guide

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How to Use this Guide

This guide was developed by the DoD Patient Safety Center to assist Patient Safety Managers in their role as FMEA team advisors and does not serve as the DoD manual on FMEAs. Review the entire guide before starting an FMEA. It is a guide to be used as a check sheet during the FMEA, to help ensure that each step of the FMEA has been fully completed and documented. Areas of the FMEA projects that have proven to be obstacles or stumbling points for other FMEA teams are underlined for your reference. If you have questions or concerns the Patient Safety Center can serve as a resource to assist in the completion of your FMEA.

ATTACHMENTS:

A. FMEA Overview (Powerpoint presentation)
B. FMEA Documentation SHEET AND Hazard Scoring Worksheets (Excel)

Section 1: Introduction to Failure Mode and Effects Analysis

Overview

Failure Mode and Effects Analysis (FMEA) is a proactive, team based, and systematic approach for identifying the ways a process or design can fail, why it might fail, and how it can be made safer. FMEA may also be referred to as Failure Mode Effect and Criticality Analysis (FMECA) or Healthcare Failure Mode and Effects analysis (HFMEA™ or HCFMEA). These are just different names for a proactive risk assessment.

FMEAs take a systems approach to finding the weaknesses in the processes, assessing the effects these weaknesses have on the system, and most importantly fixing the weaknesses before an event occurs. Putting fixes in place that eliminate or reduce the risk of the failure modes will result in a safer and more efficient system from which both the patients and the staff benefit.

The majority of FMEAs in healthcare are conducted on a process that is already in place. These FMEAs should analyze the actual process in the military treatment facility (MTF), not the "ideal" process. An FMEA can also be conducted on a process that is going to be revised or a new process that is not yet implemented (e.g. implementing an electronic records system, purchasing and implementing new equipment, redesigning the floor or workspace layout). Either option will fulfill the Joint Commission Accreditation of Healthcare Organization's (JCAHO) requirement to conduct one proactive risk assessment per year.

The FMEA process will also further develop the staff's systems thinking. Working on the analysis of a process from a systems perspective before an event occurs removes the cultural attitudes toward blame that have to be dealt with after an event. The FMEA will better prepare the staff to address events from a systems perspective, focusing on how the system sets up individuals for failure rather than trying to pin failure on individuals. It is important to remember that system failures can impact ANYONE and to reiterate this in your MTF.

Differences from Root Cause Analysis (RCA)

An FMEA is proactive whereas an RCA is reactive. An FMEA is not looking at a specific event(s), but looking at a specific process. Because the FMEA is analyzing a process, the flow chart for an FMEA is sequential versus the RCA flowchart that is a timeline. An FMEA asks, "How could the system fail?" and the RCA asks, "Why did the system fail?"

Because the FMEA is focusing on a process, the fear and resistance that often occurs in response to an RCA is removed from the FMEA. The findings and actions in an FMEA prevent failures before they occur, but the findings and actions in an RCA prevent failures from reoccurring. The goal in both an FMEA and RCA is to improve patient safety through an analysis of system weaknesses conducted by a multidisciplinary team.

Section 2: Initiating and Preparing for the FMEA

Role of the Advisor

The advisor is a person who possesses knowledge of the FMEA methods. This person does not require knowledge of the process being reviewed, rather is a person who works as an advisor to the FMEA team working closely with the team leader. The advisor must work with the executive staff during the selection of the FMEA process and the team members, and guide the team through the steps of an FMEA. The following are key items for the advisor:

- Understand the FMEA methodologies and tools.
- Work with the team leader prior to the first meeting to ensure the leader understands the FMEA process and is well prepared to lead the FMEA team.
- Assist the team leader with logistics, such as meeting rooms, meeting times, tools, etc. and communications with the team members.
- Advisor works with the executive staff and updates them throughout the FMEA.
- Ensure that the FMEA is well documented.
- Serve in this role throughout the course of the FMEA, being present for each meeting and maintaining her/his role as FMEA advisor, not team member or leader.
- Monitor the action plan, making certain that the FMEA is fully completed.

Check the steps and document progress before moving on:

- ❑ Do I understand my role as advisor?
- ❑ Am I prepared to brief the executive staff, the team leader and the FMEA team on the FMEA methodology?

Role of Leadership

The leadership must also understand FMEA methodology and the value of FMEAs as part of the patient safety program within their MTF. Leadership engagement is essential to ensure the FMEA is given the appropriate priority in the annual MTF planning process. Selection of the FMEA process should be a part of strategic planning initiatives.

Once an FMEA process has been decided upon the formal chartering of the team should come from the leadership. The leadership should support the role the team members play in the MTF patient safety efforts and thank them for their participation. It is also important that the MTF leadership communicate with the leadership of the team members' supervisors, helping the supervisors understand the importance of these staff members taking time to serve on the FMEA team and the potential benefits to the organization.

The FMEA should be briefed to the executive staff upon completion. If the executive staff is willing it could be briefed on an ongoing basis while the FMEA is conducted. In addition, follow-up on action items should be included in the quarterly and annual MTF patient safety reports.

Check the steps and document progress before moving on:

- ❑ Is leadership aware of and supportive of this FMEA?
- ❑ Has the leadership prepared to communicate the importance of the FMEA to the team members and supervisors?
- ❑ Is leadership prepared to review and support findings and action plan?

Choosing a Process

Choosing a process on which to perform an FMEA is the crucial first step. Many processes within healthcare are high risk, thus it is important to consider the processes within your MTF that pose the most risk to your patients' safety.

To choose your process there are a number of areas to evaluate. Assess the processes defined as high risk by the Joint Commission Accreditation of Health Care Organizations (JCAHO) in your MTF. Review the literature from medical and quality journals on high risk process areas. Review any literature and safety alerts sent out by the DoD, your Service, JCAHO, FDA, Veterans Affairs National Center for Patient Safety, or other safety organizations. Use your MTF resources to help identify the high risk processes in your MTF: patient safety event reports, CHCS, medical records, performance measures, and any other pertinent resources. Look for processes with a history of reported events or processes. Utilize your process experts, staff

and leadership, find out what areas they have identified as high risk through first-hand knowledge. Remember it is important to choose a process that is one of the highest risk processes in your MTF.

Check the steps and document progress before moving on:

- ❑ Why is this process high risk and how did we identify it as high risk?
- ❑ What is the effect of this process on the safety of our patients and/or staff?

Forming a Team

Assemble a multidisciplinary team that works with the process being analyzed. If the process covers many areas, try to include a team member from each area. If possible, also include a team member who is unfamiliar with the process, as this person will bring a fresh view to the process and will not have the "this is how it's done" bias.

One team member, an accepted leader with comprehensive knowledge of the process being analyzed, should be chosen as team leader. Remember, the team advisor assists the team leader with the FMEA process.

Check the steps and document progress before moving on:

- ❑ Are all areas involved in this process represented on the team or willing to serve as consultants?
- ❑ Have the team members been informed, ideally with a letter from the MTF Commander?
- ❑ Has a meeting been scheduled with the team leader?

Preparing for the FMEA

The advisor and team leader should meet prior to the first team meeting to discuss how the process was chosen, determine what information needs to be collected, and what information needs to be distributed to the team members before the meeting. This information gathering includes all applicable instructions, clinical practice guidelines, policies, current literature, reference materials, etc. that is pertinent to the process.

The advisor should also assemble any data that is available - patient safety events reported, data from CHCS or other clinical information systems, discharge data; any data sources which are collected internally or sent externally that contains pertinent information about the process being examined.

Draft an initial, "high-level" flowchart of the process being examined. One way to achieve this would be to collect and compile information on the process from the team members and flowchart it for the first meeting. Another way is to work with the team leader to draft the flowchart. This initial flowchart will assist the team in determining if they need to narrow the scope of the process.

Check the steps and document progress before moving on:

- ❑ Have we collected all the information pertinent to this process?
- ❑ Do we have an initial flowchart of the process?
- ❑ Have we sent any preparatory information to the team members?
- ❑ Is the team leader prepared for this FMEA?

Section 3: Getting Started on the FMEA

Introduction to FMEA

During the first team meeting, the advisor will explain her/his role during the FMEA process and use the PowerPoint presentation (Attachment A) provided to introduce team members to the FMEA process. In addition, it is essential to answer any questions the team members have and then allow the team leader to take over.

Narrowing the Scope

This part of the FMEA process is truly a make or break point for your FMEA. FMEAs are not a tool that will "save the world" and fix all the failure points in your MTF at one time. Choose a manageable and focused process or specific part of the process (sub-process) that allows the team to conduct an effective FMEA that will find and fix all the critical failure modes within those process boundaries. FMEAs are already challenging and when a process scope is too large it becomes extremely difficult to conduct a thorough analysis.

To narrow the scope of the process, use the initial flowchart to discuss the high-level process steps. Discuss which areas of the process have known weaknesses, consider the seriousness of weaknesses, and apply the team and staff's expert knowledge of the system. Narrow the scope through discussion of process boundaries, and determine the first and final steps of the process or sub-process. Look for areas where you have implemented new systems, redesigned/reworked systems or areas that will soon be changing their processes or equipment, all of which may result in process weaknesses. Use this analysis and discussion about the process to determine the process boundaries, defined by the first and final steps your FMEA process. Once you've determined the scope of your process, use this to help keep the team on track throughout your FMEA.

Check the steps and document progress before moving on:

- ❑ What is the scope of our process, where does it begin and end?
- ❑ Why did we choose this specific area of the process?
- ❑ Is this a manageable FMEA project?

Flowcharting the Process

Staying within the scope of the FMEA, the team should clearly define each step of the process. Remember, this should be a flow chart of the process that occurs in your MTF, not the ideal process. Using a scribe who is not a core team member, the advisor can serve in the role. Record the steps of the process on flipcharts or post-it notes. Each step should illustrate an action.

SnapCharT®, the flowcharting piece of the TapRooT® software, should be used for your flowcharts. We encourage you to use the pen/pencil method of flowcharting with flipcharts and post-its *during* the meetings. This allows the team to see the whole picture and keeps them more active in the flowcharting process. Document the flowchart in SnapCharT® once nearing completion and document changes after each meeting. Bring the SnapCharT® for the team to review and utilize as a working document at the next meeting.

Flowchart the process to reflect the most often used sequence of steps. The flowchart for an FMEA may also have decision points. For example, if the first step is "Doctor prescribes the order out loud", if this verbal order is accepted the next step is "The nurse transcribes the verbal order". If the order is not accepted in the next step may be "The doctor transcribes the verbal order". The team's goal during the flowcharting process is to provide all the process steps and the team advisor will work with the team leader to determine the best way to chart these steps, and to document the flow chart in SnapCharT®.

Validating the flowchart

Once the flowchart is completed and documented, share it with other staff members that work in the process for their input. It is especially important to ensure areas that are part of the process, but do not have members on the FMEA team, thoroughly review the process. The best way to ensure that the true process is captured is to have a team member(s) observe the process and verify the flowchart is correct.

Check the steps and document progress before moving on:

- ❑ Has the team had others who work in the process and areas that do not have team members participating on the FMEA, review the flow chart?
- ❑ Has the process been observed using with the flowchart?
- ❑ Can I hand this flowchart to someone who doesn't know the process and they will fully understand the process?

Finding Failure Modes

Using the flowchart the team should go step by step through the process discovering the failure modes by asking, "What could go wrong at this step?" This will help the team identify the failure modes at each step. Some steps may not possess any failure modes and the team may find multiple failure modes in other steps.

When analyzing the process for failure modes, think about what the desired outcome of your process is and what could happen to prevent that desired outcome. Finding the failure modes is difficult because it requires the team's knowledge AND creativity. Use the teams' experience, for example, encouraging team members to reflect on near misses and actual failure modes that incurred in the process or failure modes identified in other MTFs. Apply brainstorming techniques to help the team "think outside the box" and to encourage all team members to participate.

The advisor must guide the team to focus only on the failure modes at this point and not jump ahead. It is very easy for the team to start throwing out all the potential causes for a failure mode, but doing this will create unnecessary work.

Validating the Failure Modes

Again, once the failure modes are identified for each step, the team should validate them with staff members from any areas that are included in the process, but are not active FMEA team members. Another way to get additional input or validation is to invite these staff members to attend the meeting when the team is discussing failure modes in their process areas.

Whether you use the VA HFMEA™ method or another FMEA method, an excel worksheet (Attachment B) has been provided for the documentation of the failure modes and FMEA. You may additionally document failure modes on the flowchart; place them below the process steps using the oval shapes. This method can be seen in the example in Section 5.

Check the steps and document progress before moving on:

- ❑ Has the team looked for failure modes in each step of the process?
- ❑ Has the team focused only on failure modes, not the potential causes?
- ❑ Have the failure modes been reviewed by others who work in the process, especially any areas which do not have team members participating on the FMEA?
- ❑ Has the team worked creatively to think of ways the system could fail that has not been seen before or has never happened before?

Determining Effects and Risks of the Failure Modes

The next part is to determine the effects and the risks of the identified failure modes. The team decides what the effect is of each failure mode - what could happen if this failure occurred, what might be the consequence of the failure? For example, if the process has direct contact with the patient, what is the effect on the patient?

Next the team conducts a hazard analysis that allows the team to estimate and prioritize the risk of the failure modes. There are a number of similar numeric methods that are used for hazard analysis. The VA hazard analysis matrix and a Risk Priority Number (RPN) example are included in the FMEA tools in Section 5 as two hazard scoring options. The hazard analysis determines the severity, probability and detectability of a failure mode.

The team should determine the effects and conduct the hazard analysis of the failure modes one at a time. Once the scoring methodology has been thoroughly explained to the team members, this step can be done individually as "take home" work. The advisor can compile the scores for discussion at the next meeting or the team can score them together during the next meeting. There may be disagreement about the scoring; encourage the team to proceed with the higher score, it is a safe option that helps maintain the flow of the meeting.

After all failure modes have been analyzed they need to be prioritized. When using the VA methodology, continue with the failure modes where the scoring resulted in "Proceed? = Yes". When using alternative RPN methods, list or chart the failure modes from the highest hazard score to the lowest hazard score. Determine the RPN cutoff number and proceed with the failure modes that had RPNs higher than the cutoff. This will allow the team to focus on the failure modes that have the most risk to the patients and set aside the failure modes that have an acceptable level of risk.

Check the steps and document progress before moving on:

- ❑ Were the effects of each failure mode determined?
- ❑ Was a hazard analysis and score assigned to each failure mode?
- ❑ What are the failure modes that have the highest risk? What are the failure modes that have an acceptable risk?

Potential Causes

Now the team has narrowed the failure modes down to those that bear the most risk. Each failure mode may have a number of potential causes – situations that would cause the failure mode to occur. <u>It is essential to focus on human factors, process and systems issues that may cause the failure modes</u>.

The team can use brainstorming, current literature, and any other resources to help them identify the potential causes of each failure mode listed. As the advisor, make use of the TapRooT Root Cause Tree categories to encourage the team to consider areas of a system that may not be readily apparent. Other quality improvement tools like cause and effect (fish bone) diagrams and systems models as checklists to make certain all pieces of a system are considered.

Utilize a round robin technique to ensure that all team members participate. Encourage the team leader to ask, "Why could this failure mode occur?" For example if the failure mode is "The equipment does not turn on" ask, "Why could the equipment not turn on?" Verbal repetition of the failure modes during scoring and while finding causes will help keep the team on track. Encourage the group to be creative and find causes that may not be obvious. Document all the

potential causes for each failure mode. Analyze each cause and prioritize the causes that place the highest risks on your system.

Check the steps and document progress before moving on:

- ❑ Were potential causes determined for each failure mode?
- ❑ Were the TapRooT Root Cause Tree and the JCAHO matrix used to help encourage the team to contemplate system factors?
- ❑ Were potential causes prioritized?

Action Plans

The next step is to develop action items for each potential cause that will eliminate or reduce the risk of that cause. Again, utilize the other resources available to you. Use the literature and research materials collected in the preparation stage and search for any additional information on best practices in risk reduction for the process. Also use other resources and specialties in your MTF or on base, such as experts in human factors working in behavioral health and aerospace physiology. If a facility or preventative maintenance cause was found work with the facility and/or PM staff to develop an appropriate action. If an equipment cause was found consult with the biomedical engineering staff. Again, use your resources!

When developing actions, it is essential to consider the effects of that action on the entire process. A new way of doing something isn't always a better way. The goal is to eliminate or reduce that cause without creating new failure modes or potential causes in that or other parts of the process. If possible, prototype or test the actions before they are fully implemented. Other ways to evaluate actions are to consider how the action is going to change the process by reviewing the flowchart the team developed during the FMEA or re-assign a RPN to the failure mode with the action in place.

Outcome measures are developed to evaluate the effectiveness of the action after implementation. This will allow the team to verify that each action removed or reduced the potential cause it addressed. Upon measuring the action, if the action did not reduce or increased the weakness in the system, a new action for that cause must be developed. It is possible for

actions to have unintended consequences and these need to be addressed or they will lead to new systems problems. To develop new actions work with the person responsible for the ineffective action and leadership in the area addressed by the action. If necessary, reconvene the team to discuss the ineffective outcome measure and develop new actions for that potential cause.

Once actions are developed for each potential cause, they must be presented to leadership for approval and buy-in. Leadership buy-in is necessary, as leadership drives many actions – think about actions involving cultural changes, purchasing capability, policy decisions, enforcement of policy/procedure etc.

Each action item must have a responsible person/position clearly identified to ensure implementation and follow-up. It is best to identify a person and their position as this person may leave prior to completion and follow-up. Remember that the best person to carry out action(s) may not be a team member and other staff members in the MTF should be utilized. It is also essential to designate a timeframe for implementation of each action. The advisor should monitor actions to make sure they meet their completion dates and prove to be successful through the outcome measures.

Check the steps and document progress before moving on:

- ❑ Was an action and action outcome measure developed for each high-risk potential cause?
- ❑ Did leadership approve these actions?
- ❑ What effect will the action have on this system? Was the action tested or prototyped?
- ❑ Was a timeline set for completion and measurement of the action plan?

Sharing the results

After investing MTF staff and resources into conducting a thorough systems analysis it is essential to share and distribute your findings. Think about other systems within your MTF that may have the same failure modes. If you choose a sub-process are there steps in the larger process with the same failure modes. For example:

- After an FMEA on the identification process in the ER, apply relevant findings to the identification process in all inpatient and outpatient areas.
- After an FMEA found a failure mode related to medication or equipment, what other areas use that medication or equipment or is this a universal failure mode that applies to many types of medication or equipment?
- After an FMEA which finds the MTF culture to be a potential cause of failure modes in the system, consider other areas within the MTF where this culture affects the system and share the findings.

Consider what findings you can apply to other areas in your MTF. If there were failure modes that result in high risks within your MTF that could exist in other MTFs share your findings with your Service and the DoD level. After evaluating your actions, repeat the sharing process, communicating the effective actions throughout your MTF, Service, and DoD. This allows your work to truly have a system-wide impact.

Check the steps and document progress before moving on:

- ❑ Significant findings were shared across the MTF and if appropriate with the Service and DoD?
- ❑ Effective actions were shared across the MTF and if appropriate with the Service and DoD?

Team Debrief

Once the FMEA team has developed the action plan and assigned responsibilities reconvene the team to thank them for their participation, update on action items, and debrief the FMEA project. Ask for feedback from the team about what they got out of the project, tools they found useful or difficult, suggestions for improvement of the FMEA methods and recommendations for future FMEA, and thoughts on processes to be addressed by the next FMEA project.

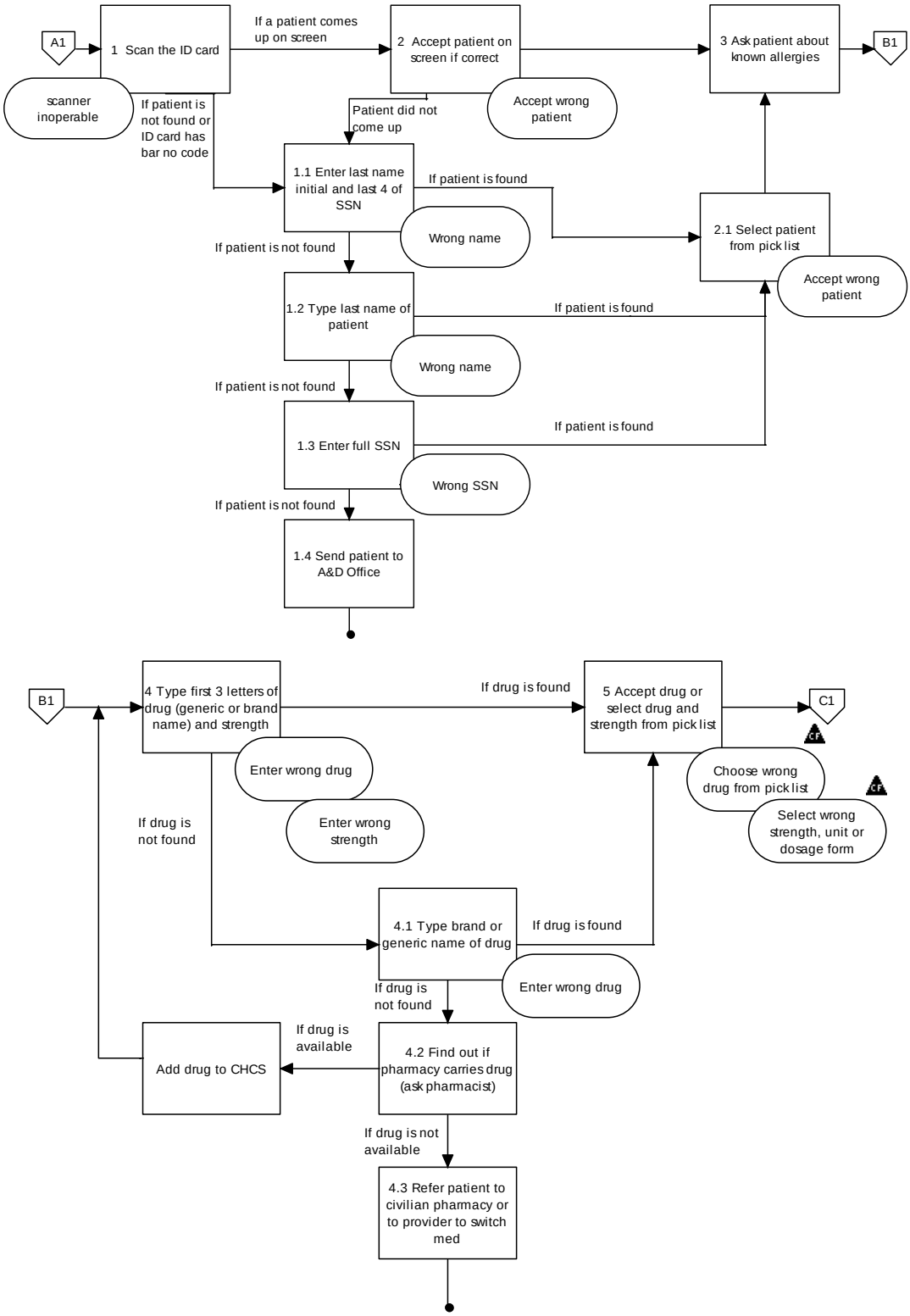
Remember that like anything, FMEAs and systems analyses will get easier with time and practice. Your hard work is significant and improves patient safety in your MTF and the DoD - congratulate yourselves on a job well done.

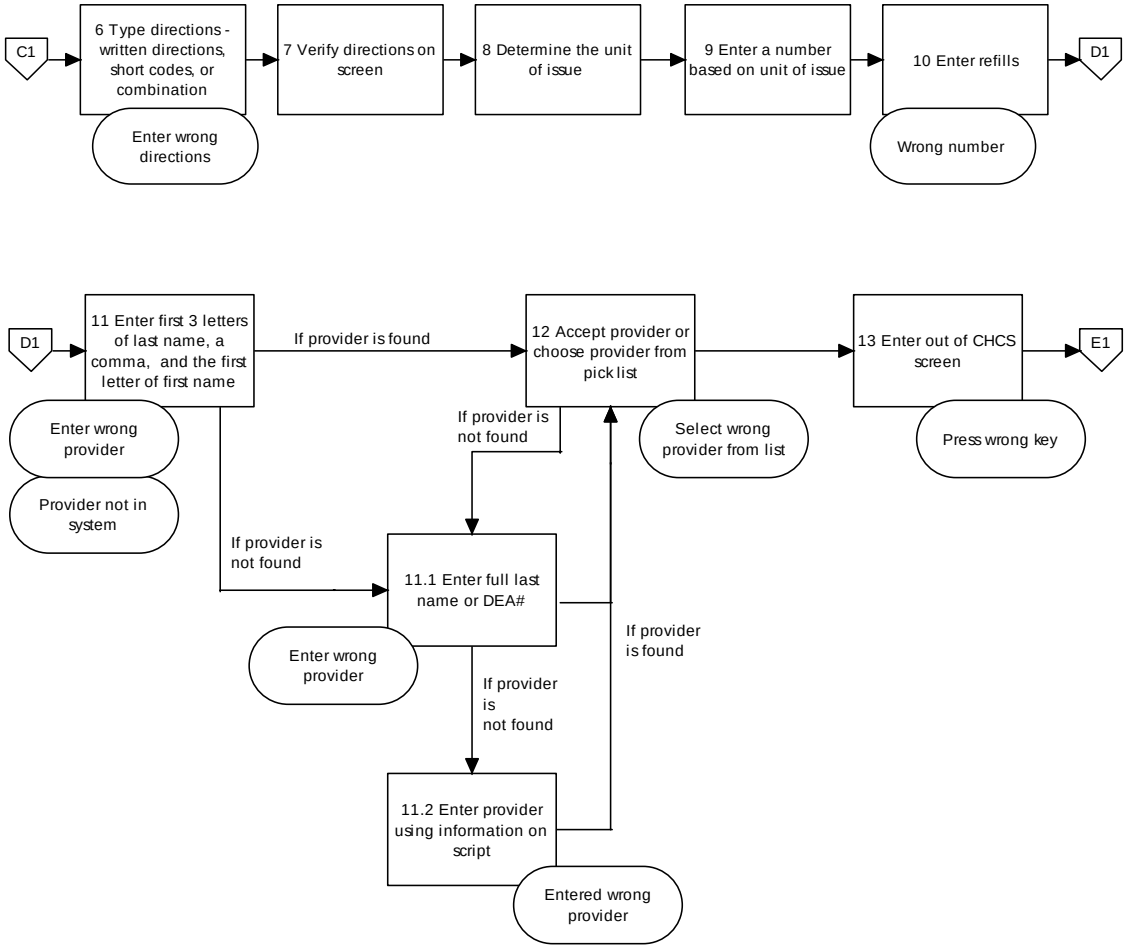
Section 4: Example of FMEA Documentation

The following FMEA has been provided as an example of the documentation that must be completed during an FMEA. The example was provided courtesy of Wright Patterson Air Force Base utilized the VA HFMEA™ methodology and has been modified.

Failure Mode and Effects Analysis				
FMEA Name	FMEA Example			
FMEA Number	2003-01			
Process	Medication Transcription Process			
Why was this process chosen?	After discussing the medication processes with the staff they highlighted the medication process as an area where they often find problems. The medication has also been highlighted as a high-risk process by JCAHO and other national bodies as an area to improve patient safety through systems analysis. Upon reviewing the MTF MEDMARX data we determined that the transcription process was reporting more systems weaknesses than the other medication process steps and the remote outpatient new prescription process was also seen to be reporting a higher number of events. We discussed the process with pharmacists in the three processes: inpatient, outpatient, and remote outpatient who also confirmed the remote outpatient pharmacy process had the most system's problems and set-ups for errors.			
Process Scope	Medication transcription process for new scriptes in the remote (not located in hospital) outpatient clinic. Process started when patient presented new script to window and completed when prescription is completely entered into CHCS.			
Core Team	*Role*	*Name*	*Position*	*Department*
	Team Leader	A. Barrett	Pharmacist	Outpatient Pharmacy
	Team Member	C. Doris	Pharmacy Tech	Outpatient Pharmacy
	Team Member	E. Fitch	Pharmacy Tech	Inpatient Pharmacy
	Team Member	G. Hallow	Doctor	
	Advisor & Scribe	I. Jenkins	PSM	Quality
	Consultant	K. Lamont	Biomedical Engineer	Facilities
Prepared By	I. Jenkins, Patient Safety Manager			
Team Debrief / Comments	Will apply these principles back in our positions. Liked conducting the project over 3 continuous days, rather than spreading it out over a number of weeks. Found hazard Analysis was confusing to use. Difficult to use TapRooT Root Cause tree with all team members, in future facilitate team to look at all areas without having to go through tree.			
FMEA Date	20-Dec-02	*Comments:* Actions will be monitored by PSM.		
Revision Date(s)		*Comments:*		
		Comments:		
		Comments:		

Flowchart Example




C1
6 Type directions - written directions, short codes, or combination
Enter wrong directions
7 Verify directions on screen
8 Determine the unit of issue
9 Enter a number based on unit of issue
10 Enter refills
Wrong number
D1
D1
11 Enter first 3 letters of last name, a comma, and the first letter of first name
Enter wrong provider
Provider not in system
If provider is found
12 Accept provider or choose provider from pick list
If provider is not found
Select wrong provider from list
13 Enter out of CHCS screen
Press wrong key
E1
If provider is not found
11.1 Enter full last name or DEA#
Enter wrong provider
If provider is found
If provider is not found
11.2 Enter provider using information on script
Entered wrong provider
E1
14 Clinical Screening checks for allergies, interactions, overlaps, or duplication
If no warning found
F1
Allergy/Interaction not in CHCS
If indications found
15 Override warning
16 Clarify w/ patient or provider
17 Do Not Fill Script

FMEA Name:	Medication Documentation for new scripts in a remote outpatient clinic								
			Scoring			Decision Analysis				
Process Step	Failure Mode	Potential Cause	Severity	Prob-ability	HAZ score	Single point weakness	Existing control measure	Detect-ability	Proceed	Reason for Stopping
1	Scanner Inoperable	→	**1**	**4**	**4**	**---**			**No**	There is another scanner in place
1+2	Enter wrong name or SSN or accept wrong patient	→	**1**	**4**	**4**	**---**	**Y**		**No**	There is a double check of the patient's last 4 SSN vs. the prescription and a review of the prescription with the patient
5	Enter wrong drug or choose wrong drug from pick list		**4**	**4**	**16**	**---**	**N**	**N**	**Yes**	
		Rushing, putting expediency over safety, Employee Communications NI	4	4	16	---	N	N	Yes	
		Lighting makes it difficult to see list and results in fatigue, Lights NI	4	4	16	---	N	N	Yes	
		Distracted - Noisy	4	4	16	---	N	N	Yes	
		Extreme temps result in distractions - Hot/cold	4	4	16	---	N	N	Yes	
		Difficult to see list - the display is too small - Displays NI	4	4	16	---	N	N	Yes	
		Look alike drug names placed near each other - Displays NI	4	4	16	---	N	N	Yes	
5	Enter wrong strength, select wrong strength, unit, or dosage form from pick list		**4**	**4**	**16**	**---**	**N**	**N**	**Yes**	
		Difficult to see list - the display is too small - Displays NI	4	4	16	---	N	N	Yes	
		Drug name field on second screen doesn't have enough character space to display strength - Displays NI	4	4	16	---	N	N	Yes	
		Different strengths, units, dosages placed near each other - Displays NI	4	4	16	---	N	N	Yes	
		Rx from doctor is poorly legible (pharm asks another pharmacist what the script is) - Turnover Process NI	4	4	16	---	N	N	Yes	

Action Plan Example

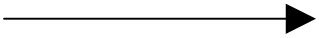
FMEA Name:	Medication Documentation for new scripts in a remote outpatient clinic				
			Action Plan		
Process Step	Failure Mode	Potential Cause	Action number	Eliminate, control, or accept	Action
1	Scanner Inoperable	→			
1+2	Enter wrong name or SSN or accept wrong patient	→			
5	Enter wrong drug or choose wrong drug from pick list				
		Rushing, putting expediency over safety, Employee Communications NI	1	Control	Track the number of times safety is brought up in the daily meetings vs. the number of times speed/waiting times are discussed until the survey is administered. Present the validated problem to management with the understanding that wait times are important, the pharmacy is aware of that and doesn't need to be emphasized on a daily basis.Educate the leadership on the emphasis on wait time creates on the patient safety culture that puts expediency over safety (staff meetings, etc.) unless there is an event. Pull the minutes to look for the wait times.
		Lighting makes it difficult to see list and results in fatigue, Lights NI	2	Control	Have the BEEs do an assessment of the environment, including lighting, heating/cooling, and noise. Utilize BEEs recommendations to take appropriate actions.
		Distracted - Noisy	2	Control	See 2 above
		Extreme temps result in distractions - Hot/cold	3	Eliminate	Monitor temperature for one week. Present temperatures to Facilities and Management. Also explain that the space was not designed for it's current usage.
		Difficult to see list - the display is too small - Displays NI	4	Eliminate	Order one new large flat screen monitors and PCs (if needed) for the pharmacy.
		Look alike drug names placed near each other - Displays NI	5	Accept	Can not be fixed, because there is no way to identify a problem until someone makes a mistake.
5	Enter wrong strength, select wrong strength, unit, or dosage form from pick list				
		Difficult to see list - the display is too small - Displays NI	3	Eliminate	See Action 4 above
		Drug name field on second screen doesn't have enough character space to display strength - Displays NI	6	Control	Print the MTF's drug names as they appear after the drug is chosen on the prescription order entry. Identify the drugs whose strength does not appear on the second screen. Revise drug names in the MTF's drug file so the strength appears after the drug is chosen during prescription order entry in CHCS. Monitor the drug names on a six-month basis.
		Different strengths, units, dosages placed near each other - Displays NI	7	Accept	Can not be fixed, because there is no way to identify a problem until someone makes a mistake.
		Rx from doctor is poorly legible (pharm asks another pharmacist what the script is) - Turnover Process NI	8.1	Accept	Monitor the illegible scripts. Using a check sheet, count the number of time a doctor needs to be called by recording each call. At the end of the month use the list to send a letter to each doctor letting them know the number of illegible scripts that were received in the pharmacy. Also send a copy of the results to the commander.
			8.2	Accept	Encourage patients to make sure they're scripts are legible through a campaign - "Can you read your prescription? Ensure that you can read your prescription before you leave your doctor's office."

Section 5: FMEA Tools

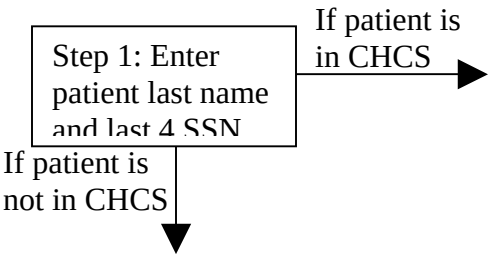
Key to FMEA Flowcharts

Process Step

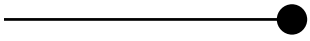
Failure Mode



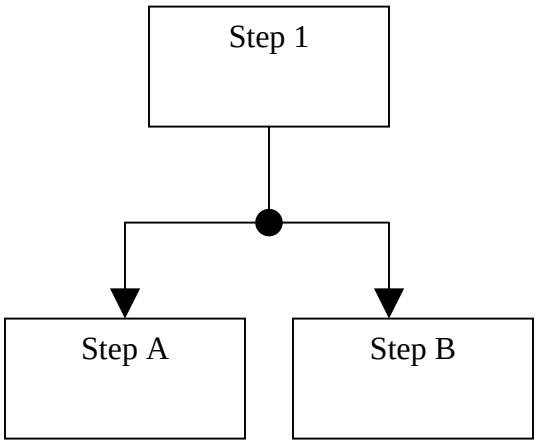
Process Flow



If… then – Dependent on the outcome in process step one



Process ends



Decision point - From Step One, decision maker chooses Step A or Step B

High hazard failure mode

Risk Assessment Tools

VA Hazard Analysis Matrix

Developed by the VA National Center for Patient Safety

SEVERITY RATING	
Catastrophic (4) Failure could cause death or injury	**Major (3)** Failure causes a high degree of customer dissatisfaction
Patient Outcome: Death or major permanent loss (sensory, motor, physiologic, or intellectual), suicide, rape, hemolytic transfusion reaction, Surgery/procedure on the wrong patient or body party, infant abduction or infant discharge to the wrong family. Visitor Outcome: Death or hospitalization of 3 or more. Staff Outcome: Death or hospitalization of 3 or more staff. Equipment or facility: Damage equal to or more than $250,000 Fire: Any fire that grows larger than an incipient stage	Patient Outcome: Permanent lessening of bodily functioning (sensory, motor, physiologic, or intellectual), disfigurement, surgical intervention required, increased length of stay for 3 or more patients, increased level of care for 3 or more patients. Visitor Outcome: Hospitalization of 1 or 2 visitors Staff Outcome: Hospitalization of 1 or 2 staff or 3 or more staff experiencing lost time or restricted duty injuries or illnesses Equipment or facility: Damage equal to or more than $100,000 Fire: N/A – see moderate or catastrophic
Moderate (2) Failure can be overcome with modifications to the process or product, but there is minor performance loss.	**Minor (1)** Failure would not be noticeable to the customer and would not affect the delivery of the service or product.
Patient Outcome: Increased length of stay or increased level of care for 1 or 2 patients. Visitor Outcome: Evaluation or treatment of 1 or 2 visitors (less than hospitalization) Staff Outcome: Medical expenses, lost time, or restricted-duty injuries or illness for 1 or 2 staff. Equipment or facility: Damage more than $10,000 but less than $100,000 Fire: Incipient stage or smaller	Patient Outcome: No injury nor increased length of stay nor increased level of care. Visitor Outcome: Evaluated and no treatment required or refused treatment. Staff Outcome: First aid treatment only, with no lost time or restricted-duty injuries or illnesses. 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: N/A – see moderate or catastrophic

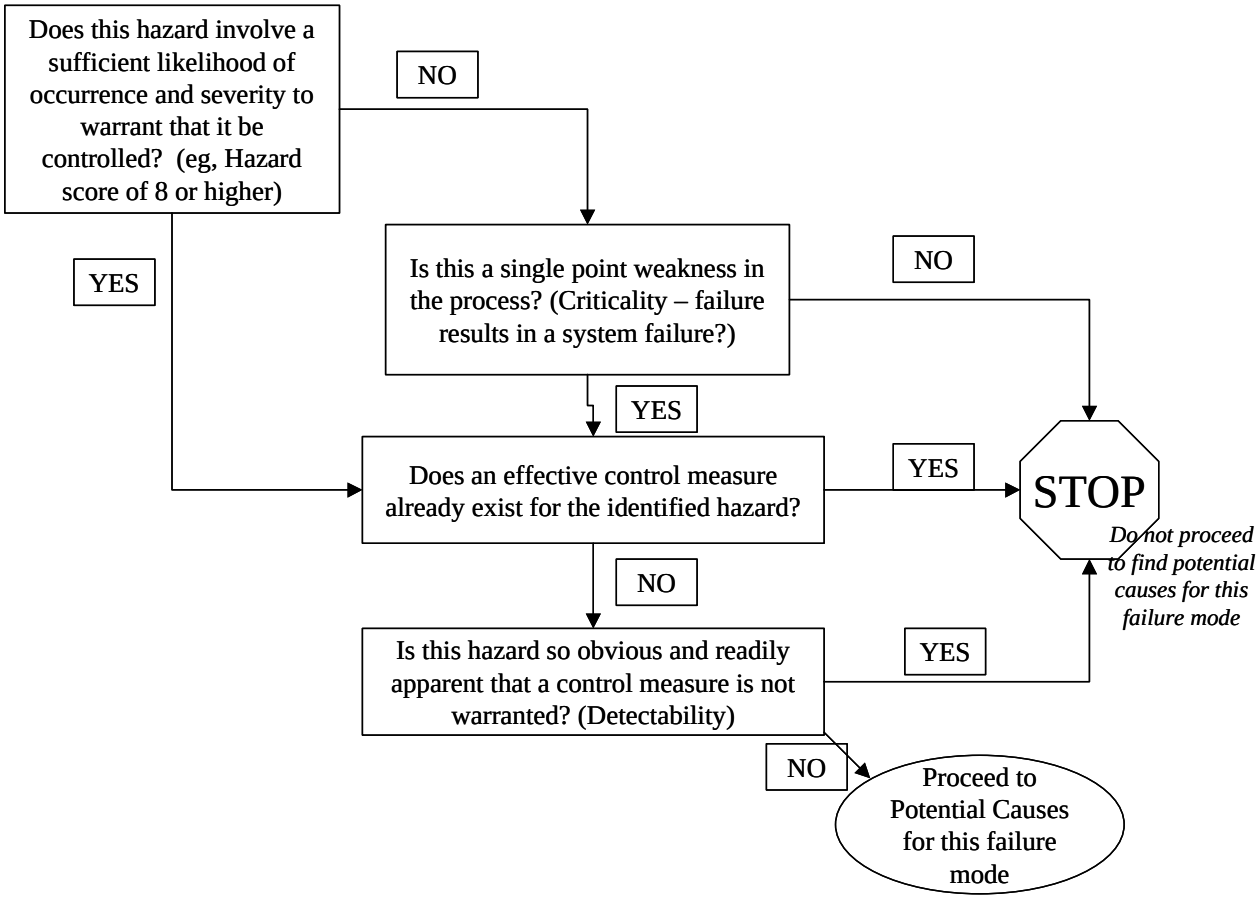
VA Hazard Analysis Matrix

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

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

HFMEA™ Decision Tree

Developed by the VA National Center for Patient Safety



Risk Priority Number (RPN) Rating Scales

SEVERITY*		
Rating	Description	Definition
10	Catastrophic	Death of individual or complete system failure
9		
8	Major injury	Major injury of individual or major effect on system
7		
6	Minor injury	Minor injury of individual or minor effect on system
5		
4	Moderate	Significant effect on individual or system with full recovery
3		
2	Minor	Minor annoyance to individual or system
1	None	Would not affect individual or system

* There are many RPN scales that can be found in the FMEA resources provided in this guide and the scales can be modified to suit your specific FMEA process.

PROBABILITY		
Rating	Description	Potential Failure Rate
10	Very High: Failure is almost inevitable	More than one occurrence per day or a probability of more than 1 occurrence in every 2 events
9		One occurrence every three to four days or a probability of 1 in 3
8	High: Repeated Failures	One occurrence per week or a probability of 1 in 8.
7		One occurrence per month or a probability of 1 in 20.
6	Moderate: Occasional failures	One occurrence every three months or a probability of 1 in 80.
5		One occurrence every six months to one year or probability of 1 in 400.
4		One occurrence per year or a probability of 1 in 2,000.
3	Low: Relatively few failures	One occurrence every one to two years or a probability of 1 in 15,000.
2		One occurrence every three to five years or a probability of 1 in 150,000.
1	Remote: Failure is unlikely	One occurrence in greater than five years or a probability of 1 in >150,000.

DETECTABILITY		
Rating	Description	Likelihood of Detection
10	**Absolute Uncertainty**	Control **cannot** detect potential cause and subsequent failure mode
9	**Very Remote**	**Very remote** chance the control will detect potential cause and subsequent failure mode
8	**Remote**	**Remote** chance the control will detect potential cause and subsequent failure mode
7	**Very Low**	**Very low** chance the control will detect potential cause and subsequent failure mode
6	**Low**	**Low** chance the control will detect potential cause and subsequent failure mode
5	**Moderate**	**Moderate** chance the control will detect potential cause and subsequent failure mode
4	**Moderately High**	**Moderately High** chance the control will detect potential cause and subsequent failure mode
3	**High**	**High** chance the control will detect potential cause and subsequent failure mode
2	**Very High**	**Very high** chance the control will detect potential cause and subsequent failure mode
1	**Almost Certain**	Control **will** detect potential cause and subsequent failure mode

Additional FMEA Resources

Books

Failure Mode and Effects Analysis in Health Care: Proactive Risk Reduction. Joint Commission on Accreditation of Healthcare Organizations, 2002.

The Basics of FMEA. McDermott, R.E., et al., New York: Quality Resources, 1996.

Error Reduction in Health Care, Spath, P.L., editor, Jossey-Bass Publishers, 2000, p.179-98

Failure Mode and Effect Analysis: FMEA from Theory to Execution. Stamatis, D.H., Milwaukee, WI: ASQ Quality Press, 1995.

Journal Articles

Assessing patient safety risk before the injury occurs: an introduction to sociotechnical probabilistic risk modelling in health care. Marx D.A., Slonim A.D., Qual Saf Health Care. Dec 2003; 12 Suppl 2:ii33-8.

Using failure mode and effects analysis to improve patient safety. Spath P.L., AORN Journal. July 2003 v78 i1 p15(23).

Using Health Care Failure Mode and Effect Analysis™: The VA National Center for Patient Safety's Prospective Risk Analysis System. DeRosier, J., et al., The Joint Commission Journal on Quality Improvement, 2002; Volume 27 Number 5:248-267.

Websites

ECRI and Millbank, Proactive Hazard Analysis in Health Care
http://www.milbank.org/reports/Proactive/020925Proactive.html - critical

Institute for Healthcare Improvement, FMEA Tool
http://www.qualityhealthcare.org/ihi/workspace/tools/fmea/

ISixSigma Healthcare, Six Sigma resources, including FMEA
http://healthcare.isixsigma.com/

Joint Commission Accreditation of Healthcare Organizations (JCAHO)
http://www.jcaho.org/accredited+organizations/patient+safety/fmeca/

National Patient Safety Foundation (NPSF)
http://www.npsf.org/html/bibliography.html

Veteran Affairs National Center for Patient Safety
http://www.patientsafety.gov/HFMEA.html

Glossary of Terms

Analysis:	The detailed examination of the elements and/or structure of a process, sub-process, or situation.
Effects:	Results or consequences of an action.
Failure:	Lack of success, nonperformance, nonoccurrence, or breaking down or ceasing to function.
Failure Mode:	The manner in which something can fail.
Failure Mode and Effects Analysis:	A team based, systematic, and proactive approach for identifying the ways a process or design can fail, why it might fail, and how it can be made safer.
High-risk care process:	Process in which a failure of some type is most likely to jeopardize patient safety.
Human Factors:	A body of scientific facts about human characteristics. The term covers all biomedical and psychosocial considerations; it includes, but is not limited to, principles and applications in the areas of human engineering, personnel selection, training, life support, job performance aides, and human performance evaluation.
Mode:	The way of operating or using a system or process, or a way or manner in which something is done.
Process:	A systematic series of actions directed to some end; a series of interrelated steps leading to a desired outcome.
Sub-process:	A component portion of the overall process.

References

1. Department of Defense. DoD Handbook: Definition of Human Factors Terms. MIL-HDBK-1908B, 1999.
2. McDermott RE, et. al. The Basics of FMEA. Portland, OR: Productivity, Inc.; 1996.
3. Joint Commission on Accreditation of Healthcare Organizations. Patient Safety Essentials for Health Care. Oakbrook Terrace, Illinois: Joint Commission Resources, Inc; 2003.
4. Joint Commission on Accreditation of Healthcare Organizations. Failure Mode and Effects Analysis in Health Care. Oakbrook Terrace, IL: Joint Commission Resources, Inc; 2002.