# Simulation – Assisted FMEA to Identify and Mitigate High-Risk Tasks for Healthcare Workers

# Acknowledgements

Dmitri Bouianov, CEO, Context VR

Ross Ehrmantraut, RN, HRET Senior Fellow, TeamCORE Clinical Manager, WWAMI Institute for Simulation in Healthcare (WISH)

Rosemarie Fernandez, MD, Associate Professor, Emergency Medicine, UW School of Medicine, Harborview Medical Center (HMC)

John Lynch, MD, MPH, Associate Professor of Medicine, Medical Director of Infection Prevention and Employee Health, UW Medicine HMC

Scott Meschke, JD, MSES, PhD, Professor, Environmental and Occupational Health Sciences, UW School of Public Health

Steve Mitchell, MD, Assistant Professor, Emergency Medicine, Acting Medical Director, Emergency Department, UW Medicine, HMC

Sarah Parker, PhD, Carilion Research Institute, Virginia Tech University

Nancy J. Simcox, MS, Environmental and Occupational Health Sciences, UW School of Public Health

David Townes, MD, MPH, DTM&H, Associate Professor, Emergency Medicine, UW School of Medicine, Harborview Medical Center (HMC)

Sarah Wolz, MS, Environmental and Occupational Health Sciences, UW School of Public Health

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# Fundamental Knowledge

## Background

Failure mode and effects analysis (FMEA) is an analysis technique for defining, identifying and eliminating known and/or potential failures, problems, and errors from system, design, process and/or service before they cause harm to the patient or provider (Stamatis, 1995). The main objective of FMEA is to identify potential failure modes, evaluate the causes and effects of different component failure modes, and determine what could eliminate or reduce the chance of failure. The results of the FMEA can help analysts identify and correct 'failure modes' that are potentially harmful to healthcare workers and patients. FMEA has been extensively used in a wide range of industries, including aerospace, automotive, nuclear, electronics, chemical, mechanical and medical technologies industries.

The purpose of FMEA is to prioritize the likelihood, frequency and/or severity of the failure modes of the product or system in order to assign the limited resources to the most serious risk items. In general, the prioritization of failure modes for corrective actions is determined by following a protocol to calculate a **risk priority number** (RPN). In order to analyze a specific product or system, a cross-functional team should be established for carrying out FMEA.

1. The first step in FMEA is to identify all possible steps in a process.

2. Systematic brainstorming and critical analysis is performed on each step to identify possible failure modes.

3. The failure modes are then assigned a numerical estimation of risk by the likelihood of occurrence (O), severity if the failure mode occurs (S) and likelihood of detection, if the failure mode occurs (D).

4. A RPN is then obtained by finding the multiplication of the O, S and D of a failure mode. The higher the RPN of a failure mode, the greater the risk is for product/ system reliability.

5. With respect to the scores of RPNs, the failure modes can be ranked and then proper actions will be preferentially taken on the high-risk failure modes.

6. RPNs should be recalculated after the corrections to see whether the risks have gone down, and to check the efficiency of the corrective action for each failure mode.

## Background (cont.)

Simulation can re-create the process being analyzed. By allowing FMEA team members to observe the steps in the process, simulation can allow a more in-depth understanding of potential failure modes. Simulating the clinical process allows the team to gauge communication, performance, and whether the steps in the process are being executed as intended. It is important here to reinforce with simulation participants that they should behave as they normally would in a real occupational situation. In other words, they should perform work-arounds and shortcuts if that is part of their daily routine. Otherwise, system-related safety threats will not come to light. Using a theoretically sound methodological approach to simulation design will help support an objective, rigorous risk analysis.

Liu HC, Liu L, Liu N: **Risk evaluation approaches in failure mode and effects analysis: A literature review.** *Expert Systems with Applications* 2013, 40(2):828-838.

# Designing Simulation to Support FMEA

## Event-based Simulation Design

Event-based design systematically identifies and introduces events within the simulation that provides known opportunities to observe behaviors of interest. Event-based simulations provide a highly replicable, predictable representation of clinical and occupational safety events that can support high level risk analyses.

**Event:** Substantive task with a clear beginning and ending

**Trigger:** Standardized, scenario-specific indicators embedded in the scenario, designed to force a transition between events

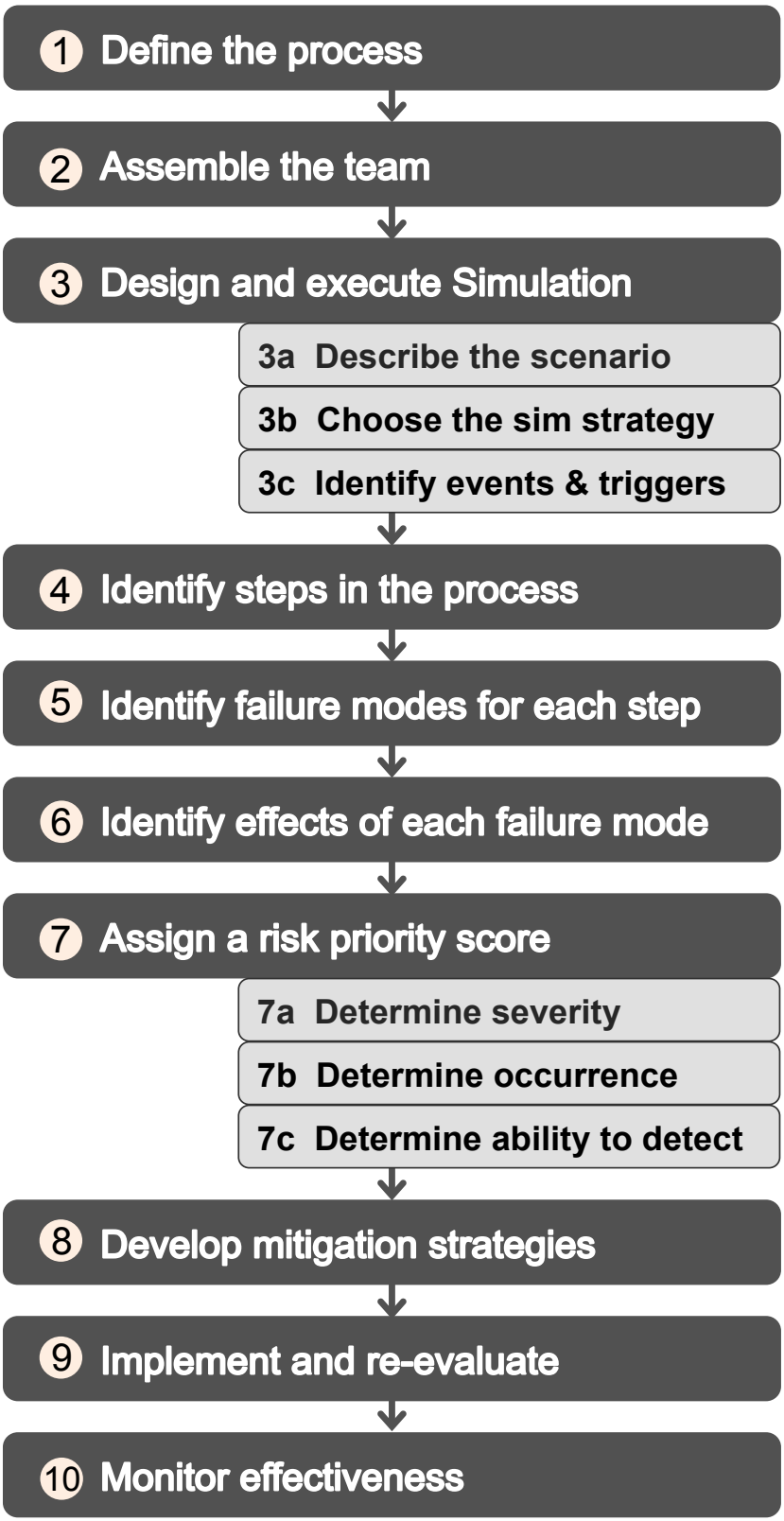
**Order:** The design and sequencing of events and triggers should depend upon the objectives and realistic progression of the scenario

**Example: Simulation to identify risks associated with hygienic care in an EVD patient**


**Behaviors**

| | | | | |
|---|---|---|---|---|
| • Gather linens<br>• Arrange waste receptacles<br>• Ensure adequate disinfectant<br>• Execute pre-brief | • Roll patient<br>• Position devices/tubes<br>• Remove head/foot<br>• Release fitted sheet<br>• Prepare new linens | • Create barrier on floor<br>• Discuss fecal management system<br>• Revisit Event 2 | • Ensure supplies duplicated on other side<br>• Gross contamination check<br>• Repeat Event 2 | • Remove materials from floor<br>• Clean/disinfect floor<br>• Clean tubing/ equipment |

# FMEA Overview



## Step 1: Define the process

It is critical that you are as specific as possible when defining the process you wish to evaluate. Starting with a clear description of the process ensures that everyone on the team understands what is being analyzed. For instance, when we approached Ebola Virus Disease (EVD) patient care, we considered processes that were under-researched and presented high risk. We therefore focused on patient hygiene in an EVD patient with copious diarrhea. While describing the process, team members found that there was additional variation present based upon the stability of the patient. We chose to concentrate our analysis on an awake, cooperative patient because it seemed to be the most frequently encountered situation. We agreed that follow-up FMEAs would be needed to address intubated, unresponsive patients.

**Consider the questions below during this step. Not all may be relevant in every situation.**

| |
|---|
| **What clinical situation or occupational safety event do you want to evaluate?** |
| **What are the characteristics of the patient(s) involved?**<br>Clinical stability, age, presence of invasive monitoring, ability to communicate, etc. |
| **What are the characteristic(s) of the environment?**<br>Time of day, census, staffing, resources available, etc. |
| **What are the characteristic(s) of the worker(s) involved?**<br>Time of day, census, staffing, resources available, etc. |
| **What pieces of the unit or system are part of the process?**<br>Paging system, security, other units, etc. |
| **Does the process vary markedly based on worker, environmental, or patient characteristics?** |

**Helpful Tips**

1. Be sure an identifiable process is chosen for FMEA. A process is a series of actions or steps taken to achieve an end.

2. Narrow the scope of focus of FMEA as much as possible. For instance, do FMEA on administration of a particular task under certain situations rather than on the task in general.

3. To get employees to support FMEA, senior management should engage frontline staff early in the process and ensure they are involved in all components of the analysis.

4. Consider using FMEA to evaluate new processes. It is a good technique for anticipating what could happen so processes can be made safer before full implementation.

### Step 2: Assemble the team

Consider who will comprise your simulation development team and who will participate in the FMEA process.

| Type of Team Member | Simulation development team | FMEA Team |
|---|---|---|
| **Healthcare worker** (represent all disciplines and ancillary staff if appropriate) | | |
| **Leadership / Management** | | |
| **Occupational safety expertise (if appropriate)** | | |
| **Simulation expertise** | | |
| **Human factors expertise** | | |
| **Safety/quality science expertise** | | |
| **Project manager** | | |
| **Recorder/note-taker** | | |

**Helpful Tips**

1. Minimize the number of management or supervisory level individuals on the team. Staff members may be inhibited from speaking up during critical discussions about process problems if their direct supervisor is in the room.

2. Involve frontline employees and those who have specific experience with the process being analyzed. It is important to understand the process as it is actually performed, including why staff make mistakes and develop work-a-rounds.

3. Include people from all shifts on the team, when possible. The experiences of staff working during the day may be much different than what happens during the evening and night shift. A successful FMEA is highly dependent on the ability of the team members to understand how a process functions at varying times and what occasionally goes wrong.

4. Meet formally as a team. It can sometimes be tempting to complete FMEA by interviewing those involved in the process, without any formal meetings of the team. While this might move the analyses along quicker, the frank discussions that occur during team meetings are more likely to lead to a successful FMEA – one that actually improves the safety of a high-risk resident care process.

## Step 3: Design and execute simulation

### 3a: Describe the scenario

Describe in a few sentences the overall scenario you wish to create. Use the process information obtained in Step 1 to determine the scenario characteristics, healthcare workers involved, and environmental cues present. Define a clear start and stop for the simulation.

### 3b: Choose the simulation strategy

Determine the modality of simulation that best fits your scenario and objectives. Consider what components need to be most "realistic" to allow a meaningful examination of risks. Make sure you are able to replicate the components of your simulation in a way that elicits meaningful behaviors from the participants.

### 3c: Event-based Simulation Design

Event-based design systematically identifies and introduces events within the simulation that provides known opportunities to observe behaviors of interest. Event-based simulations provide a highly replicable, predictable representation of clinical events that can support high level risk analyses.

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**Example: Simulation to identify risks associated with hygienic care in an EVD patient**


**Behaviors**

| | | | | |
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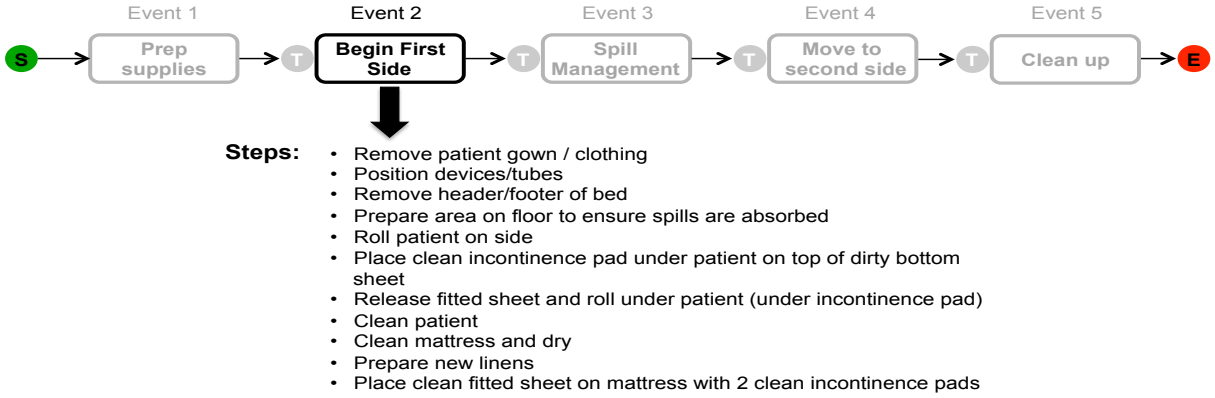
## Step 3 Worksheet

| Events | | Triggers | |
|---|---|---|---|
| **Sample** | **Intubation** Patient becomes progressively more hypoxic, requiring intubation. It is expected that the team will recognize this need early; however, the hypoxia will continue to progress until this is accomplished. | **Ta** | Increased RR to 30 with a pulse ox reading 85. |
| | | **Tb** | Patient no longer speaking, pulse ox reads 65 |
| | | **Tc** | Nurse (confederate) states "I think we need to intubate now." |
| **1** | **Nurse cleans and disinfects dirty areas.** Cleaning and decontamination of contaminated surfaces is a multistep process involving containment, pre-disinfection, cleaning and removal of gross soil, and thorough disinfection. | **1** | |
| | | **2** | |
| | | **3** | |
| **2** | | **4** | |
| | | **5** | |
| | | **6** | |
| **3** | | **7** | |
| | | **8** | |
| | | **9** | |
| **4** | | **10** | |
| | | **11** | |
| | | **12** | |
| **5** | | **13** | |
| | | **14** | |
| | | **15** | |

## Step 4: Identify steps in the process

The team should clearly define the process to be analyzed. Watching the simulation can help get everyone on the same page. There are several ways to approach this step. One way is to construct a flowchart of the steps. Write down the first step in the process and each subsequent step. Each event will likely contain multiple steps. If there is confusion about the process steps it may be necessary to refine the scope of the FMEA.

**Example: Event 2 in EVD Hygienic Care**




**Once you've determined the steps in the process, enter them into Column 1 of the FMEA worksheet.**

**Helpful Tips**

1. Be sure to involve frontline staff.
2. Start with the overall events of the simulation.
3. Watch video recordings (preferred) or live simulations to break each event into discrete steps.
4. Be specific. The more specific and discreet the steps, the more concise your risk analysis will be.
5. If team members cannot agree on how the process currently works in their area and the process scope cannot be narrowed to obtain agreement, it usually is a signal of a very unreliable process. An unreliable process is one that is not performed consistently – people pretty much do whatever works best for them.
6. Include each repetition of a step. Risks can vary based on when in the overall process a step occurs.
7. For a complex process with many steps, it may be better to do several FMEAs by breaking-up the process into manageable pieces.

## Step 5: Identify failure modes for each step in the process.

**Failure mode = something that can go wrong**

Here is where the knowledge and experience of team members combined with a robust simulation can ensure a rigorous FMEA. For each process step identified in Step 4, the team determines what can go wrong or what can fail (failure modes). The team members who do the work every day are in the best position to know what can (and does) go wrong. By observing the simulation, you ensure that aspects of the process are not forgotten. You also have the ability to have frontline providers observe the process, thus offering them a different perspective. After the possible failures are identified for one step, the team moves on to identifying failures that might occur in the next step. Step 5 is complete when the team is satisfied all possible failures have been identified for each step.

**Example: Failure modes related to one step in EVD hygienic care**

| Step | Failure mode |
|---|---|
| Positions devices / tubes | Provider forgets step |
| | Positioning is suboptimal |
| | Optimal positioning risks contamination with stool |

## Step 6: Identify effects of each failure modes

Starting with the first step in the process, the team considers each failure that was identified in Step 5 – answering the question, "What would happen if this failure occurs?" The team methodically goes through each failure identified during Step 5.

**Helpful Tips**

1. Create an atmosphere where team members feel safe talking about process mistakes, unplanned events, or work-arounds that occur.
2. To decrease "protectionism" where staff are reluctant to talk about safety threats, make it clear from the beginning that everyone makes occasional mistakes, and most mistakes are the result of a poorly designed process.
3. Sometimes the team identifies failure modes that are extremely rare - don't exclude those things!!! Be creative in your risks.
4. Video recordings of one or more simulations can help inform risks. Individuals often have such ingrained work patterns that they do not recognize risks.
5. Staff may identify places where the actual work flow deviates from the simulation, which may depict what theoretically is supposed to happen as compared with what actually does.

**Example: Failure mode effects related to one step in EVD hygienic care**

| Step | Failure Mode | Effect |
|---|---|---|
| Positions devices / tubes | Provider forgets step | Tube accidentally dislodged |
| | Positioning is suboptimal | Tube accidentally dislodged |
| | Optimal positioning risks contamination with stool | Tube becomes contaminated |

**Helpful Tips**

1. When defining outcomes that will occur following a failure, identify likely outcomes and worst-case scenarios. Do not forget that outcomes for some failures may not directly harm patients or healthcare workers and may go unnoticed, such as delays in treatment or services.
2. This may be informed by recent events in the hospital.
3. Keep in mind that failure mode effects can present a safety threat to patients, healthcare workers, and the public. For example, some failure modes could increase healthcare worker exposure to highly infectious agents during patient care.
4. You can consider “system” failures into your simulation to see the downstream effects.

## Step 7: Assign a risk priority score

### 7a: Determine severity of failure mode

The team must assign a score to rate the severity of the consequences of each failure mode. Severity is usually rated on a scale from 1 to 10, where 1 is insignificant and 10 is catastrophic. If a failure mode has more than one effect, write on the FMEA table only the highest severity rating for that failure mode. This decision can be made by the team while they are identifying the outcomes or the seriousness can be determined after all outcomes have been determined. For each outcome, the team must decide how "bad" the particular outcome would be for the patient, provider, unit, or system. This is a subjective judgment made by team members based on their knowledge and experience. Using a decision-making process such as nominal group technique or multi-voting, the team methodically agrees to a severity ranking for each outcome.

**On the FMEA table, list the severity rating for each failure mode.**

**Sample severity rating scale as applied to occupational safety risks to healthcare workers.**

| Rating | Outcome Category | Description |
|---|---|---|
| 9 – 10 | Catastrophic | HCW experiences death or major permanent loss of function (sensory, motor, physiologic, or intellectual). (e.g., death due to exposure to highly infectious agent). |
| 7 – 8 | Major | HCW experiences permanent lessening of bodily function (sensory, motor, physiologic, or intellectual), disfigurement, surgical intervention required, or increased level of care for 3 or more days (e.g., transmission and illness related to exposure to highly infectious agent). |
| 5 – 6 | Moderate | HCW experiences an event, occurrence, or situation (e.g., exposure to highly infectious agent requiring quarantine until clinically clear) which can cause harm but will not cause permanent injury or lessening of bodily function or require the delivery of additional healthcare services |
| 3 – 4 | Minor | HCW may experience a minor injury be exposed to a risk-related situation (e.g., exposure to highly infectious agent while wearing appropriate PPE), but most likely would not be affected by the failure and it would not cause any permanent injury or need for further care. |
| 1 – 2 | Near miss | HCW would not experience any injury, changes in job task, or be exposed to any physical risk (e.g., highly infectious agent). |

HCW = healthcare worker; PPE = personal protective equipment

### 7b: Determine occurrence of failure mode

The team now judges how often each failure is likely to occur. Occurrence is usually rated on a scale from 1 to 10, where 1 is extremely unlikely and 10 is inevitable. It can sometimes be problematic for team members to judge how often a failure might occur. Sometimes there is a tendency to seek the "right" answer when, without any prevalence data, a correct answer is not possible. In the absence of data, ask the team members to estimate based on their experience and a sense of what happens in their unit/institution. Ask the frontline providers on the team to estimate how often they think this failure occurs. A more accurate estimate of failure probability might be obtained if management level personnel are not in the room.

**On the FMEA table, list the occurrence rating for each failure mode.**

**Sample Occurrence Scale**

| Rating | Description |
|---|---|
| 9 – 10 | Very high probability: failure is most inevitable |
| 7 – 8 | High: repeated failures |
| 5 – 6 | Moderate: occasional failures |
| 3 – 4 | Low: relatively few failures |
| 1 – 2 | Remote: failure is unlikely |

### 7c: Determine the likelihood of detecting the failure mode

The team now must determine how likely it is that the failure mode can be detected. For each failure mode, determine the detection rating, or D. This rating estimates how well you can detect either the cause or its failure mode after they have happened but before the patient/provider/system is affected. Detection is usually rated on a scale from 1 to 10, where 1 means you are absolutely certain to detect the problem and 10 means the you are certain not to detect the problem (or no control exists).

**On the FMEA table, list the detection rating for each cause.**

**Sample Detection Scale**

| Rating | Description |
|---|---|
| 9 – 10 | Controls will not or cannot detect the existence of a failure. No known controls available to detect failure mode. |
| 7 – 8 | Controls have a poor chance of detecting the existence of failure mode. |
| 5 – 6 | Controls may detect the existence of a failure mode. |
| 3 – 4 | Controls have a good chance of detecting failure mode, process automatically detects failure mode. |
| 1 – 2 | Current controls almost certain to detect the failure mode. Reliable detection controls are known with similar processes. Process automatically prevents further processing. |

## Calculate Risk Priority Number (RPN)

## Severity X Occurrence X Detectability = RPN

*see Liu, et al for limitations and cautions associated with prioritization based on RPN

Liu HC, Liu L, Liu N: **Risk evaluation approaches in failure mode and effects analysis: A literature review**. *Expert Systems with Applications* 2013, **40**(2):828-838.

## Step 8: Develop mitigation strategies

Identify recommended actions. These actions may be design or process changes to lower severity or occurrence. They may be additional controls to improve detection. Also note who is responsible for the actions and target completion dates

To determine how the process should be changed the root cause of each failure chosen for action must be identified. The team may need to gather additional input from other staff members to help in determining the root causes of failures.

Once the cause of each failure is clear, the team develops actions to reduce or eliminate the failure. When developing these actions consider questions such as:

1. What safeguards are needed to prevent this failure from happening?
2. What would have to go wrong to have a failure like this happen? How can we prevent this from going wrong?
3. How could we change the way we do things to make sure that this failure never happens?
4. If a failure like this happened, how could we quickly catch and correct the problem before the healthcare worker ended up being harmed?
5. If the healthcare worker were harmed by this failure, how could we minimize the effect of the failure on the healthcare worker condition?