FMEA – What’s the Worst That Could Happen?

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FMEA

What’s the worst that can happen?
What is FMEA?

Failure Modes and Effects Analysis

Disciplined approach to:

• Identify potential & known failures
• Identify causes & effects of failures
• Establish risk factors
• Make accountability clearer
• Continuously improve
When to use FMEA?

- Improve a process or service
- Analyze an actual failure
- Design/redesign a process or service

Create during Analysis
Review during Improve and/or Control
Who creates FMEA?

A team made up of individuals:

• Who know the system or process best

• With a cross section of responsibilities, experiences, skills, perspectives
How to create an FMEA

Step 1
Map the process

Step 2
Analyze process steps

Step 3
Identify potential failures

Step 4
Describe effects of failure

Step 5
Determine causes

Step 6
Describe detection methods

Step 6
Calculate risk

Step 7
Take action

Step 8
Assess results
## IMPROVE FMEA™ (Failure Mode and Effects Analysis)

<table>
<thead>
<tr>
<th>Process Step</th>
<th>Potential Failure Mode</th>
<th>Potential Effects of Failure</th>
<th>Potential Cause(s)</th>
<th>Current Process Controls</th>
<th>SEV</th>
<th>OCC</th>
<th>DET</th>
<th>RPN</th>
<th>Recommended Action(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name of process step being analyzed.</td>
<td>How can the process step fail? Or How did the process step fail?</td>
<td>What are the potential cause(s) of each failure? Describe in terms of what can be corrected or controlled.</td>
<td>How do you currently prevent or detect that the failure could occur?</td>
<td>How severe are the consequences to the customer?</td>
<td>Assign a rating for each failure.</td>
<td>How often does the cause of the failure occur?</td>
<td>Assign a rating for each failure.</td>
<td>What are the actions for reducing the occurrence, improving detection, or eliminating the root cause(s)?</td>
<td></td>
</tr>
<tr>
<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Should have actions only for high RPNs or easy fixes.</td>
<td></td>
</tr>
<tr>
<td>Term</td>
<td>Rating Description</td>
<td>Rating</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<td>------------------------------------------------------------------------------------</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Critical</td>
<td>Affects patient, staff or visitor safety; catastrophic consequence.</td>
<td>10</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Moderate</td>
<td>Failure could cause performance loss but may be overcome with modification to process.</td>
<td>7</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Minor</td>
<td>Failure could cause minor performance loss but can be overcome with modification to process.</td>
<td>4</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No effect</td>
<td>Failure would not be noticeable to patient and would not affect completion of process.</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
## OCC (Occurrence Rating Scale)

<table>
<thead>
<tr>
<th>Term</th>
<th>Rating Description</th>
<th>Rating</th>
</tr>
</thead>
<tbody>
<tr>
<td>Frequent</td>
<td>* Likely to occur immediately or within short period of time.</td>
<td>10</td>
</tr>
<tr>
<td></td>
<td>* Common or occurs frequently within defined time period.</td>
<td></td>
</tr>
<tr>
<td>Occasional</td>
<td>* Probably will occur.</td>
<td>7</td>
</tr>
<tr>
<td></td>
<td>* May happen several times within defined time period.</td>
<td></td>
</tr>
<tr>
<td>Uncommon</td>
<td>* Possible to occur.</td>
<td>4</td>
</tr>
<tr>
<td></td>
<td>* May happen sometime within defined time period.</td>
<td></td>
</tr>
<tr>
<td>Remote</td>
<td>* Unlikely to occur.</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>* Doubtful but possible it may happen - usually past defined time period.</td>
<td></td>
</tr>
</tbody>
</table>
# DET (Detection Rating Scale)

<table>
<thead>
<tr>
<th>Term</th>
<th>Rating Description</th>
<th>Rating</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cannot detect failure</td>
<td>* No detection before it affects patient safety or process fails.</td>
<td>10</td>
</tr>
<tr>
<td></td>
<td>* No control or warning of failure until it affects patient or process.</td>
<td></td>
</tr>
<tr>
<td>May detect failure</td>
<td>* Could detect prior to occurring.</td>
<td>7</td>
</tr>
<tr>
<td></td>
<td>* Have a process step that will flag if a failure will occur.</td>
<td></td>
</tr>
<tr>
<td>May detect cause of failure</td>
<td>* Possible to occur.</td>
<td>4</td>
</tr>
<tr>
<td></td>
<td>* May happen sometime within defined time period.</td>
<td></td>
</tr>
<tr>
<td>Can always detect failure</td>
<td>* Can detect failure every time</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>* Detection is immediate</td>
<td></td>
</tr>
<tr>
<td>Process Step</td>
<td>Potential Failure Mode</td>
<td>Potential Effects of Failure</td>
</tr>
<tr>
<td>-------------</td>
<td>------------------------</td>
<td>-----------------------------</td>
</tr>
<tr>
<td>Print Card</td>
<td>Card printed incorrectly</td>
<td>Reissue card</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Reissue card</td>
</tr>
</tbody>
</table>

Name of process step being analyzed.

How can the process step fail? Or How did the process step fail?

What are the consequences of each failure on the process step as perceived by the customer? (Internal or External)

What are the potential cause(s) of each failure? Describe in terms of what can be corrected or controlled.

How do you currently prevent or detect that the failure could occur?

Assign a rating for each failure.

How severe are the consequences to the customer?

Assign a rating for each failure.

How often does the cause of the failure occur?

Assign a rating for each failure.

How easily can you prevent / detect the failure?

Risk Priority Number

SEV x OCC x DET
Who uses FMEA?

- Military – created FMEA in 1950s
- NASA – Apollo
- Ford – Pinto
- VA Hospital
- Joint Commission
- Institute for Healthcare Improvement
- MUSC

{ Patient Safety }
Let’s make a pot of coffee!
FMEA for making coffee

Step 1: Map the process
Step 2: Analyze process steps
Step 3: Identify potential failures
   - Wrong amount of water
   - Coffee too strong / weak
Step 4: Describe effects of failure
Step 5: Determine causes
Step 6: Describe detection methods
Step 7: Calculate risk
   - S=7
   - O=4
   - D=4
   - RPN=112
Step 8: Take action
   - Replace coffee pot
Step 9: Assess results
   - Make a new pot of coffee
Wash and dry your hands thoroughly.

Have your patient sit or lie in a comfortable position and choose an area on the right or left side of the abdomen, at least 2 inches from the belly button.

Clean the injection site with an alcohol swab and let dry.

Remove the needle cap by pulling it straight off the syringe and discard it in a sharps collector.

With your other hand, pinch an inch of the cleansed area to make a fold in the skin. Next, insert the full length of the needle straight down at a 90° angle – into the fold of skin.

Press the plunger with your thumb until the syringe is empty. Then pull the needle straight out and release the skin fold.

Point the needle down and away from yourself and others, and then push down on the plunger to activate the safety shield.

Place the used syringe in the sharps collector.

FMEA Lovenox Injection

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## FMEA Worksheet

### IMPROVE FMEA™ (Failure Mode and Effects Analysis)

**Process:** Lovenox Injections  
**Prepared by:** FMEA Team  
**Responsible:** Eric Smathers  
**FMEA Date (Original):** December 12, 2017

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<tr>
<td>Step 5</td>
<td>Finger stab</td>
<td>Infection</td>
<td>Wrong angle</td>
<td>Physical pain</td>
<td>7</td>
<td>4</td>
<td>1</td>
<td>28</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Injury</td>
<td>Wrong angle</td>
<td>Physical pain</td>
<td>4</td>
<td>4</td>
<td>1</td>
<td>16</td>
<td></td>
</tr>
</tbody>
</table>

**RPN Calculation:**  
Risk Priority Number = SEV x OCC x DET

**Recommended Actions:**  
What are the actions for reducing the occurrence, improving detection, or eliminating the root cause(s)?  
Should have actions only for high RPNs or easy fixes.
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