**FAILURE MODES AND EFFECTS ANALYSIS (FMEA)**

Category: Analysis-Design Tools

**ABSTRACT**

Failure Modes and Effects Analysis (FMEA)\(^{(G)}\) is a procedure that is performed after a failure mode effects analysis to classify each potential failure effect according to its severity and probability of occurrence.

It is a systematic, proactive method for evaluating a process\(^{(G)}\) to identify where and how it might fail and to assess the relative impact of different failures, in order to identify the parts of the process that are most in need of change. FMEA includes review of the following:

- Steps in the process
- Failure modes (What could go wrong?)
- Failure causes\(^{(G)}\) (Why would the failure happen?)
- Failure effects (What would be the consequences of each failure?).

**KEYWORDS**

*Failure Modes and Effects Analysis (FMEA), preventive action, risk assessment, Risk Priority Number (RPN)*

**OBJECTIVES**

The main objective is the prevention of problems and errors by reducing the RPN (risk priority number)

**FIELD OF APPLICATION**

It can be applied in the design of medical processes in order to prevent errors, accidents and adverse reactions. Examples of field of application are the design of the process of treatment and therapy administration.

**RELATED TOOLS**

Flowcharts, Pareto analysis, Cause\(^{(G)}\) and Effect Analysis (fishbone diagram)
The steps someone has to go through to design an FMEA form are described below.

0. **Select the process**\(^{(G)}\). The first thing the user has to do is to select the process to analyse. The importance of the process in terms of the impact of potential failures is a parameter that has to be taken into account as selection criteria.

1. **Review the process**: Gather a team (be sure to include people with various job responsibilities and levels of experience) and give each member a copy of the process blueprint or description. The process could be analysed and described in a flowchart. Also, have the team use the process so all members can become familiar with the way it works.

2. **Brainstorm potential failure modes**: Look at each stage of the process and identify ways it could potentially fail, things that might go wrong.

3. **List potential effects of each failure mode**: List the potential effect of each failure next to the failure. If a failure has more than one effect, write each in a separate row. To identify the effects and the causes\(^{(G)}\) of the effects someone can use **Cause and Effects analysis (fishbone diagram)**.

4. **Assign a severity rating for each effect**: Give each effect its own severity rating (from 1 to 10, with 10 being the most severe). If the team can't agree on a rating, hold a vote. To quantify or prioritize the effects someone can use **Pareto analysis**.

5. **Assign an occurrence rating for each failure mode**: Collect data on the failures of your product's competition. Using this information, determine how likely it is for a failure to occur and assign an appropriate rating (from 1 to 10, with 10 being the most likely).

6. **Assign a detection rating for each failure mode and effect**: List all controls currently in place to prevent each effect of a failure from occurring and assign a detection rating for each item (from 1 to 10, with 10 being a low likelihood of detection).

7. **Calculate the risk priority number (RPN) for each effect**: Multiply the severity rating by the occurrence rating by the detection rating.

8. **Prioritize the failure modes for action**: Decide which items need to be worked on right away. For example, if you end up with RPNs ranging from 50 to 500, you might want to work first on those with an RPN of 200 or higher.

9. **Take action to eliminate or reduce the high risk failure modes**: Determine what action to take with each high risk failure and assign a person to implement the action.

10. **Calculate the resulting RPN as the failure modes are reduced or eliminated**: Reassemble the team after completing the initial corrective actions and calculate a new RPN for each failure. Then you may decide you've taken enough action or you want to work on another set of failures.
11. **Use and update the FMEA form**: After a process has been analysed in terms of identify, quantify and take initial measures for the potential failures, a person has to be assigned to monitor the effectiveness of the actions taken (see step 9) and the results in case of a failure. Also new problems raised have to be analysed and inserted in the FMEA form.

A sample FMEA form is presented below.

<table>
<thead>
<tr>
<th>Process</th>
<th>Potential Failure Mode</th>
<th>Potential Effect of Failure</th>
<th>Severity</th>
<th>Potential Causes</th>
<th>Occurrence</th>
<th>Current Process Control</th>
<th>Detection</th>
<th>RPN</th>
<th>Recommended Actions</th>
<th>Person Responsible</th>
<th>Action Taken</th>
<th>Severity</th>
<th>Occurrence</th>
<th>Severity</th>
<th>SEVA</th>
<th>RPN</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</tr>
</tbody>
</table>

**Figure 1: Sample FMEA form**

**BENEFITS**

- Reduction of errors, accidents and adverse reactions
- Increase knowledge and understanding of possible failures
- Strengthen teamwork

**PREREQUISITES**

- Trained personnel
- FMEA form template of equivalent tool (e.g. software)
- Selected process description (e.g. flowchart)
- Past statistical data or records about failures
- Special team combined of key users of the process or experienced personnel related to methods and techniques used in the chosen process.
- Process possible error and problem awareness
In the following case study, "Probability" is used for "Occurrence" mentioned above. The "Detection" parameter is omitted.

<table>
<thead>
<tr>
<th>Processes &amp; Subprocesses</th>
<th>Failure Modes/Root Cause</th>
<th>Effects</th>
<th>Severity</th>
<th>Probability</th>
<th>Hazard Score</th>
<th>Actions to Reduce Failure Mode</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prescribing</td>
<td>Incorrect drug administered</td>
<td>Overtreatment, patient unsuitable for drug</td>
<td>Poor patient care</td>
<td>2</td>
<td>4</td>
<td>8</td>
</tr>
<tr>
<td></td>
<td>Wrong patient selected</td>
<td>Clinical judgment, patient unsuitable for drug</td>
<td>Improper dosing, wrong drug, allergic reaction, wrong use of substitute drug</td>
<td>4</td>
<td>3</td>
<td>12</td>
</tr>
<tr>
<td></td>
<td>Wrong dose (brand, PCA,</td>
<td>Dosage, incorrect amount, improper frequency</td>
<td>Overdose, underdose, ADR</td>
<td>4</td>
<td>3</td>
<td>12</td>
</tr>
<tr>
<td></td>
<td>Prescribed on wrong</td>
<td>Knowledge deficit, missed dose</td>
<td>Failure to detect problem easily to prevent harm</td>
<td>4</td>
<td>3</td>
<td>12</td>
</tr>
<tr>
<td></td>
<td>No order received</td>
<td>Knowledge deficit, missed dose</td>
<td>Wrong patient receives wrong drug and dose, ADR, allergic reaction</td>
<td>2</td>
<td>3</td>
<td>9</td>
</tr>
<tr>
<td></td>
<td>Unable to reach covering</td>
<td>Utilities, covering physicians</td>
<td>Poor patient care</td>
<td>2</td>
<td>2</td>
<td>4</td>
</tr>
</tbody>
</table>

**BIBLIOGRAPHY**

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