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)

DESCRIPTION

USER INSTRUCTIONS

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.

FMEA No:		Prepared by:	
Rev no/Date:		Approved by:	

Process	Potential Failure mode	Potential Effect(s) of failure	Severity	Potential Causes	Occurrence	Current process control	Detection	RPN	Recommended Actions	Person responsible	Action results				
											Actions taken	Severity	Occurrence	Detection	RPN

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 choosen process.
- Process possible error and problem awareness

EXAMPLES – CASE STUDY

In the following case study, "Probability" is used for "Occurrence" mentioned above. The "Detection" parametre is omitted.

Institute for Safe Medication Practices

Example of a Health Care Failure Mode and Effects Analysis for IV Patient Controlled Analgesia (PCA)

Processes & Subprocesses	Failure Modes (what might happen)	Causes (why it happens)	Effects	Severity	Probability	Hazard Score	Actions to Reduce Failure Mode
Prescribing							
Assess patient	Inaccurate pain assessment	Cultural influences; patient unable to articulate	Poor pain control	2	4	8	Standard scale to help assess pain; training on cultural influences
Choose analgesic/mode of delivery	Wrong analgesic selected	Clinical situation not considered (age, renal function, allergies, etc.); tolerance to opiates not considered; standard PCA protocols not followed (or not available); concomitant use of other analgesics not considered; drug shortage; knowledge deficit; improper selection of patients appropriate for PCA	Improper dosing; improper drug; allergic response; improper use of substitute drug	4	3	12	CPOE with decision support, clinical pharmacy program; standard PCA protocol with education on use; point-of-use access to drug information; feedback mechanism on drug shortages with information on substitute drugs available; selection criteria for PCA patients
Prescribe analgesic	Wrong dose (loading, PCA, constant, lock-out), route, frequency	Knowledge deficit; mental slip; wrong selection from list; information about drug not available	Overdose; under-dose; ADR	4	3	12	CPOE with decision support; clinical pharmacy program; standard PCA protocols
	Proper patient monitoring not ordered	Knowledge deficit; mental slip	Failure to detect problems early to prevent harm	4	3	12	Standard PCA order sets with monitoring guidelines
	Prescribed on wrong patient	Similar patient names; patient identifier not clear; name does not appear on screen when ordering medications	Wrong patient receives inappropriate drug and dose; ADR; allergic response	3	3	9	Match therapy to patient condition; alerts for look-alike patient names; visible demographic information on order form or screen
	No order received	Unable to reach covering physician	Poor pain control	2	2	4	Proper physician coverage and communication channels

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