



# System Safety in Healthcare

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## The Right and Wrong Ways to Perform Failure Mode and Effects Analysis (FMEA)

The objective of performing Failure Mode and Effects Analysis (FMEA) is to use sound risk management principles, coupled with innovative solutions that can assure high return on investment (ROI). Quality Guru Philip Crosby wrote in his book, *Quality is Free*, that quality is free if you do the right things at the right time. Essentially, the savings from avoiding fixes, process changes and lawsuits are much higher than the cost of doing things right. The principles of sound risk management, experienced by this paper's co-author Dev Raheja as an international engineering management consultant over 30 years, include:

- Identifying risks
- Assessing risks
- Mitigating risks
- Orchestrating risk management
- Aiming at high ROI without compromising safety

The strategy to achieve sound risk management is to work first on the top 20 percent of the risks identified to avoid 80 percent of the associated costs of not mitigating risk. This principle — known as the “80-20” rule or the Pareto Principle — applies in many industries [Ref. 1]. The next step is to work on the remaining risks.

FMEA (Failure Mode and Effects Analysis) is a risk analysis tool for proactively identifying risks in any process and preventing them from occurring before a patient is harmed. This requires brainstorming by a cross-functional patient care team.

“On the whole, hospitals still have a long way to go before they provide patient care that consistently avoids harm and promotes healing,” said Dr. Carolyn Clancy, the former head of the Agency for Healthcare Research and Quality (AHRQ) [Ref. 2]. “We recognize that safe healthcare requires more than the use of dozens of safety-related interventions that target specific risks. For patient safety to improve and to be sustained over time, an organization must undergo a culture change that makes high reliability an essential part of all that is done.”

### How Does FMEA Improve Reliability?

The *Reliability* goal involves achieving an error-free operation that can be sustained for extended periods of time. This system safety knowledge came from the aerospace, automobile and nuclear industries more than 50 years ago. Healthcare needs to accelerate the use of this knowledge, including using different tools, such as FMEA. Using FMEA is a great start, but doing FMEA right is sometimes a larger issue.

“Hospitals are still far from being highly reliable,” warned the The Joint Commission President and CEO Mark R. Chassin, M.D. and Executive Vice President for Healthcare Quality Evaluation Jerod M. Loeb, Ph.D. [Ref. 3]. They urge hospitals to make the substantial changes needed to achieve the ultimate goal of zero patient harm by adapting lessons from high-risk industries. According to Chassin and Loeb, “Too many hospitals and healthcare leaders currently experience serious safety failures as routine and inevitable parts of daily work.” They urge major changes involving leadership, safety culture and robust process improvement using the framework to make progress toward “high reliability” — the achievement of extremely high levels of safety that are maintained over long periods of time.

FMEA improves reliability by predicting failures at every step of a process, analyzing the probability of failure and then brainstorming preventive actions. Because healthcare organizations have been traditionally reactive, the Joint Commission began requiring the use of FMEA as part of accreditation standard LD.5.2 JCAHO (Joint Commission on Accreditation on Healthcare) in 2002. The Joint Commission requirements are: [ref. 4]

- Identify and prioritize high-risk processes annually
- Select at least one high-risk process for the identification of potential failure modes (e.g., what can go wrong?)
- Identify the possible effects for each failure mode
- conduct a root cause analysis for the most critical effects

## The Right Way to Conduct FMEA

For FMEA to be effective, it must be done with contributions from a cross-functional team. Table 1 shows the format and columns in a good FMEA [Ref. 5]. FMEA does not always happen this way — even the Joint Commission does not cover all these columns. But without all these columns, the analysis may not be fully comprehensive.

- Column 1 describes process steps
- Column 2 describes the failure mode (what can go wrong, including errors).
- Column 3 describes the causes of each failure mode
- Column 4 describes the effects (consequences) of each failure
- Column 5 describes the *severity* of harm (usually on a scale of 1 to 10, with 10 causing the worst harm)
- Column 6 describes the potential *frequency* of harm (worst frequency is 10)
- Column 7 describes the *detection* rating (inability to detect the possibility of harm is 10)
- Column 8 describes the *Risk Priority Number* (RPN), found by multiplying the three ratings in columns 5, 6 and 7
- Column 9 describes recommended actions to prevent harm
- Column 13 describes the revised RPN to assure the final risk is acceptable, found by multiplying the three ratings in columns 10, 11 and 12

Table 1 — FMEA Example for Emergency Care.

Process Step	Potential Failure Mode	Causes of Failure	Effects	Risk				Recommended actions	Revised Risk			
				S	F	D	RPN		S	F	D	RPN
Patient walks in for emergency care	Help not available	Shortage of staff	Has to wait in line to see the triage nurse	10	6	6	360	Improve triage Increase ER staff	3	4	3	36
				10	6	2	120	Send less critical patients to intermediate care unit	4	3	2	24
Treat patient in the trauma room	Physician tied up with another patient	Shortage of staff	Risk of patient harm may increase	8	3	2	48	Provide adequate staff  Train the trauma team  Establish trauma back-up team	4	2	1	8
Transport patient to Operating Room (OR)	Delay in reaching the OR	Elevator tied up by other users or not working	Potential death	10	4	8	320	Have OR on the same floor.  Have portable vital signs monitor during transport.  Emergency elevators from Emergency Room (ER) to OR	6	1	1	6
				10	2	4	80	Elevator Hold for Patients needing ER to OR transport	5	2	1	10

In any FMEA, the organization designates the severity, frequency and detection rating. For example, a severity rating of 1 indicates a minor harm resulting in no medical intervention needed for the patient, such as minor discomfort. A rating of 10 means the harm can result in death. A rating of 5 may require major but non-life threatening intervention [Ref. 3].

Some suggestions for high-quality FMEA include:

- Designing the process for fail-safe performance (process fails in a way that does no harm)
- Creating a process that gives early warning of major harm scenarios
- Monitoring not only the results, but also the variability in the process through statistical data. Early warnings are indicated. For example:
  - o A person was brought a metal container to the MRI area, and the MRI malfunctioned
  - o A housekeeper did not know that only bleach-based sanitizers work on *C. diff* infections. She did not eliminate the bacteria from the patient's furniture

“A common mistake in conducting FMEA is doing it after the process is already implemented. Poor planning results in financial losses. This often discourages spending new money on revising an entire process, especially with limited budgets. Therefore, marginal actions are undertaken, which may increase risks and harm.”

### The Wrong Way to Conduct FMEA

A common mistake in conducting FMEA is doing it after the process is already implemented. Poor planning results in financial losses. This often discourages spending new money on revising an entire process, especially with limited budgets. Therefore, marginal actions are undertaken, which may increase risks and harm.

Another common error is to use FMEA only on one or two critical processes every year (the minimum recommended by the Joint Commission). Why not use FMEA on *all* critical processes? The return on investment is usually high; in some cases, as much as 100 percent.

For example, a hospital in Los Angeles was sued by 206 patients because the radiologist was giving too high a radiation level for a therapy to patients by forgetting to reset the radiation to a lower safe level. The cost of preventing such harm would have

been almost zero if the equipment supplier had programmed the machine to automatically reset to a safe level after each use. This equipment supplier probably would have needed to make only a minor change in the software. The cost of settling the lawsuits was at least *10,000 percent more* than the cost of software programming.

Another concern with FMEA implementation is that the prevention process is often not robust. For example, most hospitals rely on redundancy (double checking) in assuring correctness in giving the right medication to the right patient. But that sometimes fails.

For example, a pharmacy technician, distracted by her wedding plans, made a serious mistake in preparing a chemotherapy solution. A registered senior pharmacist was supposed to do a redundant check. Due to work overload, he signed off without verifying.

Another process, triple redundancy, can protect patients much better. Some of these processes require no monetary expenditure at all; they only require a change in procedure.

For example, in surgery, the first line of defense is a “time-out” requirement for every surgery to ensure that the correct site surgery is being done on the correct patient. A second level of defense requires reading aloud the needed safety precautions so that other team members can verify accuracy. A third level of defense requires each team member to read aloud the portions assigned to him or her.

### An Example of Successful FMEA Application

Veterans Administration (VA) hospitals were pioneers in institutionalizing this tool — using the tool in every critical process. The hospitals modified the FMEA tool and call it the Healthcare Failure Mode and Effects Analysis (HFMEA).

FMEA was successfully applied in these hospitals to multiple processes, such as blood glucose monitoring, MRI safety and improving patient flow in the Emergency Department [Ref. 6]. (For a copy of their tutorial, see <https://www.patientsafety.va.gov/docs/hfmea/FMEA2.pdf>.)

## Conclusion

Given the information contained within this paper, the authors have arrived at the following conclusions when finding risk management principles to improve patient care while gaining a high ROI:

- The standard performance goal is zero mistakes and zero harm
- The most widely used tool for risk prevention is FMEA, ideally used proactively — *before* any harm is done
- Management must be informed and act on preventing risks
- The earlier the prevention process starts, the higher the return on investment ●

## References

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