

Evaluation of Failure Mode and Effect Analysis in Patient Safety Context

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Abstract

Medical errors are recognized as a major challenge to healthcare worldwide. To prevent medical errors, Failure Mode and Effect Analysis (FMEA) has been adapted from other safety-critical industries to healthcare. Although the FMEA is still underutilized in healthcare, it has begun to be exploited through various applications in the context of patient safety in recent years; therefore, its extensive results should be communicated to encourage its practice. To explore this, we have reviewed the literature on FMEA in patient safety context published since 2015 using the PubMed index. After reviewing twenty papers regarding the selection criteria, we found that FMEA can be utilized in healthcare to contribute towards proactive risk identification, medical error reduction, overall patient safety, and quality improvement. Despite its benefits, earlier studies also highlighted that safety culture should support the use of FMEA along with the required resources and training for healthcare providers. Further, FMEA can be integrated with other tools, such as incident reporting, to provide more comprehensive risk picture within the scope of risk management.

Keywords

patient safety; healthcare operations; FMEA (failure mode and effect analysis); risk identification; medical errors

1. Introduction

Safety is vital not only in healthcare organizations but to all organizations where it is most evident in quality management (Aranaz-Andrés et al., 2017). In the healthcare context, medical errors constitute a big challenge harming both patients and providers worldwide (Kurutkan et al., 2015; Saulino et al., 2017). Accordingly, previous research have contributed to incident reporting and investigation data where the focus was mainly on learning from past experiences rather than being proactive to prevent errors (Simsekler et al., 2015). However, the past may not identify the present or future comprehensively; therefore, many proactive risk identification tools have emerged towards prevention within the scope of risk management.

While the most commonly used risk identification tool in healthcare is incident reporting (Simsekler et al., 2015); recent studies promoted the potential use of proactive approaches by adapting tools from other safety-critical industries, such as aviation and oil and gas industries (Card et al., 2014). Being proactive means being up to date, and avoiding the risk before it happens or can be called anticipating the incident before it occurs. Therefore, risk management has emerged to make sure patient safety is a priority where it is the bridge between errors and risks (Simsekler, 2019). Furthermore, Failure Mode and Effect Analysis (FMEA) is considered as one of the prospective tools used for risk management (Simsekler et al., 2019).

FMEA is a systematic tool that identifies where a process can fail using failure modes and their causes along with their effects. It has been around in the last 25 years where it has been developed

in automotive, aviation, and related engineering fields to reduce failures between human and machine interaction. In the early years of the 2000s, engineering has been put into the picture in healthcare and has brought HFMEA into life, a specific FMEA to healthcare industries developed by Veteran's Administration National Centre for Patient Safety (Magnezi et al., 2016; Shorstein et al., 2017; Sorrentino, 2016). Further, it was advised by the Institute for Healthcare Improvement (IHI) to use FMEA as a proactive tool to evaluate risks following the validation by the Agency for Healthcare Research and Quality (AHRQ) (Colman et al., 2019; Sorrentino, 2016).

While FMEA has gained popularity in the healthcare field (Liu et al., 2019) in recent years, it should be evaluated to see its potential advantages and disadvantages in patient safety context.

2. Methodology

The methodology used for data extraction is a systematic review to generate relevant articles and it has been categorized into four steps as follows: (Trakulsunti et al., 2020).

1. Identify the insertion and elimination measures or acceptance criteria. Articles have been filtered for the recent years so publication dates are from 2015 to 2020 with the selection of only full-text papers.
2. Identify the source of the information generator and research keywords. PubMed is chosen as the source of information since the topic is related to healthcare. The keywords in the search engines have been written as 'FMEA', 'patient safety' and relevant combinations.
3. Describe the studies chosen. A total of twenty papers have been selected where the common ones have been excluded. Titles have been read and the ones without the required keywords are eliminated. Abstract has been read as well and the irrelevant ones are excluded.
4. Specify the process of getting the data. All relevant articles have been saved in Mendeley Software for the organization, keeping track of papers read, easiness of highlighting and writing notes on the selected paper, and helpful for citations.

The data extraction summary is represented in Figure 1 below.

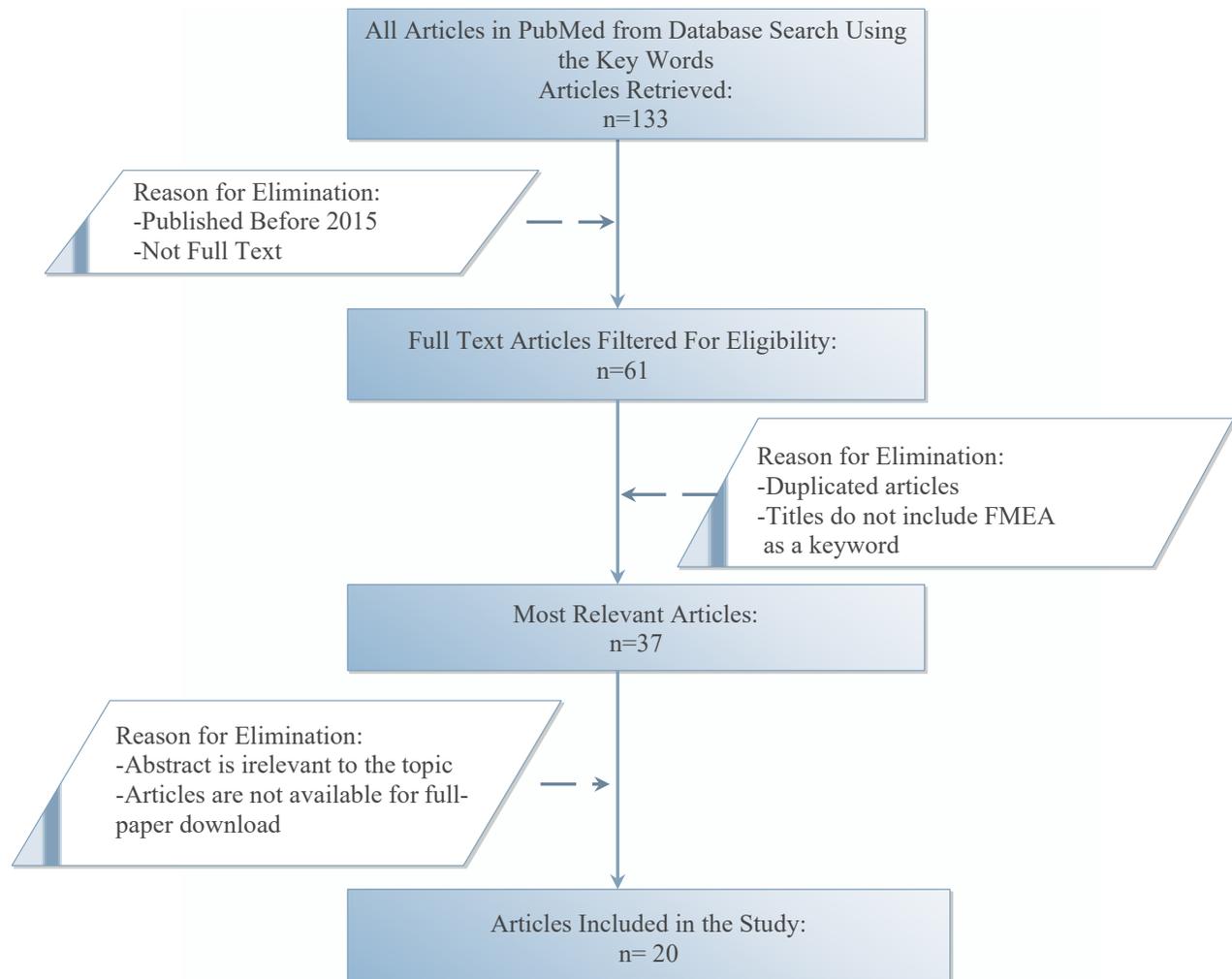


Figure 1: Methodology Summary Chart

3. Literature Review

FMEA has been implemented in various healthcare applications in recent years and most studies are the first of their kind to integrate FMEA in their unique setting.

3.1. Settings

The first initial steps in FMEA are to identify the process and then to assemble the team. In the literature, FMEA has been implemented in various processes with different number of participants and time frames. For instance, in a study conducted at a newly launched centre for hyperactivity disorder, the data is collected by a brainstorming method using 3 participants and 2 facilitators to assist and support through the whole process (Simsekler et al., 2019). The similar method of data collection is used for the administration of liquid medication in oral synergies study; however, the team members are more with nine members being involved for six months (Aranaz-Andrés et al., 2017). Adding to the brainstorming method, the authors formulated the problem and process using clinical experience, safety standards, and literature review with a team of thirteen professionals from different fields with the involvement of two patients.

In another study, twelve multidisciplinary team members at varying levels are formed with over three-month period due to the increased number of safety reporting in Emergency department handoffs; thus, the complex process is redesigned (Sorrentino, 2016). Another study has completed FMEA experiment in 4 months (Ofek et al., 2016). Additionally, experiments can also be performed in a small community with limited resources and with a duration estimate of six to twelve months (Schuller et al., 2017). Another study is focusing on the complex study of chronic pain treatment management where FMEA problem is formulated with ten pain physicians' experts from various specialities (Saulino et al., 2017). The duration sets its maximum for bilateral same-day cataract surgery which was for a year for one to two meetings in a month (Shorstein et al., 2017).

3.2. Process Description

Beside brainstorming and safety reporting tool from the initiation steps, other important tools have been applied for the flow and explanation of the process. In the hyperactivity disorder study, System Mapping Diagram (SMA) is selected, and for the stereotactic body radiation, tree generation is incorporated. In another study, a flow chart with an algorithm linked to a consecutive number to each process has been put into the system (Ofek et al., 2016; Simsekler et al., 2019). Another tool used in FMEA activity explanation is process mapping along with round table discussions and brainstorming that support in understanding the details of the complex process and making sure everyone is in the same picture (Schuller et al., 2017). Further, the process map tool using a functional block diagram is implemented for all processes and subprocesses for visualization (Sorrentino, 2016) and process trees were used in others (Shen et al., 2019; Xu et al., 2017).

It is noted in the literature that methods can be integrated with FMEA to provide better process understanding for users (Simsekler et al., 2018). A new method has been used with FMEA which is Simulation Based on Clinical System Testing (SbCt). This combination of methods has been used for a new built environment. SbCt's main goal is to assist FMEA in predicting the failure modes; thus, instead of imagining latent safety threats, simulation can be prepared through a platform to interrupt this whole process. Simulations support analyzing process scenarios and expecting the effects which feed FMEA evaluations (Colman et al., 2019). The flow chart is critical; thus, agreement of the process map must be aligned to complete the following essential step which is the failure modes analysis grid.

The evaluations that contribute to FMEA grid consist of 4 major components which are; potential failure, effect, causes, and method of detection (Arenas Jiménez et al., 2017). Effect is the symptom detected by the patient or by the healthcare system, and all causes should be stated for each potential failure to guarantee quality and ease the protection measures formulated. Method of detection is a description of how these failures can be detected. To determine the highest risks that need to be prioritized; the failures can be ranked by risk priority number (RPN), 100 indicates the highest score, for the potential failures by multiplying the following: Frequency (F) * Severity(G) * Detection of Failure (D). Frequency is how likely the failure to occur which can depend on the judgment of experts available in this study and also on the history and literature. Severity is how harmful the failure can cause which can be based on history and literature where decision tree analysis has been used in (Sorrentino, 2016) for severity score. Detection of Failure is how likely

the failure to be detected (Shorstein et al., 2017). All data including failure modes, causes, and effects are formulated in FMEA table from high to low score and the ones with the highest RPN score have been analyzed further and re-evaluated for reassurance (Saulino et al., 2017; Schuller et al., 2017). It is suggested to use and analyze the 10 highest RPN scores by the institute of healthcare improvement where control measures can then be implemented with an assigned date and person to follow up (Ofek et al., 2016; Sorrentino, 2016). However, in Chronic pain study, RPN threshold has been formulated to identify the highest risk components (Saulino et al., 2017).

FMEA grid has raised many opportunities to fix the processes as training and assessments (Shorstein et al., 2017). Lastly, a completion of FMEA study can be described as follows: evaluating the results by periodic review, audit, rounding, and observations to check the results of the study with a plan-do-study-act cycles (PDSA) (Sorrentino, 2016).

3.3. Opportunities

Medication errors are critical to many players in healthcare; pharmacists, doctors, medical administrators, clinicians, and suppliers where FMEA can play an important role in decreasing them. FMEA is considered as a risk assessment tool for numerous reasons. It is quick to implement so it does not need a lot of experience in usage. Besides, it is a systematic technique and reliable where it captures many components as it involves many sub-processes and it does not harm any patient (Ofek et al., 2016; Sorrentino, 2016). FMEA is effective to policymakers and strategy makers that aim to reduce medical errors and build a safer hospital. It is indicated that FMEA can become a universal tool in healthcare for its promising results since it is valuable in detecting present failures and future failures (Arenas Jiménez et al., 2017; Ofek et al., 2016). In fact, in oral synergies research paper, the results have shown an unexpected result where the problem is not from the availability of oral synergies stock but the fact that it is not distributed by supply; henceforth, FMEA results in an improvement of usage in existing tools (Aranaz-Andrés et al., 2017). Consequently, FMEA is helpful for a valuable output supporting the overall risk assessment, enhancing and improving safety and quality (Saulino et al., 2017; Schuller et al., 2017; Simsekler et al., 2019).

The outcome revealed by FMEA is of a high importance to health sectors that can result in many reduced critical errors where many studies have used FMEA for complex and critical processes. A life-threatening process has included FMEA to identify threats for patients experiencing Stereotactic Body Radiation Therapy where any error can lead to a serious injury (Saulino et al., 2017). In another paper, Potassium Chloride (KCL) solution has been discussed where it can be a severe medication; thus, it should be carefully prescribed, discharged, and received by patients. It has been suggested to put in place a ready-use KCL solution to minimize the risks of preparation and administration of KCL (Ofek et al., 2016). Furthermore, Radiation Therapy needs to be safe and effective since the procedure is prone to errors; thus, FMEA has been used as well (Saulino et al., 2017). It can be noticed that FMEA provides greater clarity of the processes as it gives understanding to their strengths and the weaknesses and it involves team collaboration and as a result, each member is aware of the different positions which leads to accumulating respect and trust between each other's (Sorrentino, 2016).

3.4 Challenges

The studies have shown some limitations when using FMEA as a risk identification approach. Studies (e.g. Schuller et al., 2017; Simsekler et al., 2019) have agreed that the potential cost and the amount of resources engaged in the process are the main struggle in the system where it can be stated that FMEA is a resource-intensive process. Also, FMEA is newly established, training should be prepared for the involved staff which would require even higher cost. Moreover, commitment and attendance to meetings and discussions can be of great difficulty since members in the process usually work in a healthcare organization and they cannot leave their job behind without a replacement (Sorrentino, 2016)

In the team assembly step, it is not that easy to gather a team for analysis as they are from a multidisciplinary field and mostly experts engaged; thus, they may have a busy schedule (Simsekler et al., 2019). When formulating the causes and effect, there is likely to be a potential bias in RPN scores that depend on meeting discussion and whoever is present from the members (Schuller et al., 2017). One of the other relevant drawbacks is not being able to identify the external and environmental risks as FMEA is not possible to cover all types of risks where not all concerns can be comprehended (Simsekler et al., 2019). Jiménez and colleagues (2017) mentions the possibility that not all failures have been detected in the short period of FMEA experiment implementation.

3.5 Recommendations

Given the opportunities and challenges of the studies identified, some recommendations have been made to help improve FMEA exercises in healthcare. According to (Shorstein et al., 2017), FMEA is perfect for new or redesigned processes, especially in complex working environments. It is noted in another study (Simsekler et al., 2019) that larger group number brings more accuracy, the motivation of people will result in more causes & effects of failure modes and experience of people can give more accuracy. As an example in (Shorstein et al., 2017), the data is analyzed for twenty-one surgery centres which can get accurate results and predict the risk occurrence better.

Time and meeting schedules for FMEA are crucial; however, measures need to be formulated to avoid time wasted, absence of attendees, and the bias score of RPN. It is observed in (Schuller et al., 2017) that the initiation of FMEA steps started by the facilitator or leader of FMEA where they should be trained by numerous means as courses or school and it is one of the main reasons that kept the team focused and on track. Also, it is recommended to have advanced planning of meetings and the leader should meet the attendance and is a supporter throughout the process for all attendees and relevant problems (Sorrentino, 2016). Hence, FMEA depends highly on the selection of team along with the leader which should be made carefully to select people who have interest and willingness to assist for the consistency and the effectiveness of the project (Schuller et al., 2017; Sorrentino, 2016).

Various tools, such as System Modelling Approaches (SMAs), have been implemented to avoid the drawbacks of FMEA; hence, it can assist system description (Simsekler et al., 2018). Moreover, SbCt simulations have been used for a new construction which demonstrates the great difficulty of picturing the possible failure modes; thus, SbCt can give a vivid picture for the potential failures' modes (Colman et al., 2019). Accordingly, FMEA is affected by the chosen mapping process and Healthcare organizations should not be contingent only on the FMEA tool for prioritizing patients'

safety (Simsekler et al., 2019). It is also stated that FMEA results can be used as a complement to existing strategies and FMEA process should be revisited and the effectiveness should be measured for a continuous improvement (Saulino et al., 2017).

It is clear the quantification of studies may not be as accurate since RPN can differ from one person to another; however, this should not matter as much as the unwanted outcome will always be more important to analyze (Saulino et al., 2017). In earlier studies (Bonfantini et al., 2019), the study has used other methods to reduce the subjectivity of RPN scores which are; survey questions, simulation of failure modes, and literature reviews. It is recommended in a recent study (Arenas Jiménez et al., 2017) that failures should not be described as patient symptoms but rather should be explained in physical or technical terms.

FMEA can be beneficial by identifying all the new implementations and processes and continue using reactive or retrospective measures for the failure modes that have already occurred in existing processes. Prospective measures should be used with more frequency in the FMEA table. It is also declared that FMEA is indeed costly to make; however, in the long run, it can save so many costs from medical quality and safety enhancements to improving the wellbeing and health of the patients being served. On another level, it has given people down the pyramid more emphasis on and more trust in reducing and reporting these medical errors.

4. Discussion

Evaluation of FMEA with the support and results of earlier studies have provided valuable insights. For any FMEA study, all major and minor steps are articulated for an optimum evaluation using literature review section; hence, the following six steps detailed in the table below may help for more effective and efficient delivery of FMEA outcomes.

Table 1: FMEA Process in Steps

Step	Process Name	Description
1	Specifying the critical or complex process, and identifying the topic and scope	The support of brainstorming discussions, literature reviews, and regulatory policies can be applied for better results.
2	Team assembly	The team should be chosen carefully as they can be interviewed or generally asking about them in their departments since the FMEA process needs Commitment. The team should consist of different fields experts and for better outcome; facilitator and patients should be included. Therefore, different perspectives can be generated with a wide range of strategies (Ofek et al., 2016; Schuller et al., 2017)
3	Layout the process and subprocess	Flowchart is preferably used to explain the detailed process depending on the topic and team selected using the preferred tool. The results can

		be effective if the method is chosen well (Schuller et al., 2017).
4	Potential mode failures with hazard/risk analysis for each step	A score will result based on detectability, severity, and probability of occurrence where 10 is the highest and 1 is the lowest and the product of these three is the RPN score which will result in a maximum RPN score of 100 (Magnezi et al., 2016; Ofek et al., 2016).
5	Control measures	Decision should be made to accept, eliminate, or control the failure modes. A person should be appointed to be responsible to follow up and implement the measure.
6	Evaluations	It can be noted that not all papers have this step or they have forgotten to mention. This step is important to evaluate and reassess the process (Ofek et al., 2016).

It can be observed from the first step that the processes or areas are mostly used for critical and complex system which validate the importance of utilizing FMEA. These processes selected are usually prone to human and clinical errors, or they are implemented in a new process that can be very effective and produce more safety and less time and cost in the organization or, they can be initiated in a new organization where many effects are unknown (Aranaz-Andrés et al., 2017; Ofek et al., 2016; Saulino et al., 2017; Schuller et al., 2017).

Most studies were their first time in using FMEA method in their specific field or process like IT and radiation therapies (Saulino et al., 2017; Schuller et al., 2017) which emphasizes that HFMEA has just recently joined the market. Since it is the first time for the health organization to use FMEA, it is expected for the process to take longer time than usual so time will not be a big issue if FMEA is continuously used (Schuller et al., 2017). Indeed, meetings can be a concern but if the team is selected wisely and is committed, one can make proper scheduling of meetings and make them at the same time flexible as meetings can be online for whoever cannot join the live session.

Regarding step 2, the education of members engaged in FMEA studies can be introduced as a subprocess of team selections as some trainings need to be given to the members involved in the experiment where it can be supported by a facilitator. In another format, only some materials for education are received by participants before the first meeting to be familiarized with the FMEA process (Schuller et al., 2017).

All papers have used FMEA table or grid to illustrate failure modes and their effects and causes using RPN. Facilitators are of great importance to the FMEA process as they provide lots of advantages and probably generate a more effective process. Thus, FMEA depends highly on the selection of the team to generate the best outcomes of FMEA (Sorrentino, 2016).

It can be noticed that sample size can range widely and there is no optimum sample size yet found, but the more samples, the better outcome and more accurate results. Brainstorming is a key tool and can be emphasized in the first stages of FMEA formulation and can be also utilized in meetings

and discussions (Aranaz-Andrés et al., 2017; Simsekler et al., 2019). The durations have varied from three months to twelve months and the number of members has also varied where they all depend on the limitations each healthcare possesses. It is evident that the advantages of FMEA are much more than the disadvantages as summarized in the table below which encourages its practice.

Table 2: FMEA Advantages and Disadvantages Summary

Advantages	Disadvantages
Proactive, systematic, and reliable technique.	Cost: the high cost can be represented by the resources as facilitator, training, and experiment setup costs.
Can prevent medical errors mostly in complex and dangerous environments.	Time: the time spent will be mostly in the training, lots of meetings, and the conflict of the different schedules of the participants.
Effective especially in an unknown environment as a new hospital.	Uncertainty: HFMEA is considered new where some measures are still uncertain like the sample size and the time needed to complete the experiment.
Enhance healthcare safety and quality	Difficulty of identifying external risks.
Better understanding and clarity to the process chosen	
Awareness of the hospital and activity roles by the team selected.	
Team Collaboration as participants in the experiment are from different specialisations.	
Better reputation of the hospital and less cost and time in the long run.	

Healthcare organizations should not rely only on FMEA tool for prioritizing patient’s safety as it obviously cannot cover every potential failure possible; however, FMEA is an important tool to revalidate the procedures done in healthcare and enhance patients' safety since it can articulate great opportunities (Shorstein et al., 2017).

To capture opportunities and effectiveness, working in parallel with new processes and improving the highest risks in old processes can generate great productivity and utilization of HFMEA. The aim is to have all processes covered using tools, such as FMEA, where results can be effectively monitored and anticipated for an improvement. It is about the path taken to reach that final desired outcome that can serve towards enhancing patient safety experience and FMEA should be considered and utilized as a path for the valuable results it can cultivate.

For further recommendations and discussion; healthcare staff and researchers should experiment more with FMEA and incorporate it with other risk identification tools to bring more opportunity for improvement as the current measures are insufficient. Risk identification tools can either be reactive and proactive and they should be integrated, possibly with more advanced technologies,

such as artificial intelligence (Ellahham et al., 2019), to cover all risks and produce a high optimality of FMEA (Simsekler et al., 2018, 2019).

5. Conclusion

The literature review has demonstrated key findings that outlines the objectives and the validity of FMEA use in patient safety context. These finding start by the settings where they can vary from a topic to another with a minimum of 3 months' duration and a maximum of 1 year to complete FMEA study in a new or old healthcare facility. The team selection is a key to the success of the project and should include a diverse specialities. FMEA process explanation can use different tools which depend on the decision of healthcare organization and it depends on the understanding of the project as the process should give clarity with as many details as possible. FMEA risk assessment includes causes and effects and they are of similar implementation throughout the studies where the failure modes with the highest RPN score are prioritized. Control measures are implemented for the high-risk practices with the evaluation of these measures at a later stage. In short, seven steps are configured for FMEA study and they are; process identification, team assembly, process layout, potential mode failures, control measures, and finally evaluations.

To have optimum patient safety in a healthcare environment, one must not depend only on one tool to do that as it cannot work alone in the reduction of risks since it is not possible to cover all risks available especially external risks. Consequently, other tools such as root cause analysis and safety reporting which are retrospective measures, SbCt for latent safety detection, SMA for better visualization of the process, and brainstorming for better process identification and formulation should be integrated with FMEA for better risks coverage. FMEA is a powerful prospective measure that can be used for new processes or activities. Undoubtedly, FMEA tool will take time and resources; however, the results can be overwhelming and would reduce the future cost and time. Furthermore, a learning curve would result when the FMEA process is repeated; thus, shorter duration to finish the studies.

FMEA can be summed up as a proactive tool that can anticipate potential problems, eliminate serious concerns before they occur and it demonstrates a valuable support and is significant in patients' safety and quality under the provision of care. It should be integrated with other useful tools for optimum exploitation and it should be highlighted with more emphasis assigned to it for its vital results.

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