International Journal Multidisciplinary Business Management (IJMBM)

eISSN: 2286-8445 www.ijmbm.org

Application of Failure Mode and Effects Analysis (FMEA) to Improve Medical Device Reliability

[1*]Dattu F.H.P.A, [2]Syed Shazali S.T, [3]Tanjong, S.J, [4]Abdullah, Abdul Rani Achmed

[1]*Faculty of Engineering and Technology (Mechanical), i-CATS University College Jalan Stampin Timur, 93350 Kuching, Sarawak, Malaysia*

[2,3,4]*Faculty of Engineering, Mechanical Engineering*

Universiti Malaysia Sarawak, Jln Datuk Mohammad Musa, 94300 Kota Samarahan Sarawak, Malaysia.

Abstract: Medication safety is a pressing global concern, highlighting the need for reliable and secure medical devices within the healthcare industry. Device malfunctions can severely affect patient well-being, necessitating effective engineering and maintenance practices to address these risks. This research constitutes a significant advancement in this field by utilizing Failure Modes and Effects Analysis (FMEA) to evaluate and improve the dependability and safety of medical devices. The study prioritizes risks and formulates targeted mitigation strategies by systematically identifying potential failure modes, assessing their consequences, and determining their likelihood of occurrence and detection. The comprehensive FMEA process examines operational conditions and identifies critical areas for enhancement, resulting in substantial improvements in device reliability. The findings emphasize the importance of proactive risk management and continuous improvement in the engineering and maintenance of medical devices. This paper provides a solid foundation for implementing FMEA in engineering and maintaining medical devices, offering valuable insights for manufacturers and regulatory agencies to enhance device safety and performance.

KEYWORDS: FMEA, medical device, Engineering Maintenance, Aset Management

1. INTRODUCTION

According to a study released by Healthgrades of the U.S., among the 2,500,000 accident deaths of patients from 2000 to 2002, 575,000 of them resulted from preventable medical errors (Health Grade, 2004). In the rapidly evolving healthcare field, medical devices are pivotal in diagnosis, treatment, and patient care. Their reliability and safety are paramount, as failures can lead to significant health risks, costly recalls, and regulatory non-compliance. The potential risks of medical device malfunctions underscore the need for a proactive approach to identifying and mitigating failures throughout the product lifecycle (Huusko, J. et al., 2023).

Failure Modes and Effects Analysis (FMEA) is a systematic, structured method for evaluating processes to identify where and how they might fail and assessing the relative impact of different failures (Liu et al., 2018). Originating in the aerospace and automotive industries, FMEA has proven to be an invaluable tool in pre-emptive risk management. Its application in the medical device industry is particularly critical due to its direct implications on patient safety and device efficacy. FMEA's proactive approach to identifying and mitigating potential failures is essential to ensuring the robustness of medical devices (L. Liu et al., 2012).

This paper explores the proactive application of FMEA in enhancing the reliability of medical devices. By systematically identifying potential failure modes, assessing their effects, and prioritizing them based on severity, occurrence, and detection, FMEA provides a comprehensive framework for risk management (Huang et al., 2017). The objective is to reduce the likelihood of device failure, enhance performance, and ensure compliance with stringent regulatory standards. This proactive approach to risk management can significantly improve patient outcomes and trust in healthcare systems.

The study involves a detailed FMEA process applied to various medical devices, encompassing design, manufacturing, and operational phases. This analysis identifies critical areas for improvement and develops targeted strategies to mitigate identified risks. The objectives of this research are to:

1. Identify systematically all possible ways in which medical devices can fail.
2. Prioritize failure modes based on the severity of their impact.

While FMEA is a valuable tool, it is essential to acknowledge and address its limitations. Ensuring the accuracy and completeness of data, minimizing subjectivity in risk assessment, and maintaining continuous follow-up is critical for maximizing the effectiveness of FMEA. Additionally, fostering cross-functional collaboration and leveraging expert knowledge can enhance the depth and accuracy of the analysis (Huang et al., 2020). The limitations of this study are:

1. Risk priority numbers (RPN) and other scoring systems can be highly subjective, depending on the individuals performing the analysis.
2. Unexpected or rare failure modes may be overlooked if not previously encountered or documented.
3. FMEA often focuses on individual components rather than considering the system, potentially missing interactions and dependencies between components.

The primary objective of applying FMEA to medical devices is to proactively identify and address potential failure modes to improve the reliability and safety of these critical tools. By systematically evaluating and mitigating risks, the FMEA process helps ensure that medical devices perform as intended, enhancing patient outcomes and supporting healthcare providers in delivering high-quality care (Anjalee et al., 2021).

2. LITERATURE REVIEW

FMEA originated in the aerospace industry in the 1940s and gained prominence through its adoption by the automotive industry in the 1960s. Its fundamental principles involve identifying failure modes, assessing their effects, and prioritizing them based on severity, occurrence, and detection. The structured approach helps organizations pre-emptively address potential issues, enhancing product reliability and safety (Sharma, Kapil et al., 2018).

The medical device industry has increasingly adopted FMEA as part of its risk management strategies, driven by regulatory requirements and the need to ensure patient safety. Regulatory bodies such as the FDA and ISO (specifically ISO 14971 for medical device risk management) mandate rigorous risk assessment processes, where FMEA plays a crucial role. Studies have highlighted the effectiveness of FMEA in various stages of medical device development, from design and manufacturing to post-market surveillance. Some commonly used terms related to FMEA are specified as follows (L. Liu et al., 2012):

- Severity (S): the consequences of a failure mode.
- Occurrence (O): the probability of occurrence of failure mode.
- Detection (D): the level at which potential causes of a failure mode can be inspected.

Research indicates that early application of FMEA in the design phase can significantly reduce the likelihood of failure. A study by Saulino M. (2017) demonstrated that incorporating FMEA in the design review process of implantable devices led to a substantial decrease in reported adverse events. Similarly, Simsekler et al. (2019) emphasized the importance of FMEA in identifying potential design flaws that could compromise device functionality. FMEA helps identify process-related failure modes in the manufacturing phase that could affect device quality.

According to a study by Li and He (2017), applying FMEA to the manufacturing process of catheter production resulted in improved yield rates and reduced defects. The study showed that manufacturers could enhance overall product quality by addressing critical failure points identified through FMEA.

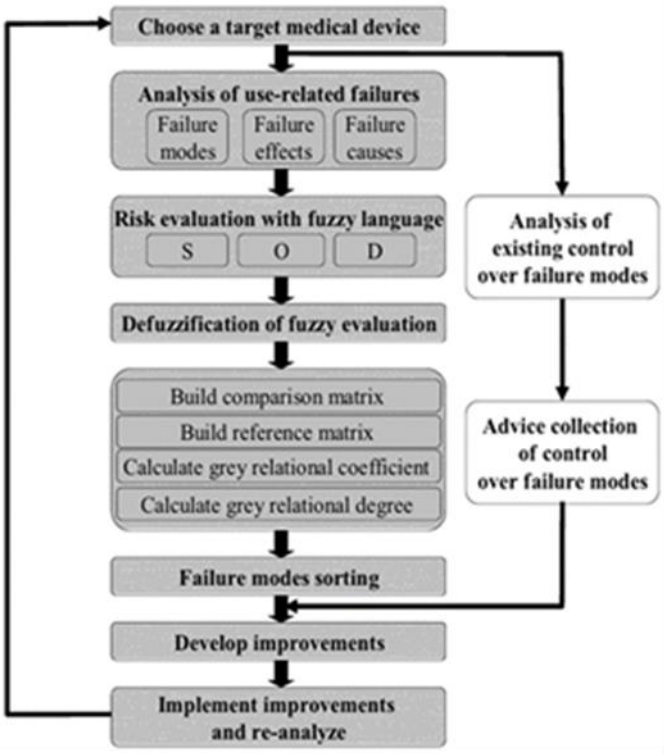

Fig 1 Improved FMEA process based on Fuzzy Mathematics and Gery Relational Analysis (L. Long et al., 2012)

Long (2012) study improved the FMEA method based on Fuzzy Mathematics and Grey Relational Analysis. It developed a better carry-out use-related risk analysis for medical devices—the analysis processes based on FMEA on the use-related risk of C-arm X-ray machines. A successful FMEA activity helps a team to identify potential failure modes, enabling the team to design that failure out of the system with the minimum effort and resource expenditure.

Recent technological advancements enhance its effectiveness, such as integrating FMEA with digital tools and machine learning. Tools like failure mode effect, criticality analysis (FMECA) software, and predictive analytics are being used to streamline the FMEA process. A study by Liu et al. (2018) demonstrated the use of machine learning algorithms to predict failure modes in real-time, significantly improving the efficiency of the FMEA process.

3. METHODOLOGY

For this study, 10 medical device records for failure modes were collected from the CMMS data of hospitals in Malaysia between 2020 and 2021. The data consists of records of asset types, locations, and work orders, the specific maintenance types, and problem descriptions.

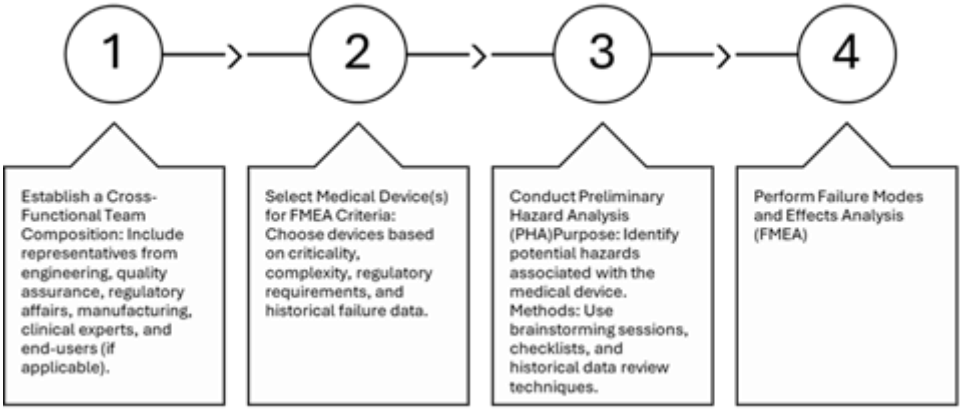

Fig 2 *The Methodology of the Study*

In this study, ten critical devices were used for the analysis, including ventilation, defibrillation, dialysis machines, infusion pumps, pacemakers, anesthesia machines, MRI machines, CT Scanners, incubators, and surgical lasers.

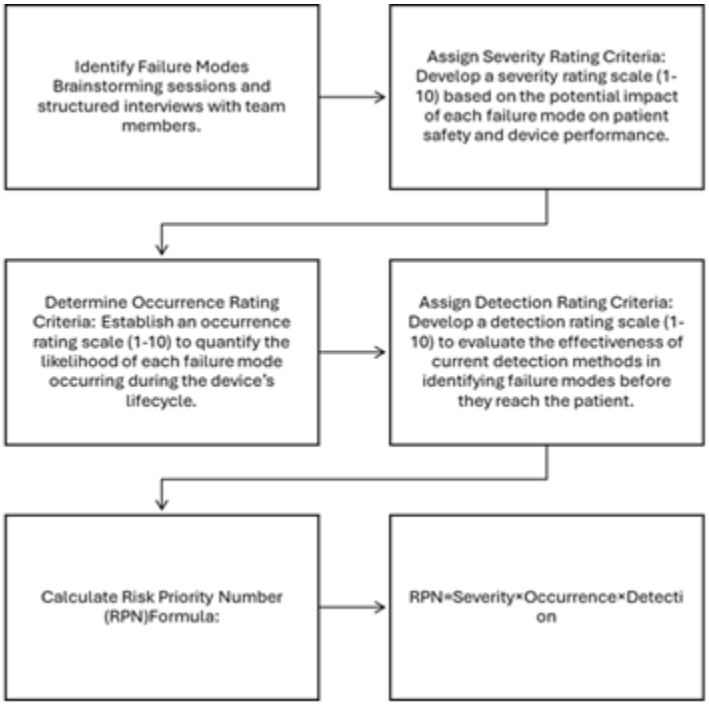

Fig 3 *The Methodology of FMEA for medical devices.*

The FMEA table for ten (10) medical devices has been developed. The severity, occurrence, and detection are numbered according to Table 3.1. To 3.3 below.

Table 1 *Severity Table*

Severity Rating	Description	Effects
1	No effects	No effects.
2-3	Minor	Minor disruption.
4-6	Moderate	Some impact on performance.
7-8	High	Significant impact on performance.
9-10	Very High	Catastrophic impact.

Table 2 *Occurrence table*

Occurrence Rating	Description	Frequency
1	Remote	Failure is unlikely.
2-3	Low	Failure is rare.
4-6	Moderate	Occasional failure.
7-8	High	Frequent failure.
9-10	Very High	Failure is almost inevitable.

Table 3 *Detection table*

Detection Rating	Description	Likelihood of Detection
1	Almost certain detection	Very high likelihood.
2-3	High likelihood detection	Control almost always detects failures.
4-6	Moderate likelihood of detection	Control has a fair chance of detecting failures.
7-8	Low likelihood of detection	Control may detect failures but are unreliable.
9-10	Very low/no likelihood of detection	Failures are unlikely to be detected.

The RPN values are interpreted according to the scale below:

Low (1 – 50)	Typically, it is less critical and may require minimal action.
Moderate (51 – 100)	Failure modes should be reviewed and possibly addressed to reduce risk.
High (101 – 150)	Failure modes require significant attention and action to mitigate.
Very high (151 – 200)	Failure modes are critical and require immediate action to address.

4. RESULTS & DISCUSSIONS

Failure Modes and Effects Analysis (FMEA) is a systematic method for evaluating processes to identify where and how they might fail and assessing the relative impact of different failures to identify the parts of the process that need the most change. In medical devices, FMEA can enhance the reliability and safety of critical devices (Mascia et al., 2020)—the main FMEA table of 10 medical devices. Table 4 shows the summary of the failure of 10 medical devices.

Table 4 The summary of the failure of the study

No	Device name	Criteria	Descriptions
1	Ventilation	Failure modes	Power failure, sensor malfunction, software bugs.
		Effects	Respiratory distress, hypoxia.
		Recommendations	Redundant power supplies, regular sensor calibration, robust software testing.
2	Defibrillation	Failure modes	Battery depletion, electrode pad failure, software errors.
		Effects	Failure to resuscitate, prolonged downtime.
		Recommendations	Battery status indicators, quality checks on electrodes, and frequent software updates.
3	Dialysis	Failure modes	Pump failure, blood leakage, dialysate contamination.
		Effects	Inadequate dialysis and infection risk.
		Recommendations	Routine pump maintenance, leak detection systems, and stringent sterilization protocols.
4	Infusion	Failure modes	Flow rate inaccuracy, occlusions, alarm failures.
		Effects	Overdose or underdose of medication, delayed treatment response.
		Recommendations	Regular calibration, occlusion sensors, and reliable alarm systems.
5	Pacemakers	Failure modes	Battery depletion, lead failure, software malfunctions.
		Effects	Arrhythmias, device failure.
		Recommendations	Enhanced battery life monitoring, lead durability testing, and firmware updates.
6	Anesthesia	Failure modes	Gas flow errors, ventilator failure, monitoring system failure.
		Effects	Hypoxia, anesthesia awareness.
		Recommendations	Real-time gas monitoring, backup ventilators, and comprehensive monitoring systems.
7	MRI	Failure modes	Magnet quench, cooling system failure, image artifact.
		Effects	Incomplete scans and patient discomfort.
		Recommendations	Regular maintenance of cooling systems, real-time quench detection, and image quality checks.
8	CT Scanners	Failure modes	X-ray tube failure, software glitches, and gantry issues.
		Effects	Inaccurate imaging increases radiation exposure.
		Recommendations	routine x-ray tube inspection, software validation, and gantry alignment checks.

9	Incubators	Failure modes	temperature control failure, humidity control failure, and alarm system failure.
		Effects	Hypothermia, dehydration, unnoticed distress.
		Recommendations	Precision temperature and humidity controls, reliable alarm systems.
10	Surgical Lasers	Failure modes	Calibration drift, power supply issues, software errors.
		Effects	Ineffective treatment, tissue damage.
		Recommendations	Regular calibration, stable power sources, and software verification.

From the FMEA table 4, many devices share similar failure modes, such as power issues (ventilation, surgical lasers), software bugs (ventilation, defibrillation, surgical lasers), and sensor or monitoring failures (ventilation, infusion pumps, anesthesia machines). The potential effects of these failure modes highlight significant risks to patient safety, including respiratory distress, inadequate treatment, hypoxia, infection risk, arrhythmias, and tissue damage.

From the FMEA table (Appendix 1), 4 devices with very high RPN, which is more than 150 scores, with more failure on mechanical components. The devices are ventilators, Anesthesia machines, CT Scanners, and incubators. The results of this FMEA application demonstrate the necessity of proactive risk management strategies to improve medical device reliability. Implementing the recommended actions and process controls can significantly reduce the likelihood of device failures and their adverse effects, ultimately enhancing patient safety and clinical outcomes. As medical technology continues to evolve, continuous improvement and adaptation of FMEA practices will remain essential in addressing emerging risks and ensuring the reliability of medical devices.

The four recommendations from this study are based on the main failure. This recommendation can be added to the Preventive maintenance work for clinical engineers. Regular maintenance and calibration are a must for all medical devices. This ensures that devices undergo frequent maintenance and calibration throughout to prevent failure. Apart from that, robust software and firmware updates are also prioritized. Implementing a rigorous process for software and firmware updates is to fix bugs and improve performance. Preventive and corrective maintenance must be performed regularly to enhance monitoring and alarms. This can improve monitoring systems and alarms to promptly detect and address potential failures. Training for each medical personnel is also important in maintenance work. Providing extensive training for medical personnel to handle device failure effectively. The application of FMEA to these ten critical medical devices highlights the importance of proactive measures in ensuring their reliability and safety. By identifying potential failure modes and their effects and implementing recommended actions, the reliability of these devices can be significantly improved, ultimately enhancing patient safety and care quality.

5. CONCLUSION & FUTURE SCOPE

The application of Failure Modes and Effects Analysis (FMEA) to improve the reliability of medical devices is a crucial proactive approach in the healthcare industry. FMEA offers a structured methodology for identifying potential failure modes, assessing their impact, and prioritizing corrective actions to mitigate risks. Through systematic analysis, FMEA enhances critical medical devices' safety, performance, and reliability, ultimately contributing to better patient outcomes and improved clinical practice.

Some recommendations for this study include leveraging big data and machine learning to enhance the accuracy and predictive power of FMEA. It utilizes real-time data from maintenance logs and clinical outcomes to continuously update and refine failure mode predictions. In addition, future works can incorporate simulation tools and modeling techniques to predict and visualize failure modes and their effects. FMEA can be used in virtual environments to test devices under various conditions. It can identify potential failures that might not be evident in real-world situations.

In conclusion, applying FMEA is vital for enhancing medical device reliability. By systematically identifying and mitigating potential failure modes, FMEA improves device performance and significantly contributes to patient safety and the overall quality of healthcare delivery. As the medical field continues to evolve, embracing FMEA and its principles will remain essential for advancing medical device technology and ensuring the highest standards of care.

ACKNOWLEGEMENT

The authors thank the i-CATS University College (i-CATS UC), Universiti Malaysia Sarawak, and UNIMAS Industrial Grant with CWorks Technologies Sdn Bhd (Project Code: IRG/F02/CWORKS/85394/2022) for their continuous support in conducting this study.

REFERENCES

1. Health Grades, Inc. Patient Safety in American hospitals, 2004.
2. Huusko, J., Kinnunen, U. M., & Saranto, K. (2023). Medical device regulation (MDR) in health technology enterprises – perspectives of managers and regulatory professionals. BMC health services research, 23(1), 310. https://doi.org/10.1186/s12913-023-09316-8
3. Huang, Jia & Li, Zhaojun & Liu, Hu-Chen. (2017). New approach for failure mode and effect analysis using linguistic distribution assessments and TODIM method. Reliability Engineering & System Safety. 167. 10.1016/j.ress.2017.06.014.
4. Huang, Jia & You, Jianxin & Liu, Hu-Chen & Song, Ming-Shun. (2020). Failure mode and effect analysis improvement: A systematic literature review and future research agenda. Reliability Engineering & System Safety. 199. 106885. 10.1016/j.ress.2020.106885.
5. Anjalee, J. A. L., Rutter, V., & Samaranayake, N. R. (2021). Application of failure mode and effects analysis (FMEA) to improve medication safety in the dispensing process - a study at a teaching hospital, Sri Lanka. BMC public health, 21(1), 1430. https://doi.org/10.1186/s12889-021-11369-5
6. Sharma, Kapil & Srivastava, Shobhit. (2018). Failure Mode and Effect Analysis (FMEA) Implementation: A Literature Review.
7. Saulino, M. F., Patel, T., & Fisher, S. P. (2017). The Application of Failure Modes and Effects Analysis Methodology to Intrathecal Drug Delivery for Pain Management. Neuromodulation: journal of the International Neuromodulation Society, 20(2), 177–186. https://doi.org/10.1111/ner.12475
8. Simsekler, M. C. E., Kaya, G. K., Ward, J. R., & Clarkson, P. J. (2019). Evaluating inputs of failure modes and effects analysis in identifying patient safety risks. International journal of health care quality assurance, 32(1), 191–207. https://doi.org/10.1108/IJHCQA-12-2017-0233
9. Li, X., He, M., & Wang, H. (2017). Application of failure mode and effect analysis in managing catheter-related blood stream infection in intensive care unit. Medicine, 96(51), e9339. https://doi.org/10.1097/MD.0000000000009339
10. Liu, Hu-Chen & You, Xiao-Yue & Tsung, Fugee & Ji, Ping. (2018). An improved approach for failure mode and effect analysis involving large group of experts: An application to the healthcare field. Quality Engineering. 30. 1-44. 10.1080/08982112.2018.1448089.
11. Mascia, A., Cirafici, A.M., Bongiovanni, A. et al. A failure mode and effect analysis (FMEA)-based approach for risk assessment of scientific processes in non-regulated research laboratories. Accred Qual Assur 25, 311–321 (2020). https://doi.org/10.1007/s00769-020-01441-9