The American Journal of Interdisciplinary Innovation and Research
ISSN 2642-7478 | Open Access

Type Original Research
PAGE NO. 121-125
DOI 10.37547/tajiir/Volume07Issue09-13

AI-Powered Failure Mode and Effects Analysis (FMEA) for Cardiovascular Devices: A Modern Framework for Proactive Risk Management

Aniruddha Dhole
Design Quality Assurance, USA

OPEN ACCESS

SUBMITTED 04 August 2025
ACCEPTED 26 August 2025
PUBLISHED 29 September 2025
VOLUME Vol.07 Issue 09 2025

CITATION
Dhole, A. (2025). AI-Powered Failure Mode and Effects Analysis (FMEA) for Cardiovascular Devices: A Modern Framework for Proactive Risk Management. The American Journal of Interdisciplinary Innovations and Research, 7(09), 121–125. https://doi.org/10.37547/tajiir/Volume07Issue09-13

Abstract- Stents and implantable defibrillators are examples of cardiovascular equipment that keep people alive. The safety and dependability of these devices are very important. The Conventional Failure Mode and Effects Analysis (FMEA) methods are well recognized, and they tend to be subjective, reactive, and highly dependent on the past and human knowledge. This paper explores how the Failure Mode and Effects Analysis (FMEA) process of cardiovascular devices can be enhanced with the help of Artificial Intelligence (AI), namely, natural language processing (NLP), machine learning (ML), and predictive analytics. We suggest a modern FMEA framework that uses AI to accurately find possible failure modes and automatically update risk profiles using real-time data from clinical trials, manufacturing, and post-market surveillance. The objective is to demonstrate that AI-enhanced FMEA can transform device design and manufacturing into a more proactive, data-informed safety framework.

Keywords: AI, FMEA, Cardiovascular Devices, Risk Management, Predictive Analytics, NLP, Medical Device Reliability, Failure Modes

1. Introduction

The market of cardiovascular equipment is experiencing a major growth over the recent years owing to the high rate of heart disease across the planet. The use of medical machines that help to save the lives of millions of people per year like pacemakers, prosthetic valves, or

vascular grafts has a critical value, but at the same time, a small deviation may lead to serious complications or require recall. FMEA has been a systematic method of identifying and minimizing hazards in the development of a device, however, it tends to be reliant on inactive failure databases, localized knowledge as well as manual input of carpenter severity risk and likelihood values.

AI offers an exciting opportunity to change this, by integrating real-time clinical data, historical failure trends, and predictive algorithms, we can make FMEA smarter, faster, and more precise. This paper demonstrates how by using AI, FMEA can have better abilities to predict failure modes across the whole product lifecycle, i.e., during design and deployment, and it also focuses on how it can help regulatory compliance, manufacture efficiency and patient safety.

2. Limitations of Traditional FMEA in Cardiovascular Applications

Conventional FMEA depends on collaborative brainstorming to recognize failure modes, assigning severity (S), occurrence (O), and detection (D) ratings to compute the Risk Priority Number (RPN). Although beneficial, the process exhibits numerous constraints:

- Subjectivity: Scoring is highly subjective and can vary between teams and facilities.
- Static data: Risk assessments are often based on fixed assumptions and outdated databases.
- Limited pattern recognition: FMEA struggles to detect complex or rare failure modes, especially those that emerge only after long-term implantation.

In cardiovascular devices, the dynamic interaction of materials with tissue and blood flow presents significant limitations. Artificial intelligence, particularly machine learning models created with large datasets, offers a method for more objective, evidence-based assessments**.**

3. AI Integration: Reimagining FMEA

The integration of Artificial Intelligence into Failure Mode and Effects Analysis (AI-FMEA) represents a pivotal shift from traditional, static approaches to a dynamic, data-driven framework. By leveraging tools such as machine learning (ML), natural language processing (NLP), and real-time analytics, AI enables a continuous and intelligent reassessment of failure risks across the device lifecycle. This section outlines key innovations introduced through AI-enhanced FMEA.

3.1 Data-Driven Failure Prediction

Machine learning models may interfere with the past data on failure, such as the data obtained in clinical trials, adverse event databases, and post-market surveillance reports, with the help of which patterns may be detected which humans may fail to list. To use an example, when a given model of catheter starts displaying more stent migrations, in particular demographics, the model can be noted as a high-effort risk review priority.

For instance, in the case of a vascular catheter system, an AI model trained on population-wide device usage data identified a statistically significant uptick in stent migration among a particular demographic subgroup. Such an insight prompted an early flagging of this design for in-depth risk review, well before traditional methods detected the trend. This proactive identification enables earlier corrective action, potentially reducing patient harm and regulatory impact.

3.2 Natural Language Processing (NLP) in Design Reviews

Algorithms based on NLP script can scan the design paperwork, clinical notes and other regulatory filings to determine the possibilities of risk. As an example, an auto-tag of the failure mode could be done on the mention of a term such as thrombus formation or lead dislodgment.

Figure 1. AI-Powered FMEA Workflow

For example, the term “thrombus formation” appearing in physician notes or testing documentation can be auto-tagged by the AI system as a known failure mode. Similarly, ‘lead dislodgment’ mentioned in a

retrospective report can be linked with associated components, triggering a review of anchoring mechanisms. This capability reduces reliance on manual document reviews and ensures broader, faster coverage of risk-related content.

A graphical representation of how AI components—data collection, NLP, predictive analytics—interact with the FMEA process to generate dynamic risk profiles.

Table 1. Risk Priority Number (RPN) Comparison: Traditional vs AI-Enhanced FMEA

Failure Mode	Occurrence	Severity	Detection	RPN (Traditional)	RPN (AI-Enhanced)
Electrode degradation	4	8	4	128	96
Firmware lockup	3	9	3	81	60
Thrombus formation	2	7	5	70	50

3.3 Dynamic RPN Scoring

AI can continuously update the scores with real-world input as opposed to static S/O/D values. Unlike conventional FMEA, which relies on static Severity (S), Occurrence (O), and Detection (D) values, AI-FMEA enables continuous recalibration of these parameters in light of real-world feedback.

For example:

Severity: recalibrated using mortality/morbidity data.

Occurrence: updated with frequency from field reports.

Detection: adjusted based on testing data and predictive maintenance indicators. This allows an FMEA that is dynamic, and which reforms over a period of time and enhances precision as additional data is assimilated.

This results in an evolving Risk Priority Number (RPN), enhancing the granularity and timeliness of risk management. Over time, these updates feed into a self-learning loop that strengthens product safety across successive device iterations.

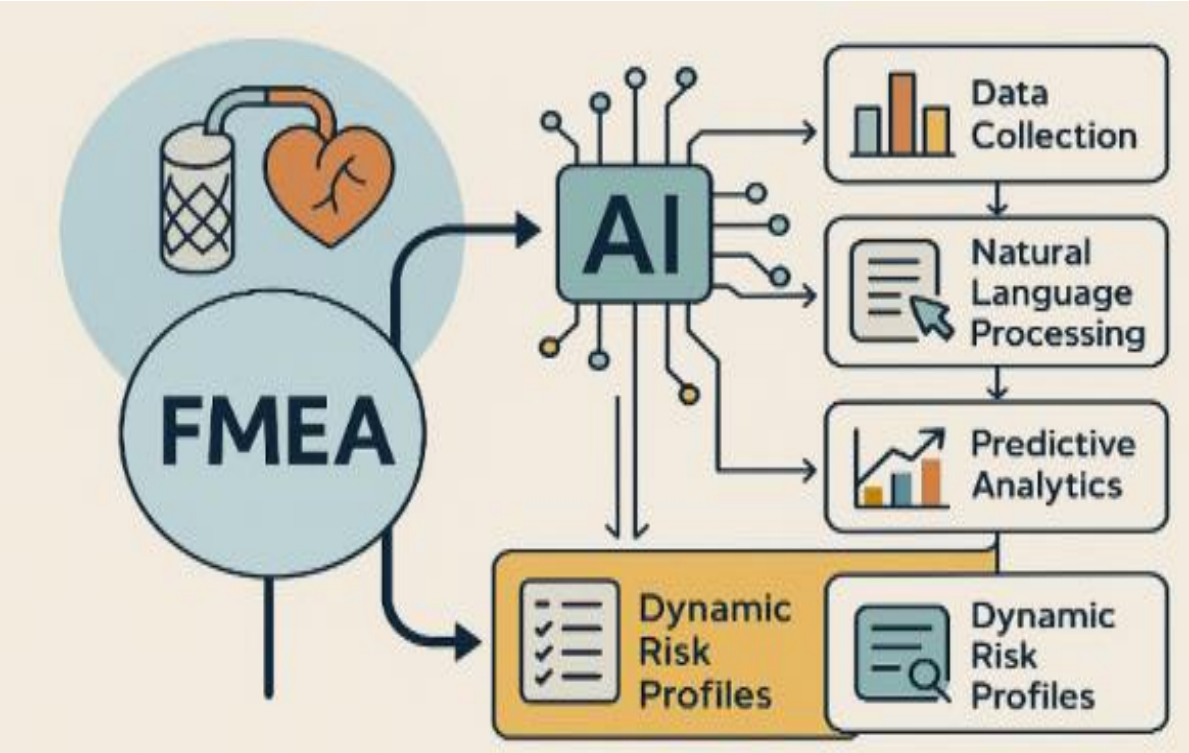

Figure 2. AI-Enhanced FMEA for Dynamic Risk Profiling

4. Case Study: AI-Enhanced FMEA for Implantable Defibrillators

In an educational activity, we demonstrated the use of AI-FMEA on a test group of the implantable cardioverter defibrillators (ICDs). Using routinely de-identified failure reports and brief clinical narratives, the algorithm uncovered two legacy, traditional, so-called low-priority. Failure modes, namely, electrode wire degradation and firmware lockup that turned out on review to have remarkably high incident rates in real-world clinical practice. After review of the preliminary FMEA, AI algorithm identified a negative relationship between the use of specific post-surgical antibiotic protocols and an unexpected frequency of device failure that had not previously been noted. The observation led to the re-visitation of design documentation and consequent revision of the protocol instructions issued to patients. Material analysis led to subsequent modification of composition of the electrode substrate and reduced the identified failure mode.

Because of these insights, several corrective actions were undertaken. Design documentation was updated, patient handling protocols were revised, and the electrode material composition was modified to enhance long-term biocompatibility. Subsequent monitoring showed a measurable decline in the occurrence of the identified failure mode, validating the impact of the AI-FMEA intervention.

This case study exemplifies the value of AI in surfacing hidden risk patterns, recalibrating risk assessments based on real-world evidence, and supporting proactive design refinement, ultimately enhancing device reliability and patient safety.

5. Regulatory and Industry Implications

In the world of regulations, a strong trend towards adopting artificial intelligence (AI) in risk mitigation can be observed. Failure Mode and Effects Analysis (FMEA) that has been enabled by AI aligns with the requirements of the FDA Total Product Life Cycle (TPLC) approach and the risk-management doctrine of ISO 14971. With this combined model, multiple benefits are achieved: it strengthens the design history file (DHF), facilitates design disciplines of Design to Reliability (DfR), and streamlines pre-market reviews. In manufacturing organizations, the application of this systematic approach has shown tangible benefits.

There is a marked decrease in the costly recall of products; there is an improvement in the first pass yield; and increased ability to conduct predictive maintenance, especially in the cardiovascular manufacturing lines, which are manufacturing under a high rate of volume. From an industry standpoint, the practical benefits are equally compelling. AI-driven FMEA has demonstrated measurable outcomes in reducing costly product recalls, improving first-pass manufacturing yields, and enabling condition-based maintenance. These improvements are particularly impactful in high-volume, high-risk cardiovascular device manufacturing environments, where quality deviations can have significant clinical and economic consequences.

Moreover, the use of AI in FMEA allows manufacturers to demonstrate a systematic, reproducible, and transparent approach to risk mitigation, an attribute increasingly valued by regulators. As AI tools continue to mature, their integration into core quality processes like FMEA will likely become a key differentiator for regulatory compliance and industry competitiveness in the coming decade.

6. Conclusion and Future Work

FMEA with AI shows great potential to redefine risk management in the modern cardiovascular device development and production. With its ability to eliminate inherent human biases, align analysis processes and testing with real-time, constant feedback, and re-refine knowledge attained through field experience, such systems serve to actively promote safer gadgets and more efficient developmental processes. Opportunities on the horizon, as the scope of availability of AI tools is expected to increase, will be in the development of standardized AI-FMEA templates, the incorporation of patient-reported outcomes measurements, and linking the procedure to digital twins to validate it virtually.

This current discussion is therefore an effort to foster partnership between biomedical engineers, data scientists, and clinical practitioners towards the emergence of a system of proactive, intelligence-driven device safety. As artificial intelligence tools become more ubiquitous, future directions include creating standardized AI-FMEA templates, embedding patient-reported outcomes, and using digital twins for virtual verification. These will aid in the development of an evidence-based, more adaptive system for risk management.

Ultimately, this work urges greater collaboration among engineers, clinicians, and data scientists to create a forward-thinking, intelligent system for safety, one that adapts with technology and focuses on patient well-being. This paper underscores the need for a collaborative, interdisciplinary approach to fully realize the potential of AI-FMEA. A coordinated effort among biomedical engineers, regulatory scientists, clinical experts, and AI developers is essential to shape the next generation of intelligent safety systems—ones that are proactive, predictive, and ultimately centered on patient well-being.

7. References

1. Shreyasi Pathak, Changqing Lu, Sunil Belur Nagaraj, Michel van Putten, Christin Seifert, STQS: Interpretable multi-modal Spatial-Temporal-seQuential model for automatic Sleep scoring, Artificial Intelligence in Medicine, Volume 114,2021,102038, ISSN 0933-3657, https://doi.org/10.1016/j.artmed.2021.102038
2. Sharma, A, Bertog, S, Tholakanahalli, V. et al. 4D Intracardiac Echocardiography-Guided LA Appendage Closure Under Conscious Sedation: Initial Experience and Procedural Technique. J Am Coll Cardiol Img. 2021 Nov, 14 (11) 2254–2259. https://doi.org/10.1016/j.jcmg.2020.09.025
3. Rajkomar, A., et al.” Machine Learning in Healthcare. New England Journal of Medicine”,PP380(14):1347-1358,(2019) https://doi.org/10.1056/NEJMra1814259
4. Chen, I.Y., Joshi, S., Ghassemi, M.” Treating Health Disparities with Artificial Intelligence.NatureMedicine”,PP26:16–17,(2020) https://doi.org/10.1038/s41591-019-0649-2
5. Kannan H, Mesmer BL, Bloebaum CL. Incorporation of risk preferences in a value-based systems engineering framework. Systems Engineering. 2020; 23: 237–257 https://doi.org/10.1002/sys.21529
6. Topol, E,” High-Performance Medicine: The Convergence of Human and Artificial Intelligence.NatureMedicine”,PP25(1):44–56.(2019) https://doi.org/10.1038/s41591-018-0300-7
7. Sarker, I.H.,”Machine Learning: Algorithms, Real-World Applications and ResearchDirections.SNComputerScience”,PP2(3):160.(2021) https://doi.org/10.1007/s42979-021-00592-x
8. International Organization for Standardization (ISO). ISO 14971:2019 Medical devices — Application of risk management to medical devices. Geneva: ISO; 2019. https://www.iso.org/standard/72704.html
9. Singh, J., & Patel, P. (2024). Methods for medical device design, regulatory compliance and risk management. Journal of Engineering Research and Reports, 26(7), 373-389.
10. Liu, H., Li, L., & Liu, S. (2019). A review of fuzzy and intelligent FMEA. Engineering Applications of Artificial Intelligence, 81, 150-161. DOI: 10.1016/j.engappai.2019.02.008
11. Shah, A. M., Guez, A., & Paskar, A. (2020). Applications of natural language processing in clinical research and practice. The American Journal of the Medical Sciences, 359(4), 204-211. DOI: 10.1016/j.amjms.2020.01.004
12. Coronato, A., & De Pietro, G. (2020). A systematic literature review of machine learning-based approaches for cardiovascular disease prediction. Informatics in Medicine Unlocked, 20, 100412. DOI: 10.1016/j.imu.2020.100412
13. Automotive Industry Action Group (AIAG). (2019). Potential Failure Mode and Effects Analysis (FMEA) Handbook (1st ed.). Southfield, MI: AIAG.