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A DECADE OF ADVERSE EVENT REPORTS LINKED TO ARTIFICIAL INTELLIGENCE (2013-2023) AN ANALYTICAL REVIEW FROM THE FDA DATA BASE

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ABSTRACT

Artificial intelligence (AI) is becoming a crucial part of contemporary healthcare systems, transforming the creation and use of medical technologies in clinical settings. AI has been increasingly incorporated into medical equipment over the past ten years, improving patient monitoring, increasing diagnostic accuracy and providing more individualized treatment alternatives. This thesis examines and interprets the patterns of AI-enabled medical devices that were authorized in the US between 2013 and 2023, paying particular attention to how these devices were distributed throughout different medical specialties. The study groups AI-integrated medical devices into four major categories: Radiology, Cardiovascular, Neurology and Others, using data gathered from the U.S. Food and Drug Administration (FDA). According to the data, radiology has a glaring dominance, which explains the results of the investigation show a clear dominance of the profound integration of AI in medical imaging technologies like MRI, CT and X-ray is demonstrated by radiology, which makes up 77% of all devices. The diagnostic procedures, disease detection rates and data interpretation have all improved thanks to these AI-powered imaging technologies. 10% of all devices are cardiovascular devices, which represent developments in risk assessment, minimally invasive intervention planning and heart health monitoring respectively. With a mere 3% representation, neurology exhibits narrowly focused applications in the development of brain-computer interfaces and the identification of neurological disorders.10% of the information falls under the "Others" group, which includes a broad range of disciplines such clinical chemistry, ophthalmology, gastroenterology-urology and hematology. Despite the very modest level of AI integration in these domains, they nevertheless reflect essential areas for innovation. For example, hematology uses AI to forecast hematopoietic disorders and analyze blood cell morphology. Similarly, advancements in the early detection of vision-related disorders like glaucoma and diabetic retinopathy are being fueled by AI applications in ophthalmology. The number of AI medical devices has been steadily increasing year over year, according to this survey, demonstrating the quick speed of technological development and rising regulatory approval. Because of its data-rich environment and machine learning algorithm compatibility, radiology continues to lead in event submissions and product approvals.

KEYWORDS

Artificial intelligence (AI), FDA's MAUDE database and Healthcare systems.

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INTRODUCTION

The term artificial intelligence (AI) describes how technology, especially computer systems, may simulate human intelligence processes. Learning, thinking, problem-solving and self-correction are some of these processes. Through its integration

into several systems and technologies, artificial intelligence (AI) has quickly changed the medical landscape by improving patient monitoring, treatment planning, and diagnostic accuracy. Artificial intelligence (AI)-powered medical devices use natural language processing, machine learning algorithms, and predictive analytics to deliver real-time insights that enhance patient outcomes and operational effectiveness. AI's significance in medical devices stems from its capacity to process and analyze enormous volumes of intricate medical data with previously unheard-of speed and accuracy. Applications range widely and are innovative, from AI-enabled imaging systems for early disease detection to surgical decision-support systems. AI not only enhances the skills of medical professionals but also lowers human error, speeds up diagnosis, and customizes patient treatment. The growing use of AI in healthcare, despite its benefits, has sparked worries about unfavorable device-related incidents. Regulatory agencies define adverse events as any occurrences that cause harm or raise the possibility of harm associated with the use of medical devices. These include problems with software bugs, algorithmic biases and unexpected results from machine learning models' incapacity to generalize across different populations in the setting of artificial intelligence. An AI diagnostic tool may, for example, perform poorly for underrepresented demographic groups, resulting in incorrect diagnoses or postponed treatments. Furthermore, patient safety may be at risk due to inadvertent interactions between AI algorithms and other medical systems that provide inaccurate results.

Examining ten years' worth of adverse event reports from the FDA database provides important context for understanding the dangers and difficulties associated with AI-powered medical devices. A review like this aids in spotting patterns and trends, which serves as a basis for creating strong regulatory frameworks and enhancing the designs of AI systems. Resolving these unfavorable occurrences is crucial to building confidence in AI systems and guaranteeing their secure and efficient incorporation into medical procedures.

Evaluate the adverse event report associated with artificial intelligence

I accessed adverse event data from the official FDA website and compiled it into a Google Excel sheet.

The data included multiple medical departments such as cardiovascular, radiology, ENT, and gynecology.

I categorized the data by department and analyzed the reported side effects using medical device codes.

The analysis was conducted using the Manufacturer and User Facility Device Experience (MAUDE) database to understand AI-related adverse events in medical devices.

Event Distribution of Radiology

The distribution of reported issues in medical device operations reveals that the most common category is incidents where no harm was reported, making up 27.3% of the total. This suggests that while issues occur, they often do not result in adverse outcomes. Equipment shutdown follows with 23.6%, indicating significant operational interruptions. Component failure accounts for 18.2%, pointing to frequent hardware or mechanical malfunctions. Software issues are also notable at 14.5%, reflecting challenges related to digital systems. Patient injuries, though less frequent, represent 9.1% of the reports and highlight the potential for serious consequences. Finally, 7.3% of the cases are still under investigation, indicating ongoing efforts to determine root causes and appropriate corrective actions. This breakdown emphasizes the need for preventive measures, continuous monitoring and strong quality control in medical device operations. The information is given in Figure No.1.

Event type of Radiology

The distribution of reported issues highlights that the majority, 80.0%, are due to malfunction, indicating that most problems stem from device performance or technical failures. Injury-related reports make up 10.0%, pointing to cases where device use led to patient harm. Data not provided

accounts for 6.0%, which may reflect incomplete reporting or missing information. Additionally, 4.0% of the issues fall under the "Other" category, capturing less common or unspecified problems. This breakdown emphasizes the critical need for consistent performance monitoring, prompt maintenance, and comprehensive reporting practices to ensure device reliability and patient safety. The information is given in Figure No.2.

Event Description cardiovascular

The distribution of reported medical device issues shows that Device Power/Failure Issues and Smartwatch Misreadings/Claims are the most frequently reported, each accounting for 15.4% of the total cases. ECG Monitoring Issues follow with 12.3%, suggesting significant challenges in accurate cardiac monitoring. Software and Connectivity Issues represent 10.8%, reflecting the role of digital integration in device reliability. Patient Mismatch/Data Errors contribute 9.2%, highlighting risks in data accuracy and patient identification. Several other categories including Battery/Overheating Issues, SpO_2 and BP Measurement Issues, Other Miscellaneous Issues and Leaks and Tubing Issues each account for 7.7% of the reports, indicating a broad range of technical and operational concerns. Lastly, Cable/Connection Issues make up 6.2%, pointing to physical infrastructure weaknesses. This distribution underlines the need for comprehensive quality assurance, device calibration and user training to ensure optimal performance and patient safety. The information is given in Figure No.3.

The departments included in the adverse event report analysis are

Hematology
General Hospital
Pathology
Anesthesiology
Gastroenterology-Urology
Neurology
Ophthalmic

Here is a brief overview of each medical specialty you've listed

Hematology

This branch of medicine focuses on the study, diagnosis, treatment and prevention of diseases related to blood and blood-forming organs. It covers conditions such as anemia, leukemia, lymphoma and clotting disorders.

General Hospital

A general hospital is a healthcare facility that is equipped to deal with a wide
range of medical conditions. It provides various services such as emergency care, surgery, internal medicine, pediatrics, and obstetrics.

Pathology

Pathology involves the study of diseases through the examination of organs, tissues, bodily fluids, and autopsies. It is essential for diagnosis and plays a crucial role in understanding disease mechanisms.

Anesthesiology

This specialty is concerned with the administration of anesthesia and the management of pain during and after surgical procedures. Anesthesiologists also oversee critical care and resuscitation

Gastroenterology-Urology

Gastroenterology deals with disorders of the digestive system, including the stomach, intestines, liver and pancreas.

Urology focuses on the urinary tract system in both genders and the male reproductive organs, dealing with conditions like kidney stones, urinary infections and prostate issues.

Neurology

Neurology is the medical field that addresses disorders of the nervous system, including the brain, spinal cord and peripheral nerves. Conditions like epilepsy, stroke, multiple sclerosis and Parkinson's disease fall under this category.

Ophthalmic

This specialty, also known as ophthalmology, deals with the diagnosis and treatment of eye disorders. It includes everything from prescribing glasses to performing complex eye surgeries such as cataract removal or retinal repair. The information is given in Figure No.4.

Event description of the all the department except Radiology and Cardiovascular of the departments

The chart titled "Distribution of Reported Medical Device and Testing Issues" highlights the various categories of problems associated with medical devices and related diagnostic tools. The most commonly reported issue is medical device malfunctions, accounting for 21.4% of the total, indicating widespread concerns regarding the reliability and proper functioning of these devices. Both lab test errors and monitoring device failures follow closely at 14.3% each, reflecting significant challenges in diagnostic accuracy and continuous patient monitoring. Software and AI-related errors represent 10.7% of the issues, pointing to the growing complexity and potential risks introduced by digital and automated systems in healthcare.

Similarly, surgical and navigation issues also make up 10.7%, which may affect the precision and outcomes of surgical procedures. Categories like implant and instrument issues, patient reactions and burns, blood and fluid monitoring errors, and other miscellaneous issues each account for 7.1%, highlighting a broad spectrum of technical, procedural, and biological risks. These findings underscore the need for improved device

design, testing, and monitoring protocols to enhance patient safety and healthcare quality. The information is given in Figure No.5.

Monitoring Errors

Suggestions and improvements Adverse drug reaction (ADR) Report.

Increased Awareness and Training

Patients, pharmacists, and healthcare professionals should all participate in regular training sessions and awareness campaigns. Participation and report quality can be greatly increased by teaching them the value of ADR reporting.

Simplify the Reporting Process

Reporting protocols must to be easy to understand. Forms need to be brief, understandable, and, if required, available in several languages. Time is saved and more users are motivated to submit ADRs when the process is simplified.

Promote Digital Reporting Tools

Create web-based portals and mobile applications to facilitate ADR reporting.

Report accuracy and timeliness can be improved by adding supporting documents (such as lab results or photos) and reporting in real-time.

Enhance Feedback Mechanisms

Reporters must to get prompt feedback on the ADRs they file. This covers follow-up details regarding the outcome or regulatory action taken in response to the report, as well as acknowledgement and thank-you notes.

Promote Patient Involvement

Patients and caregivers must to be urged to immediately report adverse drug reactions.

By enabling them to share their experiences, educational resources and streamlined forms can enhance pharmacovigilance in general.

Conduct Regular Data Analysis and Risk Assessment

Authorities should routinely analyze ADR data to identify high-risk drugs, populations, or patterns. This can lead to earlier safety alerts, drug label updates, or recalls.

Promote Collaboration Among Stakeholders

Coordination between regulatory agencies, pharmaceutical companies, hospitals, and academic institutions can improve the quality and actionability of ADR data.

Public Awareness Campaigns

Government and health authorities should conduct media campaigns to inform the general public about how and why to report ADRs. This builds a culture of shared responsibility in drug safety.

RESULTS AND DISCUSSION.

Trends in Artificial Intelligence (AI) Integration across Medical Departments (2013–2023)

The analysis of FDA-approved AI-enabled medical devices from 2013 to 2023 reveals a significant growth trend in AI adoption across multiple medical specialties. Radiology

emerged as the most dominant field, with 723 devices a clear indication of the reliance on AI for imaging diagnostics such as MRI and CT. This is

followed by Cardiovascular (98 devices), Neurology (32 devices), and Others (92 devices), which includes diverse departments like Hematology, Gastroenterology-Urology and Ophthalmology.

The widespread adoption in Radiology is driven by advancements in image recognition, automation in diagnostics, and improved disease detection capabilities. In contrast, lower numbers in areas such as Neurology and Immunology suggest that either clinical integration is still evolving or AI development in these domains is comparatively nascent or niche.

The department-wise breakdown within the "Others" category shows substantial AI presence in Hematology (18 devices) and Gastroenterology-Urology (14 devices), with smaller but notable contributions in Ophthalmology (10) and Pathology (8). This reflects a growing but uneven technological distribution across specialties.

Analysis of Adverse Event Reports for AI-Enabled Medical Devices

To evaluate the safety and real-world performance of AI-enabled devices, adverse event data was extracted from the FDA MAUDE database. Devices from various specialties were analyzed based on their malfunction types, patient impact, and manufacturer response.

Radiology Devices

Most frequent issue: Device malfunction (80%)

Common problems: Unexpected shutdowns (23.6%), component failure (18.2%), and software issues (14.5%)

Patient impact: 27.3% of incidents had no harm; 9.1% led to injuries

These results emphasize the technical vulnerabilities of AI systems, especially in automated diagnostics where uninterrupted functionality is crucial.

Cardiovascular Devices

Major issues: Device power/failure (15.4%), ECG misreadings (12.3%), smartwatch data errors (15.4%)

Event type: Malfunctions (80%), injuries (15%) and deaths (5%).

This data highlights the life-critical nature of cardiovascular devices and the potential severity of AI failures in real-time monitoring or diagnosis.

Other Departments (e.g., Neurology, Anesthesiology, Gastroenterology):

Most reported issues: Device malfunctions (21.4%), lab test errors (14.3%), monitoring failures (14.3%)

AI-specific issues: 10.7% of events were linked to software/AI failure

Although less frequent, the complexity of these specialties introduces algorithmic challenges, often linked to variability in clinical data, system integration, and user-device interaction.

Insights and Implications

The findings suggest a dual narrative: while AI integration in medical devices is accelerating-particularly in imaging and diagnostics-it also introduces a new layer of complexity that must be carefully managed. Key concerns include:

Algorithmic errors and data misclassification due to limited or biased training data

System integration issues, such as unresponsive screens or failed alerts

Overreliance on automation, risking clinical judgment errors

Regular surveillance, robust testing, and post-market evaluations are crucial to identifying hidden risks in AI systems. Additionally, educating clinicians about the limitations and proper use of AI-enabled devices can mitigate the risks associated with automation dependency.

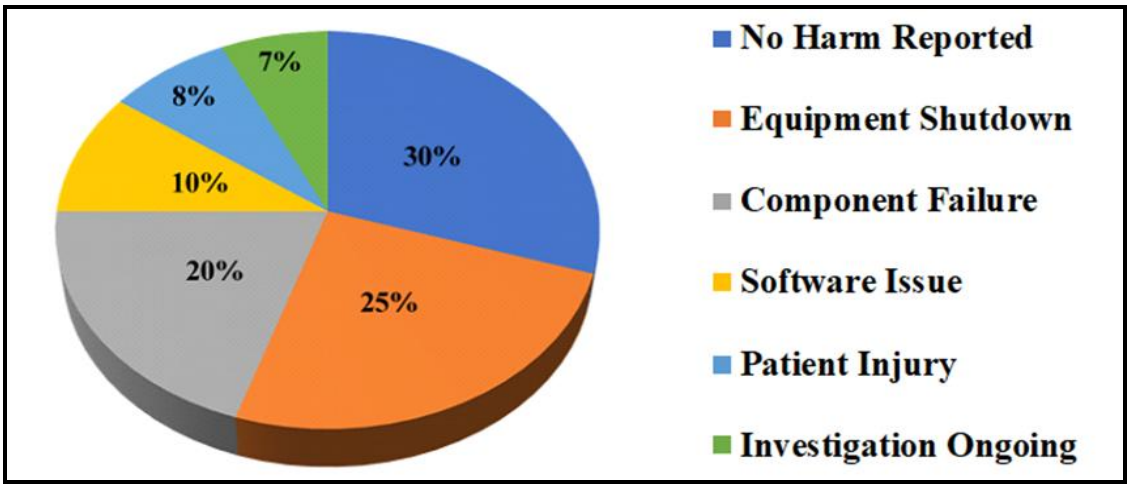


Figure No.1: Categorization of adverse events radiology associated with artificial intelligence devices

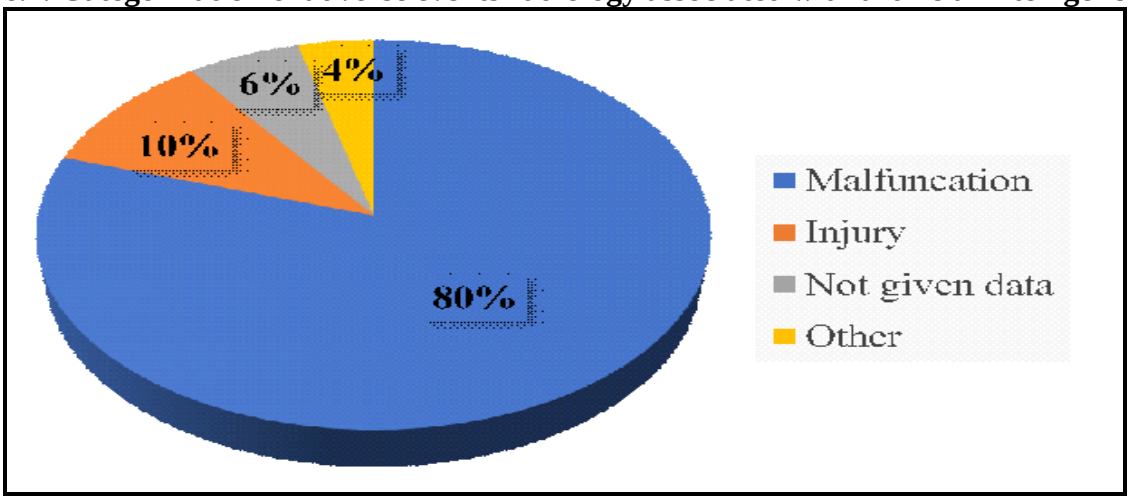


Figure No.2: Types of Adverse drug events associated with radiological artificial intelligence medical devices

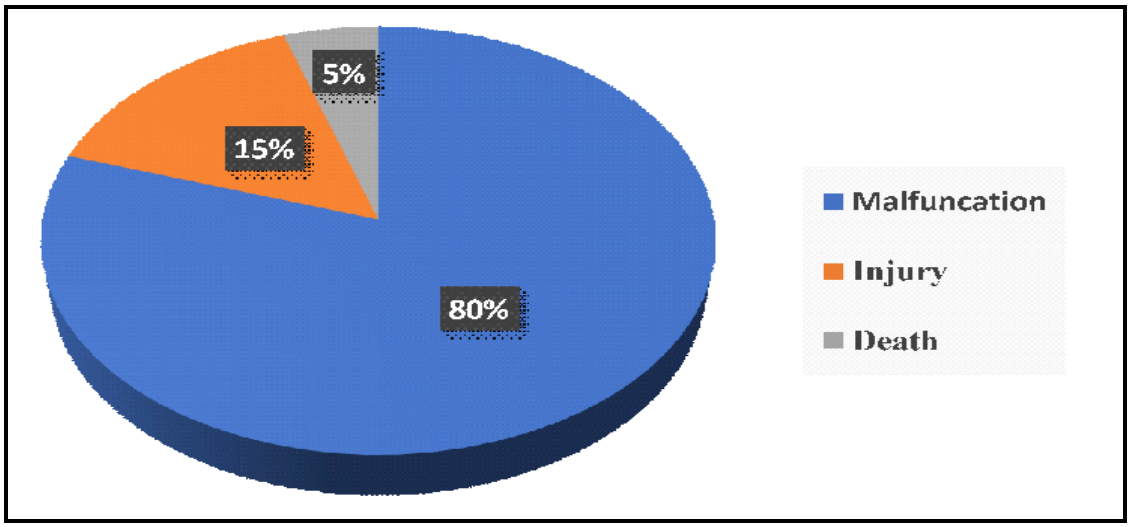


Figure No.3: Types of adverse drug events associated with cardiological artificial intelligence medical devices

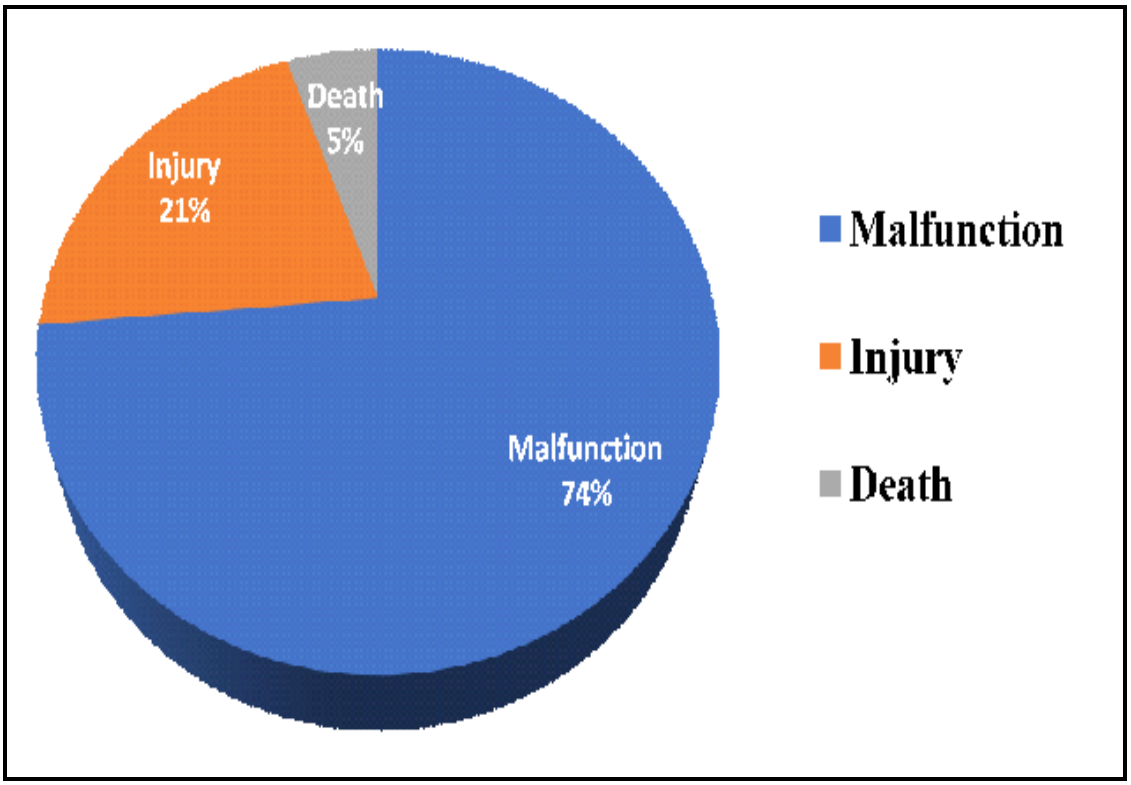


Figure No.4: Categorization of reported adverse events linked to radiology AI

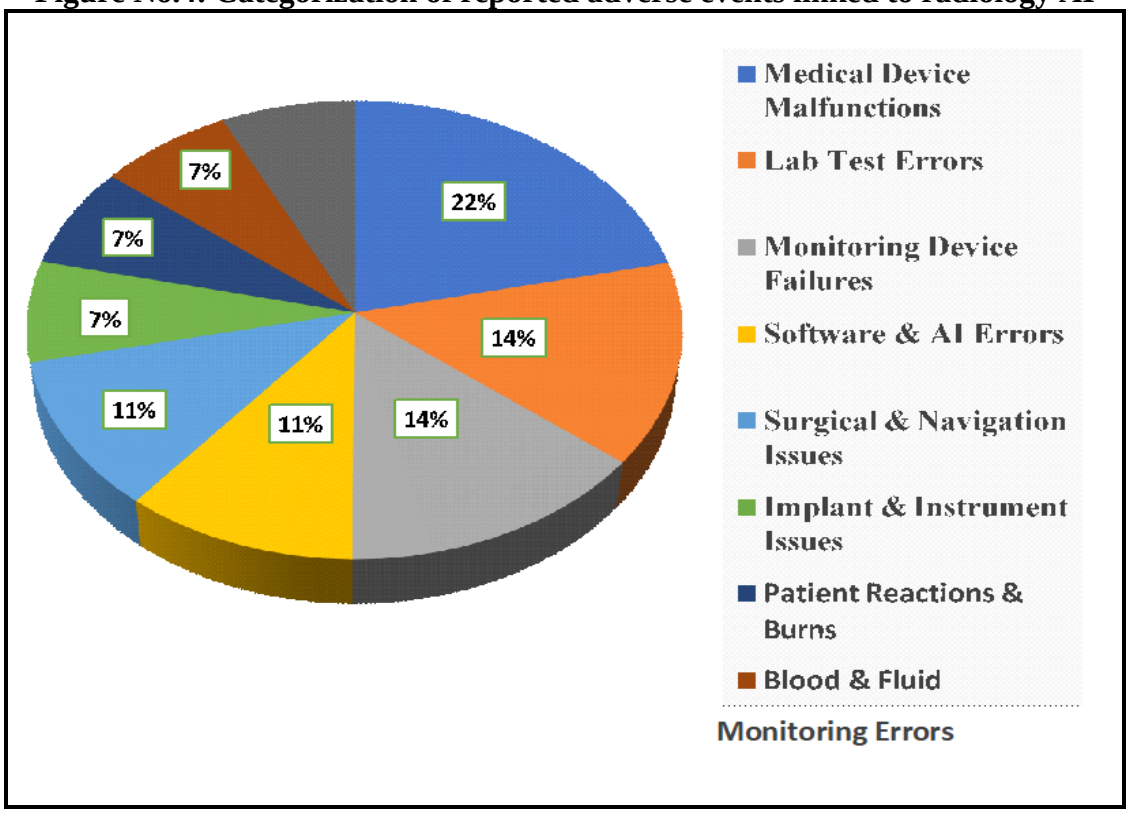


Figure No.5: Distribution of adverse event types in AI-Integrated radiology and medical devices

CONCLUSION

This provides a detailed analysis of the integration, trends and associated risks of artificial intelligence (AI) in medical devices in the United States from 2013 to 2023. Through department-wise data evaluation and adverse event analysis, several key insights have emerged. Radiology has emerged as the leading field in AI-driven medical device innovation, accounting for the highest number of device approvals. This dominance is primarily due to rapid advancements in imaging technologies and the successful integration of AI algorithms in diagnostic processes. Cardiovascular devices also showed notable growth, particularly in monitoring technologies, though with more reported issues linked to device malfunctions and connectivity problems. Other medical fields like neurology, hematology, gastroenterology-urology, ophthalmology and anesthesiology showed varying levels of AI adoption, highlighting both opportunities and limitations based on the complexity and specialization of each field.

The majority of reported problems across departments were device malfunctions, software failures, sudden shutdowns and data inconsistencies, according to a study of adverse event reports from the FDA's MAUDE database. The possibility of misdiagnosis or delayed care highlights the vital need for strong quality control, algorithm transparency and real-world validation, even though many events did not directly cause patient harm. In addition, new clinical procedures and regulatory frameworks are needed to guarantee the safe integration of AI into patient care due to the particular hazards it poses, such as algorithmic error, black-box decision-making and an excessive dependence on automation. To reduce these dangers and promote innovation in a responsible manner, developers, physicians and regulatory agencies must work together across functional boundaries, maintain consistent reporting, and conduct ongoing post-market surveillance.

In conclusion, even though AI greatly expands the capabilities of medical devices, its safe and effective implementation requires proactive risk management, well-defined regulatory frameworks, and a careful balance between patient safety and innovation. This study highlights the significance of comprehending AI's practical applications in healthcare in addition to its technological and departmental advances.

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CONFLICT OF INTEREST

We declare that we have no conflict of interest.

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