ACCSCIENCE PUBLISHING

INNOSC Theranostics and Pharmacological Sciences

REVIEW ARTICLE

Leveraging artificial intelligence to revolutionize medical device safety

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(This article belongs to the *Special Issue: Advancing Medicine and Healthcare through Federal Learning*)

Abstract

Materiovigilance is a crucial component of health-care policy designed to ensure patient safety by monitoring and addressing safety issues associated with medical devices. However, traditional systems encounter challenges related to timely reporting, standardization, and the detection of adverse events. Artificial intelligence (AI) has the potential to transform materiovigilance by improving data processing, real-time monitoring, and predictive analytics. This review explores the potential of AI in strengthening medical device safety, highlighting its benefits in enhancing patient safety, personalizing medical devices, and streamlining regulatory reporting. AI-powered systems can detect adverse events, predict patient deterioration, and provide personalized treatment plans, ultimately improving patient outcomes. Furthermore, AI enables the analysis of large and complex datasets, facilitating proactive decision-making and the early identification of emerging risks associated with medical devices. By automating routine tasks and improving accuracy, AI can significantly reduce the administrative burden on health-care professionals. In addition, AI can enhance post-market surveillance by identifying trends and anomalies in real time, thereby accelerating corrective actions. However, ethical and regulatory considerations, such as algorithmic biases, data privacy, and accountability, must be addressed to ensure the responsible development and implementation of AI in materiovigilance. Establishing robust regulatory frameworks, fostering transparency, and promoting interdisciplinary collaboration are essential to overcoming these challenges and fully realizing AI's potential in health care.

Keywords: Materiovigilance; Artificial intelligence; Medical device safety; Patient safety; Medical devices

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Citation: Mishra HP, Loriya K, Shah N, Grover S, Mishra SS. Leveraging artificial intelligence to revolutionize medical device safety. *INNOSC Theranostics and Pharmacological Sciences*. 2025;8(3):1-11.
doi: 10.36922/itps.6204

Received: November 18, 2024

Revised: January 4, 2025

Accepted: January 10, 2025

Published online: January 22, 2025

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1. Introduction

The term "materiovigilance" refers to a coordinated system for detecting, gathering, reporting, and analyzing adverse events associated with the use of medical devices.[1,2]

The primary goal of materiovigilance is to safeguard public health by monitoring and addressing potential safety issues related to medical equipment.[3] It plays a vital role in improving medical device efficiency and design, reducing complications from devices, and alerting patients and health-care providers to counterfeit or substandard devices.[4] As a crucial component of health policy in both public and private health-care settings, materiovigilance helps minimize the likelihood of incidents caused by medical equipment.[5] With the global increase in medical device use, materiovigilance has become increasingly important for ensuring patient safety and promoting the responsible use of life-saving devices.[6]

Different countries and regions, such as the United States, the European Union, Japan, China, and India, have distinct systems for implementing their materiovigilance programs.[3] For instance, the Materiovigilance Program of India, established on July 6, 2015, aims to generate safety data and track adverse events related to medical devices.[1,2] Interestingly, although many nations have established materiovigilance initiatives, these programs are often less developed and refined compared to the systems in place for medications.[7] This limitation emphasizes the ongoing need for efforts to improve post-market surveillance of medical devices. As health-care technology advances, robust materiovigilance procedures are becoming increasingly crucial, particularly with the integration of artificial intelligence (AI). AI has revolutionized post-market surveillance by enabling more effective signal detection, risk assessment, and regulatory compliance.[8] AI is transforming health-care monitoring by providing previously unattainable capabilities in patient care, disease detection, and health management. Machine learning (ML) algorithms and sophisticated data analysis enable the processing of large volumes of medical data, including electronic health records, medical imaging, and real-time patient data from medical devices.[9,10]

However, the use of AI in health-care monitoring raises concerns related to interpretability, algorithm bias, and data privacy, emphasizing the need for transparent and ethically sound AI implementation within materiovigilance frameworks.[8] In addition, the emergence of AI/ML-enabled medical devices presents new regulatory challenges, making it essential to incorporate sustainability principles into the materiovigilance ecosystem.[11]

Despite these challenges, AI holds immense potential for health-care monitoring. By integrating big data analytics, ML, and blockchain technology, AI can transform patient care models, streamline health-care delivery, and ultimately improve patient outcomes while reducing health-care costs.[12,13] The review aims to explore how the incorporation of AI into materiovigilance systems can address current challenges in medical device monitoring and ultimately enhance patient outcomes.

2. Challenges in the traditional materiovigilance system

Despite the implementation of materiovigilance programs in numerous countries, post-marketing surveillance of medical devices remains less advanced and reliable compared to that of medicines.[1,7] This circumstance suggests that traditional methods may be inadequate in monitoring and managing risks associated with medical devices once they are on the market.

There are significant variations in the materiovigilance regulatory systems of different nations, and there is insufficient empirical evidence to establish the overall superiority of any one system.[3] This lack of standardization can lead to inconsistencies in how adverse events are reported and addressed globally.

One of the primary issues that the world encounters is the underreporting of adverse events. Healthcare workers often struggle to translate their knowledge and positive attitudes into effective reporting of medical device adverse events.[2] This situation indicates that conventional systems may not be adequately encouraging reporting from those most likely to encounter these events.

Challenges including the absence of global standards and poor reporting protocols underscore the need for continuous strengthening and enhancement of materiovigilance programs to improve patient safety and medical device monitoring.

Over the past decade, AI has revolutionized materiovigilance by automating adverse event detection, data analysis, and pattern recognition. Traditional materiovigilance relied on manual data entry, static databases, and reactive approaches, often resulting in delayed detection of safety signals. In contrast, modern AI-driven systems leverage real-time monitoring, natural language processing (NLP), and predictive analytics to proactively identify risks from vast datasets, including unstructured sources such as social media and medical records. AI enhances accuracy, reduces reporting biases, and facilitates faster regulatory compliance. However, issues such as data privacy and algorithm transparency remain pivotal in ensuring the efficacy and reliability of AI in materiovigilance.[8,9]

Timely reporting of any event occurrence is important, and the reporting period is outlined in Table 1. Table 2 discusses the differences in medical device vigilance programs in India, the United States, and the United Kingdom.

Table 1. Reporting period for an event or occurrence in India[14]

Reporter	What to report	Timeline	Recipient of report
Device manufacturer	The initial report of an event on the "MDAE" reporting form, accompanied by corrective actions to protect the public from undue risk. This action serves as the first notification of a fatality or significant public threat caused by an adverse event or incident	After learning of an occurrence; within 5 working days	MvPI
Device manufacturer	The "MDAE" reporting form, which includes a report on the causation assessment and any remedial or preventative measures implemented within a certain timeframe	After learning of an occurrence; within 30 calendar days	MvPI
Health-care providers	Using the causality assessment report and "MDAE" reporting form	The "MDAE" report must be submitted within 5 working days of becoming aware of the event, and root cause analysis must be completed within the following 30 calendar days	MvPI

Abbreviations: MDAE: Medical device adverse events; MvPI: Materiovigilance program of India.

Table 2. Differences in medical device vigilance in India, the United States, and the United Kingdom[14-16]

Specifications	CDSCO (India)	FDA (US)	MHRA (UK)
Definition of medical devices	These include mechanical devices, contraceptives, disinfectants, insecticides, *in vitro* diagnostic materials, surgical dressings, surgical bandages, and devices intended for internal or external use in the diagnosis, treatment, mitigation, or prevention of disease or disorder in humans or animals	All tools, equipment, supplies, machinery, implants, software, accessories, and disinfectants used in *in vitro* testing or diagnosis fall under this category	Excludes substances used to clean medical equipment
Medical device classification	Four classes: I, II, III, and IV	Three classes: I, II, and III	Four classes: I, IIa, IIb, and III
Classification basis	Based on risk	Control level and marketing specifications	Based on risk
Medical device post-marketing surveillance	Started in 2015 under the Materiovigilance Program of India	Established in 1990 under the Safe Medical Device Act	PSURs apply to class IIa, IIb, and III medical devices under the MDR
Individuals who hold the authority to report adverse events	Manufacturers, health-care professionals, pharmacists, nurses, hospital technology managers, biomedical engineers	Manufacturers, importers, device user facilities, patients, health-care professionals, consumers	Manufacturers, users, health professionals, authorized representatives, and MHRA
Reporting requirements	Device malfunction, serious injury, death	Death, serious injury, device malfunction	Event has occurred in association with the medical device, which may have led or could potentially lead to death or serious injury
Report types	• First reporting • Trend reporting • Last reporting	• 30-day report • 5-day report • Reports of individual adverse events • Initial report • Additional reports: Semiannual reports and annual summary reports	• Early notification of adverse events • Final reports • Regular summary reporting • Trend reporting
Applicable forms	• Medical device adverse event reporting (MDAER) form • Field safety corrective action (FSCA) form	• FDA 3500 • FDA 3500A • FDA 3419 • FDA 3381 • FDA 3417	• The incident report form provided by the manufacturer • Online reporting by manufacturers through MORE

Abbreviations: CDSCO: Central drugs standard control organization; FDA: Food and drug administration; MDR: Medical devices regulation; MHRA: Medicines and health-care products regulatory agency; MORE: Manufacturer's online reporting environment; PSUR: Periodic safety update report; UK: United Kingdom; US: United States.

3. Transformation of materiovigilance through AI

AI is significantly transforming medical device surveillance by enhancing the processes of monitoring, diagnosis, and health management. Core AI technologies, including computer vision (CV), ML, artificial neural networks, and data fusion techniques, are central to these advancements.[17,18] The vast amounts of data generated by real-time sensor measurements, which are essential to medical devices, have made it possible to extract valuable insights using ML and neural networks.[19] These tools are crucial for accurate diagnosis, effective supervision of medical devices, and real-time monitoring.

In addition to these technologies, NLP plays a key role in analyzing patient data and medical records, whereas CV is essential for interpreting visual data, including images and videos.[20,21] In addition, the integration of blockchain technology with AI is enhancing data security, addressing issues of data integrity and authenticity, particularly within health-care settings.[5] This combination ensures the authenticity of acquired data, thereby strengthening the reliability of medical device surveillance.

The integration of blockchain, NLP, ML, and CV is driving significant progress in medical device surveillance. Together, these technologies improve the precision of device monitoring, enhance diagnostic capabilities, and ensure the confidentiality and integrity of medical data. As AI technology continues to evolve, its applications are expected to expand into areas such as global pandemic forecasting, personalized medicine, and predictive health care.[22,23]

AI enhances data processing, model training, and software implementation in the context of medical devices.[24] These applications improve patient outcomes, reduce the burden on health-care providers, and increase diagnostic accuracy.[25] AI has also demonstrated promise in fields such as ophthalmology, where it aids in disease detection, diagnosis, treatment planning, and tracking disease progression.[26] Figure 1 illustrates a flowchart outlining the AI workflow in materiovigilance. This workflow involves a structured process aimed at enhancing medical device monitoring and safety. It begins with data collection from diverse sources such as medical devices, clinical records, and patient feedback. The raw data undergoes preprocessing, which involves standardization, cleaning, organizing, and labeling to prepare it for AI analysis. Subsequently, AI model development utilizes advanced techniques such as anomaly detection, NLP for extracting insights from clinical text, and predictive modeling to forecast potential device failures. These AI models enable real-time monitoring, incorporating Internet of Things tracking for continuous performance assessment and generating automated alerts for anomalies. In the risk assessment stage, AI tools classify devices by risk levels and prioritize safety signals to address critical issues. Incident analysis and reporting follow, with root cause analysis identifying adverse event triggers and producing automated, standardized reports for regulatory purposes. The process concludes with decision support, where safety alerts recommend recalls or advisories, and feedback loops contribute to iterative improvements in device safety and functionality. This workflow ensures a proactive, dynamic approach to materiovigilance, leveraging AI's ability to process and analyze vast datasets for timely interventions.

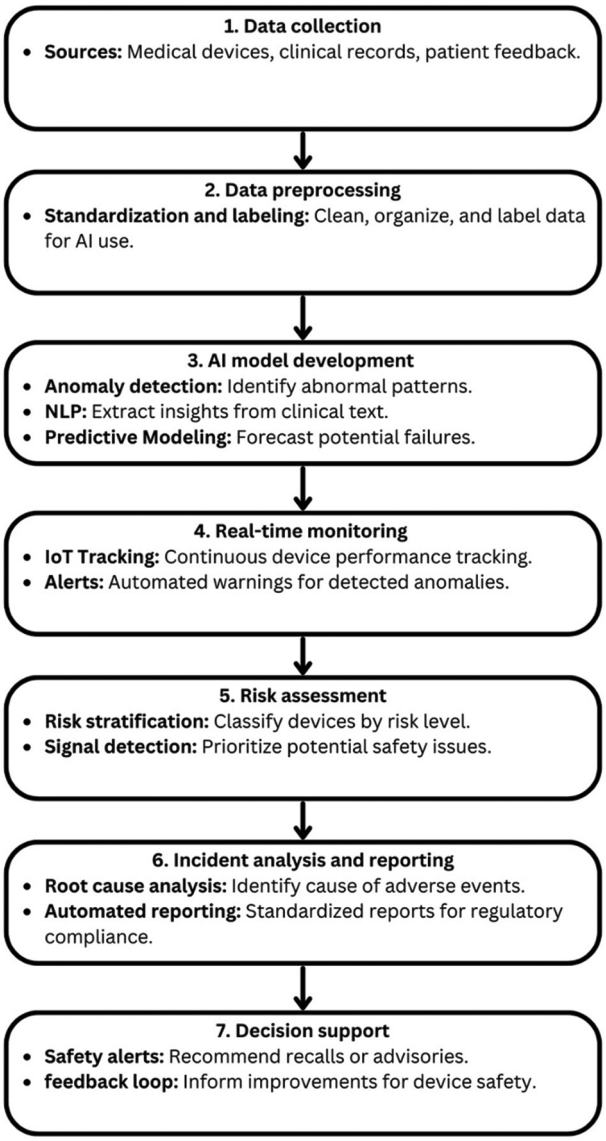


Figure 1. Flowchart of the "artificial intelligence in materiovigilance" workflow
Abbreviations: AI: Artificial intelligence; IoT: Internet of things; NLP: Natural language processing.

3.1. Real-time data monitoring and predictive analytics in patient safety

AI has proven to be a highly effective tool for improving patient safety through predictive analytics and continuous real-time data monitoring. AI-driven systems enable early identification of potential safety issues and prompt risk-reduction measures by automating the analysis of real-world data, such as patient outcomes, adverse event reports, and electronic health records.[8,9] These systems, leveraging big data analytics and ML algorithms, provide actionable insights into device safety profiles and emerging trends by identifying patterns and anomalies.

In both clinical and home settings, AI-driven systems have significantly improved the accuracy of real-time monitoring and predictive capabilities through the application of ML techniques.[27] These systems have the capacity to continuously collect and evaluate data from various sources, including physiological signals, enabling timely intervention and the early detection of potential health issues.[27,28]

AI technologies also facilitate the identification of patient decline in its pre-symptomatic stages by converting streaming clinical data into real-time visual risk assessments, thereby improving triage processes and patient care strategies.[29]

Moreover, AI systems use predictive models based on real-time patient data to generate automated alerts for health-care providers. These notifications are essential for preventing complications, ensuring timely responses, and improving patient outcomes. When abnormalities are detected, the constant flow of data processed by AI models enables real-time monitoring of clinical conditions, patient vitals, and device performance, thereby enabling prompt action.

AI-based predictive analytics also support medical professionals in complex clinical decision-making, particularly in high-stress situations such as the coronavirus disease 2019 (COVID-19) pandemic. During the pandemic, AI applications provided critical information for patient risk assessments, allowing health-care systems to efficiently manage patient loads. These systems continue to evolve, offering personalized treatment plans and enhancing diagnostic precision through predictive analytics.[28]

3.2. ML in detecting adverse events

ML models have shown significant promise in identifying and reporting safety concerns related to medical devices, particularly in the detection of adverse events. These models are trained on large datasets to detect patterns and anomalies that may indicate device malfunctions. ML algorithms have been applied in clinical trials to predict adverse outcomes, including fatalities and other critical events. For example, one study developed five ML models using data from 28,340 clinical trial reports. The best-performing model, logistic regression, achieved a receiver operating characteristic score of 0.7344.[30] This finding demonstrates how ML can assist researchers in estimating risks and predicting unfavorable events, thereby facilitating the development of more effective measures to protect participants.

Adverse events are classified using various ML techniques, such as ensemble learning, unsupervised learning, and deep learning. Algorithms such as Random Forests, Support Vector Machines, and Neural Networks analyze complex health data to classify these occurrences. These classification models are essential in the field of medical devices by identifying irregularities and managing risks in interconnected medical systems.[31]

To ensure accurate event detection, ML models require extensive data validation during training. The training data is thoroughly examined and adjusted, frequently through cross-validation methods, to maximize model performance under real-world conditions. The reliability of these models in detecting and reporting safety issues in medical devices is enhanced by continuous updates and reassessments based on new data inputs.[31] As AI continues to evolve, further advancements in the efficiency and personalization of medical device safety monitoring are anticipated, particularly with the integration of new domains such as proteomics and genomics with ML.[32]

3.3. AI for post-market surveillance of medical devices

AI-powered systems are revolutionizing post-market surveillance by providing reliable methods for monitoring device performance and safety across patient populations after deployment. One example is the Data Extraction and Longitudinal Trend Analysis (DELTA) network study, which demonstrates how computerized safety surveillance systems can monitor cardiovascular devices. By continuously analyzing routinely collected data, this system enables the prompt identification of adverse event rates associated with specific device classes. It surpasses conventional retrospective analysis techniques by offering real-time analysis, significantly accelerating the identification of safety issues.[33]

In addition, the potential of AI in real-time health monitoring is demonstrated by AI-enabled devices, such as smartwatches with atrial fibrillation detection capabilities, which have been approved by the United States Food and

Drug Administration (FDA). These devices help prevent cardiovascular complications and provide early warnings to users.[34] However, the advent of these technologies raises concerns about security, ethical bias, accountability, and clinical effectiveness in practical settings. These concerns emphasize the need for regulatory frameworks that manage these risks while ensuring fairness and transparency.[35]

AI-driven post-market surveillance provides innovative approaches to identifying adverse events and device malfunctions at an early stage. For example, a framework for monitoring AI tools used in breast cancer screening across clinical centers highlights the importance of surveillance in detecting potential software malfunctions.[36] As AI continues to develop, establishing robust quality management systems and stringent post-market monitoring procedures will be crucial to ensuring the safety and efficacy of medical devices throughout their lifecycle.[37]

3.4. AI-driven automation in regulatory reporting

AI-driven automation in regulatory reporting holds significant potential for reducing human error and enhancing operational efficiency, particularly in the areas of materiovigilance and medical device safety. By streamlining data collection, analysis, and submission procedures, organizations can improve compliance and effectiveness in the medical device industry through the integration of AI technologies.[38]

AI-driven automation has already shown considerable promise in improving case reporting, data quality, and drug safety signal detection in the context of pharmacovigilance.[39] These advancements can also benefit in monitoring of medical device safety. AI systems significantly reduce the need for manual labor by processing thousands of adverse event reports each month, analyzing data, and interpreting results at impressive speeds.[39]

Despite the numerous benefits of AI, integrating these technologies into regulatory reporting systems presents several unique challenges. Two major obstacles are the lack of unified regulatory guidance and the availability of suitable training data for ML models.[39] In addition, while the goal of complete automation is appealing, it should be approached with caution, as stated in pharmacovigilance. A collaborative approach that combines technical expertise with intelligent technology must be prioritized, aiming to augment human capabilities rather than completely replace them.[40]

3.5. Enhancing decision-making with AI-powered insight

AI-powered insights are increasingly being employed to improve decision-making across various fields, including health care. Numerous studies highlight AI's groundbreaking potential in promoting data-driven decision-making. AI's ability to swiftly and accurately process vast amounts of data has made real-time, data-driven decision-making possible. Advanced language models, such as ChatGPT, are already being used in government sectors to improve operations, policy-making, and public services such as emergency response and public health management.[41] In materiovigilance, where timely decisions are critical for patient safety, this application can be expanded. AI-driven decision-making has been shown to improve organizational performance, with big data-powered AI playing a significant part in the development of AI capabilities within organizations.[42]

Despite its considerable potential to improve decision-making, AI presents several challenges that need to be addressed. Issues such as data privacy, ethical implications, and the risk of negative outcomes from poorly implemented AI remain prevalent.[43,44] These concerns are particularly significant in the context of materiovigilance, given the sensitive nature of medical records and the possible impact on patient safety.

In conclusion, real-time, data-driven insights from AI have the potential to significantly improve decision-making in materiovigilance. However, for successful implementation, it is essential to carefully consider ethical concerns, data privacy, and the development of robust governance frameworks.[43]

4. Improving patient outcomes: Case studies of AI in materiovigilance

Technologies such as AI and ML have shown significant promise in improving patient outcomes and advancing materiovigilance processes. The utility of AI in enhancing patient safety and monitoring medical devices is demonstrated by numerous case studies.

AI has the potential to improve intraoperative patient care in anesthesiology by continuously monitoring vital signs and predicting complications, as exemplified by the Hypotension Prediction Index algorithm.[45] This AI application enables anesthesiologists to optimize medication dosages, reducing side effects and increasing effectiveness. Similarly, smartwatches with AI capabilities have proven effective in detecting cardiac arrhythmias by continuously tracking heart activity. One case study reported the use of a smartwatch to identify atrial fibrillation in a young patient, highlighting the potential of wearable AI technology for early diagnosis and intervention.[46] Furthermore, during the COVID-19 pandemic, CV and AI-driven predictive analytics were used to facilitate remote care, diagnosis, and screening.[22] These applications helped minimize physical

contact while enabling timely diagnosis and treatment, thus enhancing patient safety.

Despite the promise of AI to improve patient outcomes, several issues and inconsistencies remain. A systematic review of 53 studies on AI in patient safety revealed variability in AI reporting and the absence of standardized benchmarks.[47] This variability highlights the need for thorough validation of AI systems in real-world clinical settings to ensure their reliability in predicting safety outcomes.

To take everything into consideration, AI-powered decision support tools have demonstrated their ability to improve medication administration, patient stratification, and error detection, thereby bolstering patient safety.[47] Both in hospital and home settings, the integration of AI into patient monitoring systems has improved real-time monitoring, increased predictive accuracy, and accelerated response times.[27] However, addressing concerns related to data privacy, algorithm transparency, and integration into clinical workflows requires further investigation and validation.[48] As AI continues to evolve, it holds the potential to revolutionize materiovigilance and significantly improve patient outcomes.

AI is transforming materiovigilance, particularly in enhancing the safety and customization of medical devices. For individuals with physical disabilities, AI-optimized, 3D-printed assistive devices are improving satisfaction and mobility, fostering greater independence. A prime example is the FDA-approved Nevro HFX iQ system, an AI-powered spinal cord stimulator that personalizes pain treatment by continuously adjusting neurostimulation based on real-time patient feedback, thereby enhancing pain management. In addition, the system's adaptive algorithms detect early signs of infection or complications, allowing timely interventions. This AI-driven approach in materiovigilance exemplifies how advanced monitoring can significantly improve patient safety and outcomes.[49]

AI-powered bionic limbs by Össur further illustrate the impact of AI in materiovigilance, particularly for optimizing prosthetic limbs. These advanced prosthetics use ML to adapt in real time to each user's gait and movements, enhancing comfort, stability, and balance, even on challenging terrains. By continuously adjusting to the user's movements, they provide a more natural experience, improve mobility, and reduce the risk of falls, thereby significantly enhancing patient safety and satisfaction. This example underscores AI's role in personalizing device performance to meet individual needs, positively impacting patient outcomes.[50]

Another emerging approach to monitoring medical device safety is the concept of the digital twin. A digital twin is a virtual replica of a medical device or system, including its interactions with patients and the environment, which is powered by real-time data collection and AI-driven analysis. This virtual model mirrors the physical device's performance and the patient's response, enabling continuous monitoring of safety and performance. The digital twin can simulate various scenarios and predict potential risks or adverse events before they occur, providing an advanced layer of surveillance in materiovigilance systems. As AI enhances the digital twin, it becomes increasingly sophisticated, learning from ongoing patient interactions and device usage, thus enabling proactive safety measures. This virtual model tracks the evolution of device behavior, assesses the long-term impact of AI-driven algorithms, and predicts device performance in diverse patient populations.[51,52]

5. Ethical and regulatory considerations for AI in materiovigilance

The use of AI-powered solutions in materiovigilance raises significant ethical and legal concerns. While AI applications in this field offer increased accuracy and efficiency in detecting and recording adverse events, they also introduce complex issues related to privacy, accountability, and equity.[53,54] The question of whether AI fits within existing legal frameworks or whether a new category should be established to address its unique features and implications remains a subject of ongoing debate.[55] The integration of AI in materiovigilance necessitates the development of robust governance frameworks to address these ethical dilemmas and guide decision-making. These frameworks should consider the distinct aspects of medical device regulation while prioritizing accountability, transparency, and privacy protection.[56]

Several regulations have been proposed in various countries to address these concerns, such as the AI Act and the Medical Device Regulation in the European Union. The AI Act represents the European Union's first comprehensive regulation of AI, classifying AI systems according to their risk levels. It establishes stringent safety and ethical standards for AI applications deemed to be of higher risk. This regulation came into effect in August 2024 across the 27 European Union member states, with full enforcement scheduled for completion by August 2027.[57] Similarly, the Medical Device Regulation, which has been in effect since May 2021, governs the safety and efficacy of medical devices within the European Union. It requires manufacturers to comply with rigorous standards for design, clinical assessment, and post-market surveillance. Together, these frameworks ensure the secure

development, approval, and oversight of AI technologies and medical devices in the European Union.[58]

Nowadays, AI is increasingly being incorporated into medical devices. In Japan, the "Improvement Design within Approval for Timely Evaluation and Notice" (IDATEN) system was introduced in September 2020 to streamline the approval process for medical devices, particularly Software as a Medical Device (SaMD) that utilizes AI. Conventionally, any modifications to approved medical devices require a comprehensive review, which could be time-consuming. The IDATEN system allows for partial modifications to be approved more swiftly, facilitating continuous improvements throughout a product's lifecycle. This feature is particularly advantageous for AI-based SaMD, which may require frequent updates to enhance performance.[59]

The full potential of AI in health-care requires addressing four key ethical issues: algorithmic biases and fairness, safety and transparency, consent to use data with patient information, and data privacy.[55] One major concern with AI-enabled materiovigilance systems is legal accountability. As these systems become more autonomous, the question of who is responsible for errors or regulatory violations becomes more complex. The challenges AI poses in monitoring medical devices may require modifications to current legal frameworks, including data protection laws and liability statutes.[60] In addition, materiovigilance must adhere to ethical guidelines that prioritize transparency, fairness, and the protection of patient privacy when utilizing AI.[61,62]

A comprehensive strategy is essential for addressing these complex issues effectively. This strategy should involve the development of explicit regulatory guidelines, the enhancement of transparency programs, and the establishment of accountability frameworks.[27,58] To ensure responsible AI application in materiovigilance, ethicists, policymakers, technology developers, and legal professionals must collaborate closely.[63] Furthermore, ongoing research and open dialog are essential for staying up to date with emerging ethical concerns and ensuring the ethical use of AI technologies in materiovigilance.[54,64] By fostering a balanced framework that prioritizes patient safety, privacy rights, and ethical AI development, stakeholders can maximize the benefits of AI in materiovigilance while reducing potential risks and maintaining public trust in the health-care system.[61,62,65]

6. Conclusion: The future of AI in health-care vigilance

AI has the potential to revolutionize health care, particularly materiovigilance, by improving patient safety and outcomes through advanced data collection, real-time monitoring, and proactive risk detection. However, the implementation of AI in health care comes with significant challenges, including ethical concerns, regulatory requirements, and technological limitations. Addressing these challenges necessitates a comprehensive approach, guided by collaborative efforts among technologists, medical professionals, regulators, and ethicists. To maximize AI's benefits, the health-care industry must prioritize ongoing research, robust regulations, professional training, and a human-centered approach that complements clinical expertise. This coordinated strategy will ensure that AI-driven materiovigilance enhances, rather than replaces, human judgment, ultimately advancing health-care safety and efficacy.

Acknowledgments

None.

Funding

None.

Conflict of interest

The authors declare they have no competing interests.

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Ethics approval and consent to participate

Not applicable.

Consent for publication

Not applicable.

Availability of data

Not applicable.

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