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REVIEW

The role of post-market surveillance in monitoring of artificial intelligence enabled medical devices after deployment - a comprehensive review

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Transformative advances in diagnostics and treatment can be achieved when Artificial Intelligence (AI) is integrated into medical devices. The unique challenge with the introduction of adaptive nature of AI and ML models are safety and performance especially during longer period. Therefore, pre-market evaluation of the medical devices is not sufficient. This highlights the role of Post-market surveillance, which ensures the safe monitoring of these technologies. The performance of the AI-enabled medical devices may show variation due to changes in clinical practice, progressive disease, and unexpected change in data in real-world population unlike traditional devices. An effective Post-market surveillance for AI enabled devices must be proactive and must be data driven. To alleviate any risks which may arise, post-market surveillance (PMS) systematically collects and analyzes the data from real world. Essential elements of PMS include setting performance standards, maintaining a watch for model instability, executing user feedbacks and enforcing stringent guidelines for clear incident reporting.

Keywords: healthcare, medical devices, artificial intelligence, post-market surveillance, materiovigilance, PMCF, MvPI

Introduction

Over the past few decades, there has been a significant evolution in medical devices in the healthcare industry. Medical devices are an important aspect of healthcare as they help diagnose, monitor, and treat a wide range of medical conditions. The use of medical devices helps to improve the accuracy and effectiveness of medical treatment, leading to better patient outcomes. The medical device industry is constantly evolving and innovating, with new technologies and devices being developed all the time. This promotes advancement in the medical field and guarantees that patients have access to the newest procedures and equipment. Medical devices must undergo post-market surveillance (PMS) to guarantee their continued efficacy, performance, and safety after being on sale. It assists in detecting long-term hazards, uncommon adverse events, and device malfunctions that pre-market trials could overlook (1). By facilitating real-time signal detection, automated analysis of sizable datasets, and early detection of safety trends from adverse event databases, electronic health records (EHRs), and user input, artificial intelligence (AI) improves PMS (2). A more resilient and adaptable safety ecosystem can be achieved by using machine-learning models to forecast device failures, enhance vigilance reporting, and assist regulatory decisions (3).

Importance of AI in healthcare and post-market surveillance

AI can completely change the way we manage the operational facets of healthcare delivery, diagnose illnesses, customize therapies for each patient, and track health status in real time. AI-powered diagnostic technologies, for example, are capable of precisely analyzing medical images and frequently spotting details that human eyes might miss. Patient outcomes are greatly impacted by the earlier and more precise diagnoses that result from this precision. Similar to this, therapy customization is a step toward genuinely individualized medicine as AI algorithms can search through

enormous databases to find trends and forecast which medicines will work best for particular patient profiles. Furthermore, wearable technology and remote monitoring systems provide ongoing patient health oversight, facilitating prompt treatments and lowering readmissions to hospitals. This is just one example of how AI is being used in patient monitoring. From appointment scheduling to hospital workflow optimization, AI can improve healthcare delivery efficiency and patient satisfaction (4–6).

Due to its distinct features, including data reliance, algorithmic bias, performance drift, and changing behavior in real-world scenarios, PMS is crucial for AI-driven medical devices. AI-enabled systems, such as diagnostic imaging tools or predictive algorithms, are susceptible to changes in patient demographics, disease prevalence, or clinical workflows that can cause data drift, which can impair accuracy over time and jeopardize patient safety and efficacy (7). The benefit-risk profile of the device is maintained throughout its lifecycle thanks to PMS, which allows for continuous monitoring to proactively detect these problems, identify developing dangers, subgroup underperformance, or latent biases that might not be apparent during pre-market validation.

This necessity is emphasized by regulatory bodies: With regard to AI/ML-enabled devices, the U.S. Food and Drug Administration (FDA) uses a total product lifecycle (TPLC) strategy, which mandates that manufacturers use PMS plans to monitor performance in the real world, control drift, and reduce hazards after approval (8). Quality assurance and multi-site assessments are facilitated by tools for identifying input/output changes and performance variances (7). To ensure continued safety, detect unidentified side effects, and address systematic misuse, PMS, including post-market clinical follow-up (PMCF), is required in the EU under the medical device regulation (MDR) and AI Act. Radiologists and providers also help to monitor AI systems in use (9). A strong PMS encourages innovation through empirical data and supports prompt remedial measures, like improved training or design revisions.

Effective PMS, in the end, facilitates the transition from controlled pre-market testing to dynamic clinical deployment, protecting patients, upholding regulatory compliance, and facilitating ongoing advancements in AI-driven healthcare technology through data-driven upgrades.

Post-market surveillance (PMS)

According to Kanemasa et al. (10), post-market surveillance is the continuous evaluation of a device's performance following its release to the general public. Important information is gathered during this procedure to help identify possible flaws that might not have been noticeable during pre-market evaluations.

A post-market surveillance plan's goal is to swiftly detect any problems with device usage or design defects, which includes the following:

Data gathering

Clinical evidence needs to be continuously and proactively gathered over the course of the medical device's lifecycle. Post-market surveillance data can be collected using a number of methods, such as user surveys, patient registries, specialized PMCF studies, literature reviews, analysis of complaints and vigilance reports, and input from field workers or medical professionals. A number of variables, including the device risk categorization, the intended therapeutic use, the target patient group, and the data gaps found during pre-market studies, influence the particular approaches chosen. Systematic data collection, safe storage, and careful process review to avoid fragmentation are all necessary for effective data management. Working together with teams that deal directly with users and patients, such support workers, field engineers, or sales reps, is essential to capturing new problems, grievances, or negative experiences that could otherwise go unreported.

Data analysis

In order to identify possible issues, new trends, or innovative uses for the device, makers must perform routine, proactive analysis of post-market surveillance data. A thorough analysis of the data gathered, the use of statistical techniques to spot trends or abnormalities, and the incorporation of results from searches of the scientific literature to contrast with any previously recorded comparable problems or occurrences are all part of this process. The manufacturer's quality management system (QMS) should incorporate these ongoing analytical activities to guarantee prompt insights into actual performance and to facilitate modifications to the clinical evaluation, risk management records, and post-market monitoring plan as a whole.

Corrective measures

In order to reduce risks, any problems found during post-market operations must be addressed quickly and appropriately. A careful analysis of grievances, unfavorable incidents, and other input might help identify risks or constraints that were previously unknown. Updates of the risk management file must methodically incorporate insights from PMS and PMCF processes, which may result in design changes, improvements to the manufacturing process, improved user training initiatives, the implementation of corrective and preventive actions (CAPAs), or the start of specific PMCF studies. As a dynamic, ongoing component

of the device lifetime, post-market surveillance—including PMCF—should be seen as fostering ongoing advancements in user experience, performance, and safety.

Reporting

Periodically, manufacturers must develop and submit reports that summarize the device's performance, safety, adverse events, and any difficulties that may have arisen in the field. The unique device identification (UDI) system was implemented by the European Medical Device Regulation (EU MDR) to improve supply chain traceability and facilitate quicker identification and handling of safety issues or recalls. Jurisdictions and device classifications have different reporting requirements. For example, in the EU, the post-market surveillance report (PMSR) is usually required for Class I (low-risk) devices, while the periodic safety update report (PSUR) is required for higher-risk Class IIa, IIb, and III devices. Periodic Adverse Drug Experience Reports for pertinent items are required by the FDA in the United States (11).

Post-market surveillance conducted in traditional ways

Passive surveillance systems

Passive surveillance has been the mainstay of traditional PMS, with regulators relying on voluntary or required reports from outside parties like patients, importers, user facilities, manufacturers, and healthcare providers. This system gathers information on adverse occurrences, malfunctioning devices, fatalities, or severe injuries without the authorities' express request (12, 13). Manufacturers are required by the FDA's medical device reporting (MDR) regulation under 21 CFR Part 803 to report fatalities, serious injuries, and malfunctions within a certain timeframe (for example, 30 days for most events), whereas user facilities are required to report serious incidents (8). Although it makes up a very small portion of submissions, voluntary reporting takes place through platforms such as MedWatch and is mostly submitted by consumers and healthcare professionals (13). Similar to this, in Europe prior to the MDR directives, vigilance systems were centerd on reporting incidents to the appropriate authorities. Manufacturers were required to notify major incidents as soon as possible (for example, within 10–15 days in the case of serious cases) (14).

Traditional techniques of PMS

Conventional approaches placed a strong emphasis on vigilance and adverse event reporting. Manufacturers kept complaint handling systems in place to record user comments, malfunctions, and failures and then examine them for patterns (15). Global vigilance initiatives made cross-border report sharing easier. Hospital-based networks, such as the medical product safety network (MedSun) in the US, which collected user facility reports, and volunteer MedWatch submissions were additional components (13). Reporting was often enhanced by retrospective examination of pre-existing data, such as medical records or claims; but formal prospective studies were uncommon unless required (for example, under FDA Section 522 for high-risk devices) (16).

Limitations of traditional approaches

Although they offer wide coverage and are reasonably priced, passive systems have some serious disadvantages. Lack of awareness, time restraints, or liability concerns frequently result in underreporting, which delays signal discovery and produces incomplete data (13). Reports frequently lack specificity, determining causality can be difficult, and long-term patterns or uncommon occurrences may go overlooked. Because it depends on spontaneous submissions, standard PMS is reactive rather than preventive, which limits the ability to identify systemic problems or new hazards early on (17).

Regulatory context and evolution

In the past, agencies such as the FDA and EU competent authorities have constructed surveillance around these passive methods, adding recalls, corrections, and a few active studies when indications appeared. Particularly after MDR, which requires systematic, active PMS strategies, constraints led to shifts toward proactive approaches like registries and real-world evidence (RWE) (18). To sum up, traditional PMS was successful in capturing reported occurrences; but, it also brought attention to the necessity of more thorough, proactive monitoring to better safeguard public health in a changing medical device environment.

Post-market surveillance conducted in modern ways

Under contemporary laws such as the FDA's TPLC framework and the EU medical device regulation (MDR 2017/745), PMS for medical devices has moved toward proactive, methodical, and data-driven techniques. To identify hazards early, update benefit-risk evaluations, and promote advancements during the device lifecycle, these approaches prioritize active data collection, RWE, and ongoing monitoring (7, 15).

Proactive and systematic data collection

In order to comply with modern PMS, producers must actively and methodically collect data instead of depending just on impromptu reports. This includes literature studies, user surveys, comments from medical experts, publicly accessible statistics on comparable devices, and trend analysis. A proactive approach to gathering, documenting, and evaluating quality, performance, and safety data is required by the EU MDR (Article 83), allowing for comparisons with comparable devices and prompt remedial measures (18, 19). Through systematic evaluations, support activities, and controlled monitoring throughout user training, proactive elements foresee problems.

Post-market clinical follow-up (PMCF)

In order to verify continued safety, performance, and clinical benefit, PMCF—a proactive, ongoing task to gather clinical data from real-world use—is a crucial contemporary component (Annex XIV, Part B, MDR). By using specialized research, registries, and polls, PMCF techniques produce high-quality RWE that enhances pre-market data. PMCF for higher-risk devices guarantees performance across a range of demographics, long-term results, and the identification of new hazards (20, 21). In order to promote evidence-based updates to clinical evaluations, registries offer longitudinal data from sizable cohorts.

Real-world evidence (RWE) and advanced analytics

For thorough insights, contemporary methods use RWE from patient registries, claims data, EHRs, and device-generated data. This makes it possible to identify trends, analyze subgroups, and spot signals early on. In order to address particular issues such as algorithmic degradation, tools for AI-enabled devices track input/output changes, data drift, and performance variances across locations (7, 9). Analyzing large datasets more efficiently is made possible by statistical techniques and AI-assisted analysis.

Reporting and regulatory obligations

In accordance with EU MDR, manufacturers generate structured reports that summarize data analysis, trends, and actions. These reports are called PSURs for higher-risk (Class IIa, IIb, and III) devices and PMSRs for lower-risk (Class I) devices (22). PMS is included into lifetime management by the FDA's TPLC approach, which offers guidelines for tracking AI/ML products using predetermined metrics and flexible strategies (8). While still crucial, proactive components are added to vigilance reporting.

Benefits and integration with quality systems

By encouraging early risk mitigation, design improvements, and CAPAs, these techniques enhance patient safety and regulatory compliance. Regular reviews and changes to technical documentation are part of PMS's integration with QMS (20). Proactive surveillance fills the pre- and post-market gaps for dynamic technologies like AI, fostering innovation while reducing risks. By utilizing real-world data and cutting-edge solutions for ongoing device safety and performance, modern PMS essentially shifts surveillance from reactive to predictive.

Variation between traditional and modern post-market surveillance (PMS) for medical devices

Following its introduction to the market, medical devices are monitored for efficacy, safety, and performance through post-market surveillance, or PMS. The FDA's TPLC framework and the EU Medical Device Regulation (MDR 2017/745) require proactive, systematic, and data-driven methods that allow for earlier risk detection and continuous improvement. In contrast, traditional approaches were primarily passive and reactive, depending on impromptu reports (15, 16).

Conventional PMS was critiqued for underreporting and sluggish reaction times, frequently overlooking uncommon or chronic problems, despite its effectiveness in capturing reported occurrences (13). The FDA's move toward active surveillance through tools like National Evaluation System for Health Technology (NEST) and the EU MDR's emphasis on lifecycle monitoring are two examples of how modern PMS fills these gaps through regulatory evolution, allowing for better real-world performance assessment (23). In the case of cutting-edge gadgets like AI-enabled ones, where proactive techniques identify performance changes early, this shift represents a larger commitment to patient safety (**Table 1**).

TABLE 1 | Comparison of traditional post-market surveillance (PMS) with modern PMS.

Aspect	Traditional PMS (pre-MDR/pre-total product lifecycle [TPLC] emphasis)	Modern PMS European Medical Device Regulation (EU MDR, FDA TPLC, and contemporary guidance)
Approach	Mostly passive and reactive; relied on incident reporting that was either required or optional.	Methodical and proactive; calls for constant, active data gathering and analysis over the course of the device's existence.
Data collection	Relied on complaints, vigilance alerts, user facility reports, and adverse event reports (e.g., FDA MAUDE, MedWatch).	Integrates active and passive methodologies, including literature reviews, claims data, EHRs, patient registries, post-market clinical follow-up (PMCF) studies, user surveys, and real-world evidence (RWE).
Nature of monitoring	Event-driven and retrospective; problems are discovered only after complaints have been made, frequently after a wait.	Constant and anticipatory; comprises statistical tracking, trend analysis, and early signal identification (e.g., data drift in AI devices).
Regulatory focus	PMS is frequently voluntary or targeted for high-risk devices (e.g., FDA Section 522 research); it is restricted to the required reporting of major occurrences or malfunctions.	All classes are obliged to have a proactive PMS plan; PMCF is either necessary or justified, particularly for devices with a greater risk; and it is integrated into risk management and QMS (EU MDR Article 83).
Reporting requirements	Unplanned vigilance reports; infrequent or case-specific periodic reports.	Periodically scheduled reports that include data summaries, trends, and actions (EU MDR) include post-market surveillance report (PMSR) (low-risk/Class I) and PSUR (higher-risk/Class IIa-III).
Use of technology/analytics	Reports are manually reviewed, and statistical tools are few.	Advanced analytics, electronic data capture (EDC) technologies, AI for pattern recognition, and registries for extensive, real-time insights.
Risk mitigation	Reactive remedial measures (such as recalls) following the emergence of issues	Proactive modifications to risk files, design adjustments, CAPAs, user education, or additional research based on growing data.
Limitations/strengths	Economical, yet it has issues with delayed signals, imprecise data, and underreporting (13).	More thorough, quicker, yet requiring more resources; improves patient safety and fosters innovation (7).

Materiovigilance program of India (MvPI)

A comprehensive system of performance characterization, monitoring, identification, collection, reporting, and analysis of any adverse event brought on by medical devices is known as metrovigilance. India's medical device market is worth USD 3.1 billion. But for a long time, there was no effective mechanism in place to keep an eye on the negative outcomes associated with medical gadgets (24). At first, the Drugs and Cosmetics Act of 1940 and the Rules of 1945 governed the marketed medical devices. Later in 2017, the Medical Device Rules, 2017 (25) were formulated as a unique regulation to govern the medical devices that are offered for sale in India.

By broadening regulatory monitoring beyond conventional classifications to encompass all classes of medical equipment, categorized by risk, this reform brought Indian regulation closer to international standards. Following global best practices, the regulations standardized post-market surveillance, required reporting of adverse occurrences, and Materiovigilance (device safety monitoring). Significantly, the MDR 2017 acknowledged the need for increased regulatory infrastructure and capacity building to maintain device safety while promoting innovation and market expansion, and it placed a strong emphasis on the creation of notified organizations for conformity assessment. With the creation of the Materiovigilance Program of India (MvPI) by the Indian government, this change demonstrated India's dedication to enhancing patient safety and device quality through organized, transparent, and enforced regulatory systems (26, 27).

Medical devices in India are governed by the DCA 1940 and Rules 1945. To import, produce, sell, and distribute medical devices, the Indian government implemented the Medical Devices Rule in 2017 after consulting with the drug technical advisory board (DTAB). Notification of this regulation was sent on January 31, 2017, and it became operative on January 1, 2018 (2, 5). On July 6, 2015, the Drug Controller General of India DCG (I) introduced the MvPI at the Indian Pharmacopoeia Commission (IPC) in Ghaziabad. The main goal of this program is to educate healthcare workers about the importance of "medical device adverse events" (MDAE) (28).

Additionally, it highlights a device's benefit-risk profile, monitors MDAE, and shares these results with all pertinent parties. Overseeing adverse occurrences of medical devices identified in the Indian public is the responsibility of IPC, the National Coordination Center (NCC) for MvPI. MvPI is regulated by the Central Drug Standard Control Organization (29), and the National Health System Resource Center (NHSRC) provides technical assistance. The Sree

Chitra Institute for Medical Sciences and Technology (SCTIMST) functions as a "National Collaborating Center." To ensure that a case is complete, 26 Medical Device Monitoring Centers (MDMCs) and Adverse Drug Reaction Monitoring Centers (AMCs) have been established. These centers examine MDAE data and forward them to the NCC (30).

Objectives of materiovigilance program

1. Create and implement a country-by-nation system for monitoring adverse events linked to "medical devices" in India.
2. Examine the medical device's benefit-risk ratio and causality assessment.
3. Support regulatory agencies' decision-making process.
4. Create safety data and medical device alerts for regulators and medical professionals.
5. To reduce risk, inform various stakeholders on the safety of using medical devices.

India MDR 2017 post-market surveillance (PMS) system

A systematic PMS system is established by India's MDR 2017 and is essential for tracking the effectiveness and safety of medical devices following their introduction to the market. The MvPI, a nationwide program run by the IPC and the Central Drugs Standard Control Organization (CDSCO), collaborates with the PMS system to coordinate vigilance and adverse event reporting across healthcare settings.

Key components of India's PMS system

Adverse event reporting and materiovigilance program of India (MvPI)

An essential component of India's PMS infrastructure, the MvPI offers a framework for gathering, evaluating, and reacting to unfavorable occurrences and accidents involving devices. Across the nation, vigilance monitoring centers have been set up to help patients, healthcare providers, and manufacturers report adverse occurrences using standardized forms. In order to identify failure modes, detect safety signals, and inform regulatory choices, the obtained data is examined (31).

Complaint handling and risk-based monitoring

In accordance with the MDR 2017, manufacturers and authorized representatives in India are required to keep up a complaint handling system. The focus is on risk-based monitoring, which calls for continuous safety data gathering throughout the product lifecycle in proportion to the device risk rating. To reduce risks as soon as possible, this entails evaluating benefit-risk profiles and informing patients and healthcare professionals of any possible issues (32).

Field safety corrective actions (FSCA)

Corrective measures for field safety, including software upgrades, labeling modifications, and recalls, are required when safety issues emerge. For quick risk reduction and device safety maintenance in practical applications, manufacturers must use the designated reporting formats to inform CDSCO and stakeholders of their activities.

Post-market surveillance studies and periodic reporting

To regularly assess safety, performance, and durability under real-world use situations, the CDSCO may mandate post-market clinical trials, particularly for high-risk devices or those without thorough pre-market data. For some device classes, PSURs, which represent continuous benefit-risk analysis and regulatory compliance, are required (32).

Data analysis and stakeholder collaboration

In order to identify patterns and warning signs, India's PMS uses statistical analysis and data mining of various data sources. To guarantee proactive risk management, openness, and enhanced device standards, cooperation between manufacturers, medical experts, regulators, and patient advocacy organizations is essential (33).

Benefits of post marketing surveillance

Enhanced patient safety

By facilitating the early identification and mitigation of dangers that might not be evident during premarket testing, PMS plays a crucial role in protecting patient health. Data from the real world shows unexpected side effects, malfunctioning devices, or safety concerns in particular patient groups, like those with comorbid conditions or

in different usage situations. To ensure that devices like pacemakers or infusion pumps continue to function properly over time, PMS, for example, enables prompt interventions such as product recalls, label changes, or user training. As seen in past instances where postmarket data resulted in corrective actions for defective implants, PMS lowers the possibility of widespread problems by regularly evaluating safety. In addition to safeguarding individual patients, this proactive strategy increases public confidence in medical technology (distillersr.com, nfs.org, sternumiot.com) (11, 22, 34).

Improved product quality and innovation

Continuous improvement is fueled by PMS, which gives manufacturers useful input on device performance, usage trends, and any flaws. Real-world application data can improve safety features, functionality, and design, resulting in new iterations or product updates that better suit user needs. Reliability-enhancing technologies may be prompted by user input identifying ergonomic or material durability issues. PMS can also reveal off-label or novel applications, increasing the usefulness of a device (e.g., modifying a diagnostic tool for an unexpected anatomical region) and guiding risk management plans to reduce new risks. Businesses can better align their goods with clinical reality and increase long-term satisfaction by fostering innovation through this feedback loop (22, 35, 36).

Monitoring effectiveness and long-term outcomes

When it comes to assessing a device's effectiveness outside of the controlled setting of clinical trials, PMS is exceptional. In order to develop more effective medicines, it evaluates results in a variety of demographics, long-term durability, and combinations with other treatments. This continuous evaluation verifies initial claims and detects any performance deterioration over time for high-risk devices such as Class III implants or implants. By offering a thorough understanding of efficacy, PMS assists in streamlining treatment plans and guarantees that gadgets provide long-lasting advantages, which eventually improves patient outcomes (11, 34, 37).

Regulatory compliance and market confidence

By ensuring compliance with international regulations, a robust PMS reduces legal risks, fines, and obstacles to market access. Adherence to regulatory frameworks such as the FDA's PSURs or the EU's MDR shows a dedication to safety, which helps obtain approvals and preserve certifications like CE marking or 510(k) clearance. This improves market reputation and brand trust by establishing credibility with patients, healthcare providers, and regulators. Informed regulatory choices are also supported by transparent PMS data, which can help avoid expensive recalls by validating risk-benefit ratios and facilitating prompt remedial action (15, 22, 35).

Economic and competitive benefits for manufacturers

Through evidence-based validation, PMS distinguishes safe, effective devices from subpar ones, giving businesses a competitive edge. Since consumers and healthcare providers favor technologies with strong postmarket evidence, access to real-world data influences pricing, sales, and marketing initiatives. By resolving problems early, it can lower liability while increasing sales and market share. Additionally, PMS data might reveal new opportunities or gaps in the market, spurring innovation and long-term profitability. Effective PMS systems can simplify operations and offer a financially viable means of proving value for smaller manufacturers (15, 22).

Better informed decision-making for stakeholders

By offering clear, practical insights, PMS helps a variety of stakeholders. Data on device performance in various settings is sent to healthcare providers, supporting off-label usage and treatment decisions. It is used by payers and regulators to evaluate cost-effectiveness and compare technologies, which helps them make decisions about reimbursement and policy. Improved risk communication and safer goods indirectly benefit patients. According to DistillerSR (11), Nfs (22), and Igal Zeifman and Hadas Spektor (34), this promotes cooperation and evidence-based procedures throughout the healthcare ecosystem.

Therefore, to summarize, Over the past decade progress in medical technology has led to an evolution of medical devices and in the Healthcare Industry. These devices help in treatment, diagnosis and in monitoring the diseases. These medical devices vary from a tongue depressor to an advanced surgical robot (38). PMS has become a crucial part of the health care approval process for a certified medical device. As per directive of WHO, many countries including India have established their own post marketing surveillance system (39). In US, FDA PMS mean monitoring safety, investigating complaints, reporting corrections/removal, maintenance, device tracking with post approval studies (40). The EU MDR has a prescribed regulatory framework focusing on Clinical evidence of PMS (41). The regulatory framework is significant for manufacturers, healthcare professionals, and regulatory bodies to integrate efforts and to secure a systematic PMS mechanism globally (42).

In India, Materiovigilance is defined as a integrated systematic monitoring, identifying, and reviewing any accidents caused by the medical devices. Though, the regulations are in place many healthcare professionals may not be aware of them. So, it had to be made mandatory that all medical personal should be aware of the Medical Device Rule, 2017. Traditionally, the Post marketing surveillance of a medical device is done by collecting data, manual review, statistical analysis which leads to slow, labor driven with manual error and bias and overriding the regulations. The AI-driven pharmacovigilance enhances efficiency, improves

accuracy with rapid automated analysis using Machine Learning, NLP and deep Learning (43). The introduction of AI in Post Marketing Surveillance marks a cornerstone in the field of healthcare has brought in digital transformation as its emphasis the invaluable trait of patient safety and satisfaction of all the stake holders (44, 45). Each health care system should set up a local governance in coordination with manufacturer, regulatory body of the government to have an established ecosystem where the standards of PMS are collected, analyzed and shared to achieve an AI enhanced solution.

Conclusion

There is a need to have a strong PMS to assure continuous patient safety due to modernized global healthcare system which is evolving rapidly with respect to medical devices, from basic tools to advanced robotic systems. The FDA's Framework, EU's MDR and India's Materiovigilance Program under the 2017 Medical Device Rule supports regular monitoring and obtaining approval from these bodies. PMS is being revolutionized with AI which uses machine learning, natural language processing, and deep learning which significantly improves shareholders' confidence and patient safety by enabling quicker signal detection, precise real-world data analysis, unbiased and early risk identification.

A standardized, transparent, and AI-enhanced PMS systems requires coordinated local governance comprising manufacturers, healthcare providers, and regulators to optimize these benefits. With new medical innovations developing at a faster pace, stricter laws with AI becomes very important to maintain safe, competent, and patient-oriented healthcare.

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