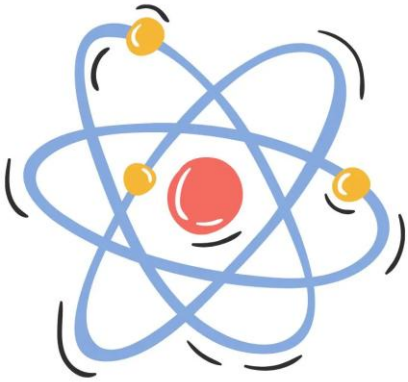

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Abstract: *The systematic efforts to prevent and mitigate the dangers posed by medical devices are one of the principal functions of materiovigilance. MvPI's inception under the Pharmacovigilance Programme in India was a significant milestone in enhancing the management of medical devices and regulatory intervention for the devices. The paper explores the roles of some members of the multidisciplinary healthcare team (physicians, nurses, biomedical engineers, pharmacists, & technical staff) and the potential device-related risk. The paper also explores the influence of maternal vigilance on the regulatory cycle (recalls & alerts, redesign & modification, & control) on the Medical Device Rules (MDR 2017). The paper also explores the current PMS in India and the positive indicators such as the rise in reporting centres, the growing number of reports submitted digitally, and the use of real-world data. India has made progress on Reporting Centre closure, Reporting Centre underuse, Reporting Centre untraceability, Reporting Centre manufacturer unaccountability, and Reporting Centre poor hospital culture weak Reporting Centre. India's progress has been compared to that of other countries in order to highlight India's progress. This comparison shows that India has made progress in reporting. India has made progress on reporting. This paper is focussed on reporting in order to enhance device safety and surveillance in India.*

Keywords: *Materiovigilance, Medical Devices, MvPI, Adverse Device Event (ADE), Post-Market Surveillance, Patient Safety, India*.

1. Introduction

India's medical device industry has changed significantly in the past 10 years as a result of improvements in technology, governmental policies aimed at promoting self-sufficiency, the emergence of initiatives like 'Make in India', the creation of medical device parks, and the expansion of healthcare requirements. India is a top competitor in Asia's rapidly growing medical device industry (Kalaiselvan et al., 2020). The country produces a wide range of medical tools, from basic, disposable supplies to sophisticated diagnostic machinery and implants. As a result of this expansion, hospitals and clinics across the country have significantly increased the volume of medical devices they use, creating a need for more thorough performance surveillance and enhanced safety monitoring. The need for PMS Systems is amplified as medical devices have the

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potential to directly touch patients and when they do, any defects or errors in the device pose a real danger to the patient's health.

Post-market surveillance is an essential practice that guarantees the evaluation of medical devices even after being commercialized. Assessments made during pre-market evaluations establish only the most basic safety and performance characteristics. Numerous risks associated with medical devices only emerge after prolonged use in actual practice (Kalaiselvan et al., 2023). Strong post-market surveillance systems are essential to mitigate avoidable harm by ensuring that adverse events are documented, appropriate corrective measures are taken, and avoidable harms are mitigated. Recent trends demonstrating India's increased reliance on medical devices amplifies the necessity and importance of an active and responsive monitoring system capable of identifying adverse events, trends in device malfunctions, and new risks in medical devices.

Historically, health care surveillance systems in India have paid greater attention to drugs, leading to well-established systems in pharmacovigilance. However, the means by which drugs and medical devices interact with the body, the risks they present, their clinical applications, and the regulatory processes surrounding them are all considerably different (Meher, 2018). The field of pharmacovigilance is concerned mainly with the monitoring of safety and adverse effects associated with drugs in which humans are subjected to chemical and/or biological interactions. In contrast, the field of materiovigilance is concerned with device related risks, such as failures in the mechanisms, software malfunctions, design problems, inadequate sterilization, and operator error. This requires the construction of an entirely new framework for medical device safety.Given this requirement, the Indian government initiated the Materiovigilance Programme of India (MvPI), situated in the Indian Pharmacopoeia Commission (IPC), in 2015, with the purpose of creating a system in India to monitor, collect, and assess negative outcomes pertaining to medical devices in India (Soni et al., 2024). Since the commencement of the MvPI, there has been an extension in the number of reporting centres, the systematization of reporting mechanisms, and the partnering with other agencies, such as the Central Drugs Standard Control Organisation (CDSCO), to improve the assessment of safety of devices in the market after the devices have been sold.

The purpose of this review article is to concentrate on the increasing importance of materiovigilance in relation to the medical devices industry in India. With new regulations

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implemented, challenges still exist, such as under reporting, limited awareness, and lack of coordinated policies. To understand how India could develop and improve the safety system in the medical device industry, this review aims to integrate the knowledge on multi-country, multi-discipline practices, and materiovigilance system.

The primary objectives of this review are:

(1) To describe the current state of materiovigilance in India and its alignment with global systems;
(2) To analyze the strengths and limitations of existing adverse event reporting mechanisms;
(3) To highlight the role of healthcare professionals and regulatory bodies in promoting device safety;
(4) To identify actionable opportunities for improving post-market surveillance and patient safety in the Indian healthcare system.

2. Overview of Materiovigilance

Materiovigilance is the continual monitoring of adverse events related to medical devices over the course of their lifecycle to ensure the devices' safety, quality, effectiveness, and availability of proper medical documentation (Yadav et al., 2025). Adverse events that negatively impact patient safety and health are related to under-appreciated issues that devices pose. In the world, however, materiovigilance is instrumental in ensuring that medical devices adequately protect the safety and provide post-market continual effectiveness and safety-abridged performance.

At the global level, the WHO advocates for the development of countries' post-market surveillance systems for medical devices and encourages the implementation of national vigilance programs. WHO guidelines emphasize the need for coordinated systems of safety reporting, safety surveillance, and safety monitoring system to be more accessible and efficient in their purpose of system safety.

In the U.S., the FDA captures and compiles adverse events from manufacturers and healthcare facilities and users and performs materiovigilance through the MAUDE (Manufacturer and User Facility Device Experience) database\. It aids in determining adverse events patterns and helps detect possible warning signs. In the European Union, there is EUDAMED, which is a centralized system that captures adverse events, clinical trials, device UDI, and manufacturers. Under the EU

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Medical Device Regulation (MDR 2017/745), manufacturers are mandates to continuous and proactivity report events and take corrective actions (Date et al., 2023). In the UK, the MHRA (Medicines and Healthcare Products Regulatory Agency) has a well-implemented vigilance system that encourages reporting of device failures, recalls, injuries, and adverse events in the system by clinicians and patients. These have the potential to serve as points of reference for India to build its own system of materiovigilance and to streamline and improve the regulation of the system.

In India, the pathway to a system for monitoring the safety of devices started with the introduction of the Materiovigilance Programme of India (MvPI) in 2015. This began with the Indian Pharmacopoeia Commission (IPC), of the Ministry of Health and Family Welfare, in collaboration with the Central Drugs Standard Control Organisation (CDSCO), and it is aimed at establishing a coordinated system for the reporting and analysis of adverse events associated with medical devices in healthcare institutions (Singh et al., 2025).

Stakeholders are as follows:

- CDSCO – the national regulator who oversees the approval and the recall of medical devices and other enforcement actions.
- IPC – serves as the National Coordination Centre (NCC) for MvPI.
- Adverse Event Monitoring Centres (AMCs) – hospitals and medical colleges that have a legal duty to report adverse events.
- NHSRC – offers assistance in training and other forms of technical support.

India has particularly enhanced one aspect of its architecture – the regulations governing medical devices – with the addition of medical device rules (MDR 2017), which categorize medical devices by class into four risk levels (A–D) and require PMS to be reported by manufacturers. Functions of MvPI include the establishment of reporting centres; creation of reporting tools; provision of root cause analysis; issuance of safety warnings and recommendations for action; regulatory actions (Hoda et al., 2020). There are now numerous methods for reporting that include the use of physical forms, online forms, email, and even telephones, which have all been designed to improve ease of reporting.

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Adverse events relating to medical devices include a wide variety of problems including device malfunction, where a device fails to work as intended; use error, where there is simply a failure in the operation of a device due to a design flaw or insufficient operation instructions; device flush, which is taken when there are any safety risks associated with the appliances; and other serious events which are highly reportable, such as failure of a device which leads to injury, infection, or death of a patient (Thacampatta et al., 2025). These types are the first step in pattern recognition in influencing corrective actions within the healthcare sector and regulation.

3. Adverse Event Reporting Systems in India: Challenges & Opportunities

The MvPI of India deals with reporting from health care providers, manufacturers, and patients. For reporting, structured MvPI reporting forms, which come in electronic and hard copy formats, are used. These forms capture information on the device, a description of the incident, the outcome for the patient, and the reporter's information (Nori et al., 2025). The online reporting portal developed under the IPC streamlines the submission and tracking of adverse event reporting. MvPI has also developed a reporting mobile app to facilitate real-time reporting of device-related incidents for reporting clinicians and biomedical engineers. The establishment of Device Vigilance Centres (DVCs) in a number of hospitals enhances the local surveillance system by conducting internal surveillance audits, training, and preliminary investigations.

The device safety monitoring systems are a new initiative in the public health system, and the safety devices monitoring initiatives in India face numerous issues. The main issue remains low awareness, fear of reporting, legal repercussions, and the belief that reporting is time-consuming. More training is needed for many medical personnel on how to recognize and document reporting of devices issues (Attri et al., 2023). The lack of a reliable feedback mechanism has further compounded the issue by leading reporters to the conclusion that the reports they submit will be ignored. The quality of reporting is also often insufficient and lacking in important details of the incidents or the devices used. The private health care sector is also under reporting the system which is a concern in MvPI since the private health care sector covers a large portion of India's population.

There are many opportunities that India has in improving its materiovigilance systems. India has a lot of opportunities in improving its systems of reliablity. Improving automated reporting

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systems that are having joined mechanisms of reporting is able to increase data capture to a great level. If Integration of MvPI to hospital Information System is done, seamless documentation can be done and issues related to the device can be auto identified (Gutte et al., 2024). AI systems having predictive analytics can be used to discover early trends and failure of the device. Installing greater device safety through Mandatory distinct post market surveillance PMS reporting from manufacturers, audits, and transparency obligations are necessary. An enhanced device safety is expected from developing a high-risk medical device national registry and a restrictive one for implants and cardiac devices that improves traceability and its extended monitoring to patients.

4. Role of Healthcare Professionals in Strengthening Materiovigilance

In India, Healthcare professionals (HCPs) constitute the first layer of the Indian materiovigilance system because they have the firsthand opportunity to assess, monitor, and analyze the various facets of a medical device's performance in actual clinical situations. HCPs have the dual ability to appreciate a medical device's clinical utility due to clinical observations and/or patient interaction and to understand the medical device's intended clinical applications, devise operational protocols, and conceptualize the clinical workflow (Chauhan et al., 2019). HCPs are in a prime position to first notice the indications of a medical device's malfunction, user errors, and adverse events. Such indications, if escalated and reported in a timely manner, can address and potentially prevent further device-related harm; enable regulatory changes to mitigate harm; and influence the design of medical devices toward the desired clinical goals; and diminish user errors. Physicians, nurses, biomedical engineers, engineers, and pharmacists have distinct but interrelated roles to boost mariovigilance and integrated healthcare level system strcutures throughout the primary healthcare system in the Indian scenario.

Physicians are the primary actors in mariovigilance because they coordinate the essential functions of diagnosing, instituting a treatment plan, and executing any procedural/ device-related interevention. They may be the first to note inconsistencies in the expected performance of the medical device, lack of responsive action, and/or the emergence of device-related adverse clinical events (CEM) as well as device-related adverse events (ADE) complications that are unexpected in the patient population (Joshi et al., 2021). They, along with their clinical and administrative colleagues, help the peers in their hierarchical structure by providing supervision and guidance on regulatory documentation of adverse device events to ensure the relevance of the clinical details

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in the event report. Reporting ADEs and CEMs along with their clinical expertise fosters a climate of safety and a spirit of cross-discipline collaboration in mariovigilance activities.

Nurses are instrumental in tracking patients outcomes after devices have been used/integrated, monitoring and documenting within to patients records idiosyncrasies whilst devices are in function (Najmi, 2022). As nurses interface directly with patients and devices (infusion pumps, catheters, monitors) they may notice details relating to potential problems of an malfunction or misuse that may otherwise be missed even by highly trained clinical staff. As such, their work in completing and submitting ADE forms and raising issues with their clinical supervisors permits their status as vital members of the reporting ecosystem.

Biomedical engineers' responsibilities span performing and/or supervising the technical analysis of devices for their utilization, in the continuous sequence of device utilization, maintenance, as well as the calibration, and design of the device to accomplish a clinical task (Rahman, 2023). They are the clinico-administrative interface to the biomedical device regulation ecosystem, as well as to determining relevant devices defective, their misuse, or even unresponsive devices due to improperly controlled clinical environments. They are significant and assist in the analysis of why the biomedical device does not function as expected and help the institution to define what can be achieved legally (CAPA).

Technicians are as frontline staff in the health services, and laboratory, radiology, and operation theatre technician are as frontline staff, including also those contracted to be with the health services, as staff to operate medical devices that are very high risk, for example those used for imaging, sterility, and that support vital functions (such as ventilators, surgical tools). They help in their documentations and reporting for the monitoring and real time reporting of technical performance of the devices used (Samal et al., 2022).

Pharmacists working in hospital medical device stores and procurement units contribute to device authenticity and compliance with storage requirements and recalls and device-tracing by batch and serial numbers. They also report devices complaints to manufacturers and regulators.

Healthcare professionals report adverse devices events resistant patterns through their professional barriers. These include lack of awareness, heavy workloads, fear of repercussions, and the

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knowledge gap regarding adverse device events. The absence of formal structured committees on materiovigilance and the lack of training in many healthcare institutions impact the efficiency for captured reports (Shukla et al., 2019). To enhance the barriers on reporting adverse event reporting, the implementation and training of healthcare professionals should be integrated with continuous building through CME events, training to inform, and the introduction of mandatory reporting failing which to justify. Additional reporting motivators could include regulatory Nd punitive reporting frameworks, and streamlined adverse event reporting templates. The integration of the clinical, technical and administrative skills of health professionals is critical to achieving multidisciplinary collaborative frameworks to improve the materiovigilance systems in India.

5. Impact of Materiovigilance on Regulatory Decision-Making & Patient Safety

Materiovigilance has been instrumental in influencing the regulatory environment by assessing the data in MvPI to develop evidence-based policy recommendations on the risks and efficacy concerning different medical devices that are in use across the country (Saranraj, 2024). Through the data collected in MvPI, regulators are able to detect safety risks, take appropriate safety measures, and ensure that the medical devices in circulation are of adequate safety and quality.

One of the most impactful achievements of the MvPI is the ability to recommend medical devices to be recalled, particularly devices that are deemed to have a threatening level of risk to the safety of patients. Medical devices may be recalled for a variety of reasons, including manufacturing defects, design issues, failure to properly sterilize the devices, or software issues (Sivagourounadin et al., 2022). MvPI reports assist in assessing the need to take mandatory or voluntary actions by providing detailed recommendations to the appropriate corrective actions that should be taken by the manufacturers. In addition, the MvPI enhances the timely provision of safety information that alerts clinicians to take caution, the clinical failure of medical devices, and the measures to be taken to prevent the clinical use of the devices (Selvam et al., 2024). In addition to safety device warnings, the data has led to the timely implementation of Field Safety Corrective Actions (FSCAs), where corrective measures are taken such as revising the instructions for use, various software updates, or the removal of certain lots from circulation. In some cases, the need to address risks and safety concerns has prompted both regulators and manufacturers to take proactive and timely actions to adjust the design of a medical device to ensure a higher level of safety and performance before its wide distribution.

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A functioning and effective system of materio-vigilance will inevitably increase the level of patient safety by minimizing the injuries that come from using medical devices, improving the outcomes of patient care, and meeting safety standards of devices. Monitoring adverse events lessens the chances of them occurring again while sustaining the opportunity for effective regulation. Furthermore, legit mitigation of risks is facilitated by materio-vigilance promoting knowledge of the devices and the recommended methods as well as attachments of the devices. It is concrete that the open approach of reporting and communication builds a positive, patient safety culture and trust within the system of health care (Sapkota et al., 2023). With the knowledge and signals of the devices, health care systems and regulatory bodies can prevent the morbidity that comes with the devices and the harmful infections that can accompany substandard clinical care.

The introduction of the Medical Device Rules (MDR) 2017 in India brought in the first regulation of Medical Devices in India which classify devices as: Class A (Low Risk), Class B (Low–Moderate Risk), Class C (Moderate–High Risk), and Class D (High Risk). These classifications determine the levels of regulatory scrutiny, the risk mitigation and documentation required, as well as the PMS (Post-Market Surveillance) obligations for each device type (Abhima et al., 2023). Under MDR 2017, manufacturers are required to participation in continuous safety monitoring that includes post market surveillance, reporting of periodic safety update reports, and to report serious adverse events to the CDSCO, which are required of them. Thus, Materiovigilance data influences as a situation that strengthens compliance, quality audits, and the overall accountability of manufacturers. The MvPI supplemented with national regulatory systems contributes to the safety and effectiveness of devices in India, as well as the legal system, and moves India closer to the ideal regulatory system.

6. Post-Market Surveillance (PMS) of Medical Devices in India

Post-market surveillance is necessary after the evaluation of the safety and effectiveness of a medical device to provide ongoing surveillance of the device (Dharman et al., 2025). In India, PMS is a function of the regulations, the device manufacturers, and the information processed by the Materiovigilance Programme of India.

The PMS in India is a combination of active surveillance, passive surveillance, and Periodic Safety Update Reports (PSURs). Active surveillance consists of international safety signal detection

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through device tracking, hospital record reviews, and specific studies pertaining to high-cost, high-risk interventional devices (e.g. permanent implants, cardiac devices). Passive surveillance occurs through the voluntary, non-mandatory submission of adverse event reports by healthcare professionals, manufacturers, patients, healthcare institutions, and regulatory authorities through the MvPI reporting channels. PSURs are submitted by manufacturers on a mandatory basis at defined intervals (Kumar & Goyal, 2025). These PSURs provide the manufacturers' estimations and analyses of safety data, risk assessment and risk management, and safety signal mitigating strategies. These elements combined form a multi-layered approach to PMS.

Over recent years, India has experienced a considerable expansion of reporting structures, with an increasing number of medical colleges, district hospitals, and private sector players joining the MvPI activities (Polillan et al., 2025). The number of reported medical devices has also increased significantly with the expanding coverage of the MDR 2017, requiring more products to be monitored for safety and also to be placed under mandatory safety monitoring. Digital reporting through mobile apps and online reporting portals complemented by electronic forms is also a trend to improve the reporting of adverse events and the completeness and quality of the data reported.

There is no doubt that stagnant performance in PMS in India continues to be a real challenge. Traceability remains a major concern, particularly with implantable devices, which are the subject of a perennial absence of comprehensive tracking and tracing system (Shukla et al., 2024). Most if not all hospitals do not perform legal audits and do not have internal safety committees, which means that the system has very low capacity for identifying some of the more persistent and recurrent problems pertaining to devices under the control of the organization. Reporting by manufacturers is also a problem because of delays in submitting PSURs, incomplete reports, and underreporting of safety data to the countries with lower safety reporting requirements. Most of these issues really do compromise the PMS and more importantly prevent rapid response on the PMS by regulators.

In India, the UDI unique Tracking and recall Deficiency and medical implants registries will enhance Primary Device Monitoring. Addressing UDI across Devices will enhance Defect and Recall Monitoring efficiency (Komban et al., 2025). A medical device registry on high-risk

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implants will assist in longitudinal studies and the generation of real-world evidence. AI and Machine Learning Predictors of Defect patterns, Algorithms of signal Regulatory on Early Deficiency. Risks will be improved by clinical, Holistic Health and device interactivity. Data Collaboration with the Regulatory FDA, MHRA, EU, and Data Centers will enhance. Reporting Pilots and Preparedness. Regulations will be reshaping the India PMS significantly, Improving Safety.

7. Discussion

The outcomes of this review are perhaps the first to underscore the impact of materovigilance on the safety of patients and the quality of medical devices used in India. National and international systems demonstrate that effective materovigilance is sustained through continuous reporting systems, efficient post-market surveillance, and integration of the stakeholders including regulators, providers, and manufacturers (Trivedi, 2022). The Materiovigilance Programme of India (MvPI) is an unprecedented development in the enhancement of the safety of devices, especially in view of the fast growth of the medical device industry and the increasing reliance on risky technologies in the medical practice. The evidence suggests that India has positively advanced in development of systems for reporting, the establishment of the regulatory, and the adaptive stakeholder systems, but several operational gaps remain to be addressed in order to realize the iron grip of materovigilance systems.

A look into India's system compared to the FDA's MAUDE, the EU's EUDAMED, and the MHRA in the UK shows some similarities and some differences. International systems benefit from an extensive history of regulations, an established culture of enforcement, mandatory reporting, and advanced reporting systems with the ability to perform real-time analytics. On the contrary, the Indian system is younger and is still developing with an increased reliance on voluntary reporting and developing digital systems (Sushma Kondaveti et al., 2024). That said, MvPI has made rapid progress in expanding its network of adverse event monitoring centres and standardizing reporting templates. India is unlike most Western systems in that it has additional challenges that include limited resources, varied levels of preparedness of the reporting hospitals, and an overall weak system for device traceability. These challenges will require additional investment and capacity-building to overcome.

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The strengths of the Indian materiovigilance framework include increasing regulatory attention to the safety of the devices, organized streams of reporting, increase interaction from all relevant parties, and efforts compatible with Medical Device Rules (MDR 2017). The program's outreach to medical colleges, district hospitals, and private hospitals reflects the increasing awareness and participation of institutions. However, underreporting, lack of engagement from manufacturers, inadequate surveillance committee participation at the hospital level, and insufficient reporting system integration with hospital information systems still exist. The absence of consistent training among the different healthcare institutions has created problems in the timely identification and reporting of adverse events.

One of the weakest spots in the system is the lack of accountability of the manufacturers. According to MDR 2017, manufacturers have obligations to do post-market surveillance, provide safety update reports and notify relevant parties in a timely manner about serious adverse events. However, it is a challenge, and there is often a lack of regulatory oversight because the reports are incomplete. The accountability of manufacturers could be improved by tightening the regulatory oversight and by introducing public reporting of non-compliance.

Translating the ideal of fostering an ethos of proactivity into practice at the institutional level is fundamental. Many hospitals still do not have specific materiovigilance committees or simply do not consider device safety to be part of their routine quality surveillance (Mukherjee et al., 2024). Formulating policies that include mandatory reporting of adverse events, integrating training, incorporating reporting of adverse device events into the digital hospital information system, and fostering non-punitive reporting of adverse events can significantly increase the rates of reporting. The discussion as a whole suggests that India is well positioned in terms of the groundwork on materiovigilance, but meeting global expectations is still going to take extensive work to improve the use of technology, reform of regulations, building capacity, and collaboration of all stakeholders.

8. Conclusion

Materiovigilance has become one of the key aspects of patient safety in the country as it ensures that medical devices are safe and effective. However, as the medical device industry and technology in India is still growing, the need for a reliable and robust system is needed. There have been some advancements with MvPI and the beginning of the implementation of the MDR 2017,

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but there are still some delays and discrepancies that need fixing such as underreporting, limited system traceability, manufacturers not complying, systems not implemented from the hospitals, and the system as a whole is still not effective.

These closing gaps have come from utilizing a fully coordinated strategic approach. Improving the fully coordinated strategies are the gaps in digital reporting systems, the registries for devices, compliance from manufacturers, and training of healthcare professionals. Strengthening reporting systems will also aid in surveillance of devices of all ages and a reporting system that is not punitive will aid in device risk detection. Using machine learning, AI, and real system reporting will aid in a predictive system that has real risk mitigation. With these collobaritive actions and further work from the regulators it can be one of the best systems in the world helping the safety of patients.

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