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# MATERIOVIGILANCE IN MEDICAL DEVICES: CURRENT PRACTICES, CHALLENGES, AND FUTURE PERSPECTIVES

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**ABSTRACT**

The World Health Organization (WHO) defines a medical device as any tool, apparatus, implant, reagent, software, or other item used for medical purposes, such as illness diagnosis, prevention, monitoring, or treatment, or for maintaining or supporting life. These days, pharmacovigilance also includes drug therapy-related problems (DTRPs) demonstrated by biologicals and blood products, medical devices, herbal remedies, and traditional, complementary, and alternative medicines (TCAMs). While pharmacovigilance (PV) and Materiovigilance (MV) have similar reporting objectives and methods, MV focuses on medical device adverse reactions and preventative techniques. Machine learning can be utilized for signal detection, safety surveillance, and the detection of ADRs or ADEs. Software as a medical device (SaMD) is defined by the International Medical Device Regulators Forum (IMDRF, https://www.imdrf.org/) as software designed for medical purposes that is not dependent on physical devices. For artificial intelligence (AI) applications, all available health data and medical images such as those from computed tomography, magnetic resonance, nuclear medicine, x-rays, and ultrasound exams may be the most intriguing. Pharmacovigilance focuses on all adverse drug reactions (ADRs), product quality flaws, medication errors, and ineffectiveness.

**KEYWORDS:** Medical Device, Pharmacovigilance, Materiovigilance, Classification of Medical Devices, Using Artificial Intelligence of Medical Device.

## INTRODUCTION

The World Health Organization (WHO)[1] defines a medical device as any tool, apparatus, implant, reagent, software, or other item used for medical purposes, such as illness diagnosis, prevention, monitoring, or treatment, or for maintaining or supporting life. The medical equipment market has grown significantly over the last few decades, from an anticipated USD 260 billion in 2006 to around USD 380 billion by 2016.[2,3] Underreporting is still prevalent at the post-marketing stage, although it is customary to record adverse events throughout phases mandatory I through III of clinical trials and only voluntarily during post-marketing times (i.e., phase IV clinical tials).[4] The Medical Devices Rules (MDR) 2017 were released by the Government of India's Ministry of Health & Family Welfare (MoHFW) in an effort to regulate medical devices with the utmost professionalism. According to the MDR, the devices are categorized as Class A (low risk), Class B (low moderate risk), Class C (moderate high risk), and Class D (high risk) according to the level of danger involved. The D Category includes cardiovascular devices such drug-eluting stents, heart valves, bioresorbable vascular scaffold systems, over-the-wire thrombectomy sets, cardiac pacemakers, cardiac portable monitors, and more. The Rules' risk-proportionate regulatory standards, which are based on best international practices, must be met by producers of medical devices, especially those connected to the cardiovascular system.[5] The idea of living data mining techniques has also been introduced by many device manufacturing firms to ensure that regulatory bodies do not get any new signals caused by the use of devices.[4]

### Pharmacovigilance and Emergence of Materiovigilance

These days, pharmacovigilance also includes drug therapy-related problems (DTRPs) demonstrated by biologicals and blood products, medical devices, herbal remedies, and traditional, complementary, and alternative medicines (TCAMs).[6-8] While pharmacovigilance (PV) and Materiovigilance (MV) have similar reporting objectives and methods, MV focuses on medical device adverse reactions and preventative techniques.[9–13] It has mostly relied on statistics from developed nations. Therefore, for a robust

medical device regulation structure, a methodical and well-framed surveillance mechanism is advised. At every stage of device development, it is also critical to identify and assess the related risks and benefits.[14] Additionally, producers and regulators must protect patients' health by preventing future recurrences; the idea of Materiovigilance can fill this gap.[15] Furthermore, it is unknown how much adverse events related to medical gadgets actually affect public health.[16] Based on insights learned from past incidents, the reporting procedures and practices of materiovigilance are designed to ensure the safety and effectiveness of medical devices throughout requirements.[17]

**Materiovigilance Programme of India (MvPI): Scope and Structure**

The CDSCO, which now governs medical devices in India, is under the jurisdiction of the Ministry of Health and Family Welfare, Government of India. In order to tighten medical device laws and establish the Medical Device Regulatory Authority of India (MDRA), the Ministry of Science and Technology introduced the Medical Devices Regulation Bill (MDRB) in 2006. The primary objective of this measure was to create and strengthen a framework for controlling the availability, caliber, and security of Indian medical equipment.[18] On January 1, 2018, the Medical Device Rules, 2017 went into effect, regulating the production, import, distribution, and sales of medical devices.[19] Biomedical Clinical Engineering Departments (BMED) or other related departments are responsible for monitoring medical devices since they are generally created utilizing engineering technologies. In India, IPC has so far set up 150 Medical Device Adverse Event Monitoring Centers (MDMCs). Finding, gathering, and reporting suspected or verified medical device associated adverse events (MDAEs) is the main duty of these MDMCs.

**MDAEs are Categorized into Five Levels**

1. Not related
2. Unlikely
3. Possible
4. Probable
5. Causal relationship.[20]

**Medical Devices Associated Adverse Events Reporting**

Global uniformity in device classification and approval procedures, or at the very least, transparency, are crucial issues to be addressed.[21] All MDAEs should be recorded, regardless of whether they are critical or not, known or unknown, connected to insufficient or missing specifications, or frequent or uncommon.[4,12,13]

**What to Report**

Regardless of a proven causal association, all MDAEs—known or unknown, significant or non-serious, infrequent or frequent—may be recorded. Any potential risk related to prior use can be recorded in the MDAEs reporting form.[13,22,23] AE details include incident description, medical device description, and associated risk to a patient.[13,22,23]

**How and Whom to Report MDAEs**

The MDAE reporting form, which is accessible on IPC's official website (www.ipc.gov.in), can be used to report MDAEs to MAMCs. Research associates from MDMCs then send this properly completed form to NCC via email at mvpi@sctimst.ac.in. As an alternative, MDAEs can be reported via the NCC PvPI toll-free helpdesk at 1800-180-3024.to the WHO-Uppsala Monitoring Center (WHO-UMC).[13,22,23]

**Reporting Criteria for Adverse Drug Reaction Found The Reporting Criteria Include the Following**

If something has happened and the manufacturer learns of it. if it is determined, using the information at hand, that the manufacturer's device is connected to the incident. due to both user mistake and any medical equipment flaws. Additionally, the TGA mandates that the maker or sponsor notify any defects.[24] CDSCO.[19, 25]

**Not-Reportable Incidents or Events**

The regulated countries, along with India[24], defined not-reportable events similarly with few exceptions. The following events[24,26,27] are exempted from reporting in all countries.

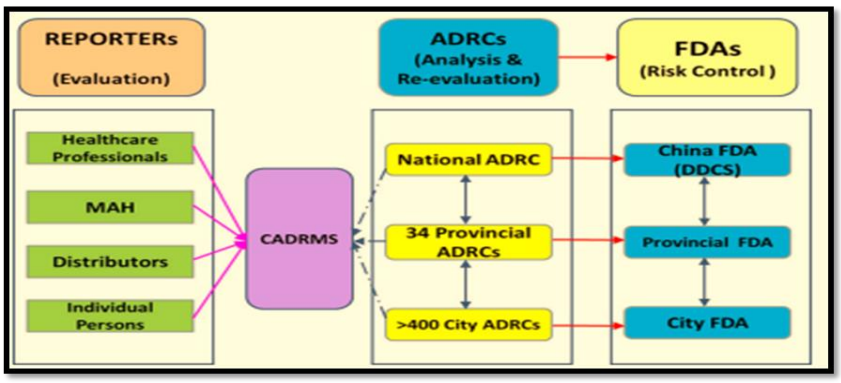


**Figure: 1. Structure of the Pharmacovigilance System in China.**

*ADRC adverse drug reaction centre, CADRMS China Adverse Drug Reaction Monitoring System, DDCS Department of Drug and Cosmetics Surveillance, FDA Food and Drug Administration, MAH marketing authorisation holder*.[35]

**The Healthcare System in China**

China's healthcare system was reorganized in the 1980s to address the demands of a rapidly developing nation with a population of approximately 1.35 billion.[28] Western medicine (WM) and traditional Chinese medicine (TCM) make up the basic healthcare system, which serves both urban and rural people. The New Rural Cooperative Medical Care System was created in 2011 as a basic health insurance program. Over 1.3 billion individuals, or up to 95% of the Chinese population, are covered by this insurance system. The introduction of this technique led to two significant advancements.[29] In China, both local provincial oversight and the central State Food and Drug Administration (SFDA) are in charge of regulating medical devices. Data connected to adverse incidents must be gathered, analyzed, evaluated, and controlled by the state. In China, the Food and Drug Administration Department may receive reports of adverse or suspected adverse events from any organization or individual.[30] The main focus of pharmacovigilance is safety management over a drug's whole life cycle. From pre-approval clinical development to product registration, post-approval production, distribution, clinical use, and supervision, there are risks associated with medicinal products at every stage. These risks can stem from a drug's inherent risks or be related to human factors like poor product quality, irrational prescriptions, inappropriate use, and so on. Each of these elements may have an effect on patients' health. The goal of setting up a pharmacovigilance system is to promptly detect adverse drug-related reactions during the medication's life cycle so that risk-reduction strategies can be implemented.[31]

**What are the Successes**

The amount and caliber of ADR reports from the CADRMS have significantly improved during the last ten years. In China, pharmacovigilance has quickly advanced to a new level. The CADRMS has 6.6 million case reports. To enable the CADRMS to play a significant role in pharmacovigilance and risk management, various methods have been investigated.[32, 33] These methods include the identification of predominant risk signals, such as puerarin-induced immune hemolytic anemia.[34] Based on risk-management data from international pharmacovigilance organizations, the CFDA will also produce the International Pharmacovigilance Newsletter. The National ADR Annual Report was first published by the CFDA in 2009. In conclusion, there has been a greater effort in ADR detection, reporting, handling, information exchange, risk reduction, and emergency management since China's pharmacovigilance system was established and improved.[35]

**Active Surveillance of Post-Marketing Pharmaceutical Products**

Some KMS projects and post-marketing clinical investigations have previously been carried out by research institutions, pharmaceutical companies, and medical organizations. Nevertheless, these research' validity, reliability, and utility have not been thoroughly examined. The International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH)—ICH Harmonized Tripartite Guideline Pharmacovigilance Planning E2E (in the European Union)[36], GVP guidelines[37], and GPP guidelines[38] by the International Society for Pharmacoepidemiology (ISPE) are some of the difficult issues that need to be further developed.

**Chinese Patent Medicines (CPMs)**

All registration-related paperwork and research, as well as all pharmacological research, including preclinical studies and clinical trials, should be meticulously prepared during the CPM registration period.[39] TCM traits with the scientific standards of pharmaceutical development. For instance, prescriptions for TCM compounds (such as Xuefuzhuyu Capsules and Kaixin Powder, which contain four and eleven distinct PSCCDs, respectively). NMPA released "Requirements and guidelines on the writing of the package leaflet (PL) of CPMs and Natural Medicines" in 2006[41] to standardize the planning and revision of CPMs' specifications and ensure rational use. In 2018, NMPA introduced guidelines that aim to provide basic guidance on the development of clinical trials and the evaluation of efficacy and safety for new CPMs in development for treatment of TCM syndromes.[40]

**Methodology Design of the Workflow of Medical Device Adverse Event Management**

A process has been developed to standardize MDAE management at hospitals in accordance with national regulations and experiences, as illustrated in Figure 2. The coordinator, a specifically designated employee from the Department of Clinical Engineering, is in charge of MDAE management. All hospital employees can report suspected MDAEs to the coordinator via a specially designed electronic portal. The coordinator must update the alert level after receiving an MDR. This is followed by an investigation involving the buyer, reporter, medical device manufacturer, supplier, and other relevant staff. The reporter will receive feedback via the electronic platform. After completing the MDAE reporting form, the coordinator notifies National Medical Devices about the incident.[42]

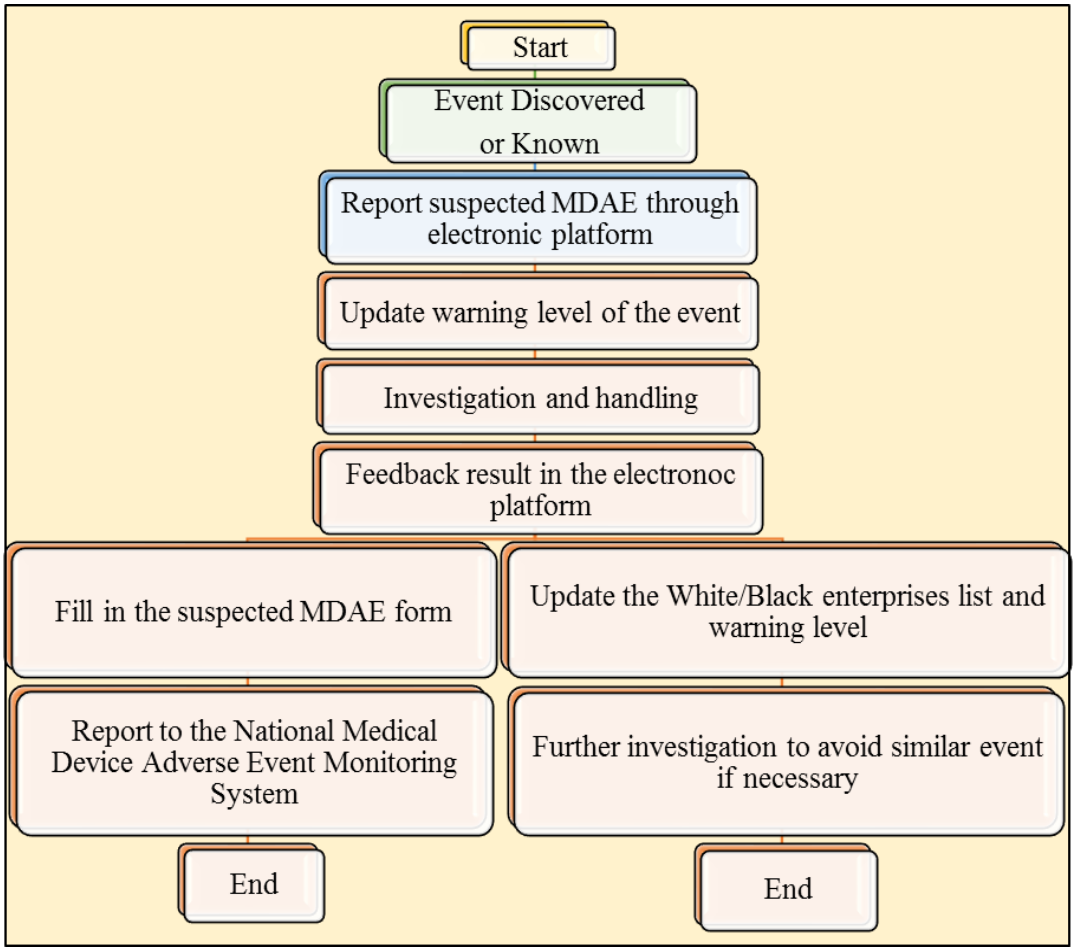


**Figure: 2. Workflow of Medical Device Adverse Events Management in A Hospital.**

Adverse Event Monitoring Information System; in the meanwhile, they will update the list of black and white businesses and, if needed, modify the alert level. If more research is required to stop the occurrence from happening again, it will be done.[42]

**Classification of Medical Devices**

Medical devices are categorized according to their indications for use, manufacturers' intended purpose for the device, and the risk associated with the device.[24, 26]

**Classification Of Medical Devices by the United States Food and Drug Administration (USFDA)**

The USFDA has divided medical devices into 16 medical specialties and divided them into three classes based on the degree of control required to ensure the device's efficacy and safety as well as information regarding marketing requirements.[24]

**Classification of Medical Devices by the Medicines and Healthcare Products Regulatory Agency (MHRA)**

Similarly, the MHRA has divided medical devices into many categories, such as general medical devices.[24, 44] The general medical equipment was then further divided into four classes according to MHRA, as shown in Table 3.[43,44]

**Table: 3. MHRA Classification of General Medical Devices.**

| Class of Device | Risk Level | Requirements | Examples |
|---|---|---|---|
| Class I | Low Risk | Premarket Notification | Dressing |
| Class IIa | Low-Medium Risk | Certification by notified body | X-Ray Film |
| Class IIb | Medium-High Risk | Certification by notified body | Blood bags, Contact lens care products |
| Class III | High Risk | Certification by notified body | Bone cement, cardiac stent |

In contrast to the regulated nations, medical gadgets in India are not categorized according to risk. Instead, it has been announced that the 10-device category of medical equipment will be subject to drug regulations.[24]

**Applications of MvPI**

**Prime Applications of MvPI**

1. To fabricate a structure for patient safety supervising.
2. Injuries & impediments prevention.

3. To generate evidence-based statistics on medical device safety.
4. To aid CDSCO in the authoritative operations on medical device utilization and share conclusive reports with different stake holders.[45]

**Types of Reports**

According to FDA, depending on the reporting time frame, the types of reports that are to be submitted by a manufacturer are of five following types.[24,26,27]

- **30 d Report**: Reports must be submitted within 30 days of the event. Deaths and major injuries are documented through complaints.
- **5 d Report**: In certain situations, the report must be sent in within five days. For some critical, unforeseen events that call for quick corrective action, this report must be submitted.[24, 46]
- **Baseline Report**: When a device model or family's event needs to be reported for the first time.[24]
- **Supplemental Report**: It is the follow-up report that must be sent in within a month after receiving new information.
- **Annual Certification**: This must be turned in within the allotted 12 months. site to reduce reporting errors.[24, 26]

The adverse event may be recorded in the UK using a variety of formats, including an initial report, trend report, periodic summary report, and final report. In contrast, the reports are categorized as initial reports by CDSCO in India.[24]

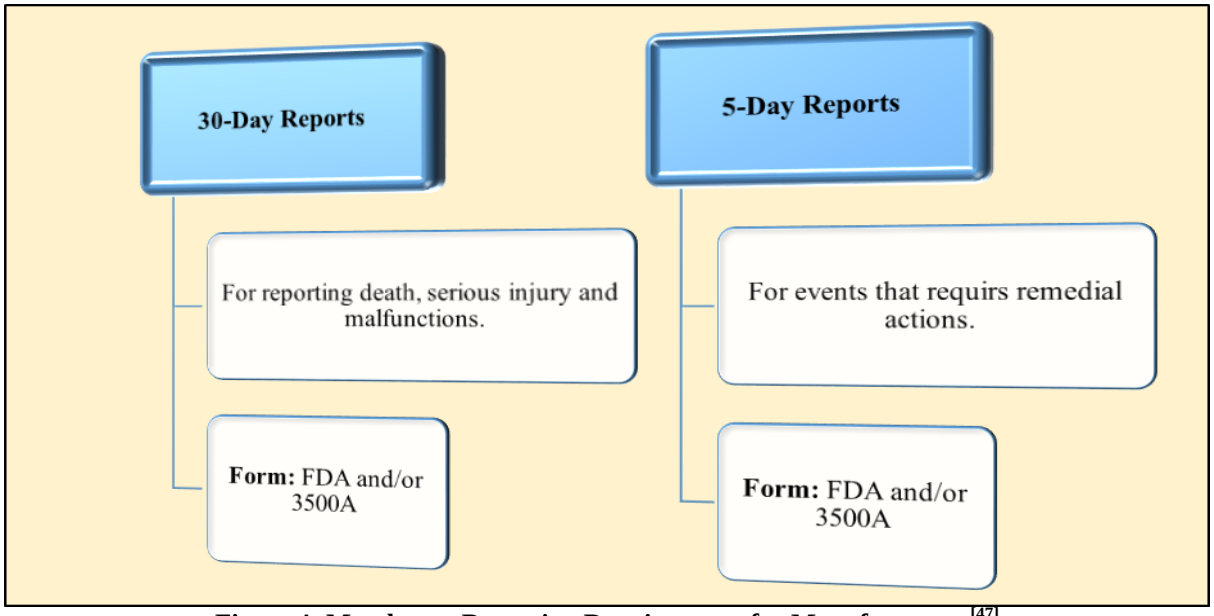


**Figure 4: Mandatory Reporting Requirements for Manufacturers.[47]**

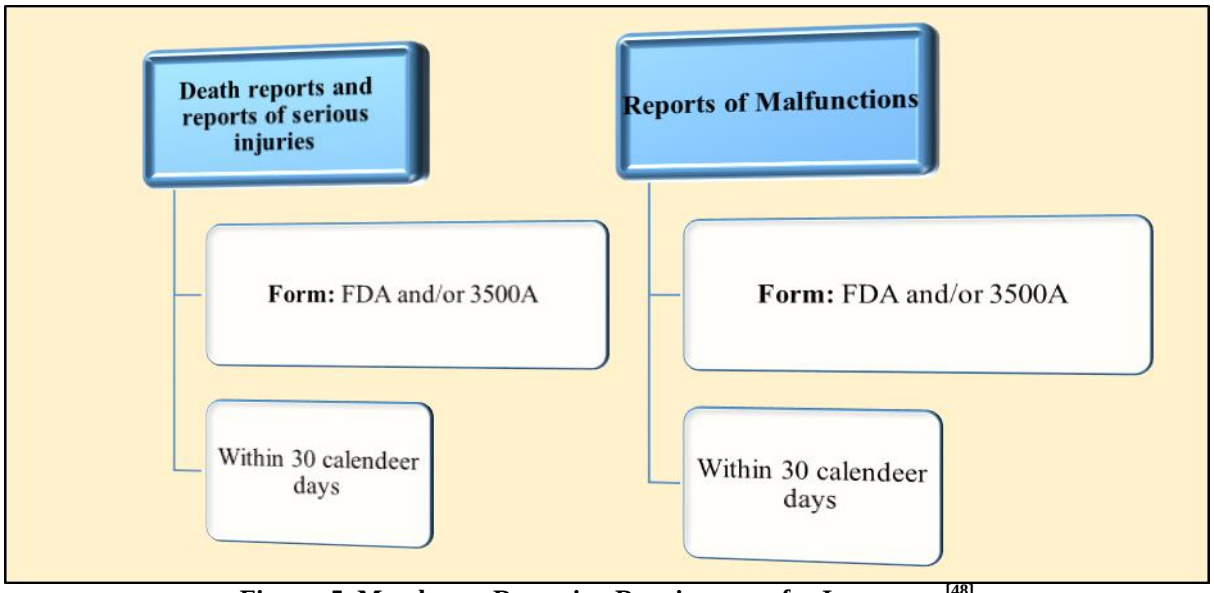


**Figure: 5. Mandatory Reporting Requirements for Importers.[48]**

## METHODS

### Study Design

This non-quantitative systematic literature review was conducted in accordance with the Cochrane Handbook for Systematic Reviews of Interventions[50] and the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) criteria.[59] Three researchers (JP, TB, and MS) independently conducted the initial screening of titles and abstracts using pre-established inclusion and exclusion criteria to evaluate whether the abstract was pertinent for article procurement. Furthermore, a second review was conducted independently by two other researchers (OA and MS).[52] Three researchers (OA, DK, and PY) independently carried out the second round of screening entire articles using the identical pre-established inclusion and exclusion criteria. Four researchers (PY, TJ, TB, MS) performed quality control (QC) for the selection of full articles. An Excel spreadsheet was used to extract all data, and the researchers also noted the reasons for removal. The fields included in the table in Online Resource 3 were part of the original Excel file (see ESM). The initial abstracts found in the literature search were used to test the Excel spreadsheet. The PRISMA flow diagram was constructed in part because to the thorough documenting of the search and review.[51]

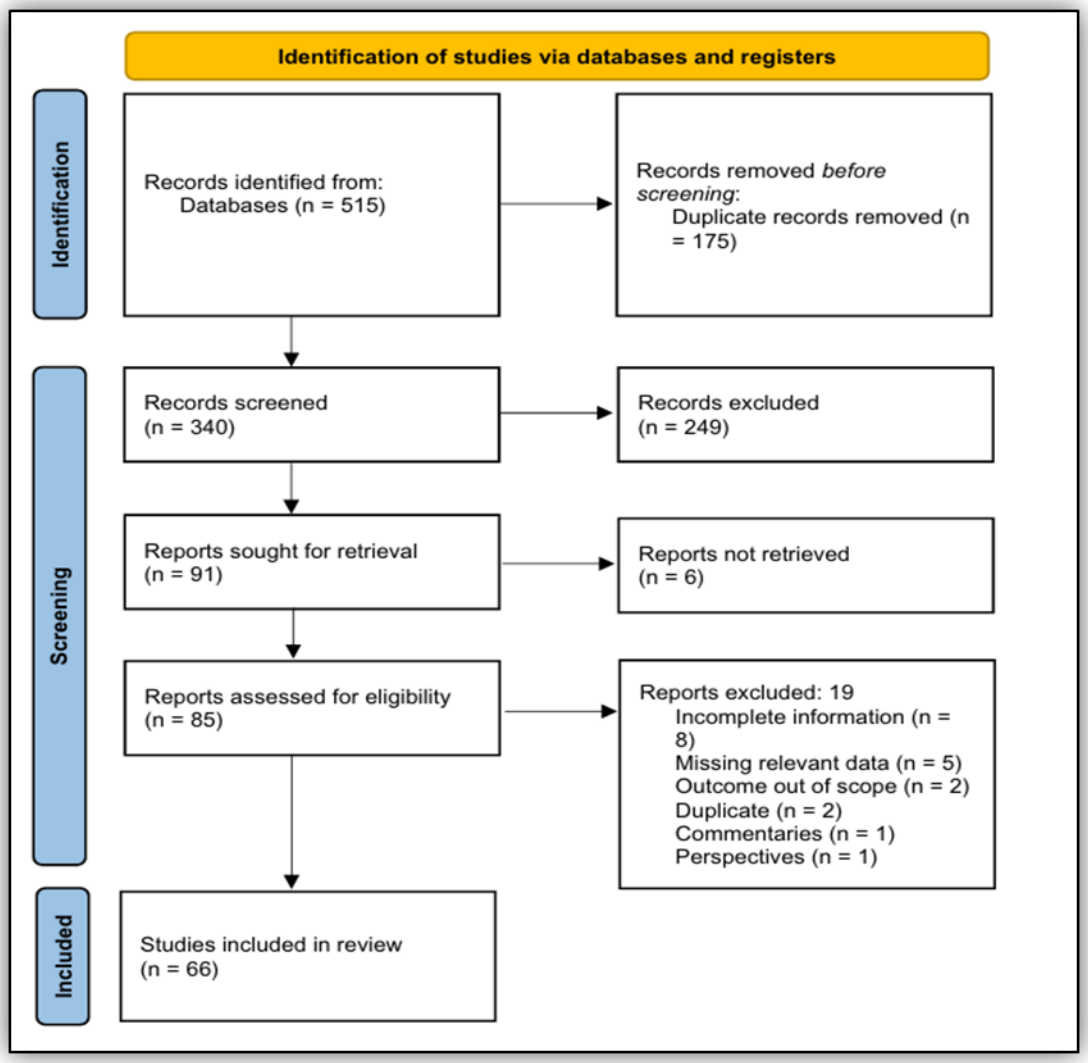


**Figure: 6. Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA)**
*Flow Diagram Showing Documentation of the Literature Search Process*[52]

### Using Artificial Intelligence to Detect Adverse Drug Reactions (ADRs) and Adverse Drug Events (ADEs)

Machine learning can be utilized for signal detection, safety surveillance, and the detection of ADRs or ADEs.[53] Automating the classification of first-person complaints of ADRs on social media is one use of machine learning. After finding micro-blog postings (Tweets) that detailed specific patient experiences, Alvaro et al. used Twitter to collect evidence regarding ADRs.[54] The ability to identify adverse drug reactions (ADRs) that medical professionals might miss, the speed at which large amounts of data can be processed and analyzed, and the abundance of personal information found in social media posts pertaining to ADRs are all

benefits of using machine learning in social media, according to a number of other articles. Excessive "noise" in the data and the casual or erratic language sometimes found in social media posts are among the drawbacks.[55–60] Another innovative method is to simulate the ADR association between a drug and symptoms using deep-learning neural networks or prediction models.[61,62] In particular, E-Synthesis is a Bayesian framework for safety evaluations that gathers information to produce the Bayesian likelihood that a medication would cause an adverse pharmacological reaction.[63]

**Using Artificial Intelligence of Medical Device**

Software as a medical device (SaMD) is defined by the International Medical Device Regulators Forum (IMDRF, https://www.imdrf.org/) as software designed for medical purposes that is not dependent on physical devices.[64] It can run on general-purpose platforms like PCs and cellphones and is independent of any hardware. The US Food and Drug Administration (FDA) have a similar stance, but stresses that SaMD needs to follow its classification guidelines according to patient risk (Class I, II, or III). The SaMD market was estimated to be worth USD 1.1 billion in 2023 and was expected to expand at a compound annual growth rate of more than 16% to reach USD 5.4 billion by 2032.[65,66]

For artificial intelligence (AI) applications, all available health data and medical images such as those from computed tomography, magnetic resonance, nuclear medicine, x-rays, and ultrasound exams may be the most intriguing. It is anticipated that artificial intelligence will soon be crucial to radiation therapy.[69,70], diagnostic imaging[67,68], and medical physics in general. It has already been shown to effectively enhance image quality[67], reduce radiation dosage[71,72], identify pathology locations and assign label types[73-79], develop and optimize protocols[80], precisely segment pathology areas and organs[81,82], and maximize technology utilization.[83] Before medical devices, including AI software tools, can be used in clinical practice, certain legal standards must be fulfilled, according to the EU Medical Device Regulation (EU MDR)[84], which replaced the EU Medical Device Directive[85] on May 26, 2021. For the first time, many of the conditions and standards of the EU MDR now apply to medical device software that health facilities design for internal use.[86] This is because of their specialized knowledge in fields like informatics, image analysis, and statistics, as well as their broad understanding of the regulatory aspects of medical physics.[87] Additionally, according to the European Guidelines on Medical Physics Expert 174[88], they play the role of inventor and protocol/process optimizer.

**In Ophthalmology**

With the ultimate goal of improving patient outcomes, AI can help improve diagnostic accuracy, offer insights into systemic disorders, streamline clinical and research operations, and optimize treatment.[89] It may be able to assist in resolving issues including the lack of ophthalmic specialists worldwide, the growing amount of complicated imaging data, and the variety in subjective human interpretation. Due to this shortfall, there is a capacity-demand imbalance that puts patients and caregivers at risk for irreparable sight loss due to treatment delays[90–92], negatively impacts their quality of life[93–95], and places a heavy financial burden on people, healthcare systems, and society.[96,97]

**Challenges**

Without the advantages of a research methodology, randomization, and a control group of individuals receiving a placebo, there are well-known inherent problems in methodically analyzing and interpreting freely submitted data involving several medications, medical conditions, and occurrences per report.[98] Additional challenges include persistent underreporting, sporadic instances of overreporting and misreporting motivated by publicity and litigation, missing and incomplete data, and inconsistent reporting and naming/coding techniques over time.[99] Determining when a signal should be enhanced to indicate a possible safety issue, when to consider a signal likely enough to be real to require follow-up, and when to trigger an alert are additional challenges.[100]

Pharmacovigilance focuses on all adverse drug reactions (ADRs), product quality flaws, medication errors, and ineffectiveness. The entire product life cycle, from pre-approval to post-marketing, is covered by the Chinese pharmacovigilance system. A fundamental tenet of ICH E2E is the planning of pharmacovigilance over a product's life cycle.[101] There are not enough PV professionals in practice, the majority of medical staff have not had PV training, and the training offered by professional courses and talents connected to PV is not flawless. The foundation of pertinent research and the prerequisites for setting up and enhancing PV systems is an adequate amount and quality of data. Important information about drug combinations, comorbidities, and laboratory markers for pertinent testing is lacking in public databases for certain populations. Therefore, it can be difficult to demonstrate a causal association between medications and adverse occurrences.

**Suggestions on How to Better Develop PV In Special Populations**

Concentrate on monitoring medication safety risks for certain populations, create system segments based on these populations, and develop and enhance institutional mechanisms and management standards. In order to successfully intercept incorrect prescriptions and achieve early detection and resolution of any difficulties, pharmacists should be assigned to different particular populations to check prescriptions. To encourage the safe and efficient use of medications, PV experts should not only mine drug safety data but also promptly educate patients, the general public, and healthcare professionals.

It is strongly advised to thoroughly report all medical records, omitting any identifying patient information, in order to increase the accuracy and analyzability of submitted medical data. A specific reward will be given to those who submit comprehensive medical records as a way to boost reporting enthusiasm. In the end, this will raise the standard of medical research by addressing the persistent problem of missing or incomplete reports.[102]

**Future Perspectives**

To safeguard public health, PV systems that can identify novel ADRs and implement regulatory measures are required. Information that can help a patient or healthcare provider make decisions has received little attention. One of PV's main objectives is to collect and disseminate information regarding the safety of drug active surveillance. When creating new techniques for active postmarketing surveillance, it is crucial to gather comprehensive and precise data on each serious reported event. Although spontaneous reporting is a useful tool for generating signals, it is less useful for identifying patient characteristics and risk factors due to the relatively low number of reports received for a particular association. PV methods must also be able to describe which patients are at risk of experiencing an adverse drug reaction (ADR). The PV method would be in line with the increasing patient involvement in medication safety as a source of information.[103]

Individual risk factors for the incidence of specific ADRs may be identified by the PV. In addition to the more conventional groups, including medical professionals, PV will need to focus on patients as a source of information in the future. In order to incorporate Good Pharmacovigilance Practice (GPP) into the processes and procedures to help assure regulatory compliance and improve clinical trial safety and post-marketing surveillance, the DCGI should currently take swift action to improve PV. If medications are to be used responsibly, a well-functioning PV system is necessary. Consumers, pharmaceutical businesses, regulatory bodies, and medical experts will all gain from it. It aids pharmaceutical corporations in keeping an eye on the risks associated with their medications. Currently, post-marketing PV is a difficult and time-consuming procedure for regulatory bodies as well as the entire business.[104] These technologies are part of a system structure that makes knowledge management, safety issue monitoring, and in-stream review easier. By increasing efficiency and offering new analytical capabilities, this highly inventive equipment and the procedures will aid in the advancement of PV. Pharmaceutical companies may use a similar strategy to quickly identify and analyze adverse drug reactions. Consumer reporting would be strengthened by transparency and communication, all of which are beneficial steps toward increasing consumer involvement in PV.[105]

Organizations that deal with drugs and biotechnology must not only screen but also proactively survey and monitor drug risk across the whole lifecycle of an item, from development to post-market.[106] India is concentrating on scalability and adaptability to make pharmacovigilance systems future-proof. Pharmacovigilance procedures are streamlined by the incorporation of cutting-edge technologies, data analytics, and automation, allowing for the quicker and more accurate detection of safety signals. Additionally, India is actively taking part in international efforts, promoting cooperation with foreign partners, and conforming to international pharmacovigilance norms. This guarantees that the nation stays at the forefront of new trends and technologies, prepared to take on new opportunities and problems in the constantly changing field of drug safety.[107]

## CONCLUSION

The science and collection of actions devoted to identifying, evaluating, comprehending, and averting side effects or any other drug-related issues is known as pharmacovigilance. It keeps an eye on the safety of medications and vaccines at every stage of their development. In this study, we concentrate on material and pharmacovigilance in China and India. These days, pharmacovigilance also addresses drug therapy-related issues produced by medical devices, and materiovigilance, which deals with adverse responses brought on by medical devices, has comparable reporting goals and methods to pharmacovigilance. The Indian government's Ministry of Health and Family Welfare, which oversees the CDSCO, developed pharmacovigilance to determine whether certain medications were exhibiting adverse drug reactions after being introduced to the market. Materiocovigilance is formed once medical devices are introduced to the market or hospital to monitor whether or not they are being utilized appropriately. We report adverse drug or device events using pharmacovigilance and materiocovigilance by following the procedure described in the research article below. to lessen the negative effects of artificial intelligence-based medications and medical devices. Members of pharmacovigilance and materiocovigilance can quickly reduce drug and device side effects with the aid of this technology. AI is particularly useful in the medical industry. With its assistance, we can diagnose a patient's illness, implement a treatment plan, and administer medication and therapy. AI can provide a writing mechanism for every task and minimize errors.

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