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The Future of Drug Safety: India's Pharmacovigilance Programme and Emerging Smart Approaches

*Zufnoon Khan; Neelam Jain[1]; Abeer Kulsoom[2]

*Research Scholar, Faculty of Pharmaceutical Sciences, Rama University, Kanpur- 209217, Uttar Pradesh, India
[1]Faculty of Pharmaceutical Sciences, Rama University, Kanpur- 209217, Uttar Pradesh, India
[2]Department of Nephrology, Banaras Hindu University, Varanasi-221005, Uttar Pradesh, India
***Corresponding author:** Zufnoon Khan, Research Scholar, Faculty of Pharmaceutical Sciences, Rama University, Kanpur-209217, Uttar Pradesh, India

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Abstract: Pharmacovigilance detects, evaluates, and prevents adverse drug reactions (ADRs), one of the primary avoidable causes of sickness and death. With the National Pharmacovigilance Program (NPP) and Pharmacovigilance Program of India (PvPI), pharmacovigilance has gained popularity in India to monitor medication safety and improve public health. Despite advances, ADR underreporting, healthcare professional ignorance, and infrastructural issues exist. India has used digital transformation, mobile applications, AI, and ML to improve ADR detection, real-time monitoring, and data analysis. Blockchain technology is being investigated for data integrity and reporting transparency. However, privacy problems, remote digital resource availability, and regulatory uncertainty restrict these ideas' potential. India plans to improve its pharmacovigilance by concentrating on genomic drug safety, worldwide cooperation, and telemedicine integration for real-time monitoring. These activities will enhance medication safety, minimize adverse drug reactions, and support global pharmacovigilance, making healthcare safer.

Keywords: *Pharmacovigilance, Adverse Drug Reactions, Digital Transformation, AI, Machine Learning, Blockchain, India, Drug Safety.*

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I. INTRODUCTION

The global issue of under-reporting adverse medication reactions is primarily due to a lack of time and the unavailability of reporting forms. To address this, the World Health Organization (WHO) has established a system for reporting all adverse medication reactions [1]. The field of pharmacovigilance emerged due to a growing understanding of adverse drug reactions. It can be defined as the science dedicated to identifying, assessing, comprehending, and preventing adverse effects or any other potential drug-related problems [2,3]. Medications have revolutionized how we treat illnesses. However, along with their many benefits, they can also lead to undesirable side effects. Adverse drug reactions (ADR) are among the top preventable causes of illness, disability, and death [4]. According to one dictionary, ADR is defined as follows: "An appreciably harmful or unpleasant reaction, that is resulting from a the intervention related to the use of a medicinal product, that is predicts risk from the future administration and the warrants prevention or a specific treatment, or an alteration of the dosage regimen, or the withdrawal of the product." In one description, pharmacovigilance is defined as "the science and practices connected to the detection, evaluation, comprehension, and prevention of adverse effects of a drug or any other probable drug-related issues." Furthermore, pharmacovigilance is sometimes referred to as "pharmacological monitoring." A committee was founded in 1848 as a reaction to the death of a girl who had received a chloroform anesthesia for the excision of an ingrown toenail. The girl was 15 years old at the time of her death [5,6]. Thalidomide was first manufactured in 1954 and became available to the public in 1956. It was commonly recommended as a safe treatment for nausea and morning sickness throughout its time on the market. However, on November 25, 1961, the manufacturer announced that it would no longer be sold. It is estimated that between 6,000 and 12,000 babies were born with severe congenital disabilities as a direct result of their mothers taking thalidomide [7].India stands as the second most populous

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country in the world, with over one billion potential drug users. While India is involved in the Uppsala monitoring center program, its contributions to the database are minimal. This challenge largely stems from the absence of a robust adverse drug reaction monitoring system and a limited understanding of reporting protocols among healthcare professionals in India. It is essential to raise awareness within the medical community about the importance of reporting adverse medication reactions to enhance public health and safety outcomes. For regulatory purposes, any incident that is reported spontaneously, even if the connection is unclear or not well-defined, is considered an adverse medication response [8].

An adverse event refers to any negative medical incident experienced by a patient who is taking a medication, and it doesn't always have to be directly related to the treatment. Adverse drug reactions are unexpected and harmful responses to a medication. In contrast to an event, a response implies that there is an assumption of a causal relationship between the drug and the incident [9].

A significant adverse event (SAE) is any unfavorable medical occurrence that occurs at any dosage:

- Results in death
- Is life-threatening (well-defined as an event in which the subject was at risk of death at the time of the event)
- Requires in-patient hospitalization or causes prolongation of existing hospitalization
- Results in persistent or significant disability/incapacity
- Is a congenital anomaly/birth defect
- It is an important medical event (defined as a medical event(s) that may not be immediately life-threatening or result in death or hospitalization but, based upon suitable medical & scientific judgment, may require intervention to prevent one of the serious outcomes as listed above) [10,11].

II. NEED OF PHARMACOVIGILANCE

The clinical development of medications is universally acknowledged as a difficult process that needs a substantial amount of time for completion. Upon marketing, a medicine exits the safeguarded scientific milieu of clinical trials and becomes available for public use. Currently, the majority of medications have undergone testing just for short-term safety and effectiveness on a restricted group of meticulously chosen people. Consequently, the need for pharmacovigilance emerges, which encompasses the prompt identification of novel adverse responses or patient subgroups exhibiting unusual sensitivity, as well as the implementation of specific interventions to mitigate such risks [12]. Furthermore, it is essential that novel and clinically developing therapies be assessed for their efficacy and safety in real-world settings post-commercialization. Additionally, further information is often required for use in certain demographic groups such as children, pregnant women, and the elderly, concerning the effectiveness and safety of prolonged use in conjunction with other medications [13]. Number of adverse effects, drug interactions, and risk factors have been reported later in the years of drug release (Table 1).

Table No 1: Common Drug Interactions [14].

Warfarin	Increased risk of bleeding
Amino glycoside	Auditory impairment, renal dysfunction
Antidiabetic	Reduce blood glucose levels
Warfarin	Increased risk of bleeding
Tetracycline	Inadequate absorption of tetracyclines
Miconazole	Severe hypoglycemia
Prednisone	Edema
Theophyllines	Insomnia, seizures, restlessness
Alprazalon, Diazepam	CNS depression, sedation
Barbiturates	Symptoms may include muscle weakness, reduced awareness, and even coma.
Ethanol	Additive CNS effect, Death
Digoxin	Plasma concentration of digoxin is reduced

This review paper gives an outline of the present state and future prospects of pharmacovigilance in India.The Indian Pharmacopoeia Commission and the Central Drugs Standard Control Organization (CDSCO) coordinate and perform pharmacovigilance in India. The IPC is responsible for maintaining and developing the pharmacovigilance database, which records suspected significant adverse reactions to drugs. The Indian Pharmacopoeia Commission (IPC) serves as a National Coordination Centre (NCC) for the Pharmacovigilance Programme of India (PvPI). The National Coordination Centre is overseen by a steering council that develops recommendations for regulatory initiatives. The National Coordination Centre monitors adverse responses to drugs in India and maintains a pharmacovigilance database [15].

III. OBJECTIVES

Ensuring patient care and safety is a top priority when combining pharmaceuticals with medical and paramedical approaches. The goals of pharmacovigilance include showing how effective drugs are by tracking their adverse effects from laboratory studies to clinical applications; improving public health and safety related to medication use; promoting the safe, responsible, and economical use of drugs; supporting education, training, and awareness in

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pharmacovigilance; and effectively engaging with the public.

Besides formulating methods and protocols for the collection and analysis of data from patients and physicians, it also communicates information to consumers, practitioners, and regulators about the effective use of drugs. This information plays a crucial role in defining the objectives of pharmacovigilance studies [16].

Table No 2: Displays the Types And Methods of Pharmacovigilance

Types / Methods	Subcategories
Passive surveillance	Spontaneous Reporting Stimulated Reporting Intensified Reporting Targeted Spontaneous Reporting
Active surveillance	Proactive systematic data gathering to detect adverse drug reactions (ADRs)
Comparative observational studies	Analyzes medication safety data across several patient cohorts
Clinical studies	Regulated studies evaluating pharmaceutical safety and effectiveness

➢ *Spontaneous Reporting*

- An operational ADR system that monitors the safety of all pharmaceuticals.
- Healthcare professionals, pharmaceutical companies, or patients voluntarily submit reports to the pharmacovigilance center.
- The reporting systems are based on the suspected adverse drug reactions.
- A central or local database is used to collect and store the data that is collected.
- Details and an explanation of a response that is supposed to have occurred.
- This material pertains to the potential negative effects of medications.
- The cases are not collected in a methodical manner.

➢ *Intensified Adr Reporting*

- This is an extension of a program that allows for reporting without being asked.
- The purpose of this is to enhance the early post-marketing adverse drug reaction reporting of the specific medications.
- This approach is often used to new pharmaceuticals, biological therapies, and drugs requiring more investigation.
- Antiretroviral medications provided via an alternative program.

➢ *Targeted Spontaneous Reporting*

- Using this method, one may learn more about the adverse drug reaction profile of a pharmaceutical that is based on the population.
- To ascertain the prevalence of a recognized adverse drug response (ADR) among a population.
- For example, monitoring renal toxicities that are linked with antiretroviral treatment regimens that are based on tenofovir and other similar drugs [17].

➢ *Active Surveillance*

Active surveillance in pharmacovigilance is a proactive approach that focuses on monitoring the safety of medications after they have been approved. This strategy involves systematically collecting and analyzing data to identify adverse drug reactions (ADRs) in real-world settings. Unlike passive surveillance, which relies on unsolicited reports, active surveillance utilizes electronic health records, claims databases, registries, and patient-reported data to gather information. Key methodologies include cohort studies, case-control studies, and signal detection algorithms. The advantages of this approach include early detection of ADRs, robust evidence from real-world data, and adherence to regulatory requirements. However, challenges such as data quality, privacy issues, and resource demands must be addressed. Applications of active surveillance include risk management planning, post-marketing studies, and comparative effectiveness research. Looking ahead, the focus will shift towards integrating real-world data, advanced analytics (like artificial intelligence), and global collaboration. By providing timely and comprehensive insights into post-market issues, active surveillance plays a crucial role in enhancing medication safety [18].

➢ *Registries*

This registry is a list of patients who have presented and have the same representation as the other patients. This image could depict a scenario or a specific exposure (medicine registry), depending on the context. By using standard questionnaires, it is possible to collect data in a prospective manner for both kinds of registrations, which vary only in the patient data that is of relevance. Pharmacological exposure and clinical symptoms may be acquired via registries for blood dyscrasias, severe skin responses, or congenital abnormalities. A case-control study compares cases from a disease registry to controls from patients with related diseases or outside the registry to assess medication exposure [19].

➢ *Cross-Sectional Study*

In cross-sectional research, information is gathered on patients' residence throughout the course of a certain time period, independent of whether or not they have been

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exposed to the illness or are currently suffering from it. A disadvantage is that the temporal relationship between exposure and outcome cannot be properly assessed in cross-sectional research.

In ecological analysis, it is used to monitor the fundamental relationship between exposure and outcome. Cross-sectional studies are most beneficial when exposures remain constant throughout time [20].

➢ *Case-Control Study*

Case-control research identifies instances of sickness (or events). Subsequently, meticulously selected individuals from the population that constituted the case's source are used as controls, individuals with the condition, or those in whom the pertinent event has not occurred. The controls must be chosen to enable a comparison of the exposure prevalence between the source population and the controls. The exposure status of the two groups is then compared using the odds ratio, which estimates the relative risk of disease between the groups [20,21].

➢ *Cohort Study*

A population at risk is monitored throughout time to follow the illness. Patients get exposure status information throughout their follow-up period. A patient may be exposed to the medicine at one follow-up point but not another [22]. Cohorts of interest are selected based on drug usage history and monitored over time in various medicine exposure studies. Cohort studies are valuable for understanding adverse event rates and relative risks [23]. Due to their administrative or billing function, they may not include all required information for a research study, such as validated diagnostic data or laboratory findings. Be mindful of privacy and privacy obligations for patient medical data, which may be utilized to create and validate test results and diagnoses [24].

IV. CURRENT SCENARIO OF PHARMACOVIGILANCE IN INDIA

➢ *National Pharmacovigilance Program (NPP)*

The National Pharmacovigilance Program of India, initiated in 2010 by the Central Drugs Standard Control Organization (CDSCO), serves as the foundation for drug safety surveillance in the nation. The initiative was initiated to meet the increasing need for an effective system to monitor and manage ADRs, especially within the context of India's swiftly developing pharmaceutical sector [25]. The NPP functions via a network of Adverse Drug Reaction Monitoring Centers (AMCs) strategically positioned nationwide to guarantee extensive coverage. The AMCs gather, evaluate, and disseminate ADR data to the National Coordination Centre (NCC), which oversees pharmacovigilance efforts nationally [26].

The NPP has played a crucial role in discovering several drug safety concerns, resulting in regulatory measures like medication recalls, label modifications, and use limitations [27]. The initiative was essential in discovering the hazards linked to pioglitazone (a diabetic medication) and mefenamic acid (a nonsteroidal anti-inflammatory medicine), resulting in regulatory measures that enhanced patient safety [28].

➢ *PvPI (Pharmacovigilance Program of India)*

The pharmacovigilance framework in India has been greatly reinforced as a result of the implementation of the Pharmacovigilance Program of India (PvPI) in the year 2010 [29]. Through a network of more than 250 adverse drug reaction monitoring sites located all throughout the country, the program is managed by the Indian Pharmacopoeia Commission (IPC), which is responsible for its coordination. Monitoring adverse drug reactions (ADRs), raising awareness among medical personnel, and ensuring the safe use of medications are the key goals of the Patient-Centered Pharmacist Index (PvPI) [30].

A significant accomplishment of the PvPI is the establishment of a comprehensive ADR reporting system, enabling healthcare professionals and patients to report ADRs via various channels, including as mobile applications, online platforms, and toll-free lines [31]. The initiative has achieved notable advancements in data analysis and signal recognition, using sophisticated statistical techniques and AI algorithms to uncover possible medication safety concerns [32].

➢ *Digital Transformation*

The digital change that has taken place in India, which has been driven by initiatives such as Digital India and the widespread use of smartphones, has been a significant contributor to the improvement of pharmacovigilance [33]. Several digital tools and platforms that enable real-time data collecting and analysis have been developed as a result of the government's drive for digitalization, which has led to the creation of these solutions. For instance, the "ADR PvPI" mobile app enables both patients and healthcare professionals to report adverse drug reactions (ADRs) in real time, which improves both the accuracy of the data and its timeliness [34].India has created web-based ADR reporting and data analysis tools in addition to mobile applications. Data exchange and analysis are straightforward with these systems' integration with EHRs and other healthcare databases [35]. Digital technologies have increased patient involvement and pharmacovigilance efficiency, making the system more patient-centric [36].

➢ *Integration of AI and ML*

Artificial intelligence (AI) and machine learning (ML) are widely used in pharmacovigilance to evaluate extensive datasets of adverse drug reaction (ADR) reports, discern trends, and forecast possible drug safety concerns [37]. Indian entrepreneurs and academic institutes are leading the development of AI-driven predictive validation systems capable of processing unstructured data from social media, electronic health records (EHRs), and several other sources [38].AI algorithms are used to identify indicators of probable adverse drug reactions from extensive datasets. Natural language processing (NLP) techniques may examine social media postings, patient forums, and medical literature

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to detect previously unrecognized medication safety concerns. These instruments are very effective in detecting uncommon adverse drug reactions that may elude conventional reporting mechanisms [39].

- *Blockchain for Data Integrity*

Blockchain technology is being investigated for pharmacovigilance data integrity and traceability. Blockchain may improve medication safety monitoring trust and transparency by being decentralized and tamper-proof [40]. Blockchain can securely store ADR reports, preventing tampering or deletion. Blockchain may improve data integrity and enable data exchange among regulatory bodies, pharmaceutical firms, and healthcare providers. Better patient outcomes may result from pharmacovigilance teamwork and coordination [41].

- *Collaboration with Global Agencies*

India engages in collaboration with international entities such as the World Health Organization (WHO) and the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) to synchronize its pharmacovigilance methods with global standards. India participates in the WHO Programme for International Drug Monitoring, which enables the sharing of ADR data across member nations [42]. India's engagement with global bodies has improved pharmacovigilance and medication safety. India helped uncover and resolve vaccination, antiretroviral, and other medication safety problems [43].

V. INNOVATIONS IN SMART PHARMACOVIGILANCE

- *AI-Driven Signal Detection*

AI algorithms are used to identify indicators of probable adverse drug reactions from extensive datasets. Natural language processing (NLP) techniques may examine social media postings, patient forums, and medical literature to detect previously unrecognized medication safety concerns. These instruments are very effective in detecting uncommon adverse drug reactions that may elude conventional reporting mechanisms [44].

- *Real-Time Data Analytics*

The use of big data analytics facilitates real-time surveillance of adverse drug reactions (ADRs), permitting expedited responses and mitigating the danger of extensive injury. Indian enterprises are creating cloud-based systems that amalgamate data from many sources, offering a holistic perspective on medication safety [45].

- *Mobile Health (mHealth) Solutions*

Mobile applications and wearable technology are used to gather real-time data on pharmaceutical consumption and patient results. These solutions enable patients to engage actively in pharmacovigilance, making the system more patient-centric [46].

- *Predictive Modeling*

Predictive models using machine learning algorithms may anticipate probable adverse medication reactions based on patient demographics, genetic variables, and drug interactions [47].

- *Social Media Monitoring*

Social media networks serve as a valuable repository of patient-reported outcomes and adverse drug reactions (ADRs). Indian academics are creating techniques to extract social media data for pharmacovigilance, enhancing conventional reporting systems [48].

VI. INTERNATIONAL ANALYSIS AND TECHNOLOGICAL PROGRESS IN PHARMACOVIGILANCE

The FDA collects adverse drug reaction (ADR) data from healthcare practitioners, patients, and pharmaceutical companies via the Adverse Event Reporting System (FAERS). The U.S. uses EHRs and hospital-insurance data to identify ADRs. AI recognizes new safety concerns and signals. India's pharmacovigilance system may leverage real-time data and EHR linkage to monitor ADRs. EudraVigilance, the EU's pharmacovigilance network, tracks and analyzes ADRs. India might gain from signal-detecting AI and ML. Integrating real-time monitoring may ease Indian ADR detection and reporting [49]. Japan (PMDA): The PMDA uses active monitoring and signal detection to administer a complex pharmacovigilance system. Japan extensively uses AI to detect ADRs utilizing pharmacogenomic data and electronic patient records. Similar methods may enhance ADR monitoring in rural India [50].Benefits for India: India might implement AI for signal detection, integrate EHRs for improved data collecting, and strengthen cross-country cooperation to monitor and report ADRs by following these worldwide precedents. Adjusting India's system to global norms will increase safety [51].

- *Advanced Technologies Shaping the Future of Pharmacovigilance*

Wearable Devices: Wearables, which include smartwatches and fitness trackers, may assist in the monitoring of patient vitals and the detection of early symptoms of adverse drug reactions (ADRs), such as changes in blood pressure or heart rate [52]. When this data is integrated with pharmacovigilance systems, it may be possible to identify adverse drug reactions in real time. Computing in the cloud and big data: Cloud-based systems have the ability to store enormous volumes of ADR data produced from a variety of sources. Traditional approaches are not as effective as big data analytics when it comes to identifying patterns and signs of adverse drug reactions(ADRs).Genetic Profiling: Pharmacogenomics has the potential to transform pharmacovigilance by identifying people who are genetically prone to particular adverse drug reactions (ADRs). This would ultimately allow for individualized treatment and monitoring techniques [53].

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➢ *Challenges in Smart Pharmacovigilance*

The use of digital technologies and big data in pharmacovigilance presents substantial issues with patient privacy and data security, necessitating adherence to rules such as the Digital Personal Data Protection Act, 2023. Moreover, whereas metropolitan locales in India possess sophisticated digital infrastructure, rural areas persist in facing challenges regarding internet connection and smartphone availability, hence constraining the effectiveness of digital pharmacovigilance initiatives [54]. A significant obstacle is the insufficient knowledge among healthcare practitioners and the general populace, which impedes the successful execution of pharmacovigilance programs [55]. The legal environment for new technologies like as AI and blockchain in pharmacovigilance is still developing, resulting in uncertainty for inventors and hindering the adoption of sophisticated solutions. Confronting these problems is essential for enhancing India's pharmacovigilance framework and guaranteeing better healthcare practices [56].

VII. FUTURE DIRECTIONS

The future of pharmacovigilance in India is contingent on a number of significant technological breakthroughs. For the effective deployment of smart pharmacovigilance, it is essential to make investments in digital infrastructure, particularly in rural regions. Personalized pharmacovigilance will be made possible by developments in genomics and precision medicine. This will make it possible to monitor the safety of drugs in a manner that is specific to each individual patient based on their genetic composition. Additionally, India need to boost global partnerships by contributing to international efforts to ensure the safety of drugs and by sharing advances throughout the globe. Increasing the real-time monitoring and reporting of adverse drug reactions (ADRs) may be accomplished via the integration of pharmacovigilance with telemedicine systems, which in turn can improve patient outcomes. Furthermore, the establishment of transparent regulatory norms for new technologies like as artificial intelligence, machine learning, and blockchain would not only promote innovation but also guarantee the protection of patients from potential risks. Taking action in these areas would contribute to the establishment of a pharmacovigilance ecosystem in India that is more strong and efficient.

VIII. CONCLUSION

The progress that India has made in the field of smart pharmacovigilance is evidence of the country's capacity to innovate and adjust to worldwide issues. Through the use of cutting-edge technology and the promotion of collaborative efforts, India is not only boosting the safety of drugs inside its borders but also serving as a model for the rest of the globe. As the nation continues to make investments in digital infrastructure and regulatory frameworks, the future of pharmacovigilance in India seems to be bright, and it has the potential to revolutionize healthcare systems all around the world.

ABBREVIATION

- **ADR**: Adverse Drug Reaction
- **AI** : Artificial Intelligence
- **CDSCO**: Central Drugs Standard Control Organization
- **IPC**: Indian Pharmacopoeia Commission
- **PvPI** : Pharmacovigilance Programme of India
- **WHO** : World Health Organization
- **EMA** : European Medicines Agency
- **USFDA**: United States Food and Drug Administration
- **MHR** : Medicines and Healthcare products Regulatory Agency (UK)
- **NCC-PvPI** : National Coordination Centre - Pharmacovigilance Programme of India
- **ADRMS**: Adverse Drug Reaction Monitoring System
- **EHR**: Electronic Health Records
- **RCT**: Randomized Controlled Trial
- **HCP**: Healthcare Professional
- **AEFI**: Adverse Event Following Immunization

AUTHOR CONTRIBUTIONS

The author conceptualized, researched, and drafted the manuscript. They performed a comprehensive review of the literature, synthesized relevant findings, and contributed to the critical analysis of the topic. Additionally, the author revised and finalized the article for publication, ensuring clarity and accuracy.

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