ADVANCES IN PHARMACOVIGILANCE IN INDIA: EMERGING TECHNOLOGIES AND FUTURE CHALLENGES

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Abstract

By detecting, tracking, and averting adverse drug reactions (ADRs), pharmacovigilance contributes significantly to patient safety. A major step toward improving medicine-safety monitoring in India was taken in 2010 with the launch of the Pharmacovigilance Program of India (PvPI). Despite these advancements, the system is still impacted by issues like underreporting ADRs, low public and healthcare professional knowledge, and insufficient reporting facilities in remote areas. Artificial intelligence, machine learning, mobile applications, and electronic health records are examples of emerging technologies that present new chances to enhance adverse-event reporting and more successfully detect any safety issues. However, accurate data, suitable training, data protection, and expert supervision are necessary for their successful application. The evolution of pharmacovigilance in India, the function of new technologies, and the main obstacles to their adoption are all covered in this paper. In order to encourage safer medication usage and better patient outcomes, it also emphasizes the necessity of improved reporting mechanisms, greater awareness, training for healthcare professionals, and easier access to pharmacovigilance services.

Keywords: Pharmacovigilance, Pharmacovigilance Programme of India, adverse drug reactions; artificial intelligence, machine learning, digital health; rural health, signal detection, patient safety

Introduction

Medication errors, adverse reactions, drug interactions, and other negative outcomes can occasionally be linked to the widespread use of medicines for the prevention and treatment of diseases. Prior to a medication's approval, clinical studies are typically limited in duration and involve a certain participant demographic. As a result, until the medication is used in regular medical practice, rare adverse responses, delayed effects, long-term safety concerns, and dangers among communities that are underrepresented in clinical trials may go unnoticed. Pharmacovigilance is therefore essential for continuously monitoring medicine safety in real-world conditions and evaluating whether the benefits of a medicine continue to outweigh its potential risks [1–3].

The World Health Organization (WHO) defines pharmacovigilance as the science and activities associated with the detection, assessment, understanding, and prevention of adverse effects and other medicine-related problems. An adverse event refers to an unfavourable medical occurrence that takes place during the use of a medicine, regardless of whether the medicine is responsible for it. An adverse drug reaction, however, refers to an undesirable response in which a possible relationship with a medicine is suspected. Thus, suspected adverse drug reactions may be reported even when there is insufficient evidence to confirm that the medicine directly caused the reaction [2,3]. India is an important country for pharmacovigilance because of its large and diverse population, widespread use of medicines in different healthcare settings, substantial pharmaceutical industry, and extensive consumption of conventional medicines, over-the-counter drugs, herbal products India's vast and varied population, extensive use of medications in various healthcare settings, sizable pharmaceutical industry, and high consumption of conventional medications, over-the-counter medications, herbal products, and traditional remedies make it a

crucial country for pharmacovigilance. Even though the nation's pharmacovigilance system has advanced significantly, more work is required to raise the calibre, comprehensiveness, and representativeness of medication safety data.

Development and Organization of Pharmacovigilance in India

In 1986, India started formally implementing adverse drug reaction (ADR) monitoring, and in 1989, regional monitoring centres were set up. In 1998, the nation became a member of the World Health Organization's Program for International Drug Monitoring. Due to a lack of resources and low reporting rates, early progress was still restricted. The Pharmacovigilance Program of India (PvPI), which started operations on July 14, 2010, replaced the National Program of Pharmacovigilance, which was first established in 2005. The National Coordination Center was replaced in April 2011 by the Indian Pharmacopeia Commission in Ghaziabad [1,5].

PvPI was created to improve nationwide medication safety monitoring. Its main duties include gathering reports of suspected adverse reactions, recognizing and analyzing safety signals, assessing the benefit-risk ratio of commercially available medications, supporting regulatory bodies in making decisions, disseminating updates on medication safety, educating pertinent parties, and encouraging the prudent and safe use of medications.

Patients, medical professionals, and other qualified individuals report suspected adverse drug reactions (ADRs) to Adverse Drug Reaction Monitoring Centers (AMCs). Through the program's reporting system, which the evaluated publications describe as including VigiFlow, the submitted data is examined and recorded as Individual Case Safety Reports (ICSRs). Authorities can express safety concerns and take appropriate regulatory action with the use of information gathered from individual incidents and combined reports [1,5]. PvPI is linked to other programs aimed at enhancing patient safety in addition to monitoring medications

Established Methods and Their Limitation

Spontaneous Reporting

One of the primary methods for keeping an eye on the safety of medications once they are put on the market is spontaneous reporting. Suspected adverse drug reactions (ADRs) can be reported by patients, healthcare providers, and other authorized individuals without according to a predetermined study methodology. This approach covers a broad spectrum of individuals, is reasonably priced, and assists in identifying unforeseen safety issues that might not have been noticed during clinical trials. However, because the entire number of people exposed to the medication is frequently unknown, it is typically challenging to ascertain the true frequency of an adverse event.

Additionally, the accuracy of data interpretation may be limited by underreporting, duplicate submissions, insufficient clinical information, increased reporting after media attention, and other possible causes of the reported occurrence [11,12].

Active Surveillance and Observational Studies

A methodical technique for keeping an eye on medications and spotting any safety concerns is called active surveillance. Electronic health records, patient registries, insurance claims, follow-up systems, and observational research are all used in it. Researchers can assess possible risks in particular populations and compare health outcomes across defined groups with the aid of cohort and case-control studies. However, trustworthy data, accurate identification of medication exposure and health outcomes, suitable comparison groups, sufficient sample sizes, and careful evaluation of confounding variables and missing information are all necessary for these approaches to be effective (12,13).

Signal Detection and Assessment

A safety signal is information that indicates a potential new causal relationship or a previously unidentified feature of a known association, which requires further investigation. Such signals can be identified through clinical observations or by examining patterns in accumulated adverse drug reaction reports. Statistical tools help detect unusual trends in reporting; however, identifying a statistical signal does not necessarily mean that the medicine caused the reported event. Further evaluation involves expert judgement, verification of case information, examination of the timing of events, assessment of alternative explanations, evaluation of biological plausibility, and review of additional evidence. Therefore, effective signal management requires the integration of computational techniques, clinical expertise, and

a well-documented decision-making process [10,14].

Advances in Indian Pharmacovigilance

Reporting Awareness and Capacity Building

The Pharmacovigilance Programme of India (PvPI) promotes adverse drug reaction (ADR) reporting through educational programmes, workshops, newsletters, training sessions, and collaboration with different stakeholders. Providing reporting forms in Indian languages and offering simple reporting methods for healthcare professionals and consumers can improve participation. Education should also reduce the fear of blame or legal action. Suspected adverse drug reactions can be reported even if their cause is not confirmed, as causality is evaluated later.

Digital Reporting and Data Management

Digital reporting systems help improve the speed of data transfer, maintain consistency in reports, simplify case processing, and support data sharing. VigiFlow and mobile applications contribute to the digital development of pharmacovigilance in India. However, digital tools alone cannot guarantee accurate and complete reports. Simple reporting forms, proper follow-up, duplicate report detection, secure data access, and integration with clinical information systems are also essential.

Links with Public-Health Programmes and Product Categories

Collaboration between PvPI and national public-health programmes helps monitor the safety of medicines and vaccines. Special attention is required for patients receiving long-term or combination treatments for tuberculosis and HIV. Other important areas include blood safety monitoring (haemovigilance) and medical-device vigilance. Safety monitoring should also cover generic medicines, fixed-dose combinations, biosimilars, antidiabetic drugs, cardiovascular medicines, antipsychotics, contrast agents, and products used in major public-health programmes [11,15].

Herbal and Traditional Medicines

Monitoring herbal and traditional medicines is difficult because their composition and quality may differ between products. Problems such as contamination, adulteration, incorrect labelling, and interactions with conventional medicines can complicate the evaluation of adverse reactions. Reports should include details such as the product name, manufacturer, ingredients, batch number, dose, duration of use, other medicines taken, and patient outcome whenever available. Herbal and traditional products should also be included in pharmacovigilance activities, without assuming that they are responsible for every reported reaction.

Emerging Technologies and Their Potential Applications

Artificial Intelligence and Machine Learning

Artificial intelligence (AI) and machine learning (ML) can support pharmacovigilance teams by organising and prioritising adverse drug reaction reports, detecting patterns in large datasets, categorising similar clinical events, identifying potential relationships between medicines and adverse events, and improving case-processing activities. These technologies can also analyse unstructured text and detect missing, incomplete, or inconsistent information that requires further investigation. They are particularly useful when the large volume and diversity of reports make manual assessment challenging [3,4].

Despite these benefits, several limitations must be considered. Models developed using incomplete datasets or information primarily collected from urban populations may reproduce existing reporting biases and perform poorly in rural communities, regional languages, rare adverse events, and less frequently used medicines. Identified patterns may also result from confounding factors, increased reporting following public attention, or inaccurate data. Therefore, AI and ML models should be validated using relevant external datasets, evaluated

across different population groups, and continuously monitored. Transparency, data privacy, and human supervision are also essential. AI should assist pharmacovigilance professionals rather than independently determine causality or replace regulatory decision-making.

Natural Language Processing and Multilingual Reporting

Natural language processing (NLP) can help extract and organize information from free-text adverse drug reaction reports and clinical records into structured data, such as medicine names, symptoms, onset dates, and patient outcomes. Speech-to-text applications and multilingual reporting interfaces may simplify the reporting process for individuals who experience difficulties using conventional forms. The rural review identifies interactive voice-response systems, regional-language reporting, and the conversion of verbal descriptions into structured information as promising approaches [4]. However, these systems should be tested across different accents and dialects, and users must have the opportunity to correct transcription errors and clarify unclear information.

Mobile Health, Telemedicine, and Connected Digital Systems

Mobile health applications can make adverse drug reaction (ADR) reporting more accessible to patients and frontline healthcare workers. Telemedicine services may also help healthcare professionals identify suspected adverse reactions during follow-up consultations and forward relevant information to pharmacovigilance monitoring centres. The rural review recommends connecting pharmacovigilance activities with existing healthcare infrastructure and government initiatives, including the National Health Mission and Ayushman Bharat Digital Mission [4]. These initiatives represent possible implementation pathways and do not imply that complete integration has already been achieved nationwide.

Effective implementation requires digital platforms to exchange information securely and consistently. Reports should ideally be recorded once and reused for appropriate purposes, subject to informed consent and suitable access restrictions. Standardized data definitions, reliable medicine identification systems, secure communication interfaces, electronic audit trails, and clearly defined follow-up responsibilities are necessary to ensure data quality, maintain confidentiality, and improve coordination between healthcare providers and pharmacovigilance centers.

Non-digital methods of reporting should continue to be available alongside digital systems. This ensures that individuals facing unreliable internet access, limited availability of electronic devices, or inadequate digital literacy can report suspected adverse drug reactions without difficulty.

Offline-First Systems and Delay-Tolerant Networking

Delay-tolerant networking is considered a promising approach for regions where internet access is limited or unstable. Under the store–carry–forward method, community health workers can enter adverse drug reaction (ADR) details into a local device and transfer the information to another connected device during a subsequent visit to a primary health center or supervisory meeting. The collected data can then be uploaded once network connectivity is restored [4].

Despite its potential benefits in remote areas, this approach requires practical evaluation before large-scale use. Key concerns include safeguarding confidential information, preventing data loss caused by missing devices, managing synchronization errors, avoiding duplicate entries, minimizing reporting delays, and reducing the extra workload placed on healthcare workers.

Blockchain and Data Provenance

Blockchain technology has been proposed as a means of strengthening data traceability and making records of information exchanges and decisions more resistant to unnoticed changes [3,4]. Within pharmacovigilance, a permission-based blockchain system could maintain a record of when adverse drug reaction reports are submitted or updated, while sensitive patient information is stored separately in a securely managed database.

Nevertheless, blockchain cannot verify whether a report is accurate, establish that a particular medicine caused an adverse event, or prevent under-reporting. Its implementation may also involve higher costs and difficulties related to governance, scalability, and privacy protection. Therefore, its usefulness should be assessed against simpler and more economical alternatives, including secure databases and electronic audit trails, before it is adopted on a wider scale.

Real-World Data and Pharmacogenomics

Integrating pharmacovigilance reports with electronic health records, patient registries, laboratory results, and well-managed real-world datasets can help researchers examine risk factors and assess medicine safety in everyday clinical settings. Pharmacogenomics can also support personalized risk evaluation by investigating how genetic differences affect an individual's response to medicines.

Successful implementation of these approaches depends on the availability of representative data, reliable clinical interpretation, appropriate consent, and effective data governance. Their effectiveness should also be demonstrated through evidence that they improve clinical care or regulatory decision-making. These technologies should be regarded as developing tools that strengthen existing pharmacovigilance practices rather than replace established drug safety monitoring systems [13].

Future Challenges

Under-reporting and Unequal Participation

A significant number of suspected adverse drug reactions are not reported, which reduces the ability of pharmacovigilance systems to identify and assess medicine-related safety concerns. Major reasons for under-reporting include inadequate awareness, time constraints, uncertainty about which reactions should be reported, insufficient feedback, complicated reporting procedures, and fear of being blamed. Increasing participation among patients and community health workers could improve reporting coverage. However, their responsibilities, training requirements, referral procedures, and involvement in clinical assessment must be clearly established [1–4].

Inequality Between Rural and Urban Settings

The 2026 rural review highlights a disparity between the rural population's share of the total population and its contribution to adverse drug reaction reports [4]. Several factors contribute to this gap, including unreliable electricity and internet connectivity, a shortage of trained healthcare personnel, long distances to Adverse Drug Reaction Monitoring Centers (AMCs), language barriers, limited health literacy, and social conditions that may prevent individuals from openly discussing their symptoms.

Consequently, medicine-related safety issues affecting people who depend on primary healthcare facilities, community health workers, or a combination of conventional and traditional treatment practices may remain undetected. Therefore, improving rural participation should be considered an essential indicator for evaluating the effectiveness and inclusiveness of pharmacovigilance programmes.

Data Quality, Interoperability, and Privacy

Adverse drug reaction reports may lack essential details, such as dates, dosage information, patient outcomes, concomitant medicines, laboratory results, and other information required to evaluate alternative causes. In addition, different reporting systems may follow inconsistent coding practices, identification methods, and data formats. Although linking information from multiple sources can improve safety analysis, it may also increase the risk of identifying individuals, unauthorized data access, and misuse of information for purposes beyond its original intent. Effective data governance should therefore include data minimization, access based on user roles, defined data-retention periods, audit trails, appropriate consent or other lawful grounds for processing, incident-response procedures, and clear accountability. [8,9]

New Therapies and Complex Exposures

Pharmacovigilance systems must continuously adapt to developments in biological medicines, biosimilars, vaccines, combination therapies, long-term treatments, medical devices, diagnostic products, and the use of multiple medicines by individual patients. In certain situations,

distinguishing an adverse drug reaction from symptoms caused by the underlying disease can be challenging. Accurate identification of generic medicines and products involving complex manufacturing processes or supply chains is also important for reliable case evaluation and safety assessment [6,7].

Responsible Use of Artificial Intelligence

The use of automated technologies may create a misleading impression of accuracy when their findings are accepted without proper verification. False-positive alerts can consume valuable time and resources, whereas false-negative results may cause important safety signals to be missed. Furthermore, AI models may lack clear explanations for their predictions, produce unequal results across population groups, or lose accuracy as reporting patterns and practices change over time. To ensure responsible implementation, every AI-assisted workflow should specify its intended use, acceptable performance standards, validation datasets, human oversight responsibilities, audit procedures, and conditions requiring model suspension or retraining [9,10].

Long-Term Funding and Workforce

The successful adoption of new technologies requires continuous financial support for system maintenance, cybersecurity, technical assistance, data management, and staff training, in addition to the initial cost of purchasing equipment and software. Adverse Drug Reaction Monitoring Centres (AMCs) and peripheral healthcare facilities also require sufficient staffing, dedicated working time, and efficient reporting procedures. Pharmacists, nurses, physicians, pharmacologists, public health professionals, and patient representatives can all contribute valuable and complementary expertise. Sustainable progress is more achievable when pharmacovigilance is incorporated into routine healthcare activities and professional education rather than relying primarily on occasional awareness campaigns.[16,17]

Recommended Roadmap for India

1. Improve ADR Reporting at the Point of Care: Introduce simple and standardized reporting procedures, conduct regular training programmes, and provide feedback to reporters. Make reporting convenient for healthcare professionals and consumers, and encourage the reporting of suspected reactions even before their causes are confirmed.

2. Focus on Rural and Underserved Areas: Introduce multilingual, low-bandwidth, and offline reporting tools through pilot projects. Train ASHAs, ANMs, nurses, and pharmacists to identify and report suspected adverse drug reactions. Establish effective communication between peripheral healthcare facilities and district-level Adverse Drug Reaction Monitoring Centres (AMCs).

3. Enhance Data Quality and System Integration: Use standardised reporting formats and medicine identification systems. Ensure that missing information is identified, duplicate reports are detected, and data are transferred securely. Integrate clinical information systems wherever feasible.

4. Apply AI for Decision Support: Use artificial intelligence initially for specific tasks, such as detecting duplicate reports, checking data completeness, classifying reports, and prioritising potential safety signals. Validate these tools using local data, assess their performance across different population groups, and maintain human supervision, proper documentation, and audit procedures.

5. Expand Active Safety Monitoring: Use patient registries and routinely collected healthcare data to investigate safety concerns involving selected medicines, populations, and public-health programmes. Establish clear research methods and outcome measures in advance, while considering confounding factors, missing information, and limitations in data integration.

6. Strengthen Monitoring of Different Products: Collect relevant information about manufacturers and batch numbers. Develop appropriate safety-monitoring methods for biological products, vaccines, medical devices, diagnostic products, herbal and traditional medicines, and complex treatment regimens.

7. Ensure Data Privacy and Public Confidence: Protect patient information through secure storage, controlled access, safe data transfer, data minimization, and audit trails. Clearly explain how reported information is used and how patient confidentiality is maintained.

8. Evaluate Safety Outcomes: Measure the effectiveness of pharmacovigilance using indicators beyond the total number of reports. These should include report completeness, reporting speed, successful follow-up, time required to assess safety signals, representation of different regions and populations, regulatory actions, and improvements in patient safety.

9. Assess New Technologies Before Expansion: Evaluate whether blockchain and other advanced technologies provide meaningful advantages over secure databases and audit systems. Conduct pilot studies, independent evaluations, cost assessments, and consultations with stakeholders before introducing these technologies on a national scale.

Conclusion

Through the Pharmacovigilance Program of India (PvPI), which is overseen by the Indian Pharmacopeia Commission (IPC), India has established a nationwide pharmacovigilance system. Medicine safety has been reinforced by its network of Adverse Drug Reaction Monitoring Centers (AMCs), computerized reporting systems, training programs, and partnerships with other safety-monitoring projects. However, the quality of reports, prompt risk identification, regulatory action, and advancements in patient safety should all be taken into consideration when evaluating progress, in addition to the quantity of reports received or technology employed.

New approaches to enhancing pharmacovigilance are provided by emerging technologies like as blockchain, real-world data, telemedicine, artificial intelligence, machine learning, mobile applications, and pharmacogenomics. Reliable data, appropriate validation, system compatibility, data privacy, sufficient funding, and ongoing oversight by qualified experts are all necessary for their efficient usage. Increasing engagement in underprivileged and rural communities should receive special focus. Reducing current reporting gaps may be aided by offline reporting options, regional language interfaces, community health workers' participation, and improved connectivity between AMCs and peripheral healthcare facilities. All things considered, a successful and long-lasting pharmacovigilance system should incorporate well-established clinical evaluation and reporting techniques with carefully considered technical advancements, open governance, and frequent patient and reporter input. These initiatives have the potential to improve medication safety oversight and promote improved health outcomes throughout India

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