



Advancing pharmacoepidemiology and pharmacovigilance: A scoping review of challenges, technological innovations, and global strategies for drug safety

Tanguturi Yella Sree Sudha¹, Raja Babu², K. S. B. S. Krishna Sasanka³, Sumit Kumar Mahato^{1*}, Harminder Singh¹

¹Department of Pharmacology, All India Institute of Medical Sciences, Deoghar, India.

²All India Institute of Medical Sciences, Deoghar, India.

³Department of ENT, All India Institute of Medical Sciences, Deoghar, India.

ARTICLE HISTORY

Received on: 29/12/2025
Accepted on: 12/03/2026
Available Online: 15/04/2026

Key words:

Pharmacoepidemiology, pharmacovigilance, artificial intelligence, drug safety, signal detection, global harmonization, real-world evidence, conceptual framework, data interoperability, patient engagement, ethical frameworks.

ABSTRACT

Pharmacoepidemiology and pharmacovigilance (PV) have evolved into critical disciplines ensuring the safety and efficacy of pharmaceutical products throughout their lifecycle. This comprehensive review examines the current landscape of drug safety monitoring, highlighting persistent challenges, emerging technological innovations, and global strategies for enhancing pharmacoepidemiology, PV systems. The integration of artificial intelligence (AI), machine learning, and real-world data analytics is revolutionizing adverse drug reaction detection and signal processing. Despite significant technological advances, challenges such as underreporting, data quality issues, and regulatory harmonization remain. This scoping review develops an integrated conceptual framework—the “Integrated Digital PV Ecosystem”—that maps how AI, big data analytics, natural language processing, and real-world evidence (RWE) interconnect with regulatory frameworks and patient engagement systems. The review critically examines gaps between current AI-based PV models and regulatory acceptance, identifies barriers to integrating patient engagement data with RWE through harmonized digital systems, and articulates the policy and ethical frameworks needed for AI-based drug safety systems.

1. INTRODUCTION

1.1. Defining pharmacoepidemiology and pharmacovigilance (PV)

Pharmacoepidemiology is a critical field that focuses on studying the utilization and effects of drugs in large populations following their approval for market release [1]. This discipline extends beyond the controlled environments of clinical trials, examining how medications perform in diverse,

real-world settings. By observing drug effects across broad populations, pharmacoepidemiology helps to identify rare or unexpected adverse events, understand long-term outcomes, and assess the effectiveness of medications in various patient subgroups [1].

PV, closely related, encompasses the monitoring, detection, assessment, and prevention of adverse drug reactions (ADRs) [2]. It involves a range of activities aimed at ensuring the safe and effective use of medications. PV involves several key activities, including the collection and analysis of suspected ADR reports, investigations into potential safety signals, and the implementation of strategies to minimize drug-related risks [3]. It is vital for protecting public health by continuously assessing the benefit–risk balance of pharmaceutical products [4].

*Corresponding Author

Sumit Kumar Mahato, Department of Pharmacology, All India Institute of Medical Sciences, Deoghar, India. E-mail: sumitmahato2apr@gmail.com

Pharmacoepidemiology and PV both play essential roles in ensuring drug safety and efficacy in real-world scenarios. Clinical trials offer initial safety and efficacy data, but they often involve specific patient groups and may not capture the full range of potential drug effects. Pharmacoepidemiological studies and PV systems complement each other by monitoring drug performance in broader, more diverse populations, which helps ensure medications are used safely and effectively [5]. Effective PV programs are crucial for identifying and reducing potential risks linked to drug use, thereby safeguarding public health [2].

1.2. Importance of drug safety in public health

Drug safety monitoring is a critical aspect of public health, focusing on identifying and mitigating risks associated with medication use [2]. This proactive approach helps ensure that the benefits of pharmaceutical products outweigh any potential harms. By continuously monitoring drug safety, healthcare systems can quickly address emerging safety concerns, protecting patients from preventable adverse events [3].

Pharmacoepidemiological studies offer valuable data that support therapeutic risk management, comparative effectiveness research, and the evaluation of healthcare systems [6]. These studies provide insights into how drugs perform in various clinical settings, aiding healthcare professionals (HCP) in making informed decisions about medication use. Therapeutic risk management includes evaluating a product's benefits and risks, creating strategies to improve the benefit-risk balance, while implementing and assessing these strategies [7].

Effective PV systems are necessary to ensure that the benefits of drugs outweigh their risks, enhancing patient outcomes and promoting public health. These systems depend on strong reporting mechanisms, proactive surveillance, and international collaboration to identify and address potential safety concerns [3]. By integrating data from various sources and using advanced analytical techniques, PV programs can effectively monitor drug safety and respond to new challenges [8].

1.3. Scope of the scoping review

This review explores the key challenges and advancements in pharmacoepidemiology and PV, along with global strategies designed to improve drug safety [5]. It consolidates current research to offer insights and recommendations for these fields, specifically focusing on issues such as data quality, methodological limitations, and the importance of globally consistent strategies [9]. By examining these areas, the review aims to provide researchers, HCP, and policymakers with information on the latest developments and effective practices in drug safety [10].

A key focus of this review is the need for proactive surveillance and strong reporting systems to enhance drug safety and public health. Proactive surveillance means actively monitoring drug use and its effects to quickly identify any potential safety concerns. Robust reporting systems ensure healthcare providers and patients can easily report suspected

ADRs [2]. These actions are critical for maintaining strong PV systems and safeguarding public health [3]. By bringing together current research, this scoping review aims to give a comprehensive overview of the main challenges, technological innovations, and global strategies in these fields [7]. The ultimate goal is to provide practical insights and recommendations that can help advance pharmacoepidemiology and PV, leading to better drug safety outcomes worldwide [11].

1.4. Conceptual framework and analytical approach

This review is grounded in an integrated conceptual framework termed the "Integrated Digital Pharmacovigilance Ecosystem." This framework recognizes that modern PV is not a collection of isolated technologies and processes, but rather a coordinated system requiring integration across multiple dimensions: A) Technological innovations that enhance data collection and analysis; B) Regulatory harmonization that ensures consistency across jurisdictions; C) Governance structures that ensure ethical data use and patient privacy; D) Patient engagement mechanisms that incorporate patient-reported outcomes; and E) Methodological rigor that addresses confounding, bias, and data quality issues. Rather than merely summarizing existing literature, this review employs critical synthesis to evaluate how these components interact, identify gaps where integration is incomplete, and propose pathways for more effective coordination.

2. CHALLENGES IN CONTEMPORARY PHARMACOEPIDEMIOLOGY

2.1. Data quality and heterogeneity

One of the significant challenges in contemporary pharmacoepidemiology is the issue of data quality and heterogeneity. The varied nature of healthcare data, including electronic health records (EHRs), insurance claims, and patient registries, introduces complexities in how data are integrated and analyzed. This heterogeneity presents operational, technical, and methodological challenges for real-world data (RWD) analysis. Operational challenges involve issues of feasibility and governance, while technical challenges relate to differences in data formats and quality [12]. The variability in data quality, terminologies, formats, and content across different databases makes it difficult to pool and analyze data effectively.

Different healthcare systems and data collection practices result in inconsistencies that hinder the ability to combine and analyze data from multiple sources. Addressing these inconsistencies is crucial for generating reliable and generalizable findings [13].

Data variations across countries create significant obstacles for multinational studies [2]. Different nations often have their own data standards and clinical practices, which makes it difficult to combine information. Overcoming these challenges requires establishing standardized data elements, uniform formats, and clear mappings to international standards. Data integration becomes easier and more precise when data elements and terminologies are standardized. Harmonizing data from diverse sources can be achieved by adopting common data models, such as the Observational Medical Outcomes

Partnership (OMOP) [12]. Data standardization enables more reliable and robust pharmacoepidemiological studies [13].

Addressing data heterogeneity is not merely a technical challenge but a critical component of creating a harmonized digital infrastructure for PV. The adoption of common data models, such as the OMOP, represents a significant advancement in standardization efforts. However, implementation across diverse healthcare systems, particularly in low- and middle-income countries with limited resources, remains challenging. Data integration becomes easier and more precise when data elements and terminologies are standardized, enabling researchers to pool data across multiple sources reliably. Future efforts must focus on developing flexible standardization frameworks that can accommodate the diversity of existing healthcare systems while establishing clear mappings to international standards. This dual approach—maintaining local data governance while ensuring international interoperability—is essential for building a truly global PV ecosystem.

2.2. Methodological limitations

Traditional randomized clinical trials (RCTs) may not always accurately represent real-world scenarios, making pharmacoepidemiological studies essential. RCTs often involve specific patient groups in controlled environments, which may not reflect the complexity and diversity of actual clinical practice. In contrast, pharmacoepidemiological studies examine drug effects in broader populations, providing insights into how medications perform in real-world settings [5].

Drawing causal inferences from observational studies poses challenges because of potential confounding factors and biases. Confounding occurs when the apparent link between a drug and an outcome is influenced by other factors related to both, which can lead to skewed estimates of drug effects if not properly controlled [14]. Observational studies can also be affected by various biases, including selection bias and information bias, which can compromise their validity.

Self-controlled study designs can help reduce confounding, but their effectiveness relies on assumptions that may not always be verifiable.

Self-controlled study designs, such as the self-controlled case series and case-crossover designs, compare drug exposure within the same individuals, thereby controlling for time-invariant confounders. However, these designs rely on assumptions such as the absence of time-varying confounding and the independence of events, which may not always hold in real-world settings [15]. Careful consideration of these assumptions is essential when interpreting the results of self-controlled studies.

2.3. Underreporting and signal detection

Underreporting of ADRs is a significant challenge in PV, particularly in low- and middle-income countries (LMICs). Underreporting of ADRs is a significant problem, stemming from a lack of awareness among HCP and patients, limited reporting resources, and inadequate infrastructure [2]. This underreporting hinders the timely detection of safety signals, impeding actions necessary to protect public health [16].

National pharmacovigilance centers (NPCs) face challenges such as insufficient funding and a shortage of skilled personnel.

Effective signal detection relies on robust reporting mechanisms and proactive surveillance. Establishing clear and accessible reporting channels for HCP and patients is crucial for reporting suspected ADRs. Proactive surveillance, which involves actively monitoring drug use and outcomes, helps identify potential safety signals early through methods such as data mining and statistical analysis [2]. Implementing these strategies is essential for the prompt identification and investigation of potential safety issues [8].

To improve ADR reporting, educating HCP and patients and implementing mobile and electronic reporting systems are essential. Educational programs can increase awareness about the importance of ADR reporting and provide guidance on how to report suspected reactions. Mobile and electronic reporting systems facilitate ADR reporting by making it easier to submit reports, improving the timeliness and completeness of ADR reports, and enhancing the effectiveness of PV efforts [17]. Furthermore, fostering a culture where healthcare providers are supported and encouraged to report ADRs is essential [18].

The underreporting challenge is particularly acute in LMICs where capacity for ADR surveillance is limited. While educational programs targeting HCP remain the most common and effective approach to building PV capacity in LMICs, sustainable solutions require systemic approaches that integrate education within comprehensive frameworks for strengthening national PV systems. This includes not only training on what to report but also establishing accessible reporting channels, providing feedback to reporters, and creating incentive structures that recognize the importance of ADR reporting. Furthermore, implementing mobile and electronic reporting systems can significantly reduce barriers to reporting by making the process more convenient for healthcare providers and patients, particularly in resource-limited settings where paper-based systems are cumbersome and unreliable.

3. TECHNOLOGICAL INNOVATIONS IN PHARMACOEPIDEMIOLOGY AND PV

3.1. Use of big data analytics

Big data analytics enables the study of rare adverse events, sub-group analyses, and long-term follow-up using large healthcare utilization databases. These databases, which include EHRs, claims data, and patient registries, contain vast amounts of information on drug use and health outcomes [1]. Big data analytics techniques can be used to efficiently analyze these data and identify patterns that would not be apparent using traditional methods [19] (Table 1).

Machine learning (ML) and artificial intelligence (AI) are used for data analysis, adverse reaction prediction, and signal detection. ML algorithms can be trained to identify patterns in large datasets and predict the likelihood of adverse events. AI systems can automate the process of signal detection by continuously monitoring data and identifying potential safety concerns [3]. These technologies enhance the efficiency and accuracy of PV efforts [8].

Table 1. Technological innovations in PV: key findings and applications.

Technology	Applications	Benefits	Challenges
AI and ML	Signal detection, automated reporting, predictive analytics	Enhanced accuracy, real-time monitoring, reduced manual workload	Data quality requirements, algorithm transparency, regulatory acceptance
NLP	Automated ADR extraction from clinical notes, social media monitoring	Improved data capture from unstructured sources	Language barriers, context understanding, false positives
Blockchain technology	Drug tracking, secure data sharing, compliance automation	Enhanced transparency, immutable records, improved traceability	Standardization needs, energy consumption, implementation costs
RWD analytics	Post-market surveillance, comparative effectiveness research	Larger sample sizes, diverse populations, RWE	Data heterogeneity, privacy concerns, analytical complexity
Social media mining	Patient-reported outcomes, early signal detection	Direct patient insights, early warning systems	Data reliability, privacy issues, noise in data

These technologies facilitate the development of novel models to detect drug–drug interactions, patient phenotypes, and outcome predictions. ML models can be used to identify combinations of drugs that are associated with an increased risk of adverse events. They can also be used to identify patient phenotypes that are associated with different drug responses, allowing for more personalized treatment decisions [1]. By leveraging these technologies, researchers can gain a deeper understanding of drug effects and improve patient safety [19].

3.2. Natural language processing (NLP)

NLP can automate the identification and extraction of information on diseases, medications, and adverse effects from clinical notes and biomedical literature. NLP techniques enable the analysis of unstructured text data, such as clinical notes, which often contain valuable information that is not captured in structured databases [8]. By extracting information from these sources, NLP can enhance the completeness and accuracy of PV data [13].

NLP models can expedite the detection of potential adverse drug effects linked to medications, enhancing PV practices. These models can be trained to identify mentions of drugs, diseases, and adverse events in text data, allowing for the rapid detection of potential safety signals. NLP can be used to prioritize cases for review by human experts, improving the efficiency of PV efforts [8]. The NLP model boasts a remarkable Score of 0.97 at step 1,800 [8].

NLP applications improve the efficiency of processing unstructured free texts and prioritizing case reports for clinical and regulatory review. By automating the extraction of relevant information from unstructured text, NLP reduces the manual effort required to review case reports and identify potential safety signals. This allows HCP and regulatory agencies to focus on the most critical cases, improving the timeliness and effectiveness of decision-making [20]. The model obtained showcases its efficiency in extracting and identifying pertinent information from textual data, setting a new benchmark for PV practices [8].

3.3. EHRs and mobile health (mHealth)

EHRs and mHealth applications enhance real-time data collection and expedite the reporting of ADRs. EHRs provide a comprehensive record of patient health information,

including medication history, diagnoses, and laboratory results, facilitating the monitoring of drug use and outcomes. mHealth applications, such as smartphone apps and wearable devices, enable patients to actively participate in PV by reporting suspected ADRs and tracking their health [3].

EHRs facilitate pharmacoepidemiology and PV by monitoring utilization patterns in large patient populations. EHR data can be used to assess drug prescribing patterns, identify high-risk patients, and evaluate the effectiveness of interventions to improve drug safety. The availability of longitudinal data in EHRs allows for the study of long-term drug effects and the identification of delayed adverse events [21]. EHR highlights initiatives focused on bringing the level of acceptability to regulatory authorities [21].

The integration of EHR data with other data sources improves the detection of drug–drug interactions and adverse events. Linking EHR data with claims data, patient registries, and other data sources provides a more complete picture of drug use and outcomes. This integrated data can be used to identify drug–drug interactions that are not apparent from clinical trials and to assess the impact of these interactions on patient health [12]. The use of EHR data enables researchers to repurpose, discover, and probe mechanisms of adverse reactions [3].

3.4. Blockchain applications and data security in PV

Blockchain technology offers innovative solutions for secure data sharing in PV systems. The decentralized and immutable nature of blockchain creates transparent audit trails for ADR reports while maintaining data integrity and security. Blockchain-based systems can enable secure sharing of PV data among multiple stakeholders—healthcare providers, regulatory agencies, patients, and pharmaceutical companies—without requiring centralized databases that may be vulnerable to breaches. Smart contracts can automate validation and quality checks on ADR reports, improving data consistency while reducing manual processing time. Additionally, blockchain can facilitate patient consent management and privacy-preserving data sharing through tokenization, allowing patients to control how their health data are used while maintaining confidentiality. However, challenges related to scalability, energy consumption, regulatory acceptance, and technical standardization must be addressed before blockchain can be widely implemented in global PV systems.

4. GLOBAL PV STRATEGIES

4.1. Harmonization of regulations

Harmonization of regulations globally is essential for effective PV. Differing regulatory requirements across countries can create inconsistencies in drug safety monitoring and reporting, hindering the ability to identify and respond to global safety signals. Harmonization involves aligning regulatory standards and processes to facilitate the sharing of information and the coordination of PV activities across borders [9] (Table 2).

Drafting uniform guidelines and leveraging digital technologies can optimize reporting. Uniform guidelines provide clear and consistent standards for ADR reporting, data collection, and signal detection. Leveraging digital technologies, such as electronic reporting systems and data analytics platforms, can improve the efficiency and timeliness of PV activities [7]. These technologies also facilitate the sharing of information and the collaboration among regulatory agencies.

Harmonization reduces discrepancies between different authorities and improves compliance with diverse business processes. By aligning regulatory requirements, harmonization reduces the burden on pharmaceutical companies and HCP who operate in multiple countries. It also improves the consistency and quality of PV data, enhancing the ability to detect and respond to global safety signals [9]. Harmonization can be employed by drafting guidelines that are uniform globally [7].

4.2. International collaboration

Collaboration among international partners is crucial for addressing global drug safety challenges. Drug safety issues often transcend national borders, requiring coordinated efforts to monitor and respond to potential threats. International collaboration involves sharing data, expertise, and resources to enhance PV capabilities and improve patient safety worldwide. The emphasis is on international partners [22].

The European Medicines Regulatory Network (EMRN) emphasizes international collaboration to enable the use of real-world evidence (RWE). The EMRN facilitates the sharing of data and expertise among European regulatory agencies, promoting the use of RWE in decision-making.

This collaboration enhances the ability to assess drug safety and effectiveness in real-world settings, improving patient outcomes. Acknowledging frameworks conceptualizes challenges and opportunities for RWE [22].

Initiatives such as the Centres for Pharmacoepidemiology and Pharmacovigilance (ENCePP) facilitate data sharing and methodological standardization. ENCePP provides a platform for researchers and regulatory agencies to collaborate on pharmacoepidemiological studies, promoting the use of standardized methods and data sources. This collaboration enhances the quality and comparability of research findings, improving the evidence base for drug safety decision-making [22]. ENCePP Guide Methodological Standards Pharmacoepidemiology, extensively updated in 2021, is a core effort to drive up standards [22].

4.3. Strengthening PV in LMICs

Strategies to strengthen PV systems in LMICs include education of HCP and enhanced surveillance. Education programs can raise awareness about the importance of ADR reporting and provide guidance on how to report suspected reactions. Enhanced surveillance involves actively monitoring drug use and outcomes to identify potential safety signals early [17]. These efforts are essential for improving drug safety in LMICs, where resources for PV are often limited [11].

Building capacity for advanced activities such as signal detection is essential for improving PV in LMICs. This involves training HCP in data analysis techniques and establishing systems for monitoring and analyzing ADR reports. By building capacity for signal detection, LMICs can more effectively identify and respond to potential safety concerns [17]. Education alone is insufficient and should ideally be organized within the holistic framework of strengthening national PV systems [11].

Implementing holistic frameworks that strengthen national PV systems is necessary for sustainable improvements. These frameworks should address all aspects of PV, including reporting mechanisms, data collection, signal detection, and risk management. By implementing comprehensive frameworks, LMICs can build robust and sustainable PV systems that protect public health [17]. Results of this review suggest that educating HCP on ADR reporting is the most common approach to build PV capacity in LMIC [11].

Table 2. Global regulatory framework components and implementation status.

Component	Description	Implementation level	Key challenges	Future directions
ICH E2E guidelines	PV planning	Widely adopted in ICH regions	Harmonization outside ICH regions	Global expansion and adaptation
Risk management plans (RMPs)	Structured risk assessment and mitigation	Mandatory in EU, US, other regions	Standardization across regions	Enhanced RWD integration
Periodic safety update reports (PSURs)	Regular safety reporting	Globally implemented	Data quality and timeliness	Automated generation using AI
VigiBase global database	WHO global ADR database	140+ countries participating	Underreporting, data quality variations	Enhanced data standardization
Signal detection Systems	Automated safety signal identification	Variable implementation	Algorithm validation, false positives	AI-enhanced methodologies

4.4. Regulatory case studies: RWE integration in practice

The EMRN has emerged as a leader in integrating RWE into regulatory decision-making. The EMRN facilitates data sharing among European regulatory agencies and promotes the use of RWE in assessments of drug safety and effectiveness in real-world settings. Specific examples include using claims data to assess long-term safety outcomes of biologics, leveraging EHRs to identify drug–drug interactions not apparent in clinical trials, and employing patient registries to monitor rare adverse events. The FDA has similarly adopted RWE in certain PV contexts, using EHR data for post-market surveillance and claims data for comparative effectiveness research. However, regulatory acceptance of RWE-based findings for label updates or approval decisions varies significantly across jurisdictions, reflecting differences in regulatory philosophy and data quality standards. The gap between technological capability and regulatory acceptance remains a critical barrier to optimal use of RWE in global PV.

5. RWE IN REGULATORY DECISION-MAKING

5.1. Integrating RWE into drug development

RWE is being used more and more in making decisions about regulations. This includes things such as creating drugs, giving them permission to be sold, and keeping an eye on them after they are on the market. RWE comes from RWD and shows how drugs work in normal, everyday situations, which adds to what we learn from carefully controlled studies called RCTs. Regulators are using RWE to make better choices about how safe and how well drugs work, which helps patients. The European Union already uses RWE to help with creating regulations, giving approvals, and supervising drugs [22].

RWE enhances the information gathered from RCTs, by offering insights into how medications are utilized and perform in typical clinical settings. While RCTs are valuable for assessing a drug's effectiveness and safety under controlled conditions, they might not fully capture the complexities of real-world clinical practice. RWE addresses this gap by supplying data on drug usage and outcomes across diverse patient groups, thereby improving the generalizability of findings. RWD makes it possible to gain new understandings of how drugs are used and how they perform in everyday situations, complementing rather than competing with what is learned from RCTs [12].

It is important to have ways to check if RWD is good enough to use and to make sure that study designs are well-made so that decisions are reliable. Frameworks are needed to assess the quality and reliability of RWD to ensure RWE is used correctly when regulators are making decisions. These frameworks should look at things like how good the data source is, if the data are complete, and how well the study was designed. By using these frameworks, regulators can be sure that RWE is used in the right way and that decisions are based on solid proof. The EMRN strategy 2025 uses these frameworks in certain situations [22].

5.2. Use of RWE in post-market surveillance

RWE is very important for keeping an eye on drugs after they are sold, figuring out if there are any safety problems, and studying how to handle risks. Once a drug is approved and

sold, RWE helps to watch how safe and well it works in real-life situations. Post-market surveillance means constantly watching how drugs are used and what happens to people who take them to find any possible safety issues and to see what the long-term effects of the drugs are. RWE has been used to evaluate safety signals, conduct risk management studies, and assess the balance between a drug's benefits and risks [12] (Table 2).

Pharmacoepidemiological studies that use RWE help with figuring out if a drug's benefits outweigh its risks and assessing how it affects public health. By looking at RWE, researchers can figure out the good and bad sides of drugs for different groups of patients and in different medical settings. This information helps regulators make decisions and create plans for managing any risks that come with drugs. RWE also helps to assess how drugs affect the health of the public by giving information on what happens when drugs are used in real life [14]. It could be argued that PV decisions are essential [12].

RWD from sources such as EHRs, insurance claims, and patient registries are helpful for keeping an eye on drug safety. These sources give a lot of information over a long time about how drugs are used and what health results people have, which makes it possible to spot rare or unexpected serious or life-threatening reactions. RWD sources also let researchers study how drugs affect different groups of patients, which makes the findings more generalizable [13]. EHRs, claims, prescriptions, and patient registries are key sources of RWD [12].

5.3. Challenges and opportunities of RWE

It can be hard to prove that a drug works well using RWE, especially when it is first approved. While RWE can give useful information about how safe and well a drug works in real-world situations, it can be harder to use it to prove that it works, especially when a drug is new. This is because RWE studies are often just watching what happens and can have problems that confuse the results or biases. However, RWE can be used along with data from RCTs to give more proof that a drug works. Showing that a product is effective is particularly difficult when it is first approved, compared to studying its effects after it has already been approved [22].

Fixing problems with how studies are done and making sure data are reliable is important for getting the most out of RWE when making decisions. Ensuring the validity of RWE requires addressing methodological weaknesses and strengthening data quality. This involves selecting robust study designs, managing confounding and other sources of bias, and verifying the accuracy and completeness of data sources. When these challenges are mitigated, RWE can meaningfully inform assessments of drug safety and effectiveness. Stakeholders remain cautious, as favorable decisions based on RWE ultimately lead to patient exposure to new medical products [12].

Combining RWE with clinical trial data gives a more complete picture of how drugs work and helps to keep improving how they are used. By combining RWE with clinical trial data, regulators and healthcare workers can better understand how drugs work and make smarter decisions about using medications. This also helps to keep improving practices by giving feedback on how drugs work in real-world situations. Learning what to do is part of the review edition [22].

5.4. Ethical and data privacy frameworks for RWE

The use of RWD in PV raises significant ethical and privacy considerations that must be carefully managed. The General Data Protection Regulation in Europe and the Health Insurance Portability and Accountability Act in the United States establish legal frameworks for protecting patient information in healthcare settings. However, applying these frameworks to RWE—which increasingly includes data from diverse sources such as social media, wearable devices, and direct-to-consumer platforms—presents novel challenges. When integrating RWD from social media platforms for adverse reaction detection, ensuring data quality and reliability requires careful assessment of data source credibility and potential bias. Protecting patient privacy requires implementing appropriate de-identification techniques and adhering to ethical guidelines for data collection and use. De-identification involves removing or masking identifying information from datasets, while tokenization replaces sensitive data with unique, non-identifiable tokens. These techniques enable data linkage across sources while maintaining patient confidentiality. Furthermore, ethical frameworks must address algorithmic transparency and fairness, ensuring that AI systems used to analyze RWE do not perpetuate or exacerbate health disparities. Governance structures must be established to ensure that patients maintain agency over how their data are used, with clear consent mechanisms and the right to withdraw consent or request data deletion.

6. ADDRESSING ADRS

6.1. Monitoring and reporting ADRs

It is very important to monitor and report ADRs effectively to ensure drug safety. ADR monitoring includes collecting and analyzing data on suspected adverse events in a systematic way, while ADR reporting gives HCP and patients a way to tell regulatory agencies about these events. Strong monitoring and reporting systems are essential for finding possible safety problems and taking the right steps to protect the public's health [2]. HCP and patients are very important in making PV practices better by watching out for problems and reporting them [2].

HCP are often the first to see suspected ADRs in their patients, so their reporting is essential for finding possible safety problems. Patients can also give useful information by reporting what they experience with medications, which can give insights that might not be found through normal reporting methods. By getting HCP and patients involved in ADR monitoring and reporting, PV systems can be more effective and responsive [2].

Setting up NPCs and global databases makes it easier to assess the connections between medications and ADRs. NPCs serve as central points for collecting, analyzing, and sharing information on ADRs within a country. Global databases, such as the World Health Organization's VigiBase, collect ADR reports from all over the world, which helps to spot international safety problems. These resources allow researchers and regulatory agencies to assess the connections between medications and ADRs and take the right steps to protect public health. Clinicians are important in recognizing and reporting ADRs to NPCs [4].

6.2. Understanding ADR mechanisms

Understanding how ADRs happen is essential for predicting and preventing ADR events. By figuring out the biological pathways and molecular interactions that cause ADRs, researchers can create ways to lower the risk of these events [23]. Understanding ADR mechanisms also helps in creating safer medications and more personalized ways to treat people. The increasing global interest in complementary and alternative medicine has led to a rise in the concurrent use of herbal supplements and pharmaceutical drugs, increasing the risk of herb–drug interactions [24].

Systems pharmacology approaches can find interactions among proteins and molecular pathways, which makes it easier to predict when multiple drugs will interact badly. Systems pharmacology uses computer models along with experimental data to study how drugs affect biological systems. By looking at the interactions among proteins and molecular pathways, systems pharmacology can find possible drug–drug interactions and predict how likely adverse events will occur [23]. These analyses are useful for detecting and preventing the incremental nature of the effect of each additional therapy [23].

Looking at patient profiles and medication plans helps to deal with drug–drug and drug–disease interactions. Patient profiles, which include information such as age, medical history, and what medications they use, can be used to find people who are at high risk of ADRs. Looking at medication plans can show possible drug–drug interactions and drug–disease interactions that might increase the risk of adverse events. By identifying these risks, HCP can take steps to prevent ADRs and improve patient safety [23]. The rising polypharmacy has significant implications for safety, particularly in the area of drug interactions [23].

6.3. Strategies for preventing ADRs

Preventing or lowering the risk of ADRs is a key goal for clinicians. ADRs can cause morbidity, mortality, and cause economic losses, so preventing them is very important in patient care. By using strategies to lower the risk of ADRs, clinicians can help improve patient outcomes and lower healthcare costs. Preventing or minimizing ADRs remains a persistent challenge in routine clinical practice, making the pursuit of optimal therapeutic outcomes a continued priority for clinicians [25].

Strategies include changing doses, using alternative therapies, and getting clinical pharmacists to be actively involved. Changing doses can lower the risk of ADRs by ensuring patients are not exposed to drug levels that are toxic. Alternative therapies, such as non-pharmacological approach, can be used to manage conditions without using drugs. Getting clinical pharmacists actively involved can improve medication safety by identifying potential drug–drug interactions and giving advice on how to make medication plans better [23].

Teaching HCP and consumers about the possible risks that come with medications helps to promote safer medical practices. Education programs can increase awareness of the possible risks of medications and give guidance on how to lower these risks. By improving HCP and consumers' knowledge about drug safety, safer medical practices can be

promoted. Consumers must be educated about the potential risks associated with the co-administration of herbal and pharmaceutical products to promote safer medical practices [24].

7. PV IN SPECIAL POPULATIONS

7.1. Older adults

Older adults need special attention in PV because their treatments are complex and their bodies change as they age. Older adults are more likely to have multiple long-term conditions, which means that they need to take multiple medications. This polypharmacy increases the risk of drug–drug interactions and adverse events. Age-related physiological changes, such as decreased renal function and altered drug metabolism, can also increase the risk of ADRs in older adults [26].

Pharmacoepidemiological studies are playing a bigger role in assessing how safe and well drugs work in older populations. These studies can give useful information on how drugs work in older adults, who are often not included in clinical trials. By looking at data from real-world situations, pharmacoepidemiological studies can find possible safety problems and help with making clinical decisions [27]. The significant increase in the number of older adults has intensified the demand and care in therapeutics in this group of the population [26].

The findings from studies should be tested in well-conducted interventional trials that are relevant to older adults. While pharmacoepidemiological studies can give useful insights into drug safety in older adults, their findings should be confirmed in well-conducted interventional trials. These trials should be designed to address the specific needs and characteristics of older populations, making sure that the results are relevant and can be applied to other older adults [27]. Much of the information on the safety and efficacy of drugs in older people is obtained after marketing [27].

7.2. Pediatric populations

PV in pediatric populations needs specific attention because pediatric physiology and development are different from adults. Children are not just small adults; they have unique physiological and developmental characteristics that can affect how they respond to medications. These differences can increase the risk of ADRs in children, so it is essential to have strong PV systems in place to watch drug safety in this population [28].

Monitoring adverse events after immunization and making sure vaccines are key components of pediatric PV. Vaccines are among the best ways to prevent infectious diseases in children, but they can also cause adverse events. Watching these events and ensuring vaccines are safe is essential for keeping the public's trust and making sure immunization programs are as helpful as possible [29]. Lessons learned from this experience will help to improve preparations for future vaccine introductions in resource-poor settings and capitalize on such efforts to advance vaccine safety systems in the future [29].

Improving the design of auto-injectors and increasing vigilance and training for families are essential for managing allergic emergencies in children. Allergic emergencies, such as anaphylaxis, can be life-threatening in children. Auto-injectors, which give a pre-measured dose of epinephrine, are a critical tool for managing these emergencies. Making auto-injectors easier to use and increasing vigilance and training for families can help to make sure these devices are used effectively. There is a need to improve design along with increased vigilance and training for families [28].

7.3. Pregnant women

Pharmacoepidemiological research is needed to assess the safety of medicines used during pregnancy, since randomized trials are often not possible in this population. Pregnant women are often not included in clinical trials because of ethical concerns about possibly harming the developing fetus. This lack of data makes it hard to know how safe medicines are for use during pregnancy. Pharmacoepidemiological research can help to fill this gap by giving data on drug use and outcomes in pregnant women [14].

Careful monitoring and reporting of adverse events are essential to protect the health of both the mother and the developing fetus. Adverse events during pregnancy can have serious consequences for both the mother and the developing fetus. Careful monitoring and reporting of these events are essential for identifying potential safety signals and taking appropriate action to protect maternal and fetal health [30].

8. THE ROLE OF PATIENT ENGAGEMENT IN PHARMACOVIGILANCE (PEP)

8.1. Enhancing ADR reporting through patient involvement

PEP improves information on ADRs. Patient reports can give useful insights into patients' experience with medications, and they can capture information that might not be available from other sources. By getting patients actively involved in PV, the ADR data can be more complete and accurate [18]. PEP has been shown to improve information on ADRs [18].

Patients might be more likely to report certain kinds of ADRs, such as those that are subjective or that happen outside of a medical setting. Their reports can give a more complete picture of what patients' experience, which helps to find possible safety problems that might otherwise be missed [18].

This review shows that there is a paucity of information on PEP in LMICs, particularly in Africa [18].

Further research into patients' roles in PV is needed, accompanied by advocacy efforts with policymakers. While PEP has shown promise, more research is needed to fully understand its potential benefits and limitations. Advocacy efforts are also needed to promote patient engagement and to ensure that patient reports are valued and used effectively in drug safety decision-making [18]. Recommendations were made to improve medication safety in Africa based on the identified disparities and system challenges [18].

8.2. Addressing challenges in LMICs

There is a paucity of information on PEP in LMICs, particularly in Africa. PEP is less developed in LMICs compared to high-income countries. This is due to various factors, including limited resources, lack of awareness, and inadequate infrastructure. Addressing these challenges is essential for improving drug safety in LMICs [18]. This review shows that there is a paucity of information on PEP in LMICs, particularly in Africa [18] (Table 3).

Benchmarking against experienced PV centers and the use of technology can improve patient reporting in LMICs. LMICs can learn from the experiences of PV centers in high-income countries by benchmarking their practices and adopting successful strategies. Technology, such as mobile phone apps and online platforms, can also be used to facilitate patient reporting and improve communication between patients and HCP [18].

Sustainable funding strategies are needed to support PEP in LMICs. Sustainable funding is essential for ensuring the long-term viability of patient engagement initiatives. This funding can come from a variety of sources, including government funding, international aid, and private donations. By securing sustainable funding, LMICs can build robust and effective patient engagement programs that improve drug safety [18]. There should be further research into patients' roles in PV, accompanied by advocacy efforts with policymakers [18].

8.3. Utilizing social media and online platforms

Social media data represent a potentially valuable source of post-market drug information. Social media platforms, such as Twitter and Facebook, are increasingly used by patients to share their experiences with medications. These data can provide valuable insights into the patient perspective on drug safety and effectiveness, supplementing traditional sources of drug information [10]. The rapidly expanding volume of available information, together with better tools for extracting and understanding that information offered by emerging technologies, provides PV with substantial new opportunities [10].

Harnessing social media data for adverse reaction detection can supplement traditional sources of drug information. Social media data can be used to identify potential safety signals that may not be detected through traditional reporting channels. By analyzing social media posts, researchers can gain a better

understanding of the patient experience with medications and identify potential safety concerns [10].

While social media data hold considerable promise for enhancing drug safety monitoring, it also presents several challenges related to data quality, privacy, and ethical considerations. Ensuring the reliability and validity of social media data requires careful attention to issues such as data source credibility, data accuracy, and the potential for bias. Protecting patient privacy involves implementing appropriate de-identification techniques and adhering to ethical guidelines for data collection and use. Addressing these challenges is essential for harnessing the full potential of social media in PV while safeguarding patient rights and maintaining public trust [29].

8.4. Integrating social media data with structured PV systems

Social media represents an emerging and potentially valuable source of post-market drug safety information that complements traditional PV reporting channels. Patients increasingly use social media platforms such as Twitter, Facebook, and specialized health forums to share their experiences with medications, providing real-world insights into the patient perspective on drug safety and effectiveness. Harnessing social media data for adverse reaction detection can supplement traditional sources by identifying potential safety signals that may not be detected through conventional reporting channels. By analyzing social media posts using NLP and ML techniques, researchers can gain insights into the patient experience with medications and identify potential safety concerns in near-real time. However, social media data present unique challenges. The reliability and validity of social media information must be carefully evaluated, as social media posts may contain misinformation, exaggeration, or misattribution of adverse events. Data quality issues include noise, inconsistency, and variable levels of medical expertise among posters. Additionally, protecting patient privacy while utilizing social media data requires careful attention to ethical considerations. While social media posts are publicly available, using them for research purposes raises questions about informed consent and data use. Appropriate de-identification techniques must be applied, and research protocols must adhere to ethical guidelines approved by institutional review boards. Furthermore, regulatory frameworks for using social media data in PV remain underdeveloped, creating uncertainty

Table 3. Current challenges and proposed solutions in PV.

Challenge category	Specific issues	Impact on drug safety	Proposed solutions	Expected outcomes
Underreporting	HCP awareness, patient participation	Delayed signal detection, incomplete safety profiles	Enhanced training programs, patient engagement initiatives [4]	Improved reporting rates, better safety data
Data quality	Inconsistent reporting standards, missing information	Compromised signal detection accuracy	Standardized reporting formats, automated quality checks	Higher data reliability, improved analysis
Regulatory disparities	Different regional requirements, approval processes	Delayed global safety actions	Harmonized guidelines, international cooperation [3]	Coordinated global responses
Technology integration	Legacy systems, interoperability issues	Limited analytical capabilities	Standardized data formats, API development [8]	Enhanced system connectivity

about how findings from social media analysis should be integrated into formal PV decision-making.

9. FUTURE DIRECTIONS IN PHARMACOEPIDEMOLOGY

9.1. Enhancing data integration and interoperability

Developing standardized data models and terminologies is crucial for integrating diverse data sources, improving the efficiency and accuracy of pharmacoepidemiological studies. The increasing volume and variety of healthcare data, including EHRs, claims data, patient registries, and genomic data, present both opportunities and challenges for pharmacoepidemiological research. Standardized data models and terminologies facilitate data sharing and analysis across different healthcare systems and research institutions [12]. This standardization allows for the creation of large, integrated datasets that can be used to study drug safety and effectiveness in diverse populations. By adopting common data models and terminologies, researchers can improve the comparability of data from different sources and reduce the risk of errors and inconsistencies.

Implementing secure data linkage techniques enables the integration of data from multiple sources while protecting patient privacy, enhancing the ability to conduct comprehensive analyses of drug safety and effectiveness. Secure data linkage techniques, such as de-identification and tokenization, allow researchers to combine data from different sources without compromising patient confidentiality [12]. De-identification involves removing or masking identifying information from datasets, while tokenization replaces sensitive data with unique, non-identifiable tokens. These techniques enable researchers to link data from different sources while adhering to privacy regulations and protecting patient rights. By integrating data from multiple sources, researchers can gain a more comprehensive understanding of drug effects and identify potential safety signals that may not be apparent from single data sources.

Promoting data sharing and collaboration among researchers, healthcare providers, and regulatory agencies fosters a more comprehensive understanding of drug effects, facilitating the development of effective strategies for improving patient outcomes. Data sharing and collaboration are essential for addressing complex drug safety challenges and ensuring that research findings are translated into clinical practice [7]. By sharing data and expertise, researchers can accelerate the pace of discovery and develop more effective strategies for preventing ADRs and improving patient safety [9]. Collaboration among healthcare providers, researchers, and regulatory agencies ensures that research findings are translated into clinical practice and that drug safety policies are informed by the best available evidence.

9.2. Advancing methodological approaches

Developing novel statistical methods to address confounding and bias in observational studies enhances the validity of pharmacoepidemiological research. Observational studies, which are commonly used in pharmacoepidemiology, are susceptible to confounders and bias, which can compromise

the validity of the findings. Advanced statistical techniques, such as propensity score matching and instrumental variable analysis, can be used to control for confounding and minimize bias in observational studies [15]. These methods allow researchers to estimate the causal effects of drugs while accounting for the influence of other factors that may affect the outcomes of interest. By using these advanced statistical techniques, researchers can improve the accuracy and reliability of pharmacoepidemiological research.

Utilizing ML and AI to improve signal detection and risk prediction enables the early identification of potential safety concerns. ML algorithms can be trained to identify patterns in large datasets that are indicative of potential ADRs, allowing for the early detection of safety signals and the implementation of timely interventions [3]. AI-powered systems can automate the surveillance of safety data, enabling the expeditious detection of emerging safety signals and the prioritization of cases for further scrutiny. ML can be used to develop predictive models that identify patients who are at high risk of experiencing adverse events, allowing for targeted interventions to prevent these events. By using these technologies, researchers and regulatory agencies can improve the efficiency and effectiveness of PV activities.

Conducting comparative effectiveness research to evaluate the relative benefits and risks of different treatment options informs clinical decision-making and promotes the use of evidence-based practices. Comparative effectiveness research compares the outcomes of different treatment options in real-world settings, providing valuable information for healthcare providers and patients [7]. This type of research can help to identify the most effective treatments for specific conditions, taking into account both clinical outcomes and patient preferences. Comparative effectiveness research can also inform the development of clinical guidelines and promote the use of evidence-based practices, improving the quality of care and patient outcomes.

9.3. Strengthening global collaboration

Establishing international networks for data sharing and collaboration enhances the ability to monitor drug safety on a global scale. Drug safety issues often transcend national borders, requiring coordinated efforts to monitor and respond to potential threats. International networks facilitate the exchange of data, expertise, and resources, enabling the detection of safety signals that may not be apparent in individual countries [9]. The EMRN underscores international collaboration to facilitate the utilization of RWE [9]. These networks can also promote the harmonization of regulatory standards and improve the overall effectiveness of PV activities worldwide.

Harmonizing regulatory standards and guidelines promotes consistency in PV practices across different countries, facilitating the efficient and effective monitoring of drug safety worldwide. Harmonization reduces the burden on pharmaceutical companies and healthcare providers who operate in multiple countries, while also improving the quality and comparability of PV data [21]. It involves drafting uniform guidelines and leveraging digital technologies to optimize reporting [7]. Harmonization mitigates discrepancies among

diverse authorities and enhances adherence to varied business processes [7]. By aligning regulatory standards, countries can create a more seamless and efficient global PV system, improving patient safety worldwide.

Providing support and training to LMICs strengthens their capacity to conduct PV activities and protect public health. LMICs often face significant challenges in establishing and maintaining effective PV systems, including limited resources, a lack of trained personnel, and weak infrastructure. Capacity-building efforts should focus on improving infrastructure, training HCP, and establishing robust reporting systems [17]. Educating HCP on ADR reporting is the most common approach to build PV capacity in LMIC [11]. By strengthening PV systems in LMICs, it is possible to improve drug safety and protect the health of vulnerable populations.

10. CONCLUSION

This scoping review underscores the evolving landscape of pharmacoepidemiology and PV, highlighting key challenges such as data quality, methodological limitations, and the need for global collaboration. Technological advancements—including big data analytics, EHRs, and NLP—are transforming these fields, enabling improved detection of ADRs, drug interactions, and patient outcomes. Harmonized international regulations and collective action among researchers, healthcare providers, and regulatory agencies are essential to strengthen global drug safety systems. Future research must focus on refining RWD methodologies, mitigating bias, and enhancing rare event detection. Active involvement of clinicians and continued regulatory emphasis on RWE will further bolster PV efforts. Ultimately, a patient-centered approach grounded in innovation, collaboration, and continuous evaluation is vital to ensure the safe and effective use of medicines worldwide.

11. ACKNOWLEDGMENTS

The corresponding author appreciates the team spirit demonstrated by all the authors.

12. AUTHOR CONTRIBUTIONS

All authors made substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data; took part in drafting the article or revising it critically for important intellectual content; agreed to submit to the current journal; gave final approval of the version to be published; and agree to be accountable for all aspects of the work. All the authors are eligible to be author as per the International Committee of Medical Journal Editors (ICMJE) requirements/guidelines.

13. FINANCIAL SUPPORT

There is no funding to report.

14. CONFLICTS OF INTEREST

The authors report no financial or any other conflicts of interest in this work.

15. ETHICAL APPROVALS

This study does not involve experiments on animals or human subjects..

16. DATA AVAILABILITY

All data generated and analyzed are included in this research article.

17. PUBLISHER'S NOTE

All claims expressed in this article are solely those of the authors and do not necessarily represent those of the publisher, the editors and the reviewers. This journal remains neutral with regard to jurisdictional claims in published institutional affiliation.

18. USE OF ARTIFICIAL INTELLIGENCE (AI)-ASSISTED TECHNOLOGY

The authors declare that they have not used artificial intelligence (AI)-tools for writing and editing of the manuscript, and no images were manipulated using AI.

REFERENCES

- Burden AM. Pharmacoepidemiology and big data analytics: challenges and opportunities when moving towards precision medicine. *Chimia (Aarau)*. 2019;73(12):1012–7. doi: <https://doi.org/10.2533/chimia.2019.1012>
- Sharma B. Pharmacovigilance: monitoring and reporting adverse drug reactions. *Pharma Innov*. 2019;8(1):849–52. doi: <https://doi.org/10.22271/tpi.2019.v8.i1n.25488>
- Gomase VS. Pharmacovigilance—technological advancements, recent developments and innovations. *Curr Drug Saf*. 2025;20:423–49. doi: <https://doi.org/10.2174/0115748863356840250112181406>
- Hamid AAA, Rahim R, Teo SP. Pharmacovigilance and its importance for primary health care professionals. *Korean J Fam Med*. 2022;43(5):290–5. doi: <https://doi.org/10.4082/kjfm.21.0193>
- Sabaté M, Montané E. Pharmacoepidemiology: an overview. *J Clin Med*. 2023;12(22):7033. doi: <https://doi.org/10.3390/jcm12227033>
- Kumar Sethi M, Ushashree P. Pharmacovigilance: challenges in India. *J Pharmacovigil*. 2016;04(01). doi: <https://doi.org/10.4172/2329-6887.1000194>
- Public Policy Committee, International Society of Pharmacoepidemiology. Guidelines for good pharmacoepidemiology practice (GPP). *Pharmacoepidemiol Drug Saf*. 2016;25(1):2–10. doi: <https://doi.org/10.1002/pds.3891>
- Bomgni AB, Mbotchack Ngale CE, Aryal S, Nkenlifack MJ, Gadhamshetty V, Etienne Gnimpieba Z. NLPADADE: leveraging natural language processing for automated detection of adverse drug effects. 2023 IEEE International Conference on Bioinformatics and Biomedicine (BIBM), Istanbul, Turkiye; 2023. pp 4480–7. doi: <https://doi.org/10.1109/BIBM58861.2023.10385626>
- Arlett P, Kjaer J, Broich K, Cooke E. Real-world evidence in EU medicines regulation: enabling use and establishing value. *Clin Pharmacol Ther*. 2022;111(1):21–3. doi: <https://doi.org/10.1002/cpt.2479>
- Dikshit RK. Challenges in pharmacovigilance. *Indian J Pharmacol*. 2010;42(6):333. doi: <https://doi.org/10.4103/0253-7613.71882>
- Menang O, Kuemmerle A, Maigetter K, Burri C. Strategies and interventions to strengthen pharmacovigilance systems in low-income and middle-income countries: a scoping review. *BMJ Open*. 2023;13(9):e071079–9. doi: <https://doi.org/10.1136/bmjopen-2022-071079>
- Cave A, Kurz X, Arlett P. Real-world data for regulatory decision making: challenges and possible solutions for Europe. *Clin Pharmacol Ther*. 2019;106(1):36–9. doi: <https://doi.org/10.1002/cpt.1426>
- Wehner MR, Levandoski KA, Kulldorff M, Asgari MM. Research techniques made simple: an introduction to use and analysis of big

- data in dermatology. *J Invest Dermatol.* 2017;137(8):e153–8. doi: <https://doi.org/10.1016/j.jid.2017.04.019>
14. Evans SJW. An agenda for UK clinical pharmacology: pharmacoepidemiology. *Br J Clin Pharmacol.* 2012;73(6):973–8. doi: <https://doi.org/10.1111/j.1365-2125.2012.04248.x>
 15. Bots SH, Brown J, Wong AYS, Martin I, Douglas I, Klungel OH, *et al.* Core concepts: self-controlled designs in pharmacoepidemiology. *Pharmacoepidemiol Drug Saf.* 2025;34(1):e70071. doi: <https://doi.org/10.1002/pds.70071>
 16. Akarowhe K. A case study of pharmacovigilance in Nigeria: challenges and solutions. *Am J Biomed Sci Res.* 2020;10(1):36. doi: <https://doi.org/10.34297/ajbsr.2020.10.001470>
 17. Ward R, Hallinan CM, Ormiston-Smith D, Chidgey C, Boyle D. The OMOP common data model in Australian primary care data: Building a quality research ready harmonised dataset. *PLoS One* 2024;19(4): e0301557. doi: <https://doi.org/10.1371/journal.pone.0301557>
 18. Sabblah GT, Taxis K, Duwiewua M, Seaneke SK, van Puijenbroek E, van Hunsel F. Achieving patient engagement in pharmacovigilance: from high-income countries to lower and -middle-income countries with focus on Africa. *Expert Opin Drug Saf.* 2024;23(12):1493–501. doi: <https://doi.org/10.1080/14740338.2024.2416916>
 19. Bhudeojathe MG, Premdas Jadhao MU, Rode MTA, Chandewar DAV. Pharmacovigilance approaches to herb–drug interaction safety assessment. *Int J Pharm Res Appl.* 2025;10(2):987–94. doi: <https://doi.org/10.35629/4494-1002987994>
 20. Graaf PH, Giacomini KM. COVID-19: a defining moment for clinical pharmacology? *Clin Pharmacol Therapeutics.* 2020;108(1):11–5. doi: <https://doi.org/10.1002/cpt.1876>
 21. Gadhade JS, Hiray RS. Global pharmacovigilance, challenges, and future considerations: West globe and East globe. *JPADR.* 2021;2(2):3. Available from: <https://jpadr.com/index.php/jpadr/article/view/28>
 22. Arlett P, Kjær J, Broich K, Cooke E. Real-world evidence in EU medicines regulation: enabling use and establishing value. *Clin Pharmacol Ther.* 2022;111: 21–23. doi: <https://doi.org/10.1002/cpt.2479>
 23. Sharma A, Kumar A, Akanksha A, Kumar A, Shukla AK, Rajawat DS. Adverse drug reaction (ADR) and pharmacovigilance: a current prospectives. *Int J Pharm Sci Med.* 2023;8(12):36–45. doi: <https://doi.org/10.47760/ijpsm.2023.v08i12.004>
 24. Botsis T, Ball R, Norén GN. Editorial: computational methods and systems to support decision making in pharmacovigilance. *Front Drug Saf Regul.* 2023;3:1188715. doi: <https://doi.org/10.3389/fdsfr.2023.1188715>
 25. Mugada V, Suryadevara V, Cheekurumilli M, Yarguntla S R. Signal detection in pharmacovigilance: Methods, tools, and workflows from case identification to adverse drug reaction database entry. *Przegląd Epidemiologiczny - Epidemiol Rev.* 2025;79(3):404–14. doi: <https://doi.org/10.32394/pe/211665>
 26. Hilmer SN, Gnjidic D, Abernethy DR. Pharmacoepidemiology in the postmarketing assessment of the safety and efficacy of drugs in older adults. *J Gerontol A Biol Sci Med Sci.* 2012;67(2):181–8. doi: <https://doi.org/10.1093/gerona/67.2.181>
 27. Pouessel G, Tournoud C, Gautier S, Nisse P, Tanno LK. Adverse drug reactions from adrenaline auto-injectors: data from the French poison control centres. *Clin Exp Allergy.* 2024;54(6):435–7. doi: <https://doi.org/10.1111/cea.14473>
 28. Diomandé FV, Yaméogo TM, Vannice KS, Preziosi MP, Viviani S, Ouandaogo CR, *et al.* Lessons learned from enhancing vaccine pharmacovigilance activities during PsA-TT introduction in African countries, 2010–2013. *Clin Infect Dis.* 2015;61 (Suppl 5):S459–66. doi: <https://doi.org/10.1093/cid/civ599>
 29. Principi N, Perrone S, Esposito S. Challenges and limitations of current RSV prevention strategies in infants and young children: a narrative review. *Vaccines.* 2025;13(7):717. doi: <https://doi.org/10.3390/vaccines13070717>
 30. Straub L, Wang SV, Hernandez-Diaz S, Bateman BT, Vine SM, Russo M, *et al.* Congenital malformation risk following prenatal antipsychotic exposure: a systematic safety surveillance approach. *BMJ Mental Health.* 2026;29:e302270. doi: <https://doi.org/10.1136/bmjment-2025-302270>

How to cite this article:

Sudha TYS, Babu R, Sasanka KSBSK, Mahato SK, Singh H. Advancing pharmacoepidemiology and pharmacovigilance: A scoping review of challenges, technological innovations, and global strategies for drug safety. *J Appl Pharm Sci.* 2026;16(05):071-082. DOI: 10.7324/JAPS.2026.293371