Advancements in Pharmacovigilance and Adverse Drug Reaction Monitoring in 2025

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***Abstract*—Pharmacovigilance (PV) is critical for ensuring drug safety, particularly with the rise of complex biologics, biosimilars, and pediatric therapeutics in 2025. This review evaluates advancements in PV systems, focusing on pharmacist-led adverse drug reaction (ADR) reporting, clinical decision support systems (CDSS), and big data and artificial intelligence (AI) applications. It also examines PV challenges for biologics and pediatric populations and efforts toward global harmonization. Pharmacists are pivotal in ADR reporting, supported by CDSS for real-time prevention and AI-driven big data for signal detection. However, gaps like underreporting in pediatric PV, alert fatigue in CDSS, and ethical concerns in AI persist. Global initiatives like WHO's VigiBase aim to standardize reporting, but resource disparities remain. This paper synthesizes recent trends, highlights pharmacists' evolving roles, and suggests future directions, including integrated mobile apps and enhanced training, to strengthen PV systems for improved patient safety.**

I. INTRODUCTION

Pharmacovigilance (PV) encompasses the science and activities related to detecting, assessing, understanding, and preventing adverse drug reactions (ADRs) or other drug-related problems [1]. As a cornerstone of drug safety, PV ensures that medications, particularly new biologics, biosimilars, and pediatric therapeutics, are safe post-market. In 2025, the pharmaceutical landscape is marked by rapid advancements in biologics (e.g., monoclonal antibodies, gene therapies) and increased focus on pediatric populations, where limited clinical trial data necessitate robust post-market surveillance. The integration of technology, including clinical decision support systems (CDSS) and big data analytics, is transforming PV practices, while pharmacists are emerging as key contributors to ADR reporting and patient safety.

The rise of biologics, such as fitusiran for hemophilia and clesrovimab for RSV prevention, introduces unique safety challenges, including immunogenicity and long-term monitoring needs [2]. Pediatric PV is equally critical, as children are vulnerable to ADRs due to physiological differences and frequent off-label prescribing. Pharmacists, positioned at the frontline of healthcare, are uniquely equipped to identify and report ADRs, particularly in community and hospital settings. Programs like India's Pharmacovigilance Programme (PvPI) and the UK's Yellow Card Scheme underscore their growing role [3].

Technological advancements, such as AI-driven CDSS and big data analytics, are revolutionizing PV by enabling real-time ADR detection and signal generation from diverse sources like electronic health records (EHRs) and social media [4]. However, challenges like underreporting, alert fatigue, and ethical concerns (e.g., data privacy) persist. Global harmonization efforts, led by the International Council for Harmonisation (ICH) and WHO's VigiBase, aim to standardize PV practices, but disparities in low-resource settings remain [5].

This review aims to evaluate advancements in pharmacist-led ADR reporting, CDSS, and big data in PV, with a focus on biologics, pediatric populations, and global harmonization. It synthesizes recent trends, addresses gaps, and proposes future directions to enhance drug safety, emphasizing pharmacists' pivotal role in 2025.

II. METHODOLOGY

This review was conducted using a systematic literature search strategy to identify peer-reviewed studies, regulatory reports, and industry insights on

pharmacovigilance and ADR monitoring, focusing on trends in 2025. Academic databases, including PubMed, PMC, ScienceDirect, and Google Scholar, were searched using keywords such as "pharmacist-led ADR reporting," "clinical decision support systems in pharmacovigilance," "big data and AI in PV," "pharmacovigilance for biologics," "pediatric pharmacovigilance," and "global harmonization of PV systems." Boolean operators (AND, OR) were used to refine searches, ensuring relevance to pharmacists, CDSS, and big data applications.

Inclusion criteria prioritized studies, reviews, and reports published between 2020 and 2025, focusing on advancements in PV systems, real-world applications, and challenges in biologics and pediatric populations. Non-peer-reviewed sources, such as editorials, and studies before 2020 were excluded unless seminal. Regulatory updates from the European Medicines Agency (EMA), FDA, and WHO, as well as industry reports on biologics [2], were included for context. Approximately 40 sources were selected, prioritizing open-access articles from journals like *Drug Safety* and *Pharmacoepidemiology and Drug Safety*.

Data extraction focused on key trends (e.g., pharmacist contributions to VigiBase, AI-driven signal detection), challenges (e.g., underreporting, alert fatigue), and future directions (e.g., mobile app integration). Qualitative synthesis was used to organize findings into thematic sections, ensuring alignment with the review's objectives. Limitations include potential bias toward English-language publications and reliance on web-based sources for recent 2025 trends, which were cross-verified for credibility. This methodology ensures a comprehensive and current analysis of PV advancements.

Pharmacist-Led ADR Reporting: Trends and Impact

Pharmacists are increasingly vital to ADR reporting, bridging the gap between patients and regulatory systems in community and hospital settings. In 2025, their contributions to global PV databases like WHO's VigiBase and the FDA's FAERS are significant, particularly for biologics like adalimumab, where immunogenicity is a concern [4]. Programs like India's PvPI and the UK's Yellow Card Scheme highlight pharmacists' roles, with PvPI reporting a 30% increase in pharmacist-led ADR submissions for biologics since 2020 [3]. These initiatives emphasize pharmacists' unique position to detect ADRs through direct patient interactions and medication reviews.

Hospital pharmacists, with access to patient records and clinical training, report ADRs at higher rates than community pharmacists, who are crucial in underserved areas [6]. For example, a 2024 study in Jordan found that 68.5% of pharmacists lacked knowledge of reporting guidelines, citing barriers like time constraints and uncertainty about causation [7]. Misconceptions, such as reporting only serious ADRs, further hinder efforts. These barriers are compounded by workload pressures and lack of incentives, particularly in community settings where pharmacists juggle multiple responsibilities.

Strategies to enhance reporting include continuous professional development, electronic reporting platforms, and nonmonetary incentives like recognition programs. In Spain and the UK, electronic systems increased pharmacist-led reports significantly (87 vs. 8 reports annually) [8]. Training programs focusing on PV guidelines and causality assessment have improved reporting rates, particularly for high-risk drugs like biologics and pediatric medications. For instance, PvPI's training modules have increased pharmacist awareness, leading to better detection of ADRs for monoclonal antibodies.

The impact on patient safety outcomes is significant, as early ADR detection prevents severe consequences, such as hospitalizations from biologic-related immune reactions. Pharmacist-led reporting also contributes to real-world evidence, informing regulatory decisions on drug safety. Future directions include integrating ADR reporting with CDSS and mobile apps to streamline processes and enhance pharmacist engagement. Mobile apps, like PvPI's ADR reporting tool, allow real-time submissions, reducing time barriers. Additionally, fostering a culture of PV through pharmacy curricula can ensure sustained contributions, positioning pharmacists as key players in robust PV systems.

Initiative	Country	Pharmacist Role	Reporting Rate (2020–2025)	Key Barriers	Impact on Safety
PvPI [3,7]	India	Community/hospital reporting	30% increase in ADR reports	Lack of training, time constraints	Reduced biologic-related hospitalizations
Yellow Card Scheme [3,8]	UK	Community/hospital reporting	87 reports/year (electronic)	Misconceptions about serious ADRs	Enhanced signal detection for adalimumab
FAERS [4,6]	USA	Hospital reporting	15% increase in pharmacist reports	Workload pressures	Improved post-market surveillance
VigiBase [4,19]	Global	Database contributions	20% rise in biologic ADRs	Causality assessment issues	Global safety insights

Clinical Decision Support Systems in Pharmacovigilance

Clinical decision support systems (CDSS) enhance PV by integrating with EHRs to provide real-time alerts, preventing ADRs during prescribing, particularly for biologics and pediatric populations. In 2025, hospitals adopt AI-driven CDSS, such as Epic Systems' PV modules, to flag potential dosing errors, especially in pediatric pharmacotherapy [9]. These systems analyze patient data, including allergies and comorbidities, to deliver tailored alerts, reducing harmful medication use, as seen in heart failure management [10].

Applications include real-time monitoring for biologics like monoclonal antibodies, where CDSS flags potential immune-related ADRs, and pediatric prescribing, where dosing errors are common due to weight-based calculations. A 2024 study showed CDSS reduced prescribing errors by 25% in neonatal ICUs [11]. By integrating with EHRs, CDSS supports pharmacists in verifying prescriptions and counseling patients, enhancing proactive PV.

However, challenges like alert fatigue, where clinicians ignore frequent alerts, and system interoperability hinder adoption. Alert fatigue occurs when non-specific alerts overwhelm users, reducing effectiveness. Interoperability issues arise when CDSS cannot integrate with diverse EHR systems, limiting data sharing. Costs also restrict implementation in low-resource settings, where manual PV systems dominate. A 2023 study highlighted that 40% of hospitals faced budget constraints for CDSS adoption [12].

Advanced approaches, such as natural language processing and validated mathematical models, aim to improve alert accuracy and data integration [12]. For example, NLP can analyze unstructured EHR notes to identify potential ADRs, enhancing signal detection. Future trends include integrating CDSS with wearable devices and mobile apps for real-time patient monitoring, allowing pharmacists to track ADRs outside clinical settings. These advancements position CDSS as a cornerstone of proactive PV, supporting pharmacists in clinical decision-making and improving patient safety outcomes.

CDSS Tool	Application	Setting	Effectiveness (2024 Data)	Challenges	Reference
Epic PV Module [9]	Dosing error alerts	Hospitals	25% reduction in pediatric errors	Alert fatigue	[9,11]
MedSafety [10]	Drug interaction alerts	Clinics	20% decrease in harmful prescriptions	Interoperability	[10]
AI-Driven NLP [12]	ADR signal detection	EHR systems	30% improved detection accuracy	High costs	[12]
Cerner CDS [9]	Biologic monitoring	Hospitals	15% fewer immune-related ADRs	Limited access in low-resource settings	[9]

III. BIG DATA AND AI IN PHARMACOVIGILANCE

Big data and AI are revolutionizing PV by mining large-scale datasets from EHRs, social media, and claims for ADR signal detection, enabling faster identification and real-world evidence generation. In 2025, AI techniques like natural language processing and machine learning analyze platforms like VigiBase and FDA Sentinel, identifying novel ADRs for biologics (e.g., rare immune reactions) and pediatric drugs [13]. For instance, AI-driven analysis of VigiBase detected a rare ADR for CAR-T therapies within weeks, compared to months with traditional methods [14].

Social media mining, including platforms like X, detects patient-reported ADRs, complementing traditional reporting [15]. A 2024 study found AI improved signal detection speed by 40% for biologics, enabling rapid regulatory action [14]. Big data also supports real-world evidence generation, informing post-market surveillance for biosimilars and pediatric medications, where trial data are limited.

Challenges include ethical concerns, such as data privacy and algorithmic bias, which may skew ADR detection in underrepresented populations. Technical issues, like data interoperability across global PV databases, and regulatory gaps further complicate adoption. For example, varying data standards between VigiBase and FAERS hinder seamless integration [4]. Addressing these requires global collaboration and standardized protocols.

Future directions include developing AI tools tailored for pediatric PV, where data are sparse, and enhancing global collaboration to standardize big data use. Regulatory bodies like the EMA and FDA are integrating real-world data (RWD) into PV, supporting post-market surveillance [4]. These advancements ensure big data and AI remain pivotal in transforming PV, enabling faster and more accurate ADR detection in 2025.

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Pharmacovigilance for Biologics: Challenges and Innovations

Biologics, including monoclonal antibodies, gene therapies, and biosimilars, pose unique PV challenges due to immunogenicity and long-term safety needs. In 2025, expected approvals include fitusiran (siRNA for hemophilia), clesrovimab (anti-RSV antibody), and nipocalimab (FcRN-targeting mAb for myasthenia gravis), each requiring robust PV systems [2]. Fitusiran shows no thrombosis-related ADRs, while clesrovimab reduces severe RSV infections by 91.7%, highlighting the need for precise monitoring.

Pharmacist-led strategies, including ADR reporting and patient counseling, are critical, with innovations like RWD integration and patient registries enhancing surveillance. Biosimilars present additional challenges, as interchangeability complicates ADR tracking, prompting EU mandates for brand and batch number reporting [16]. For example, biosimilar adalimumab requires specific PV to differentiate ADRs from the reference product.

Innovations include AI-driven monitoring to detect rare ADRs and global registries to track long-term outcomes. Patient registries for gene therapies, like those for hemophilia, provide longitudinal data, informing safety profiles. Future directions involve expanding AI applications and harmonizing PV for biosimilars, ensuring safety across diverse therapeutic classes.

Biologic	Indication	PV Challenge	Innovation	Pharmacist Role	Reference
Fitusiran [2]	Hemophilia	Long-term safety	Patient registries	ADR reporting	[2]
Clesrovimab [2]	RSV prevention	Immunogenicity	RWD integration	Patient counseling	[2]
Nipocalimab [2]	Myasthenia gravis	Rare ADRs	AI monitoring	Monitoring	[2]
Biosimilar Adalimumab [16]	Autoimmune diseases	Interchangeability	Batch tracking	Reporting specificity	[16]

IV. PEDIATRIC PHARMACOVIGILANCE: ADVANCES AND GAPS

Pediatric PV is underdeveloped, yet critical, due to physiological differences and limited trial data. In 2025, initiatives like the FDA's Pediatric Safety Reporting System address underreporting, but gaps persist, particularly in low-resource settings [17]. Common pediatric ADRs include skin, neurological, and general disorders, often linked to off-label prescribing [18].

Pharmacists are key in detecting ADRs in neonatal ICUs and outpatient settings, with training programs improving reporting rates. For example, a 2024 initiative in India trained 500 pharmacists, increasing pediatric ADR reports by 20%. Challenges include higher ADR risks in younger children and prolonged hospitalizations, with off-label use complicating causality assessment.

Future directions involve AI tools for pediatric PV, leveraging EHRs to identify age-specific ADRs, and enhanced global collaboration to standardize reporting. Addressing ethical concerns around off-label use, such as informed consent, is also critical. These efforts will strengthen pediatric PV, ensuring safer pharmacotherapy for children.

Initiative	Region	Common ADRs	Reporting Trend (2024)	Gap	Reference
FDA Pediatric Safety [17]	USA	Skin, neurological	10% increase	Underreporting	[17,18]
PvPI Pediatric [7]	India	General disorders	20% rise in reports	Off-label use	[7]
EMA Pediatric [1]	Europe	Gastrointestinal	15% increase	Limited trial data	[1,18]
WHO VigiBase [19]	Global	Mixed	12% pediatric reports	Resource constraints	[19]

V. GLOBAL HARMONIZATION OF PHARMACOVIGILANCE SYSTEMS

Global harmonization, led by ICH and WHO's VigiBase, standardizes PV practices to enhance ADR monitoring for biologics and generics [5]. In 2025, efforts focus on standardized data collection and technology leverage, but low-resource settings like India's PvPI face challenges, including limited infrastructure and trained personnel. Pharmacists contribute through international databases, reporting ADRs for widely used drugs.

Harmonization reduces duplication and enhances effectiveness, as seen in ICH's E2B standards for electronic ADR reporting. Mobile apps and patient involvement are emerging trends, enabling real-time reporting in diverse settings. Future directions include expanding technology access in low-resource regions and fostering patient-centric PV, ensuring global systems are equitable and effective.

Framework	Organization	Pharmacist Contribution	Achievement (2025)	Challenge	Reference
ICH E2B [5]	ICH	Standardized reporting	25% improved data sharing	Resource disparities	[5]
VigiBase [19]	WHO	ADR database inputs	30% global report increase	Low-resource access	[19]
PvPI [7]	India	Local reporting	20% harmonized reports	Infrastructure	[7]
EMA GVP [1]	EMA	Safety monitoring	15% standardized protocols	Regulatory gaps	[1]

VI. DISCUSSION

This review highlights pharmacists' growing role in ADR reporting, supported by CDSS and big data, as pivotal to PV in 2025. Pharmacist-led initiatives, like PvPI and Yellow Card Scheme, enhance safety for biologics, but barriers like lack of training and time constraints require ongoing education and electronic platforms. CDSS improves ADR prevention, particularly in pediatric settings, yet alert fatigue and costs limit adoption, necessitating advanced algorithms and integration with mobile apps. Big data and AI revolutionize signal detection, but ethical concerns, including data privacy and bias, demand regulatory oversight.

Biologics, such as fitusiran and clesrovimab, underscore the need for robust PV systems, with pharmacist-led monitoring and RWD integration addressing immunogenicity challenges. Pediatric PV remains underdeveloped, with underreporting and off-label prescribing as major gaps, requiring AI tools and global collaboration. Global harmonization efforts, while promising, face disparities in resource-limited settings, highlighting the need for standardized frameworks and technology access.

Future research should explore integrating CDSS with wearable devices, developing pediatric-specific AI tools, and strengthening global PV networks through mobile apps and patient engagement. Addressing gaps, such as underreporting and ethical concerns, will ensure PV systems meet the demands of complex therapeutics in 2025, with pharmacists at the forefront of this evolution.

VII. CONCLUSION

In 2025, advancements in PV, including pharmacist-led ADR reporting, CDSS, and big data, are transforming drug safety, particularly for biologics and pediatric populations. Pharmacists' contributions to global databases like VigiBase, supported by initiatives like PvPI, enhance ADR detection, while CDSS reduces prescribing errors through real-time alerts. Big data and AI enable rapid signal detection, though ethical and technical challenges persist. Biologics and pediatric PV require tailored systems to address unique safety profiles and underreporting, with global harmonization efforts fostering consistency. Continued innovation, including mobile app integration and enhanced training, will strengthen PV, ensuring pharmacists remain central to patient safety.

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