International Journal of Pharmaceutical Research and Applications
Volume 10, Issue 4 July-Aug 2025, pp: 883-884 www.ijprajournal.com ISSN: 2456-4494

Current Perspectives and Barriers in Pharmacovigilance: Implications for Pharmacy Practice

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Date of Submission: 15-08-2025 Date of Acceptance: 25-08-2025

ABSTRACT
Pharmacovigilance (PV) is critical for identifying, assessing, and preventing adverse drug reactions (ADRs), which significantly burden global healthcare systems. India's Pharmacovigilance Programme of India (PvPI) serves as the primary mechanism for drug safety monitoring. Recent developments include the integration of electronic health records, artificial intelligence (AI) for signal detection, patient-reporting platforms, and social media surveillance. Nonetheless, persistent challenges such as under-reporting, inadequate training, resource limitations, and low awareness continue to impede optimal PV implementation [1–3]. Pharmacists, with their specialized knowledge, are uniquely positioned to improve PV through detection, reporting, and patient counseling. This review evaluates technological advancements, discusses pharmacists' roles, identifies challenges, and proposes strategies for strengthening PV systems. Enhanced pharmacist engagement and technology adoption hold promise for improved medication safety and public confidence.

I. INTRODUCTION

Pharmacovigilance is defined by WHO as the 'science and activities related to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem' [1]. ADRs are a significant global health concern, contributing to hospital admissions, morbidity, and escalating healthcare costs [4]. India established the Pharmacovigilance Programme of India (PvPI) in 2010 to centralize ADR reporting and enhance patient safety [5]. Pharmacists are central to this initiative due to their expertise in therapeutic management and patient interaction [6].

II. EVOLUTION AND REGULATORY FRAMEWORK OF PV

The WHO's Programme for International Drug Monitoring and its global ADR database, VigiBase, are coordinated by the Uppsala Monitoring Centre (UMC) [7]. Regulatory frameworks such as the FDA's MedWatch and EMA's EudraVigilance underpin ADR reporting in Western settings [8]. PvPI operates through ADR Monitoring Centers (AMCs), leveraging the Vigiflow platform for data collection and analysis [5]. The Drugs and Cosmetics Act mandates pharmaceutical companies to have pharmacovigilance systems in place, including reporting obligations for vaccines, under CDSCO guidance [9]

III. EMERGING TRENDS IN PHARMACOVIGILANCE

3.1 Active Surveillance: PV is shifting from passive, spontaneous reporting to structured, active surveillance methods like cohort event monitoring [10].

3.2 Digital Integration: Electronic Health Records (EHRs) are being integrated into PV systems to enable real-time ADR monitoring, reducing detection time and enhancing data precision [11].

3.3 Artificial Intelligence Applications: AI automates case processing, data mining, and signal detection. Advances include deep learning and NLP techniques to analyze unstructured data efficiently [2,12].

3.4 Patient Reporting & Social Media: Mobile apps and social media platforms are increasingly being leveraged to collect ADR reports from patients, supplementing traditional channels [13].

3.5 Pharmacogenomics: Tools like PharmGKB support personalized PV practices by tailoring drug safety based on genetic profiles, reducing ADR risk [14].

IV. ROLE OF PHARMACISTS IN PV

Hospital Pharmacists review medication regimens, detect ADR patterns, and coordinate spontaneous reporting.

Community Pharmacists identify ADRs related to OTC medications, herbal products, and provide safety counseling.

Academic Pharmacists integrate PV education into curricula and train future pharmacists.

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Telepharmacy extends PV services to remote and underserved areas, improving access and ADR reporting [15].

V. CHALLENGES IN PV IMPLEMENTATION

Under-reporting, especially in India, remains a major barrier due to lack of awareness and infrastructure [10].

Limited awareness among healthcare professionals leads to under-utilization of reporting systems [5].

Resource constraints impair functionality in low-resource settings.

Concerns about confidentiality and legal repercussions deter reporting.

Low patient engagement—many patients do not recognize ADRs or understand reporting mechanisms [13].

VI. STRENGTHENING PV SYSTEMS

Education & Training: Regular workshops and continuous professional development in PV practices.

Recognition & Incentives: Programs to acknowledge consistent ADR reporters.

Public Awareness Campaigns: Empower patients to participate in ADR reporting.

Regulatory–Academic Collaboration: Joint initiatives to strengthen PV infrastructure and culture.

Integration into Routine Pharmacy Practice: Making ADR reporting a standard operational activity.

VII. FUTURE OUTLOOK

The convergence of big data, AI, EHRs, and standardized global frameworks will further transform PV. Sustainable pharmacist involvement and global harmonization are vital to building resilient drug safety ecosystems.

VIII. CONCLUSION

Pharmacovigilance is fundamental to safeguarding patients from medication hazards. While technological innovations offer new potential, persistent barriers such as under-reporting and low awareness must be addressed. With proactive pharmacist engagement, strategic interventions, and robust training, PV systems can evolve to deliver safer, more reliable healthcare.

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