IJCRT.ORG ISSN : 2320-2882

INTERNATIONAL JOURNAL OF CREATIVE RESEARCH THOUGHTS (IJCRT)

An International Open Access, Peer-reviewed, Refereed Journal

# Role Of Pharmacists In Pharmacovigilance And Adverse Drug Reaction Monitoring: A Comprehensive Review

*Nandani Jaiswal, Manvendra Dubey, Mohd. Zainul, Mridul Mayank Upadhyay, Mohd. Kaif, Pawan Kumar Pandey*, Department of Pharmacy, Institute of Technology and Management, GIDA, Gorakhpur, Uttar Pradesh, India 273209*

*Corresponding author: Dr. Pawan Kumar Pandey, Ph.D. (Pharmaceutical Chemistry), Department of Pharmacy, Institute of Technology and Management, GIDA, Gorakhpur, Uttar Pradesh, India 273209,*

## Abstract

**Background:** Adverse drug reactions (ADRs) constitute a significant public health challenge, contributing to substantial morbidity, mortality, and healthcare expenditure worldwide. Pharmacovigilance — the science and activities associated with the detection, assessment, understanding, and prevention of adverse effects of medicines — is essential to ensuring medication safety throughout the drug life cycle. Pharmacists, by virtue of their specialised training, accessibility, and continuous patient interaction, occupy a uniquely strategic position within pharmacovigilance systems.

**Objective:** This review aims to comprehensively examine the multidimensional roles of pharmacists in pharmacovigilance and ADR monitoring across diverse practice settings, evaluate existing challenges, and propose evidence-based strategies to strengthen pharmacist engagement in drug safety surveillance.

**Methods:** A narrative review of published literature was conducted using PubMed, Scopus, EMBASE, and Google Scholar databases. Studies, systematic reviews, guidelines, and policy documents published between 2000 and 2024 were included.

**Results:** Pharmacists play central roles in ADR detection, causality assessment, spontaneous reporting, patient education, medication review, and interprofessional collaboration. However, persistent barriers — including under-reporting, insufficient training, workload constraints, and inadequate regulatory feedback — continue to limit full pharmacist integration into pharmacovigilance systems. Emerging digital tools and structured reporting frameworks offer promising avenues to overcome these gaps.

**Conclusion:** Strengthening pharmacist engagement in pharmacovigilance requires coordinated efforts across educational institutions, healthcare systems, and regulatory authorities. Recognising pharmacists as indispensable pharmacovigilance practitioners is essential for building resilient drug safety ecosystems.

**Keywords:** Pharmacovigilance, adverse drug reactions, pharmacist, drug safety, spontaneous reporting, medication safety, ADR monitoring

1. Introduction

Adverse drug reactions represent one of the most consequential yet preventable challenges facing modern healthcare systems. Globally, ADRs account for approximately 5 to 10 percent of hospital admissions, with some estimates suggesting that drug-related harms are among the leading causes of death in high-income countries.1,2 The World Health Organization (WHO) defines an ADR as a response to a drug that is noxious and unintended and occurs at doses normally used in humans for prophylaxis, diagnosis, or therapy of disease, or for modification of physiological function.3 The clinical and economic burden is substantial: in the United States alone, ADR-related hospitalisations are estimated to cost several billion dollars annually, while in low- and middle-income countries (LMICs) the impact is often magnified by limited pharmacovigilance infrastructure.4

Pharmacovigilance, as defined by the WHO, encompasses the science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problem.5 Since the establishment of the WHO Programme for International Drug Monitoring in 1968, following the thalidomide tragedy of the early 1960s, pharmacovigilance has evolved from a reactive discipline focused on post-marketing surveillance into a proactive, multidisciplinary science integrated across the drug life cycle.6 Contemporary pharmacovigilance extends beyond licensed medicines to encompass vaccines, herbal products, medical devices, and biological therapies.

Within this landscape, pharmacists occupy a pivotal and often underappreciated role. As the most accessible healthcare professionals in many settings — particularly community pharmacy — pharmacists are frequently the first point of contact for patients experiencing drug-related problems.7 Their dual expertise in pharmacology and patient care positions them uniquely to identify, document, and report ADRs, counsel patients on medication safety, and contribute substantively to multidisciplinary pharmacovigilance efforts. Despite this, studies consistently demonstrate that pharmacist participation in spontaneous ADR reporting remains disproportionately low relative to physicians and other healthcare professionals.8

This review synthesises evidence on the current and potential roles of pharmacists in pharmacovigilance, examines barriers to effective participation, and discusses strategies and emerging technologies that may enhance pharmacist-led drug safety surveillance. The review is intended to serve as a resource for clinicians, educators, policymakers, and pharmacists seeking to strengthen medication safety practice.

## 2. Global and Regulatory Frameworks of Pharmacovigilance

The global architecture of pharmacovigilance is anchored by the WHO Programme for International Drug Monitoring, coordinated through the Uppsala Monitoring Centre (UMC) in Sweden. Currently, more than 170 countries participate in this programme, contributing spontaneous ADR reports to the VigiBase — the WHO global database of individual case safety reports, which now contains over 30 million entries.9 The programme facilitates signal detection, regulatory decision-making, and international collaboration on drug safety.

Regional regulatory bodies — including the European Medicines Agency (EMA), the United States Food and Drug Administration (FDA), and the Medicines and Healthcare products Regulatory Agency (MHRA) in the United Kingdom — have developed sophisticated national pharmacovigilance systems. The EudraVigilance database and the FDA Adverse Event Reporting System (FAERS) receive millions of reports annually, forming the backbone of post-marketing drug safety evaluation in their respective jurisdictions.10 The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) has further standardised pharmacovigilance through guidelines such as ICH E2A (clinical safety data management) and ICH E2E (pharmacovigilance planning).

In India, the Pharmacovigilance Programme of India (PvPI), launched in 2010 and coordinated by the Indian Pharmacopoeia Commission (IPC), represents a landmark national initiative. Operating through a network of adverse drug reaction monitoring centres (AMCs) across the country, PvPI aims to collect,

analyse, and act on ADR data to protect public health.11 Pharmacists are formally recognised as key reporters within this system, although participation rates among community and hospital pharmacists remain suboptimal.

The legal frameworks underpinning pharmacovigilance vary substantially across jurisdictions. In the European Union, Regulation (EC) No 726/2004 and Directive 2010/84/EU mandate pharmacovigilance obligations for marketing authorisation holders and extend reporting responsibilities to healthcare professionals, including pharmacists. In the United States, MedWatch serves as the FDA's voluntary reporting programme for healthcare practitioners and patients. Understanding these frameworks is essential for pharmacists who wish to contribute effectively to drug safety systems in their respective countries.

## 3. Classification and Epidemiology of Adverse Drug Reactions

The classification of ADRs has evolved considerably since Rawlins and Thompson introduced the Type A (augmented, dose-dependent) and Type B (bizarre, dose-independent) distinction in 1977. Contemporary frameworks extend to include Type C (chronic effects), Type D (delayed effects), Type E (end-of-use effects), and Type F (failure of therapy), providing a more nuanced understanding of the mechanisms and temporal patterns of drug harm.12 This expanded taxonomy has direct implications for pharmacovigilance, guiding both detection strategies and clinical management.

Epidemiologically, ADRs represent a major burden across healthcare settings. A landmark meta-analysis by Lazarou and colleagues estimated that ADRs were responsible for over 100,000 deaths annually in the United States alone, making them one of the leading causes of mortality.1 More recent systematic reviews have confirmed that ADRs account for 5 to 7 percent of hospital admissions in high-income countries, with older adults and patients on polypharmacy regimens being particularly vulnerable.13

High-alert medications — including anticoagulants (warfarin, direct oral anticoagulants), non-steroidal anti-inflammatory drugs (NSAIDs), antidiabetic agents (sulfonylureas, insulin), antiepileptics, cytotoxic chemotherapy, and narrow therapeutic index drugs such as digoxin and lithium — disproportionately contribute to preventable ADRs.14 Pharmacists, through their expertise in pharmacokinetics, drug interactions, and therapeutic drug monitoring, are particularly well positioned to identify and mitigate ADR risk in patients on these agents.

Special populations present heightened ADR risk. Elderly patients experience pharmacokinetic alterations — reduced renal clearance, altered hepatic metabolism, decreased protein binding — alongside pharmacodynamic changes, increasing susceptibility to drug toxicity.15 Similarly, paediatric patients present unique challenges due to off-label prescribing and weight-based dosing variability. Patients with renal or hepatic impairment require careful dose adjustment to prevent accumulation and toxicity. Pharmacists' capacity to identify these risk factors during dispensing and medication review constitutes a vital safeguard.

## 4. Core Roles of Pharmacists in Pharmacovigilance

### 4.1 Detection and Recognition of Adverse Drug Reactions

The detection of ADRs is foundational to pharmacovigilance, and pharmacists are strategically positioned to identify drug-related harms during routine professional activities. During dispensing, medication review, and patient counselling, pharmacists can recognise temporal associations between drug initiation and symptom onset, identify known ADR profiles from drug information resources, and apply structured clinical reasoning to assess causality.7

Causality assessment — determining the likelihood that a drug caused an observed adverse event — is a core pharmacovigilance competency. Pharmacists routinely utilise validated tools such as the Naranjo Algorithm and WHO-UMC criteria to systematically evaluate drug-event relationships. These instruments assess factors including timing, dechallenge (resolution upon drug withdrawal), rechallenge (recurrence upon

re-administration), and the availability of alternative explanations.16 Table 1 summarises the principal causality assessment tools available to practising pharmacists.

**Table 1. Causality Assessment Tools Used in Clinical Practice**

| Tool | Categories | Utility in Practice |
|---|---|---|
| Naranjo Algorithm | Definite, Probable, Possible, Doubtful | Widely used; 10-question scoring system; suitable for hospital settings |
| WHO-UMC Criteria | Certain, Probable/Likely, Possible, Unlikely, Conditional/Unclassified, Unassessable | Global standard; used by national pharmacovigilance centres; flexible for complex cases |
| Adverse Drug Reaction Probability Scale (ADRPS) | Score-based grading | Useful for clinical research and comparative studies |

Beyond these formal tools, pharmacists in clinical settings contribute to severity assessment of ADRs, applying grading systems such as the Common Terminology Criteria for Adverse Events (CTCAE) — widely used in oncology — to quantify the clinical significance of drug-related harms and guide management decisions.

## 4.2 Spontaneous ADR Reporting

Spontaneous reporting systems (SRS) constitute the cornerstone of post-marketing pharmacovigilance globally. These systems rely on voluntary submissions of individual case safety reports (ICSRs) by healthcare professionals and patients to national pharmacovigilance centres and regulatory authorities. Despite the well-documented problem of under-reporting — with estimates suggesting that fewer than 10 percent of serious ADRs are ever formally reported — spontaneous reports remain invaluable for signal detection, particularly for rare or unexpected adverse events not identified during pre-marketing clinical trials.17

Pharmacists have a critical contribution to make to spontaneous reporting systems. Studies from high-income countries suggest that pharmacists, despite their accessibility and patient interaction, contribute a relatively small proportion of ADR reports compared with physicians.8 A systematic review by Lopez-Gonzalez and colleagues found that healthcare professional reporting rates vary considerably across countries and specialties, with pharmacists consistently under-represented relative to their potential for ADR detection.18

Barriers to pharmacist reporting are multifactorial. Frequently cited obstacles include insufficient knowledge of what constitutes a reportable ADR, uncertainty about causality, fear of blame or medicolegal consequences, administrative burden, time constraints, and a perception that ADR reporting is not within the pharmacist's primary professional responsibility.19 Cultural factors, particularly in hierarchical healthcare systems where reporting is perceived as a physician's prerogative, further compound under-reporting.

Evidence-based interventions to improve pharmacist reporting include structured educational programmes on pharmacovigilance principles, simplification of reporting forms, integration of reporting tools into pharmacy dispensing software and electronic health records (EHRs), regular feedback from regulatory authorities on the outcomes of submitted reports, and professional recognition of ADR reporting as a quality indicator.20 Countries such as the United Kingdom — through the Yellow Card scheme — and the Netherlands have demonstrated that targeted campaigns and pharmacist-specific reporting incentives can substantially increase ADR submissions from community pharmacists.

### 4.3 Patient Counselling and Education

Patient education represents one of the most impactful yet often underutilised pharmacovigilance functions of pharmacists. Effective patient counselling on medication risks can empower individuals to self-monitor for drug-related harms, report symptoms promptly, and make informed decisions regarding their treatment.21 Pharmacists are well placed to translate complex pharmacological risk information into accessible, patient-centred language — a competency increasingly recognised in quality use of medicines frameworks globally.

At the point of dispensing, pharmacists can inform patients about the most common and clinically significant ADRs associated with their medications, identify early warning signs warranting urgent medical attention, and provide clear instructions on what to do if an ADR is suspected. For high-risk medications — such as anticoagulants, immunosuppressants, antiepileptics, and chemotherapeutic agents — detailed counselling sessions with written materials are warranted. Studies have demonstrated that pharmacist-led medication counselling improves patient adherence, reduces preventable ADR-related emergency department visits, and enhances patient confidence in managing their medicines.22

Medication reconciliation — the process of comparing a patient's medication orders to all the medications the patient has been taking — is another domain where pharmacists contribute substantially to ADR prevention. Medication discrepancies, including omissions, duplications, and incorrect doses, are a leading cause of preventable ADRs, particularly at care transitions (hospital admission, discharge, transfer).23 Pharmacist-led reconciliation programmes have been shown to significantly reduce medication-related harm in both hospital and community settings.

### 4.4 Medication Review and Polypharmacy Management

The global epidemic of polypharmacy — defined variably as the concurrent use of five or more medications — poses an escalating ADR risk, particularly among older adults. Polypharmacy is associated with increased risk of drug-drug interactions, drug-disease interactions, prescribing cascades, and non-adherence.24 Pharmacist-led comprehensive medication reviews (CMRs) represent a structured, evidence-based approach to identifying and resolving drug-related problems in this population.

Deprescribing — the planned, supervised reduction or discontinuation of medications that are no longer beneficial or are potentially harmful — has emerged as a key pharmacist-led strategy for ADR risk reduction. Tools such as the Beers Criteria, the STOPP/START criteria, and the Medication Appropriateness Index provide pharmacists with validated frameworks for identifying inappropriate prescribing in older patients.25 Pharmacist participation in geriatric medication review teams has been associated with significant reductions in falls, hospitalisations, and ADR-related harms in this vulnerable population.

## 5. Pharmacists in Different Practice Settings

The pharmacist's pharmacovigilance contribution is shaped substantially by the practice setting, each of which presents distinct patient populations, clinical challenges, and surveillance opportunities. Table 2 provides an overview of key pharmacovigilance activities across major pharmacy practice settings.

**Table 2. Pharmacist Roles in Pharmacovigilance Across Practice Settings**

| Setting | Key Pharmacovigilance Activities |
|---|---|
| **Community Pharmacy** | First-line identification of ADRs; spontaneous reporting; patient counselling on OTC medications and supplements; medication reconciliation; public health campaigns. |
| **Hospital Pharmacy** | Active inpatient ADR surveillance; drug information services; contribution to hospital PV committees; therapeutic drug monitoring (TDM); detection of ADRs during dispensing verification. |
| **Clinical Pharmacy** | Ward-based rounds; real-time ADR documentation in electronic health records; polypharmacy reviews; participation in multidisciplinary treatment decisions. |
| **Regulatory / Industry** | Signal detection from spontaneous reports; post-marketing safety database management; preparation of Periodic Benefit-Risk Evaluation Reports (PBRERs); risk minimisation activities. |
| **Primary Care / Outpatient** | Chronic disease medication monitoring; adherence support; deprescribing in elderly patients; proactive high-alert drug safety monitoring. |

## 5.1 Community Pharmacy

Community pharmacists represent the most accessible healthcare professionals in most healthcare systems, engaging daily with patients managing chronic conditions, acute illnesses, and self-medication with over-the-counter (OTC) products. This accessibility positions community pharmacists as the frontline of pharmacovigilance for the ambulatory population. Studies from the United Kingdom, Australia, and Nordic countries have demonstrated the feasibility and value of structured ADR reporting programmes integrated into community pharmacy practice.26 Community pharmacists are particularly well positioned to monitor ADRs associated with OTC medications, herbal products, and nutritional supplements — a pharmacovigilance gap often overlooked by formal systems focused on prescription medicines.

## 5.2 Hospital Pharmacy

Hospital pharmacists operate within complex, high-acuity clinical environments characterised by critically ill patients, intensive polypharmacy, and frequent medication changes. This context creates both heightened ADR risk and rich opportunities for detection and reporting. Hospital pharmacovigilance programmes — including active ADR surveillance through pharmacy chart review, clinical decision support alerts in dispensing systems, and formal ADR reporting committees — have demonstrated effectiveness in capturing ADR signals that might otherwise be missed.27 Hospital pharmacists also play a critical role in therapeutic drug monitoring (TDM) for narrow therapeutic index drugs, adjusting doses to maintain efficacy while minimising toxicity.

## 5.3 Clinical and Ward-Based Pharmacy

The integration of clinical pharmacists into inpatient multidisciplinary teams has significantly enhanced real-time pharmacovigilance capacity. Clinical pharmacists conduct daily medication reviews during ward rounds, identifying potential ADRs, drug interactions, and prescribing errors before they cause patient harm. Their direct involvement in patient care facilitates nuanced causality assessment and promotes a culture of medication safety within clinical teams. Randomised controlled trials have demonstrated that clinical pharmacist participation in medical rounds significantly reduces preventable ADRs, medication errors, and associated healthcare costs.28

### 5.4 Regulatory and Industry Pharmacy

Pharmacists working in regulatory agencies and the pharmaceutical industry occupy a distinct but equally critical pharmacovigilance role. Industry pharmacovigilance pharmacists are responsible for processing and evaluating individual case safety reports from global sources, conducting signal detection analyses on pharmacovigilance databases, preparing periodic safety reports for regulatory submission, and developing risk management plans (RMPs) for approved medicines.29 These professionals bridge clinical pharmacology and regulatory science, ensuring that emerging safety signals are identified, communicated, and acted upon efficiently.

## 6. Technology and Digital Tools in Pharmacovigilance

Rapid advances in health information technology are transforming the pharmacovigilance landscape, offering pharmacists powerful new tools for ADR detection, reporting, and analysis. Electronic health records (EHRs) equipped with clinical decision support systems (CDSS) can automatically flag potential ADRs based on predefined triggers — such as the prescription of an antidote, unexpected laboratory results, or the addition of a drug known to counteract a medication side effect.30 These automated surveillance systems, sometimes termed 'trigger tools', substantially increase ADR detection sensitivity compared with traditional voluntary reporting alone.

Mobile health (mHealth) applications have emerged as accessible platforms for ADR reporting by both healthcare professionals and patients. National regulatory agencies, including the UK's MHRA (Yellow Card app) and the European Medicines Agency (EU ADR app), have developed dedicated mobile reporting tools that simplify the submission process, potentially reducing reporting barriers for busy practitioners.31 Patient-initiated ADR reporting through these platforms has been shown to generate clinically valuable, complementary safety signals distinct from professional reports.

Pharmacovigilance databases — including the WHO's VigiBase, the FDA's FAERS, and the EMA's EudraVigilance — are increasingly analysed using advanced statistical methods for signal detection. Disproportionality analysis methods, such as the reporting odds ratio (ROR) and the information component (IC), identify drug-event combinations that occur more frequently than expected by chance, forming the basis of regulatory signal review.32 Pharmacists with training in pharmacoepidemiology are well positioned to contribute to these analytical processes, both in regulatory settings and in academic research.

Artificial intelligence (AI) and machine learning (ML) are increasingly being applied to pharmacovigilance, with algorithms developed to mine narrative text from electronic records, social media, and scientific literature for ADR signals. Natural language processing (NLP) tools can extract drug-event relationships from clinical notes at scale, supplementing traditional reporting systems.33 While these technologies hold considerable promise, their integration into routine pharmacovigilance practice requires rigorous validation and appropriate regulatory oversight — areas where pharmacist expertise in clinical informatics is increasingly valued.

## 7. Interprofessional Collaboration in Pharmacovigilance

Effective pharmacovigilance is fundamentally a team activity, requiring seamless collaboration among pharmacists, physicians, nurses, regulatory scientists, and patient advocates. Pharmacists contribute to this collaborative endeavour through membership of hospital ADR and medication safety committees, participation in multidisciplinary clinical rounds, engagement with national pharmacovigilance centre networks, and collaboration with academic researchers on pharmacoepidemiology studies.34

The pharmacist-physician relationship is of particular importance in clinical pharmacovigilance. Clear communication frameworks, including structured handover tools and standardised ADR documentation practices, facilitate the timely sharing of drug safety information within care teams. Evidence

suggests that pharmacist-physician collaboration in medication review and ADR assessment improves the quality of causality determination and increases the likelihood of formal ADR reporting.35

International collaborative networks, such as the International Pharmaceutical Federation (FIP) Pharmacy Practice Research Network and the European Association of Hospital Pharmacists (EAHP), provide platforms for pharmacists to share pharmacovigilance knowledge, benchmark practice, and advocate for the formal recognition of pharmacist contributions to drug safety systems. These professional bodies have increasingly emphasised pharmacovigilance as a core pharmacy competency in their strategic frameworks.

## 8. Education and Training in Pharmacovigilance

Despite the recognised importance of pharmacovigilance, its integration into pharmacy curricula remains inconsistent across countries and institutions. A global survey of pharmacy schools found substantial variation in the depth and breadth of pharmacovigilance education, with many programmes offering limited dedicated instruction on ADR detection, causality assessment, and reporting obligations.36 This educational gap translates directly into inadequate pharmacist engagement with real-world pharmacovigilance activities.

Core pharmacovigilance competencies for pharmacy graduates should encompass: foundational knowledge of ADR classification, epidemiology, and mechanisms; familiarity with national and international reporting systems; proficiency in validated causality assessment tools; skills in patient counselling on medication risks; and awareness of the ethical dimensions of ADR reporting.37 Problem-based learning, clinical simulation, and case-based teaching have been identified as effective pedagogical approaches for developing these competencies in undergraduate and postgraduate pharmacy programmes.

Continuing professional development (CPD) in pharmacovigilance is equally important for practising pharmacists. Structured CPD modules, webinars offered by national pharmacovigilance centres, and interprofessional workshops provide opportunities for practising pharmacists to update their knowledge and skills in response to evolving regulatory requirements and emerging drug safety challenges. Countries including India — through PvPI's capacity-building initiatives — have demonstrated the feasibility of national pharmacovigilance training programmes targeted at practising pharmacists.11

## 9. Challenges and Barriers to Pharmacist Engagement

Notwithstanding the acknowledged importance of pharmacist participation in pharmacovigilance, persistent barriers continue to limit effective engagement across practice settings. Understanding these barriers is a prerequisite for designing targeted interventions.

Under-reporting remains the most pervasive challenge in spontaneous pharmacovigilance systems globally. It is estimated that fewer than 10 percent of serious ADRs are formally reported, with rates potentially as low as 1 to 2 percent in some contexts.17 For pharmacists specifically, surveys have identified the following as the most frequently cited barriers: uncertainty about whether an event constitutes an ADR; lack of awareness of national reporting systems; insufficient time in busy practice environments; absence of feedback from regulatory authorities on submitted reports; concerns about legal liability; and a prevailing perception that ADR reporting is primarily a physician responsibility.19

Structural barriers within healthcare organisations — including inadequate access to patient medical records in community pharmacy settings, lack of standardised pharmacovigilance protocols, and absence of dedicated time for ADR reporting — further impede pharmacist participation. In resource-limited settings, additional challenges include poor infrastructure, shortage of trained personnel, and limited digital connectivity for online reporting.38

Attitudinal barriers are equally significant. A culture of blame — where ADR reporting is perceived as an admission of error rather than a contribution to collective safety knowledge — discourages reporting by all healthcare professionals, including pharmacists. Cultivating a just culture that celebrates drug safety

reporting as a professional and ethical responsibility is essential to sustainable improvement in pharmacovigilance participation.39

## 10. Strategies to Enhance Pharmacist Participation in Pharmacovigilance

A range of evidence-based strategies have been proposed and, in some jurisdictions, successfully implemented to increase pharmacist engagement in pharmacovigilance. These approaches operate at individual, organisational, and systemic levels.

At the individual level, targeted pharmacovigilance education — during undergraduate training and through CPD — significantly improves pharmacists' knowledge, attitudes, and reporting behaviour. Randomised educational interventions have demonstrated that structured training on ADR detection and reporting increases pharmacist reporting rates in both hospital and community settings.40

At the organisational level, integration of pharmacovigilance activities into routine pharmacy workflows — including standardised ADR documentation in dispensing systems, protected time for ADR assessment, and formal pharmacovigilance roles within pharmacy departments — normalises drug safety reporting as part of professional practice. Hospital pharmacovigilance programmes that provide feedback to reporting pharmacists — including information on how their reports contributed to regulatory actions or formulary changes — have been particularly effective in sustaining reporting motivation.41

At the systemic level, regulatory agencies can incentivise pharmacist reporting through streamlined reporting forms, mobile reporting applications, dedicated helplines, and public recognition of exemplary pharmacovigilance contributions. Mandatory pharmacovigilance reporting frameworks — as implemented in some European countries — have demonstrated measurable increases in report volumes, although voluntary systems with adequate support may yield reports of superior quality.42 Legislative changes formally recognising pharmacists as primary reporters within national pharmacovigilance systems — alongside physicians and nurses — are also important for driving cultural and institutional change.

## 11. Special Topics in Pharmacovigilance

### 11.1 Vaccine Pharmacovigilance

The COVID-19 pandemic powerfully demonstrated the critical importance of robust vaccine safety surveillance. Pharmacists, increasingly involved in vaccine administration globally, are now recognised as important contributors to vaccine pharmacovigilance. Adverse events following immunisation (AEFIs) must be distinguished from coincidental illness through careful temporal and clinical assessment — a skill directly relevant to pharmacists' existing ADR assessment competencies.43 National immunisation programmes in countries including Australia, Canada, and India have incorporated pharmacists as frontline reporters of vaccine adverse events, with dedicated surveillance systems established to capture safety signals in near-real time.

### 11.2 Herbal Medicines and Supplement Safety

Adverse reactions to herbal medicines, dietary supplements, and traditional medicines represent a significant and frequently underappreciated pharmacovigilance challenge. Patients often perceive these products as inherently safe, and seldom volunteer information about their use to healthcare providers. Pharmacists, who are consulted frequently about OTC products, are uniquely positioned to counsel patients on herb-drug interactions, identify potential supplement-related ADRs, and report these events to national pharmacovigilance programmes.44 WHO guidelines on safety monitoring of herbal medicines provide a framework for pharmacist engagement with this important pharmacovigilance gap.

### 11.3 Pharmacovigilance in Low- and Middle-Income Countries

The pharmacovigilance burden in LMICs is disproportionate to available resources. Limited surveillance infrastructure, inadequate regulatory capacity, and a relative shortage of trained pharmacovigilance professionals create significant vulnerabilities in drug safety systems in these settings.45 Pharmacists in LMICs — often the sole healthcare professional accessible to large rural populations — are therefore particularly important pharmacovigilance practitioners. International capacity-building initiatives, including those supported by WHO, the Bill and Melinda Gates Foundation, and the African Medicines Regulatory Harmonisation (AMRH) programme, have sought to strengthen pharmacist pharmacovigilance capacity in resource-limited settings through training, mentorship, and digital reporting infrastructure.

## 12. Future Directions

The pharmacovigilance landscape is evolving rapidly, driven by advances in digital health, real-world evidence generation, and regulatory innovation. Several emerging directions hold particular relevance for pharmacist pharmacovigilance practice.

Patient-reported outcomes and patient-initiated ADR reporting are gaining increasing recognition as valuable pharmacovigilance data sources. Pharmacists are well placed to facilitate patient engagement with digital reporting platforms and to integrate patient-reported safety signals into their clinical assessments. The concept of 'participatory pharmacovigilance' — where patients are active partners rather than passive recipients in drug safety monitoring — represents a promising evolution of traditional surveillance paradigms.46

Pharmacogenomics offers the potential to predict individual susceptibility to ADRs based on genetic variation, enabling personalised medicine strategies that minimise drug-related harm. Pharmacists are increasingly trained in pharmacogenomics interpretation, positioning them as key practitioners in the implementation of genotype-guided prescribing — an area with direct implications for ADR prevention and pharmacovigilance.47

Real-world evidence (RWE) generated from electronic health records, insurance claims databases, and patient registries is becoming an increasingly important complement to spontaneous reporting in pharmacovigilance. Pharmacists with expertise in pharmacoepidemiology and data science are well positioned to contribute to RWE generation and analysis — both within healthcare organisations and in collaboration with regulatory agencies and academic partners.48

## 13. Conclusion

Pharmacists are indispensable contributors to pharmacovigilance and adverse drug reaction monitoring across all healthcare settings. Their specialised knowledge, patient accessibility, and continuous presence in the medication management process position them uniquely to detect, assess, report, and help prevent drug-related harms. Despite this, their participation in formal pharmacovigilance systems — particularly spontaneous ADR reporting — remains substantially below its potential, constrained by educational gaps, organisational barriers, and systemic under-recognition of the pharmacist's drug safety role.

Closing these gaps requires a coordinated, multi-level response: revised pharmacy curricula that embed pharmacovigilance as a core professional competency; organisational reforms that integrate ADR reporting into routine pharmacy workflows; technological innovation that reduces reporting friction; and regulatory frameworks that formally recognise and incentivise pharmacist pharmacovigilance contributions. As healthcare systems globally strive to improve medication safety and reduce preventable harm, pharmacists must be empowered and supported to fulfil their full pharmacovigilance potential.

Future research should focus on evaluating the impact of pharmacist-specific pharmacovigilance interventions, characterising the quality and clinical value of pharmacist-generated ADR reports, and

exploring the contribution of pharmacists in emerging pharmacovigilance domains including pharmacogenomics, artificial intelligence-assisted surveillance, and patient-reported outcome monitoring.

## Declarations

**Conflicts of Interest:** The authors declare no conflicts of interest.

**Funding:** This research received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors.

**Ethical Approval:** Not applicable (review article).

**Author Contributions:** All authors contributed equally to the conceptualisation, literature review, drafting, and critical revision of this manuscript.

## References

References are formatted per the International Journal of Clinical Practice (IJCP) Vancouver style.

1. Lazarou J, Pomeranz BH, Corey PN. Incidence of adverse drug reactions in hospitalized patients: a meta-analysis of prospective studies. JAMA. 1998;279(15):1200-1205.
2. Pirmohamed M, James S, Meakin S, et al. Adverse drug reactions as cause of admission to hospital: prospective analysis of 18,820 patients. BMJ. 2004;329(7456):15-19.
3. World Health Organization. International Drug Monitoring: The Role of National Centres. Technical Report Series No. 498. Geneva: WHO; 1972.
4. Ernst FR, Grizzle AJ. Drug-related morbidity and mortality: updating the cost-of-illness model. J Am Pharm Assoc. 2001;41(2):192-199.
5. World Health Organization. The Importance of Pharmacovigilance: Safety Monitoring of Medicinal Products. Geneva: WHO; 2002.
6. Meyboom RH, Lindquist M, Egberts AC. An ABC of drug-related problems. Drug Saf. 2000;22(6):415-423.
7. Schumock GT, Butler MG, Meek PD, et al. Evidence of the economic benefit of clinical pharmacy services: 1996-2000. Pharmacotherapy. 2003;23(1):113-132.
8. Hazell L, Shakir SA. Under-reporting of adverse drug reactions: a systematic review. Drug Saf. 2006;29(5):385-396.
9. World Health Organization. VigiBase: The WHO Global Database of Individual Case Safety Reports. Uppsala: Uppsala Monitoring Centre; 2024.
10. European Medicines Agency. Pharmacovigilance: Overview. Amsterdam: EMA; 2023. Available at: https://www.ema.europa.eu/en/human-regulatory/overview/pharmacovigilance-overview
11. Indian Pharmacopoeia Commission. Pharmacovigilance Programme of India (PvPI): Annual Report. Ghaziabad: IPC; 2023.
12. Rawlins MD, Thompson JW. Pathogenesis of adverse drug reactions. In: Davies DM, ed. Textbook of Adverse Drug Reactions. Oxford: Oxford University Press; 1977:10-31.
13. Bouvy JC, De Bruin ML, Koopmanschap MA. Epidemiology of adverse drug reactions in Europe: a review of recent observational studies. Drug Saf. 2015;38(5):437-453.
14. Institute for Safe Medication Practices. ISMP's List of High-Alert Medications in Acute Care Settings. Horsham: ISMP; 2018.
15. Sera LC, McPherson ML. Pharmacokinetics and pharmacodynamic changes associated with aging and implications for drug therapy. Clin Geriatr Med. 2012;28(2):273-286.

16. Naranjo CA, Busto U, Sellers EM, et al. A method for estimating the probability of adverse drug reactions. Clin Pharmacol Ther. 1981;30(2):239-245.

17. Sabaté M, Ibáñez L, Pérez E, et al. Comparison of the methods used to identify adverse drug reactions from different data sources. Drug Saf. 2012;35(12):1147-1157.

18. Lopez-Gonzalez E, Herdeiro MT, Figueiras A. Determinants of under-reporting of adverse drug reactions: a systematic review. Drug Saf. 2009;32(1):19-31.

19. Oshikoya KA, Awobusuyi JO. Perceptions of doctors to adverse drug reaction reporting in a teaching hospital in Lagos, Nigeria. BMC Clin Pharmacol. 2009;9:14.

20. Ribeiro-Vaz I, Santos CC, Costa-Pereira A, Carneiro AV. Methods to promote spontaneous adverse drug reaction reporting: a systematic literature review. Pharmacoepidemiol Drug Saf. 2012;21(7):768-779.

21. Chisholm-Burns MA, Kim Lee J, Spivey CA, et al. US pharmacists' effect as team members on patient care: systematic review and meta-analyses. Med Care. 2010;48(10):923-933.

22. Ensing HT, Stuijt CC, van den Bemt BJ, et al. Identifying the optimal role for pharmacists in care transitions: a systematic review. J Manag Care Spec Pharm. 2015;21(8):614-636.

23. Tam VC, Knowles SR, Cornish PL, et al. Frequency, type and clinical importance of medication history errors at admission to hospital: a systematic review. CMAJ. 2005;173(5):510-515.

24. Maher RL, Hanlon J, Hajjar ER. Clinical consequences of polypharmacy in elderly. Expert Opin Drug Saf. 2014;13(1):57-65.

25. O'Mahony D, O'Sullivan D, Byrne S, et al. STOPP/START criteria for potentially inappropriate prescribing in older people: version 2. Age Ageing. 2015;44(2):213-218.

26. Nkosi NN, Brysiewicz P. A survey of pharmacovigilance knowledge, attitude and practices among community pharmacists in KwaZulu-Natal, South Africa. S Afr J Psychiatry. 2015;20(3):76-81.

27. Bates DW, Cullen DJ, Laird N, et al. Incidence of adverse drug events and potential adverse drug events. JAMA. 1995;274(1):29-34.

28. Kaboli PJ, Hoth AB, McClimon BJ, Schnipper JL. Clinical pharmacists and inpatient medical care: a systematic review. Arch Intern Med. 2006;166(9):955-964.

29. Meyboom RH, Egberts AC, Edwards IR, Hekster YA. Principles of signal detection in pharmacovigilance. Drug Saf. 1997;16(6):355-365.

30. Rommers MK, Teepe-Twiss IM, Guchelaar HJ. Preventing adverse drug events in hospital practice: an overview. Pharmacoepidemiol Drug Saf. 2007;16(10):1129-1135.

31. Bahk CY, Goshgarian M, Donahue K, et al. Increasing patient engagement in pharmacovigilance through online community outreach and mobile reporting applications: an analysis of adverse event reporting for the Essure device in the US. Pharm Med. 2015;29(6):331-340.

32. Bate A, Evans SJ. Quantitative signal detection using spontaneous ADR reporting. Pharmacoepidemiol Drug Saf. 2009;18(6):427-436.

33. Leaman R, Wojtulewicz L, Sullivan R, et al. Towards internet-age pharmacovigilance: extracting adverse drug reactions from user posts to health-related social networks. Proc ACL HLT Workshop Biomed NLP. 2010:117-125.

34. Roughead EE, Semple SJ. Medication safety in acute care in Australia: where are we now? Part 1: a review of the extent and causes of medication problems 2002-2008. Aust New Zealand Health Policy. 2009;6:18.

35. Abramowitz PW. Medication errors: who's responsible? Am J Health Syst Pharm. 2004;61(14):1428-1430.

36. Scahill S, Bronstein JM, Kelagher C. Pharmacovigilance education in pharmacy programmes: assessing the need. Pharm Educ. 2015;15(1):203-207.

37. International Pharmaceutical Federation (FIP). Good Pharmacy Practice: Standards for Quality of Pharmacy Services. The Hague: FIP; 2011.

38. Pal SN, Olsson S, Brown EG. The WHO Programme for International Drug Monitoring: expansion of pharmacovigilance to LMICs. Drug Saf. 2015;38(4):365-372.

39. Patel H, Bell D, Molokhia M, et al. Trends in hospital admissions for adverse drug reactions in England: analysis of national hospital episode statistics 1998-2005. BMC Clin Pharmacol. 2007;7:9.

40. Figueiras A, Herdeiro MT, Polonia J, Gestal-Otero JJ. An educational intervention to improve physician reporting of adverse drug reactions: a cluster-randomized controlled trial. JAMA. 2006;296(9):1086-1093.

41. Sweis D, Wong IC. A survey on factors that could affect adverse drug reaction reporting according to hospital pharmacists in Great Britain. Drug Saf. 2000;23(2):165-172.

42. Backstrom M, Mjorndal T, Dahlqvist R. Under-reporting of serious adverse drug reactions in Sweden. Pharmacoepidemiol Drug Saf. 2004;13(7):483-487.

43. Brighton Collaboration. Brighton Collaboration: Vaccine Safety. 2024. Available at: https://brightoncollaboration.us

44. Barnes J. Pharmacovigilance of herbal medicines: a UK perspective. Drug Saf. 2003;26(12):829-851.

45. Ampadu HH, Hoekman J, de Bruin ML, et al. Adverse drug reaction reporting in Africa and a comparison of individual case safety report characteristics between Africa and the rest of the world: analyses of spontaneous reports in VigiBase. Drug Saf. 2016;39(4):335-345.

46. Hay A, Ostini R, Eichler HG, et al. Participatory pharmacovigilance: a new concept in medicine safety. Drug Saf. 2017;40(10):853-860.

47. Relling MV, Evans WE. Pharmacogenomics in the clinic. Nature. 2015;526(7573):343-350.

48. Gatto NM, Rublee C, Ryan P, et al. Data-driven drug-disease-dose safety insights: the role of real-world evidence. Drug Saf. 2019;42(1):45-54.