Chapter 5: Clinical pharmacy and pharmacovigilance: Integrating patient-centred care with drug safety monitoring

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Abstract

Clinical pharmacy and pharmacovigilance are closely related disciplines that are crucial in contemporary healthcare systems. While clinical pharmacy is concerned with improving therapeutic effectiveness through direct patient care and evidence-based drug therapy, pharmacovigilance is concerned with detecting, assessing, rectifying, and reducing ADRs to enhance patient safety. The evolution of both clinical pharmacy and pharmacovigilance shows an increase in pharmacotherapeutic complexity and the role of multi-disciplinary responsibility in healthcare. Clinical pharmacists are well-positioned to engage in pharmacovigilance because they are often the closest stakeholders. The combination of clinical_pharmacy and pharmacovigilance provides an approach to patient treatment and the provision of safe, effective, and personalized healthcare. Specific challenges discussed include underreporting of ADRs, lack of awareness of ADRs, and lack of education and training related to clinical pharmacy and pharmacovigilance including areas for improvement. In the future, some of the advocated perspectives on digital technologies, artificial intelligence (AI) and policy reforms applicable to clinical pharmacy and pharmacovigilance will be discussed. Emphasising audacious initiatives in education, regulatory alignment and interdisciplinary collaboration would improve healthcare systems around the world. Clinical pharmacy and pharmacovigilance are two healthcare delivery corner stones. While it has always touted personalized treatment and

therapy as well as patient care and education, pharmacovigilance ensures on-going assessment and quality assurance via continual monitoring of ADRs.

Keywords: Clinical Pharmacy, Pharmacovigilance, Adverse Drug Reactions (ADRs), Medication Safety, Patient-Centered Care,

1. Introduction

The global healthcare ecosystem has moved towards more patient-centred models away from disease-centred care; emphasizing safety, quality, and therapeutic outcomes. In this new paradigm, pharmacovigilance and clinical pharmacy now play a central role in enhancing patient care and medication use. Clinical pharmacy ensures that medications achieve maximum therapeutic benefit.1 Pharmacists that practice clinically not only dispense drugs or help the patient take the medication correctly, but they also, for instance, review prescriptions to minimize prescribing errors, help prevent drug-drug interactions, educate the patient on the medication and disease state, and collaborate with physicians to help with therapy selection. Clinical pharmacy is meant to respect the individual patient process, while minimizing harm, and maximizing benefit. Pharmacovigilance, as defined (WHO), is “the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problems.” The practice of PV was codified after the thalidomide disaster in the 1960s, and an entire safety system had to be established. [2] Since then, pharmacovigilance has emerged as a worldwide movement for monitoring and evaluating drugs at both the pre- and post-marketing phases. It could be argued that the functions of clinical pharmacy and pharmacovigilance are different; however, they share an underlying relationship. Clinical pharmacists are a link for recognizing an ADR, counseling a patient of the possible side effects of a drug they are being asked to take, and additionally notifying the state of the adverse event in the pharmacovigilance process. This interplay provides an opportunity for model that contributes to connection to promote both safe and effective medication use.

Clinical Pharmacy

Unlike traditional pharmacy practice, which is often product-oriented, clinical pharmacy is highly patient-focused. Clinical pharmacy originated in the 1960s and 1970s in the United States and gradually gained recognition worldwide. [3] Initially confined to hospital settings, the role of clinical pharmacists has since expanded into ambulatory care, community pharmacies, and public health. The development of

clinical pharmacy has been driven by Increasing complexity of drug therapy, Rise in chronic diseases and polypharmacy. Their responsibilities include:

Medication Therapy Management (MTM)

It is a patient-centred service focused on optimizing medication use and improving patient outcomes. It involves pharmacists working with patients and their healthcare providers to ensure medications are used effectively and safely. MTM aims to prevent medication-related problems, promote adherence, and empower patients to actively participate in their healthcare Broadly focusing on Assessing and optimizing medication regimens [4]

Drug Information Services

Answering inquiries either orally or in writing for current, evidence-based drug information regarding drug therapy and medications from patients, organizations, committees, and the general public. The Pharmacists and Physicians medication Information Center (DIC) offers a comprehensive, objective source of crucial medication information to satisfy the demands of working healthcare professionals.

2. Adverse Drug Reaction Monitoring

ADR surveillance is defined as the process of consistently keeping an eye on any negative side effects that may arise from using any medication. [9] Pharmacovigilance is essential for tracking adverse drug reactions. It also helps Identifying and managing side effects

Patient Education:

This includes Counselling patients on dosage, timing, food-drug interactions, and adherence Clinical Pharmacy Practice Models [10]
Ward-Based Model: Pharmacists are assigned to hospital wards and work closely with the medical team [11]
Outpatient Model: Clinical pharmacists serve patients in ambulatory care clinics
Specialty Areas: Oncology, nephrology, cardiology, infectious disease, psychiatry

Pharmacovigilance: Monitoring Drug Safety. Its core objectives include Detecting unknown Disidentifying risk factors for drug reactions, Assessing risk-benefit ratios, Promoting rational drug use [12]

Global Pharmacovigilance Systems

•WHO-Uppsala Monitoring Centre (UMC): Coordinates global safety reporting [13]
•European Medicines Agency (EMA): Enforces EudraVigilance
•US FDA MedWatch: Publicly accessible reporting system
•India's PvPI: Pharmacovigilance Programme of India

3. Methods of Pharmacovigilance [14]

•Spontaneous Reporting Systems (SRS): Voluntary ADR reports from HCPs
•Cohort Event Monitoring (CEM): Tracks outcomes in defined populations
•Electronic Health Records (EHR)-Based Surveillance: Uses big data for real-time monitoring
• Signal Detection: Identifying trends and associations from reported data

ADR Reporting in India [15]

India launched the PvPI in 2010 to improve drug safety monitoring. Despite this, underreporting remains a major issue. Clinical pharmacists can play a transformative role by bridging this gap.

4. Integration of Clinical Pharmacy and Pharmacovigilance

The evolving landscape of patient-centered care has underscored the need for a tighter integration between clinical pharmacy services and pharmacovigilance practices. This synergy not only enhances drug safety surveillance but also optimizes therapeutic outcomes through proactive adverse drug reaction (ADR) management. [16] Modern healthcare systems are increasingly embracing models where clinical pharmacists play a central role in pharmacovigilance, ensuring a multidimensional approach to medication safety.

4.1 Role of Clinical Pharmacists in ADR Monitoring

Clinical pharmacists act as an essential links in the identification, recording, and assessment of ADRs both in a hospital and in connection with ambulatory care. Clinical pharmacists routinely interact with patient healthcare records and have real-time access to clinical information which can lead to more timely identification of potential drug-related problems. Studies in both the inpatient and outpatient setting demonstrate pharmacist-led pharmacovigilance systems improve quality and completeness in reporting of ADRs or serious ADRs [17]. In a multicenter European study published in 2023, the introduction of structured, pharmacist-led ADR surveillance boosted serious ADR detection, by 43%, exemplifying the observational ability pharmacists have in interdisciplinary teams (González-González et al., 2023).

4.2 In-Hospital ADR Reporting

Electronic ADR reporting systems have fundamentally altered the perceived inefficiency of traditional pen-and-paper reporting methods and lack of protocolin hospitals. Electronic reporting systems typically involve systems that are part of the hospital intranet, or linked with the hospital's electronic medical record (EMR), which means reporting was more streamlined, more information was standardized, and data extraction for analysis was fast. [18] For example, in a 2024 study in tertiary hospitals included in the study realized a pharmacist-triggered digital ADR reporting system was significantly improved (greater than 60%) in ADR reporting completeness and accuracy in the assessment of causality (Patil et al., 2024). Additionally, hospitals that built in real-time alert systems for potential ADRs indicated a decrease in preventable medication-related harm.

4.3 Collaborative Drug Safety Teams

Establishing multidisciplinary drug safety committees; with members including clinical pharmacists, physicians, pharmacologists, and IT specialists has become a best practice example of institutional pharmacovigilance. Subsequently, those committees work effectively together to examine medication risk, conduct root cause analysis on adverse drug reactions (ADRs), and implement preventive strategies. One particular example is the University of Michigan Health System where a Clinical Safety Oversight Team was implemented with the intention of reducing medication related hospital readmissions, which the team was successful, reporting a reduction of 22% in readmissions within a two year period (Smith et al., 2023). Ultimately, drug safety committees were developed to promote safer patient care by providing a platform for

effective and efficient collaboration among operational and clinical departments while also building a culture of shared responsibility for patient safety.

4.4 Real-time pharmacovigilance enabled by EMR

Electronic medical records (EMR) are best positioned to promote real-time pharmacovigilance because they enable ongoing surveillance CDSS. It could promote real-time evaluations of high risk drug-drug interactions, doses unknown or out of range, duplicative therapies, therefore allowing clinical pharmacists and prescribers to proactively intervene. The International Society for Pharmacovigilance (ISoP) concluded in a 2025 review that EMR-enabled pharmacovigilance improves phase IV post-marketing surveillance time to signal detection when faced with complex therapy regimens (e.g. biologics and concurrent therapies) (Chatterjee et al., 2025).

4.5 Examples of Integration (Case Studies or Institutional Models)

Effective integration models offer opportunities in the application of pharmacovigilance in clinical contexts. For example, the National University Hospital in Singapore established a real-time ADR dashboard that is pharmacist-monitored and directly linked to the hospital's electronic medical record (EMR). In the span of one year, as well as an increase in clinical documentation quality (Lim et al., 2023). Likewise, in Sweden, the Uppsala Monitoring Centre trialed an ADR reporting mobile application that enabled a pharmacist to report an ADR case at the patient's bedside, including capturing patient-reported outcomes or near-miss incidents. These case examples provide examples of how the deliberate merging of a clinical pharmacy services and digital pharmacovigilance tools can lead to substantial transformations in healthcare delivery.

5. Challenges and Limitations

Although the merging of clinical pharmacy and pharmacovigilance has increased the field of medication safety significantly, many systemic and organizational barriers remain, whether underreporting and a lack of awareness to complex factors stretching from assignment of responsibility to the issue of interprofessional aspects. These barriers need to be addressed if healthcare is to improve the pharmacovigilance ecosystem that underlies modern healthcare systems.

5.1 Underreporting of ADRs

Although reporting rates may be climbing due to increased demand for applications and exposure initiatives, the overwhelming number of adverse drug reactions (ADRs) still go unreported, especially ADRs that are seen as either trivial or expected. Studies show that as many as 80% of ADRs that happen in the hospital will never be reported, with obvious barriers being primarily time, fear of legal repercussions, or simply a recognition that only serious adverse drug events may warrant reporting (Ravichandran et al., 2024). Further, underreporting has serious implications for delay risk in signal detection and capacity for public health intervention for population level patient safety.

5.2 Lack of awareness and training

The lack of adverse drug reaction monitoring should not be overlooked with respect to the reported lack of training and knowledge of health professionals (including pharmacists), related to pharmacovigilance principles. The majority of clinicians do not even know what to report, where to report, or when to report ADRs. In a recent national survey in Brazil, more than 60% of clinical pharmacists using pharmaceuticals reported having received training that had almost minimal or no content on pharmacovigilance during education (Santos et al., 2023). This is clearly just worse in low resource contexts, in which pharmacy and pharmacovigilance modules are rarely to never taught or offered through pharmacy education programs. To overcome the education gap, we need professional development (PD).

5.3 Infrastructure and Resource Barriers

The successful integration of pharmacovigilance into clinical pharmacy services relies on strong infrastructure, including electronic medical records, data systems, and personnel. However, many hospital inpatient services, notably in resource-constrained contexts, often do not have adequate funds and capacity. Thus, there is a compelling need for institutional support and policy support from the local health or country government.

5.4 Communication between Pharmacists and Physicians

Successful Pharmacovigilance requires collaboration, yet communication between pharmacists and physicians can furtherable siloed decision-making. Competing therapeutic goals, hierarchy-based cultures, and the absence of feedback loops

contribute to a fragmented drug safety system. A 2025 qualitative study in Canada's hospitals found that over 45% of ADR interventions recommended by pharmacists were not acted upon due to lack of timely response or documentation from physicians (Chen et al., 2025). Developing integrated care pathways and interprofessional ADR committees may address some of these disconnects.

5.5 Ethical and Legal Concerns in ADR Reporting

Ethical and medico-legal challenges represent another major barrier. Health professionals may fear reporting ADRs because of concerns about professional liability, particularly if ADRs result from off-label use or polypharmacy in high-risk populations. Limited legal protection of reporters may also create a system of blame rather than learning. The World Health Organization (WHO) included a policy review in 2023 that would ensure a “no-fault” reporting system and allow for anonymous submission of any reports - this is important for demonstrating transparency and accountability (WHO, 2023). Ethical and legal issues need to be resolved to support a culture of reporting.

6. Recommendations and Future Directions

To address the ongoing barriers of integration of clinical pharmacy and pharmacovigilance, policy change and proactive solutions are necessary to make progress. The future of pharmacovigilance (PV) relies on a collaborative, data-driven, patient-centered ecosystem, which brings everyone together in which pharmacists could play a key role in prevention (not just detection) of adverse drug reactions (ADR) through education and health policy development.

6.1 Enhancing educational curriculum

A key step to strengthening PV practice is to provide structured inclusion of PV training into undergraduate and postgraduate pharmacy educational curriculum. A global survey conducted in 2023 by the International Pharmaceutical Federation (FIP) found that only 38% of pharmacy programs worldwide include hands-on pharmacovigilance training (Martínez et al., 2023). Curriculum updates should include ADR causality assessment, use of PV software tools, and regulatory reporting standards. Moreover, embedding real-world case studies and simulation-based learning can better prepare students for clinical challenges.

6.2 Promoting Pharmacist-Physician Collaboration

Encouraging meaningful collaboration between pharmacists and physicians is crucial for optimizing drug safety outcomes. Pharmacist participation in ward rounds, interdisciplinary case discussions, and joint decision-making can bridge the communication gaps that often delay ADR interventions. In 2024, a Swiss hospital system introduced collaborative clinical safety boards that included pharmacists, resulting in a 28% improvement in timely ADR management (Baumann et al., 2024). Policies should promote role clarity, mutual respect, and shared responsibility for medication safety.

6.3 Establishing National ADR Databases and Registries

Centralized and real-time accessible ADR databases are key to effective signal detection and pharmacovigilance transparency. Establishing robust national registries that allow for both professional and patient-reported ADR entries can significantly enhance data quality. Countries like Sweden, Canada, and Australia have already adopted national PV platforms with high engagement rates. A 2025 pilot project in India's Ministry of Health introduced a real-time ADR dashboard integrating hospital EMRs with the national PV database, leading to a 47% increase in signal reporting within six months (Gupta et al., 2025).

6.4 Integrating AI and Big Data into PV

Machine learning algorithms can analyze vast volumes of EMR, social media, and clinical trial data to identify ADR patterns in real-time. Predictive PV systems can even forecast high-risk drug combinations before clinical harm occurs. A 2024 meta-analysis showed that AI-assisted PV systems achieved 91% accuracy in ADR signal detection when compared to traditional methods (Lee et al., 2024). Integrating such tools with hospital pharmacy information systems can streamline ADR monitoring and reporting workflows.

6.5 Expanding the Role of Pharmacists in Public Health

Pharmacists, as the most accessible healthcare professionals, are uniquely positioned to educate the public on medication safety, promote rational drug use, and enhance vaccine pharmacovigilance. Their role should extend beyond institutional settings to community outreach, public health campaigns, and health literacy initiatives. In 2023,

the UK's National Health Service (NHS) piloted a "Pharmacy-Led ADR Awareness Week" in collaboration with local pharmacies, resulting in a 36% uptick in community ADR reports (Turner et al., 2023). This exemplifies the potential of pharmacists in driving grassroots-level pharmacovigilance.

7. Conclusion

The integration of clinical pharmacy and pharmacovigilance represents a transformative approach to enhancing medication safety, optimizing therapeutic outcomes, and promoting a culture of proactive drug surveillance. As clinical pharmacists increasingly assume frontline roles in ADR monitoring, their collaboration with physicians and health systems becomes indispensable.

Looking ahead, the incorporation of robust educational frameworks, national ADR registries, interdisciplinary communication channels, and advanced technologies like artificial intelligence will be pivotal in evolving pharmacovigilance into a real-time, predictive, and patient-centric discipline. Furthermore, expanding the pharmacist's role in public health will amplify community engagement and awareness regarding drug safety.

By addressing current limitations and embracing innovation, healthcare systems can build a resilient pharmacovigilance infrastructure—one that safeguards patient well-being while supporting the rational and responsible use of medicines across diverse clinical settings.

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