

Role of Pharmacist in Adverse Drug Reaction Reporting and Pharmacovigilance: A Narrative Review

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Abstract: Adverse drug reactions (ADRs) remain a leading cause of morbidity, hospital admission, and avoidable healthcare cost worldwide, and pharmacovigilance (PV) has consequently become a central pillar of medicines-safety systems. Pharmacists, by virtue of their pharmacological training and frequent, accessible contact with patients across community, hospital, and industry settings, occupy a strategic position within this system. This narrative review examines the role of the pharmacist in ADR reporting and pharmacovigilance, with particular reference to the Pharmacovigilance Programme of India (PvPI). Literature was reviewed from PubMed, Google Scholar, and ScienceDirect, together with official PvPI and WHO publications, covering the historical evolution of pharmacovigilance, the specific contributions of pharmacists to ADR detection and reporting, causality-assessment tools such as the Naranjo algorithm and WHO-UMC scale, and global evidence on pharmacists' knowledge, attitudes, and practices. Across the reviewed literature, pharmacists consistently report positive attitudes toward ADR reporting, yet actual reporting rates remain low, a gap attributed to factors described as the "five dwarfs" of underreporting - ignorance, lethargy, complacency, diffidence, and insecurity - together with workload pressures, limited procedural training, and absent feedback mechanisms. PvPI has expanded substantially since its 2010 launch, achieving WHO Collaborating Centre status in 2017, yet underreporting from the private sector and state-level disparities persist. Strengthening the pharmacist's contribution will require curricular reform pairing theory with practical reporting training, continued simplification of reporting infrastructure, and structured feedback to reporters.

Keywords: Pharmacovigilance; Adverse Drug Reaction; Pharmacist; ADR Reporting; Pharmacovigilance Programme of India; Patient Safety

1. Introduction

The World Health Organization (WHO) defines an adverse drug reaction (ADR) as a response to a drug that is noxious and unintended, occurring at doses normally used for prophylaxis, diagnosis, or treatment of disease [1]. ADRs are among the leading causes of morbidity and mortality worldwide and account for a substantial, largely preventable, share of hospital admissions [2]. Pharmacovigilance (PV) - "the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other possible drug-related problems" [1] - emerged as a formal discipline following the thalidomide tragedy of the late 1950s and early 1960s, leading to the WHO Programme for International Drug Monitoring in 1968 [3].

Pharmacists, owing to their pharmacological training and frequent, accessible patient contact across community, hospital, and industry settings, are widely recognised as central to effective pharmacovigilance [4]. Professional bodies increasingly regard ADR reporting as part of the pharmacist's core responsibility, and pharmacists generally express positive attitudes toward it. Nevertheless, a substantial literature documents a persistent gap between this recognised responsibility and actual reporting behaviour [5,6]. This review synthesises the published literature on the pharmacist's role in ADR reporting and pharmacovigilance, with specific reference to the Pharmacovigilance Programme of India (PvPI).

2. Methodology

This is a narrative literature review. Sources were identified through PubMed, Google Scholar, and ScienceDirect, supplemented by official PvPI and WHO publications, using search terms including "pharmacovigilance", "adverse drug reaction", "pharmacist", "ADR reporting", "underreporting", "knowledge attitude practice", and "Pharmacovigilance Programme of India". Priority was given to peer-reviewed review articles, systematic reviews, and large surveys published within approximately the last fifteen years, supplemented by foundational earlier publications of continuing relevance.

3. The Pharmacovigilance Programme of India

India joined the WHO Programme for International Drug Monitoring in 1997 through three regional centres [7]. The Pharmacovigilance Programme of India (PvPI) in its current form was launched by the Ministry of Health and Family Welfare on 14 July 2010, with coordination shifting to the Indian Pharmacopoeia Commission, Ghaziabad, in April 2011 [7,8]. PvPI now operates through a large network of ADR Monitoring Centres (AMCs) established in medical colleges and hospitals nationwide, supported by an online reporting portal, a toll-free helpline, and the ADR PvPI mobile application [8]. The programme has contributed to concrete regulatory action, including safety-label revisions, and was designated a WHO Collaborating Centre for Pharmacovigilance in 2017 [9]. Persistent challenges include underreporting from the private sector, variable report quality, and state-level disparities in AMC coverage [9].

4. Role of the Pharmacist in Pharmacovigilance

Pharmacists contribute to pharmacovigilance through ADR detection during patient counselling and medication review, causality assessment using structured tools such as the Naranjo algorithm [10] and the WHO-UMC causality scale [11], spontaneous reporting to regulatory centres, and participation in institutional drug-safety committees. Hospital pharmacists are positioned to detect ADRs responsible for an estimated five percent of hospital admissions, most of which are preventable [12]. Community pharmacists are frequently a patient's first point of contact for medication-related concerns, particularly for chronic and over-the-counter therapy [4].

Global survey literature consistently finds that pharmacists hold positive attitudes toward ADR reporting yet report comparatively low actual reporting experience. A systematic review of studies from 2012 to 2022 found that while 20-96% of healthcare professionals expressed positive attitudes toward pharmacovigilance, only 12-61% had ever submitted an ADR report, and up to three-quarters were unaware of their national pharmacovigilance centre [6].

5. Underreporting: Extent and Determinants

Underreporting is consistently identified as the principal limitation of spontaneous reporting systems [9,13]. A systematic review update of factors associated with underreporting found sociodemographic characteristics to be weakly associated with reporting behaviour, whereas knowledge- and attitude-related factors - described as the "five dwarfs" of ignorance, lethargy, complacency, diffidence, and insecurity - remained the dominant determinants, together with the absence of structured feedback to reporters [13]. Pharmacist-specific barriers additionally include heavy workload, uncertainty about reportable events, and limited institutional encouragement [5,14].

6. Strategies for Improvement

Educational interventions pairing theoretical instruction with practical reporting exercises have been associated with measurable improvements in both knowledge and self-reported reporting behaviour [15]. Digitisation of reporting infrastructure - web portals, mobile applications, and integration with electronic health records - has been shown to reduce the administrative burden associated with reporting and increase uptake [13]. Structured feedback loops between AMCs and individual reporters, and formal institutional recognition of pharmacovigilance activity, are further recommended to sustain reporting behaviour over time [9,12].

7. Conclusion

Pharmacists are widely recognised as central to effective pharmacovigilance, yet a persistent gap remains between this recognised role and actual ADR reporting practice. This gap is attributable primarily to knowledge- and attitude-related barriers rather than to unwillingness to participate, and is compounded by workload pressures and limited procedural

training. PvPI has achieved substantial institutional progress since 2010, but underreporting, particularly from the private sector, remains unresolved. Strengthening the pharmacist's contribution to pharmacovigilance in India will require curricular reform, continued simplification of reporting infrastructure, and structured feedback mechanisms to sustain reporting behaviour.

Conflict of Interest

The author declares no conflict of interest.

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