International Journal of Basic & Clinical Pharmacology
Dwivedi KL et al. Int J Basic Clin Pharmacol. 2025 Jul;14(4):480-486
http://www.ijbcp.com
pISSN 2319-2003 | eISSN 2279-0780

DOI: https://dx.doi.org/10.18203/2319-2003.ijbcp20251830

Original Research Article

Assessment of knowledge, attitude, and practice of pharmacovigilance among healthcare workers: a cross-sectional study from North India

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Received: 31 March 2025
Revised: 07 May 2025
Accepted: 09 May 2025

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ABSTRACT

Background: Adverse drug reactions (ADRs) are a significant cause of morbidity and mortality worldwide. Pharmacovigilance (PV) plays a crucial role in detecting, understanding, and preventing ADRs to ensure drug safety. This study aims to assess the knowledge, attitude, and practice (KAP) of pharmacovigilance among healthcare professionals, identifying barriers and areas for improvement to enhance ADR reporting.
Methods: A cross-sectional study was conducted among healthcare professionals in government and private healthcare facilities in Lucknow, Uttar Pradesh, India. A structured questionnaire was distributed via Google Forms, with 265 participants responding. Statistical analysis involved descriptive statistics, summarizing categorical variables as frequencies and percentages.
Results: Among the 265 participants, 59% were aged 20-30 years, and 66.9% were female. Educational qualifications included nursing (69.6%), MBBS (12.5%), MD/MS (9.1%), and DM/MCh (3.4%). Formal training in pharmacovigilance was reported by 45.1%. Regarding knowledge, 82% correctly identified pharmacovigilance, 68.2% knew CDSCO as the regulatory body, and 57.8% were aware of the Pharmacovigilance Programme of India (PvPI). Although 41.8% frequently encountered ADRs, only 34.4% had reported multiple ADRs, while 43.2% had never reported an ADR. The main barriers included lack of knowledge about the reporting process (49%) and time constraints (30.3%).
Conclusion: Despite awareness and a positive attitude toward pharmacovigilance, ADR reporting remains inadequate due to knowledge gaps and systemic barriers. Strengthening pharmacovigilance education, simplifying reporting mechanisms, and fostering institutional support can enhance ADR reporting practices, ultimately improving patient safety.

Keywords: Adverse drug reactions, Pharmacovigilance, Knowledge, Attitude, Practice, Patient safety

INTRODUCTION

An adverse drug reaction (ADR) has been defined by the World Health Organization (WHO) as "a noxious, unanticipated response to a drug that occurs at doses used in humans for prophylaxis, diagnosis, therapy of disease, or modification of physiological function".[1] Worldwide, adverse drug reactions (ADRs) represent a significant cause of illness and mortality. The study and practice of identifying, comprehending, and preventing adverse

effects or any other issue pertaining to medications is known as pharmacovigilance (PV).[2] The Indian Pharmacopoeia Commission (IPC) is in charge of coordinating PV activities in India.[3] In addition to serving as a World Health Organization Collaborating Centre for PV in public health initiatives and regulatory services, the IPC creates and manages the PV database, which includes all observed probable adverse drug reactions.[4]

India is referred to as "the pharmacy of the world" since it generates a significant quantity of generic pharmaceutical items for the global market.[5] For this reason alone, it needs a well-designed healthcare system in which all medical personnel are aware of the potential risks and advantages of the medications as well as the need to monitor and report adverse drug reactions in order to conduct better quality medications and ensure patient safety.

All medical personnel in India, including physicians, nurses, and pharmacists, are permitted to report ADRs by completing an ADR form provided by the Central Drugs Standard Control Organization (CDSCO).[6] Sweden's Uppsala Monitoring Centre (UMC), under WHO, maintains VigiBase, the world's largest and continuously updated global database of suspected adverse drug reactions, containing about 40 million reports since 1968 and integrated with WHO Drug and MedDRA for standardized data management.[7]

Figure 1: Structured framework of the Google form questionnaire on pharmacovigilance.

The Indian pharmacopoeia commission (IPC), serving as the central hub for the pharmacovigilance programme of India (PvPI), plays a crucial role in regulating medication use and ensuring drug safety nationwide through the robust

techno-science-based system introduced by the Ministry of Health and Family Welfare, Government of India, in July 2010.[8]

With this background, this study was conducted to emphasize the importance of sensitizing healthcare workers toward pharmacovigilance, as they play a crucial role in ensuring the routine practice of ADR reporting.

Recognizing that early exposure and awareness can significantly enhance vigilance and reporting behaviours, this study aims to assess the KAP of pharmacovigilance among medical students.

By evaluating their current understanding, perceptions, and engagement in ADR reporting, the study seeks to identify gaps and areas for improvement, ultimately contributing to a more robust pharmacovigilance system in future clinical practice.

METHODS

Study type

This was a cross-sectional study.

Study place

The study was conducted among healthcare workers in healthcare facilities in Lucknow, Uttar Pradesh, India, specifically at the Hind Institute of Medical Sciences, Barabanki, and Chandan Hospital, Lucknow.

Study duration

The study period was of 5 months from September 2024 to December 2024.

The study was done to assess their KAP regarding pharmacovigilance and ADR reporting. A structured questionnaire (Figure 1) was designed and distributed using Google Forms. A total of 265 participants responded to the survey.

The questionnaire consisted of four sections.

Demographic information

This section included details about age, gender, educational qualification, specialization, clinical experience, type of institution, and prior training in pharmacovigilance.

Knowledge of pharmacovigilance

This section assessed participants' understanding of pharmacovigilance, its regulatory authorities, ADR reporting systems, and the location of the adverse drug reaction monitoring center (AMC) in their institutions. Additionally, it included questions on sources of ADR information and their first exposure to the term "pharmacovigilance."

Attitude towards pharmacovigilance

This section evaluated healthcare workers' perceptions of the necessity, importance, and responsibility of ADR reporting, as well as their willingness to encourage colleagues and the adequacy of institutional support.

Practice of ADR reporting

This section explored participants' actual experiences with ADRs, their reporting behavior, barriers to reporting, methods used for reporting, frequency of documentation, use of technology, and follow-up on reported ADRs.

Statistical analysis

The survey responses were collected electronically via Google Forms and analyzed using descriptive statistics. Categorical variables were summarized as frequencies and percentages.

RESULTS

Demographic characteristics

The study included 265 healthcare workers, with the majority (59%) belonging to the 20–30 years age group, followed by 28% in the 31–40 years bracket. Female respondents (66.9%) significantly outnumbered male participants (33.1%).

A large portion (69.6%) held a nursing degree, while only a small proportion had advanced medical qualifications such as MD/MS (9.1%) or DM/MCh (3.4%). Half of the participants (50.4%) reported less than five years of clinical experience, and only 45.1% had received formal training in pharmacovigilance or ADR reporting, highlighting a foundational training gap (Table 1).

Knowledge regarding pharmacovigilance

Participants demonstrated generally good awareness, with 82% correctly identifying pharmacovigilance as the science of detecting, assessing, understanding, and preventing ADRs, and 83.8% recognizing its main function as ADR monitoring and prevention. However, only 68.2% correctly named CDSCO as the regulatory authority, and just 57.8% were familiar with the Pharmacovigilance Programme of India (PvPI). While 80.5% agreed that all suspected ADRs should be reported, a notable 29.8% first encountered the term “pharmacovigilance” during this survey-underscoring the need for early and consistent education (Table 2).

Attitudes toward pharmacovigilance

The majority of respondents held positive attitudes, with 71% agreeing that ADR reporting is necessary and 64% believing it enhances healthcare outcomes. A significant number (58.8%) supported the inclusion of pharmacovigilance in medical training. Most clinicians (83.7%) perceived ADR reporting as a professional obligation rather than an optional task. Additionally, 77% favoured incentivizing ADR reporting to increase participation, while 75.4% encouraged their colleagues and juniors to report ADRs. Institutional support was deemed adequate by 69.8% of participants (Table 3).

Practice of ADR reporting

In practice, there was a notable gap between experience and action. Although 41.8% of respondents frequently encountered ADRs, 43.2% had never reported one. The main barrier identified was lack of knowledge about the reporting process (49%), followed by lack of time (30.3%). Only 40% had received formal training in ADR reporting, though a promising 79.2% expressed a willingness to receive additional training. Use of digital tools was moderately high, with 57.7% utilizing online portals or apps for ADR reporting.

Table 1: Demographic characteristics of participants.

Characteristic	Category	Frequency (N)	%
Age group (in years)	20–30	156	59.0
	31–40	75	28.0
	>40	34	13.0
Gender	Male	88	33.1
	Female	178	66.9
Educational qualification	Nursing degree	183	69.6
	MBBS	33	12.5
	MD/MS	24	9.1
	DM/MCh	9	3.4
Clinical experience (in years)	<5	133	50.4
	5–10	86	32.6
	11–20	36	13.6
	>20	9	3.4
Formal training in PV/ADR	Yes	120	45.1
	No	146	54.9

Table 2: Knowledge regarding pharmacovigilance.

Knowledge item	Correct response	Frequency (N)	%
Definition of pharmacovigilance	Yes	217	82.0
Main function of PV	Yes	222	83.8
Regulatory body (CDSCO)	Yes	178	68.2
Awareness of ADR monitoring centre location	Yes	206	77.8
Awareness of PvPI	Yes	153	57.8
All suspected ADRs should be reported	Yes	213	80.5
First exposure to term: during this survey	-	79	29.8
First exposure to term: during student years	-	97	36.6
First exposure to term: via literature	-	89	33.6

Table 3: Attitudes toward pharmacovigilance.

Attitudinal statement	Agree/strongly agree (N)	%
ADR reporting is necessary	188	71.0
ADR reporting improves healthcare outcomes	170	64.0
Pharmacovigilance should be taught in detail	156	58.8
ADR reporting is a core duty	222	83.7
ADR reporting should be incentivized	204	77.0
Encourage others to report ADRs	200	75.4
Institutional support is sufficient	185	69.8

Table 4: Practice of ADR reporting.

Practice element	Category/response	Frequency (N)	%
Frequency of encountering ADRs	Frequently	111	41.8
	Occasionally	91	34.3
	Never	63	23.8
Primary barriers to ADR reporting	Unaware of reporting process	130	49.0
	Lack of time	80	30.3
	Non-severe perception	50	18.8
	Legal fears	2	0.7
	Lack of institutional support	3	1.2
Prior ADR reporting history	Multiple reports	91	34.4
	Reported once	59	22.4
	Never reported	115	43.2
Preferred ADR reporting method	PvPI online portal	109	41.3
	Manual forms	103	38.9
	Informal means	53	19.8
Formal training received	Yes	106	40.0
	No	159	60.0
Desire for additional training	Yes	210	79.2
Use of digital tools for ADR reporting	Yes	153	57.7
	No	112	42.3

DISCUSSION

Physicians, pharmacists, nurses, and other critical health care professionals have a great deal of responsibility when it comes to reporting adverse drug reactions (ADRs). ADR reporting is a crucial part of any pharmacovigilance program. An essential technique for reporting adverse drug reactions (ADRs) and new ADRs of novel drugs is the spontaneous reporting system.[9] This study provides crucial insights into the current state of pharmacovigilance (PV) awareness among healthcare workers.

In this study we found that a significant proportion of healthcare workers were aware of the fundamental concepts of pharmacovigilance. Most participants correctly defined pharmacovigilance, and recognized its primary function in monitoring and preventing ADRs. However, a knowledge gap exists regarding the regulatory framework, as only 68.2% of respondents correctly identified the Central Drugs Standard Control Organization (CDSCO) as India's governing body for PV activities.

Moreover, only 57.8% were aware of the Pharmacovigilance Programme of India (PvPI), highlighting a need for enhanced awareness initiatives. Similarly, Alshabi et al in their study reported a good knowledge of PV and ADRs in the healthcare workers, however Upadhyaya et al in their study reported that postgraduate resident doctors were a lack of correct knowledge about ADRs reporting and pharmacovigilance.[10,11] One concerning finding observed in this study is that nearly 30% of participants encountered the term "pharmacovigilance" for the first time during the survey, indicating limited exposure during their medical training. This emphasizes the necessity for early integration of PV education into medical and nursing curricula to ensure better understanding and implementation. Similar observation was also reported by Guner et al in their study, where they reported that the term “pharmacovigilance” was heard for the first time in by 35.5% of the participants in their survey.[12]

In this study, generally positive attitude among healthcare professionals towards ADR reporting was observed, with 71% acknowledging its necessity and 83.7% recognizing it as a core professional responsibility. Additionally, while 77% favoured incentives for ADR reporting, 23% believed reporting should remain voluntary. While intrinsic motivation is key, structured incentive programs such as certificates, professional recognition, and performance-based rewards may enhance ADR reporting rates. Similar observation was also reported by Hussain et al, in their study where they found that most of the participants exhibited a positive attitude regarding ADR reporting including 49.1% of physicians, 70.2% of pharmacists, and 76.1% of nurses.[13]

In this study we observed that the practice of ADR reporting appears unsatisfactory, despite high awareness and positive attitudes. While 41.8% of participants frequently encountered ADRs in their clinical practice, only 34.4% had reported multiple ADRs, and 43.2% had never reported an ADR. This discrepancy between awareness and actual practice is a critical issue in pharmacovigilance. Barriers to ADR reporting were prominently identified as a lack of knowledge about the reporting process (49%), time constraints (30.3%), and

perceptions that ADRs were not severe enough to warrant reporting (18.8%).

Fear of legal consequences (0.7%) and inadequate institutional support (1.2%) were less commonly cited, suggesting that educational interventions and workflow integration may be more effective solutions than legal reassurances. Lack of a professional environment was identified as a significant barrier in studies from Khan et al. and Amin et al.[14,15] Insufficient clinical knowledge was also highlighted as a barrier, in studies from Al-Hazmi et al, Suyagh et al, Radhakrishnan et al and a multi-centric study from AlShammari et al.[16-19]

Incorporating pharmacovigilance training into undergraduate and postgraduate curricula across all healthcare disciplines is essential. Additionally, workshops, webinars, and continuous medical education (CME) programs can reinforce knowledge and best practices. Healthcare institutions should cultivate a culture of pharmacovigilance by integrating ADR reporting into standard clinical workflows, ensuring that healthcare workers are supported and encouraged to report.

CONCLUSION

The study offers relevant information about healthcare professionals' knowledge of pharmacovigilance in North India. Despite widespread awareness and a generally positive perspective, there are still large gaps in ADR reporting practices because of obstacles such time constraints, a lack of understanding of reporting protocols, and the belief that ADRs are unimportant. Strengthening pharmacovigilance education, simplifying reporting mechanisms, and institutional support can contribute to a more robust pharmacovigilance system, ultimately improving patient safety.

Funding: No funding sources
Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee

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Cite this article as: Dwivedi KL, Pandey RK, Dwivedi V, Pandey AR, Raj N. Assessment of knowledge, attitude, and practice of pharmacovigilance among healthcare workers: a cross-sectional study from North India. Int J Basic Clin Pharmacol 2025;14:480-6.