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Original Research Article

Assessment of knowledge, attitude and practices of pharmacovigilance among health care professionals at a tertiary care teaching hospital in Central India

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ABSTRACT

Background: Adverse drug reactions (ADRs) are a significant cause of morbidity and mortality worldwide and remain substantially underreported. Pharmacovigilance and spontaneous ADR reporting by health care professionals (HCPs) are critical to identify and mitigate drug-related harm. Our study assessed knowledge, attitude and practice (KAP) regarding pharmacovigilance and explored factors underlying ADR underreporting among HCPs at a tertiary teaching hospital in central India.
Methods: A cross-sectional questionnaire-based survey was administered via Google forms to 160 consenting HCPs (48 doctors, 112 nurses) at a tertiary care teaching hospital. The instrument contained 15 KAP items (5 knowledge-yes/no; 5 attitude-5-point Likert; 5 practice-yes/no) plus a multiple-option item on causes of underreporting. Pretesting, expert validation and Cronbach's α (0.773) were done. Descriptive statistics were computed.
Results: All doctors (100%) correctly identified ADRs and life-threatening potential; 93.8% recognized that rare ADRs are primarily identified in post-marketing (phase IV) surveillance. Nurses demonstrated high recognition of ADR concept (88.4%) but lower awareness on some specifics (e.g., 67.9% aware that rare ADRs appear in phase IV). Practice differed markedly: while 91.7% of doctors reported routinely encountering ADRs and 89.6% acknowledged ADR documentation, only 16.7% of doctors reported using the covigilance programme of India (PvPI) mobile app; nurses reported substantially lower active reporting behaviours (practice item responses range 6.3-48.2%). Major reasons for underreporting cited were lack of knowledge (doctors 85.4%, nurses 75.0%), difficulty in causality decision (doctors 56.3%, nurses 48.2%), and limited access to reporting forms (doctors 47.9%, nurses 36.6%).
Conclusions: HCPs exhibited satisfactory knowledge and positive attitudes but suboptimal reporting practices, especially among nurses. Interventions such as targeted training, simplified reporting pathways, and institutional pharmacovigilance centres are recommended to improve ADR reporting rates.

Keywords: Pharmacovigilance, Adverse drug reactions, Knowledge, Attitude, Practice, ADR reporting

INTRODUCTION

Adverse drug reactions (ADRs) represent a major public health concern, contributing substantially to morbidity, hospital admissions and healthcare costs worldwide. The world health organization (WHO) defines ADRs as "any noxious and unintended response to a medicinal product at normal doses used for prophylaxis, diagnosis, or therapy".[1]

Estimates suggest that a large proportion of ADRs are preventable; early detection and reporting are pivotal for patient safety and rational drug use.[2-4] Despite established systems such as the pharma PvPI, underreporting remains

a persistent global problem: only a fraction of actual ADR events enter national and international pharmacovigilance databases.[5-7]

Spontaneous reporting by clinicians, nurses and pharmacists is essential for signal detection in the post-marketing phase (phase IV). However, numerous factors such as lack of awareness, confusion over causality, time constraints, and fear of medico-legal consequences have been implicated in underreporting.[8-11]

In India, where drug utilization is enormous and polypharmacy is common, strengthening pharmacovigilance culture in healthcare institutions is particularly important.[6,12]

Although several Indian studies have assessed pharmacovigilance KAP, most are limited to single professional group. Data from government teaching hospitals in central India, especially comparing doctors and nurses, remain scarce.

Our study aims to evaluate the KAP of pharmacovigilance among HCPs at a tertiary care teaching hospital in central India and to identify barriers to ADR reporting. The results are intended to guide targeted interventions such as training programs, workflow changes and promotion of mobile reporting tools.

METHODS

This was a cross-sectional, questionnaire-based study conducted at a tertiary care teaching hospital in central India from March 2025 to April 2025. Ethical approval was obtained from the institutional ethics committee and written informed consent was taken from all participants prior to data collection.

Licensed HCPs, both doctors and nurses who were permanently employed and directly involved in patient care, were eligible. Medical/nursing students, interns, alternative medicine practitioners and administrative HCPs were excluded.

The sampling frame consisted of 455 HCPs employed at time of the study; with a 5% margin of error, 95% CI, and 80% response distribution, required sample size was 160. A convenience sampling approach was used, and 160 respondents completed survey (48 doctors and 112 nurses).

Self-administered close-ended questionnaire developed to assess KAP regarding pharmacovigilance and ADR reporting. The instrument comprised five knowledge items (Yes/No), five attitude items on a 5-point Likert scale, five practice items (Yes/No), and one multiple-option item listing potential reasons for underreporting.

The questionnaire underwent content validation by three senior pharmacology professors and was pilot-tested on 10 residents. Cronbach's alpha for internal consistency was 0.773. Final questionnaire was deployed via Google Forms and responses were collected over 1 month. Participation was voluntary and anonymous. Data was analyzed descriptively using frequencies and percentages, and results were presented separately for doctors and nurses.

RESULTS

A total of 160 HCPs participated in the study, comprising 48 doctors (30.0%) and 112 nurses (70.0%). All respondents were working in clinical departments at a tertiary care teaching hospital in central India. The gender and age distribution were not analyzed, as the focus was on profession-based differences in pharmacovigilance awareness and practices. All participants completed the questionnaire fully, yielding a 100% usable response rate among those who accessed the form.

The overall knowledge of pharmacovigilance and ADR reporting was satisfactory among doctors and moderate among nurses (Table 1).

All doctors (100%) were aware of what constitutes an ADR, and a similar proportion (100%) recognized that ADRs can be life-threatening. Most doctors (93.75%) correctly identified that rare ADRs are detected during post-marketing surveillance (Phase IV trials), while among nurses this awareness was considerably lower (67.86%).

Awareness of national programs was variable: 70.83% of doctors knew about the PvPI, whereas only 16.96% of nurses were aware of its existence. Knowledge of the PvPI mobile app was also limited, even among doctors (70.83%) and particularly low among nurses (6.25%).

Table 1: Knowledge of pharmacovigilance and ADRs among doctors and nurses, (n=160).

Questions	Doctors (Yes, %)	Nurses (Yes, %)
Are you aware of what an ADR is?	100	88.39
Are you aware that rare ADRs can only be identified in phase 4 of clinical trials (after market approval)?	93.75	67.86
Are you aware that severe ADRs can be life-threatening and potentially fatal?	100	93.75
Are you aware of the existence of the national PvPI?	70.83	16.96
Are you aware of the PvPI mobile (smartphone) application for ADR reporting?	70.83	6.25

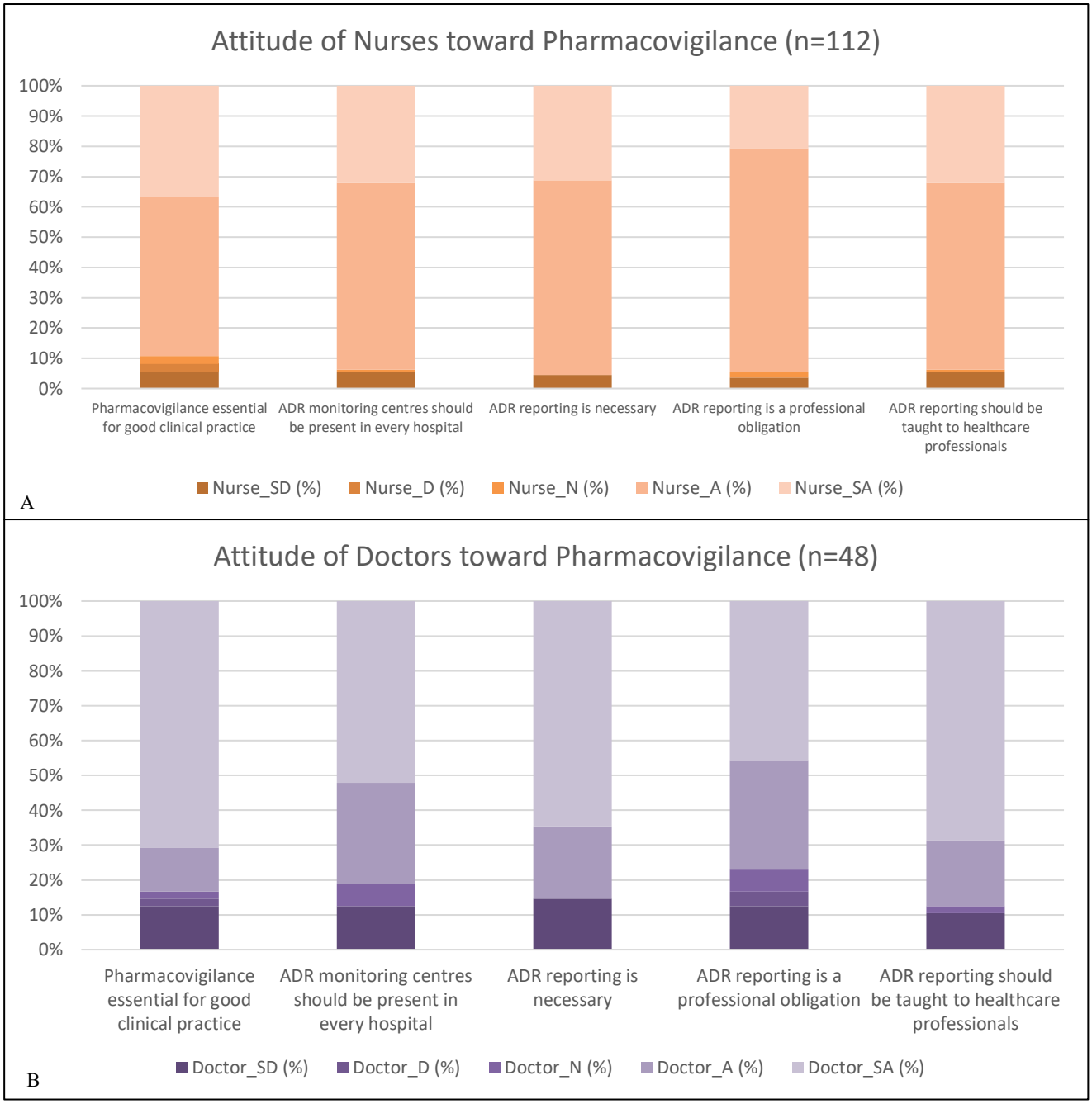

Figure 1 (A and B): Distribution of attitude responses among doctors and nurses, (n=160).

*100 % stacked bar chart showing proportion of "Strongly Disagree" to "Strongly Agree" responses for each attitude item.

Doctors therefore demonstrated uniformly high knowledge across items, while nurses showed partial understanding, especially regarding formal pharmacovigilance systems and reporting tools.

Attitudes toward pharmacovigilance were generally positive in both groups, although doctors expressed stronger agreement across most items.

As shown in Figure 1, most respondents supported pharmacovigilance and ADR reporting as integral to professional and institutional practice.

Among doctors, 70.83% strongly agreed that pharmacovigilance is essential for good clinical practice, and 68.75% strongly agreed that ADR reporting should be formally taught to healthcare professionals. Similarly, 64.58% strongly agreed that ADR reporting is necessary, while 45.83% strongly agreed it is a professional obligation.

Among nurses, the responses were more evenly distributed between agree and strongly agree, suggesting a positive but less emphatic attitude. For instance, 74.11% of nurses

agreed that ADR reporting is a professional duty, but only 20.54% strongly agreed.

Overall, both doctors and nurses exhibited favourable attitudes toward pharmacovigilance, with doctors showing higher intensity of agreement and nurses expressing broader consensus in the "agree" category.

Despite good knowledge and positive attitudes, actual pharmacovigilance practices were comparatively weak in both groups, particularly among nurses (Table 2).

Among doctors, 64.58% had encountered ADRs in their practice and 70.83% had reported at least one ADR, while only 24.11% of nurses had done so. Similarly, 89.58% of doctors had read ADR-related literature, compared to 48.21% of nurses.

Only 16.67% of doctors and 6.25% of nurses reported using the PvPI mobile application, indicating low digital reporting engagement. Access to and familiarity with ADR reporting forms also remained limited among nurses (16.96%) versus doctors (70.83%).

While Doctors exhibited better self-reported pharmacovigilance behaviour, both professional groups demonstrated a significant knowledge–practice gap and underutilization of reporting tools.

Table 2: ADR reporting practices among doctors and nurses, (n=160).

Questions	Doctors (Yes, %)	Nurses (Yes, %)
Have you ever seen any ADRs in any patient in your professional practice?	64.58	15.18
Have you ever read an article about ADRs or ADR reporting?	89.58	48.21
Have you ever reported an ADR seen by you in your practice?	70.83	24.11
If you are aware of PvPI mobile application, have you reported any ADR through this app?	16.67	6.25
Have you ever seen the ADR reporting form?	70.83	16.96

Respondents were allowed to select multiple reasons for not reporting ADRs (Table 3). The most frequently cited reason among doctors was lack of knowledge on how to report (85.42%), followed by difficulty in deciding whether an ADR had occurred (56.25%) and no access to reporting forms (47.92%).

Among nurses, the top reasons were also lack of knowledge (75.0%) and difficulty in determining ADR occurrence (48.21%), followed by lack of time (33.04%) and fear of legal consequences (30.36%).

Table 3: Reported reasons for underreporting of ADRs among HCPs, (n=160).

Reason for underreporting	Doctors (%)	Nurses (%)
Lack of knowledge on how to report	85.42	75.00
Lethargy or apathy	41.67	17.86
Difficulty in deciding whether ADR has occurred	56.25	48.21
Belief that a single unreported case will not affect database	43.75	14.29
No access to ADR reporting forms	47.92	36.61
Lack of time	31.25	33.04
Fear of legal consequences	47.92	30.36

These findings clearly indicate that knowledge gaps, logistical barriers, and uncertainty in causality remain the dominant contributors to underreporting among both groups.

DISCUSSION

Our study highlights a recurring pattern observed in many KAP studies on pharmacovigilance: knowledge and attitudes toward ADR reporting among healthcare professionals are generally favorable, yet actual reporting practices lag behind.[8-12] Our findings show near universal conceptual awareness among doctors and high though variable awareness among nurses. Attitude scores indicate positive disposition toward the importance of ADR reporting. Yet practice metrics, particularly use of formal reporting mechanisms and the PvPI mobile app, were notably low.

Nurses reported markedly less exposure to ADRs and less engagement with reporting tools compared with doctors. The knowledge-practice gap suggests that awareness alone does not translate into reporting behaviour; structural and procedural barriers such as lack of forms, time constraints, and uncertainty in causality impede action. Uncertainty in causality assessment was frequently cited-clinicians often avoid reporting suspected ADRs out of concern that a doubtful association may reflect badly on their prescribing or lead to unnecessary work.[13] Nursing participation in ADR detection and reporting may also be under-appreciated, as nurses often lack empowerment or training to report ADRs routinely.[14]

The low uptake of the PvPI mobile app (16.7% doctors; 6.25% nurses) is concerning but not surprising. Mobile reporting tools can simplify submission but require awareness, workflow integration and ease of use.[15] Institutional reinforcement, training, and recognition of reporters can foster a stronger reporting culture. Findings

align with prior Indian and global studies showing similar gaps and barriers.[7,8,12,16,17]

A further dimension of the study involved exploring the reasons for underreporting. The most frequent cause cited by both doctors and nurses was lack of knowledge on how to report ADRs, emphasizing that awareness alone does not guarantee procedural familiarity. Other prominent barriers included difficulty in deciding causality, limited access to reporting forms, and fear of legal consequences. Similar findings have been observed in other Indian and international KAP studies, underscoring that underreporting often results not from negligence but from systemic and educational shortcomings.[8,9,11] Addressing these through targeted, practice-oriented training and simplified reporting mechanisms could significantly improve participation in pharmacovigilance programs.

Implications for practice and policy

Training

Regular, mandatory pharmacovigilance workshops for all cadres (doctors, nurses, pharmacists) focusing on what to report, how to use reporting forms and apps, and simple causality assessment tools.

Systems

Ensure availability of reporting forms, easy online submission portals and mobile app promotion. Integrate ADR reporting prompts into electronic medical records.

Culture

Encourage non-punitive reporting, provide feedback to reporters, and highlight the public health value of each report.

Nursing empowerment

Develop nurse-led ADR surveillance roles and clear protocols enabling nursing staff to record and escalate suspected ADRs.

Strengths and limitations

Strengths of this study include use of a validated instrument, pilot testing and assessment of internal consistency (Cronbach's α=0.773). Inclusion of both doctors and nurses allowed meaningful comparisons across professional groups.

Limitations include the convenience sampling and single-centre design, which limit generalizability. Self-reported practices may be subject to recall or social desirability bias. The higher proportion of nurses, while reflective of workforce distribution, may influence aggregate metrics. Also, non-response bias cannot be ruled out, as those more aware or interested in pharmacovigilance may have been more likely to participate. Finally, the cross-sectional design limits causal inference.

CONCLUSION

Our survey shows good baseline knowledge and positive attitudes toward pharmacovigilance among healthcare professionals at a tertiary teaching hospital in central India, but substantially lower reporting practices, particularly among nurses and regarding use of digital reporting tools. Addressing barriers through structured training, simplified systems and institutional support is essential to strengthen ADR reporting and patient safety.

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REFERENCES

1. World Health Organization. Safety of medicines: a guide to detecting and reporting adverse drug reactions. Geneva: World Health Organization; 2002. Available at: https://www.who.int/publications/i/item/WHO-EDM-QSM-2002-2. Accessed on 14 May 2025.
2. Jeetu G, Anusha G. Pharmacovigilance: A worldwide master key for drug safety monitoring. J Young Pharm. 2010;2(3):315-20.
3. Patel KJ, Kedia MS, Bajpai D, Mehta SS, Kshirsagar NA, Gogtay NJ. Evaluation of the prevalence and economic burden of adverse drug reactions presenting to the medical emergency department of a tertiary referral centre: a prospective study. BMC Clin Pharmacol. 2007;7:8.
4. Beijer HJ, de Blaey CJ. Hospitalisations caused by adverse drug reactions (ADR): a meta-analysis of observational studies. Pharm World Sci. 2002;24(2):46-54.
5. Smith CC, Bennett PM, Pearce HM, Harrison PI, Reynolds DJ, Aronson JK, et al. Adverse drug reactions in a hospital general medical unit meriting notification to the Committee on Safety of Medicines. Br J Clin Pharmacol. 1996;42(4):423-9.
6. Pathak AK, Kumar M, Dokania S, Mohan L, Dikshit H. A retrospective analysis of reporting of adverse drug reactions in a tertiary care teaching hospital: one year survey. J Clin Diagn Res. 2016;10(8):FC01-4.
7. Bhagavathula AS, Elnour AA, Jamshed SQ, Shehab A. Health professionals' knowledge, attitudes and practices about pharmacovigilance in India: a

systematic review and meta-analysis. PLoS One. 2016;11(3):e0152221.
8. Desai C, Panchal J, Dikshit R, Iyer G, Shah S. An evaluation of knowledge, attitude, and practice of adverse drug reaction reporting among prescribers at a tertiary care hospital. Perspect Clin Res. 2011;2(4):129-33.
9. Tekel MT, Bekalu AF, Sema FD. Knowledge, attitude, and practice of medical, pharmacy, and nursing students towards pharmacovigilance and adverse drug reaction reporting at University of Gondar College of Medicine and Health Sciences, Northwest Ethiopia: a cross-sectional study. Adv Med Educ Pract. 2021;12:1129-39.
10. Adisa R, Omitogun TI. Awareness, knowledge, attitude and practice of adverse drug reaction reporting among health workers and patients in selected primary healthcare centres in Ibadan, southwestern Nigeria. BMC Health Serv Res. 2019;19(1):926.
11. Khan Z, Karatas Y, Hamid SM. Evaluation of health care professionals' knowledge, attitudes, practices and barriers to pharmacovigilance and adverse drug reaction reporting: a cross-sectional multicentral study. PLoS One. 2023;18(5):e0285811.
12. Kiyoshi K. Signal Detection from Spontaneous Reports. Jap J Pharmacoepidemiol. 2001;6:101-8.
13. Hazell L, Shakir SA. Under-reporting of adverse drug reactions: a systematic review. Drug Saf. 2006;29(5):385-96.
14. Vessal G, Mardani Z, Mollai M. Knowledge, attitudes, and perceptions of pharmacists to adverse drug reaction reporting in Iran. Pharm World Sci. 2009;31(2):183-7.
15. Parracha ER, Advinha AM, Lopes MJ, Oliveira-Martins S. Mobile apps for quick adverse drug reaction report: A scoping review. Pharmacoepidemiol Drug Saf. 2023;32(1):19-27.
16. 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.
17. Pirmohamed M, James S, Meakin S, Green C, Scott AK, Walley TJ, et al. Adverse drug reactions as cause of admission to hospital: prospective analysis of 18 820 patients. BMJ. 2004;329(7456):15-9.

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