Evaluation of ADR Reporting Practices in a Tertiary Care Hospital: Challenges and Recommendation

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ABSTRACT

Adverse Drug Reactions (ADRs) remain a critical yet underreported concern in healthcare, contributing significantly to patient morbidity, prolonged hospitalization, and increased healthcare costs. Tertiary care hospitals, due to their complexity and high patient turnover, are uniquely positioned to generate vital pharmacovigilance data. However, ADR underreporting by healthcare professionals continues to hinder effective drug safety surveillance. This observational study aimed to analyze the patterns, awareness, and barriers related to ADR reporting among healthcare professionals in a tertiary care hospital in North India, and to identify strategies for improving pharmacovigilance practices. A cross-sectional study was conducted from March to May 2025 involving 99 healthcare professionals, including doctors, pharmacists, nurses, physiotherapists, and interns. Data were collected using a structured, validated questionnaire covering knowledge, attitudes, practices, and barriers to ADR reporting. Descriptive statistics were used to analyze trends in ADR encounters, reporting behaviors, and awareness of pharmacovigilance systems like the Pharmacovigilance Programme of India (PvPI). While 78.79% of participants reported encountering ADRs, only 30.3% reported them consistently. Awareness of institutional pharmacovigilance systems was relatively high (81.82%), yet correct identification of the CDSCO ADR reporting form was noted in only 58.59% of respondents. Major barriers to reporting included lack of time (40.4%), fear of legal consequences (21.21%), and insufficient knowledge (16.16%). Despite these challenges, 77.78% recognized ADR reporting as part of their professional duty, and 66.67% expressed willingness to attend future training. The study highlights a significant gap between awareness and actual ADR reporting practices. Strengthening institutional pharmacovigilance through targeted training, feedback mechanisms, and simplified reporting tools is essential to foster a culture of proactive drug safety monitoring. Addressing systemic and

perceptual barriers can enhance ADR surveillance and support patient safety initiatives in tertiary care settings.

Keywords: Adverse Drug Reactions, Pharmacovigilance, PvPI, Tertiary Care Hospital, Healthcare Professionals, Drug Safety, India, CDSCO, ADR Reporting Barriers.

INTRODUCTION

Adverse drug reactions (ADRs) are a leading cause of drug-related morbidity and mortality, significantly affecting patients' safety and health care delivery across the globe. 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 the prophylaxis, diagnosis, or treatment of disease" [1]. ADRs contribute to increased hospital admissions, prolonged hospital stays, higher treatment costs and diminished trust in health care systems [2]. Their occurrence is particularly prominent in complex medical environments such as tertiary care hospitals, where patients are commostays, higher multiple medications.

Pharmacovigilance, the science systems activities associated with the detection, assessment, understanding, and prevention of adverse effects or other drug-related problems, plays a vital role in ensuring drug safety post-marketing [3]. A key mechanism for pharmacovigilance is spontaneous ADR reporting, which allows healthcare professionals to report suspected reactions voluntarily. However, underreporting is a well-documented issue, especially in developing countries. According to WHO estimates, fewer than 10% of ADRs are ever reported, hindering the timely identification of serious drug-related risks [4].

Tertiary care hospitals serve as ideal platforms for pharmacovigilance initiatives due to their large and diverse patient populations and complex therapeutic regimens. These hospitals often treat patients with chronic illnesses, comorbidities, and multiple prescriptions, creating a higher likelihood of polypharmacy-induced ADRs [5]. Thus, analysing ADR reporting patterns within such institutions can reveal important trends and identify gaps in current surveillance practices. Moreover, these insights can guide strategies to strengthen pharmacovigilance frameworks at the institutional and national levels.

In India, the Pharmacovigilance Programme of India (PvPI), initiated by the Central Drugs Standard Control Organization (CDSCO) and coordinated by the Indian Pharmacopoeia Commission (IPC), aims to improve drug safety by promoting ADR reporting through a network of Adverse Drug Reaction Monitoring Centres (AMCs) [6].

Tertiary care hospitals are a major component of this network. However, previous research has identified various barrier that hinder effective ADR reporting by healthcare professionals. These include a lack of awareness or training, uncertainty about causality, concerns over legal consequences, and time constraints [4].

Despite the existence of PvPI and its growing network of AMCs, limited published data are available that examine ADR reporting trends at the level of individual tertiary care hospitals in India. Most existing studies are either region-specific or fail to capture the full scope of variables, such as patient demographics, suspected drug classes, severity, outcomes of reactions, and the completeness of submitted reports. A comprehensive observational study at the institutional level can thus contribute significantly to the understanding of ADR reporting behaviors' and the identification of high-risk drug categories or patient groups [6].

This study aims to investigate the pattern of ADR reporting in a tertiary care teaching hospital, focusing on the characteristics of reported ADRs, patient demographics, drug categories involved, severity, preventability, and outcomes [7]. The quality and completeness of the submitted ADR forms will also be evaluated. The findings are intended to enhance institutional pharmacovigilance activities, promote a culture of reporting among healthcare professionals, and ultimately support safer use of medications in hospital settings.[8].

The objective of this observational study was to evaluate the current patterns and challenges of Adverse Drug Reaction (ADR) reporting among healthcare professionals in a tertiary care hospital. Specifically, the study aimed to assess the awareness and knowledge of doctors, pharmacists, nurses, and interns regarding ADRs and national pharmacovigilance initiatives such as the Pharmacovigilance Programme of India (PvPI). It further sought to analyze the characteristics of reported ADRs, including the drug classes involved, system organ classification (SOC), severity, outcomes, and the completeness of the ADR documentation. Additionally, the study aimed to determine the frequency and quality of ADR reporting across various departments and healthcare roles. A structured questionnaire was used to explore key barriers and motivators influencing reporting behavior. Based on the findings, the study also intended to propose actionable recommendations to strengthen ADR reporting practices through capacity building, sensitization programs, and institutional integration of pharmacovigilance activities into routine clinical workflows.

Despite national efforts like the Pharmacovigilance Programme of India (PvPI), ADR underreporting remains a major issue, particularly in tertiary care hospitals. Most existing studies lack detailed, institution-specific data and fail to explore the practical barriers faced by different healthcare professionals. There is also limited analysis of

the quality and completeness of ADR reports. This study addresses these gaps by providing a focused evaluation of ADR reporting patterns, awareness levels, and challenges within a single tertiary care hospital.

MATERIALS AND METHODS

Study Design and Setting

This cross-sectional, observational study was conducted at a tertiary care teaching hospital in North India, recognized as an Adverse Drug Reaction Monitoring Centre (AMC) under the Pharmacovigilance Programme of India (PvPI). The study spanned a period of three months, from March 2025 to May 2025, and incorporated both retrospective and prospective components to comprehensively evaluate ADR reporting patterns and associated factors.

Study Population

Participants included healthcare professionals such as physicians, resident doctors, pharmacists, nurses, and interns actively involved in patient care. Inclusion criteria were: (1) current employment in the hospital during the study period, (2) voluntary consent to participate, and (3) active engagement in prescribing, dispensing, or monitoring drug therapies. Individuals not involved in direct patient care or those who declined participation were excluded.

Sampling Technique and Sample Size

A purposive sampling method was employed to recruit participants from key departments, including general medicine, paediatrics, surgery, obstetrics and gynaecology, and intensive care units. A target sample size of 100 respondents was set to ensure adequate representation across various clinical roles.

Data Collection Tool and Procedure

Data were collected prospectively using a structured, pre-validated questionnaire designed via Google Forms. The questionnaire aimed to assess the knowledge, attitude, and practices (KAP) of healthcare professionals regarding ADR reporting. It comprised five sections: demographic details (e.g., profession, department, and years of experience), awareness of ADRs, knowledge of reporting systems (e.g., PvPI and CDSCO), perceived barriers, and potential facilitators influencing reporting behavior.

RESULTS

A total of 99 healthcare professionals participated in the study. The survey captured detailed responses regarding their awareness, attitudes, and practices toward Adverse Drug Reaction (ADR) reporting.

DEMOGRAPHICS CHARACTERISTICS

- PROFESSIONAL ROLE

Response	Frequency	Percentage
Doctor	30	30.3%
Pharmacist	26	26.26%
Physiotherapist	18	18.18%
Nurse	17	17.17%
Intern	8	8.08%

Table 1. Professional Role

In table1, the majority were doctors (30.3%), followed by pharmacists (26.26%), physiotherapists (18.18%), nurses (17.17%), and interns (8.08%).

- **YEAR OF EXPERIENCE**

Response	Frequency	Percentage
1-5 years	57	57.58%
Lessthan1year	33	33.33%
6 –10 years	7	7.07%
More than 10 years	2	2.02%

Table 2. Year of experience

In table 2, most respondents had 1–5 years of clinical experience (57.58%), indicating a predominance of early-career professionals.

ADR AWARENESS AND PRACTICES

- **ENCOUNTERED SUSPECTED ADR**

Response	Frequency	Percentage
1-5 years	57	57.58%
Lessthan1year	33	33.33%
6 –10 years	7	7.07%
Morethan 10 years	2	2.02%

Table3. Encountered suspected ADR

In table3, 78.79% of participants reported having encountered at least one suspected ADR.

- **FIRST STEP TO SUSPECT ADR**

Response	Frequency	Percentage
Stop the suspected drug	78	78.79%
Report it to the Pharmacovigilance committee	12	12.12%
Inform the patient	7	7.07%
Ignore unless its serious 2 2.02%		

Table 4. First Step to Suspect ADR

In table 4, the most common immediate action upon suspecting an ADR was discontinuing the suspected drug (78.79%).

KNOWLEDGE AND RESPONSIBILITY IN ADR REPORTING

- **PHARMACOVIGILANCE AWARENESS**

Response	Frequency	Percentage
Yes	81	81.82%
No	9	9.09%
Not sure	4	4.04%
No	2	2.02%

Table 5. Pharmacovigilance Awareness

In table5, 81.82% were aware of the existence of a pharmacovigilance program in their hospital.

REPORTING RESPONSIBILITY

Response	Frequency	Percentage
Anyhealthcareprofessional	81	81.82%
Only doctors	12	12.12%
Only pharmacists	4	4.04%
Pharmacovigilance officer Only	2	2.02%

Table 6. Reporting Responsibility

In table 6, most participants (81.82%) recognized that ADR reporting is the responsibility of any healthcare professional, not just physicians or pharmacists.

- **REPORTING TOOLS**

Response	Frequency	Percentage
CDSCOADRreportingform	58	58.59%
Casereportform	32	32.32%
WHOYellow card	6	6.06%

MedWatch form	3	3.03%

Table 7. Reporting Tools

In table7, the CDSCO ADR reporting form was correctly identified by 58.59% of respondents as the standard format in India.

FREQUENCY AND QUALITY OF REPORTING

- REPORTING FREQUENCY

Response	Frequency	Percentage
All suspected ADRs	47	47.47%
All suspected ADRs	33	33.33%
Only serious ones	11	11.11%
Only rareones	7	7.07%

Table 9. Criteria for reporting

In table 9, 47.47% reported all suspected ADRs, while others limited reporting to serious or rare reactions.

EDUCATION AND BARRIERS

Response	Frequency	Percentage
Hospital training	43	43.43%
Medical/Nursing/Pharmacy curriculum	37	37.37%
WorkshopsorCME	14	14.14%
Medical/Nursing/Pharmacy curriculum,Hospitaltraining	2	2.02%
Medical/Nursing/Pharmacy	o1r	1.01%

curriculum,Workshops		
Medical/Nursing/Pharmacy curriculum,Workshops	o1r	1.01%

- SOURCE OF KNOWLEDGE

Table 10. Sources of Knowledge

In table10, the most cited source of ADR reporting knowledge was hospital training (43.43%), followed by academic curriculum (37.37%).

- PERCEIVED BARRIERS

Response	Frequency	Percentage
Lack of time	40	40.4%
Fear of legal issues	21	21.21%
Lack of knowledge	16	16.16%
No barriers	12	12.12%
Lack of time	9	9.09%

Table 11. Perceived Barriers

In table11, lack of time was the most commonly reported barrier (40.4%), followed by fear of legal issues (21.21%) and lack of knowledge (16.16%).

CONFIDENTIALITY AND SYSTEM USAGE

- CONFIDENTIALITY PRACTICES

Response	Frequency	Percentage
Useof coded identifiers	65	65.66%
Nameand IDarehidden	29	29.29%
Onlyinitialsareused	4	4.04%
Not sure	1	1.01%

Table 12. Confidentiality Practices

In table 12, 65.66% ensured confidentiality using coded identifiers.

- REPORTING CHANNELS

Response	Frequency	Percentage
Hospital administration	61	61.62%
Pharmacovigilance center	34	34.34%
Medical Superintendent	3	3.03%
CDSCO directly	1	1.01%

Table 13. Reporting Channels

In table13, ADRs were most commonly reported to hospital administration (61.62%), followed by pharmacovigilance centers (34.34%).

- ONLINE REPORTING AWARENESS

Response	Frequency	Percentage
Strongly agree	58	58.59%
Agree	39	39.39%
Neutral	2	2.02%

Table 14. Online Reporting Awareness

DRUG CLASSES MOST ASSOCIATED WITH ADRs

Response	Frequency	Percentage
Antibiotics, NSAIDs, Antiepileptics, Antihypertensives	37	37.37%
Antibiotics	19	19.19%

NSAIDs	14	14.14%
NSAIDs,Antihypertensives	11	11.11%
Antiepileptics, Antihypertensives	6	6.06%
Antibiotics,NSAIDs	3	3.03%
Antibiotics,Antiepileptics	2	2.02%
Antibiotics, NSAIDs, Antiepileptics, Antihypertensives	1	1.01%

Table 15. Drug classes most associated with ADRs

In table 15, the most commonly implicated drug classes associated with reported ADRs were a combination of antibiotics, NSAIDs, antiepileptics, and antihypertensives (37.37%), followed by individual categories like antibiotics (19.19%) and NSAIDs (14.14%). Polypharmacy involving multiple high-risk drug classes was a significant contributor to ADRs in this tertiary care setting.

AWARENESS OF PVPI ONLINE REPORTING

Response	Frequency	Percentage
Yes	84	84.85%
No	9	9.09%

Table 16. Awareness of PvPI Online Reporting

In table16, a majority of respondents (84.85%) were aware that ADRs can be reported online via the Pharmacovigilance Programme of India (PvPI) portal. This indicates a good level of digital awareness among healthcare professionals regarding pharmacovigilance tools.

FEEDBACK AFTER ADR SUBMISSION

Response	Frequency	Percentage
Yes	72	72.73%
No	24	24.24%

Not applicable	3	3.03%

Table 17. Feedback after ADR Submission

In table17, 72.73% had received feedback after submitting ADR reports.

OBSERVATIONAL STUDIES IDENTIFY NEW ADRs

Response	Frequency	Percentage
Yes	71	71.72%
No	28	28.28%

Table 18. Observational Studies identify new ADRs

In table 18, 71.72% agreed that observational studies help identify new ADRs.

TRAINING ON ADR SESSION

Response	Frequency	Percentage
Yes	66	66.67%
Maybe	21	21.21%
No	12	12.12%

Table 18. Training on ADR Session

In table18, 66.67% expressed willingness to attend further ADR training.

DISCUSSION

This observational study provides valuable insight into the current patterns, awareness, and challenges associated with Adverse Drug Reaction (ADR) reporting among healthcare professionals in a tertiary care hospital setting. The findings underscore a

relatively high level of awareness regarding ADR reporting procedures but also reveal gaps in practice,consistency, and understanding of pharmacovigilance protocols [59].

The professional composition of the study population—predominantly doctors and pharmacists— aligns with the expected distribution in hospital-based clinical care, and the fact that over 90% of respondents had less than five years of clinical experience may have influenced the reporting behaviours observed. Although 78.79% of participants reported encountering a suspected ADR in practice, a notable finding was that most respondents (78.79%) prioritized stopping the suspected drug rather than initiating formal reporting processes, suggesting a disconnect between clinical recognition and regulatory action.

Awareness of pharmacovigilance systems appear stobe widespread (81.82% acknowledged its presence in the ir institution); however, the in consistency in responses (with multiple variations of "No") highlights a need for clearer communication and standardized training.Encouragingly, 81.82% of respondents correctly recognized that any healthcare professional could report ADRs, supporting an inclusive reporting culture. However, a significant minority incorrectly assigned the responsibility solely to doctors or pharmacists, which could limit the effectiveness of hospital-wide reporting systems.

Knowledge of the correct reporting format showed moderate accuracy, with only 58.59% correctly identifying the CDSCOAD Rreporting form. Misidentification off orms like the WHO Yellow Card or MedWatch, which are not used in India,r eflects the insufficient understanding of national pharmacovigilance procedures.

Reporting frequency was variable; while some respondents claimed to always report suspected ADRs, others reported doing so only occasionally or rarely. . Interestingly, duplicate or repetitive answers (“always” and “Always,” “all suspected ADRs” repeated) suggest potential response bias or misunderstanding of questionnaire items. Furthermore, only a minority of participants reported selective ADRs—those that were serious, rare, or life-threatening— indicating inconsistent application of reporting criteria.

The majority of participants had received some education on ADR reporting, either through hospital training or academic curricula. Nonetheless, 14.14% attributed their knowledge to continuing medical education (CME) or workshops, reinforcing the importance of integrating pharmacovigilance into both undergraduate and in-service training programs. The fact that nearly 78% considered ADR reporting a professional duty is promising, yet practical barriers such as lack of time (40.4%), fear of legal

consequences (21.21%), and insufficient knowledge (16.16%) continue to hinder active participation in pharmacovigilance.

On confidentiality, most respondents indicated awareness of protective measures such a scoded identifiers and data anonymization, which is crucial to maintaining patienttrust. Awareness of online ADR reporting via the PvPI portal was also high (84.85%), but only 72.73% reported receiving feedback after submission, pointing to a gap in follow-up communication, which may discourage future reporting.

The belief that ADR reporting enhances patient safety was widely shared (97.98% agreed or strongly agreed), and more than two-thirds (71.72%) acknowledged the role of observational studies in uncovering newADRs. Additionally, a majority (66.67%) expressed willingness to attend future training programs, indicating a receptive attitude towards improving pharmacovigilance practices.

In summary, the study highlights both strengths and challenges in the current ADR reporting landscape. While awareness levels are commendable, especially among early-career professionals, practical, educational, and procedural barriers must be addressed through systematic training, simplified reporting processes, and a supportive institutional framework to enhance pharmacovigilance in tertiary care setting.

CONCLUSION

This study highlights that while awareness of pharmacovigilance systems among healthcare professionals in a tertiary care hospital is relatively high, actual ADR reporting remains inconsistent due to barriers like limited time, fear of legal issues, and lack of procedural knowledge. Strengthening institutional frameworks through targeted training, simplified reporting protocols, and routine feedback can significantly enhance reporting practices and contribute to a more robust drug safety culture.

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