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Original Research Article

Knowledge and Attitude towards ADR Reporting among Tertiary Hospital Healthcare Professionals

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Abstract:

Introduction: Adverse Drug Reactions (ADRs) pose a serious challenge to healthcare by increasing patient morbidity, prolonging hospital stays, and adding financial strain. Accurate ADR reporting, particularly in developing countries, is crucial for ensuring drug safety, yet underreporting remains prevalent due to limited awareness, training, and resources among healthcare professionals.

Materials and Methods: This cross-sectional study surveyed healthcare professionals in a tertiary hospital in western Gujarat, aligned with the Pharmacovigilance Programme of India. Using a structured questionnaire covering knowledge and attitudes toward ADR reporting, data was collected from various departments to assess pharmacovigilance practices. Statistical analysis was performed with SPSS 22.1, and confidentiality was maintained throughout the study.

Results: The survey included 244 healthcare professionals, primarily physicians (90.7%), with pharmacists comprising 9.3% of the sample. Findings showed that 48.4% of respondents had encountered an adverse drug reaction (ADR), yet only 44.3% reported these incidents to a pharmacovigilance center. While 60.2% received formal training on ADR reporting, only 27.9% reported receiving "drug alerts." Adherence to ADR minimization guidelines was observed in 58.6% of participants, and 41.4% maintained records of ADRs encountered. Overall, the results highlight gaps in ADR reporting practices despite positive attitudes, with barriers such as limited training and lack of consistent access to drug safety information.

Conclusion: Our study underscores the need for enhanced training and streamlined reporting systems to improve ADR reporting practices among healthcare professionals. Despite positive attitudes, limited knowledge and access to safety resources hinder consistent reporting, indicating areas for targeted intervention to strengthen pharmacovigilance.

Keywords: Adverse Drug Reactions, Pharmacovigilance, Healthcare Professionals, ADR Reporting.

Introduction

Adverse Drug Reactions (ADRs) represent a significant challenge in healthcare, affecting patient safety and outcomes worldwide. [1] ADRs can lead to increased morbidity, extended hospital stays, and substantial financial burdens on healthcare systems. [2] Despite their impact, ADRs are often underreported, especially in developing countries where awareness and resources are sometimes limited. Accurate ADR reporting is essential for monitoring drug safety, identifying risk factors, and improving therapeutic practices to prevent adverse events. [3] In developing countries, the burden of ADRs is likely even greater due to factors such as widespread self-medication practices and the presence of counterfeit or adulterated drugs. [4] A study conducted in India highlighted that 0.7% of hospital admissions were attributed to ADRs, and 3.7% of hospitalized patients experienced ADRs, with fatal outcomes occurring in 1.3% of cases. [5]

Healthcare professionals play a critical role in identifying, reporting, and managing ADRs. Their knowledge, attitudes, and practices towards ADR reporting directly influence the quality of data gathered, impacting drug safety surveillance and regulatory measures. [6] However, various factors such as lack of awareness, insufficient training, and time constraints often hinder effective reporting. Internationally, the Uppsala Monitoring Center in Sweden manages the global ADR database, although it is estimated that only 6-10% of ADRs worldwide are reported. [7] In India, the Ministry of Health & Family Welfare launched the Pharmacovigilance Programme of India (PvPI) in 2010 to enhance the safety and efficacy of

marketed drugs. [8] Despite the PvPI's efforts, ADR reporting remains low among healthcare professionals in India. Studies have shown that a positive attitude towards ADR reporting, supported by adequate knowledge and awareness, can significantly improve reporting rates and contribute to safer patient care. [9,10] This study aims to assess the knowledge, attitude, and practices (KAP) related to ADR reporting among healthcare professionals in tertiary hospitals.

Material and Methods

This cross-sectional, questionnaire-based survey was conducted in a tertiary care hospital in western Gujarat and was aligned with the Pharmacovigilance Programme of India (PvPI). The survey targeted healthcare professionals, including doctors and nurses, across all hospital departments to capture comprehensive data from a diverse range of clinical backgrounds. The study aimed to assess knowledge, attitudes, and practices related to adverse drug reaction (ADR) reporting among healthcare providers, contributing valuable insights to pharmacovigilance efforts in this region.

The study used a structured questionnaire adapted from existing validated tools, with modifications tailored to the hospital's specific environment. The finalized questionnaire consisted of five sections: demographic details (age, gender, specialty), knowledge of ADR reporting (12 questions) and attitudes toward reporting (4 questions). The survey's purpose was explained to each participant, and questionnaires were distributed in regular departmental meetings, allowing participants 30 minutes to complete them.

The questionnaire was primarily multiple-choice, with participants selecting the most accurate answers, and each correct response earning one point. The scoring system had a maximum of 19 points, distributed as follows: knowledge (9 points) and attitude (5 points). The survey was administered both in person and online, with distribution facilitated through departmental meetings and hospital administrators. Data collection was conducted using SPSS 22.1 for statistical analysis to interpret responses and gain insights into ADR reporting practices among healthcare professionals in the tertiary care setting. Confidentiality was ensured throughout, with participants fully briefed on the study's purpose and assured of data privacy.

Results

In this study, a total of 244 healthcare professionals participated, with a mean age of 32.5 years (±7.1). The sample included 58.6% males (n=143) and 41.4% females (n=101), representing a balanced gender distribution across the participants. The majority of the professionals were physicians, making up 90.7% (n=221) of the sample, while pharmacists comprised 9.3% (n=23). In terms of job nature, a substantial portion of the participants held temporary positions (64.0%, n=156), while 36.0% (n=88) were in permanent roles.

This study assessed healthcare professionals' knowledge and attitudes toward adverse drug reactions (ADRs) and pharmacovigilance. While 34.4% identified pharmacovigilance as monitoring ADRs within hospitals, only 13.1% were aware of official ADR reporting systems abroad, and 24.2% knew of drugs withdrawn due to safety concerns. About 43.4% identified impaired kidney function as a key ADR risk factor, but awareness of reporting authorities and databases was limited, with 50.8% unsure about the WHO's official ADR database. Information sources varied, with 33.6% using online resources, and 62.7% disagreed that minor side effects like mild headaches or nausea should go unreported, indicating a cautious stance on ADR reporting.

Table 1: Knowledge about ADRs

Knowledge Assessment Questions	Response Options	Respondents n (%)
1. What is the primary purpose of pharmacovigilance?	(a) Monitoring adverse drug reactions within hospitals	84 (34.4%)
	(b) Enhancing drug safety through continuous assessment	65 (26.6%)
	(c) Identifying, understanding, and preventing adverse drug effects	64 (26.2%)
	(d) Researching the frequency of adverse reactions after drug approval	30 (12.3%)
	(e) Not sure	1 (0.5%)
2. How would you best define an adverse drug reaction (ADR)?	(a) A harmful and unintended effect occurring at standard doses for treatment or prevention	74 (30.3%)
	(b) An unintended harmful effect occurring at typical doses for therapeutic use	85 (34.8%)
	(c) Any medical issue that appears during treatment, regardless of direct cause	60 (24.6%)
	(d) An adverse effect recorded in medical literature with-	25 (10.2%)

	in expected rates	
	(e) Don't know	0 (0.0%)
3. Do you know if other countries have official systems for reporting ADRs?	(a) Yes	32 (13.1%)
	(b) No	212 (86.9%)
4. Are you aware of any drug that has been withdrawn globally due to safety concerns?	(a) Yes	59 (24.2%)
	(b) No	120 (49.2%)
	(c) Unsure	65 (26.6%)
5. Have you ever discussed adverse drug reactions with colleagues or peers?	(a) Yes	41 (16.8%)
	(b) No	203 (83.2%)
6. Do you know where the international center for monitoring drug safety is located?	(a) Sweden	58 (23.8%)
	(b) England	33 (13.5%)
	(c) USA	51 (20.9%)
	(d) France	102 (41.8%)
. Which of the following factors is most commonly associated with an increased likelihood of adverse drug reactions?	(a) Advanced age	18 (7.4%)
	(b) Impaired kidney function	106 (43.4%)
	(c) Chronic visual impairment	17 (7.0%)
	(d) All of the above	53 (21.7%)
	(e) Not sure	50 (20.5%)
8. Where should a serious adverse event be reported in India?	(a) Medical Council of India	28 (11.5%)
	(b) Pharmacy Council of India	94 (38.5%)
	(c) Ministry of Health and Family Welfare	51 (20.9%)
	(d) No specific authority for reporting	43 (17.6%)
	(e) Not sure	28 (11.5%)
9. How would you classify the types of ADRs?	(a) Type A, B, C, D, E, F, and G	85 (34.8%)
	(b) By categories such as 1, 2, 3, etc.	14 (5.7%)
	(c) Known, unknown, common, and rare	64 (26.2%)
	(d) Reversible and irreversible	60 (24.6%)
	(e) Not sure	21 (8.6%)
10. Which of the following is the WHO's official database for ADR reporting?	(a) ADR Advisory Committee	30 (12.3%)
	(b) MedSafe	33 (13.5%)
	(c) VigiBase	43 (17.6%)
	(d) MedWatch	14 (5.7%)
	(e) Not sure	124 (50.8%)
11. Where do you usually gather information about ADRs for new drugs?	(a) Textbooks	47 (19.3%)
	(b) Medical journals	33 (13.5%)
	(c) Online resources	82 (33.6%)
	(d) Pharmaceutical representatives	2 (0.8%)
	(e) Conferences and seminars	12 (4.9%)
	(f) Direct mail brochures	10 (4.1%)
	(g) All of the above	58 (23.8%)
12. Minor side effects like mild headaches and nausea need not be reported. Do you agree?	(a) Strongly agree	43 (17.6%)
	(b) Agree	48 (19.7%)
	(c) Disagree	68 (27.9%)
	(d) Strongly disagree	85 (34.8%)

The study revealed that healthcare professionals held positive attitudes toward ADR reporting, with 72.1% strongly agreeing that it is beneficial to healthcare, 68.9% strongly agreeing that it should be encouraged, and 66.4% strongly agreeing that it enhances drug safety. However, reporting challenges were noted, as 37.7% strongly agreed and 41.8% agreed that ADR reporting is challenging to complete. Only a small proportion disagreed or strongly disagreed with the benefits and necessity of ADR reporting, indicating overall support despite perceived difficulties.

Table 2: Attitudes toward ADR Reporting

Respondents' Attitudes Toward ADR Reporting	ADR reporting is beneficial to healthcare	ADR reporting should be encouraged	ADR reporting enhances drug safety	ADR reporting is challenging to complete
Strongly Agreed	176 (72.1%)	168 (68.9%)	162 (66.4%)	92 (37.7%)
Agreed	60 (24.6%)	65 (26.6%)	72 (29.5%)	102 (41.8%)
Disagreed	5 (2.0%)	7 (2.9%)	8 (3.3%)	38 (15.6%)
Strongly Disagreed	3 (1.2%)	4 (1.6%)	2 (0.8%)	12 (4.9%)

In this study, 48.4% of respondents reported encountering adverse drug reactions (ADRs), while 44.3% had formally reported an ADR to the pharmacovigilance center. Around 27.9% received "drug alerts," and 58.6% adhered to guidelines for minimizing ADRs. Additionally, 60.2% had received formal training on ADR reporting during their professional education, and 41.4% maintained records of ADRs they encountered.

Table 3: Practice of pharmacovigilance among the healthcare professionals

Question	Pharmacist (n=23)	Physician/ Resident/Interns (n=221)	Total Response in Affirmative n (%)
Have encountered an adverse drug reaction (ADR)	10 (43.5%)	108 (48.9%)	118 (48.4%)
Reported an ADR to the pharmacovigilance center	8 (34.8%)	100 (45.2%)	108 (44.3%)
Have received "drug alerts" notifications	6 (26.1%)	62 (28.1%)	68 (27.9%)
Follow guidelines to minimize ADRs	14 (60.9%)	129 (58.4%)	143 (58.6%)
Received formal training on ADR reporting during their professional education	12 (52.2%)	135 (61.1%)	147 (60.2%)
Maintain records of encountered ADRs	9 (39.1%)	92 (41.6%)	101 (41.4%)

Discussion

Our study reveals gaps in knowledge regarding pharmacovigilance and adverse drug reactions (ADRs) among healthcare professionals, with only 34.4% identifying the primary purpose of pharmacovigilance and a significant portion (86.9%) unaware of international ADR reporting systems. Similar trends are observed globally. Ganesan et al. [11] reported that healthcare providers often understand the basic concept of ADR monitoring but lack a thorough grasp of its procedures, contributing to underreporting. Shakya-Gurung et al. [12] in Nepal found a notable deficit in healthcare professionals' knowledge, emphasizing the challenges in spontaneous ADR reporting due to limited pharmacovigilance training, similar to our findings. Moinuddin et al. [13] in Saudi Arabia also reported low awareness levels about formal ADR reporting mechanisms, which further underlines the need for increased awareness and training on a global scale. Studies by Nisa et al. [9] and Ali et al. [14] in Pakistan echoed these results, revealing that many healthcare professionals are unfamiliar with core pharmacovigilance concepts and that training programs significantly improve awareness and reporting consistency.

Our study also highlights that only 24.2% of respondents were aware of drugs withdrawn due to safety concerns, underscoring limited pharmacovigilance engagement. This finding aligns with Shrestha et al. [12] in Kathmandu, where underreporting was attributed to a lack of understanding about the importance of pharmacovigilance in patient safety. Similar observations were made by Khaja et al. [13], who reported that healthcare professionals in Riyadh had limited knowledge about drug safety monitoring, with only a small percentage understanding the critical role of ADR reporting in patient safety. Okezie et al. [15] in Nigeria and Agrawal et al. [16] also noted similar gaps, where knowledge limitations impacted reporting rates. Collectively, these studies emphasize a global trend: inadequate pharmacovigilance training leads to underreporting and reduced engagement in ADR monitoring. Our study, in line with these international findings, indicates that comprehensive, targeted pharmacovigilance education is necessary to foster a culture of safety reporting among healthcare professionals worldwide.

Our study's findings reveal a generally positive attitude among healthcare professionals towards ADR reporting, with a substantial portion (72.1%) strongly agreeing that ADR reporting is beneficial to healthcare, and 68.9% supporting its encouragement. This aligns with results from Ganesan et al. [11], where a majority of respondents also recognized ADR reporting as a professional obligation. Shrestha et al. [12] found similar support in Nepal, with healthcare

professionals expressing that ADR reporting contributes to safer healthcare practices. Moreover, Khaja et al. [13] in Saudi Arabia noted high agreement (over 90%) that ADR reporting should be mandatory, reflecting a strong positive attitude towards its role in healthcare. These positive attitudes are echoed in studies by Gidey et al. [17] in Ethiopia and Ali et al. [14] in Pakistan, both emphasizing the perceived importance of ADR reporting in enhancing patient safety.

However, our study also identifies challenges in ADR reporting, with 37.7% strongly agreeing that the process is challenging, and 41.8% agreeing with this sentiment. This challenge has been observed in other settings as well. For instance, Shakya-Gurung et al. [12] noted that a significant barrier to ADR reporting was the perceived complexity of the reporting process. Moinuddin et al. [13] reported similar concerns, where workload and complicated reporting requirements were seen as deterrents. Nisa et al. [9] and Ganesan et al. [11] observed that, despite recognizing the importance of ADR reporting, healthcare professionals frequently felt constrained by time and procedural complexities. Collectively, these studies suggest that while healthcare professionals acknowledge the importance of ADR reporting, simplifying the reporting process and providing additional support may enhance participation and address these challenges globally.

Our study on pharmacovigilance practices among healthcare professionals shows that while nearly half (48.4%) have encountered an adverse drug reaction (ADR), only 44.3% have reported these incidents to a pharmacovigilance center. This pattern reflects global findings; Ganesan et al. [11] in South India similarly reported that although healthcare providers often encounter ADRs, underreporting remains a significant challenge due to factors like inadequate training and a lack of reporting habit. Shrestha et al. [12] and Moinuddin et al. [13] both observed that healthcare professionals frequently fail to report ADRs even after encountering them, indicating that awareness alone does not always translate into reporting practices. In Ethiopia, Gidey et al. [17] noted that only a small fraction of healthcare professionals regularly report ADRs, attributing this to insufficient training on pharmacovigilance procedures.

Our data also show that only 27.9% have received "drug alerts," and 58.6% reported adherence to guidelines for minimizing ADRs, suggesting some level of engagement with preventive practices. Similar findings were reported by Nisa et al. [9], where professionals acknowledged the importance of adhering to guidelines but lacked consistent access to drug safety updates. Khaja et al. [13] noted that regular receipt of drug alerts and accessible information on ADR guidelines could significantly improve compliance. Furthermore, our study found that 60.2% had received formal training on ADR reporting, which is consistent with the findings of Riordan et al. [6], where training significantly increased reporting rates and guideline adherence. However, in Nigeria, Okezie et al. [15] found that training is still inadequate, highlighting the need for structured pharmacovigilance education in both undergraduate and postgraduate programs.

Finally, only 41.4% of participants in our study reported maintaining records of encountered ADRs, a practice essential for continuity in ADR monitoring. Similar limitations in record-keeping were noted by Adithan et al. [18] and Shakya-Gurung et al. [12], who found that even with high ADR encounter rates, few healthcare professionals maintain proper documentation, primarily due to time constraints and a lack of supportive infrastructure. These findings collectively suggest that while there is awareness and initial engagement with pharmacovigilance practices, consistent reporting, training, and infrastructure improvements are needed to bridge the gap between knowledge and practice in ADR reporting worldwide.

A limitation of our study is the reliance on self-reported data, which may be subject to response bias, as participants might overstate their knowledge or practices regarding ADR reporting. Additionally, our study sample was limited to a specific region, which may affect the generalizability of the findings to broader healthcare settings. The cross-sectional design also limits our ability to observe changes in knowledge or practice over time, suggesting that further longitudinal studies could provide deeper insights into the impact of ongoing pharmacovigilance training and resources.

Conclusion

In conclusion, our study highlights that while healthcare professionals possess a basic understanding of pharmacovigilance and the importance of ADR reporting, substantial gaps remain in the practical application of this knowledge. The positive attitudes toward ADR reporting reflect a willingness to engage, yet barriers such as inadequate training, limited access to drug safety alerts, and procedural challenges inhibit consistent reporting and record-keeping. These findings underscore the need for targeted interventions, including enhanced pharmacovigilance training programs, streamlined reporting systems, and improved access to drug safety information. Strengthening these areas can promote a more proactive and systematic approach

to ADR reporting, ultimately contributing to improved patient safety and healthcare outcomes.

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