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Original Research Article

Adverse drug reaction reporting practices and reasons for underreporting among healthcare professionals in a tertiary care hospital: a questionnaire-based study

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ABSTRACT

Background: Adverse drug reactions (ADRs) are a major global public health issue. When severe it can lead to morbidity, mortality, hospital admissions, increased risk of readmission, longer hospital stays, and other negative outcomes. Unfortunately, underreporting is a major limitation of spontaneous notification systems, with only 6-10% of all ADRs reported, weakening pharmacovigilance and jeopardizes patient safety. This study was done to evaluate ADR-reporting practices and reasons for underreporting among healthcare professionals at a tertiary-care hospital.
Methods: A cross-sectional, questionnaire-based study was conducted using an online self-administered form circulated to all doctors and nurses at the study site. Data from 111 respondents were analysed. The questionnaire covered knowledge, attitudes and practices related to ADR reporting and perceived barriers to its reporting.
Results: Of 400 healthcare practitioners (HCPs) only 111 responded (27.75%). Among the 111 respondents; 77% knew the meaning of pharmacovigilance, 82% of respondents felt qualified to report ADRs, only 64.9% were aware of what to report, and even fewer (53.2%) knew how to report an ADR. Only 30 (27.0%) reported ever submitting an ADR report, while 81 (73.0%) had never reported. Among these non-reporters, the commonest barriers were lack of knowledge about the reporting procedure, uncertainty regarding causality, time constraints, and the perception that observed events were already known or not sufficiently serious to warrant reporting. Awareness of the institutional reporting mechanism and of national pharmacovigilance pathways was low.
Conclusions: Although awareness of pharmacovigilance was high, actual ADR reporting was low, hindered by unfamiliarity with processes, time constraints, and poor access to ADR reporting forms. Practical steps like hands-on training, simplified reporting, institutional support, and regular feedback are needed to convert positive attitudes into sustained reporting. Multicentre and longitudinal studies should evaluate these interventions.

Keywords: Pharmacovigilance, Underreporting of ADRs, Adverse drug reaction reporting systems, Knowledge attitude practice, Barriers

INTRODUCTION

An adverse drug reaction (ADR) can be defined as 'an appreciably harmful or unpleasant reaction resulting from an intervention related to the use of a medicinal product; adverse effects usually predict hazard from future administration and warrant prevention, or specific treatment, or alteration of the dosage regimen, or withdrawal of the product'.[1]

As per World Health Organization (WHO) "safety of medicines is an essential part of patient safety, and global drug safety depends on strong national systems that monitor the development and quality of medicines, report

their harmful effects, and provide accurate information for their safe use".[2]

Ensuring public health and safety from ADRs is crucial in clinical settings. ADRs are a major global public health issue. Severe cases can lead to morbidity, mortality, hospital admissions, increased risk of readmission, longer hospital stays, and other negative outcomes. Furthermore, adverse drug reactions affect patients' quality of life and could overburden the hospital system.[3]

Preventing and detecting adverse effects from medicines is termed pharmacovigilance.[2] Pharmacovigilance (Pv) is a key tool for improving patient safety and care by identifying and assessing problems associated with medication use. This helps prevent reactions and maximise therapeutic outcomes.[4]

Unfortunately, underreporting is a major limitation of spontaneous notification systems, with only 6-10% of all ADRs reported. The high rate of underreporting prevents ADRs from being quantified and makes it difficult to calculate their impact in terms of incidence and risk. Additionally, it delays the activation of warning signals, which can have negative effects on public health. Delays in restricting or withdrawing a drug thus affects many more patients.[5]

In India, all healthcare practitioners (HCPs), including doctors, post-graduate students and nurses, can report an ADR by completing a suspected ADR reporting form from Central Drugs Standard Control Organization (CDSCO) or Pharmacovigilance Programme of India (PvPI) which maintains the Indian database for ADR reports. The WHO Sweden Uppsala Monitoring Centre (UMC) administers the international database for ADR reports.[6]

It is critical for HCPs to understand how and where to report an ADR. HCPs active engagement in the Pv program can improve ADR reporting and medication safety outcomes. India makes a minimal contribution to the UMC database. Many studies show that there is a lack of awareness among HCPs about India's existing Pv program, which is connected with underreporting of ADR.[7] Knowledge, attitude, and practice (KAP) studies aid in strengthening the present Pv system, reducing drug reactions related problems in our country, and investigating the causes of underreporting.[8] Hence the objective of this study was to evaluate the ADR practices followed by the HCPs and to explore reasons for underreporting of ADRs.

METHODS

This was a cross-sectional, single-centre observational study conducted at Hinduhridaysamrat Balasaheb Thackeray Medical College and Dr. Rustom Narsi Cooper Municipal General Hospital, a tertiary care teaching hospital in Mumbai, over a period of two months from 15 April 2025 to 15 June 2025.

Selection criteria

The study included healthcare professionals (HCPs) working at the study centre, comprising doctors (residents and faculty) and nurses. Participants who did not provide consent were excluded from the study.

Procedure

A pre-validated, questionnaire-guided approach was used for data collection through an online Google form. The questionnaire consisted of four domains assessing knowledge, attitude, practices (KAP), and barriers related to ADR reporting.

A universal sampling method was employed, and all eligible HCPs were invited to participate. Informed consent was obtained electronically from all participants prior to inclusion. The study aimed to evaluate the extent and reasons for underreporting of ADRs in an ADR monitoring centre (AMC) functioning under the Pharmacovigilance Programme of India.

Data analysis

The collected data was sorted, coded, and entered into a Microsoft Excel spreadsheet for ease of management, and the computed data was then exported to statistical package for the social sciences (SPSS) version 27.0 for analysis. The data was summarised using descriptive statistics, such as frequency and percentages.

RESULTS

The study was conducted in a tertiary care hospital to assess the KAP of HCPs regarding ADR reporting. Of 400 HCPs only 111 (27.75%) participated in the study, including 52 junior residents, 25 faculty members (senior residents, assistant professors, associate professors, and professors) and 34 nursing staff; demographic characteristics represented in Table 1. The department-wise distribution of participants was also analysed (Figure 1). Department wise the contribution to study was: maximum response was from nursing 21.6%, medicine 13.5%, pharmacology 10.8%, surgery 8.1%, pathology 7.2%, community medicine 6.3%, physiology 5.4%, psychiatry 4.5%, paediatrics 2.7%, dermatology, 2.7%, anatomy 2.7%, respiratory medicine 1.8%, radiology 1.8%, forensic medicine 1.8%, OBGY 1.8%, ENT 0.9%, ophthalmology 0.9%, occupational health 0.9%, anaesthesia 0.9%, orthopaedics 0.9%, biochemistry 0.9% and others 2%.

Knowledge and awareness of pharmacovigilance and ADR reporting

In the study, participants were asked to define "pharmacovigilance" (Figure 2). The majority (77.5%) correctly identified it as "surveillance of ADRs". Other responses included: "surveillance of medicines" (13.5%),

"control of use of medicines" (3.6%), "medicine regulation" (2.75%), "control of illegal drugs" (1.83%), and "safety and efficacy of medicine" (0.92%).

Table 1: Demographic characteristics of study participants.

Variables	Frequency (n)	Percentage (%)
Total HCPs approached	400	100
Participants included	111	27.75
Designation		
Junior Residents	52	46.85
Faculty (SR, Assistant, Associate, Professor)	25	22.52
Nursing staff	34	30.63

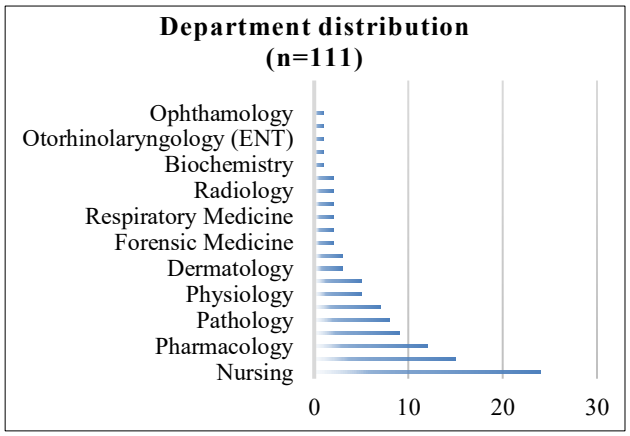

Figure 1: Department wise distribution of participants.

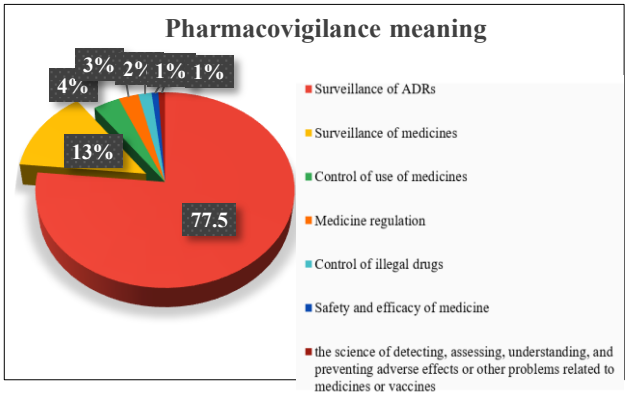

Figure 2: "PV meaning" responses from participants.

The majority of participants demonstrated a high level of awareness of pharmacovigilance and ADR reporting. 75.7% of HCPs were aware of the PvPI, and 69.4% were aware of the presence of an AMC in the institution, while 34 participants (30.6%) were unaware of the AMC centre's existence. Also, within the latter group (n=34), 22 respondents belonged to clinical departments, while 12 were from non-clinical or para-clinical departments.

While 82% of respondents felt qualified to report ADRs, only 64.9% were aware of what to report, and even fewer (53.2%) knew how to report an ADR.

Perceived attitude towards ADR reporting

HCPs showed a positive attitude toward ADR reporting, recognizing its significance in ensuring patient safety. A majority (91.9%) agreed that ADR monitoring and reporting is a professional obligation. Furthermore, 96.4% of participants supported making ADR reporting mandatory in post-marketing surveillance to enhance drug safety monitoring. Nearly all respondents (98.2%) believed that ADR reporting sensitization programs should be included in Continuing Medical Education (CME) sessions. Also, 99.1% reported that even their reporting of single ADR can significantly contribute to the ADR database.

ADR reporting practices among HCPs

Despite the high awareness and positive attitude, actual ADR reporting rates remained low. Only 27% (30 responses) of HCPs had ever reported an ADR and 73% (81 responses) never filled an ADR form.

Participants were asked ADRs (Figure 3) caused by which of the following class of drugs are to be reported; 72.1% responded all class of drugs i.e. herbal, non-allopathic and allopathic causing ADRs are to be reported, while 25.2% responded for only allopathic class of drugs causing ADRs are to be reported.

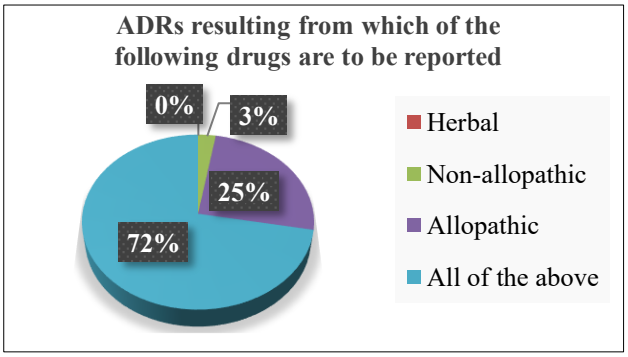

Figure 3: ADRs resulting from different drug classes are to be reported.

When participants were asked what kind of ADRs (Figure 4) should be reported for a drug, 89.2% of them stated both serious and non-serious ADRs should be reported, while only 9% and 1.8% of them considered only serious and only non-serious, respectively. Summary of the above results are represented in Table 2.

Barriers to ADR reporting

Among the 81 responses (73%) who had never reported an ADR (Figure 5), the most frequently cited barriers were

lack of knowledge on how to fill an ADR form (19 responses), followed by multiple barriers (selected "all of the above") (16 responses).

Table 2: Awareness, attitudes, and practices related to ADR reporting.

Parameter	Findings (%)
Awareness of Pharmacovigilance Programme of India (PvPI)	75.7
Awareness of ADR Monitoring Centre (AMC) in institution	69.4
Feel qualified to report ADRs	82
Aware of what to report in an ADR form	64.9
Aware of how to report an ADR	53.2
Have ever filled an ADR form	27
Believe ADR reporting is a professional obligation	91.9
Support mandatory ADR reporting in post-marketing surveillance	96.4
Support ADR training in CME sessions	98.2

Table 3: Most common barriers for underreporting ADRs.

Reason for underreporting	Number of responses (n=81)	Percentage (%)
Do not know how to fill an ADR form	19	23.45
Multiple barriers (selected "All of the above")	16	19.75
Difficulty identifying ADR cause (multiple drugs prescribed)	8	9.82
Lack of time to fill ADR form	7	8.64
Inadequate availability of ADR forms	6	7.41

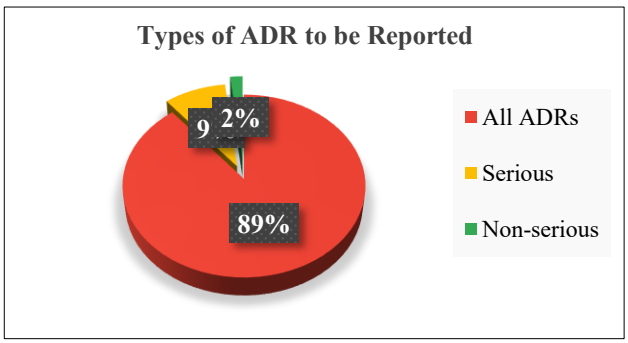

Figure 4: Types of ADR to be reported.

Other reasons included difficulty in identifying ADR causes when multiple drugs were prescribed (8 responses), lack of time to report ADRs (7 responses), inadequate availability of ADR forms (6 responses), procrastination (2 response), never came across any (2 responses) and not eligible to fill (1 response). Most common reasons for underreporting can be seen in Table 3.

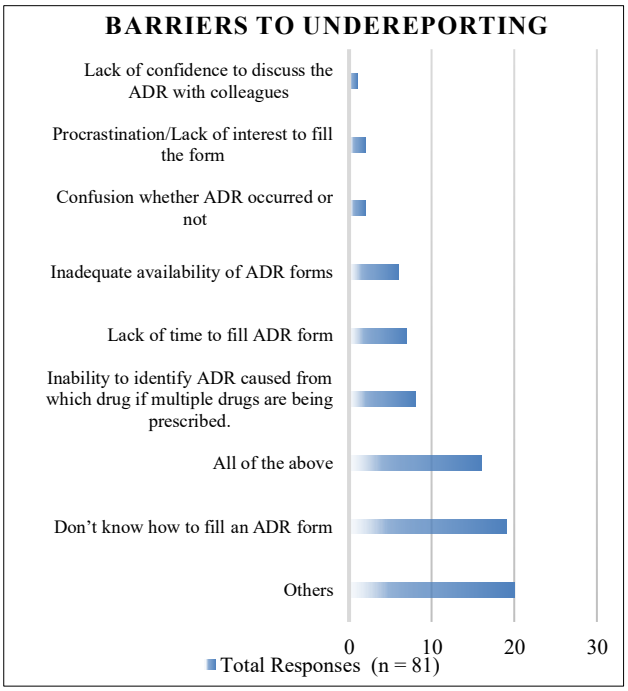

Figure 5: Barriers to underreporting.

DISCUSSION

In our study, we discovered that 75.68% of respondents are aware of the PvPI, and 76.58% correctly identified the meaning of "pharmacovigilance" as the surveillance of adverse drug reactions. This suggests that HCPs in our study have a fundamental theoretical understanding of drug safety monitoring. However, as later findings show, awareness does not always translate into practice.

69.37% of respondents were aware that their institution has an AMC. While this is a positive finding, it also indicates that 30.63% of HCPs are unaware of a critical resource within their own institution, which may impede ADR reporting. These findings suggest a gap in knowledge regarding the actual process of ADR reporting, despite general awareness of its importance.

When asked about their confidence in filling an ADR reporting form, 81.98% believed they were qualified to do so. However, only 64.86% reported being aware of what to report, and 53.15% knew how to submit an ADR form. This gap between perceived competence and actual knowledge of ADR reporting procedures is concerning, as it indicates that many HCPs might not report ADRs simply because they are unsure of the exact process.

In a study done by Nadew et al, out of 407 doctors only 94 (27.4%) of doctors had ever reported ADRs to national pharmacovigilance centre. The study showed that sex (AOR=3.51, 95% CI: 1.76–7.03), work experience (AOR=4.59, 95% CI: 1.21–17.40), existence of ADR reporting form (AOR=3.96, 95% CI: 1.07–14.61) and reporting to respective marketing authorization holders (AOR=21.41, 95% CI: 5.89–77.88) were significantly associated with ADR reporting practices.[9]

In our study, an overwhelming 91.89% recognized ADR reporting as a professional obligation, suggesting a strong ethical and professional commitment to drug safety monitoring. However, barriers in training and accessibility might still prevent actual reporting.

A significant 98.20% of respondents supported the idea of India having its own ADR database, reinforcing the need for a national drug safety surveillance system. Additionally, 99.10% agreed that reporting even a single ADR could significantly contribute to the database, showing a high level of awareness about the importance of ADR reporting in improving patient safety. Also, 96.40% of respondents supported making ADR reporting sensitization a mandatory part of CME sessions. This highlights the need for structured training programs that not only educate healthcare professionals but also provide practical guidance on ow to report ADRs efficiently.

Despite this, only 27% of respondents had ever filled an ADR form, indicating a major gap between knowledge and actual reporting practice. This is in line with existing literature that highlights underreporting as a major challenge in pharmacovigilance systems globally and the need for targeted interventions to bridge this gap and improve ADR reporting rates.

In a study done by Datta et al, the overall correct response rate to the knowledge-based questions was 56.3%. While 97% of respondents were of the view that ADR reporting was necessary, 35% of the respondents felt that the difficulty in deciding the causality of an ADR discouraged them from reporting. 79% of the respondents were not aware of the presence of an AMC in the hospital, and 87% of the respondents admitted that they were not sending filled ADR forms to the AMC.[10]

In our study, when asked about the types of drugs for which ADRs should be reported, 72.07% chose "all of the above", implying that they understood ADRs could occur with various drug classes. Similarly, 89.19% believed that all types of ADRs should be reported, indicating a strong conceptual understanding. A significant positive finding is that 98% of respondents supported making ADR reporting mandatory during post-marketing surveillance. This suggests that participants were aware of the fact that many adverse effects are only identified after widespread drug use in phase 4 of clinical trials.

One of the most striking findings is that 73% of respondents had never filled an ADR form, despite high awareness levels. This indicates the presence of significant barriers to reporting, such as fear of legal consequences, lack of time, uncertainty about what and how to report, limited accessibility to ADR reporting forms. Also, the study by Nadew et al, showed poor awareness and training on risk of under-reporting, feeling that reporting is minor, absence of appropriate reporting tools, delay and/or absence of feedback on reported ADRs, overly burdened doctors, negligence, fear of legal liability and communication gap were cited by key informants as barriers for reporting practice.[9]

Another study done by Khan et al, states the major factors found to be responsible for underreporting of ADR include inadequate risk perception about newly marketed drugs (77.9%), fear factor (73.5%), diffidence (67.7%), lack of clarity of information on ADR form about reporting (52.9%), lethargy (42.7%), insufficient training to identify ADRs (41.2%), lack of awareness about existence of pharmacovigilance program (30.9%) and ADR monitoring center in the institute (19.1%), and inadequate risk perception of over-the-counter (OTC) product (20.6%) and herbal medicines (13.2%). Experience and position did not influence the knowledge and attitudes of doctors.[11]

Also, there was a systematic review done by Garcia-Abeijon et al, 65 studies were included which shows underreporting reasons. While health professional sociodemographic characteristics did not influence underreporting, knowledge and attitudes continue to show a significant effect: ignorance (only serious ADRs need to be reported) in 86.2%; lethargy (procrastination, lack of interest, and other excuses) in 84.6%; complacency (the belief that only well tolerated drugs are allowed on the market) in 46.2%; diffidence (fear of appearing ridiculous for reporting merely suspected ADRs) in 44.6%; and insecurity (it is nearly impossible to determine whether or not a drug is responsible for a specific adverse reaction) in 33.8%. In this review, non-obligation to reporting and confidentiality emerge as new reasons for underreporting.[12]

Finally, a study done by Katekhaye et al, where a total of one-hundred and fifty doctors [91 (60.7%) PGs and 59 (39.3%) medical teachers] participated. Overall, 48.7% were males. 96% believed that Pv is important in medical practice but only 79.3% knew the definition. Only 24.7% were aware of the existing PvPI whereas the international collaborating center was known to 26% of the participants. 96% believed that it is the duty of a treating physician to report an ADR while 36.7% felt that ADR reporting should be the responsibility of a separate team. Surprisingly, 54% felt that financial aid should be provided for ADR reporting. 42.7% have not reported any ADR whilst only 16% have reported more than 10 ADRs in their career. To create an ADR database (79.3%) was the common expectation from the Pv center. 98.7% suggested CME and

trainings to improve the effectiveness of Pv in Indian setting.[13]

To sum up these findings suggest that both educational interventions and system-level improvements are necessary to enhance ADR reporting practices. The results indicate that while HCPs recognize the importance of ADR reporting, lack of practical knowledge and structural barriers hinder effective reporting.

Addressing these challenges through training programs, digital reporting tools, and policy changes can significantly improve ADR monitoring and contribute to patient safety.

Limitations

The study has certain limitations that may impact its generalizability. The sample size may not be large enough to represent the entire HCPs, and responses could be biased towards individuals already interested in Pv, as those unaware or uninterested in ADR reporting may not have participated. Since the study relies on self-reported data, there is a risk of response bias, with participants potentially overstating their awareness or providing socially desirable answers rather than reflecting actual practices.

Additionally, being conducted in a single tertiary care hospital, the findings may not be applicable to other healthcare settings such as rural hospitals, private clinics, or smaller institutions, where policies, training, and Pv culture differ.

The study also does not account for external factors like workload, time constraints, which could significantly impact ADR reporting.

Lastly, as a cross-sectional study, it captures data at a single point in time and does not assess the long-term impact of interventions such as training programs or policy changes on ADR reporting practices.

CONCLUSION

Although awareness of pharmacovigilance was high, actual ADR reporting was low, hindered by unfamiliarity with processes, time constraints, and poor access to ADR reporting forms. Practical steps like hands-on training, simplified reporting, institutional support, and regular feedback are needed to convert positive attitudes into sustained reporting. Multicentre and longitudinal studies should evaluate these interventions.

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