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Original Research Article

Exploring postgraduate medical student's knowledge, attitude and practices towards monitoring and reporting of adverse drug reactions in tertiary care teaching hospital, Gujarat: A cross-sectional study

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ABSTRACT

Background: Prescription of drugs should always be done carefully to minimize adverse effects. Studies show that a significant percentage of patients experience adverse drug reactions (ADRs) that lead to hospital admission. India's ADR reporting rate is below 1%, while the world rate is 5%. Postgraduate medical students are crucial in ensuring the safe and effective use of drugs through their responsibilities in prescribing, administering, and monitoring drugs in patients. Their knowledge, attitudes, and practices towards pharmacovigilance are essential.

Objective: The study aimed to evaluate the basic knowledge, attitudes, and practices of postgraduate medical students regarding Pharmacovigilance.

Results: The cross-sectional study used a pre-validated Google form questionnaire sent via electronic device. The questionnaire consists of three sections: knowledge, attitude, and practice. All three sections have 10 multiple-choice questions each. Each true answer to a question from the knowledge section will get 1 mark. Attitude and practice questions were Likert-based questions. The data was analysed using descriptive statistics. A total of 105 responses were recorded. Overall knowledge of monitoring and reporting of ADRs in postgraduate medical students is 53.04% with the lowest understanding observed in the question regarding "Example of Type A ADRs," which is at 35.20%. 51.40% of participants have an attitude to participate in the training of ADR reporting. 64.80% of participants routinely provide counselling to patients on the potential side effects of medications. Patients with good knowledge of monitoring and reporting ADRs have higher odds of demonstrating good practices.

Conclusion: Imparting the knowledge and awareness of pharmacovigilance among the residents employing continuous educational intervention would bring updated knowledge of practice for drug safety into their everyday clinical practice and also bring the adverse drug reactions reporting culture among them.

1. Introduction

None of the therapeutic drugs are devoid of adverse effects. Therefore, drugs should be prescribed with care, taking into account the risk/benefit ratio.[1] The World Health Organization (WHO) defined "adverse drug reactions (ADRs)" as any noxious, unintended, and undesired effect of a drug, that occurs at doses used in humans for prophylaxis, diagnosis, or cure of a disease.[2] ADRs are already established reasons for mortality and morbidity worldwide.[3]

Pharmacotherapeutic agents have been associated with serious side effects, ranging from minor inconvenience to permanent disability and death. In India and many other highly developed industrialized countries, studies suggest that about 0.2%–24% of patients with ADRs are

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hospitalized.[4,5] ADR also significantly impacts costs in the health care system.[6]

To monitor ADRs worldwide, the World Health Organization (WHO) defined pharmacovigilance as the detection, assessment, management, prevention, and reporting of suspected ADRs, which is the responsibility of healthcare professionals (HCPs).[7] In India, the Ministry of Health and Family Welfare initiated the National Pharmacovigilance (PV) Program, which requires the active involvement of healthcare professionals such as doctors, pharmacists, and nurses.[3] However, India only contributes less than 1% in ADR reporting, which is significantly lower than the world rate of 5%.[8]

The success of the PV program in India depends on the active involvement of healthcare professionals.[9,10] They should know how and where to report an ADR.[11] Spontaneous reports of ADRs have some advantages for identifying potential safety signals, but there are obvious drawbacks, such as underreporting, poor reporting quality, difficulty quantifying risk, and an unknown number of individuals who have been exposed.[12]

Although most studies show that physicians, pharmacists, and nurses have reasonable knowledge of and attitudes toward ADR reporting, severe ADRs are still underreported.[13] Lack of knowledge, attitude, and practice (KAP) regarding ADR reporting is one reason for underreporting.[14] These problems can be addressed by ADR monitoring centres (AMCs) through strategies including imparting continuous awareness of ADR reporting, highlighting the different aspects of reporting ADRs, and emphasizing the role of healthcare professionals (HCPs) in drug safety issues.[15]

PV studies are emerging nowadays due to the advent of new drugs and a quite number of drugs withdrawn due to ADRs.[16] Although the Pharmacovigilance Programme of India (PvPI) contributes to the Uppsala Monitoring Centre database due to the lack of a vibrant ADR monitoring and reporting system among healthcare workers, the reports contributed by India are very few.[17] To enhance the reporting rate, it is essential to improve the knowledge, attitude, and practice (KAP) of all healthcare professionals, especially postgraduates (PGs) concerning ADR reporting and PV. PGs play a prime role in treating patients in any medical college, as they are the workforce of a teaching institute and the primary point of contact for any ADR encountered by the patient.

This study was such a step taken to evaluate the basic knowledge, practices methods concerning severe ADR monitoring, to explore the barriers to ADR reporting, the factors affecting practices in ADR monitoring and reporting, and attitudes towards severe ADR monitoring and PV among Postgraduate medical students at tertiary care hospital attached to a government medical college in Gujarat.

2. Materials and Methods

2.1. Study setting

This was a cross-sectional study among postgraduate medical students at a tertiary care hospital attached to a government medical college in Gujarat between April to July 2023. Institutional ethics committee approval was obtained (46/01/2023). Informed consent was obtained from all participants. A universal sampling technique was used, and of all the PGs invited to participate in the study, 150 attended out of them 105 completed the questionnaire. Eligibility participants were postgraduate medical students who worked at clinical/non-clinical departments in a tertiary care hospital attached to a government medical college in Gujarat and those who gave informed consent to participate in the study were included. Those who did not give consent were excluded.

2.2. Study instrument

A knowledge, attitude, and practice-based questionnaire on ADR reporting and PV program was prepared. HCPs with expertise in the field of pharmacovigilance and ADRs evaluated the developed questionnaire for content validity. The questionnaire was semi-structured, predesigned, pretested, and validated using the research tool for data collection.[18] A few changes were made as per the study requirement and the questionnaire had finally 30 questions. The questionnaire was distributed to PGs in an electric form, in which the purpose of the study was provided and informed consent obtained, and they were asked to fill out the questionnaire. After 2 weeks, non-responders were sent a reminder of the questionnaire.

2.3. Questionnaire design

The self-administered questionnaire was composed of 30 mandatory multiple-choice items and it was developed based on scientific literature and the practice experience of the authors. The questionnaire consists of four main parts:[1] Demographic variables like gender, age, and working in clinical/non-clinical departments;[2] Knowledge part: contained 10 questions made up of the Definition of ADRs, who can report, how, and where to report, Causality assessment, Pharmacovigilance, etc., we set multiple-choice questions, each question has a correct answer, and the correct answer receives 1 point, while the incorrect answer receives 0 points;[3] Attitude part: contained 10 questions made up of concerning and willingness about ADR reporting, This part was provided on a 4 points Likert scale (0=very negative, 1=Negative, 2= Very positive, 3=very positive) to indicate that they had positive or negative attitude towards Monitoring and reporting ADRs and pharmacovigilance;[4] Practice part: contained 10 questions made up of routine practicing towards monitoring and

reporting of ADRs and pharmacovigilance. This part was provided on a 4-point Likert scale (0=Never, 1=rarely, 2= Often, 3=Always) to indicate that they had good or bad practices towards Monitoring and reporting ADRs and pharmacovigilance.

2.4. Data processing

After data collection, data was entered into Microsoft Excel as codes and transferred into SPSS (ver. 26) for analysis. For describing demographic variables, descriptive statistics are used, using percentages or frequencies to demonstrate categorical variables. Categorical data was analyzed with a statistical chi-square test to determine the associated factors. The statistical significance level was set at $P < 0.05$.

3. Results

4. Background characteristics of respondents

The study revealed that 59% of the participants belonged to the ≤27 years age group. The overall mean and standard deviation of the age of those participants were 27.24 ± 2.73 years. Approximately half (51%) of the participants were working in clinical departments. Among all the participants, 56% were female, and 44% were male (Table 1).

Table 1: Background characteristics of participants

Background Characteristics	Frequency	Percentage
Age		
≤27 years	62	59
>27 years	43	41
Sex		
Male	46	44
Female	59	56
Branch		
Clinical	53	51
Non-clinical	52	49

4.1. Knowledge regarding monitoring and reporting of ADRs

It's important to remember that the average knowledge regarding monitoring and reporting adverse drug reactions (ADRs) is 5.5±2.37 SD. Those who achieved a score above the mean are considered to have good knowledge regarding the monitoring and reporting of ADRs. The correct responses to all knowledge questions are shown in Chart 1. Interestingly, the least correct question about knowledge is "Which of the following is an example of a Type A adverse drug reaction?" with only about 35.20% of participants knowing the example of types of ADRs. Additionally, about 36.20% of participants knew about the factors considered when performing a causality assessment of an ADR. It's also worth noting that PGs working in clinical departments have 1.52 times higher odds (CI 95% 0.70 to 3.29, P: 0.2813) of having good knowledge (Table 2).

4.2. Attitude regarding monitoring and reporting of ADRs

In the 4-point Likert-based questionnaire mean attitude towards monitoring and reporting ADRs is 18.71±4.67 SD. We considered that those who achieved a score above the mean have a good attitude towards monitoring and reporting ADRs. Responses to all attitude questions are shown in Chart 2. A total of 57 (54.28%) participants have a good attitude regarding monitoring and reporting of ADRs. PGs working in clinical departments have 1.2 times higher odds (CI 95% 0.55 to 2.60, P: 0.6304) of having a good attitude (Table 3).

4.3. Practice towards monitoring and reporting of ADRs

The mean practice towards monitoring and reporting ADRs in the 4-point Likert-based questionnaire is 19.09 ± 4.64 SD. It was considered that those who achieved a score above the mean have good practice in monitoring and reporting ADRs. Responses to all practice questions are shown in Chart 3. Additionally, 64.80% of participants responded that they always provide counseling to their patients on the potential side effects of medications in a good practice way.. 61.90% of participants always document any suspected ADRs in their patient's medical records. It was also found that PGs working in clinical departments have 3.16 times higher odds *(CI 95% 1.36 to 7.34, P: 0.0074)* of having good practice (Table 4).

Patients with good knowledge of monitoring and reporting ADRs have 4.72 times higher odds (CI 95% 1.93 to 11.55, P: 0.0007) of demonstrating good practices.

5. Discussion

PGs are an invaluable source of collecting and reporting the ADRs.[3] This cross-sectional study had a reasonable overall response rate, just half of the PGs knew about pharmacovigilance.[13] While knowledge is important, other barriers such as time constraints, lack of interest, and awareness about the existing reporting system can hinder ADR reporting.[19]

The key element to identify a suspected ADR in the current study was the temporal relationship between the administration of a medicine and the observation of an adverse effect. Overall, the known general methods of ADR identification in the current study were similar to the previous studies.[20,21] Patient history taking was the most common way of identifying severe ADRs, in line with the previous studies,[22] and using specific criteria for severe ADR identification was needed, as reported in the previous

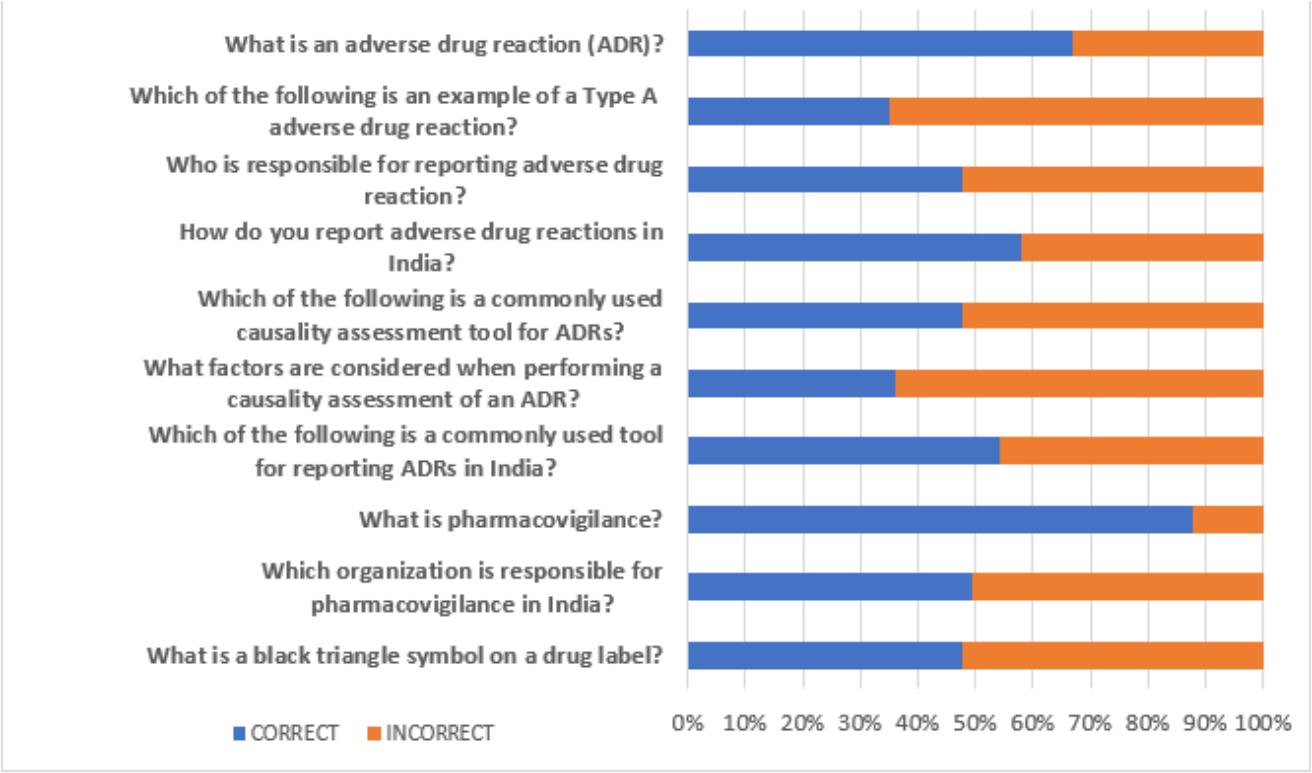

Chart 1: Correct responses to all knowledge questions

Table 2: Association between knowledge and background characteristics

Variables[n(%)]	Knowledge		Odds ratio(95% CI)	P-value
	Good [n(%)]	Bad		
Branch				
Clinical [53(50.47)]	28(26.66)	25(23.80)	1.52(0.70 to 3.29)	0.2813
Non-clinical [52(49.52)]	22(20.95)	30(28.57)		
Age				
≤27 years [62(59.04)]	30(28.57)	32(30.47)	1.0781(0.49 to 2.35)	0.8499
>27 years [43(40.95)]	20(19.04)	23(21.90)		
Sex				
Male [46(43.80)]	23(21.90)	23(1.90)	1.1852(0.54 to 2.56)	0.6663
Female [59(56.19)]	27(25.71)	32(30.47)		

Table 3: Association between attitude and background characteristics

Variables [n(%)]	Attitude		Odds ratio(95% CI)	P-value
	Good [n(%)]	Bad		
Branch				
Clinical [53(50.47)]	30(28.57)	23(21.90)	1.2077(0.55 to 2.60)	0.6304
Non-clinical [52(49.52)]	27(25.71)	25(23.80)		
Age				
≤27 years [62(59.04)]	38(36.19)	24(22.85)	4.0903(0.90 to 4.40)	0.0853
>27 years [43(40.95)]	19(18.09)	24(22.85)		
Sex				
Male [46(43.80)]	27(25.71)	19(18.09)	1.3727(0.63 to 2.99)	0.4237
Female [59(56.19)]	30(28.57)	29(27.61)		

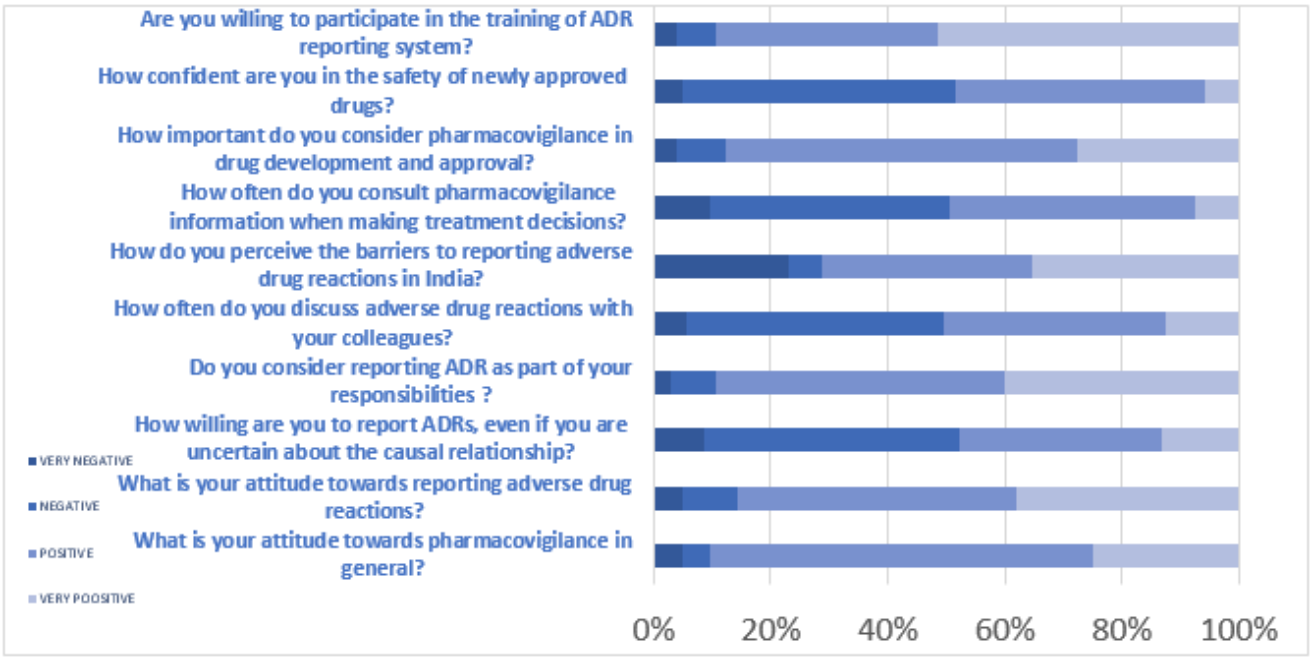

Chart 2: Responses to all attitude questions

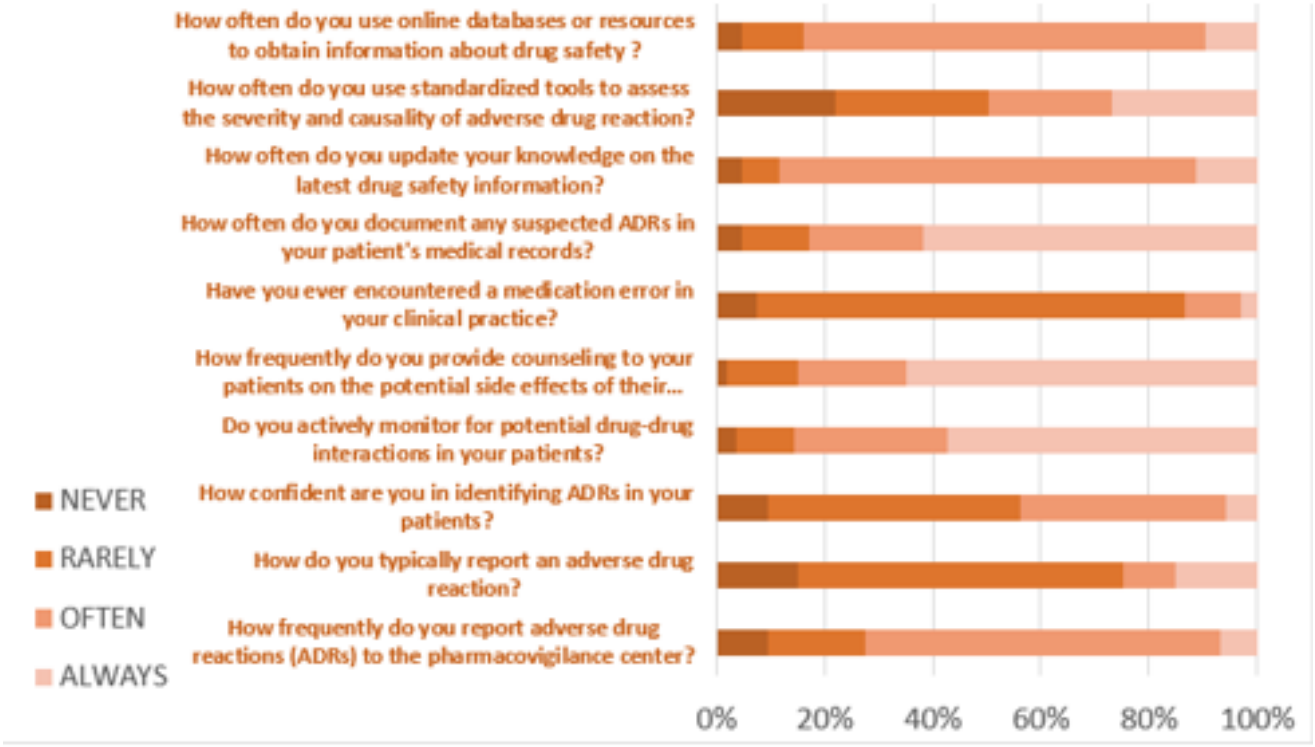

Chart 3: Responses to all practice questions

Table 4: Association between practice and background characteristics

Variables[n (%)]	Practice		Odds ratio(95% CI)	P-value
	Good [n(%)]	Bad		
Branch				
Clinical [53(50.47)]	41(39.04)	12(11.42)	3.16(1.36 to 7.34)	0.0074*
Non-clinical [52(49.52)]	27(25.71)	25(23.80)		
Age				
≤27 years [62(59.04)]	43(40.95)	19(18.09)	1.6295(0.72 to 3.66)	0.2383
>27 years [43(40.95)]	25(23.80)	18(17.14)		
Sex				
Male [46(43.80)]	28(26.66)	18(17.14)	0.7389(0.33 to 1.65)	0.4615
Female [59(56.19)]	40(38.09)	19(18.09)		

studies.[23–25] This suggests that the selection of methods for ADR identification by HCPs depends on their pattern of patient care.[13]

Few respondents were aware of causality tools, such as the WHO-UMC criteria and Naranjo's algorithm, despite reports of the widespread use of these tools.[26,27]

Therefore, strategies to increase knowledge about the causality assessment methods of ADRs should be established for all HCPs.[13] This study found that the most used methods of ADR prevention by all residents were providing patient advice about recurrent drug allergy and recording ADR history in medical notes, which is also in line with the previous studies.[28,29] Residents were aware of patient safety, particularly regarding recurrent drug allergies. Different professions used varied ADR prevention methods aligned with their roles. Physicians focused on patient-related methods and recorded safety data in medical notes instead of using systemic processes like computer databases or drug allergy stickers.

The most common barrier to ADR reporting by all professions was the uncertainty about the causal relationship between drugs and reactions. Similar results were found in the previous studies.[13] This is regrettable since regulatory authorities only require a suspicion that a drug was linked to an adverse effect. The knowledge of a causal relationship should be promoted among HCPs. The other barriers to ADR reporting found in this study were at rates similar to those found in the previous studies.[30–34]

Despite these challenges, our study found that 90.5% of PGs had a positive attitude towards pharmacovigilance. However, our study includes all the steps in the monitoring and reporting of severe ADRs, whereas the other studies only measure the attitudes towards ADR reporting. Additionally, 13.3% of PGs were always willing to report ADRs, even if they were uncertain about the causal relationship, while 43.8% were open to discussing ADRs with colleagues.

Sharma and Kellarai felt that the interns and PGs were poor in ADR reporting, as >65% had not reported any ADR.[35] It is alarming and disheartening to note that, in this study also, the PGs who had reported an ADR previously were very minimal. In this study, only 7% of PGs always reported ADRs to the pharmacovigilance centre, while 65.7% often reported them and 18.1% rarely did. The respondents' practical issues on ADR underreporting were not aware of filling up the suspected ADR form due to the non-availability of ADR forms and lack of time. Several studies have demonstrated the same trend of underreporting among health-care professionals.[36–38]

Interestingly, 57% of PGs actively monitored potential drug interactions in their patients, and 97% never encountered a medication error in their clinical practice. PGs also provided counselling to patients on the potential side effects of medications and documented suspected ADRs in patients' medical records.

Finally, our study found that 89.5% of PGs were willing to participate in ADR reporting system training, indicating a strong desire to improve their knowledge and skills in this area. Thus, the need for reporting ADRs had to be emphasized to all the PGs by periodical educational interventions on a routine basis. Therefore, we recommend that such educational intervention programs should be a part of Internship/undergraduate training programs. Several similar studies should be conducted among all healthcare professionals and paramedics to improve the KAP of PV in India.

5.1. Limitation

It is important to note that our study was limited to a single center and, therefore, the findings may not be applicable to a wider population. Moreover, the study relied on participants' self-assessment of their knowledge, attitudes, and practices regarding ADRs. This could have led to social expectation bias, as some participants may have been unwilling to reveal any practice flaws. However, we used anonymity to minimize this bias during the investigation. The major limitation of our study was the small sample size, which may have restricted its applicability to a larger medical community.

6. Conclusion

Based on our study, we have concluded that only 7% of PGs always report ADRs in their routine practice. However, we have found that 89.5% of PGs are willing to participate in training for the ADR reporting system. We believe that educational interventions on a routine basis for PGs in all departments, including clinical and non-clinical, can increase the number of adverse events reported in the tertiary care center. Similar studies have shown that educational interventions can improve the knowledge, attitude, and practice of healthcare professionals in reporting ADRs. We recommend revisions to include the application of PV in medical practice in the present academic curriculum. Overall, an increase in reporting can strengthen signals, which is a basic necessity for any regulatory and safety actions taken by regulatory authorities.

7. Author Contributions

The author contributed to developing, collecting, analysing, and approving the report, and is accountable for all aspects of the work.

8. Source of Funding

None.

9. Conflict of Interest

The author reports no conflicts of interest in this work.

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