

EVALUATION OF KNOWLEDGE, ATTITUDE, AND PRACTICE ABOUT PHARMACOVIGILANCE AMONG NURSING STAFF AT TERTIARY CARE TEACHING HOSPITAL

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ABSTRACT

Objectives: The primary objective of this study was to evaluate the knowledge, attitude, and practice of nursing staff about pharmacovigilance and adverse drug reactions (ADRs) reporting in a tertiary care teaching hospital. The secondary objective was to assess the causes of underreporting of ADRs.

Methods: A cross-sectional questionnaire-based study was carried out using a pre-designed structured questionnaire, adapted from previous studies and validated internally among the members of the pharmacovigilance committee. This questionnaire was provided to the nurses of all wards and out-patient department in a tertiary care teaching hospital of Gujarat, after taking their written informed consent. The data were evaluated for further analysis.

Results: Out of 309 participants, 73.38% had appropriate knowledge about pharmacovigilance and ADRs and 72.41% had a positive attitude toward the safety of drugs and reporting of ADRs. Out of 309 nurses, 55.34% of nurses came across an ADR and 3.56% of nurses had reported an ADR. According to the evaluated data, the reasons for underreporting of ADRs were lack of awareness, lack of time, and fear of legal implications. Out of all participants, 4.85% had attended ADR training/awareness sessions.

Conclusion: In the present study, nursing staff at a tertiary care teaching hospital had good knowledge and positive attitude toward pharmacovigilance but at the same time application of the same was lacking. Exposure to awareness programs and seminars about pharmacovigilance and hands-on ADR training sessions can improve the practice of nurses about pharmacovigilance.

Keywords: Adverse drug reactions, Attitude, Knowledge, Nurses, Pharmacovigilance, Practice.

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INTRODUCTION

Adverse drug reaction (ADR) is defined as "Noxious and unintended response to the medicine that occurs at doses normally used in humans for the prophylaxis, diagnosis or treatment of disease or for the modification of physiological function" [1]. ADRs are one of the major causes of morbidity and mortality all over the world [2]. Not a single drug is free of adverse effects but its use must have an acceptable risk-benefit ratio [3].

During clinical trials, the drug is evaluated for its safety and efficacy in a very small number of selected individuals and for a shorter duration. Hence, rare and long-term adverse effects may be detected after these medicines have been used by a heterogeneous population including people with other concurrent diseases and over a longer period of time [4]. Thus, continuous monitoring of drug is needed in post-marketing drug surveillance to report any undocumented ADRs [5].

The World Health Organization defined pharmacovigilance as "The pharmacological science and activities related to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problems" [6]. The Central Drugs Standard Control Organization has started the Pharmacovigilance Program of India (PvPI) in July, 2010. The purpose of PvPI is to collect data, analyze it and use the inferences to recommend regulatory interventions as well as communicating risks to the healthcare professionals (HCPs) and the public [7].

Under PvPI, all approved medical colleges and hospitals have ADR monitoring centers (AMC) to promote pharmacovigilance activities, report ADRs, and provide training and education to the HCPs [8]. Hospitals are the important places where serious ADRs are most likely

to be seen [9,10]. As nursing staff play a vital role in providing care and treatment to patients in government hospitals, knowledge about ADRs and pharmacovigilance is of prime importance for them. By understanding and reporting ADRs, nursing staff can strengthen PvPI.

Thus, we carried out this study with an aim to evaluate the knowledge, attitude, and practice (KAP) of pharmacovigilance and ADRs reporting among nurses, which may help us to provide the present scenario about reporting of ADRs and challenges to improve it.

METHODS

A cross-sectional questionnaire-based study was conducted on the nursing staff of SSG Hospital, Vadodara after getting approval from the institutional ethics committee. A pre-designed structured questionnaire was developed from the previous studies and was validated internally among the members of the pharmacovigilance committee [2,5,9,11-14]. The questionnaire consisted of a total of 21 multiple-choice questions.

The staff nurses were contacted personally and explained about the study objective. The questionnaire was provided to all the nurses of wards and out-patient department (OPD) in a tertiary care teaching hospital of Gujarat, after taking their written informed consent. The recorded data were entered in Microsoft Excel Version 2021 and analyzed in numbers and percentages.

RESULTS

The KAP study on pharmacovigilance was done on the nursing staff of SSG Hospital, Vadodara. A total of 309 staff nurses participated in the study.

Assessment of knowledge about pharmacovigilance

Knowledge about pharmacovigilance among the nursing staff was assessed by part 1 (question no. 1–8) of the questionnaire. The answers seeking knowledge of participants about pharmacovigilance are depicted in Table 1. For question 1, 133 (43.04%) staff nurses were knowing that pharmacovigilance deals with the adverse effects of drugs. 248 (80.26%) staff nurses were knowing what ADR is. 232 (75.08%) participants had knowledge about serious ADR. 197 (63.75%) staff nurses provided correct responses when asked about “who can report an ADR?.” 249 (80.58%) nurses had marked answer correctly when asked about the type of ADR reporting. 299 (96.76%) staff nurses had knowledge about PvPI and ADR reporting. 236 (76.38%) participants had given correct answers when asked about methods of reporting an ADR. Question 8 described in which languages ADR reporting forms are available, to which 220 (71.20%) staff nurses gave correct responses.

Assessment of attitude toward pharmacovigilance

Attitude toward pharmacovigilance among the nursing staff was assessed by part 2 (questions no. 9–15) of the questionnaire. The answers seeking the attitude of participants toward pharmacovigilance are depicted in Table 2. 300 (97.09%) participants agreed that all the drugs are not safe. 306 (99.03%) staff nurses think that ADR reporting is necessary and 276 (89.32%) participants think that ADR reporting is mandatory. 302 (97.73%) participants think that ADR reporting can increase the patient’s safety. 305 (98.71%) staff nurses think that they can play an important role in patient’s safety. On asking whether ADR training sessions will be helpful to nursing staff, 301 (97.41%) of participants had given positive responses. Reasons for not reporting an ADR by HCPs are given in Fig. 1. According to participants the most common reason for not reporting an ADR is a lack of awareness about the ADR reporting system, which contributes 64.63%. Other reasons are lack of time and fear of legal implications contributing about 21.46% and 9.51%, respectively. 4.39% of participants think that ADR reporting is not the priority that is why HCPs are not reporting an ADR.

Assessment of practice of pharmacovigilance

Practice of pharmacovigilance among the nursing staff was assessed by part 3 (question no. 16–21) of the questionnaire. The answers seeking participant’s practice of pharmacovigilance are depicted in Table 3. 171 (55.34%) staff nurses had come across an ADR. As given in Fig. 2, the most common ADRs that have been noticed by nursing staff are rashes followed by itching, redness, rigors, nausea, vomiting, shivering, swelling, fever, chills, up rolling of eyeballs, irritability, breathlessness, chest pain, cyanosis, crust formation, and death in descending order. The most common drugs causing ADRs according to participants are given in Fig. 3, which include injections of Vancomycin, Multivitamin, Paracetamol, Metronidazole, Metoclopramide, Linezolid, Ciprofloxacin, Ofloxacin, and Ceftriaxone as well as tablets of Carbamazepine and Allopurinol. 33 (10.68%) of nursing staff had seen the ADR reporting form. 11 (3.56%) participants had reported an ADR. 15 (4.85%) staff nurses had attended ADR training/awareness sessions. 11 (3.56%) participants have been trained on how to fill up an ADR reporting form.

DISCUSSION

In the present study, overall, 73.38% of participants had correct knowledge about pharmacovigilance and ADR reporting. The highest knowledge was about the program that deals with ADR reporting followed by what is ADR while the lowest knowledge was about what pharmacovigilance deals with followed by who can do ADR reporting in a hospital. More than half of nurses knew what are serious ADRs, how to report an ADR, and in which languages the ADR reporting forms are available. As nursing staff plays an important role in patient care, topics, such as ADRs and pharmacovigilance are already been included in their undergraduate pharmacology curriculum [12]. Despite of frequent awareness sessions, we observed that nursing staffs are familiar with the terms related to PvPI, but in-depth knowledge is lacking. Reasons for that may be a lack of reporting culture, high patient load, lack of time, etc.

Table 1: Knowledge about pharmacovigilance

S. No.	Questions	Correct response (n=309)	
		n	%
1.	Pharmacovigilance deals with which of the following?	133	43.04
2.	What is an adverse drug reaction?	248	80.26
3.	Which of the following is/are considered as serious adverse drug reactions?	232	75.08
4.	Who can do reporting of an ADR in a hospital?	197	63.75
5.	What type of ADR should be reported?	249	80.58
6.	Which of the following program deals with reporting of an adverse drug reaction?	299	96.76
7.	How can we report an ADR?	236	76.38
8.	In which languages ADR reporting forms are available?	220	71.20

ADR: Adverse drug reaction

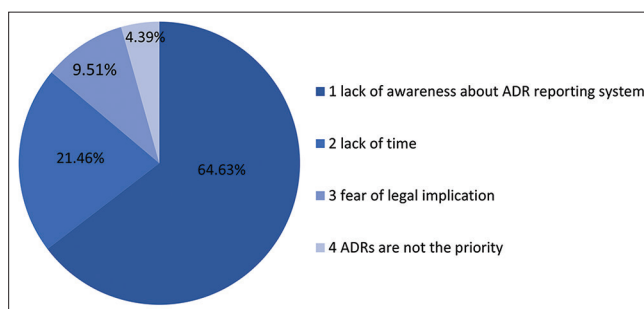


Fig. 1: Reasons for not reporting adverse drug reaction

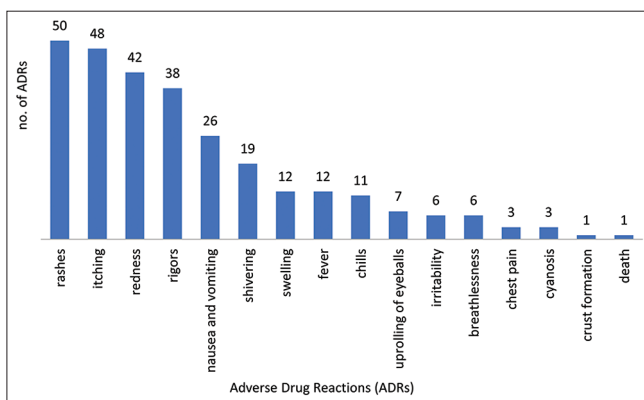


Fig. 2: Adverse drug reactions noticed by staff nurses

Overall, there was a highly positive attitude toward pharmacovigilance and ADR reporting. Attitude toward the safety of drugs, importance of ADR reporting, and the role of nursing staff in the safety of patients was positive. Many nurses thought that ADR training sessions will be helpful to them. Hence, frequent ADR training sessions and a constant reminder about ADR reporting by various charts and posters in wards, OPDs and nursing stations can improve their participation in pharmacovigilance.

In the present study, practice of the ADR reporting was very low. In our study, 55.34% of nurses had come across at least one ADR but, only 3.56% had reported any ADR. The reasons for underreporting were also evaluated in the study that includes lack of awareness about the ADR reporting system, lack of time, fear of legal implications, and their perception that ADR reporting is not a priority for them. Many of the

Table 2: Attitude toward pharmacovigilance

S. No.	Questions	Response (n=309)			
		Yes		No	
		n	%	n	%
1.	Do you think that all drugs are safe?	9	2.91	300	97.09
2.	Do you think reporting an ADR is necessary?	306	99.03	3	0.97
3.	Do you think reporting an ADR is mandatory?	276	89.32	33	10.68
4.	Do you think reporting an ADR will increase patient safety?	302	97.73	7	2.27
5.	Do you think that staff nurses can play an important role in patient safety?	305	98.71	4	1.29
6.	Do you think that ADR training sessions will be helpful to nursing staff?	301	97.41	8	2.59

ADR: Adverse drug reaction

Table 3: Practice of pharmacovigilance

S. No.	Questions	Response (n=309)			
		Yes		No	
		n	%	n	%
1.	Have you ever come across any ADR?	171	55.34	138	44.66
2.	Have you ever seen the ADR reporting form?	33	10.68	276	89.32
3.	Have you ever reported an ADR?	11	3.56	298	96.44
4.	Have you attended any ADR training/awareness sessions?	15	4.85	294	95.15
5.	Have you ever been trained on how to fill up the ADR reporting form?	11	3.56	298	96.44

ADR: Adverse drug reaction

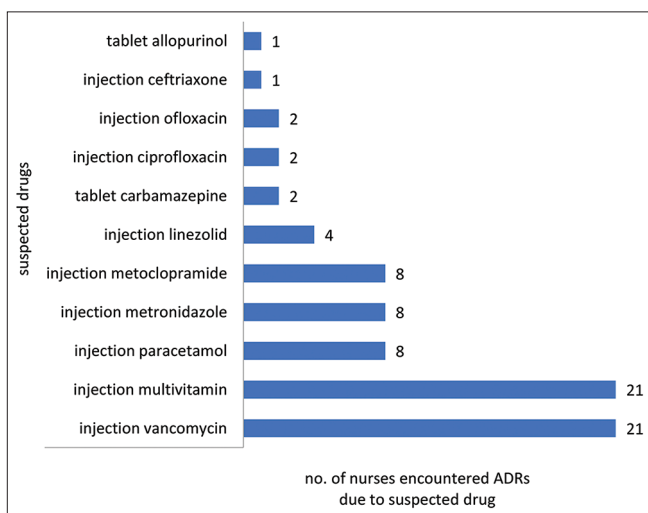


Fig. 3: Drugs causing adverse drug reactions as observed by staff nurses

nurses had informed the treating doctor about the occurrence of the ADR but not reported it to the AMC of the institute. This might be due to the unawareness about the existence of the institutional AMC or they do not take themselves as competent authority to report an ADR [15]. A smaller number of nurses had attended ADR training/awareness sessions. This may be the reason of unawareness regarding the ADR reporting.

Based on findings from other KAP studies done on HCPs, different reasons for underreporting include difficulty to decide whether ADR has occurred or not, lack of training, ignorance of reporting procedure, unavailability of ADR reporting forms, forgetting to report an ADR, workload, no remuneration, concern that report may be wrong and wrong concept about not reporting well-known or mild ADR [2,5,16-19].

Findings from this study showed that the majority of the nurses have sufficient knowledge and positive attitudes but poor practice about pharmacovigilance and ADR reporting. They might have studied some

parts of pharmacovigilance and ADR reporting during under graduation curriculum but did not practice ADR reporting. Hence, it is important to involve them in ADR reporting on practical grounds because having good knowledge and attitude about ADR reporting only will not be adequate [14].

CONCLUSION

In the present study, nursing staff at a tertiary care teaching hospital had good knowledge and positive attitude toward pharmacovigilance but at the same time application of the same was lacking. There is a huge gap between the ADRs experienced and ADRs reported by the nurses, which can be filled by making them frequently exposed to awareness programs and seminars about pharmacovigilance and hands-on ADR training sessions. Periodic interactions with nurses can help to know about the problems they are facing while reporting the ADRs.

ETHICAL APPROVAL

The study was approved by the Institutional Ethics Committee for Biomedical and Health Research Government Medical College and S.S.G Hospital, Vadodara with number IECBHR/174–2023 on March 31, 2023.

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AUTHOR'S CONTRIBUTIONS

Dr. Rushita Bhungaliya: Research investigator, data collection, data analysis, manuscript preparation; Dr. Nimit Goswami: Research investigator, concept, manuscript review and editing, supervision; Dr. Shreya Shah: Research investigator, manuscript review and editing.

CONFLICTS OF INTEREST

None.

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