

A Cross-Sectional Study on the Knowledge, Attitude and Practices of Pharmacovigilance among Nursing Staff at a Medical College Hospital, Karamsad, Gujarat, India

Nitin Kothari¹, Mahesh Kumar Choudhary², Twinkal Upadhyay³, Punita Kumari Patera⁴

¹Professor and Head, Department of Pharmacology, Government Medical College, Dungarpur, Rajasthan.

²Associate Professor, Department of Community Medicine, RVRS (Government) Medical College, Bhilwara, Rajasthan.

³Assistant Professor, Department of Biochemistry, PDU Medical College, Rajkot, Gujarat.

⁴Ph.D Scholar, Department of Biochemistry, Pacific Medical College and Hospital, Udaipur, Rajasthan.

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Corresponding author: Punita Kumari Patera

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Abstract

Objective: This study aimed at investigating the knowledge, attitude and practice toward pharmacovigilance and ADRs reporting among nursing staff at a teaching training hospital.

Methods: This was a cross-sectional, observational, questionnaire-based study conducted in Shri Krishna Hospital and Medical Research Centre, attached to Pramukhswami medical college, Karamsad, Gujarat.

Results: Total 43 nursing staffs completed the questionnaire and were included for the study. The demographic profile of participants in our study includes 62% women and 38% men. The Mean age of the respondents was 35 years. 83 percent of the nursing staff have heard the term 'pharmacovigilance' but only 58 percent were aware of it accurately. Nearly half of the nursing staff were aware about any drug that has been banned due to ADRs. The awareness about Pharmacovigilance Programme of India was found very limited in the nursing staff. Majority of the nursing staff admitted that ADR reporting is very important and compulsory, they also felt that pharmacovigilance should be taught actively to students as a part of the nursing curriculum. More than three-fourth of the nursing staff replied that they have free access to ADR reporting forms and nearly half of them only have taken training for the same. Our study also revealed that only 49 percent of the nursing staff have reported ADRs.

Conclusion: Nursing staff are often the source in alerting the responsible physician about possible ADRs. There is thus a logical reason to involve nursing staff and encourage them to contribute in ADR reporting system.

Keywords: Pharmacovigilance, Nursing staff, ADR reporting.

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Introduction

Adverse drug reactions (ADRs) remains one of the most prime reasons of morbidity and mortality worldwide [1]. In the Indian market, drugs are irrationally prescribed and misused due to lack of medication safety practices and failures in the regulatory environment. The misuse and faulty prescription of drugs, accounts for considerable development of adverse drug reactions (ADRs). ADRs are one of the major causes of mortality and morbidity, unplanned hospitalization and increased healthcare cost worldwide [2–5]. Thus, early identification of ADRs is extremely important for both government as well as non-government health care organizations.

Spontaneous reporting system of ADR is one of the principle methods used globally to monitor the benefit and hazard of drugs. This voluntary reporting system has the potential to identify rare and unexpected ADRs more quickly, than any other study design. The rate at which ADRs are reported depends on many factors such as time since the launch of PV programs, regulations and attitude of health-care professionals [6].

Pharmacovigilance (PV) was officially introduced in December 1961 with the publication of a letter (case report) in the *Lancet* by W. McBride, the Australian doctor who first suspected a causal link between serious fetal deformities (phacomelia) and thalidomide, a drug used during pregnancy. Thalidomide was used as an antiemetic and sedative drug in pregnant women [7].

In 1968, World Health Organization (WHO) promoted the “Programme for International Drug Monitoring”, a pilot project aimed to centralize world data on adverse drug reactions (ADRs). In particular, the main aim of the “WHO Programme” was to identify the earliest possible PV signals. The term PV was proposed in the mid-70s by a French group of pharmacologists and toxicologists to define the activities, promoting the

assessment of risks of side effects potentially associated with the drug treatment [8].

According to WHO, Pharmacovigilance (PV) is defined as the pharmacological science and activities relating to the monitoring, detection, assessment, understanding and prevention of adverse drug reactions (ADRs) [9]. The PV Programme of India (PvPI) was launched with a mission to safeguard the health of the Indian population by ensuring the safety of the marketed drugs [10].

Nursing staff are often the source for alerting the responsible physician about possible ADRs. There is thus a logical reason to involve nursing staff and encourage them to contribute in ADR reporting system. Although many studies in India have been conducted on the Knowledge, Attitude & Practice (KAP) towards pharmacovigilance among the health-care professionals, it is obligatory to conduct similar studies in our hospital with the objective to evaluate the KAP towards pharmacovigilance and ADRs reporting among nursing-care professionals, as these groups of professionals are most closely involved in the care of the patients admitted to the hospital and therefore most likely to encounter ADRs. The objective of this study was to assess the KAP towards pharmacovigilance and ADRs reporting among nursing staff, at a tertiary level teaching and training hospital.

Materials and Methods

This was a cross-sectional questionnaire-based study, consisting of five knowledge-related, three attitude related and three practice based questions with multiple choice options. This study was conducted at Shri Krishna Hospital and Medical Research Centre (a tertiary level teaching and training hospital) attached to Pramukhswami Medical College, Karamsad, Gujarat. These questions were analyzed, pre-tested and validated by expert colleagues. Based on the feedback from colleagues, certain ambiguous natured

questions were re-framed. After finalizing questions and seeking approval from the IEC, this study was conducted. The nursing staff in various departments were briefed about purpose of the study and those who were willing to participate were asked to fill the questionnaire. Any clarification needed in the understanding of the questionnaire was provided. The total duration of this study was 2 months.

Inclusion criteria

The nursing staff, who voluntarily gave informed consent and responded to all the questions were included in the study.

Exclusion criteria

Incomplete responses, those who didn't

return the response sheet and those who were not willing to participate in study were excluded from the study.

Results

A total number of 72 nursing staff were enrolled in the study but only 43 of them participated and completed their questionnaire forms, were included for the study. The data were entered into Microsoft Excel software and analyzed. All the answers are described in terms of numbers and percentages for the KAP questionnaire. The demographic profile of participants in our study includes 62% women and 38% men. The Mean age of the respondents was 35 years. Findings of the present study are described in Tables 1-3.

Table 1: Knowledge regarding pharmacovigilance and ADR reporting among nursing staff

S. No.	Knowledge domain questions	Responses given by the participants			
		Complete Knowledge	Partial Knowledge	Didn't have Knowledge	Total
1.	Have you ever heard the name of pharmacovigilance	36 (83.7)	0	7 (16.3)	43 (100)
2.	What is pharmacovigilance	25 (58.1)	10 (23.3)	8 (18.6)	43 (100)
3.	Knowledge about new indication of established drug is also an objective of pharmacovigilance	14 (32.6)	0	29 (67.4)	43 (100)
4.	Knowledge about any drug that has been banned due to ADR	23 (53.5)	0	20 (46.5)	43 (100)
5.	Knowledge about National Pharmacovigilance Policy	12 (27.9)	1 (2.3)	30 (69.8)	43 (100)

*Figure in parenthesis suggest the percentage

Table 2: Attitude towards pharmacovigilance and ADR reporting among nursing staff

S. No.	Attitude domain questions	Responses given by the participants			
		Positive	Negative	No Response	Total
1.	ADR reporting is (Compulsory/ Voluntary)	37 (86)	6 (14)	0	43 (100)
2.	The importance of ADR reporting (Very Important/ Important)	33 (76.7)	10 (33.3)	0	43 (100)
3.	Pharmacovigilance should be included in nursing curriculum (Yes/No)	32 (74.7)	10 (14)	1 (2.3)	43 (100)

*Figure in parenthesis suggest the percentage

Table 3: Practice of pharmacovigilance and ADR reporting among nursing staff

S. No.	Practice domain questions	Responses given by the participants			
		Positive	Negative	No Response	Total
1.	Easy access to ADR reporting form	33 (76.7)	9 (20.9)	1 (2.3)	43 (100)
2.	Trained on how to report ADR	21 (48.8)	22 (51.2)	0	43 (100)
3.	Ever reported ADR	21 (48.8)	21 (48.8)	1 (2.3)	43 (100)

*Figure in parenthesis suggest the percentage

Of the respondents, 83 percent of the nursing staff have heard the term 'pharmacovigilance' but only 58 percent were aware of it accurately. Only one-third of the nursing staff had knowledge about the other objectives of pharmacovigilance and nearly half of the nursing staff were aware about any drug that has been banned due to ADRs. The awareness about Pharmacovigilance Programme of India was found very limited in the nursing staff (Table 1).

In this study, majority of the nursing staff admitted that ADR reporting is very important and compulsory, they also felt that pharmacovigilance should be taught actively to students as a part of the nursing curriculum (Table 2). More than three-fourth of the nursing staff replied that they have free access to ADR reporting forms and nearly half of them only have taken training for the same. Our study also revealed that only 49 percent of the nursing staff have reported ADRs (Table 3).

Discussion

The knowledge, attitude and practice of the nursing staff towards pharmacovigilance were evaluated using five knowledge related, three attitudes related and three practice-based questions. In our study, the overall response rate was 59.7 %, which is higher than that reported in other studies [11]. The response rate of 44.8 % was reported in study carried out at Sholapur, Maharashtra [12], 63 % at Mysore [13] and 46 % at Delhi [14].

Regarding the knowledge domain, our study found that 83 % of the nursing staff have heard the term 'pharmacovigilance' but only 58 % were aware of it accurately, which was good as compared to other study in which more than 50 % of the health care workers were not aware of pharmacovigilance [15].

In our study 53 % of the nursing staff had knowledge about any drug that has been banned due to ADR which was found less as compared to the study conducted at Karnataka, which revealed that 63 % participants were aware of the same [16]. The awareness about Pharmacovigilance Programme of India was 28 % in our study, which is higher than the study conducted by Anuradha CR et al, in which about 16 % of participants were aware that the National Pharmacovigilance Programme of India (NPP) was governed by Drug Controller General of India [17].

Regarding the attitude domain, our study revealed that more than three-fourth of the nursing staff believed that Pharmacovigilance was very important and compulsory, whereas a study conducted at Delhi [14] shows that 52.60 % of respondents believed that ADR reporting was a professional obligation and 90.00% believed that ADR reporting was necessary. An another study found that total of 92.67% health-care professionals agreed that reporting of ADR was necessary [16].

In our study, 74 % participants felt that pharmacovigilance should be taught actively

to students as a part of nursing curriculum while in study conducted at Chennai [17], about 99.3 % participants agreed that pharmacovigilance should be taught in detail to health-care professionals.

Regarding practice domain in our study, 76 % of the nursing staff replied that they have easy access to ADR reporting forms and 49 % nursing staff have reported ADRs which were found higher from the study conducted by Bangalore [11] and Chennai [17]. Regarding training of pharmacovigilance and ADR reporting in our study, 49 % were trained to report ADR whereas in other study conducted at Chennai, only 16.7 % were trained for the same [17].

Conclusion

Nursing staff are often the source in alerting the responsible physician about possible ADRs. There is thus a logical reason to involve nursing staff and encourage them to contribute in ADR reporting system. In our study, participants answered satisfactorily towards knowledge and attitude however there was poor response with respect to practice domain. Underreporting of ADRs is one of the prime hurdle in the pathway of National Pharmacovigilance Programme.

Our study center has been a nodal center for National Pharmacovigilance Programme. Even then, this kind of poor ADR reporting is disappointing. So imparting knowledge about pharmacovigilance through various training programmes will definitely improve ADR reporting in India. Likewise, concept of Pharmacovigilance should also be well introduced in the early curriculum of nursing training to ensure safer patient outcomes and to foster a better reporting culture nationwide.

Limitation of this study was that we cannot generalize our observed findings due to our short study population. Hence, we recommend many more studies of similar

nature to be carried out in nursing staff, which will add to the pool of data from different geographical parts of country and will also help in developing strategies to improve knowledge, attitude and practice of pharmacovigilance in India.

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