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Original Research Article

Awareness study of Pharmacovigilance among the health care professionals (nursing staff) at tertiary care hospital, Solapur, Maharashtra, India

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ABSTRACT

Background: Early detection of adverse drug reaction is one step towards the prevention of ADRs. Foundation of Pharmacovigilance is spontaneous reporting which is minimal in India. Among the all health care professionals, nurses are caregivers at bedside. Improvement in knowledge and practice of adverse drug reaction reporting among nurses will definitely increases spontaneous reporting. In this study, knowledge, attitude and practice of nursing staff about pharmacovigilance was evaluated.
Methods: It was prospective, cross-sectional, observational, questionnaire-based study among the nurses of the tertiary care hospital Solapur. A questionnaire evaluating knowledge, attitude and practice was distributed among nursing staff and filled questionnaire were collected back and analyzed by microsoft excel 2013.
Results: Response rate of our study was 44.88%. 38.61% doctors were knowing meaning of pharmacovigilance while 61.38% participants knew that all drugs available in market are not safe. Taking proper medication history before prescribing drugs was considered important by 92.57% participants. 79.70% participants were aware about Pharmacovigilance program of India. 64.35% doctors answered correctly to elements which are mandatory to record. Only 24.75% participants were knowing the basis that pharmcovigilance provides for.
Conclusions: Nursing staff of tertiary care hospital, Solapur had very appreciable and positive attitude towards pharmacovigilance but there is a need for improvement in knowledge and practice of ADR reporting.

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

INTRODUCTION

According to World Health Organization (WHO) definition, an adverse drug reaction (ADR) is any noxious, unintended and undesired effect of a drug, which occurs at doses used in humans for prophylaxis, diagnosis, or cure of a disease.[1] Drugs available in market are not free from ADRs. Then also ADR reporting rate in India is below 1% compared to the worldwide rate of 5%.[2] Currently it appears that ADR reporting is not considered as a part of routine professional practice. It might be because of lack of knowledge and sensitization about ADR reporting.[2]

Pharmacovigilance is the science and activities relating to detection, assessment, understanding and prevention of adverse effects or any other drug-related problems.[3] Pharmacovigilance Programme of India (PvPI) came into action from July 2010.[4] The spontaneous reporting of ADRs is considered as foundation of post-marketing

surveillance of drug safety. Success of Pharmacovigilance Programme of India wholely depends on active participation of healthcare professionals. This active participation recquires initiativeness and willingness. Although India is participating in the global ADR monitoring center, it is very little. Nowadays participation is increased but not up to mark.

Studies conducted in different countries to assess the knowledge, attitude, and practices (KAP) of the HCPs. In Nigeria, 42.9% of doctors and 35% of nurses had knowledge regarding ADR reporting whereas in China, only 2.7% of doctors and 1.6% of nurses had correct knowledge of ADRs.[5,6] It can be concluded from such observations that both the doctors and nurses lacked adequate KAP on monitoring, detection, and reporting of adverse events. It can also be inferred that nurses had marginally less KAP than the doctors. Since nurses spend more time in patient care; it was hypothesized that nurses can play an important role in monitoring, detection, and reporting of adverse event.

In order to improve reporting rate, it is essential to improve knowledge and practice of the nursing staff. This study was a step in same direction to evaluate basic knowledge, attitude and practices of nursing staff.

METHODS

This was a prospective, cross-sectional, observational, questionnaire-based study, conducted at tertiary care teaching hospital, Solapur. Prior approval was taken from the Institutional Ethics Committee to conduct the study among the nursing staff of the tertiary care hospital, Solapur.

Nurses from all specialties working in the hospital were enrolled in the study. Written consent was taken from the participants prior the data collection. Those who were not willing to participate or did not return the questionnaire within the stipulated time were excluded.

Structured pretested questionnaire containing 25 questions, out of which 15 questions to study knowledge regarding the ADR reporting system, 4 for attitude and 6 to study practices of ADR reporting. Three questions were open ended, while the others were close ended. The participants were personally briefed about the study questionnaire and were requested to complete and return the questionnaire immediately.

The information was recorded and analyzed using the Microsoft Excel worksheet (Microsoft Office 2013).

RESULTS

The questionnaire was administered to 450 nurses, out of these 202 were returned, so the response rate is 44.88%.

A total of 124 respondents out of 202 (61.38%) stated that they believe all drugs available in the market are not safe. According to one hundred and forty respondents (69.30%), serious adverse event includes life threatening event, disability, death, hospitalization.

Table 1: Questions related to knowledge.

Knowledge related questions	Correct response	Incorrect response
Safety of available drugs in market	124 (61.38%)	78
Identification of serious adverse event among given options	140 (69.30%),	62
Meaning of Pharmacovigilance	78 (38.61%)	124
Who can report ADR	150 (74.25%)	52
ADR reporting by non-medical person to medical person	162 (80.19%)	40
ADR reporting is professional obligation	8 (3.97)	194
Pharmacovigilance's usefulness in educating doctors about ADR and in regulation of drug use	167 (82.67%)	35
Main purpose of Pharmacovigilance	167 (82.67%)	35
Pharmacovigilance provides basis for assessing	50 (24.75%)	152
Activities involved in Pharmacovigilance	145 (71.78%)	57
Regarding voluntary reporting	156 (77.22%)	46
Pharmacovigilance International Collaborating Center	3 (1.48%)	199
Pharmacovigilance National Collaborating Center	2 (0.99%)	200
ADR monitoring Center in Maharashtra	48 (23.76%)	154
Awareness of Pharmacovigilance Programme of India	161 (79.70%)	41

Taking proper medication history before prescribing drugs was considered to be important by 187 (92.57%) of the respondents. 183 respondents (90.59%) said that it is necessary to make ADR reporting.

Only 78 respondents (38.61%) were knowing correct meaning of term Pharmacovigilance which is nothing but adverse drug reaction monitoring. 150 respondents (74.25%) believed ADR reporting can be done by all

healthcare professionals (doctors, nurses, pharmacists). 162 respondents (80.19%) answered that non-medical persons should report ADR, if they experience any, to nearby medical person as early as possible.

Table 2: Questions related to attitude.

Attitude related questions	Correct response	Incorrect response
Importance of taking medication history	187 (92.57%)	15
Necessity of ADR reporting in today's clinical practice	183 (90.59%)	19
ADR reporting and monitoring system would benefit the patient	193 (95.54%)	9

Majority of 202 respondents, total 190 (94.05%) said they encountered common ADRs (headache, fever, vomiting) frequently. So, they believe that these common ADRs should be reported. According to 130 respondents out of 202 (64.35%), mandatory elements while recording ADR involves identifiable patient's details, identifiable reporter's details and details about suspected medicinal products.

Table 3: Questions related to practice.

Practice questions	Correct=02	Incorrect=202
Regarding reporting of common ADRs (headache, fever, vomiting)	12 (5.95%)	190
Elements mandatory to record	130 (64.35%)	72
Keeping record of ADR	185 (91.58%)	17
Maintaining confidentiality while ADR reporting	126 (62.37%)	76
Patient's identity kept confidential?	127 (62.87%)	75
Report's identity kept confidential?	99 (49%)	103

ADR reporting is professional obligation, 194 respondents (96.03%) were agree to this sentence while only 8 were not agree. Keeping records of experienced ADR found to be important by 185 respondents (91.58%). 193 respondents (95.54%) had strong thinking that ADR reporting and monitoring system would definitely benefit the patients. Maintaining confidentiality while reporting ADR, 126 respondents (62.37%) felt it necessary.

136 respondents said yes, they worry about legal problems; 54 respondents said no and 12 respondents were not knowing answer to this question. 167 respondents (82.67%) believed that the information generated in Pharmacovigilance is useful in educating doctors about ADR and in the official regulation of drug use.

The main purpose of Pharmacovigilance is to reduce the risk of drug related harm to patient and it has important role in rational use of medicine. 167 (82.67%) respondents were knowing this aim of Pharmacovigilance. Pharmacovigilance provides basis for assessing safety of medicines and only 50 respondents (24.75%) answered it correctly. Activities involved in Pharmacovigilance are post marketing surveillance, prescription event monitoring and anecdotal care reports. 145 respondents (71.78%) mentioned it. 156 respondents (77.22%) believed voluntary reporting of ADR depends on initiative and willingness of health professional.

Only 3 respondents, 2 respondents and 48 respondents were knowing Pharmacovigilance International Collaborating Center, Pharmacovigilance National Collaborating Center and ADR monitoring Center in Maharashtra respectively. 161 respondents (79.70%) were aware about the Pharmacovigilance Programme of India. 127 and 99 respondents said yes, confidentiality of patient's identity and reporter's identity should be maintained respectively.

DISCUSSION

Pharmacovigilance has been defined by the WHO as the "science and activities relating to the detection, assessment, understanding and prevention of adverse events or any other drug related problems".[7] Voluntary reporting ADR is an essential component of Pharmacovigilance which is minimal in India. From the results, it was noticed that the knowledge on meaning of pharmacovigilance and basis it provides is very low.

Present study showed little awareness about the ADR reporting system among nurses at tertiary care hospital. The percentage of response was found to be less (44.88%) as compared to other similar study carried out at Mysore by Scandarshee with colleague (63%) and it was 46% in study at Delhi by Kumari S.[3,8]

In present study 82.67% nursing staff were aware about the main purpose of Pharmacovigilance. In other similar study, it was 40.86%.[8] The knowledge on location of International and National center was very poor. Regarding international collaborating center for ADR monitoring, correct answer was given by only 1.48% nursing staff which is very low compared to 17.39% found in study by Sunita Kumar at Apollo Hospital, Delhi.[8]

Then they were asked about National Pharmacovigilance center, only 0.99% respondent gave answer correctly. In other similar studies, it was 46.95%., 7.9 % in study by Scandarshee at South Indian Tertiary Care Center and an Iranian study, which states that 48% nurses were aware of

ADR center.[3,8,9] 74.25% respondents said doctors, nurses and pharmacists are responsible for reporting ADR while in other similar study conducted by Sunita Kumar at Delhi found it 52.60% and an Iranian study where 91% of the respondents propounded that ADR reporting is one of the duties of health-care professionals.[8,9]

The factors, which have resulted in under-reporting of ADR according to our study, include lack of knowledge about ADR forms for reporting ADR, ignorance about pharmacovigilance system, and also not being sure of the type of reactions to be reported. According to a study conducted by Vallano et al, four types of obstacles to spontaneous reporting were considered particularly important: Problems with the ADRs diagnosis; problems with the usual workload and lack of time; problems related to the organization and activities of the pharmacovigilance system; problems related to potential conflicts.[10] There are many vigorous activities going on regarding pharmacovigilance conducted by Pharmacovigilance Programme in India, and still, there is a lack of awareness to be filled by educating nurses, doctors, and other health-care professionals regarding this issue.[3] 52.60 % of respondents said ADR reporting is professional obligation in study conducted at Delhi but in present study 96.03% accepted it. 90.00% nurses said ADR reporting is necessary in same study and in present study 91.58% agreed. Only 23.76% respondents were following ADR monitoring center in Maharashtra and no single respondent could identify Dr. V. M. Govt. Medical College as an ADR reporting center in Solapur.

CONCLUSION

The results of our study showed that nurses who participated in this study had poor knowledge about ADR reporting system, they knew very less about the purpose of pharmacovigilance and its usefulness. The level of attitude of our nurses was favorable but practice of ADR reporting was very poor. Number of cases reported to center was very poor. Therefore, an educational intervention on Pharmacovigilance should be incorporated during their nursing courses, it is necessary to conduct continuous ADR-related educational programs, training programs until we reach the point that voluntary reporting of ADRs becomes habitual and routine among nursing staff.

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