



Pharmacology

KNOWLEDGE, ATTITUDE AND PRACTICE OF PHARMACOVIGILANCE AMONG NURSES IN A TERTIARY CARE HOSPITAL

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ABSTRACT **INTRODUCTION:** Nurses are key professionals involved in administering of medicines. They have utmost responsibility to report adverse drug reactions. The study was conducted to determine the level of overall skill in pharmacovigilance among the nurses.

AIM AND OBJECTIVES: To assess the knowledge, attitude and practice of pharmacovigilance among nursing staff in a tertiary care hospital

MATERIALS AND METHODS: A questionnaire based cross-sectional, observational study was conducted among nurses in the inpatient departments of various specialties of Saveetha Medical College and Hospital, Chennai. Written informed consent was taken from the participants. A semi-structured questionnaire was administered to 100 nurses.

RESULTS: Majority of the participants were female (98%). The study showed that the nurses had poor knowledge and a negligent attitude towards pharmacovigilance. This is evident in the fact that only 36 % of the participants could define the term pharmacovigilance and 21% considered that ADR reporting should be made mandatory.

CONCLUSION: Continued medical education in hospitals is required not only for the clinicians but also for the nurses to improve the standard of Pharmacovigilance Programme of India.

KEYWORDS : Pharmacovigilance, Adverse Drug Reactions, Nurses

INTRODUCTION

The biggest bane to pharmacovigilance is the low numbers of adverse drug reaction reports from nurses in the hospital. Pharmacovigilance is an essential part of healthcare whose objective is to improve patients' safety. According to a study conducted in Jammu and Kashmir in India 2014, 56.45% was found to be the functional rate of adverse drug reactions monitoring centre (1) evidenced by the fact around 40 centres staying nonfunctional although they are operational mostly. According to a study conducted in the United Kingdom, over a span of 3 years between 1990 and 1993 there were 1420 reports of suspected adverse drug reactions, a rate of 68.7 per 1000 admissions indicating a worldwide prevalence in the underreporting of Adverse drug reactions (2). Another study conducted in Dharmapuri and Krishnagiri, Tamilnadu in 2015 concluded that there is poor knowledge towards adverse drug reactions reporting among healthcare professionals in the area as evidenced by a low number i.e. 14.3% of the interviewed healthcare professionals being knowledgeable about the process of reporting adverse drug reactions (3). This indicates that the problems surrounding pharmacovigilance are universal in nature. Pharmacovigilance has been defined as "the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug related problem" (4). In 2010, the Pharmacovigilance Programme of India was initiated for monitoring adverse drug reactions in the country. The main aim of the program is to protect public health by ensuring the safety of pharmaceutical products. Although this programme has had an impact as evidenced by a study conducted in New Delhi in 2017 which concluded that while an encouraging attitude toward pharmacovigilance exists among the healthcare workers and students of the institution, proper education of healthcare workers should be the goal in order to sustain and improve the attitude towards pharmacovigilance (5). A nurse's fundamental obligation is to report every adverse drug reaction and help strengthen the pharmacovigilance programme of India. There is no availability of data on the knowledge, attitude and practice of pharmacovigilance among the nurses within the institute. This data would help to improve the quality of the existing pharmacovigilance program within the institute.

MATERIALS AND METHODS

A questionnaire based cross-sectional, observational study was conducted in the inpatient departments of various specialties of Saveetha hospital, Chennai. Written informed consent was taken from the survey. Institutional review board approval was also obtained prior to starting the study.

Nurses working in the inpatient departments of the hospital were included in the study. A pre-tested semi-structured questionnaire was used in the study. There were 12 questions relating to the basic knowledge and information about pharmacovigilance, 7 questions relating to attitude, and 6 questions related to their practice of pharmacovigilance in the course of their job. The sample size was 100. The nurses were given the questionnaire after explaining to them the purpose of the study. They were requested to complete the questionnaire and give it back immediately to maximize the response rate. A descriptive analysis of the data was done using SPSS software version 22. Data analysis was carried out using Microsoft Excel spreadsheet and percentage of observations was noted.

RESULTS

Of the total respondents, 26 % were from the general medicine department, 19 % from the surgery department, 18 % from the orthopedics department and 12 % from the obstetrics and gynecology department. The remaining 25 % were from departments such as pediatrics, psychiatry, casualty and neonatology. Majority of the respondents (98 %) were female and the rest (2%) were male. Most (88 %) had a bachelors degree while the rest (22 %) had a diploma in nursing. Most of the respondents were in the ages between 20 and 25 (74 %) with 22 % falling between the ages 26 and 30. The rest (4%) were above the age of 30. More than half (54 %) had a professional experience of less than 2 years. 39 % had a professional experience of more than 3 years and less than 5 years. Only 7 % of the respondents had professional experience of more than 5 years.

Table 1. Demographic Details:

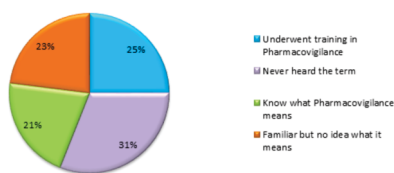
S.No	Parameters		Percentage
1	Age (in years)	21 -25	74 %
		26 - 30	22 %
		31 - 35	3 %
		> 35	1 %
2	Sex	Male	2 %
		Female	98 %
3	Qualification	Bachelors degree	88 %
		Diploma	22. %
4	Professional Experience	< 2 years	54 %
		3 to 5 years	39 %
		6 to 8 years	6. %
		> 8 years	1 %

The questions that assessed knowledge of pharmacovigilance had

been answered correctly at a rate of 33 % whereas the questions that assessed attitude towards pharmacovigilance were answered correctly about 35 % of the time. Questions relating to practice of pharmacovigilance were answered correctly 41 % of the time.

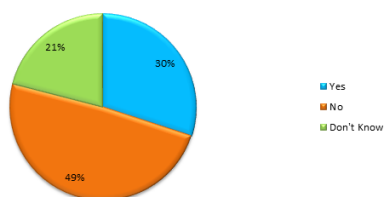
Regarding knowledge, 31 % of the participants had not heard the term pharmacovigilance in their lives. Whereas 23% were familiar with the term but had no idea what it meant. That is, 54 % of the participants in the study did not know what the term pharmacovigilance meant. In a similar study conducted among pharmacists in Namakkal, Tamil Nadu 34.6% of pharmacists could define the term 'pharmacovigilance' to an acceptable extent and 34.3% knew about the National Pharmacovigilance Programme in India (6). 21 % of the nurses knew what the term meant and another 25 % had taken special training or orientation in pharmacovigilance. Only 35 % of the participants could define an adverse drug reaction. Only 41 % and 42 % of the participants were aware of the presence of Pharmacovigilance program of India and adverse drug reactions reporting system of Saveetha Hospital respectively. Only 27% knew where the pharmacovigilance centre of India is located

Do you know what Pharmacovigilance means?



With respect to attitude towards pharmacovigilance, more than half the participants (51%) believed that nurses are not responsible for reporting adverse drug reactions. 49% believed reporting of adverse drug reactions wasn't necessary and another 21 % didn't know if it was necessary while only 30 % believed that reporting of adverse drug reactions was a necessity. Also, only 30% of the participants believed reporting of adverse drug reactions improved patient safety while the rest didn't know if it improves patient safety or thought it didn't improve patient safety. Only 43% thought pharmacovigilance should be taught in detail to healthcare professionals. Only a meager 47% thought reporting adverse drug reactions was a professional obligation for them. Moreover only 23% had read an article on Pharmacovigilance

Do you think ADR reporting is necessary



On the subject of practice of pharmacovigilance, 55% of the nurses hadn't seen a single adverse drug reactions in their patients. A remarkable 75% of the nurses hadn't reported a single adverse drug reactions to an A adverse drug reaction monitoring centre. Thankfully, 63% of the nurses had seen an adverse drug reactions reporting form by the time of the study and 52% reported that they had been trained to report adverse drug reactions as students.

DISCUSSION

The main purpose of pharmacovigilance is to ensure safe use of drugs by the patient hence it is an essential component of healthcare. Disappointingly it is not viewed as such by the healthcare community as shown in our study. Reporting of adverse drug reactions by all involved in the use of medicines, which includes doctors, nurses, pharmacists, patients, and the general public, is the first step in the process. The study being presented was conducted in Saveetha medical college (Tertiary healthcare hospital). The study showed that the nurses who are often the first people to come across adverse drug reactions in patients had poor knowledge and a negligent attitude towards pharmacovigilance. This is evident in the fact that only 36 % of the participants could define the term pharmacovigilance the actual

practice of reporting was even more minimal among the participants. The study revealed that not many (41%) professionals know about the pharmacovigilance program run by the Government of India, and an even fewer number (23%) knew about the organization responsible for this and the international organization (World Health Organization – Uppsala Monitoring Centre) monitoring the same. Although it is worrying, this of knowledge about pharmacovigilance is not the major problem surrounding reporting of adverse drug reactions in the institution. The major problem is, as explained below the alarmingly negative attitude towards pharmacovigilance. Pharmacovigilance, in general is thought of as an 'extra' that may be done after providing healthcare and not as the integral part of healthcare it is supposed to be.

This is more concerning than the lack of knowledge as knowledge can be taught with ease to the healthcare workers but without a positive attitude towards pharmacovigilance it would be of no use as reporting adverse drug reactions would still be considered a luxury than a necessity. This is evidenced by a study conducted in 2012 that concluded that while the knowledge of physicians and nurses on the topic of pharmacovigilance was good when it came to practicing reporting of adverse drug reactions the execution was severely lacking(7). According to another study conducted in New Delhi the, general mood surrounding pharmacovigilance was positive and practice of reporting adverse drug reactions was average indicating that some parts of the country have already started to improve (8). Though it is a promising start there is a long journey to embark on before reaching ideal levels.

An important finding of the study was that, while only a few nurses knew about the existence of adverse drug reactions reporting system in the institution, a larger number knew what the adverse drug reactions reporting form looks like and were trained to report adverse drug reactions as students. This is an encouraging sign because although awareness about the existence of an adverse drug reactions reporting system in the institution requires improvement, the practical aspect of reporting adverse drug reactions is not affected to such an extent. Even though it is not ideal, it is a good start nonetheless. There is a need to generate awareness regarding the other facilities (other than the adverse drug reactions reporting form) available for reporting adverse drug reactions, such as a designated officer for pharmacovigilance activities and the several sources of information available in the campus to facilitate adverse drug reactions reporting.

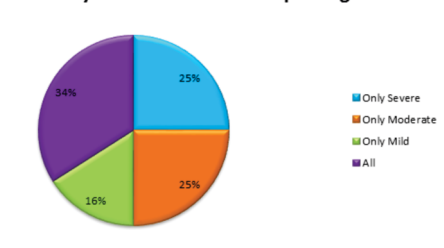
Another problem causing a low number of adverse drug reactions reports in the institution are an increased workload on the nurses with 32 % of the nurses feeling that they simply do not have the time to report adverse drug reactions, this can however be dealt with through adequate recruitment and proper distribution of work. 40% of the nurses thought that a single unreported adverse drug reaction will not affect the database, this is another example of the problems in attitude toward pharmacovigilance that can be avoided by proper education of the nurses and other healthcare professionals.

A study conducted in 2017 in West Bengal revealed similar reasons such as inefficient time management, and improper workload distribution and absence of remuneration for the efforts being the ultimate causes responsible for the appalling numbers surrounding pharmacovigilance (9). This proves that healthcare workers all over the nation think of reporting adverse drug reactions as a luxury that is not part of their workload. They should not expect remuneration as it is a part of their responsibility which is to provide genuinely good healthcare to their patients. In order to improve adverse drug reactions reporting, continuous medical education, training and proper sensitization of healthcare professionals can help combating the existing scenario. One should not be surprised by the fact that only 25 % of the nurses have reported an adverse drug reactions in their lives. Such low numbers are the norm considering the pathetic state of attitude towards and knowledge of pharmacovigilance. With improvement in education of the nurses about pharmacovigilance practice of reporting adverse drug reactions will automatically increase.

A discouraging finding of this study was that only 21% considered that adverse drug reactions reporting is important and should be made mandatory. This is in stark contrast to healthcare workers abroad who are generally supportive of their adverse drug reactions reporting systems as shown by a study conducted in the United Kingdom which states that pharmacists have a adequate knowledge and are

encouraging towards the Yellow Card spontaneous adverse drug reactions reporting scheme. Continued efforts in raising awareness and guidance will be important in maintaining and increasing adverse drug reactions reports from pharmacists (10). Only 43% thought pharmacovigilance should be taught during their training. Moreover, only 47% of the participants thought that adverse drug reactions reporting is a professional obligation for them. These are examples of the problem in the attitude towards pharmacovigilance (as discussed above). Only 23% of the participants surveyed knew about Central Drugs Standard Control Organisation being the regulatory body for reporting adverse drug reactions in India. Another 23% knew about the international regulatory body being in Sweden. This highlights the deficiency in knowledge among the nurses that took part in the study.

Severity of ADRs that need reporting



One encouraging aspect was that 34% of the participants thought all adverse drug reactions irrespective of the severity need reporting. Although 34% is a good start it is far from ideal and thus there still is a need to emphasize to the healthcare providers that all adverse reactions must be reported whether mild or serious. 63% of the nurses had seen an adverse drug reactions reporting form by the time of the study and 52% reported that they had been trained to report adverse drug reactions as students. Although these numbers are not as bad as some other aspects of the study there is still a long way to go to achieve the goals of the Pharmacovigilance programme of India suggesting that there is a need for more interventions, continuous medical education, and workshops to improve awareness about the pharmacovigilance program and the various facilities available for adverse drug reactions monitoring in the institution. The improved awareness would in turn help change the mindset of healthcare professionals from 'Pharmacovigilance is a luxury that may be practiced whenever it pleases them' to 'Pharmacovigilance is a necessity that must be included routinely in healthcare'. This shift in attitude will then result in an increased knowledge about pharmacovigilance subsequently improving practice of pharmacovigilance which is the ultimate goal. The first step is the most crucial and difficult one as the idea that pharmacovigilance is a luxury is prevalent not only in India but even in most developed countries and involves not only the nurses but is system wide affecting everyone involved in healthcare from doctors to patients. One of the ways to improve pharmacovigilance is to make it an essential requirement in a nurse's resume. This would ensure proper knowledge about the topic among future nurses. A study conducted in 2005 concluded that developing a more functional relationship between doctors and adverse drug monitoring centres is one of the key solutions to the problems surrounding pharmacovigilance (11). A similar study to ours conducted in 2016 concluded that the while nurses who took part in the study had average knowledge on the subject they did not understand why it has to be done leading to low numbers when it came to actual practice of pharmacovigilance (12).

CONCLUSION

The questions that assessed knowledge of pharmacovigilance had been answered correctly at a rate of 33% whereas the questions that assessed attitude towards pharmacovigilance were answered correctly about 35% of the time. Questions relating to practice of pharmacovigilance were answered correctly 41% of the time. Continuous medical education programs need to be conducted to educate all healthcare providers and especially nurses about the importance of a pharmacovigilance program, the role of nurses in ensuring its success and the various facilities available in the institution for reporting adverse drug reactions. The need for an efficient pharmacovigilance program has been realized to ensure safe use of medicines. Its success will depend upon the involvement of nurses as they are often the ones who are with the patients when an adverse drug reactions occurs. Hence even adverse drug reactions that are missed by the patients themselves and the doctors can be detected by a nurse well trained in pharmacovigilance.

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