

Assessment of knowledge of pharmacovigilance among the nurses of tertiary care hospital

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ABSTRACT

Background: The Pharmacovigilance Programme of India envisages that “All” health care professionals will play an important role in making the program a success. Nurses and midwives have better population outreach as compared to physicians alone. The objectives were to assess the knowledge of pharmacovigilance among the nurses of a tertiary care hospital.

Methods: The study was conducted from the month of March 2015 to July 2015. Nurses were provided pre-structured questionnaire for filling after explaining the aim and objectives of the study. Responses were pooled and analyzed.

Results: 100 nurses returned completed forms. 63% respondents had heard about the term pharmacovigilance. 41% of these could correctly define it. All the respondents had heard about adverse drug reaction (ADR), 39% could correctly define it. 35% of the participants were of the opinion that both doctors and nurses should report ADR. 76% were not aware of any National Programme of Pharmacovigilance. 72% of nurses claimed to be aware of common ADRs of the drugs they routinely administered by them. 81% of the nurses were not routinely informed to be on lookout for specific drug reactions by the treating physicians. 91% of nurses were of the opinion that periodic pharmacovigilance training will benefit ADR reporting with 58% favoring yearly workshops.

Conclusion: The present study focused on the major lacunae in efficient ADR reporting. Nurses being a major stakeholder in healthcare delivery, can be mobilized in the field of ADR reporting, which currently is not the norm, albeit with adequate training.

Keywords: Pharmacovigilance, Nurses, Adverse drug reactions, Adverse drug reaction reporting systems

INTRODUCTION

Pharmacovigilance is defined by the World Health Organization as the science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problem. It deals with preventing and minimizing the morbidity associated with the use of various medicines.

National Pharmacovigilance Programme of India (PvPI) was launched by Central Drugs Standard Control Organization (CDSCO) in November of 2004 under the aegis of Director General of Health Sciences, Union Ministry of Health and Family Welfare (MOHFW).^{1,2} The program was aimed to collate, analyze, and archive adverse drug reaction (ADR) data for making a regulatory decision regarding the drugs marketed in India. The PvPI envisages that “All” health care professionals will play an important role in making the program a success.

As per the recent health care statistics, India had approximately 0.7 physicians/1000 population³ and 1.7 nurses/1000 population⁴ in 2011-2012. These statistics show that nurses and midwives have better population outreach as compared to physicians alone. Nurses also form an important cog in the wheel of health care delivery and are often direct provider of health care delivery under the supervision of treating physicians.

As nurses form an invaluable asset in providing quality health care to the patient, their knowledge about ADR can be used to prevent, minimize, and monitor such episodes. Hence, we proposed to undertake the present study to assess the knowledge of pharmacovigilance in nurses.

Aim and objectives

To assess the knowledge of pharmacovigilance among the nurses of tertiary care hospital.

METHODS

The proposed study was conducted in Chhatrapati Shivaji Maharaj Sarvopachar Rughalaya (CSMSR), Solapur. The proposal of the study was submitted to the Ethics Committee of Dr. V. M. G. M. C and CSMSR, Solapur, and appropriate ethical clearance was obtained via letter No. GMC/IEC/Pharmac/Proposal No.1114043. The study was conducted from the month of March 2015 to July 2015. 127 nurses were approached for the survey. They were explained the aim, objectives, and purpose of the study. They were provided a pre-tested, structured questionnaire and their responses were noted. The questionnaire contained demographic data as well as pre-tested questions intended to assess the knowledge of pharmacovigilance among the nurses. The questionnaire also incorporated the opinions of the study participants regarding efficient pharmacovigilance reporting. 100 nurses out of 127 returned the completely filled questionnaires. These responses were used for analysis. The responses were pooled together, and appropriate statistical analysis in terms of percentage comparison was done on the pooled data to evaluate the knowledge of pharmacovigilance among the nurses.

RESULTS

127 nurses participated in the study. 100 nurses returned the completely filled questionnaire and were analyzed for the study. Table 1 denotes the demographic aspects of the participants. Mean age group of the study group was 42 years. 93% respondents were females, and 7% were males. Table 2 and Figure 1 denotes the awareness regarding pharmacovigilance among the participants. 63% respondents had heard about the term pharmacovigilance. 41% of these could correctly define it. All the respondents had heard about the term ADR. However, only 39% could correctly define it. 94% of the study participants deemed ADR reporting as an important process. Table 3 denotes the knowledge of nurses with respect to ADR reporting. 35% of the participants were of the opinion that both Doctors and Nurses should report ADR. 65% opined that it's either the doctors or nurses' individual job to report ADR. 24% of the participants were aware of some national program for ADR reporting, 76% were not aware of any such program. None of the participants could accurately name the said program. 55% of nurses were not aware of any provision of pharmacovigilance center at their parent institute. 67% of the participants reported that they had encountered a medical condition strongly suspected due to a drug. 72% of nurses claimed to be aware of common ADRs of the drugs they routinely administered in their respective wards. 81% of the nurses stated that they were not routinely informed to be on lookout for specific drug reactions by the treating physicians. As Figure 2 shows, 41% of the nurses were of the opinion that compulsory reporting will help ADR reporting while 33% favored voluntary reporting and 26% had no opinion. As shown by Figure 3, 54% of participants favored

reporting ADR via an ADR form and a drop-box, 27% on the phone, and 19% favored computer based reporting. Table 4 shows that 91% of nurses were of the opinion that periodic pharmacovigilance training will benefit ADR reporting. 58% favored yearly workshops, while 27%, 1%, 14% favored 6 monthly, 3 monthly, and 3 yearly workshops 3 yearly workshops Figure 4.

DISCUSSION

PvPI was launched in July 2010 by CDSCO, under the aegis of MOHFW. The mission of PvPI is to safeguard the health of Indian population by ensuring that the benefit

Table 1: Demographic data.

| Demographic characteristics | |
|-----------------------------|--------|
| Age (in years) | Years |
| Mean±SD | 42±2.5 |
| Sex (n=100) (%) | (n) |
| Male | 7 |
| Female | 93 |

SD: Standard deviation

Table 2: Knowledge about pharmacovigilance.

| Questions | Yes (%) | No (%) |
|----------------------------------------|---------|--------|
| Heard about pharmacovigilance? (n=100) | 63 | 37 |
| Heard about ADR? (n=100) | 100 | 0 |
| Correctly defined ADR? (n=63) | 39 | 61 |

ADR: Adverse drug reaction

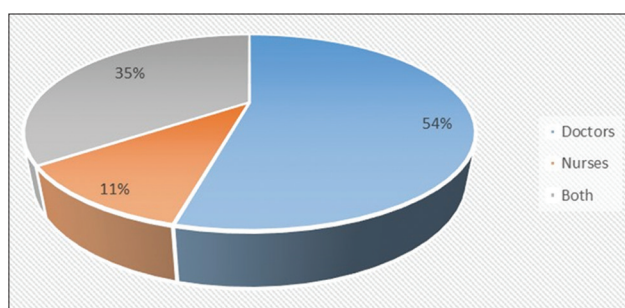
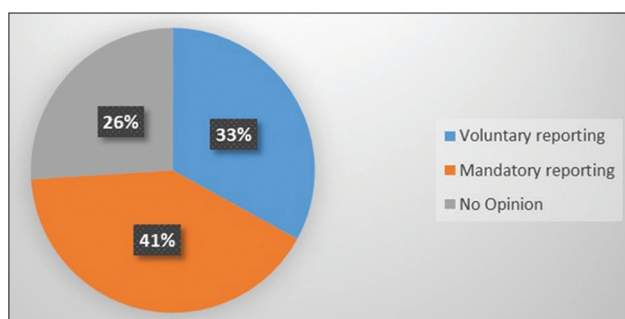
Table 3: ADR reporting.

| | |
|----------------------------------------------------------------------------------|-------------------------------------------------------------------------|
| Who can report ADR? (n=100) | Doctors: 54% Nurses: 11% Both: 35% |
| Are you aware of national program for ADR reporting (n=100) | Yes: 24% No: 76% |
| Do you know the ADR of drugs you commonly administer? (n=100) | Yes: 72% No: 28% |
| Are you routinely informed about potential ADR by prescribing physician? (n=100) | Yes: 19% No: 81% |
| What will make ADR reporting efficient? (n=100) | Voluntary reporting: 33% Mandatory reporting: 41% No opinion: 26% |
| How will you prefer to report suspected ADRs? (n=100) | Drop-box: 54% Telephone: 27% Computer based reporting: 19% |

ADR: Adverse drug reaction

Table 4: Pharmacovigilance training.

| | |
|------------------------------------------------------------------|----------------------------------------------------------------------------------|
| Do you think pharmacovigilance training will be helpful? (n=100) | Yes: 91% No: 9% |
| How often do you think it should be conducted? (n=100) | Every 3 monthly: 1% Every 6 monthly: 27% Yearly: 58% Every 3 years: 14% |

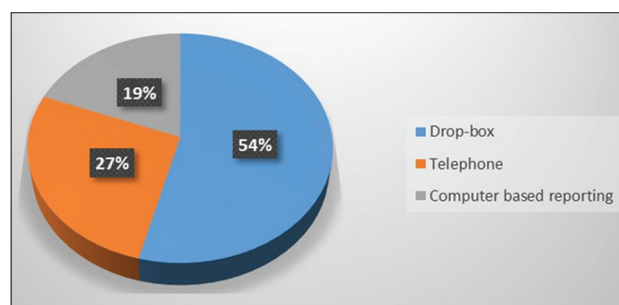
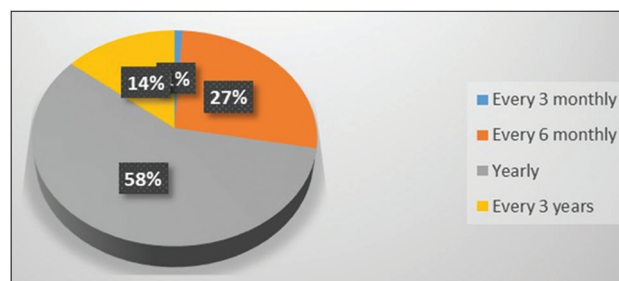
**Figure 1: Who can report adverse drug reaction?****Figure 2: What will make adverse drug reaction reporting efficient?**

of the use of medicines outweighs the risks associated with its use.^{1,2} ADR reporting forms an important part of this program.

Our study aimed to assess the knowledge of pharmacovigilance and ADR reporting in the nursing staff as they have better penetration in the population as compared to physicians.^{3,4}

In the present study, only 63% of the participants had heard about pharmacovigilance. All the participants had heard about ADR. However, only 39% could correctly define it. This observation was very less as compared to one observed in a study conducted by Hajebi et al.,⁵ where 75% of the participants could correctly define ADR. Similarly, in a study conducted by John et al.,⁶ where 83.5% of nurses could correctly define ADR and pharmacovigilance.

In the present study, 46% of the nurses were of the opinion that nurses were part of ADR reporting. This opinion was considerably less than one observed in a study conducted by Ekman et al.,⁷ where 58% of the nurses were aware that ADR reporting is an important aspect of nursing care.

**Figure 3: How will you prefer to report suspected adverse drug reactions?****Figure 4: How often do you think pharmacovigilance training should be conducted?**

In a study conducted by Alan et al.,⁸ 65% of nurses had encountered an ADR at least once. This finding was reflected in the present study, where 67% of nurses had reported encountering at least one ADR.

In the present study, nurses preferred ADR reporting via a filled ADR form and a drop-box (54%) over other methods such as a phone call (27%) and computer based (19%) reporting. This was in contrast to the preference encountered in a study conducted by Ekman et al.,⁷ where 84% of the participants favored an Internet and computer based reporting. This may be due to the fact that Indian nurses were uncomfortable with technology. Ekman et al.,⁷ reported that 88% of nurses were eager to undergo professional training in pharmacovigilance to better the ADR reporting. This finding was mirrored in the present study where 91% of the nurses were enthusiastic about a pharmacovigilance and ADR reporting workshop. 58% of the participants favored yearly workshops to help them report ADR in a better way.

The present study also draws attention to the fact that only 24% of the nurses were aware of PvPI. Hence, adequate training programs must be initiated to increase awareness among the program. Hence, adequate training programs must be initiated to increase awareness amongst the nurses regarding the programme. The present study also highlighted the fact that prescribing physicians seldom (19%) warned the nurses to be on lookout for specific ADRs in the drugs they prescribed. Hence, the onus is on the prescribing physicians to sensitize the nurses to potential ADRs. This can improve ADR reporting.

The present study focuses on the major lacunae in efficient ADR reporting. Nurses being a major stakeholder in healthcare delivery, can be mobilized in the field of ADR reporting, which currently is not the norm, albeit with adequate training.

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Conflict of interest: None declared

Ethical approval: The study was approved by the Institutional Ethics Committee

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