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**Original Research Article** 

# Assessment of Knowledge, Attitude and Practices towards Pharmacovigilance among Nurses of a Tertiary Care Teaching Hospital

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#### Abstract:

**Introduction:** As Nurses are close to the patients, their role is important in Adverse Drug Reaction (ADR) reporting. Thus, this study was carried out among nurses of tertiary care teaching hospital.

Aims and objectives: This study was planned to assess knowledge, attitude and practices (KAP) of pharmacovigilance among nurses of tertiary care teaching hospital.

**Method:** A questionnaire-based, prospective and observational study was conducted after taken approval from Ethics committee. Total 45 Nurses were voluntary participated in this study. Data were collected in the form of Pre-tested and validated questionnaire consisting of 10 questions about pharmacovigilance. The filled questionnaires were collected and analyzed on Microsoft Excel Sheet.

**Results:** According to the result of present study all nurses were familiar with term of pharmacovigilance and 89% of them were aware of pharmacovigilance programme of India. Out of total filled questionnaire received, most of nurses (93%) believed that all the drugs available in the market are not safe and only 8% believed that patient can also report ADRs. The major factor discouraging for reporting ADR was lack of knowledge regarding where to report ADR.

**Conclusion:** This study has shown that majority of the participants had correct knowledge and positive attitude about pharmacovigilance, In spite of that, reporting rate of ADRs is very low. Hence, steps should be taken to raise awareness among them is important.

Keywords: Adverse Drug Reaction, Nurses, KAP Study.

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#### Introduction

Adverse drug reactions (ADRs) are known as very important causes for hospitalization. ADRs occur approximately in 30% of hospitalized patients and patients in the ICU wards are exposed to more danger than the others. ADRs can be a threat for patient's safety and quality of their life and may impose a lot of costs on the health systems. The important point about ADRs is pharmacovigilance or the methods used for their recording, evaluation and prevention.[1] The World Health Organization (WHO) has defined adverse drug reaction (ADR) as "a response to a drug which is noxious and unintended and which occurs at doses normally used in man for prophylaxis, diagnosis, or therapy of disease or for the modification of physiologic function"[2]

The word "Pharmacovigilance" is as follows: Pharmakon (Greek word for "drug") and vigilare (Latin word for "to keep watch"). The major key role in Pharmacovigilance programs is played by healthcare professionals such as physicians, pharmacist, and nurses but with an estimated median underreporting rate (defined as the percentage of ADRs detected from intensive data collection that was not reported to relevant spontaneous reporting systems) of 94%. it is noted that underreporting is very common and occurs frequently for serious and unlabelled reactions. The detection of important ADRs is delayed due to this. [3]

Pharmacovigilance is defined by the WHO as "the science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other possible drug-related problem, particularly long-term and short-term adverse effects of medicines" [3]

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According to studies from many contexts, healthcare workers have insufficient awareness about pharmacovigilance as well as attitudes that are linked to a high level of under-reporting. [4,5] Out of the several methods of detecting ADRs, spontaneous reporting is the one that has contributed significantly to improved levels of pharmacovigilance in many countries. [6,7] It is essential to enhance the knowledge, attitude, and perception of all healthcare workers for better reporting of ADRs. Among all healthcare workers, Nurses are close to the patients, their role is important in Adverse Drug Reaction (ADR) reporting. Thus, this study was carried out with aim to assess knowledge, attitude and practices (KAP) of pharmacovigilance among nurses of tertiary care teaching hospital.

### Methodology

**Study Site:** The study was conducted at C. U. Shah medical college and hospital, Surendranagar, Gujarat, a tertiary care teaching hospital. Study was conducted between months of 18 December 2021 to 1 February 2022. for the period of two months.

**Type of study:** It was a questionnaire-based, prospective and observational study.

**Sample size:** Convenient sampling method was used in which all staff nurses having basic degree of nursing and midwifery who gave consent to participate were enrolled in the study.

**Study Process:** The study was started after receiving approval from the Institutional Ethics Committee of the college (CUSMC/IEC(HR)/RP-01/2021/Approval-RP01/1577). The questionnaires toward pharmacovigilance and ADRs were prepared and then after it were peer reviewed and validated by expert faculty members. A questionnaires consisting of total 10 questions, among these questions, 5 questions were related to the knowledge, 3 questions about attitude and the remaining 2 questions were related to the practice.

All study participants were contacted directly and explained the purpose of the study and distributed the questionnaires, to fill them and hand it back. Any clarification needed in understanding the questionnaires and additional time to filled form was provided. The questionnaire was analyzed, question-wise and their percentage value was calculated with the help of Microsoft excel spread sheet in MS Office 2007.

### Results

In present study, total 80 questioner form were distributed to staff nurses. Out of them 45 questioner form were filled and return staff nurses. Out of the total (n = 45) staff nurses, 70% were female and 30% were male staff nurses.

# Analysis of knowledge regarding pharmacovigilance:

A questionnaire consisting of 5 questions were related to the knowledge of pharmacovigilance and ADR reporting. According to analysis of data, 100% staff nurses had knowledge about the term pharmacovigilance. While only 33% staff nurses had knowledge of correct definition of pharmacovigilance [Figure: 1].

As shown in Table 1, 88.60% staff nurses were aware of Pharmacovigilance Programme of India (PVPI). While only 48.90% staff nurse agreed that they had an information regarding how to report adverse drug reaction at the site of their service. Only 38% staff nurse had knowledge about name to coordinating faculty member, whom to contact for reporting ADR. 69% staff nurse had knowledge that only serious adverse drug reactions should be reported. (Figure 2)

# Analysis of attitude regarding pharmacovigilance:

A questionnaire consisting of 3 questions were related to attitude of staff nurses in reference to pharmacovigilance and ADR reporting. According to result who are qualified to report ADRs, 95.60% staff nurses had given their opinion that only medical practitioners qualified to report ADRs, while 62% staff nurses had given their opinion that only nurses qualified to report ADRs. Only 9% staff nurses had given their opinion that patients also qualified to report ADRs. (Figure 3) As shown in Table 1, 93% staff nurses believed that all the drugs available in market were safe.

# Analysis of practice regarding pharmacovigilance:

A questionnaires consisting of 2 questions were related to practice toward ADR reporting by staff nurses. As shown in Figure 4, 86% of staff nurse were witnessed of any type of ADR during practice. Among them 80% staff nurse had reported ADR. But only 4% staff nurses were aware about where to report ADR.

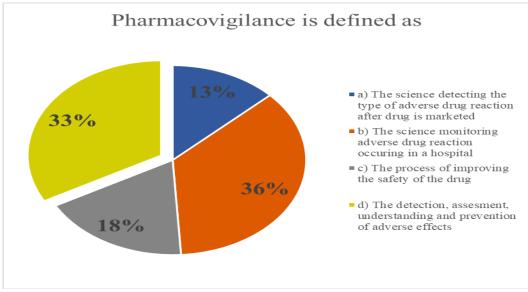


Figure 1: Knowledge regarding definition of pharmacovigilance

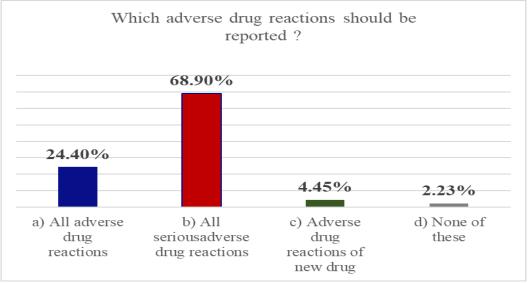


Figure 2: Knowledge regarding reporting of ADR

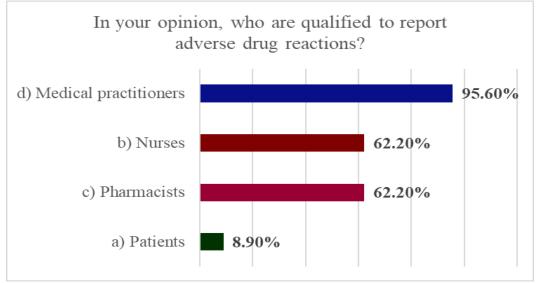


Figure 3: Opinion toward who can report ADRs

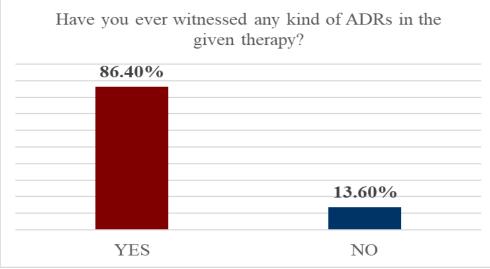


Figure 4: Witness of any kind of ADRs during practice

Questions	Yes	No
Analysis of knowledge towards pharmacovigilance		
Are you familiar with the term of pharmacovigilance?	100%	0%
Are you aware of pharmacovigilance programme of India?	88.60%	11.40%
Have you ever given information how to report adverse drug reaction at the	48.90%	51.10%
site of your service?		
If yes, then mention the name of faculty to contact ADR reporting?	Aware - 38%	
Analysis of attitude towards pharmacovigilance		
Do you believe all the drugs available in market are safe?	93%	7%
Analysis of practice towards pharmacovigilance		
Have you ever reported adverse drug reaction?	80%	20%
If yes, where it reported?	Pharmacology departm	ment - 4%

Table 1: Questions regarding pharmacovigilance
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### Discussion

Hospital nurses play an important role in ADRs reporting, because they are close to the patient and have good knowledge of health criteria, symptoms, drugs and ADRs. Given their unique position in drug administration and recording side effects, nurses are well-placed to monitor the patients' response to drugs. [8] It is important for the nursing staff to participate in spontaneous reporting scheme because they spend more time in the wards and it is most likely that any acute ADR will first be observed by them. In countries where nurses are already participating in the ADR reporting scheme, studies have shown that they indeed contribute positively toward the promotion of ADR reporting.[9,10]

In present study, all staff nurses (100%) were familiar with the term of Pharmacovigilance, while similar study conducted by Veena et al., only 38% participants heard the term Pharmacovigilance.[11] Knowledge of nursing staff in medical field is very effective to decrease the rate of occurrence of ADRs. Only 33% of staff nurse had correct knowledge regarding definition of Pharmacovigilance, which is similar to study conducted by Hammour et al. in which 36% of participants had knowledge about Pharmacovigilance.[12] It is important to report all type of ADRs to improve safety of patient. In present study 24.40% nurses had a opinion that all ADRs should be reported which was similar to study conducted by Veena et al. in that study 33% participants had an opinion that all ADRs should be reported. [11]

The spontaneous reporting of ADR, especially by the nurse who come across the patients initially, is very much vital for the success of the PvPI program. Regarding awareness of pharmacovigilance programme of India, in present study 89% staff nurses were aware about PvPI, which was in contrast to study of Veena et al. which shows that only 29% nurses were aware about PvPI programme of India. [11]

It is important to give training to nurses regarding how to report ADRs for increase reporting rate of ADRs. In present study more than 50% nurses agreed that they had given information to how to report ADRs at their service, where as in study conducted by Bepari et al. 89% nurses agreed that training was given how to report ADRs.[13] Not only medical practitioners, all health care providers and patients and their relatives can also report ADRs. In present study 95% of staff nurses had given their opinion that only medical practitioners were qualified to report ADRs, that in contrast to study conducted by Veena et al. only 22% had given their opinion that only medical practitioners were qualified to report ADRs.[11] Not only Knowledge but keen observation and efficient reporting form the basics of Pharmacovigilance.

During practice 86% of staff nurse were witnessed of any type of ADR during practice and 80% of them had reported ADRs, similarly a study conducted by Ahmed et al. 72% participants witnessed any type of ADR during practice and in contrast to that a study of Bogolubova et al. only 21% nurses reported ADRs. [14.15]

Strength of present study is that nurses were enrolled for the study as they are very close to patients and easily identify any kind of ADRs and limitation is it was conducted at a single centre.

### Conclusion

This study showed that majority of the participants had correct knowledge and positive attitude about pharmacovigilance and also understand the need for reporting, in spite of that, reporting rate of ADRs is very low, it may be due to lack of awareness about what, where and how to report. Hence, steps should be taken to raise awareness among them through various means like Workshops/CME/Conferences.

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