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Awareness of Operation Theatre and ICU Nurses about Pharmacovigilance: A Questionnaire Based Study

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Abstract

Background & Aim of the Study: The main objective of the Pharmacovigilance programme of India is to create a nationwide system of adverse drug reporting by health care professionals and patients. Nurses are the most essential health care givers who closely monitor the patient health and safety. This study was conducted to assess the Knowledge, Attitude, and Practices (KAP) of Nurses about Pharmacovigilance & Adverse drug reactions (ADR) reporting in tertiary care hospitals in Tamilnadu. *Materials and Methods*: This is a questionnaire based study with both open and close ended questions on different aspects of Knowledge [6], Attitude [8], and Practice [6] questions. Among 200 OT and ICU Nurses of tertiary care hospitals, 174 responded (87%). KAP among study subjects was measured in Percentages based on their responses. *Results*: ADR reporting was considered very important by 93.10% of nurses, primarily for improving patient's safety (69.54%) and identifying new ADRs (57.47%). Majority of nurses (79.88%) opined that all ADRs should be reported, 25.28% are aware about Pharmacovigilance Centre in the hospitals. However, 88.50% said that proper training should be provided to report ADR. *Conclusion*: The Nurses are aware of ADR reporting and their importance. However, under reporting and lack of knowledge are clearly evident.

Keywords: Pharmacovigilance; ADR; Awareness; OT and ICU Nurses; Questionnaire.

Introduction

Adverse reactions are a major global public health problem as the drugs undergo experimentation before approval in limited number of humans [1]. It is very difficult to pick up rare adverse effects until the drug is marketed in the community level. Hospital admissions due to adverse drug reactions are a national problem with mortality, morbidity and costs that can be easily prevented with proper system in place [2,4]. Pharmacovigilance, is the science and activities relating to the detection, assessment, understanding and prevention of adverse events or any other possible drug-related problems. Pharmacovigilance programme of India (PvPI) was launched in July 2010. The aim and objectives of PvPI are to monitor adverse drug reaction in Indian population and to protect health of the patients by assuring drug safety, to create awareness among health care professionals about importance of ADR reporting and to monitor benefit-Risk profile of medicines. The ADR monitoring centres have been started in medical college hospitals throughout the country as a part of PvPI programme and adverse reactions are reported to regional centres and to national coordinating centre at Ghaziabad through software called vigiflow. One of the main aims of the PvPI is to emerge as a national centre of excellence for pharmacovigilance activities and to create a database of adverse reactions in Indian population and to exchange of information with other national centres

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across the globe. Pharmacovigilance protects the safety of Indian population from risky drugs by supporting regulatory authorities in decision making process on use of drugs. Adverse drug reactions can be reported by doctors, nurses, pharmacists and patients [3,5].

Many studies have been done to assess the awareness of healthcare providers about pharmacovigilance. They have highlighted poor ADR reporting practices due to lack of time, unavailability of ADR forms, lack of knowledge about the methods of reporting ADR [6, 7]. Underreporting of ADR can be improved by imparting knowledge regarding ADR reporting by sensitization in different methods like lectures, reminders, pamphlets, posters and continuing educational programme [8]. This study is aimed at one of the essential health care providers viz. nurses who are involved in immediate care and close monitoring of the patients in operation theatres and Intensive care units. This study was conducted to assess the awareness of Operation theatre(OT) and Intensive care unit (ICU) Nurses about ADR reporting and Pharmacovigilance. This is a questionnaire based study assessing the knowledge, attitude and practice of ADR reporting in OT & ICU nurses working in tertiary care medical college hospitals in Tamilnadu.

Methodology

This is a prospective questionnaire based study with both open and close ended questions. This study was conducted in tertiary care medical college hospitals in Tamilnadu. The study was conducted on qualified OT & ICU nurses working in the tertiary care hospitals. The nursing students and trainee nurses were not included in the study. The sample size was calculated based on the previous study data to be 195. Duration of the study was 3 months and study period was between January to March 2016. The Tool used to assess the awareness was a pre validated questionnaire about Knowledge [6], Attitude [8], and Practice [8] (KAP) consisting totally 22 questions in simple English along with demographic profile of the participants. The questions were multiple response and free response type questions.

The questionnaire was taken from similar studies conducted among nurses from literature review and proper permission was obtained appropriately. The questionnaire was validated with three experts trained in Pharmacovigilance and peer group evaluation with nurses, pharmacologists and anaesthetists was done. Ethics committee approval was obtained for the study and written informed consent was obtained from the participants.

The questionnaire was distributed to the OT and ICU nurses of the hospitals by the investigators involved in the study. Those who were willing to participate were given the questionnaire and participants were asked to fill the questionnaire at their free time and hand over or drop it in the nurse's station or in the Pharmacovigilance centre where a box was kept to avoid bias and undue influence on the participants by the investigators. More than one answer is allowed in some of the questions. The doubts and queries regarding the questionnaire were answered appropriately. The investigators phone numbers were provided in the questionnaire in case of queries.

Confidentiality of the participants was maintained by removing identifiers from the questionnaire. After the handing over of the filled up questionnaire the participants were provided a handout of the pharmacovigilance methods and safety of medication use after the completion and returning of the questionnaire. Analysis of the data was done by assigning numerical values to the questions except open ended questions and measured by percentages.

Results

In the knowledge towards pharmacovigilance 88.5% of the nurses said that all drugs available in market are not safe. 75.2% said that ADRs can be reported by even Nurses, Pharmacists and other Medical personnel. 28.1% said that ADRs should be reported only when they are serious and life threatening. 16% said that only ADRs for new drugs should be reported. 20.28% nurses were aware about their hospitals' Pharmacovigilance centre. 68.3% were aware about drugs that were banned due to ADR.

In the questions about attitude towards pharmacovigilance 93.10% of the nurses thought that it was very important to report ADRs for improving patient safety (69.54%) and to identify new ADRs (57.47%). 22.4% think that ADR reporting is time consuming activity. All the nurses think that regular ADR reporting would benefit the patient. 88.5% think that proper training should be given to health care professionals for reporting ADR. 64.9% support 'Direct ADR reporting by Patients. 82.7% expects feedback from ADR monitoring centre. 92.5% think that ADR monitoring is a professional obligation duty.

Table 1: Knowledge towards pharmacovigilance and adverse drug reactions among the study population

Knowledge Assessment Questions	Yes	No	Don't know
Do you believe all the drugs available in the market are safe	17 (9.7%)	154(88.5%)*	3(1.7%)
Should ADRs be reported only by physicians	20 (11.4%)	131(75.2%)*	23(13.2%)
ADRs should be reported only when they are serious and life threatening	49(28.1%)	121(69.5%)*	4(2.2%)
ADR's should be reported only for new drugs	28(16%)	139(79.8%)*	7(4%)
Is there any approved ADR reporting and monitoring centre in your knowledge	104(59.7%)*	33(18.9%)	36(20.6%)
Are you aware of any drug that has been banned due to ADR	119(68.3%)*	47(27%)	8(4.5%)

*- correct response indicates good knowledge

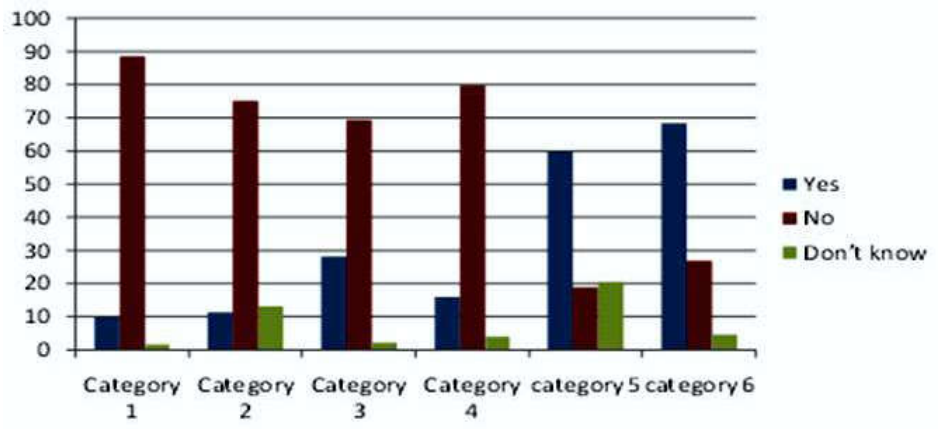

Fig. 1: Knowledge towards pharmacovigilance and adverse drug reactions among the study population

Table 2: Attitude towards pharmacovigilance and adverse drug reactions among the study population

	Awareness Assessment Questions	Yes	No	Don't know
1.	Do you think it is important to report ADR	162(93.1%)*	10(5.7%)	2(1.1%)
2.	Do you feel that ADR reporting is time consuming activity with no outcome	39(22.4%)	120(68.9%)*	15(8.6%)
3.	Do you think that ADR reporting and monitoring system would benefit the patient ?	174(100%)*	0	0
4.	Do you feel that proper training should be provided to health care professionals reporting ADR ?	154(88.5%)*	18(10.3%)	2(1.1%)
5.	Do you worry about reporting ADR on the drugs prescribed by you to the patients?	46(26.4%)	126(72.4%)*	2(1.1%)
6.	Do you support 'Direct ADR reporting' by the patients instead of physicians ?	113(64.9%)*	58(33.3%)	3(1.7%)
7.	Do you expect feedback from ADR monitoring center if you report an ADR?	144(82.7%)*	21(12%)	9(5.1%)
8.	ADR reporting is a professional obligation (duty)	161(92.5%)*	6(3.4%)	7(4%)

*- indicates positive attitude towards pharmacovigilance and ADR

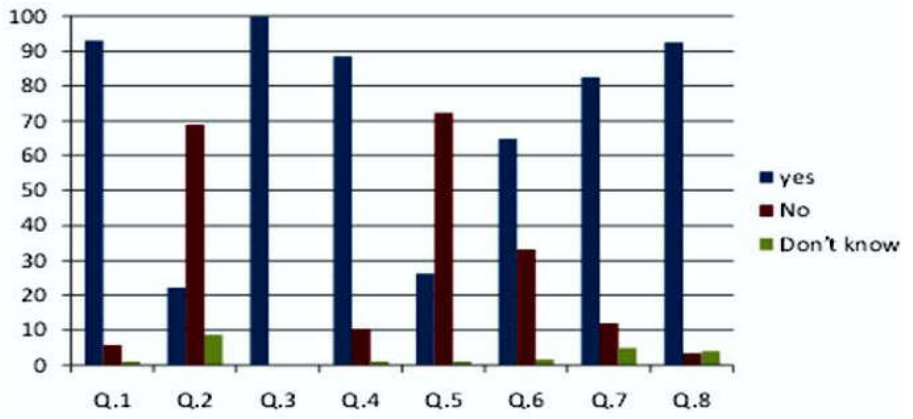

Fig. 2: Attitude towards pharmacovigilance and adverse drug reactions among the study population

Table 3: Practices towards pharmacovigilance and adverse drug reactions among the study population

Practice Assessment Questions	Frequency	Percentage
Have you ever experienced an ADR in patients in your practice- yes	91	52.2%
No	74	42.5%
Don't know	9	5.1%
Factors that discourage you from reporting ADR s		
Managing patients was more important than reporting ADR	63	36.2%
Do not know where to report	29	16.6%
Do not know how to report	27	15.5%
Hesitation due to legality issues	26	14.9%
I do not think it is vital and important to report ADR	12	6.8%
From which sources,do you gather information about ADRs to new drugs		
Drug advertisements and product catalogues	60	34.4%
Journals	44	25.2%
Internet	37	21.2%
Seminars/Conferences	31	17.8%
Text books	22	12.6%
Medical representatives	15	8.6%
Direct mail brochures	8	4.5%
4. Do you have free access to ADR reporting forms Yes	153	87.9%
No	18	10.3%
Don't know	3	1.7%
Which method would you prefer to send ADR information to an ADR reporting centre		
Direct contact	91	52.2%
E mail / Website	40	22.9%
Telephone	20	11.4%
Post	12	6.8%
Others (ADR form)	9	5.1%

Table 4: Suggestions made by the study subjects in improving ADR reporting

S. No	Suggestion	Frequency	Percentage
1.	Make reporting of ADR simple	22	12.6%
2.	Continuing education and awareness about ADR reporting and Pharmacovigilance	20	11.4%
3.	Provide Electronic options to report ADR	22	12.6%
4.	Circulating informative handouts and drug alert newsletters periodically	16	9.1%
5.	Provide feedback to the reports	21	12%
6.	Make reporting of ADR mandatory	13	7.4%
7.	Recruiting assisstants to healthcare providers in helping them to report ADR	14	8%
8.	Provide toll free numbers	11	6.3%
9.	Ensure confidentiality of the reports	10	5.7%
10.	Encourage by giving awards / credits to the ADR reports	11	6.3%
11.	Provide financial compensation to submit ADR reports	9	5.1%

In the practice towards pharmacovigilance 52.2% nurses told that they have come across ADRs in patients. 36.2% said that managing patients was more important than reporting ADR, 16.6% did not know where to report and 15.5% did not know how to report. 34.4% gather information about ADR from drug advertisements, 25.2% from journals and 21.2% from internet source. 10.3% said that they don't have free access to ADR reporting forms.

52.2% preferred "Direct contact method" to send ADR information to reporting centre, 22.98% preferred E-mail. 60.9% said that they frequently report ADR with Antibiotics, 17.2% said analgesics.

Discussion

Identification of the gaps in knowledge, attitude and practices of nurses in ADR reporting will help us to know the factors for underreporting. Indeed, recent studies have shown that if an educational intervention is designed on the basis of gaps detected in health care providers' knowledge and attitudes, the reporting rate can be sharply increased. The present study is a questionnaire based study which included OT & ICU Nurses from tertiary care medical college hospitals in Tamilnadu. In contrast to a study done to assess the awareness of nurses and midwives in turkey which reported nurse/midwives working

in different hospitals have insufficient knowledge of pharmacovigilance practices; in our study nurses had a sufficient knowledge about pharmacovigilance.

Overall 88.5% of nurses opined that drugs in the market are not safe and only 28% of them thought that only serious ADRs should be reported. 35% Nurses gain information about drugs through advertisements and product catalogues in our study whereas in a study done by Alan et al it was reported 90% of nurses checked the product information before administration of drugs [9]. About 20% nurses only had knowledge about their hospitals' Pharmacovigilance centre and its location which is an important factor that should be a reason for underreporting of ADR. Majority of them think that ADR reporting is very important while few of them think it is a time consuming activity. In 1986 model of reporting factors, Inman et al has reported lethargy, as a factor that hinder or justify non-reporting. Among these is 'don't have time' to report which denotes burden of care. Many of them supported direct ADR reporting by patients which has come into practice in Pharmacovigilance programme of India. The most reported ADRs according to nurses in our study were antibiotics, analgesics similar to the reports of a study by Ulfvarson et al [10].

Majority (91%) of them knew that they should report and have free access to ADR reporting forms but they have lack of knowledge about where and how to report ADR and 14% worried about legal issues. The study shows that while there is good knowledge and right attitude for ADR reporting existed among most nurses, but the actual practice was lacking. Hence it is necessary to impart them proper knowledge, legal issues and practical methods how to report ADR to them. This can be done by conducting regular sensitization training programmes and demonstration workshops for Nurses and creating awareness through posters, handouts, newsletters and advertisements and skits.

Conclusion

In our study the knowledge and attitude about the ADR reporting and Pharmacovigilance among OT and ICU nurses were good but the practice of reporting ADR was lacking due to belief it is a time consuming activity affecting patient care duties and unawareness about how and where to report the ADR. The nurses' top three suggestions to improve ADR reporting were 1) To make reporting easy and simple 2) Sensitization awareness programmes 3) Providing feedback for the ADR reported by them by the pharmacovigilance centre and introduction of electronic methods to report ADR.

Conflicts of Interest

The authors have declared that there is no conflict of interests.

Acknowledgement

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