

doi: <http://dx.doi.org/10.18203/2319-2003.ijbcp20150883>**Research Article****Assessment of knowledge, attitude and perception of Pharmacovigilance among nurses in a rural tertiary care center****Manu Gangadhar*, Deepika Guruppanavar**

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ABSTRACT

Background: Pharmacovigilance (PV) is an integral and essential part of patient care. PV deals with the science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problems. The aims of PV are to improve patient care, public health and safety in relation to the use of medicines, to contribute to the assessment of benefit, harm, effectiveness and risk of medicines, encouraging their safe, rational and more effective use, to promote understanding, education and clinical training in PV and its effective communication to health professionals and the public. The objective of present study was to assess the knowledge, attitude and perception of PV among nurses in a rural tertiary care center, Adichunchanagiri Institute of Medical Sciences (AIMS), B G Nagar.

Methods: A cross-sectional questionnaire-based study was conducted among nurses of AIMS, B G Nagar, Mandya, Karnataka.

Results: A total of 94 respondents were analyzed. 75.53% of participants knew the definition of PV, 77.65% participants knew the international PV reporting centers, 81.91% have knowledge about regulatory body responsible for monitoring adverse drug reactions (ADRs), 80.85% have good orientation of specific ADR format, 98.93% of nurses thought ADR reporting is necessary, 86.13% have attitude of encouraging non-medical persons to report ADR and 95.74% of nurses want PV to be taught in detail and 87.23% nurses reported that they came across ADRs. 31.91% participants are not aware about how to report ADR. Lack of knowledge about the reporting procedure is the major reason for under-reporting.

Conclusions: The majority of nurses has good knowledge and attitude toward PV and understand the need for reporting in our study, but unfortunately the actual practice of ADR reporting is still deficient among them. Training programs and continued medical education type of interventions periodically can improve the knowledge toward PV.

Keywords: Pharmacovigilance, Knowledge, Attitude, Perception, Tertiary care center

INTRODUCTION

Pharmacovigilance (PV) is a science and activities relating to detection, assessment, understanding, and prevention of adverse effects or any other drug-related problems.¹

WHO defines adverse drug reactions (ADR) as “a response to a drug which is noxious and unintended and which occurs at doses normally used in man for the prophylaxis, diagnosis or therapy of disease or for the modification of physiological function.”²

PV is an integral and essential part of patient care. Health care systems rely mainly on the detection and reporting of

the suspected ADR, to identify the new reactions, record the frequency with which they are reported, evaluate factors that may increase risk and provide information to prescribers, with a view to prevent future ADRs. With this view, National PV Program was launched in India.³ It was launched in 2004 by the Ministry of Health and Family Welfare, Government of India with the goal to ensure the benefits of use of medicine and outweighs the risks and thus safeguard the health of the Indian population.⁴

PV program has played a major role in the detection of ADRs and banning of several drugs from the market. However, underreporting of ADR is one of the major problems

associated with PV program. Even in countries like the UK whose PV program are well-established, a high level of underreporting is documented.⁵

The success of PV program is mainly concerned with the active involvement of health care professionals (physicians, dentists, nurses, and pharmacists). It's a well-known fact that an inadequate awareness about the PV system among the health care professionals is the leading cause of underreporting.⁶

A nurse is the first member to observe the patient while the patient is admitted in the hospital. The nurse can even teach the patient and attendants the signs and symptoms that should be reported immediately versus those that can be held until the next visit unless it is bothersome.⁵ Nurses being the first contact with patients throughout the period of stay in hospital, also need to be sensitized regarding reporting culture. Principles of safety of medicines are essential in nursery practices which require the right medicine to be given to the right patient in the right way and dose and at the right time. They observe the effects and adverse reactions of medicines after implementation and take interventions accordingly.⁷

Only a few studies evaluating the awareness of nurse regarding PV has been conducted.⁸⁻¹⁰ Hence, this study is to evaluate the knowledge, attitude, and perception of PV and ADR reporting among nurses in a tertiary care rural hospital in South Karnataka.

METHODS

Study design and study setting

This was a cross-sectional, questionnaire-based study conducted in Adichunchanagiri Institute of Medical Sciences, B G Nagar, Mandya district, Karnataka, a rural tertiary care teaching hospital during the period of March-June 2015 after obtaining permission from the Institutional Ethics Committee, Adichunchanagiri Institute of Medical Sciences, B G Nagar.

Study participants

In our study, nurses from the hospital participated.

Aims and objectives

To assess knowledge, attitude and perception of PV among nurses of rural tertiary care teaching center.

Study procedure

With the permission of Institutional Ethics Committee, the participating nurses were explained about the purpose of the study and confidentiality was ensured. They were

asked to fill up a printed, semi-structured questionnaire after obtaining informed consent. 94 completed questionnaires were considered for the study out of 125 nurses.

The questionnaire contained questions regarding knowledge of PV (PV definition, purpose, methodology of reporting ADRs, centers of PV). Attitude and perception toward reporting ADRs (factors discouraging them from reporting ADRs, whether they have come across with any ADRs, awareness about ADR format, any ADRs reported recently).

Statistical analysis

The returned questionnaires were checked for completeness of data. Descriptive data were expressed as percentages.

RESULTS

A total of 94 nursing faculties were assessed for their knowledge, attitude and perception regarding PV.

The respondents were 94 out of 125 (75.2%). Definition of PV was shown in Figure 1, important purpose of PV depicted in Figure 2. Duration of reporting serious adverse event after onset in India to regulatory body is shown in Figure 3. International center for ADR monitoring and regulatory body responsible for monitoring ADR in India is shown in Figures 4 and 5, respectively.

Figures 6 and 7 explain the response regarding eligibility to report ADR in hospital and attitude and perception of nurses regarding PV.

DISCUSSION

ADRs are one of the most serious worldwide health problems globally and our country in no exception. Rational drug use lays down an ethical burden on the shoulder of doctors, nurses and all health care professionals to ensure the proper treatment of their patients. One of its components is to report ADRs to the concerned system.¹¹

PV deals with detection, assessment, understanding and prevention of adverse effects or any other drug-related problems. The ultimate aim of PV is to ensure patient safety

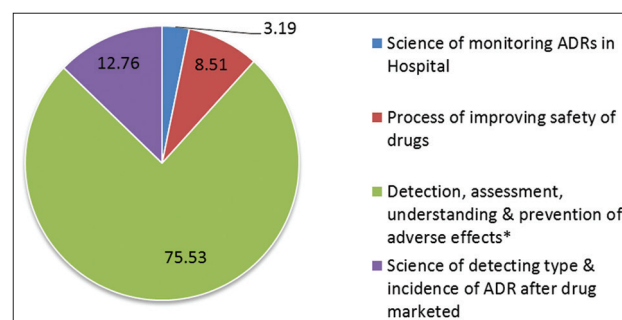


Figure 1: Definition of Pharmacovigilance.

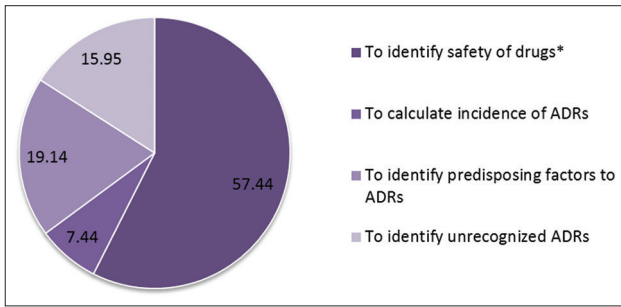


Figure 2: Important purpose of Pharmacovigilance.

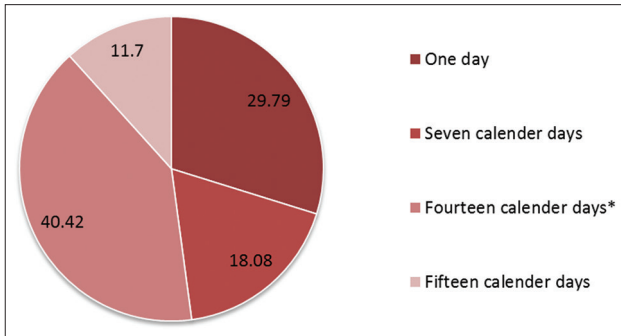


Figure 3: Serious adverse event in India should be reported to regulatory body.

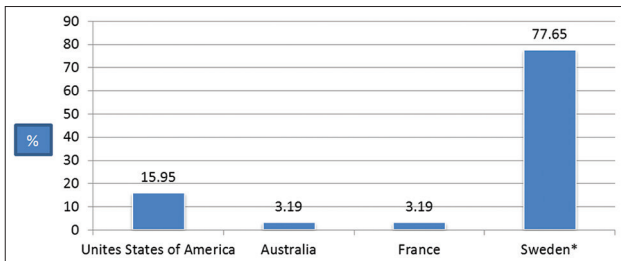


Figure 4: International center for adverse drug reactions monitoring is located.

and rational use of medicines, once a new medicine is released from general use in the society. The most important outcome of PV is prevention of patients being affected unnecessary negative consequences of pharmacotherapy.¹²

PV programs have played a major role in detection of ADRs and banning of several drugs from the market. However, underreporting of ADRs is very common. Health care professionals are to be sensitized and motivated regarding ADR reporting.¹³

Our study aimed to evaluate the knowledge, attitude and perception of nurses regarding PV. It was observed that 75.53% of participants knew the definition of PV, 77.65% knew the international PV reporting centers, 81.91% have knowledge about regulatory body responsible for monitoring ADRs, 80.85% have good orientation of specific ADR format, 98.93% of nurses thought ADR reporting is necessary, 86.13% have attitude of encouraging non-medical persons to report ADR and 95.74% of nurses want PV to be

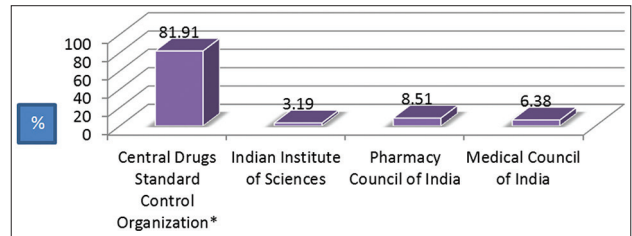


Figure 5: Regulatory body responsible for monitoring adverse drug reactions in India.

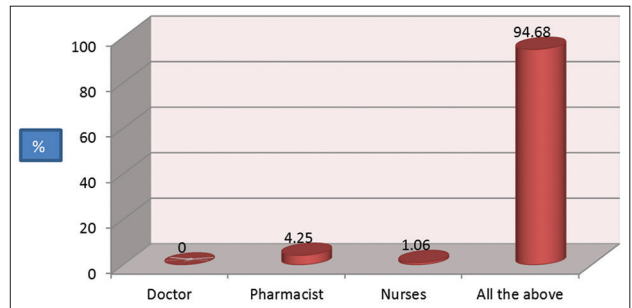


Figure 6: Adverse drug reactions reporting in the hospital.

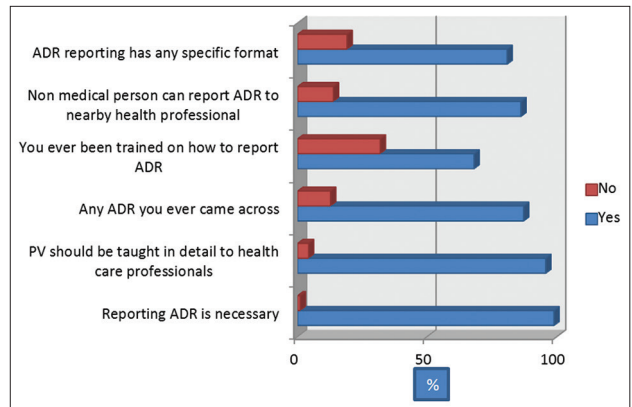


Figure 7: Attitude and perception of nurses regarding Pharmacovigilance.

taught in detail and 87.23% nurses reported that they came across ADRs.

Important limitations of this study is that findings could not be applied or generalized to the wider community as this study is restricted among nurses at the rural hospital. Similar subsequent interventions are required so as to confirm the above findings. So, we recommend that such education programs should be included in the nursing curriculum. Several similar studies should be conducted among nurses and other health care professionals to improve the knowledge of PV in our country.

CONCLUSIONS

In our study, majority of nurses has good knowledge and attitude toward PV as they understand the need for reporting.

Periodic training programs and educational interventions like conducting workshops, continued medical educations for nurses will improve the current ADR reporting system. PV should be included in nursing curriculum. Nurse's active participation in spontaneous reporting would go a long way in ensuring patient safety.

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Conflict of interest: None declared

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

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