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Original Research Article

Knowledge, attitude and practice of adverse drug reactions reporting among nurses in a tertiary care centre

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ABSTRACT

Background: Adverse drug reactions are one of the major medicine related problem related to pharmacotherapy which may lead to increased morbidity and mortality causing increased hospital stay and financial burden on the society. Spontaneous voluntary reporting of adverse drug reaction can play a vital role in generating safety signals in which nurses can play important role, hence this study was undertaken to evaluate the knowledge attitude and practice of ADR reporting along with factors affecting reporting among nurses.

Methods: The present study was a cross sectional questionnaire based study, which included nurses of a tertiary care hospital in central India. We tried to find out the possible ways to perk up spontaneous reporting of ADR and factors responsible for scarce reporting of ADRs.

Results: After analyzing the data, we observed few of responders were aware of the ADR reporting system and the most encouraging finding was that majority of the responders were of the view that this reporting system is necessary. However, response to practice related questions was below average. Main factors which discouraged ADR reporting by nurses was thinking that reporting would lead to extra work and non availability of forms.

Conclusions: The deficiencies in ADR reporting require awareness so as to perquisite spontaneous reporting and improve safety of patients. Training to nurses will lead to improvement in reporting of ADR.

Keywords: Pharmacovigilance, Spontaneous reporting, Under reporting

INTRODUCTION

Modern therapeutics has led to influx of newer drugs which has led to change the way in which diseases are treated. Although, they have better efficacy but adverse effects to medicines are common cause of morbidity and mortality. The world Health Organization defines an adverse drug reaction as a response to a drug which is noxious, unintended and which occurs at a dose normally used in man for the prophylaxis, diagnosis, or therapy of diseases or for modification of physiological function.[1] Adverse drug reactions (ADRs) may arise due to immunological and non-immunological mechanism.[2] ADRs defined as type A type B, type C, type D, Type E, Type F.[3] ADRs are important public health problem imposing a considerable economic burden on the society and health care systems. To undergo drug treatment, you have to be very careful because no medicinal product is entirely or absolutely safe for all people, in all places, at all time. ADRs lead to number of medical and economic consequences like prolong hospital stay; increase in the cost of treatment and risk of death also increases. ADRs accounts for 0.2-24% of hospital admissions, 3.7% of the

patient experiences fatal ADRs.[4,5] Hence early detection and prevention is necessary.

Pharmacovigillance is a science and activities related to detection, assessment, understanding and prevention of adverse effects or any other drug related problems. (1) Reporting of each and every case of ADR is important; however, reporting of previously unknown ADR, rare ADR and serious unlabeled ADR reporting is more important to get insight and new knowledge regarding ADRs.[6] The probability of causative agent is assessed by the ADR probability and classified as certain, probable, possible, unlikely, conditional, unassesable a scale developed by WHO used in national pharmacovigilance programme.[7] Gross under reporting of ADR is a cause for a concern, it delays early detection of ADR and can increase associated morbidity, mortality in the patient.[8] The reasons for which may be funds, lack of trained staff and lack of awareness about detection, communication and spontaneous monitoring of ADR.[5]

Monitoring of adverse drugs reactions is carried out by various methods, of which voluntary or spontaneous reporting is commonly practiced. This system offers many advantages. It is inexpensive and easy to operate. It encompasses all drugs and patient populations, including special groups. However, under reporting and inability to calculate the incidences of ADRs are inherent disadvantages of this method. In order to improve participation of nurses in spontaneous reporting, it might be necessary to design strategies that modify both the intrinsic (knowledge, attitude and practice) and the extrinsic factors (relationship between healthcare professionals and patients, health system and regulators).[9]

Reporting ADRs is a paramount importance for the success of a pharmacovigilance program of a country. Among the health care providers, nurses can play important role to monitor and report ADRs. Knowledge of pharmacovigilance program and positive attitude of nurses towards reporting of ADRs can significantly boost the spontaneous reporting. Several factors influence reporting behavior among health care providers such as; financial incentives for reporting; fear of litigation; belief that serious ADRs are well documented; uncertainty of an ADR, a single ADR report may not contribute and lack of interest or lack of time.[10] Identifying the factors influencing reporting is essential to suggest measures to enhance reporting. Several studies carried out to assess the knowledge, attitude, and practice among nurses have documented that the knowledge of ADR reporting procedure is inadequate among nurses.[11,12-15]

Before carrying out any intervention, it is necessary to evaluate the baseline KAP of the nurses regarding ADR monitoring and pharmacovigilance so that the intervention can be targeted, based on the specific findings. Identifying the factor influencing reporting is essential to suggest measures to enhance reporting. Hence, this study was carried out to assess the three quotients- knowledge (K), attitude (A) and practice (P). Considering the deep concern over the pharmacovigilance prevailing amongst the nurses the present study was done to know the KAP of pharmacovigilance among nurses of NKP Salve Institute of Medical Science and Research Center (NKPSIMS&RC), Nagpur, Maharashtra.

METHODS

It was cross sectional, questionnaire based study.

The study was conducted at Lata Mangeshkar Hospital, Nagpur, Maharashtra. A total 200 nurses working at Lata Mangeshkar Hospital, Nagpur participated in the present study. The present study was done in a duration of one month from September to October 2015.

Data recording

Data recording was done by interviewing the study subjects as per designed and pretested proforma at each visit by the principle investigator.

Statistical analysis

Collected data was entered and analyzed by Epi-info software

Aims and objectives

- To evaluate the knowledge, attitude and practice about ADR reporting among nurses in tertiary care center.
- To know about factors which would encourage and reason for deficient reporting of ADRs

RESULTS

A total of 200 nurses working in the hospital were included in the study. Questions 1 to 9 sought information about knowledge of the nurses regarding ADRs reporting system. 51% respondents were aware of existing ADR reporting system of suspected ADR.

61.5% of respondents were aware of pharmacovigilance centre in the college. For the question asked about type of ADR should be reported 65% knew that all ADR should be reported. Just 49% had knowledge that ADRs should be reported to ADR reporting centre. Another question sought information about the scales used to establish the causality assessment of ADRs and according to the data only 11% of the nurses gave correct response.

Questions 10-19 sought information about attitude of these nurses towards ADR reporting system. In this study it was observed that reporting of ADR is necessary according to majority (80%) of the respondents. A question which investigated the importance of ADR reporting, 70% of nurses felt it will lead to better care of patients and 55%

were of opinion to identify serious new ADR which is an encouraging finding (Figure 2).

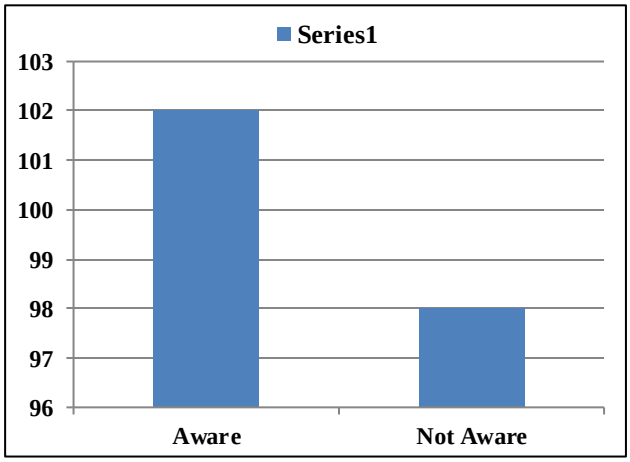

Figure 1: Awareness of ADR reporting.

Table 1: Knowledge amongst nurses for ADR reporting.

Knowledge about ADR reporting	Yes		No	
Are you aware of suspected ADR reporting system in India?	102	51%	98	49%
Are you aware of Adverse reaction monitoring centre (AMC) in college	123	61.5%	77	38.5%
Are you aware of any drug that has been banned recently due to ADR?	110	55%	90	45%
Which type of ADR should be reported?				
a) None			10(5%)	
b) All ADRs			130(65%)	
c) Others (all serious, to new drugs, unknown to old drugs)			60(30%)	
To whom ADR should be reported?				
a) ADR reporting center			98(49%)	
b) Others (HOD of institute, nearby hospital, drug manufacturer)			52(26%)	
c) All of the above			50(25%)	
Which of the following scales is used to establish the causality of an ADR?				
a) No response			110(55%)	
b) Hardwig and Siegel			22(11%)	
c) WHO-UMC scale			22(11%)	
d) Naranjo scale			36(18%)	
e) Schumock and Thomton scale			18(9%)	

Table 2 shows the main factors discouraging ADRs reporting as stated by nurses; lead to extra work 70%, reporting forms are not available 65%, lack of time 64%.

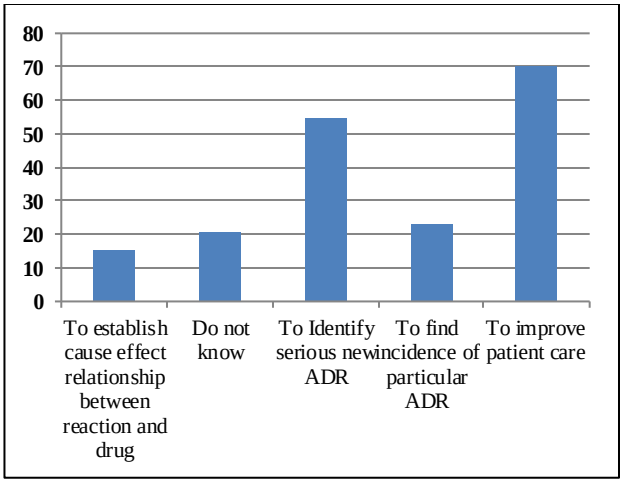

Figure 2: Importance of ADR reporting.

Table 2: Reasons discouraging ADRs reporting.

Reasons discouraging to report ADRs	Responses	
	N	%
Concern that report may be wrong	121	61.5
Lack of time to fill	128	64
Not confident to decide whether ADR or not	118	55
Concern that report will generate extra work	140	70
Fear of legal liability	98	49
Assuming that only one ADR makes no significant contribution	110	55
Reporting forms are not available when needed	130	65
Other colleagues are not reporting	109	54.5

Table 3 shows the factors important to improve reporting as stated by participants; Most of the respondents 70% gave first preference to the educational intervention. Another important way which can improve reporting is training by 68.5% of the respondents.

Table 3: Factors to encourage ADR reporting.

Possible ways to improve ADR reporting	Responses	
	n	%
Awareness among nurses	140	70
Hiding the identity of reporter	120	60
Training to the nurses	137	68.5
Remuneration for ADR submission	113	56.5
Providing electronic option for submission	93	46.5
Providing toll free number for reporting	107	53.5

Question 20 to 25 (Table 4) sought information about practices of nurses about ADR reporting system. Just 11% of the responders had ever reported any suspected ADR (Figure 3).

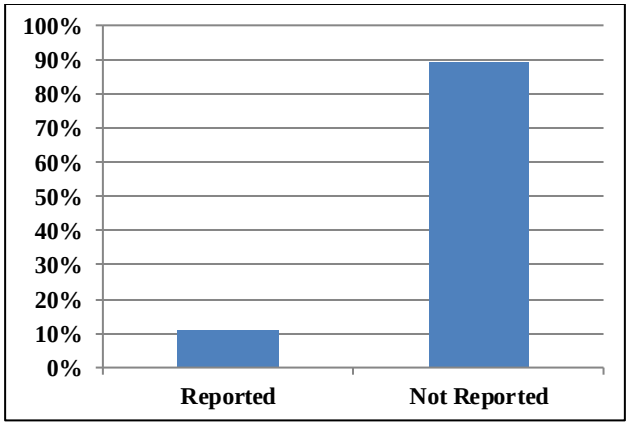

Figure 3: ADR reporting practices.

Table 4: Practice of ADRs reporting among nurses.

Practices of ADR reporting	Yes		No	
	n	%	n	%
Have you ever reported any suspected adverse drug reaction?	22	11%	178	89%
Have you attended any CME on ADR reporting?	37	18.5%	163	81.5%
Have you ever shared information about ADR with anyone?	87	43.5%	113	56.5%
Have you ever come across with an ADR?	81	40.5%	119	59.5%
Have you ever been trained on how to report ADRs?	21	10.5%	179	89.5%
Do you keep records of ADR?	31	15.5%	169	84.5%

DISCUSSION

The ultimate aim of pharmacovigilance is to ensure patients safety and rational use of medicines. The contribution of India to WHO global individual case safety reports is 3%.[16] In India 64.4% physicians reported ADRs followed by 15 % of pharmacists and 20.4% other health professionals including nurses and physiotherapist while 0.016% non health care professionals reported ADR to Pharmacovigilance programme of India (PvPI) between July 2011 to December 2012.[17,18] Under reporting of ADRs is a universal phenomenon, that exist as an inherent weakness of current voluntary reporting scheme.[2] Along with various other factors knowledge attitude and practice of healthcare professionals play a significant role in spontaneous reporting of ADRs.[19] Many a times, nurses, are the first contact with patients throughout the day, they observe the effects and adverse reactions of medicines, therefore the present study was undertaken to assess the knowledge attitude and practice of nurses on ADR reporting.[20] From the analysis of data generated in our study, it was revealed that knowledge about ADR reporting exist among nurses in addition to right perception towards ADR reporting, which was the encouraging. But it is not reflected when it comes to the act of reporting of ADRs. The practice ADR reporting is discouraging. Our study observed that despite the adequate knowledge (51%) and attitude (80%) among nurses only 11% have ever reported any ADRs indicating the existence of poor ADR reporting. Conducting regular Continuing Medical Education (CME) giving information regarding correct filling of ADR forms and training nurses regarding reporting of ADRs is important to improve reporting of ADRs. These measures could improve the quantum and quality of the reports. Improving ADR reporting, apart from reducing the incidence of adverse drug reactions in clinical practice, will also lead to reduction in health care costs. Thus the overall result of the study indicates the need to extend the level of sensitization for health care workers to improve their ADR reporting.

CONCLUSION

The present study shows that though the level of knowledge about ADR reporting and attitude towards it was adequate, yet nurses showed poor practice. Therefore, there is need to increase the awareness regarding the importance of ADR reporting through CME at regular interval, providing electronic option for reporting, training the nurses on how to report an ADR and also including pharmacovigilance awareness programs for undergraduates. All these steps would further help the nurses to contribute to pharmacovigilance efficacy.

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

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