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A cross sectional questionnaire based study of knowledge, attitude and practices of pharmacovigilance programme among staff nurses in a teaching tertiary care hospital

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ABSTRACT

Background

Since the inception of Pharmacovigilance programme (PVP) in our institution spontaneous reporting of adverse drug reactions (ADRs) has been minimal. Under reporting of ADRs is a known fact due to variable knowledge, attitude and practices (KAP) of healthcare professionals which prompted us to know the KAP of nursing staff in our institution.

Material and Methods

A questionnaire based cross sectional study using a pre designed set of questions. Study included 134 staff nurses from government medical college and associated hospitals Srinagar J&K India.

Results

Our study using KAP questionnaire revealed that in knowledge based questions 59% participant were aware of the health care professional responsible for reporting ADR, 70% were aware of PVP, 11% were how to fill ADR form, 38% were knowing ADRs of which drugs to be reported and 27% were knowing the time period within which a serious ADR needs to be reported. All attitude based questions scored high on attitude based questions. Contrary to expectations from knowledge and attitude of participating staff nurses the practice of ADR reporting was very poor.

Conclusion

There is a need for curriculum development in order to impart teaching and hands on training to improve knowledge and practices of ADR reporting

Keywords: Pharmacovigilance, Adverse drug reaction, KAP

INTRODUCTION

The success of Pharmacovigilance Programme (PVP) at the level of adverse drug reaction (ADR) monitoring centre in a tertiary care hospital is dependent on sustained collaboration commitment between various partners. There is a little prospect of this happening in the absence of sound knowledge of collaborating partners. Most healthcare providers receive minimal, if any, education in pharmacovigilance (PV), either during their undergraduate or postgraduate training. What little training they may receive is usually centered on the knowledge of adverse drug reactions caused by medicines rather than on the practices required to identify, report and manage common ADRs.

Current curriculum in the training programmes of professionals do not cover all the skills needed for pharmacovigilance [1] as well as there is inadequacy of knowledge. [2, 3] Lack of knowledge about how to report ADRs are among the basic reasons of the low rate of ADR reporting. [4, 5] Active participation of reporters form the cornerstone of the success of spontaneous reporting system. Initially physicians were the only professionals required to report an ADR because of their training to exercise the skill of differential diagnosis. However, different kinds of drug related problems are reported by different healthcare professionals. In a tertiary care setup the nursing staff is the first point of contact for the inpatients especially for a drug related event. It is the nurses who are responsible for drug administration, monitoring and would be first to recognize an ADR. In our recent study only 37% of the ADRs were reported by nurses spontaneously from inpatient department. [6]

Before a robust ADR monitoring can be set, one has to be aware of the weaknesses and deficiencies of the present system in order to increase their impact. A study of Knowledge, Attitude and practice (KAP) of the nursing staff needs to be assessed. A KAP survey is a representative study of a specific population to collect information on what is known, believed and done in relation to a particular topic. In most KAP surveys, data are collected by an interviewer using a structured, standardized questionnaire. These data then can be analyzed quantitatively or qualitatively depending on the objectives and design of the study. A KAP survey gathers information about what respondents know about an issue, what they think about it and what they actually do with regard to taking action related to the issue. KAP surveys can identify knowledge gaps, cultural beliefs, or behavioral patterns that may facilitate understanding and action, as well as pose problems or create barriers to resolving an issue.

MATERIAL METHODS

This study was conducted in department of pharmacology government medical college Srinagar J&K India. A total of 134 nurses from the associated hospitals of the medical college were involved in the study. It was a cross sectional questionnaire based study. A questionnaire was designed to assess, their knowledge, attitude and practice of Pharmacovigilance. There were sixteen questions of which ten related to knowledge, three related to attitude, and three related to practice.

RESULTS

Table 1

Table 1			
S Question	% of correct	% of incorrect	
N	response	response	
1 The healthcare professional responsible for reporting ADRs in a hospit	ital		
is/are?			
Doctor	59	41	
Pharmacist			
Nurse			
All of the above			
2 How the name/identity of the patient is submitted in suspected ADR			
reporting form?			

	Correct full name		
	Only Surname	11	89
	Only initials		
2	Serial Number		
3	Which kind of drugs is/are included for reporting suspected ADRs?		
	Allopathic drugs		
	Homeopathic drugs	38	62
	Traditional medicine formulations		
	All drugs		
4	Which one of the following information about suspected drug /drugs is		
	NOT submitted in suspected ADR reporting form?		
	Name		
	Manufacturer	41	59
	Batch No./Lot No.		
	Dispenser/Pharmacist		
5	The international centre for adverse drug reaction monitoring is located		
	in?	10.5	89.5
	United States Of America		
	Canada		
	Sweden		
	India		
6	A serious adverse event in India should be reported to regulatory body		
	within?		
	One day	27	73
	Seven Calendar days		
	Fourteen calendar days		
	Fifteen calendar days		
7	It is important to report ADRs leading to?		
	Hospitalization		
	Congenital abnormality	51.5	48.5
	Patient death		
	All of above		
8	The definition of Pharmacovigilance includes?		
	Detection of ADRs		
	Assesment of ADR	70	30
	Understanding and prevention of ADR		
	All of the above		

9	Match the ADR reporting system to the respective countries (Write the	
	number in appropriate boxes)	

Yellow card	India	14	86
Green card	Australia		

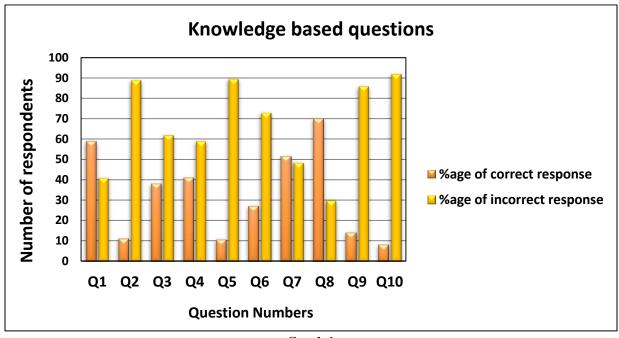
ADR reporting form United Kingdom Blue card Scotland

11 The software used to forward the ADR report to NCC is?

VigiAccess Vigibase

Vigibase 8 92

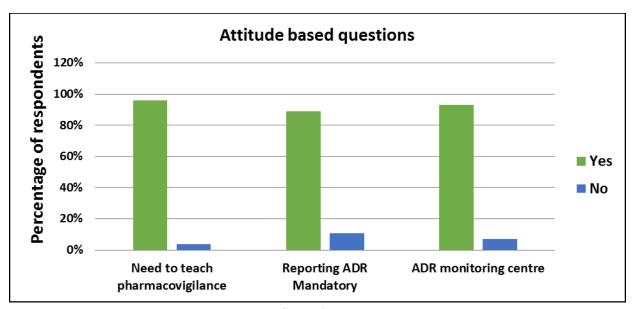
VigiFlow VigiLyze



Graph 1

Table 2

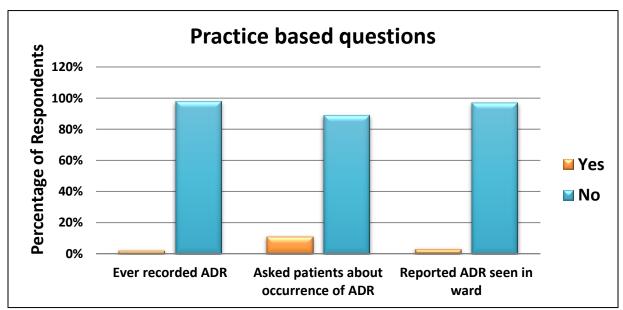
Sr.No	Question	Yes	No
1	Do you think there is need to teach Pharmacovigilance to health care professionals?	96%	4%
2	Do you think reporting of Adverse drug reaction should be made mandatory?	89%	11%
3	Do you think there is a need for ADR monitoring Centre in every hospital?	93%	7%



Graph 2.

Table 3.

Sr.No	Question	Yes	No
1	Have you ever recorded ADR in ADR reporting form (IPC) attached in IPD case sheet?	2%	98%
2	Do you ask patients about occurrence of any ADR?	11%	89%
3	Do you report ADR seen in ward?	3%	97%



Graph 3.

DISCUSSION

There was a general universal agreement among staff nurses on attitude based questions (Table 2). 96% agreed to requirement for teaching PV, 89% believed ADRs should be mandatorily reported and 93% wanted an ADR monitoring center be established in every hospital reflecting the belief in the seriousness of ADRs, [7]

Regarding knowledge about PV only a few students were able to correctly answer questions relating to ADR reporting form (Table 1).59 % of respondents correctly knew the healthcare professional responsible for reporting, 11% correctly knew how to fill the patient details, 41 % correctly knew the drug information to be reported and 27% knew the time period within which to report a serious ADR. This shows that the majority of the nursing staff poorly understood the concept of PV thereby reflecting a need for educational programmes. [3, 7, 8]

As expected from knowledge based questions the nurses fared more poorly on practice based questions (Table 3). Only 11% had asked patients about ADR occurrence and dismal 2% and 3% of the nurses has recorded an ADR and reported and ADR

respectively, reflecting poor reporting by nurses. [6] Descriptive analysis of the data indicates the positive attitude of the nursing staff towards learning as well as establishing and reporting of the ADRs indicating they were well aware and knowledgeable about PV. It would be safe to imply that previous sensitization programmes were conducted in the right direction. Despite the positive attitude displayed, the nursing staff did not do well on the knowledge based as well as practice based questions reflecting improper, inadequate or even deficiency in the training process reflecting a need for hands on workshop for reporting and identifying the adverse drug reactions. [9]

CONCLUSION

This study concludes that even though the previous sensitization programmes conducted in Government Medical College Srinagar have helped in the attitude of the nursing staff towards the importance and implementing of PVP. There is a need for curriculum development in order to impart teaching and hands on training to improve knowledge and practices of ADR reporting. These efforts would be in the right direction for augmenting actual reporting of ADRs by the staff nurses.

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