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Healthcare Professionals Knowledge Attitude and Practices towards Pharmacovigilance and Adverse Drug Reactions (ADRS) in India

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Abstract: ***The current prospective observational study of six month duration was designed to evaluate the Knowledge Attitude and Practice among doctors, nurses and pharmacists working towards ADRs and pharmacovigilance. A questionnaire which was suitable for assessing the basic Knowledge, Attitude and the Practice (KAP) of pharmacovigilance was designed and distributed among healthcare professionals in a tertiary care teaching hospital of south India. Among the total 220 healthcare professionals working in the hospital only 75% (n=165) provided their responses. Of these responses 45.45% (n= 100) were analyzed and the rest were not included because of incomplete information. The study showed that the knowledge of Healthcare professionals in general was less about the National Pharmacovigilance Programme and its members, International centre and the WHO online database of monitoring and reporting ADRs. The results of the study strongly suggest that underreporting of ADRs is associated with gaps in the knowledge and attitudes.***

Keywords: Adverse drug reactions, healthcare professionals, K A P, pharmacovigilance, rational drug use.

1. Introduction

The safe use of medicine is an important aspect that affects each and every member of society. Nowadays, reducing the incidence and consequences associated with ADRs is a crucial challenge in drug use. Despite the importance of medicine in the prevention and curing of diseases, its usage is usually associated with undesirable adverse reactions and sometimes fatal reactions [5].ADRs are a major problem in drug therapy and lead to increased morbidity and mortality, unnecessary hospital admissions and drug withdrawal. Moreover, most of these studies have a short period of follow up which eliminates the capability to detect the ADRs associated with the long term use of drugs [7] [10].It has been reported that there is an absence of a total figure of the incidence as well as the economic burden of ADRs. This absence is attributed to several factors including the difference in drug policy between the communities, methods used to detect ADR, and the terminology used to describe the adverse event. The global interest in the monitoring of drug safety showed a remarkable increase in the last four decades especially after the thalidomide disaster in the sixties [4]. The thalidomide disasteropened up the issue of drug safety for the public and healthcare professionals alike and brought about an awareness of the importance of the systemic surveillance of drugs for Adverse Drug Reactions (ADRs). [6]

Adverse Drug Reactions (ADRs) are defined as unintended consequences suspected to be related to the use of medicinal products, including herbal medicines (WHO, 1972). ADRs are often associated with high mortality and morbidity rates. They were believed to be the 4th to the 6th largest causes of death in the United States and were responsible for 0.3% to more than 10 % hospital admission in some countries and up to 20% of healthcare budget spent on drug complication and ADRs consequences [8].

Adverse drug reactions have a major impact on the public health system and impose unnecessary and unreasonable economic burdens on the society although most of these ADRs are preventable. The tragedy of the thalidomide disaster in 1960s has led many countries to set their observational systems for early detection of potential adverse drug reactions associated with pharmacotherapy. These systems became known as the pharmacovigilance systems.

Pharmacovigilance has been defined by the World Health Organization (WHO) as “the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug related problems” (WHO, 2002a). Pharmacovigilance plays a crucial role in the study of medication safety [9] and now it is regarded as the quality control system of the society.

Spontaneous reporting is considered the main mechanism in the pharmacovigilance system by which the ADRs are identified after the drug is released onto the market and it is the foundation of the WHO data base [6].

Unfortunately, the spontaneous ADR reporting system is affected by a number of weaknesses, the most noticeable of these being the phenomena of ADRs underreporting from healthcare professionals. The reasons behind underreporting were not well documented in the developing countries although it had been proposed early in the developed countries, there were numerous obstacles preventing health care professionals from ADRs reporting as noted in the literature [2] [1] [3]. Physicians, dentists, pharmacists and

recently patients are encouraged to report suspected ADRs to Pharmacovigilance Programme India (PvPI). The Indian Spontaneous Reporting System (SRS) like other SRSs around the world suffers from ADR under-reporting from healthcare providers.

One of the pivotal objectives of the spontaneous reporting of ADRs is to generate signals about new possible ADRs. SRS basically relies on the voluntary reporting of suspected ADRs from health-care professionals and in some countries from the patients themselves. Thus the aim of the present study was to gain insight into the knowledge, attitude and perception and to explore the reasons behind under-reporting of ADRs among of Healthcare providers / professionals in India.

2. Methodology

Study site: The study entitled "Healthcare professionals knowledge, attitude and practice towards Pharmacovigilance and Adverse Drug Reactions in India" was carried out in a 1200 bedded tertiary care hospital located at Anantapur, Andhra Pradesh.

Study Design: A Prospective Observational study was carried out to evaluate the KAP among (Healthcare Professionals) doctors, nurses and pharmacists working towards ADRs and pharmacovigilance.

Study Duration:06 Months (April-September 2014)

Study Population & Sampling: Total of 100 participants as Healthcare professionals (10 pharmacists, 60 nurses and 30 doctors).

Inclusion and exclusion criteria: All the healthcare professionals working in the hospital during the study period were included. The healthcare professionals who were not willing to participate in the study and the ones who were on leave were excluded.

Design of KAP Questionnaire: The questionnaire was a 22 item inventory titled Standard KAP Questionnaire, the items were generated from the literature and adaptation from previous studies and a two-step validation process was followed for its accuracy and uniqueness. Initially, the questionnaire comprised of 30 inventories, modified to 22 in final by 02 step validation process.

Validation of Questionnaire: In step 01, Questionnaire Validation Three faculties with expertise knowledge and practice in drug use research and ADR reporting studies were asked to evaluate the clarity, relevance and conciseness of items included in the questionnaire (limitations on questionnaire was a feedback which was rectified by eliminating 08 questions which was felt more complex for the participants). The observations and comments of the lecturers were taken in to the account. In step 02, Questionnaire validation to test the validity and reliability of the questionnaire, the survey form was pilot tested by administering it to sample of 15 Healthcare professionals who did not participate in the study. The overall Cronbach's alpha value calculated was 0.72, which required no further modifications in questionnaire.

The final KAP questionnaire consisted of 22 questions out of which: Section A: Includes 12 questions related to basic knowledge and information about pharmacovigilance. Section B: Includes 05 questions related to student's attitude.Section C: Includes 05 questions related to perception regarding identification of ADR and reporting nature.

Method of obtaining the knowledge, attitude and practice responses: Different systems were applied for obtaining reply from different healthcare professionals. Physicians were contacted directly in their department and the questionnaires were distributed. The responses from the nurses were collected during an educational programorganized for the nurses by the In-charge nursing department. The responses from pharmacists were collected during a Continuing Pharmacy Education (CPE) program conducted for them by the Department of Hospital Pharmacy. Every healthcare professional was given 45 minutes to fill up the questionnaire. Any clarification needed in understanding the questionnaire was provided.

3. Results & Discussion

Among the total 220 healthcare professionals working in the hospital only 75% (n=165) provided their responses. Of these responses 45.45% (n= 100) were analyzed and the rest 29.55% (n=65) were not included in the analysis because of incomplete information. Demographic details of the participants involved in the study was categorized based on gender distribution, age distribution, professional status and educational qualification the results of which were thoroughly analyzed and reported in Table. 1.

Table 1: Demographic details of the Healthcare professionals

S.no	Demographic details	No. of Participants		
01	Gender Distribution			
	Male	34		
	Female	66		
02	Age Distribution (Years)		Male	Female
	Up to 20	04	02	02
	21 – 30	44	12	32
	31 – 40	28	09	19
	41 – 50	15	05	10
	51 – 60	05	02	03
	> 60	04	04	-
03	Professional Status		Male	Female
	Doctors	30	21	09
	Nurses	60	05	55
	Pharmacists	10	08	02
04	Educational Qualification		Male	Female
	MBBS	14	10	04
	MBBS with specialty	16	11	05
	BSc in Nursing	43	05	38
	Diploma in Nursing	17	-	17
	B. Pharmacy	04	03	01
	D. Pharmacy	06	05	01

On correlating the gender distribution with age distribution, nearly 44 participants' falls within the age group of 21 – 30 years, out of which 32 are female and 12 are male. Positive responses to the self-administered KAP Questionnaire are

reported in Table. 2. To the best of our knowledge, this was the first study in the resource limited setting of draught prone region of Andhra Pradesh, South India that evaluated the KAP of healthcare professionals regarding ADRs and pharmacovigilance. Overall, the KAP scores of the professionals were low as the participation was lower and ignorance was one of the factors among HCP's. Demographic detail reported that participants were maximum female in comparison to male and also the ratio of healthcare professional were female (Nurses) in the study.

Table 2: Positive Response of Self-Administered K A P Questionnaire

S. no	Knowledge based Questions	Correct Answer		Doctors	Nurses	Pharmacists
01	Pharmacovigilance is the study relates to	Detection, assessment, understanding & prevention of adverse effects		24 (80%)	25 (41.67%)	04 (40%)
02	Which methods is commonly employed by the pharmaceutical companies to monitor ADRs of new drugs launched in the market	Post marketing surveillance		15 (50%)	20 (33.33%)	03 (30%)
03	Pharmacovigilance includes	DRP's, Herbal products, Medical devices & Vaccines.		20 (66.67%)	14 (23.33%)	04 (40%)
04	Are you aware of existence of NPC in India	YES		21 (70%)	21 (35%)	05 (50%)
05	If yes, then where is it located	CDSCO		16 (53.33%)	10 (16.67%)	02 (20%)
06	NPP in India was officially inaugurated in year	2004, New Delhi		10 (33.30%)	09 (15%)	02 (20%)
07	NPP India, comprises of how many members	10		08 (26.67%)	05 (8.33%)	02 (20%)
08	The international center for adverse drug reaction monitoring is located	Sweden		08 (26.67%)	05 (8.33%)	02 (20%)
09	In India, Pharmacovigilance reporting should be sent to regulatory body within	07 Days		05 (16.67%)	06 (10%)	02 (20%)
10	The Chairman of PvPI in India	DCGI		10 (33.30%)	08 (13.33%)	02 (20%)
11	WHO online databases for reporting ADR's	Vigibase		08 (26.67%)	10 (16.67%)	01 (10%)
12	The ADR reporting system followed in India	ADR reporting form		08 (26.67%)	12 (20%)	02 (20%)
13	Do you think reporting ADR's is necessary?	√		30 (100%)	30 (50%)	04 (40%)
14	Do you think reporting ADR's to be made mandatory?		X	18 (60%)	25 (41.67%)	04 (40%)
15	Do you think reporting ADR's is your professional obligation?		X	25 (83.33)	30 (50%)	04 (40%)
16	Do you think ADR form is Complex to fill?		X	20 (66.67%)	30 (50%)	08 (80%)
17	Do you think ADR reporting should hide the identity of HCP's?		X	15 (50%)	10 (16.67%)	08 (80%)
18	Have you ever came across with an ADR and reported it?	√		10 (33.30%)	05 (8.33%)	02 (20%)
19	Have you ever read any article regarding Adverse Drug Reactions?	√		18 (60%)	08 (13.33%)	02 (20%)
20	Have you ever been trained on how to report ADR's?	√		05 (16.67%)	05 (8.33%)	02 (20%)
21	Have you came across any patient experiencing ADRs?	√		08 (26.67%)	10 (16.67%)	01 (10%)
22	Are you following any approaches in preventing ADRs / prevented ADRs	√		05 (16.67%)	10 (16.67%)	01 (10%)

The most important outcome of pharmacovigilance is the prevention of patients being affected by unnecessary negative consequences of pharmacotherapy for which evaluation of KAP on pharmacovigilance and ADRs reporting is necessary. Pharmacovigilance programs have played a major role in detection of ADRs and banning of several drugs from the market. However, under-reporting of ADRs is one of the major problems associated with pharmacovigilance programs. The present study showed that doctors and pharmacists had a slightly higher score than the nurses. Among doctors and pharmacists, doctors had relatively higher scores.

The study showed that the knowledge of Healthcare professionals in general was less about the National Pharmacovigilance Programme and its members, NPP inauguration and duration of reporting ADRs, international centre and the WHO online database of monitoring and reporting ADRs. In specific, Nurses were having poor knowledge on pharmacovigilance and ADRs reporting. A

majority of the healthcare professionals opined that the ADR reporting should be compulsory and some felt that filling of ADR form is complex. To improve the spontaneity in the reporting rates, the doctors suggested the organization of training programmes (regular seminars / workshops) and an uncomplicated reporting system with a quick feedback regarding their specific reports and educational intervention could increase the physicians' awareness on ADRs and that the physicians would be able to incorporate the knowledge that they gained from their training into their everyday clinical practice.

4. Conclusion

The results of the study strongly suggest that underreporting of ADRs is associated with gaps in the knowledge and attitudes. In our study, the healthcare professionals at the tertiary care teaching hospital had a relatively better knowledge but limited attitude and practices towards ADRs and pharmacovigilance. The majority of the healthcare professionals felt ADR monitoring to be important, but only a few had ever reported an ADR to the pharma covigilance center. The findings of the study suggest that there is a need for continuous educational initiatives for the doctors, nurses and the pharmacists. An educational intervention can increase awareness of pharmacovigilance among the participants (healthcare professionals) and incorporate this gained knowledge of pharmacovigilance for opting career and routine clinical practice.

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Author Profile

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