

Assessment of Knowledge, Awareness and Practices among Healthcare Professionals about Pharmacovigilance and Adverse Drug Reactions Reporting In King George Hospital, Visakhapatnam

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Abstract

Background: Adverse drug reactions are scantily reported by healthcare professionals worldwide and in particular in developing countries. Therefore the aim of the current study was to assess the knowledge, awareness and practices of health care professionals about pharmacovigilance and adverse drug reaction reporting of King George Hospital, Visakhapatnam. **Methods:** A cross-sectional study using a validated questionnaire was designed to assess the awareness of ADRs, knowledge of Pharmacovigilance system and practices of Pharmacovigilance system. The questionnaire was distributed to randomly selected healthcare professionals (n= 350) such as doctors, pharmacists and nurses. Completed questionnaires were collected and data were analyzed. Data are expressed in number as well as percentage. **Results:** Of the 350 questionnaires circulated, a total of 250 healthcare professionals responded. HealthCare professional categories involved in the study were 100 doctors, 100 nurses and 50 pharmacists. And the overall percent of the respondents who accepted to enroll in the study was about 75.4%. **Conclusion:** In the present study, we observed that healthcare professionals have inadequate knowledge about the concept and the process of Pharmacovigilance and spontaneous ADRs reporting system. However, they had positive approach towards Pharmacovigilance but little experience with reporting. Our study has demonstrated a lack of knowledge and awareness of Pharmacovigilance and ADRs reporting among healthcare professionals in the hospital.

Key words: Pharmacovigilance, Adverse drug reactions (ADR), Questionnaire, awareness and practices, health care professionals.

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I. Introduction

Medicine safety monitoring is an essential element in healthcare system. Therefore the Ministry of Health and Family Welfare (MoHFW), Government of India started a nationwide pharmacovigilance program in India (PvPI) in the year 2010 to monitor the Adverse Drug Reactions (ADRs) with the mission to ensure that the benefits of medicine outweighs the risks and thus safeguard the health of the population^[1,2,3,4,5,6]. Indian Pharmacopoeia Commission (IPC) under the MoHFW, functioning as National Coordinating Center (NCC) for PvPI since April 2011. To monitor the ADRs, ADR Monitoring Centers (AMC) has been established across the country under PvPI. Currently one hundred and fifty AMCs are functioning to monitor ADRs in their hospital and periphery as well. As India is participating in the WHO international drug monitoring program, NCC-PVPI is responsible in committing Individual Case Safety Reports (ICSRs) to the Uppsala Monitoring Center (UMC), Sweden. Over 4 years, NCC played a significant role in creating awareness among health care professionals. As a net result, reporting of ADRs led to more than hundred and twenty five thousand number of individual case safety reports till April 2015. Currently, Indian contribution to WHO global individual case safety reports database is 2%.^[4]

Adverse drug reactions (ADRs) continue to present as one of the greatest hindrances towards the attainment of the gold standard of quality and safety in healthcare delivery worldwide. It has been shown that ADRs occur almost daily in small and large hospitals and outpatient departments with overall incidence of 15.1%. Much of these ADRs (50%) were preventable. Thus there is a serious need to develop effective strategy for detecting and reporting ADRs within the framework of a functional and efficient pharmacovigilance system.^[7] In 1989, under the Drug Controller General of India, ADR monitoring system with 6 centers in Delhi, Mumbai, Chandigarh, Pondicherry and Calcutta were started with spontaneous reporting, Intensive hospital monitoring and focused reporting^[7]. At around the same time Indian council of Medical Research Delhi initiated an intensive hospital monitoring program, focusing on smaller /district level hospitals Following the first international conference on ADR monitoring and prevention in Mumbai, with the initiative of former DCGI, India joined the WHO UMC program in 1998, with national center in Delhi AIIMS and WHO special center in GSMC KEM hospital, Mumbai^[8].

India has more than 5,00,000 qualified Doctors and 15,000 hospitals having bed strength of 6, 24,000. It is the fourth largest producer of pharmaceutical products in the world. It is emerging as an important clinical trials center in the world^[9]. Many new drugs are being introduced in our country. Therefore, there is a need for a strong pharmacovigilance system in the country to protect the population from the potential harm that may be caused by some of these new drugs^[4,10]. Although, India is participating in the program, its contribution to UMC database is very little^[2]. The PV Program of India was launched with a broad objective in patient safety for more than one billion people of India. Pharmacovigilance is a part of patient care aimed at getting the best result of treatment with medicines and other related products. Adverse drug reactions are inadequately reported by healthcare professionals worldwide and in particular in developing countries. Therefore the aim of the current study was to assess the knowledge, awareness and practices of health care professionals about pharmacovigilance and Adverse Drug reaction (ADR) reporting.

II. Aims And Objectives

To assess knowledge, awareness and practices of health care professionals about adverse drug reporting and pharmacovigilance at King George Hospital, Visakhapatnam.

III. Methodology

Study design

This was a randomized, cross-sectional, observational, questionnaire based study conducted in King George Hospital, Visakhapatnam. The study involved health care professionals including doctors, nurses and pharmacists. The study was conducted for a period of three months from May 2017 to July 2017.

Sampling Method

This study used a random sampling method. All the health care professional subjects to the inclusion and exclusion criteria are enrolled in the study. A total of 250 health care professionals were included in the study.

Design of The Questionnaire

A questionnaire was developed to obtain information on the knowledge and awareness about pharmacovigilance and adverse drug reactions reporting. Content validity was assessed by distributing the questionnaire to 10 health care professionals recruited to complete the validation process. The final form of the questionnaire consisted of healthcare professionals' demographic data, and a total of 10 questions that can assess participants knowledge, awareness and practices towards pharmacovigilance and ADRs reporting.

Data Collection Procedure

The healthcare professionals (doctors, pharmacists and nurses) were provided with a copy of the questionnaire after explanation of the objectives of the study. During the survey, the purpose of the study was explained to participants, both verbally and by covering letter which was attached with consent form and ethical clearance. Health care professionals who agreed to participate in the study were requested to complete the questionnaire and hand it back immediately. Participants were told that all information provided was completely confidential and the results would be presented anonymously. Those who were very busy at the moment, questionnaires were left to them and collected after a maximum of two working days. The returned questionnaires were checked for completeness, consistency and clarity before collected.

Ethical Considerations

The study received ethical clearance from institutional ethical committee Permission to do the study was granted by the Heads of the departments of King George hospital after receiving the request letter to conduct the study.

Data Treatment And Analysis

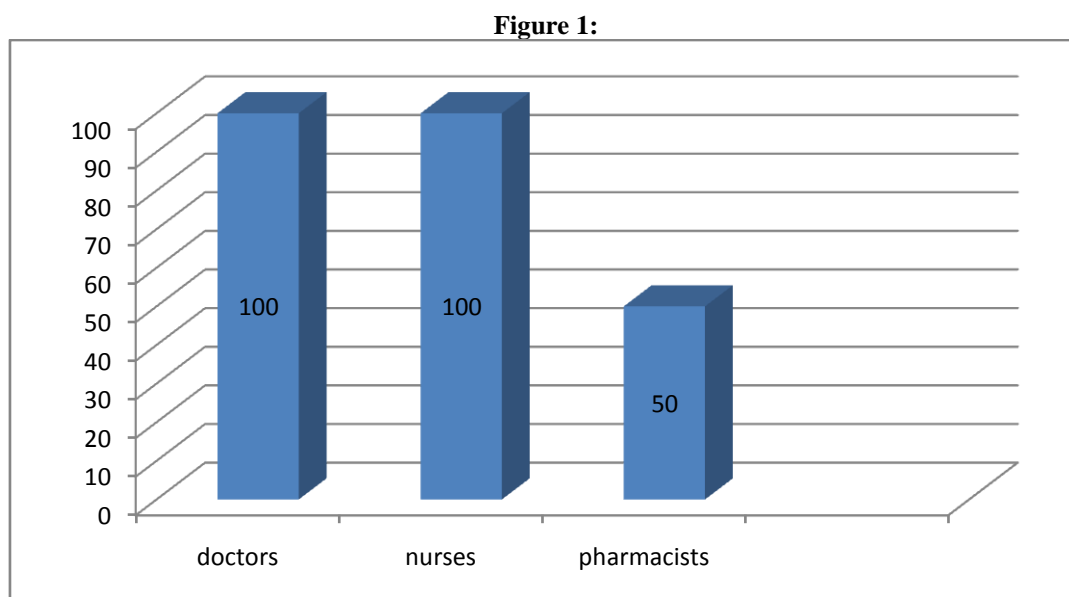
All questionnaires were identified by instituting identification number and the questions were coded. The filled questionnaires were analyzed as per the objectives of the study. The various parameters such as gender, age, professional differentiations, specializations based on years of experience and the 'Knowledge, awareness practices' questionnaire were analyzed. The data obtained were entered in Microsoft excel spreadsheet and were analyzed. Results are expressed in absolute number and percentages. The data were analyzed, $P < 0.05$ is considered significant.

IV. Results

A total of 350 questionnaires were circulated to healthcare professionals. 250 healthcare professionals were assessed using knowledge, awareness and practices questionnaire prepared by ourselves out of these 100 were doctors, 100 were nurses and 50 were pharmacists. The statistical significance was taken at 95% confidence interval ($p < 0.05$)

Demographics

Among 250 persons, 46.6% ($n=115$) were females and 53.4% ($n=135$) were males. In this study male respondents were more compared to female respondents. Out of them 100 were doctors (40%), 100 were nurses (40%) and 50 were pharmacists (20%). (Figure: 1)

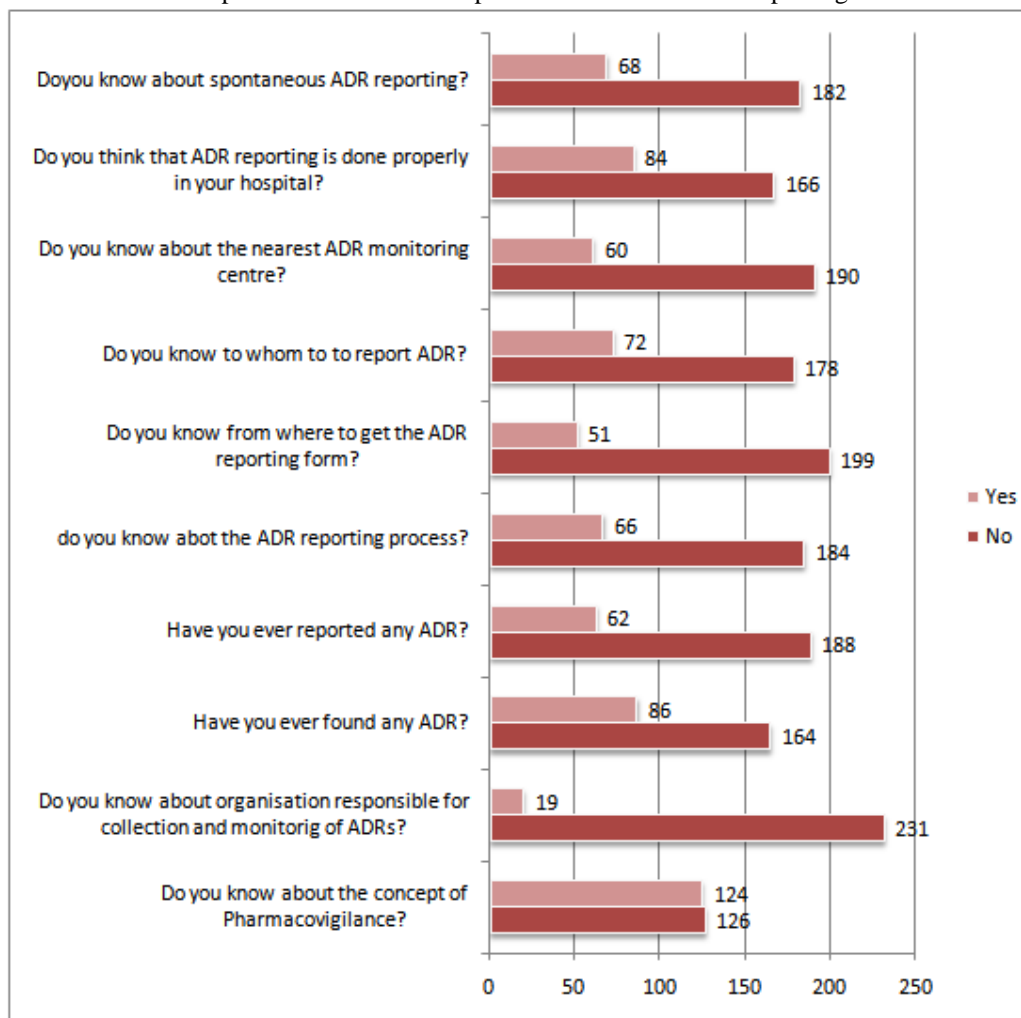


Awareness And Practices Of Healthcare Professionals about Pharmacovigilance and ADR Reporting:

The result of the survey is as follows:

Among the 250 most of them completed the questionnaire. The result is not so encouraging for the society as even in the present days the awareness of Pharmacovigilance and ADR reporting is very low, even among the professionals including doctors, nurses and pharmacists (Figure:2).

Figure 2: Awareness and practices of health care professionals about ADR reporting and Pharmacovigilance



Out of conducting the survey among 250 professionals its result found that only 124 professionals are aware of Pharmacovigilance, which is about only 49.6% of the total surveyed. 126 professionals were unaware of Pharmacovigilance (50.4%).

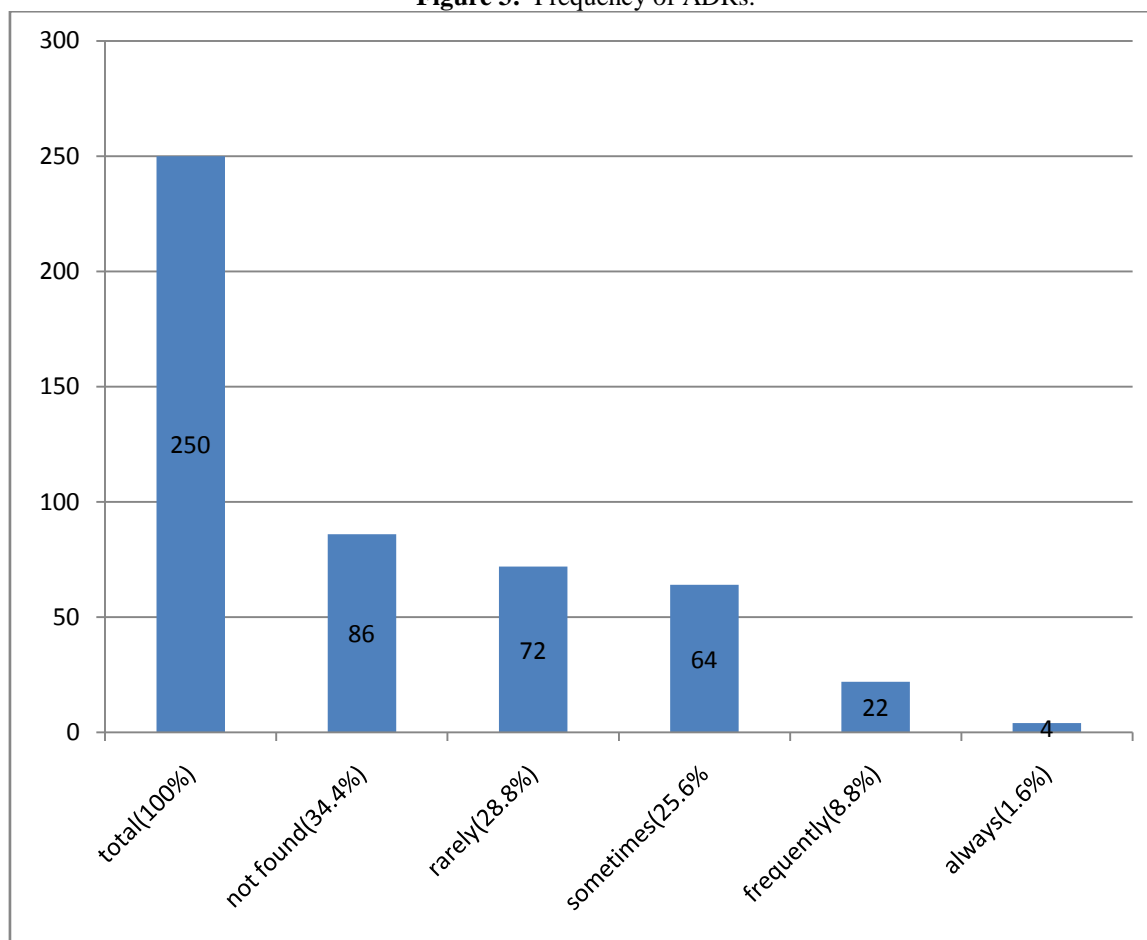
WHO defines Pharmacovigilance as “the science which deals with detection, assessment, understanding and prevention of ADR”, however, in this study 124 (49.6%) of healthcare professionals are aware about the concept of pharmacovigilance but only 52(41.9%) of the health care professionals defined it correctly out of the 124(49.6%) (Table 1).

Table 1: Distribution of Respondents based on definition of Pharmacovigilance.

definition	N%
Detection, assessment, understanding and prevention of ADR	52(41.9)
Prevention of side effects	26(21)
Monitoring of ADR in hospital	27(22)
Do not know the definition	19(15)
total	124(100)

Out of the 250 surveyed professionals the frequency of finding ADR is as follows:- 86 Professionals have not found any ADR in their career (34.4%), 72 found it rarely (28.8%), 64 professionals found it sometimes (25.6%), 22 people found it frequently (8.8%) and 4 people found it always (1.6%) (Figure 3).

Figure 3: Frequency of ADRs.

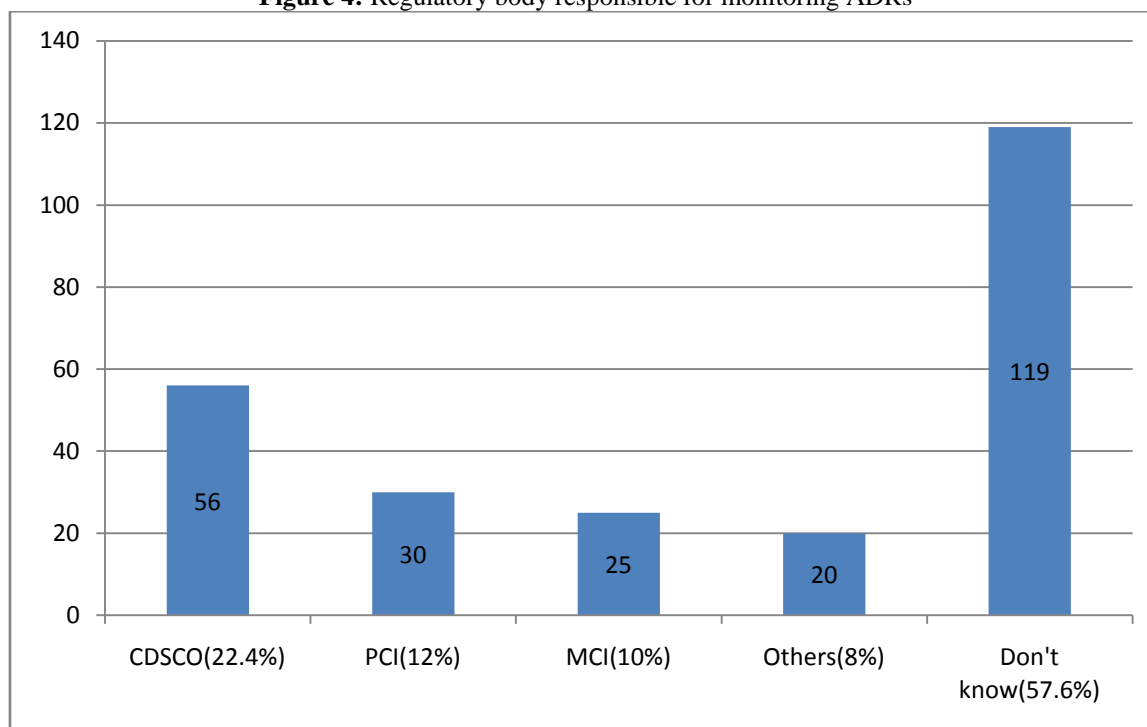


Out of 250 surveyed professionals it is found that 62 are aware of reporting an ADR (24.8%) and remaining 188 professionals don't even know to report an ADR. i.e.75.2 % don't know where to report ADR. Out of 250 professionals it is found that only 68 are familiar with ADR reporting (27.2%) and 182 are not familiar with ADR reporting (72.8%). The source of ADR form is known for only 51 people (20.4%) and unknown for 199 people(79.6%) out of 250 professionals included in the survey. The knowledge about ADR reporting authority or to whom to report ADR is unknown in most professionals as only 72 were known (28.8%) and remaining 178 do not know (71.2%).

Out of the 250 professionals surveyed, only 60 know (24%) which is the nearest ADR reporting center and remaining 190 were not familiar with the nearest ADR reporting center (76%). Out of 250 surveyed professionals it is found that 231 (92.4%) of the healthcare professionals are unaware of the organization responsible for the collection and monitoring of ADR.

Also 56(22.4) of the professionals said that the Central Drugs Standard Control Organization (CDSCO) is responsible, 30(12%) said that the pharmacy council of India is responsible and remaining 25 (10%) said that the medical council of India is responsible and 20(8%) said that some other organizations are responsible for monitoring of ADR (Figure:4).

Figure 4: Regulatory body responsible for monitoring ADRs

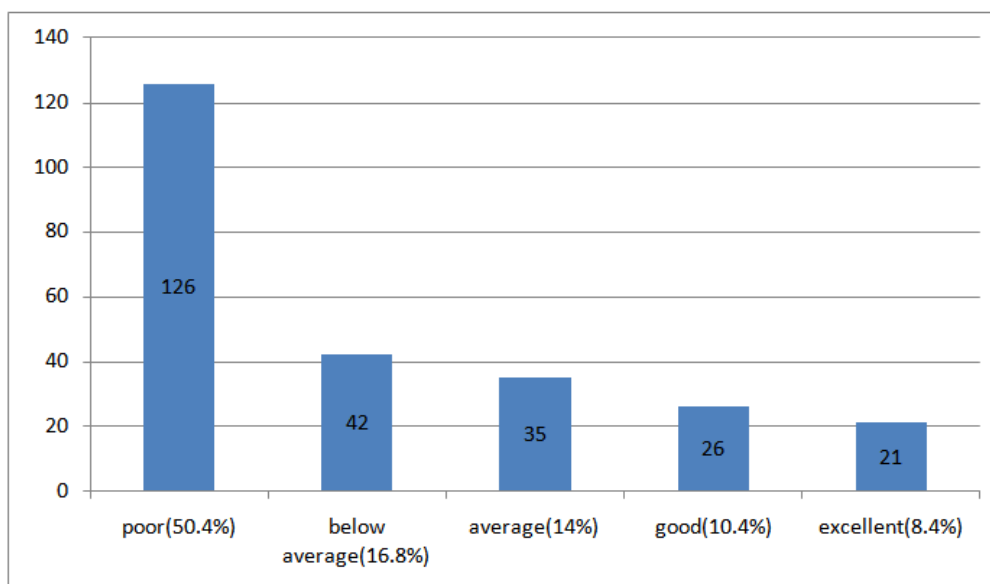


Out of the 250 professionals surveyed 84 people (33.6%) think that the working of ADR reporting system in their area is working proper and remaining 166(66.4%) were thinking that the ADR reporting is not working smoothly or they are unaware of ADR reporting process. Out of the 250 surveyed professionals only 68 people (27.2%) out of them are heard or known about the spontaneous ADR reporting. The remaining 182 people (72.8%) i.e. The majority of professionals don't know about the spontaneous ADR reporting and all.

Score of Awareness And Practices of Healthcare Professionals About Pharmacovigilance and ADR Reporting:

Score is given as excellent for 8 or above 8 points, good for 6 and 7, average for 4 and 5, below average for 2 and 3 and poor for 0 and 1. Surprisingly, the result was appalling, it is found that out of 250 people, 126 of them are having score 0 or 1(50.4%), 42 have scored 2-3(16.8%), 35 score i.e.4 or 5 (14%), 26 professional have good score i.e.6 or 7 (10.4%), and remaining 21 professionals scored excellent score i.e. 8 or above (8.4%) (Figure: 5).

Figure 5: Score of awareness and practices of health care professionals



Awareness And Practices Of Healthcare Professionals Towards Pharmacovigilance And ADR Reporting

By gender, age, category, profession, experience, awareness and practices of healthcare professionals about pharmacovigilance and Adverse Drug Reaction reporting had been assessed during the survey and found it as $(1.6 \pm .32)$ with 95% accuracy (i.e. < 0.05). Pharmacists and other pharmaceutical professionals (i.e. pharmaceutical technicians and pharmaceutical assistants) were found to have more knowledge on ADRs reporting than nurses (P value < 0.05). Also indicates the influence of experience to ADRs reporting knowledge. Respondents who had more than 10 years experience were more knowledgeable (18%) as compared to those with 5 to 10 years and below 5 years experience (P value < 0.05).

Table 2: Level of awareness and practices by profession and experience

Category	Class	Awareness and practices of health care professionals about pharmacovigilance		Total	P value
		Good score>6	Poor score<6		
Age	<30	4(1.6%)	46(18.4%)	50	<0.05
	30-50	19(7.6%)	156(62.4%)	175	<0.05
	>50	7(2.8%)	18(7.2%)	25	<0.05
Profession	Pharmacists Doctors	30(12%)	20(8%)	50	<0.05
	Nurses	76(30.4%)	24(9.6%)	100	<0.05
		44(17.6%)	56(22.4%)	100	<0.05
Experience in years	<5	8(3.2%)	43(17.2%)	51	<0.05
	5-10	10(4%)	65(26%)	75	<0.05
	>10	45(18%)	79(31.6%)	124	<0.05

V. Discussion

Pharmacovigilance (PV) programs have played a major role in detection of ADRs and withdrawing 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. We performed a cross sectional questionnaire survey to assess knowledge, awareness and practices of health care professionals about pharmacovigilance and ADR reporting in Visakhapatnam district.

Our study aimed to evaluate the knowledge, awareness and practices of health care professionals about pharmacovigilance and ADR reporting and a total of 350 questionnaire were circulated to healthcare professionals. 250 healthcare professionals participated to fill the questionnaire form. And the overall percent of the respondents who accepted to enroll in the study was about 75.4%.

Out of the 250 surveyed professionals the frequency of finding ADR is as follows:-Out of the 250 respondents 86 Professionals have not found any ADR in their career (34.4%) or they are unaware about it, 72 found it rarely (28.8%), 64 professionals found it sometimes (25.6%), 22 people found it frequently (8.8%) and 4 people found it always (1.6%).

Out of the total respondents 135 (54%) were male and 115 (36%) were female. Out of the total participants 49.6% were aware about pharmacovigilance and 50.4% were unaware about pharmacovigilance

Out of the total participants, 20.8 % had fair knowledge and 79.2% had poor knowledge about ADR. Out of 250 professionals it is found that only 66 know how to report ADR (26.4%) and 184 are not familiar with

ADR reporting (73.61%). The source of ADR form is known for only 51 people (20.4%) and unknown for 199 people (79.6%) out of 250 professionals included in the survey. Out of the 250 professionals surveyed, only 60 know (24%) which is the nearest ADR reporting center and remaining 190 not familiar with the nearest ADR reporting center (76%). Out of the 250 professionals surveyed 84 people (33.6%) think ADR reporting is done promptly and remaining 166 (66.45%) were thinking that the ADR reporting is not going smoothly or they are unaware of reporting ADR. Out of the 250 surveyed professionals only 68 people (27.2%) out of them have heard or know about the spontaneous ADR reporting, the remaining 182 people (72.80%) do not know it. That means the majority of professionals don't know about the spontaneous ADR reporting¹¹.

Hence from the results it is clear that out of the 250 health care professionals 124 (49.6%) professionals are knowledgeable and aware about pharmacovigilance. In the conducted survey, a total of 100 were doctors and out of them 76 know about pharmacovigilance and remaining 24 are unaware of that. Out of 100 nurses surveyed 44 are aware of pharmacovigilance and remaining 56 are unaware of that. From 50 pharmacists surveyed 30 are aware of pharmacovigilance and remaining 20 are unaware of pharmacovigilance.

The awareness program should focus on the filling method of the ADRs form and the details of the reporting procedure. Underreporting of ADRs is a common event in spontaneous post-marketing surveillance programs. Underreporting may delay signal detection and cause underestimation of the size of a problem^{12,13}. To correct underreporting scenario is difficult, because the extent is unknown and variable. In various studies obstacles to improve monitoring and reporting of ADRs have been analyzed and can be summarized as: fear of personal and organizational liability, lack of resources for surveillance and reporting, labor intensive, complex, and time-consuming reporting processes, uncertainty in causal relationship between drug and adverse effect, minimal feedback provided to reporters, no incentives, rewards, or motivation to report, lack of knowledge and confidence to distinguish between significant ADRs and minor ones, surveillance and reporting functions without guidance. Several methods can be suggested to improve ADR reporting^{14,15}. These include creating awareness about ADR monitoring among health care professionals and consumers, through educational interventions [e.g. seminars, CMEs], make ADR reporting forms easily available and simplifying the process of ADR reporting. Feedback from ADR monitoring centers about the causality and severity of ADRs reported by physicians would also encourage them to continue reporting^{18,19}. The main reasons for underreporting of ADRs are lack of time, poor knowledge on the reporting mechanisms, and unfamiliarity with the existence of national pharmacovigilance system, belief that the ADR was already well known, and doubt about the importance of the ADRs reporting and fear to report ADRs¹⁹.

VI. Conclusion

This is the study to assess the knowledge, awareness and practices of medical personnel towards ADRs reporting and pharmacovigilance. Although the pharmacovigilance system has been present for many years now, this study disclosed that there is a gross deficit of reporting adverse drug reactions by the medical staff. The study reports indicate that there is a lack of knowledge towards ADRs reporting among healthcare professionals at King George Hospital. The study indicates that only 20.8% of the interviewed healthcare professionals were knowledgeable to ADRs reporting process in terms of what is to be reported, who should report, when to report, how to report and where to report the ADRs. In the present study, we observed that doctors have more awareness and knowledge about PV and ADR reporting compared to other health care professionals. PV plays a crucial role in meeting the challenges posed by the pharmaceutical products, all of which carry an unavoidable and sometimes unpredictable potential for harm. These results also suggest that pharmacists have little knowledge about the concept and the process of pharmacovigilance and the spontaneous ADRs reporting system. However the pharmacists have a positive approach towards pharmacovigilance, but meagre experience with reporting. Educational programs are needed to increase the pharmacists role and their knowledge about the reporting process and thus to have a positive impact on patient caring process. Also, more number of pharmacists should be recruited in the hospital to ensure the continuous process of ADR reporting. The present study also reveals the fact that only 44% of the nurses were aware of PvPI. Hence, regular training programs must be conducted to increase awareness amongst the nurses regarding the program. In conclusion, interventions can improve knowledge, awareness and practices of healthcare professionals about ADR that is a great issue of importance regarding PV and public health. Under-reporting of ADRs can be due to many reasons. Widening the reporter base by extending it to nurses, pharmacists, and other healthcare professionals would also help to strengthen ADR reporting.

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