

A Survey on Knowledge, Attitude and Practice of Pharmacovigilance towards Adverse drug reactions reporting among Doctors and Nurses in a Tertiary Care Hospital in South India

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ABSTRACT

Background: Spontaneous reporting of adverse drug reaction is globally practiced it under pharmacovigilance programme. But the major drawback of this system is underreporting. In this context the present survey was conducted, to assess the knowledge, attitude and practice of spontaneous ADR reporting among doctors and nurses in a tertiary care teaching hospital in South India. **Methods:** A cross-sectional questionnaire-based survey was conducted among doctors and nurses in a tertiary care teaching hospital in South India. A pre-designed and structured multiple choice questionnaire containing 19 questions was used to assess knowledge (1-9), attitude (10-14) and practice (15-19). The data obtained were analyzed using appropriate statistical analysis through SPSS version 19.0. **Results:** A total of 318 healthcare professionals participated in the study. Among them 46.2% were doctors, and 53.8% were nurses. The participants had good knowledge regarding the purpose of monitoring ADRs, type of ADRs to report, who can report, etc. They also felt reporting of ADRs is a professional obligation and all ADRs should be reported. There was no significant difference in the knowledge and attitude between doctors and nurses. The practice of ADR reporting was significantly higher in doctors compared to nurses. **Conclusion:**

The present study indicates that majority of participants have good knowledge about local hospital based ADR monitoring. However, the transition from knowledge to practice was not adequate. ADR reporting can be further increased by improving access to ADR reporting forms, using user-friendly methods such as electronic reporting and by educational interventions targeting especially the junior healthcare professionals.

Key words: Adverse drug reactions, Knowledge, Attitude and practice, Survey questionnaire.

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INTRODUCTION

Adverse drug reactions (ADRs) affect irrespective of the age group of patients worldwide with varying magnitude of causing morbidity and mortality.¹ ADRs are reported to be the 4-6th leading cause of death in United States of America (USA).² The burden of ADRs is expected to be even higher in developing countries due to extensive prevalence of self-medication, fake and adulterated medicine.^{3,4} A study from South India revealed that 0.7% of hospital admissions were due to ADRs and a total of 3.7% hospitalized patients experienced ADRs, of which death accounts for 1.3%.⁵ The magnitude was even higher in the emergency department where 6.89% of admissions were due to ADRs.⁶

Spontaneous reporting system (SRS) of ADRs is one of the principle methods used globally to monitor the benefit and hazard of drugs. This type of reporting is voluntary in nature and reported by healthcare professionals or consumers when they become suspicious of any adverse reaction to any medication. This system has the potential to identify rare, unexpected ADRs more quickly than any other study designs.⁷ The rate at which ADRs are reported depends on many factors such as time since the launch of pharmacovigilance programmes, regulations and attitude of healthcare professionals.⁸ The Uppsala Monitoring Center (UMC) Sweden maintains the global database of ADRs reported from pharmacovigilance programme of various countries. However, it is estimated that only 6-10% of ADRs reported worldwide.⁹ The Pharmacovigilance

Programme of India (PvPI) was launched under the Ministry of Health & Family Welfare in July 2010 to safeguard the health of the Indian population by ensuring the safety and efficacy of marketed drugs.¹⁰

The Adverse drug monitoring center (AMC) in Jawaharlal Institute of Post Graduate Medical Education and Research (JIPMER) was also established in the year 2010 under PvPI. Despite four years of its existence, spontaneous reporting of ADRs is less among the healthcare professionals.¹¹ This underreporting may be due to lack of adequate knowledge, attitude and practice among healthcare professionals towards ADR reporting.¹² However, to improve the ADR reporting culture among the healthcare professionals, it is essential to develop the knowledge, attitude and practice of pharmacovigilance.¹³ Based on this context the present survey was framed, to assess the knowledge, attitude and practice of spontaneous ADR reporting among doctors and nurses.

MATERIALS AND METHODS

Study design

A cross-sectional questionnaire-based survey was conducted from November 2014 to January 2015 under the AMC which is running under PvPI. The study was approved by Institute ethics committee (Human studies, Reference number: JIP/IEC/SC/2012/2/29). The study was conducted according to Declaration of Helsinki guidelines. It was conducted in different departments of JIPMER, Puducherry, a tertiary care teaching

hospital in South India, involving doctors and nurses working in departments of General Medicine, Pulmonary Medicine, Pediatrics, Psychiatry, Cardiology, Neurology, Dermatology & Sexually Transmitted Disease, Endocrinology, Medical Oncology, Clinical Immunology and Nephrology.

Study Instruments: The survey tool used was based on pre-designed questionnaires adopted from previous studies¹⁴⁻¹⁶ with minor modification done according to our hospital environment. The modified questionnaire was pretested in each five participants of doctors, nurses, and suitable modifications were done before initiation of the survey. The questionnaire survey consists of demographic characteristics of participants, their knowledge of pharmacovigilance (Q no. 1-9), attitude towards ADR reporting (Q. no. 10-14), and practice of pharmacovigilance (Q. no. 15-19). After explaining the purpose of the survey, the final version of the questionnaire was distributed to the doctors and nurses during their departmental activities. The participants were given 30 mins to provide the necessary information. The response format included multiple choice questions in which the participants were asked to choose the correct answer from provided list of options. Each right answer was awarded one mark and the maximum score was 19 (knowledge 9, attitude 5 and practice 5).

Statistical analysis

The completed questionnaire information was recorded using Microsoft Excel spreadsheet (Microsoft Office 2007). The information from the returned questionnaire was coded and entered into Statistical Package for Social Sciences (SPSS) version 19.0 software for analysis. The normality of the data tested using Kolmogorov-Smirnov test. The results were presented in median \pm Interquartile range (IQR) and confidence interval. The comparison of knowledge, attitude and practice (KAP) between doctors and nurses for each question was analyzed using Chi-square test. The scores of knowledge, attitude, and practice of pharmacovigilance between group and subgroup was analyzed using Mann-Whitney U test. Spearman correlation was used to observe the association of knowledge and attitude regarding the practice of ADR reporting. The p value was set at <0.05 with a confidence interval of 95%.

RESULTS

The questionnaire was administered to 318 participants of which 147 were doctors, and 171 were nurses. Among doctors 114 were junior level doctors (includes junior and senior residents) and 33 were senior level doctors (those with more than three years of experience post MD/MS). 50% of the participants were males (n=159) and 50% females (n=159). Among doctors more than one-fourth of participants were in general medicine 41(28%), followed by dermatology 18(12%), psychiatric 14(9.5%), pediatrics 13(9%), cardiology 10(7%), neurology 9(6%), nephrology 8(5.5%), pulmonary medicine 7(5%), medical oncology 7(7%), Clinical Immunology 6(4%), endocrinology 6(4%), medical gastroenterology 6(4%) and pediatric neonatology 2(1%).

While assessing the knowledge of pharmacovigilance among the doctors and nurses towards ADR reporting, around 70% of the participants in both the groups were aware of the location of ADR monitoring center in the Institute, purpose of monitoring ADR and a form used to notifying ADR. More than 80% participants were aware regarding who can report ADR and more than 90% were aware of what type of ADRs reported. Nurses (29%) were better aware of the local intercom number to report ADR while on the other hand doctors (36%) were more aware of the drugs withdrawn due to ADRs (Table 1). Regarding attitude among healthcare professionals towards ADRs reporting showed that more than two-third of doctors and nurses felt that reporting of ADR is necessary (89% and 94%) and is a professional obligation (70% and 67%). Around 55% of the healthcare professionals believed that the method of ADR

reporting is user-friendly in the Institute. Around 40% of the participants felt there are drawbacks in the current system of ADR monitoring in the Institute. However, 67% of the doctors and 52% nurses believed that ADR can cause significant illness or death to the patient (Table 1). Concerning the practice of pharmacovigilance 93% of doctors and 77% of nurses have seen patients experiencing ADRs but at the same time, only 52% of physician and 25% of nurses reported ADRs to AMC in the Institute. More than 50% of doctors and nurses agreed on ease of access to ADR reporting forms in the Institute. The habit of reading articles (50.5%) regarding ADRs and attending training programme (22%) on ADR reporting doctors were more compared to nurses (Table 1).

There was no significant difference in knowledge and attitude scores towards reporting of ADRs between doctors and nurses (Table 2). The median (IQR) practice score was significantly higher in doctors 2(2) than nurses 2(1). The median total score was also significantly greater in doctors 11(3) than nurses 10(3).

Similarly, while comparing the knowledge, attitude and practice between senior and junior level doctors (Table 3), senior level doctors had a significantly higher score in knowledge, practice and overall score. Similarly, senior level nurses had a significantly higher score in attitude and overall score, while there is no significant difference in knowledge and practice.

Among various factors, awareness of the existence of ADR monitoring center, knowledge about the use of ADR forms and its access and experience of attending training programs on ADR reporting contributed significantly for ADR reporting (Table 4).

DISCUSSION

The present study is a questionnaire-based survey conducted to assess the knowledge, attitude and practice of pharmacovigilance towards ADR reporting among doctors and nurses working in medicine and allied departments of a tertiary care teaching hospital. Worldwide, underreporting of ADR is a well-recognized problem associated with spontaneous ADR reporting system. Amongst various factors knowledge, attitude and practice of healthcare professionals play a significant role in spontaneous reporting of ADRs.¹⁶ Hence, the present study was undertaken to assess the knowledge, attitude and practice of healthcare professionals on ADR reporting. A total of 147 doctors and 171 nurses from various specialties and super specialties had participated in the survey. Our study had the greater number of junior doctors and nurses compared to senior doctors and nurses in contrast to the study conducted in Turkey and Nigeria.¹⁷⁻¹⁸ The higher participation of younger generation probably due to the difference in the distribution pattern of healthcare professionals in different countries.

The questionnaire had 19 questions in total. The knowledge based questions assessed, knowledge regarding various aspects of pharmacovigilance such as a location of local and national ADR monitoring centers, purpose, type of ADRs to be reported, who can report and how ADR reporting done. The attitude based-questions assessed the view of the participants regarding the impact of ADR, current system of Pharmacovigilance, obligation towards ADR reporting. The practice based-questions determined practice concerning reading articles, attending the training program and reporting ADR. In our study, 84% of doctors and 85% of nurses rightly recognizes who all can report ADR, compared to other study conducted in India, where only 69% of physician and 30% of nurses knew this.¹⁹ It shows that our study participants have positive sign there is broad acceptance of spontaneous reporting system to support the PvPI. The present survey observed that majority of the participants had good knowledge regarding the purpose of monitoring ADRs and locations of AMC in the institute, which is less another Indian study.¹⁵ This difference, may be because our ADR monitoring center was one

Table 1: Knowledge, attitude and practice (KAP) of ADR reporting among healthcare professionals

Knowledge, attitude and practice related questions	Doctors (N=147)	Nurses (N= 171)	p value
	Correct response n (%)	Correct response n (%)	
Location of AMC in the Institute	110 (75)	123 (73)	0.649
Purpose of monitoring ADRs	118 (80)	134 (78)	0.78
Drug withdrawn from the Indian market due to ADRs	53 (36)	19 (11)	< 0.001*
Form is used to notify ADRs to AMC	99 (67)	123 (72)	0.444
Intercom telephone number for reporting ADRs to AMC in the Institute	13 (9)	50 (29)	< 0.001*
Location of National coordinating center in India	55 (37)	61 (36)	0.838
Who can report ADRs	124 (84)	146 (85)	0.922
Which ADR should be reported	135 (92)	154 (90)	0.723
Location of AMC – OPD in the Institute	82 (56)	93 (54)	0.891
User friendly nature of ADR reporting system	80 (54)	96 (56)	0.846
Faith on ADR can cause significant illness or death to patients in sometimes	99 (67)	89(52)	0.008*
Need for reporting all ADRs	131 (89)	161 (94)	0.153
Reporting ADR as a professional obligation	103 (70)	114 (67)	0.597
Drawbacks in the current system of ADR monitoring	77 (53)	113(67)	0.018*
Previously reported ADRs	76 (52)	43 (25)	< 0.001*
Habit of reading ADR articles	74 (50.5)	52 (30)	< 0.001*
Patients experiencing ADRs seen by healthcare professionals	134 (93)	131 (77)	< 0.001*
Attended training program on ADR reporting	32 (22)	9 (5)	< 0.001*
Easy access to ADR reporting forms	75 (51)	92 (54)	0.702

*p<0.05, calculated by Chi-square test.

ADR-Adverse drug reactions, AMC-Adverse drug reaction monitoring center, OPD-Out Patient Department.

Table 2: Comparison of Knowledge, attitude and practice (KAP) of ADR reporting between doctors and nurses

KAP	Doctors (N = 147)	Nurse (N =171)	p value
Knowledge			
Median (IQR)	6 (2)	5 (2)	0.340
CI	5.10-5.64	5.01-5.52	
Attitude			
Median (IQR)	4 (1)	3 (1)	0.900
CI	3.14-3.53	3.18-3.52	
Practice			
Median (IQR)	2 (2)	2 (1)	< 0.001*
CI	1.98-2.31	1.53-1.79	
Total score (KAP)			
Median (IQR)	11 (3)	10 (3)	0.012*
CI	10.41-11.28	9.90-10.66	

Mann Whitney U test, *p value < 0.05, CI – Confidence Interval, IQR- Interquartile Range.

Table 3: Comparison of Knowledge, attitude and practice (KAP) of ADR reporting among different categories of doctors and nurses

KAP	Junior doctors	Senior doctors	p value	Junior nurses	Senior nurses	p value
	(N = 114)	(N = 33)		(N = 141)	(N = 30)	
Knowledge						
Median (IQR)	5 (2)	6 (3)	0.009*	5 (2)	6(2)	0.083
CI	4.87-5.48	5.45-6.61		4.87-5.44	5.22-6.38	
Attitude						
Median (IQR)	3.5 (1)	4 (2)	0.866	3 (1)	4 (1)	< 0.001*
CI	3.10-3.54	2.93-3.80		2.99-3.35	3.9- 4.5	
Practice						
Median (IQR)	2 (2)	3 (2)	0.001*	2 (1)	2 (1)	0.573
CI	1.8-2.17	2.35-3.05		1.49-1.79	1.48-2.06	
Total score (KAP)						
Median (IQR)	11 (3)	12 (2)	0.001*	10 (4)	12 (3)	< 0.001*
CI	9.99-10.97	11.23-12.95		9.55-10.38	10.91-12.62	

Mann Whitney U test, *p value < 0.05, CI - Confidence Interval, IQR - Interquartile range.

Junior doctors- Doing post graduate or after completion of postgraduate less than three years of experience, Senior doctors- After completion of post graduate more than three years of experience.

Junior nurses- After completion of graduation less than five years of experience. Senior nurses-After completion of graduation more than five years of experience.

Table 4: Factors contributing to ADR reporting among doctors and nurses

Factors contributing to ADR reporting	Spearman's correlation coefficient Sig. (2-tailed) (N = 318)
Location of AMC in the Institute	r = 0.188*
Form is used to notify ADRs to AMC in the Institute	r = 0.367*
Attended training program on ADR reporting	r = 0.168*
Easy access to ADR reporting forms	r = 0.345*

Spearman's correlation, *p value < 0.05, ADRs-Adverse drug reactions, AMC-Adverse drug reaction monitoring center.

among the regional pharmacovigilance centers for previous National pharmacovigilance programme (NPvP 2004). Through this programme the healthcare professionals might have become aware of the purpose of monitoring ADRs and location of ADR monitoring center in the Institute. In our survey 67% of doctors and 72% of nurses knew the form used to notify ADR in the Institute whereas reporting of ADR through intercom telephone number was known only to 9% of doctors and 28% of nurses. The reason may be the practice of ADR reporting attributed by the healthcare professionals where they report ADR in a simplified form and place it in drop boxes present in the departments, and this will be later collected by the technical associate and residents during ward rounds and transcribed to ADR form under PvPI. Only 37% of healthcare professionals were aware of the location of National coordinating center for pharmacovigilance programme of India this is almost similar to the previous study conducted in Gujarat.²⁰

In our study about 89% of the doctors and 94% of nurses shared the view that reporting of all ADR was necessary to increase the patient safety, but only 70% of physician and 67% of nurses consider it to be a professional obligation. It is a positive indication of the need for ADR reporting, and

this finding is almost similar to previous studies.^{16,21} Only 67% of doctors and 52% of nurses believe ADR can sometimes cause death or significant illness to the patients. The reason may be the health care professionals believe that only safe drugs are marketed.²²

The practice of healthcare professionals towards ADR reporting was below compared to expectation because we observed from our study that 93% of the doctors and 77% of nurses have seen patients experiencing ADRs but only 52% of doctors and 25% of nurses reported them to ADR monitoring center. These findings are similar to other studies reported by various countries.^{23,24} Another interesting finding noticed in our survey was that only 22% of doctors and 5% of nurses had previous training on how to report ADRs and only half of the participants from both categories felt that they had easy access to ADR reporting forms. Addressing these factors and clarifying the misunderstandings about ADR reporting may help in improving the conversion attitude towards practice of reporting ADR.²⁵

While comparing knowledge, attitude and practice of reporting ADR between doctors and nurses the level of knowledge and attitude were similar. However, doctors had a better score regarding practice. This may

be because of the belief that reporting ADRs is primarily the duty of the treating physicians and other factors such as anxiety regarding the consequences, uncertainty about the ADRs, difficulty in causality assessment and the additional burden of paperwork. The total scores also significantly higher in doctors compared to nurses. Similarly, when comparing based on the level of experience the senior level doctors and nurses had a significantly higher score than their juniors. This may be due to better awareness and understanding of the local pharmacovigilance system that is in existence for the last five years. This shows the importance of conducting regular pharmacovigilance training programme to ensure that the newer and junior faculties are trained periodically.^{16,26-28} The study also emphasizes on the fact that certain factors such as knowledge about the ADR forms and its ease of access, previous exposure to training programs on pharmacovigilance contribution of ADR reporting.

CONCLUSION

The present study indicates that majority of participants have good knowledge about local hospital based ADR monitoring and national

level pharmacovigilance programme. However, the transition from knowledge to practice is not adequate. This may be due to the attitude of the health care professionals towards ADR reporting. ADR reporting can be further increased by improving access to ADR reporting forms, using user-friendly methods such as electronic reporting and by educational interventions targeting especially the junior healthcare professionals. Effect of awareness program on improvement in knowledge, attitude and practice of pharmacovigilance will be studied to see if there is an impact on ADR reporting.

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CONFLICT OF INTEREST

The author declare no conflict of interest.

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ABBREVIATIONS USED

ADR: Adverse drug reaction, **AMC:** Adverse drug reaction monitoring center, **KAP:** Knowledge, Attitude, Practice, **NPvP:** National Pharmacovigilance Programme, **PvPI:** Pharmacovigilance Programme of India, **SRS:** Spontaneous reporting system.

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