

## QUESTIONNAIRE-BASED STUDY ON THE ASSESSMENT OF DOCTOR OF PHARMACY INTERNS' KNOWLEDGE, ATTITUDE, AND PRACTICES REGARDING THE PHARMACOVIGILANCE

MEDA VENKATASUBBAIAH<sup>1\*</sup>, DWARAKANADHA REDDY P<sup>2</sup>, SUGGALA V SATYANARAYANA<sup>3</sup>

<sup>1</sup>Research Scholar, Jawaharlal Nehru Technological University Anantapur, Ananthapuramu, Andhra Pradesh, India. <sup>2</sup>Department of Pharmaceutics, Annamacharya College of Pharmacy, Rajampet, Andhra Pradesh, India. <sup>3</sup>Department of Chemical Engineering, JNTUA College of Engineering, Ananthapuramu, Andhra Pradesh, India. E-mail: pharmachinna@gmail.com

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### ABSTRACT

**Objectives:** The present study was contemplated and done to assess the knowledge, attitude, and practices (KAP) toward adverse drug reactions (ADR) reporting and Pharmacovigilance (PV) of the Doctor of Pharmacy Pharm.D interns for the first time in South India, to get an insight into their awareness and reporting culture.

**Methods:** A cross-sectional descriptive KAP questionnaire-based study was conducted for 6 months on Pharm.D interns.

**Results:** A total of 603 Pharm.D interns were participated, among them 578 (95.85%) were considered for the analysis. On an average of 78.25% of the participants had a good knowledge, around 82% were aware that patients' will be benefited from the ADR reporting. The majority of the participants had a positive attitude. Moreover, 59% had reported the ADRs through different ADR reporting procedures 52% were advised the awareness programs for improving the reporting culture, and 34% had the difficulty in deciding or diagnosing the ADR.

**Conclusion:** The KAP of the Pharm.D interns toward the ADR reporting and PV is appreciable and may reduce the burden on the other healthcare workers and improve patient care.

**Keywords:** Knowledge, Attitude, Practices, Pharmacovigilance.

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### INTRODUCTION

Adverse drug reactions (ADRs) are one of the major problems associated with medicines. ADRs are responsible for a significant number of hospital admissions [1]. The World Health Organization (WHO) defines an ADR as "a response to a drug which is noxious and unintended, and which occurs at doses normally used in man for the prophylaxis, diagnosis, or therapy of disease, or for the modification of physiological function" [2-4].

According to ASHP, ADRs results in temporary or permanent harm, disability, or death or that requires discontinuing the drug, changing the drug therapy, modifying the dose, necessitates admission to a hospital, prolongs stay in a health-care facility, necessitates supportive treatment, significantly complicates diagnosis, and negatively affects prognosis and became as global problem in both developing and developed countries with a significant number of morbidity and mortality [5,6]. Hence, the detection, recording, and reporting of ADRs becomes vital in the safe use of medicines. For this purpose, the concept of Pharmacovigilance (PV) was introduced to enhance the patients' safety and maximize therapeutic outcomes [7].

According to the WHO, PV is "the science and the activities which relate to the detection, assessment, understanding, and the prevention of adverse effects or any other drug-related problems" [8]. The National Programme of PV renamed as the PV Programme of India (PvPI) in 2010 and became a WHO Collaborating Centre for PV. However, several challenges are faced by the PvPI, and one of the challenges is creating continual awareness in the healthcare workers (HCPs) and general public about the ADR reporting [9,10].

India is participating in the program, its contribution to the Uppsala Monitoring Centre (UMC) database is 2% only; still, and further active

participation is required to increase spontaneous reporting [11]. Lack of awareness about PV is one of the most important causes of such under-reporting, the reasons for which may be due to lack of trained staff and lack of awareness regarding detection, communication, and spontaneous monitoring of ADRs among the health-care professionals (physicians, nurses, pharmacist, and dentists). To improve participation of health-care professionals in spontaneous reporting, it might be necessary to design strategies that modify Knowledge, Attitude, and Practice (KAP) about PV and ADR reporting [7,12,13]. Studies conducted in the medical interns, nurses and hospital pharmacists suggested that the continual awareness programs on ADR reporting and PV might improve their practicing skills and paves the way toward the quality of care [12,14-17]. Review conducted by Saleh on the KAP of HCPs on ADR reporting and PV has revealed the necessity of awareness on PV in ADRs reporting [5].

Kalaiselvan *et al.* reported that the majority of ADRs were reported by physicians than pharmacists, as they are mainly confined to the drug distribution and do not have much scope in ADRs reporting [18]. Nowadays in the Indian health-care system, pharmacists are also involving in direct patient care through clinical pharmacy services [19]. Along with other health-care professional students (MBBS and Nursing) Doctor of Pharmacy (Pharm.D) students also would be trained in the hospital. In internship or residency training student is exposed to actual pharmacy practice or clinical pharmacy services includes drug therapy monitoring, medication history interview and patient counseling, Identifying and resolve drug-related problems especially ADR.

As of our knowledge in India, there are no/very few data available on the KAP of Pharm.D interns on ADR reporting and PV. Therefore, the present study was contemplated and done to assess the KAP of the Pharm.D interns in South India region regarding ADR reporting

and PV, to get an insight to understand their awareness and reporting culture.

## METHODS

A cross-sectional descriptive questionnaire based study was conducted on Pharm.D interns of various hospitals in the state of Andhra Pradesh, India, for a period of 6 months. A self-designed and pre-validated questionnaire was circulated to the respondents after explaining about the purpose of the study and getting their oral consent. Moreover, we also obtained the feedback from the respondents. Then, the filled questionnaires were screened for their completeness and the data were entered into the spread sheets (MS Excel) for the analysis.

### KAP questionnaire

Study instrument, that is, KAP questionnaire was prepared using standard literature and self-knowledge and experience. It is designed for both the assessment and improving the knowledge and awareness among the participants. The prepared questionnaire was peer reviewed by the panel of three subject experts, one language expert, and one non subject expert. Moreover, it was tested in pilot group consist of 30 subjects for knowing its readability and understandability. The finalized questionnaire was used for assessing the KAP from the study participants.

This questionnaire consist four sections includes demographics, KAP. A total of 27 questions were related to the Knowledge [14], attitude [7], and Practice [6] of ADR reporting and the PV. All the questions were developed in the view of knowing their knowledge on ADRs and PV, to assess their perception toward the ADR reporting and its importance, and to know their ADR reporting habits.

### Statistical analysis

All data summaries and listings were generated using MS Excel, under the Micro-Soft XP operating system 2013. Descriptive statistics such as percentage, mean, SD were used to analyze the data.

## RESULTS

A total of 603 Pharm.D interns were participated and given their responses among them 578 (95.85%) were considered for the analysis and because of incomplete information the remaining responses were excluded, of 578 respondents, majority were females (n=406; 70.24%). The average age of the respondents' was 22.98 ( $\pm 1.11$ ) years.

### Knowledge of the Pharm.D interns about adverse drug reporting and PV

An extensive questionnaire was prepared to know the knowledge of the Pharm.D interns on the identification of ADR, its management, reporting process, and preventive measures; this section includes a total of 14 questions. Except question 14 (81%), participants had given answers to all the questions. Around 63% were knows the correct definition of the ADR; 75% were defined the term PV correctly, around 82% of interns know that patients' will be benefited from the ADR reporting, more than 90% of the participants were known to the ADR identification procedures and mandatory reporting information (91% and 93%). Table 1 explains the all questions and responses related to the knowledge of the study participants.

### Attitude of the Pharm.D interns about adverse drug reporting and PV

Implementation of any system, the approach and interest of the stakeholders' are of utmost most important. It is of two ways, that is, interest in knowing and thought of practicing, with this study, we tried to know the attitude of the Pharm.D interns toward the ADR reporting, PV and challenges in the reporting. The majority of the participants had the positive attitude. A significant number of the participants, that is, 78% were accepted that the close monitoring is needed for the new drugs in the market; around 70% were opinioned as the Indian Drug safety monitoring system is in developing stage. We have depicted the

opinions of the study participants toward the ADR reporting and PV in Table 2.

### Practice of the Pharm.D interns about adverse drug reporting and PV

Out of 578, majority of the respondents, that is, 340 (59%) have reported the ADRs through different ADR reporting procedures, that is, directly to the ADR monitoring center 275 (81%), to PvPI through email 41 (12%), and very few members have used mobile app. Table 3 explains the practice habits of the Pharm.D interns toward the ADR reporting and PV.

## DISCUSSION

Knowledge is the basic component of any activity in the health-care system, without this a complete patient care cannot be achieved, all the HCPs should be familiar with the drug safety issues and as these may cause significant loss to the patient if they are unnoticed. In our study, on an average 78.25% of the participants had the knowledge about the identification of ADR, its management, reporting process, preventive measures, and PV importance. When compared to other studies' participants, the knowledge of our study participants is good, Tew *et al.* [20] study also stated that the pharmacist has higher knowledge of ADR reporting compare to doctors (mean score 76.9 $\pm$ 13.87 vs. 66.9 $\pm$ 19.86); Komaram *et al.* [11] concluded that only 56% of medical interns (n=28) had the knowledge on PV and ADRs. In Sushma *et al.* [21] study, 94% of the interns selected the correct definition of the ADR and all the participants opinioned the ADR monitoring system can improve the patient care in the hospital. In Garg *et al.* [22] study, 50% of the study participants had the knowledge of PV and 42% of medical interns knows about the existence of the National PV center, however in a study conducted by Shakya *et al.*, [23] only 15.4% of the participants were known the existence of national PV center.

To improve the reporting culture among the patient community PvPI has introduced medicine's side effects reporting form in ten Indian languages [24], but this information is less known by the HCPs, in our study, only 27% were aware of this, as HCPs are the best communicators' of the information to the patients PvPI has to take necessary steps to improve the awareness about the availability and easy methods of reporting in both the patients and HCPs. Successful management of the ADRs depends on knowledge on the risk factors and expected negative consequences of them, majority of the study participants had the good knowledge, that is, 93% and 94% were answered correctly for questions related to the risk factors and negative consequences, respectively. In the management of any serious ADR, the suspected drug to be withdrawn first, in our study, 57% of the study participants were aware this.

According to the IPC-PvPI guidance document for spontaneous ADR Reporting Version: 1.0 [25] all types of suspected ADRs irrespective of whether they are known or unknown, serious or non-serious, frequent or rare, and regardless of an established causal relationship are need to be reported. In this study, the majority of the participants (86%) were aware that all types of ADRs are need to be reported to build the evidence on the drug safety, in Sushma *et al.* [21] study, more than 70% of the participants felt that only significant and severe ADRs should be reported. Reporting of drug's safety information is of equal responsibility of the all HCPs and patients including their care takers, especially Pharm.D professionals as they are involving in the direct patient care and takes the responsibility of patient education with this study it is proved that the Pharm.D professionals were very well known about their responsibility. Clinical pharmacist should aware of the drugs banned time to time to instruct the prescribers, nurses, and hospital/dispensing pharmacist to avoid them in their practices, we found that 81% of the participants were named at least one banned drug in India due to safety issues, In Garg *et al.* [22] study, 59% were had the knowledge of drugs banned in India due to their safety issues. This indicates Pharm.D interns had good knowledge on the drugs banned.

Question	Frequency of correct answer	
	n=578	Percentage
What do you mean by an adverse drug reaction (ADR)?	364	62.98
What do you mean by Pharmacovigilance?	434	75.09
Are you aware of the existence of the ADR monitoring system and reporting procedures in India?	504	87.20
Ultimately, who benefits from the ADR reporting?	473	81.83
How Can We Identify ADRs in a Patient?	529	91.52
How do we get an ADR reporting form?	487	84.26
What is the mandatory information required to fill an ADR reporting form?	537	92.91
In how many languages Indian Pharmacopoeial Commission (IPC) medicines side effects reporting form for the patient is available?	157	27.16
What are the possible risk factors for the occurrence of ADRs?	540	93.43
What may be the consequence/s of an ADR in the patient?	545	94.29
What is the initial measure to be taken in the management of serious ADR?	328	56.75
Which types of ADRs are needed to be reported?	496	85.81
Who is responsible for reporting an ADR in a hospital/community?	471	81.49
Name any drug/s banned due to ADRs in India	467	80.80

ADR: Adverse drug reactions

Table 2: Responses to the attitude related questions

Question	Responses (%)			
Do you think that the close monitoring is required for new drugs?	Yes 453 (78.37)	No 5 (0.87)	Maybe 104 (18.17)	Can't Say 16 (2.77)
What is the status of the ADR reporting system in India?	Developed 21 (3.63)	Developing 403 (69.72)	Infancy 122 (21.11)	Don't know 32 (5.54)
Do you agree that Pharmacovigilance as a subject to be taught in all the healthcare professional programs.	Agree 381 (65.92)	Strongly Agree 174 (30.10)	Disagree 19 (3.29)	Strongly Disagree 4 (0.69)
What is your option about the establishment of the ADR Monitoring Centre in every hospital?	Every hospital 345(59.69)	Depends on Beds 131 (22.66)	One in the city 80 (13.84)	Not necessary in every hospital 22 (3.81)
Reasons for the withdrawal/Banning of drugs from the market	Common and serious ADRs 134 (23.18)	Costly and ineffective 7(1.21)	Defects in the Manufacturing 12 (2.08)	All 425 (73.53)
Which factor discourages you from reporting the ADRs?	Difficulty In Decision 194 (33.56)	Treatment is important 42 (7.27)	Fear of -ve impact 11 (1.90)	Lack of time 86 (14.88)
	Legal issues 18 (3.11)	No remuneration 16 (2.77)	Not Aware 47 (8.13)	One ADR May Not Affect 59 (10.21)
	Problem of Confidentiality 42 (7.27)		No encouragement 5 (0.87)	
What is your idea for improving the ADR reporting status among health-care professionals?	Awareness Program 299 (51.73)	Establishment of AMCs 217 (37.54)	Feedback on the Reported ADR 56 (9.69)	No idea 6 (1.04)

ADR: Adverse drug reactions

Table 3: Assessment of the practice

Question	Response			
Have you ever reported ADR to the PV center? (n=578)	Yes 340 (58.82)	No 205 (35.47)	Don't Know Where to report 33 (5.71)	
How did you report the ADRs? (n=340)	AMC 275 (81%)	PvPI through E-mail 41 (12%)	Mobile App 24(7.06)	
Which causality technique did you apply? (n=340)	Narinjo's Scale 233(68.53)	WHO scale 107 (31.47)		
Did you ever counsel the patients regarding the possibility of the ADRs and instructed to communicate their ADR information to their physician?	Yes 279 (48.27)	Counseled and not instructed 217 (37.54)	NO 27 (4.67)	Not identified ADRs in my patients 55 (9.52)
Have you attended any awareness program on Pharmacovigilance?	Yes 294 (50.87)	No 227 (39.27)	Not Specifically 56 (9.69)	
Have you anytime read an article on the prevention of ADR?	Yes 368 (63.67)	No 148 (25.61)	Not Sure 61 (10.55)	

ADR: Adverse drug reactions, WHO: World Health Organization

As of our knowledge and research, we found that majority of the health-care curriculums includes the very less practical aspects of the PV, and most of the professionals are percepts that the reporting of ADRs is of

less importance than the treatment. All the health-care professionals should have sufficient knowledge regarding the PV and its scope to monitor, manage, and prevention of ADRs and it should be inculcate

from their learning stage to improve the knowledge, positive attitude and become as the habit, in our study, a majority (96%) of the Pharm.D interns were agreed the need of the inclusion of PV as a subject in the curriculum of all the health-care programs of them 30% were strongly agreed to the same. In Tew *et al.* [20] study, the majority of doctors and pharmacists have also agreed and suggested the same, and Shakya *et al.* [23] have also supported our results, where 88.6% of the participants were believed the same.

The national PV organization recommends the drug regulatory authority on the actions to be taken on the marketed drugs after analyzing the safety data being collected from the HCPs, Pharma industry and patients, these recommendations includes label changes, restriction of use, and withdrawal/banning, a significant number our study participants be sentient that the drugs could be withdrawn from the market due to their common and serious ADRs in the patients.

ADR monitoring centers under PvPI plays a major role in implementing the guidelines of and achieving the goals of the national PV, in view of this, we tried to find the need of these centers in the hospital setup and found, 60% of the participants were felt that there is a need of ADR monitoring center in every hospital. About 23% were felt as it would be based on the bed strength in a hospital, in a study conducted by Shakya *et al.*, [23] majority (81.5%) of the participants have also believed the same, and Garg *et al.* [22] study, 50% respondents said that every hospital should have an ADR reporting center. In Komaram *et al.* [11] study, 61.03% of the participants showed positive attitude toward the reporting and also opinioned to establish ADR monitoring center in every hospital and need to have PV as a subject in their course.

According to the studies [11,12], India's contribution to the UMC database is 2% only and they expressed the need of improving the reporting culture among the HCPs. Found the reasons for not reporting ADRs by the participants and majority (34%) had the difficulty in deciding or diagnosing the ADR, 15% said lack of time, and only 10% percept that one ADR may not affect the ADR database. More or less to our findings other HCPs' of the studies have also reported the reasons for the under reporting. Sushma *et al.* [21] study found that 29% had the difficulties in confirming ADR. In Tew *et al.* [20] study, 50% of pharmacists and 30.7% doctors have assumed that reporting of one ADR does not have any significance. In Garg *et al.*, [22] 58.8% of the participants does not know how and where to report an ADR. Belete *et al.* [26] have also found the discouraging factors such as lack of feedback (58.8%), unavailability of reporting forms (46.4%), do not know where to report (46.4%), and no certain evidence on causal relation (35.9%). Subish *et al.* [27] have also identified similar reasons for under reporting, which includes, 14.3% participants were not felt the importance of reporting the ADRs irrespective of their frequency and severity; and lack of awareness (14.3%). Kaur *et al.* [1] have also found the similar reasons for under reporting. The PvPI should identify and take necessary steps in overcoming this wrong perceptions and discouraging factors in the reports.

We have also assessed the ideas of Pharm.D interns in improving ADR reporting among HCPs, 52% were advised the awareness programs on ADR reporting procedures and their importance and 38% felt there is a need for the establishment of ADR monitoring center in the hospital, and 10% of the respondents said that reporting status can be improved through feedback to the reporter regarding the ADRs reported by them. In Garg *et al.* [22] study, 33% of the participants believed the necessary of ADR monitoring and 67% felt it as mandatory in the hospitals. In Sushma *et al.*, [21] study all of the respondents (100%), have suggested the establishment of ADR monitoring center and 58% were advised educational programs for improving ADR reporting in the hospital. In Tew *et al.*, [20] study also all the study participants agreed that the ADR reporting is mandatory. An interventional educational study was conducted by Opadeyi *et al.* [28] and found the significant improvement HCPs knowledge and practice. However, they also suggested further specific educational programs are needed in improving the attitude of

the participants toward ADRs and PV. Farha *et al.* [13] have also found a significant improvement in both the knowledge (by 67.9%  $p < 0.05$ ) and perception (by 10.1%  $p < 0.05$ ) of PV among healthcare providers following educational workshop.

Any evidence until unless it is communicated or shown it will be considered as not happened or done, hiding/not reporting the ADRs may pave the way to higher prevalence with more consequences, which, in turn, gives negative opinion on the prescribers and drugs, reporting can minimize the reoccurrence and prevalence in the patients and prevents unnecessary hospitalizations and cost burdens [5-7]. PvPI is participating world drug safety monitoring program, its contribution to the UMC database is 2% only; still, and further active participation is required to increase spontaneous reporting [11].

Analysis of 23,975 Individual Case Study Reports reported to the PvPI by Kalaiselvan *et al.* [19] found the reporting status of the HCPs is low even low in hospital pharmacists. In contrast to this, in our study, a significant number of Pharm.D interns (Trainee Clinical Pharmacists) (59%) have reported at least one ADR during their course of study. Some other studies have also identified the under reporting by HCPs than expected, in Shakya *et al.* [23] study, only 4.9% were reported the ADRs. Garg *et al.* [22] have also found low ADR reporting in their study participants. In Belete *et al.* [25] study, 17 (14.91%) respondents had recorded and reported at least one ADR from past 1 year. Only 21.43% had reported ADRs in Sushma *et al.* [21] study, only 12.4% had reported an ADR with the majority being Interns. AlShammari *et al.* [29] have also reported the under reporting in HCPs. In Joubert *et al.* [17] study, 44.1% of the community and hospital pharmacists were found to practicing ADR reporting. Our study results proved that the Pharm.D professionals are actively involving in the reporting of ADRs and helping the other HCPs and patients.

Assessment of the causality is an important step in the management of ADRs, though it is a non-essential element in the filling of the suspected ADR reporting form, all the reports in the study have assessed the causality using different standard causality assessment scales and majority have used Naranjo's causality scale (69%) and WHO's causality scale (31%). In Katekhaye *et al.* [30] study, 20% of the doctors were used Naranjo's causality scale for establishing the relation between the drug and the reaction.

One of the preventive methods for the re-occurrence of ADR in the same patient is clear instructions and education of the patient about their ADRs and asking them to inform about their drug allergic history to their next prescriber, as a clinical pharmacist it is the prime responsibility of the Pharm.D interns to counsel the patient accordingly to prevent the re-occurrence. In this study, we found that the majority (95%) of the interns were counseled their patients during their internship practice, of them 48% were instructed the patients to inform about their ADR/s to the next prescriber to prevent re-prescription of the same suspected drug and 37% were counseled but not instructed to inform about their ADR/s to the next prescriber. In Belete *et al.* [25] study, 44 (38.60%) HCPs have not been counsel their patients on possible ADRs to their medications. In Rajalakshmi *et al.* [31] study, 39.60% of the nurses were counseled their patients on ADRs.

In our study, majority, that is, 64% and 51% of the respondents has the habit of reading articles regarding the prevention of ADRs and attending the awareness programs on PV respectively, which is a good practice for improving their knowledge about the ADR management and to improve the patient care. Similar to our study Manjhi *et al.* [12] have also reported that more than 60% of their study participants had the habit of reading articles on the prevention of the ADRs. However, Shakya *et al.* [23] reported that only 38.4% has the practice of reading article related to the PV.

Our results proved the capability and positive attitude of the Pharm.D professionals toward the patient safety, and also the involvement of

Pharm.D interns in the drug therapy monitoring in collaboration with other HCPs.

## CONCLUSION

The KAP of the Pharm.D interns toward the ADR reporting and PV is appreciable and may reduce the burden on the other HCPs and improve the patient care. However, further improvement is required in the reporting of ADRs and PvPI should take necessary steps in minimizing the challenges in the reporting through educational awareness programs and encouraging them to follow the latest decisions/policies of the PvPI.

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## CONFLICTS OF INTEREST

No conflicts of interest.

## AUTHORS' CONTRIBUTIONS

MVS and PDR have contributed to the conception, design, and data collection, PDR and SVS analyzed the data. The manuscript was written by MVS and reviewed by PDR and SVS. All authors read and approved the final manuscript.

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