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RESEARCH ARTICLE

Knowledge, attitude, and practices (KAP) of the Pharm.D interns towards adverse drug reaction (ADR) reporting and pharmacovigilance

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Abstract

Introduction: Lack of awareness about pharmacovigilance (PV) is one of the most important causes of under-reporting, which is widespread and poses a daunting challenge in India. The aim of this study is to assess and to document the knowledge, attitude, and practices (KAP) of Doctor of Pharmacy (Pharm.D) interns who practicing in hospitals with regards to PV and adverse drug reaction (ADR) reporting and to identify the causes of under reporting. **Methods:** This cross-sectional descriptive study was conducted for a period of six months across ten hospitals in Andhra Pradesh, India. **Results:** Overall, 578 responses were analysed, 78% of the participants had good knowledge on reporting ADR, 82% were aware that patient will be benefited from the ADR reporting, and the majority of the participants had a positive attitude towards reporting ADR. Fifty-nine percentage of the participants had reported the ADRs through different ADR reporting procedures, 52% were advised the awareness programmes for improving the reporting culture, and 34% had the difficulty in deciding or diagnosing the ADR. **Conclusion:** The KAP of the Pharm.D interns is appreciable and may reduce the burden on the other healthcare providers and improve patient care.

Introduction

Adverse drug reactions (ADRs) are one of the major problems associated with medicines. ADRs are responsible for a significant number of hospital admissions (Kaur *et al.,* 2015). 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 the modification of physiological function" (Alsaleh *et al.,* 2017). While an adverse drug event (ADE) is an injury resulting from the use of a drug, it includes harm caused by the drug (ADR and overdoses) and harm from the use of the drug, including dose reductions and discontinuations of drug therapy (Chen *et al.,* 2015).

According to the American Society of Health-System Pharmacists (ASHP), ADRs may result in temporary or permanent harm, disability, or death or that may require discontinuing the drug, changing the drug therapy, modifying the dose, necessitates hospitalization, prolonged stay in a health care facility, necessitates supportive treatment, significantly complicates diagnosis, or negatively affects prognosis. ADRs are a global problem for both developing and developed countries with significant morbidity and mortality; these negative consequences are also reported with 'over the counter' drugs, but this is not

reported as extensively (American Society of Health-System Pharmacists, 1995; Gosh *et al.,* 2011; Kumar *et al.,* 2019; Saleh *et al.,* 2016). 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, an important tool to identify the safety issues associated the drug use and to enhance patient safety and maximise therapeutic outcomes (Alsaleh *et al.*, 2017).

According to 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". The Uppsala Monitoring Centre (UMC, WHO), Sweden, maintains the international database of the ADR reports (WHO, 2002a). PV in India was initiated in 1986; in 2005, India launched the National Programme of Pharmacovigilance, renamed as the Pharmacovigilance Programme of India (PvPI) before becoming a WHO Collaborating Centre for Pharmacovigilance in 2010. PvPI safeguards the health of the community through monitoring and assessing the risks and benefits associated with drug use with the support of 250 ADR monitoring centres across India. However, several challenges are faced by the PvPI, and one of the challenges is creating continual awareness in the healthcare providers and the general public about the ADR reporting (Kalaiselvan *et al.*, 2019). India's contribution to the UMC database is just 2%; more active participation is required to increase spontaneous reporting (Komaram *et al.,* 2016).

Lack of awareness about PV is one of the most important causes of such under-reporting, which is widespread and poses a challenge in PV in India. The reasons for which may be lack of trained staff and lack of awareness regarding detection, communication, and spontaneous monitoring of ADRs among the healthcare professionals (HCPs), e.g. physicians, nurses, pharmacist, and dentists. All HCPs should report ADRs as part of their professional responsibility. To improve the participation of HCPs in spontaneous reporting, it might be necessary to design strategies that modify knowledge, attitude, and practice about PV and ADR reporting (Manjhi *et al.,* 2016). HCPs are in the best position to report on ADRs what they observed in their everyday patient care and is influenced by their KAP of ADR reporting and PV (Alsaleh *et al.,* 2017; Farha *et al.,* 2018). HCPs' awareness and perceptions towards PV has a major impact on patient safety reporting, and studies also revealed that inadequate perception might eventually affect the reporting rate (Farha *et al.,* 2018). Studies conducted with medical interns, nurses, and hospital pharmacists suggested that the continual awareness programs on ADR reporting, PV and making reporting mandatory might improve their practising skills and improves the quality of care. Nurses have less awareness of ADR reporting and PV, and only a few reported ADRs compared with medical interns. Hospital pharmacists showed less knowledge of ADR reporting than other HCPs (Manjhi PK *et al.,* 2015; Joubert *et al.,* 2016; Alsaleh *et al.*, 2017; Goel *et al.,* 2017; Singh *et al.,* 2018). A review conducted by Saleh and authors (2016) on knowledge of HCPs on ADR reporting and PV has concluded that there is a necessity to improve the awareness on PV and which is helpful in ADRs reporting.

Kalaiselvan and authors (2014) reported that in India, analysis of 23,975 Individual Case Study Reports (ICSRs) revealed that the majority of ADRs were reported by physicians, and relatively lower reporting was done by the pharmacists and other HCPs. In India, hospital pharmacists do not have scope and opportunity for ADR reporting as they are mainly confined to drug distribution. Most of the patients were reporting ADRs to the treating physician.

Currently, in the Indian healthcare system, pharmacists are more involved with indirect patient care through clinical pharmacy services. To strengthen the healthcare system and improve quality patient care, a Pharm.D course was introduced in 2008 as per Regulations framed under section 10 of the Pharmacy Act, 1948 (8 of 1948) by the Pharmacy Council of India (PCI). Along with other healthcare professional students (Medicine and Nursing), Pharm.D students were trained in the hospital. During this internship or residency, training the students are exposed to actual pharmacy practice or clinical pharmacy services includes monitor drug therapy, obtain medication history interviews and counsel the patients, identify and resolve drug-related problems, detect, assess and monitor adverse drug reactions, and interpret selected laboratory results (as monitoring parameters in therapeutics) of specific disease states, under supervision so that they may become capable of functioning independently.

It has become essential to assess and improve the Pharm.D interns' KAP towards ADR reporting and PV in order to improve drug safety. In this context, the present study was aimed to assess and document the KAP of Pharm.D interns practising in ten hospitals of Andhra Pradesh, India, with regard to PV and ADR reporting and to identify the causes of under-reporting.

Methods

Following ethical committee approval (Institutional Ethical Committee, Rajiv Gandhi Institute of Medical Sciences, Kadapa, IEC/Acd./2018/0014), a cross-sectional descriptive questionnaire-based study was

conducted on Pharm.D interns of ten hospitals in the state of Andhra Pradesh, India, for six months. A self-designed and pre-validated questionnaire was circulated to the Pharm.D interns after explaining the purpose of the study and getting their oral consent. Then the filled questionnaires were screened for their completeness, and the data was entered into spreadsheets (Microsoft Excel) for the analysis.

This study adopted the KAP questionnaire, which had been implemented in other studies (Joubert *et al.*, 2016; Alsalehet al., 2017; Garg *et al.*, 2017; Goel *et al.*, 2017; Katekhaye *et al.*, 2017; AlShammari *et al.*, 2018; Belete *et al.*, 2019; Opadeyi *et al.*, 2019)

KAP questionnaire

This questionnaire consisted of two parts; part 1 includes participants' demographics, and the latter part includes three subdivisions for knowledge, attitude, and practice related questions and options. A total of 27 multiple options and close-ended questions related to the Knowledge (14), attitude (7), and Practice (6) of ADR reporting and the PV were included.

The KAP questionnaire was peer-reviewed by a panel of three subject experts, including a language expert and a non-subject expert. It was pre-validated in the pilot group, which consisted of 30 subjects for access to its readability and understandability. Based on the data from the pilot study, the questionnaire was updated to improve the language, and ambiguous questions were removed.

Statistical analysis

All data summaries and listings were generated using Microsoft Excel. Descriptive statistics were used to analyse the data.

Results

In total, 603 questionnaires were circulated to the Pharm.D interns across ten hospitals in Andhra Pradesh, India. Of these, 578 (95.85%) were considered for the analysis and the remaining were excluded due to incompleteness. The majority of participants were females (n=406; 70.24%), and the mean (SD) age of the total participants was 22.98 ± 1.11 years.

Knowledge, attitude and practice of interns

Out of 578 Pharm.D interns, 62.98% and 75.09% have defined the terms ADR and PV correctly, majority of the participants (81.83%) indicated that patients are ultimate beneficiaries of the ADR reporting, a greater part of the participants were aware of the ADR identification procedures and the mandatory information required for ADR reporting (91% and 93%, respectively). The remaining knowledge information is shown in Table I.

Table I: Responses to the knowledge related questions

Question	Frequency of correct answer	
	n= 578	%
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 Pharmacopoeia 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

The majority of the participants had a positive attitude toward the ADR reporting ad PV. A significant number of the participants (78.4%) were accepted the need for close monitoring of the new drugs; around three fourth of the participants (69.7%) have opinioned that the Indian Drug safety monitoring system is in the developing stage. The most frequent factors that contribute to under-reporting were difficulty in decision making (33.5%) and lack of time (14.9%). Half of the participants suggested awareness programs on safety monitoring and its importance for improving the ADR reporting status. We have depicted the attitude information of study participants in Table II.

Table II: Responses to the attitude related questions

Question	Responses (%) (n=578)			
Do you think that 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 is a subject to be taught in all 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 the negative 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 programme 299 (51.73)	Establishment of AMCs 217 (37.54)	Feedback on the reported ADR 56 (9.69)	No idea 6 (1.04)

The majority of the respondents, 340 (59%), had reported an ADR at least once. A greater portion of these ADR reporters (81%) have reported directly to the ADR monitoring centres, and very few used a mobile app (7%). Half of the participants have attended the PV awareness programs previously, and 64% had read the literature on the prevention of ADRs. Table III explains the practice habits of the Pharm.D interns towards the ADR reporting and PV.

Table III: Assessment of the practice

Question	Responses (%) (n=578)			
Have you ever reported ADR to the PV centre?	Yes 340 (58.82)	No 205 (35.47)	Don't know where to report 33 (5.71)	
How did you report the ADRs?*	Adverse drug reaction monitoring centre (AMC) 275 (81)	PvPI through email 41 (12)	Mobile App 24 (7.06)	
Which causality technique did you apply?*	Naranjo's Scale 233(68.53)	WHO scale 107 (31.47)		
Did you ever counsel the patients regarding the possibility of the ADRs and instructed them to communicate their ADR information to their physician?	Yes 279 (48.27)	Counselled 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)	

*there were 340 respondents for these questions.

Discussion

Knowledge is the basic component of any activity in the health care system; without this, complete patient care cannot be achieved. All HCPs should be familiar with the drug safety issues as these may cause significant loss of care and safety for the patient if they are unnoticed. In this study, an average of 78.25% of participants knew the detection, management, reporting of ADRs, the importance of the PV, and its existence. The knowledge is found to be good when compared to other studies (Sushma *et al.,* 2011; Komaram *et al.,* 2016*;* Tew *et al.,* 2016; Garg *et al.,* 2017; Shakya *et al.,* 2019).

Information about the availability of the PvPI-IPC medicine side-effects reporting form is available in 10 Indian languages (Indian Pharmacopoeia Commission, 2014), but this is less known, as only 27% of interns were aware of this information; HCPs should know and communicate about ADRs and the methods of reporting.

Knowledge of the risk factors and expected negative consequences of an ADR are important for the rational management of the ADR. In this study, the majority of the participants had good knowledge and answered correctly the questions related to the risk factors (93.4%) and negative consequences (94.3%). More than half of the study participants (56.7%) knew the management of serious ADRs.

According to the IPC-PvPI guidance document for spontaneous ADR Reporting Version: 1.0 (Indian Pharmacopoeia Commission, 2014), 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 need to be reported; the majority of the participants (86%) were aware that all types of ADRs need to be reported to build the evidence on drug safety. In the study conducted by Sushma and authors (2011), more than 70% of the participants felt that only significant and severe ADRs should be reported.

Both the HCPs and the patients (including their carers) had equal responsibility for reporting drug safety issues, as they act as the primary source of information. All HCPs, especially clinical pharmacists/Pharm.D interns, should take this responsibility along with patient education. This study proved that Pharm.D professionals were aware, with 81.49% of the participants knowing their responsibility.

Clinical pharmacists should have updated knowledge about the banned drugs to instruct the prescribers, nurses, and hospital/dispensing pharmacist accordingly to avoid their use; in this study, a significant number (80.8%) of participants have named at least one banned drug in India due to safety issues, in the study conducted by Garg and authors (2017), more than half of the participants (59%) knew about the same. These results indicate that Pharm.D interns had good knowledge of the drugs banned.

Attitude

The majority of healthcare curricula had included some small practical aspects of PV, and most of the professionals' attitudes were that the reporting of ADRs is of less importance than the treatment. All healthcare professionals should have enough knowledge about PV and its scope to identify, manage, and prevent ADRs and be inculcated from initial learning stages to improve knowledge, positive attitudes. In this study, 96% of the Pharm.D interns agreed on the need for the inclusion of PV as a subject in healthcare curricula. In the studies by Komaram and authors (2016), and Tew and authors (2016), the majority of the participants also indicated similar agreement together with Shakya and authors (2019), which also supports this study's findings, with 88.6% of participants agreeing similarly.

Based on the safety reports received from the HCPs, Pharma industry and other stakeholders, we suggest that HCPs and patients need greater awareness of the process of data collection and utilisation that is used to regulate drug usage and which helps in improving reporting culture. A significant number of participants in this study were aware that the drugs could be withdrawn from the market owing to their serious ADRs in the patients.

An attitude of Pharm.D interns towards the need for ADR monitoring centres under the PvPI for implementing the national guidelines for PV in improving the safe use of drugs is attempted to be evaluated in this study. More than half of the participants (60%) agreed for a need for ADR monitoring centres in every hospital, which is similar to studies conducted by Shakya and authors (2019) (81.5%), Garg and authors (2017) (50%), and Komaram and authors (2016) (61%).

Factors contributing to under-reporting

According to the studies conducted by Komaram and authors (2016) and Manjhi and authors (2016), India's contribution to the Uppsala Monitoring Centre (UMC) database is just 2% and needs to improve the reporting culture among the HCPs. The reasons for the under-reporting of ADRs were evaluated. There were 33.56% had difficulty in deciding or diagnosing the ADR, 15% reported lack of time, and around 10% of interns were of the perception that 'one ADR' would not influence the ADR database.

Sushma and authors (2011) found that 59% of their participants had reported a lack of facilities, and 29% had difficulties in confirmation of ADRs. Tew and authors (2016) reported that 50% of pharmacists and 30% of doctors in their study had assumed that the reporting of one ADR does not have any significance in PV. In the study conducted by Garg and authors (2017), 58.8% of the participants do not know how and where to report an ADR. Belete and authors (2019) have also found discouraging factors like lack of feedback (58.8%), unavailability of reporting forms (46.4%), not knowing where to report (46.4%), or no certain evidence on causal relation (35.9%). Subish and authors (2011) have also identified similar reasons for under-reporting, which includes 14.3% of participants having underestimated the importance of reporting the ADRs irrespective of their frequency and severity. Kaur and authors (2015) have also found similar reasons for under-reporting.

The ideas of Pharm.D interns in improving ADR reporting among HCPs were evaluated. There were 52% of respondents advised awareness programs, and 38% suggesting a need for the establishment of an ADR monitoring centre in hospitals; 10% of the respondents said that reporting status could be improved through feedback to the reporter of the ADRs. In the study conducted by Garg and authors (2017), 33% of the participants believed the necessity of ADR monitoring, and 67% felt it was mandatory in the hospitals. In the Sushma and authors (2011) study, all of the respondents suggested the establishment of an ADR monitoring centre, and 58% advised educational programs for improving ADR reporting in hospitals. In the Tew and authors (2016) study, all the study participants agreed that ADR reporting should be mandatory. Interventional educational studies conducted by Opadeyi and authors (2019), and Farha and authors (2018), have found a significant improvement in HCPs' knowledge, perception and practice through the educational program. However, they also suggested further specific educational programs are needed in improving the attitude of the participants towards ADRs and PV.

Practice

Any information, unless documented, can be considered as 'not happened'; reporting ADRs may pave the way to higher prevalence with more consequences, which in turn gives a negative opinion to the prescribers. However, reporting can lower the reoccurrence and prevalence in patients and prevents unnecessary hospitalisations and cost burdens (Gosh *et al.*, 2011; Saleh *et al.*, 2016; Alsaleh *et al.*, 2017). PvPI is participating in the world's drug safety monitoring program, but its contribution to the UMC database is 2% only; active participation of all the stakeholders may increase more spontaneous reporting (Komaram *et al.*, 2016).

Kalaiselvan and authors (2014) have analysed 23,975 Individual Case Study Reports (ICSRs) and concluded that the reporting status of the HCPs is low and even lower with hospital pharmacists. In this study, 59% of Pharm.D interns have reported at least one ADR during their training. Other studies have also identified under-reporting by HCPs: Shakya and authors (2019) study, 4.9%; Belete and authors (2019) study 14.91%; in Sushma and authors (2011), 12.4%; Al Shammari and authors (2018) at 27%; Joubert and authors (2016) study, 44.1% of the community and hospital pharmacists participated in ADR reporting. This study results show that Pharm.D professionals are actively involved in the reporting of ADRs and supporting other HCPs and patients.

Causality assessment is important for managing ADRs; all the reporters (340) have assessed the causality by using standard causality assessment scales. Most have used Naranjo's causality scale (69%), followed by the WHO causality scale (31%). In the Katekhaye and authors (2017) study, 20% of the physicians used Narinjo's causality scale for establishing the relation between the drug and the reaction.

Collection of patients' allergic history and patient education/counselling about the safe use of drugs will play a vital role in minimising/prevention of ADR reoccurrence. It is the prime responsibility of the Pharm.D interns to counsel the patient so as to minimise reoccurrence. In this study, most (95%) of the interns have counselled their patients during their internship, and 48% have instructed the patients to inform their physicians to prevent repeat prescription of the same drug; 37% have counselled but not instructed to inform about their ADR(s) to the next prescriber. In the Belete and authors (2019) study, 38.6% HCPs have not counselled their patients on possible ADRs. In the Rajalakshmi and authors (2017) study, 39.6% of the nurses counselled their patients on ADRs.

In this study, the majority of the respondents have the habit of reading articles about the prevention of ADRs (64%) and attending the awareness programs on PV (51%), which is good practice for improving their knowledge of ADR management and patient care. Similar to this study results, Manjhi and authors (2016) have also reported 60% of study participants had a habit of reading articles, but with a smaller proportion of 38.4% participants reporting this in the Shakya and authors (2019) study.

These study findings showed the ability and positive attitude of the Pharm.D interns towards patient safety

and involvement in drug therapy monitoring and collaboration with other HCPs.

Limitations

This study did not compare the KAP of the Pharm.D interns with other HCPs' KAP, and similar types of studies with comparative groups are needed to do in other parts of the country.

Conclusion

The KAP of the Pharm.D interns towards the ADR reporting and PV were good. However, an improvement is required in the reporting of ADRs, and PvPI should take the necessary steps in minimizing the challenges in under-reporting through educational awareness programs, encouraging HCPs to follow the latest decisions/policies of the PvPI. With enhanced knowledge of ADR monitoring and patient counselling, using Pharm.D professionals can be a feasible option for the healthcare system to reduce the burden on the other HCPs.

Conflicts of interest:

No conflicts of interest

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