

# Assessment of Knowledge, Awareness and Practices among Healthcare Professionals about Pharmacovigilance and Adverse Drug Reactions Reporting in Dharmapuri and Krishnagiri Districts of Tamilnadu, India

Shyam Kumar Damodar<sup>1\*</sup>, Jitto Joseph<sup>1</sup>, Suhas Cheaten<sup>1</sup>, Nanjappan Rajendran<sup>1</sup>, Pranav M Vijayan<sup>1</sup>, G Guru<sup>2</sup>

<sup>1</sup>Department of Pharmacy Practice, Padmavathi College of Pharmacy, Dharmapuri, Tamil Nadu, INDIA.

<sup>2</sup>Department of Pharmacology, Padmavathi College of Pharmacy, Dharmapuri, Tamil Nadu, INDIA.

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\*Correspondence to:

Dr. Shyam kumar D,

PharmD, Department of Pharmacy Practice,  
Padmavathi College of Pharmacy, Dharmapuri,  
TamilNadu, INDIA.

Email: [shyampharmd@gmail.com](mailto:shyampharmd@gmail.com)

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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 Dharmapuri and Krishnagiri districts in Tamil Nadu. **Methods:** A cross-sectional study using a validated questionnaire was designed to address 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, nurses and pharmacists' technicians of hospitals. Completed questionnaires were collected and data were analyzed. Data were expressed in number as well as percentage. **Results:** Of the 350 questionnaires circulated, a total of 264 healthcare professionals responded. HealthCare professional categories involved in the study were these 86 were doctors, 91 were nurses and 87 were pharmacists. These 86 were doctors, 91 were nurses and 87 were 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 little knowledge about the concept and the process of Pharmacovigilance and spontaneous ADRs reporting system. However, they had positive approach towards Pharmacovigilance but very little experience with reporting. Our study has demonstrated a lack of knowledge and awareness of Pharmacovigilance and ADRs reporting among healthcare professionals in hospitals and also there is a need of a nearby ADR monitoring centre in Dharmapuri and Krishnagiri area.

**Key words:** Pharmacovigilance, Adverse drug reactions (ADR), Questionnaire, Awareness and practices, Health care professionals.

## INTRODUCTION

Medicine safety monitoring is an essential element in healthcare system. Therefore the Ministry of Health and Family Welfare (MoHFW), Government of India launched a nationwide pharmacovigilance program in India (PvPI) in the year 2010 to monitor the Adverse Drug Reactions (ADRs) with the mission to ensure the benefits of medicine outweighs the risks and thus safeguard the health of the population.<sup>[1,2,3,4,5,6]</sup> Indian Pharmacopoeia Commission (IPC) under the MoHFW, functioning as National Coordinating Centre (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), Swede. 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%.<sup>[4]</sup>

Adverse drug reactions (ADRs) continue to present as one of the greatest challenges 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 medium-sized hospitals and outpatient departments with overall incidence of 15.1%. Much of these ADRs (50%) were preventable. Thus there is a dire need to develop effective strategy for detecting and reporting ADRs within the framework of a functional and efficient pharmacovigilance system.<sup>[7]</sup> 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.<sup>[7]</sup> 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 centre in Delhi AIIMS and WHO special centre in GSMC KEM hospital, Mumbai.<sup>[8]</sup>

India has more than half a million qualified Doctors and 15,000 hospitals having bed strength of 6, 24,000. It is the fourth largest producer of pharmaceuticals in the world. It is emerging as an important clinical trial hub in the world.<sup>[9]</sup> Many new drugs are being introduced in our country. Therefore, there is a need for a vibrant pharmacovigilance system in the country to protect the population from the potential harm that may be

caused by some of these new drugs.<sup>[4,10]</sup> Although, India is participating in the program, its contribution to UMC database is very little. The PV Program of India was launched with a broad objective in patient safety for more than one billion people of India.

Pharmacovigilance is an arm of patient care aimed at getting the best outcome of treatment with medicines and other related products. 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 (ADR) reporting of Dharmapuri and Krishnagiri districts in Tamil Nadu, India.

## METHODOLOGY

### Study design

This was a randomized, cross-sectional, observational, questionnaire-based study conducted in Dharmapuri and Krishnagiri districts in Tamil Nadu targeted government medical colleges, tertiary hospitals primary, primary health care centers and retail pharmacies from two districts namely Dharmapuri town, Palacode, Kadathur, Bommidi, Harur and Krishnagiri town. 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 264 health care professionals were included in the study.

### Design Of The Questionnaire

A questionnaire was developed to obtain information on the knowledge and awareness of 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 respondents knowledge awareness and practices towards pharmacovigilance and ADRs reporting.

### Data Collection Procedure

The healthcare professionals (doctors, pharmacists, nurses and pharmacists) 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 medical officers of the hospitals and pharmacy owners 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 wise distribution, Age wise distribution, 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.

## RESULTS

A total of 350 questionnaires was circulated to healthcare professionals. Out of this 264 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%. The healthcare professionals were assessed using knowledge, awareness and practices questionnaire prepared by ourselves out of these 86 were doctors, 91 were nurses and 87 were pharmacists. The statistical significance was taken at 95% confidence interval ( $p < 0.05$ ).

### Demographics

Among 264 patients, 46.6% (n=123) were females and 53.4% (n=141) were males. In this study male respondents were more compared to female respondents. Mainly conducted surveys among the doctors nurses and pharmacists. Out of them 86 where doctors (32.57%), 91 where nurses (34.47%) and 87 where pharmacists (32.95%). The most surveyed in this survey are nurses (34.47 %). (Figure:1)

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

The survey, conducted among 264 professionals and the result of the survey is as follows: - Each and every category explained below the main report. Among the 264 most of them completed the questionnaire. The result is not so good for the society as even in the modern days the awareness of Pharmacovigilance and ADR reporting is very low, even among the professionals including doctors, nurses and pharmacists (Figure:2).

Out of conducting the survey among 264 professionals its result found that only 108 professionals are aware of Pharmacovigilance, which is about only 40.90% of the total surveyed. 156 professionals were unaware of Pharmacovigilance (59.09%).

WHO defines Pharmacovigilance as "the science which deals with detection, assessment, understanding and prevention of ADR", however, in this study 108 (40.9%) of healthcare professionals are aware about the concept of

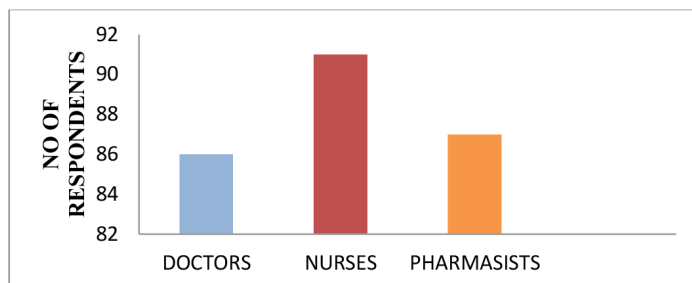


Figure 1: Professional wise differentiation of Respondents.

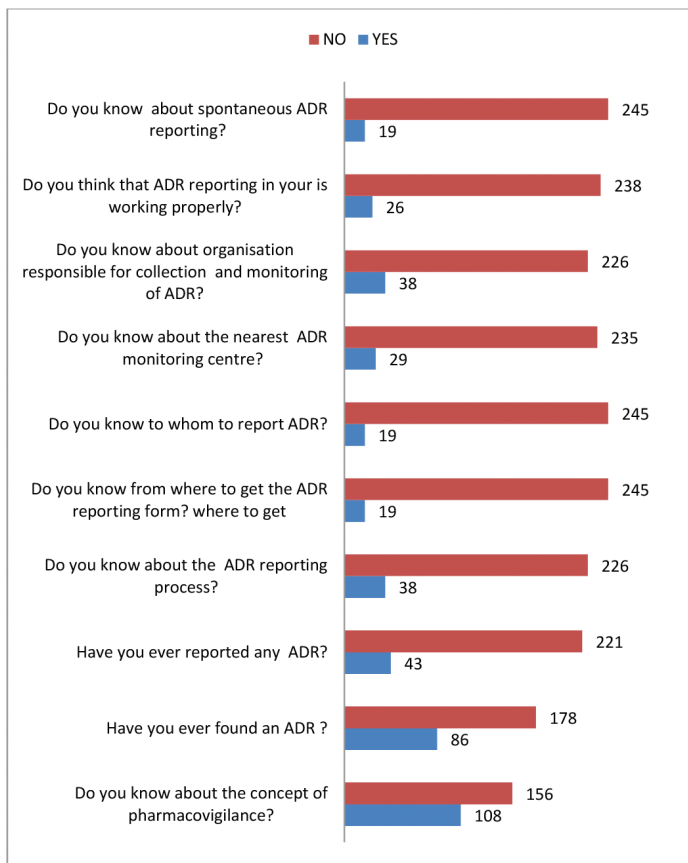


Figure 2: Awareness and practices of HCPs about Pharmacovigilance and ADRs.

pharmacovigilance but only 45(42%) of the health care professionals defined it correctly out of the 108(40.9%) (Table 1).

Out of the 264 surveyed professionals the frequency of finding ADR is as follows:- 96 Professionals are not found any ADR in their career (36.36%), Seventytwo found it rarely (27.27%), 74 professionals found it sometimes (28.03%), 20 people found it frequently (7.57%) and 2 people found it always (0.75%) (Figure 3). Out of 264 surveyed professionals it is found that 43 are aware of reporting an ADR (16.28%) and remaining 221 professionals don't even know to report an ADR. i.e.83.72 % don't know where to report ADR. Out of 264 professionals it is found that only 38 are familiar with ADR reporting (14.39%) and 226 are not familiar with ADR reporting (85.61%). The source of ADR form is known for only 19 people (7.19%) and unknown for 245 people(92.80%) out of 264 professionals included in the survey. The knowledge about ADR reporting authority or to whom

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

Definition	N (%)
Detection assessment understanding and prevention of ADR	45 (42)
Prevention of side effects	23 (21)
Monitoring of ADR in hospital	25 (23)
Don't know the definition	15 (14)
TOTAL	108 (100)

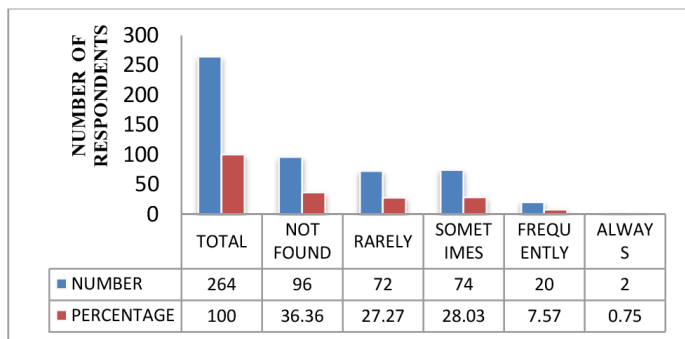


Figure 3: Frequency of ADRs.

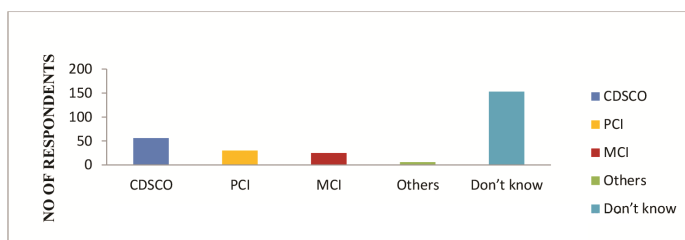


Figure 4 : Regulatory body responsible for monitoring adverse drug reactions in india.

to report ADR is unknown in most professionals as only 19 were known (7.19%) and remaining two hundred and forty five were unknown (92.80%). Out of the 264 professionals were surveyed, only 29 knows (10.98%) which is the nearest ADR reporting centre and remaining 235 were not familiar with the nearest ADR reporting centre (89.02%). Out of 264 surveyed professionals it is found that 153 (58%) of the healthcare professionals are unaware of the organization responsible for the collection and monitoring of ADR. Also 56(21%) of the professionals said that the central drugs standard control organization (CDSCO) is responsible and remaining 30(11.3%) said that the pharmacy council of India is responsible and remaining 25 (9.5%) said that the medical council of India is responsible and 6 (2.7%) said that some other organizations are responsible for monitoring of ADR (Figure:4).

Out of the two hundred and sixty four professionals were surveyed 26 people (9.84%) thinking the working of ADR reporting system in their area is working properly and remaining 238 (90.15%) were thinking that the ADR reporting is not working smoothly or they are unaware of ADR reporting process. Out of the 264 surveyed professionals only 19 people (7.19%) out of them are heard or known about the spontaneous ADR reporting. The remaining 245 people (92.80%) 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 shocking, it is found that out of two hundred and sixty four people, 178 of them are having score 0 or 1 (67.42 %), 43 professionals scored below average i.e.2 or 3 score (16.28%), 14 professionals have average score i.e.4 or 5 (5.30%), 15 professional have good score i.e.6 or 7 (5.68%), and remaining 14 professionals scored excellent score i.e. 8 or above (5.30%) (Figure: 5). Mean score of awareness and practices of healthcare professionals about pharmacovigilance and ADR reporting (Figure: 6)

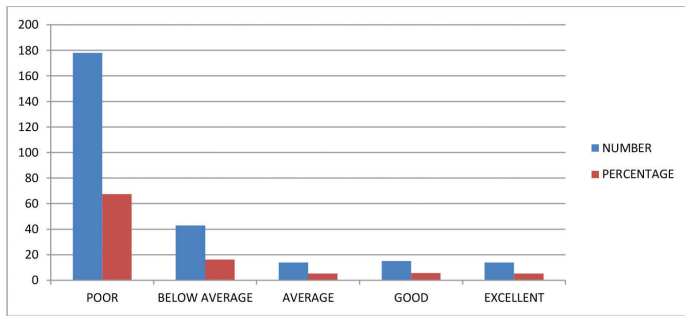


Figure 5: Score of Awareness and Practices among HCPs.

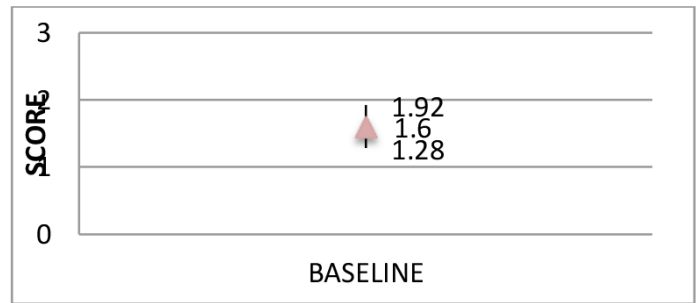


Figure 6: Mean score of awareness and practices of healthcare professionals.

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

CATEGORY	CLASS	Awareness and practices of healthcare professionals about pharmacovigilance		TOTAL	P VALUE
		GOOD SCORE>6	POOR SCORE<6		
Age Group	<30	3(5%)	51(95%)	60	<0.05
	30 -50	19(10.85%)	162(89.15%)	175	<0.05
	>50	7(24.13%)	22(75.87%)	29	<0.05
Profession	PHARMACIST	12(13.79%)	75(86.21%)	87	<0.05
	DOCTOR	14(16.27%)	72(83.73%)	86	<0.05
	NURSE	3(3.29%)	88(96.71%)	91	<0.05
Experience	<5	2(3.07%)	63(96.93%)	65	<0.05
	5-10	9(9.89%)	82(90.11%)	91	<0.05
	>10	18(16.66%)	90(93.34%)	108	<0.05

### 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.  $<0.05$ ). Table :2 illustrates how healthcare professionals awareness and practices of pharmacovigilance ADRs reporting correlates with sex, age, profession, experience of the respondents. Male respondents were more aware about ADRs reporting (18.4%) as compared to female respondents (13.8%) (P value = 0.000). Respondents aged 30-50 years and above were more knowledgeable (10.85%) about ADRs reporting than those aged above 50 years (P value  $< 0.05$ ). Pharmacists and other pharmaceutical professionals (i.e. pharmaceutical technicians and pharmaceutical assistants) were found to have more knowledge on ADRs reporting than other 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 (16.66%) as compared to those with 5 to 10 years and below 5 years experience (P value  $< 0.05$ ).

### DISCUSSION

Pharmacovigilance (PV) programs have played a major role in detection of ADRs and banning 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 Dharmapuri and Krishnagiri districts in Tamil Nadu. To the

best of our knowledge this is the first study in Dharmapuri and Krishnagiri districts to assess the knowledge, awareness and practice, health care professionals towards ADRs reporting and pharmacovigilance, despite the fact that pharmacovigilance system has been present for many years now.

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. Out of this 264 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%. There are 350 healthcare professionals were offered to participate in the study, around 264 respondents involving 86 doctors 91 nurses and 87 pharmacists completely filled questionnaire and were selected for analysis

Out of the 264 surveyed professionals the frequency of finding ADR is as follows:-Out of the 264 respondents 96 Professionals were not found any ADR in their career (36.36%) or they are unaware about it 72 found it rarely (27.27%), 74 professionals found it sometimes (28.03%), 20 people found it frequently (7.57%) and 2 people found it always (0.75%). The healthcare professionals were asked about the availability of the pharmacovigilance system in their area, the majority of participants answered that there was no pharmacovigilance system nearby. It was noted that healthcare professionals (physicians, pharmacists, nurses and pharmacists) working in hospitals have insufficient knowledge of pharmacovigilance practices. Out of the total respondents 173 (65.5%) was male and 91 (34.46%) was female. Out of the total participants 41% were aware about pharmacovigilance and 59% were unaware about pharmacovigilance.



Out of the total respondents, 14 % had fair knowledge and 86% had poor knowledge about ADR. Out of 264 professionals it is found that only 38 know how to report ADR (14.39%) and 226 are not familiar with ADR reporting (85.61%). The source of ADR form is known for only 19 people (7.19%) and unknown for 245 people (92.80%) out of 264 professionals included in the survey. Out of the 264 professionals were surveyed, only 29 were know (10.98%) which is the nearest ADR reporting centre and remaining 235 not familiar with the nearest ADR reporting centre (89.02%). Out of the 264 professionals were surveyed 26 people (9.84%) thinking that working of ADR reporting is working correctly and remaining 238 (90.15%) were thinking that the ADR reporting is not working smoothly or they are unaware of reporting ADR. Out of the 264 surveyed professionals only 19 people (7.19%) out of them are heard or known about the spontaneous ADR reporting, the remaining 245 people (92.80%). That is the majority of professionals don't know about the spontaneous ADR reporting.<sup>[11]</sup>

Hence from the results it is clear that out of the 264 health care professionals 108 (40.9%) professionals are knowledgeable and aware about pharmacovigilance. In the conducted survey, a total of 86 were doctors and out of them 60 are aware of pharmacovigilance and remaining 26 are unaware of that. Out of 91 nurses surveyed are aware of pharmacovigilance and remaining 75 are unaware of that. From 87 pharmacists surveyed and 30 are aware of pharmacovigilance and remaining 57 are unaware of pharmacovigilance.

The findings of this study are similar to a study conducted at Kumarapalayam (Amy Elizabeth Jaibu, *et al.*, 2015) in Tamil Nadu. 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.<sup>[12,13]</sup> To correct underreporting scenario is difficult, so that the extent is unknown and variable. In various studies barriers 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, ambiguity in causal relationship between drug and adverse event, 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.<sup>[14,15]</sup> These include creating awareness about ADR monitoring among health care professionals and consumers, through appropriate 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.<sup>[18,19]</sup> 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 ADRs.<sup>[9,16,17]</sup>

## CONCLUSION

This is the first study in Dharmapuri and Krishnagiri to assess the knowledge, awareness and practices of healthcare professionals towards ADRs reporting and pharmacovigilance, despite the fact that pharmacovigilance system has been present for many years now. What was evident from the study is that there is a gross problem of reporting adverse drug reactions by the healthcare professionals. The study findings indicate that there is poor knowledge towards ADRs reporting among healthcare professionals in

this area. The study indicates that only 14.3% 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 encountered in the patients. 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 continues to play a crucial role in meeting the challenges posed by the ever increasing range and potency of medicines, all of which carry an inevitable 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 had a positive approach towards pharmacovigilance, but very little experience with reporting. Educational programs are needed to increase the pharmacists role and their knowledge about the reporting process and its requirements, and thus to have a positive impact on patient caring process. The present study also draws attention to the fact that only 19% of the nurses were aware of PvPI. Hence, adequate training programs must be initiated to increase awareness among the program. Hence, adequate training programs must be initiated 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 various 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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