

# Responses of Healthcare Professionals to a Standard Self-Administered Questionnaire on Pharmacovigilance and Adverse Drug Reactions in South India

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## ABSTRACT

**Background:** Healthcare professionals play an integral role in the success of safety surveillance of drugs, thereby reducing the drug toxicity, a major limitation in providing health care to patients at a global level, which affects patient's recovery as well as the economy of health care. **Objectives:** The current cross sectional survey of six months duration was performed in a tertiary hospital of south India to assess the knowledge, opinions and perception of healthcare professionals towards pharmacovigilance and adverse drug reactions (ADRs). **Methods:** The purpose and need of study was explained to all healthcare professionals (doctors, nurses and pharmacists) to whom a standard 25 inventories (12 knowledge; and 13 opinion and perception based) open-ended questionnaire in English language was administered. All the responses were entered in to Microsoft Excel sheet and analyzed; statistically significant level was set at <0.05 with a confidence interval of 95%. **Results:** Out of 120 healthcare professionals 66.67% were physicians, 26.67% were nurses and 6.66% were pharmacists. The study observed equal distribution of gender, in which 35.83% were between age group of 21-30 years, mean age was 30 years. The very robust findings of our study are the intra professional responses towards knowledge, opinion and perception on pharmacovigilance and adverse drug reactions found deprived in nurses in comparison to pharmacist and doctors. **Conclusion:** In conclusion,

the study re-accentuates regular and periodic sensitization and orientation of healthcare professionals on pharmacovigilance would bring deep-seated improvement in adverse drug reactions reporting rate.

**Key words:** Adverse drug reactions, open-ended questionnaire, cross sectional, healthcare professionals

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## INTRODUCTION

Drugs are the most common medical interventions, primarily used to relieve sufferings. But it has been recognized long ago that drug themselves can prove fatal; as the saying rightly goes "Drugs are Double Edged Weapons". Adverse reaction monitoring and reporting are very important in identifying the adverse reaction trends in local population.<sup>[1]</sup> Medications have caused and will continue to cause harm to a number of people's lives alongside many benefits. Adverse Drug Reactions (ADRs) are a major problem and are one of the leading causes of mortality and morbidity.<sup>[2,3]</sup>

Drug safety and pharmacovigilance remains a dynamic clinical and scientific discipline. Pharmacovigilance is defined by the World Health Organization (WHO) as 'the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem';<sup>[4]</sup> it plays a vital role in ensuring that doctors, together with the patient, have enough information to make a decision when it comes to choosing a drug for treatment.<sup>[5]</sup>

The success of a pharmacovigilance program depends upon the involvement of the healthcare professionals and reporting the ADRs. Being the key healthcare professionals, the doctors, nurses and pharmacists have immense responsibility in reporting ADRs and strengthening the pharmacovigilance mechanisms that exists in their vicinity. Providing information on suspected ADRs is as much a moral duty for the doctor as other aspects of patient care.<sup>[6]</sup> Therefore, pharmacovigilance programme plays a vital role in ensuring the drugs' safety. In many countries (including India) a pharmacovigilance system is operational; however, under-reporting is a major problem.<sup>[7-10]</sup>

Under reporting of adverse drug reactions (ADRs) is very common. It has been estimated that only 6–10% of all the ADRs are reported.<sup>[11]</sup> Under reporting (UR) of adverse drug reactions (ADRs) is widespread and a daunting challenge in pharmacovigilance (PV).<sup>[12,13]</sup>

This is because primarily most countries, including India follow the spontaneous or voluntary system of ADR reporting.<sup>[14]</sup> However, the intensive monitoring in PV amplifies the detection of ADR.<sup>[15]</sup> Various approaches have been recommended to intensify ADR reporting.<sup>[16]</sup> An increase has been observed in the current reporting culture of ADRs under Pharmacovigilance Programme of India (PvPI) after conducting regular training and awareness programme and circulating the 'PvPI Drug Safety Newsletter'. Healthcare professionals (HCPs) reports ADRs to nearest ADR Monitoring Centers (AMCs) under PvPI and the same is collected and collated by the Indian Pharmacopoeia Commission (IPC), National Coordination Centre (NCC).<sup>[17]</sup> Studies document the widespread problems of UR in PV.<sup>[18,19]</sup> But, we failed to cite any Indian study based on facts and figures to define this problem.<sup>[14]</sup>

Knowledge and attitudes of health professionals appear to be strongly associated with underreporting in a high proportion of studies.<sup>[20]</sup> Therefore, it is important to know the opinions, perceptions and attitudes of healthcare professionals with respect to ADRs which can improve the spontaneous reporting of ADRs. Thus, the objective of our study was to analyze healthcare professional's response towards a self-administered questionnaire on pharmacovigilance and adverse drug reactions, in a tertiary teaching healthcare setting and to examine

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reasons of underreporting of adverse drug reactions in a resource limited background of South India.

## MATERIALS AND METHODS

### Study design and setting

A cross sectional, questionnaire survey was performed in a tertiary teaching hospital located at a resource limited background of South India.

### Ethical considerations

The study was conducted after Institutional Ethics Committee (IEC) approval.

### Study period

The study was conducted for a period of 6 months from October 2015 to March 2016.

### Selection criteria

Healthcare professionals (physicians, pharmacists and nurses) who showed their willingness towards the study were included and healthcare professionals with illustrative unwillingness and allied health professionals were excluded from the study.

### Sample size

A total of 120 healthcare professionals, including 80 physicians, 32 nurses and 8 pharmacists participated in the study.

### Study procedure

Designing of protocol and standard self-administered questionnaire

This segment initially involved preparation of protocol defining the purpose of study; with unbiased, well referred, critically evaluated scientific literatures. Followed by development of a predesigned, organized, open-ended 25 inventories standard questionnaire to assess the knowledge, opinions and perceptions of healthcare professionals with respect to pharmacovigilance and adverse drug reactions, while designing the questionnaire previous literatures were reviewed.<sup>[21-25]</sup>

### Standard Knowledge Attitude Perception (KAP) questionnaire

The KAP questionnaire totally comprised of 25 inventories, the details are as follows:

- i. Knowledge based inventories: The assessment of participant's knowledge about pharmacovigilance and adverse drug reactions included 12 inventories on definition and objectives of pharmacovigilance; National Pharmacovigilance Programme (NPP) India, its establishment and constitution; definition of ADRs, array of ADRs report submission and hierarchy of pharmacovigilance centers, International Drug Monitoring Centre (IDM), NCC-PvPI database and total number of AMC in India.
- ii. Opinions and perception based inventories: The assessment of participant's opinion and perception about pharmacovigilance and adverse drug reactions were clubbed together as 13 inventories on necessity, duration of reporting ADRs and its association with patient health outcomes; complexities and responsibilities in reporting ADRs; reported any ADRs, publication of studies and practicing of approaches in prevention of ADRs.
- iii. Pilot study

The KAP questionnaire on pharmacovigilance and adverse drug reactions was pilot tested by administering it to sample of 10 healthcare professionals who did not participate in the study to identify and

modify the complexities in understanding during survey.

### Cronbach's alpha value

The internal consistency of the questionnaire based on Cronbach's alpha coefficient was 0.42; hence, the research study with 25 inventory KAP questionnaire was found reliable and valid. Furthermore, the draft of questionnaire was evaluated by a panel of healthcare practitioners and academicians, with subject expertise on pharmacovigilance, pharmacology and clinical pharmacy for the clarity, relevance and conciseness of inventories.

### Data collection

The purpose and need of study was explained to all healthcare professionals individually in English language, who showed willingness towards survey to whom the standard KAP questionnaire was administered and responses were obtained; and extrapolated for further result analysis.

### Statistical analysis

All the responses were entered in to Microsoft Excel sheet and analyzed; the statistically significant level was set at <0.05 with a confidence interval of 95%. The variables were characterized by their frequencies, and differences between groups were assessed using Chi-square tests.

## RESULTS

The KAP survey questionnaire was administered to 200 healthcare professionals, out of which 75% (150) provided their responses, of these responses 80% (120) was considered based on completeness of information.

### Demographic details of study participants

The demographic details of the participants involved in survey was categorized based on gender distribution, age distribution, educational qualification and professional status, in our study there was equal distribution of gender, in which 35.83% were between age group of 21-30 years respectively. Furthermore, the mean age of the study participants was 30 years. Out of 120 respondents based profession two-third (66.67%) were physicians, 26.67% were nurses and 6.66% were pharmacists. Nearly half the respondents (n=58, 48.33%) were Master of Medicine or Master of Surgery, followed by 18.33% of Bachelor of Medicine and Bachelor of Surgery (MBBS), 15% of Bachelor of Science in Nursing (B.Sc. Nursing) and 4.17% of Degree in Bachelor of Pharmacy, results of which are thoroughly analyzed and reported in Table 1: (Demographic particulars of healthcare professionals).

### Responses of healthcare professionals towards knowledge based inventories

Healthcare professionals (doctors, nurses and pharmacists) knowledge on pharmacovigilance and ADRs were studied from 12 inventories of KAP questionnaire as positive and negative responses, results of which are thoroughly assessed and reported in Table 2: (Responses of healthcare professionals towards knowledge based inventories). The differences among healthcare professionals to knowledge based inventories were found statistically significant (P<0.005).

### Responses of healthcare professionals towards opinion and perception based inventories

Opinions and perception of healthcare professionals to pharmacovigilance and ADRs were studied from 13 inventories of KAP questionnaire; surveyed responses were thoroughly assessed and reported in Table 3: (Responses of healthcare professionals towards opinion and perception based inventories). The differences among healthcare professionals to opinion and perception based inventories were found statistically significant (P<0.005).

## DISCUSSION

Adverse drug reactions (ADRs) are global problems of major concern. They affect both children and adults with varying magnitudes, causing both morbidity and mortality<sup>[26]</sup> and also a major impact on public health.<sup>[27]</sup> The ADR reporting rate in India is below 1% compared to the worldwide rate of 5%<sup>[28]</sup>. Healthcare professionals play an integral role in the success of safety surveillance of drugs.<sup>[29]</sup> The success of a pharmacovigilance programme depends upon the active involvement of Healthcare Professionals such as doctors, nurses and pharmacists.

**Table 1:** Demography particulars of healthcare professionals (n=120)

Demographic details	Frequency (%)
Gender	
Male	59 (49.17)
Female	61 (50.83)
Mean age (in years)	30 ± 16.51
Age distribution (in years)	
21-30	43 (35.83)
31-40	45 (37.5)
41-50	20 (16.67)
51-60	12 (10)
Healthcare professionals based on profession	
Doctors	80 (66.67)
Nurses	32 (26.67)
Pharmacists	8 (6.66)
Educational qualification	
MBBS with specialization	58 (48.33)
MBBS	22 (18.33)
B. Sc Nursing	18 (15)
Diploma in nursing	14 (11.67)
B. Pharmacy	5 (4.17)
D. Pharmacy	3 (2.5)

**Table 2:** Responses of healthcare professionals towards knowledge based inventories.

Knowledge based inventories	Responses of Doctors (%)		Responses of Nurses (%)		Responses of Pharmacists (%)		Total Responses (%)		value
	+ve	-ve	+ve	-ve	+ve	-ve	+ve	-ve	
Do you know what Pharmacovigilance is?	53 (66.25)	27 (33.75)	11 (34.37)	21 (65.63)	7 (87.5)	1 (12.5)	71 (59.17)	49 (40.83)	0.002
Pharmacovigilance includes?	50 (62.5)	30 (37.5)	10 (31.25)	22 (68.75)	6 (75)	2 (25)	66 (55)	54 (45)	0.005
National Pharmacovigilance Programme (NPP) of India was officially inaugurated in year?	17 (21.25)	63 (78.75)	3 (9.37)	29 (90.63)	5 (62.5)	3 (37.5)	25 (20.83)	95 (79.17)	0.004
National Pharmacovigilance Programme (NPP) of India is governed by?	47 (58.75)	33 (41.25)	9 (28.13)	23 (71.87)	7 (87.5)	1 (12.5)	63 (52.5)	57 (47.5)	0.001
The Chairman of NPP?	11 (13.75)	69 (86.25)	7 (21.87)	25 (78.13)	4 (50)	4 (50)	22 (18.33)	98 (81.67)	0.034
Abbreviation of NCC-PvPI?	27 (33.75)	53 (66.25)	6 (18.75)	26 (81.25)	5 (62.5)	3 (37.5)	38 (31.67)	82 (68.33)	0.046
Do you know what Adverse drug reactions are?	55 (68.75)	25 (31.25)	14 (62.5)	18 (37.5)	6 (75)	2 (25)	75 (62.5)	45 (37.5)	0.018
Hierarchy of Pharmacovigilance centers in India	43 (53.75)	37 (46.25)	9 (28.12)	23 (71.88)	5 (62.5)	3 (37.5)	57 (47.5)	63 (52.5)	0.033
The order of ADR report submission is	46 (57.5)	34 (42.5)	7 (21.87)	25 (78.13)	5 (62.5)	3 (37.5)	58 (48.33)	62 (51.67)	0.002
The International centre of Adverse Drug Reaction monitoring is located in?	41 (51.25)	39 (48.75)	11 (34.37)	21 (65.63)	6 (75)	2 (25)	58 (48.33)	62 (51.67)	0.802
Online databases for reporting ADR's in NCC-PvPI	47 (58.75)	33 (41.25)	9 (28.13)	23 (71.87)	3 (37.5)	5 (62.5)	59 (49.17)	61 (50.83)	0.010
Total number of ADRs Monitoring Centres (AMCs) connected with Vigiflow	10 (12.5)	70 (87.5)	6 (18.75)	26 (81.25)	4 (50)	4 (50)	20 (16.67)	100 (83.33)	0.023

NPP-National Pharmacovigilance Programme, NCC- National Coordination Centre, PvPI-Pharmacovigilance Programme of India, ADR-Adverse Drug Reaction

<sup>[30]</sup> Hence, the current cross sectional study was performed to assess the knowledge, opinions and perception of healthcare professionals towards pharmacovigilance and adverse drug reactions in a tertiary teaching hospital of south India.

The current study involved a total of 120 healthcare professionals; similar finding was reported by Choudhary, in Tamil Nadu,<sup>[31,32]</sup> out of which 50.83% and 49.17% were female and male and mean age distribution was 30 years, similar finding was reported by Gupta in Tamil Nadu.<sup>[21]</sup>

In our study 59.17% and 55% of healthcare professionals gave positive response about definition of pharmacovigilance similar findings was reported by Torwane in Bhopal, Madhya Pradesh,<sup>[33]</sup> and about pharmacovigilance which was found higher than result of Chenchu *et al.* in Andhra Pradesh.<sup>[22]</sup> Only 20.83% of our healthcare professionals knows about the NPP in India, which was comparatively lower than the HCPs practicing in both rural and urbanized healthcare settings of south India observed in study reported by Nasr<sup>[34]</sup> and also lowest in comparison to results of Hardeep Bajaj, Jalandhar.<sup>[35]</sup> Furthermore, the responses of HCPs in our study on NPP constitution, and governance was very lower than the findings of Gupta in Tamil Nadu<sup>[21]</sup> and similar that of study reported by Chenchu *et al.* in Andhra Pradesh.<sup>[22]</sup> In our study 62.5% of HCPs knows about ADRs, findings of which are lower than findings reported by Muraraiah in Bangalore.<sup>[36]</sup> Around 48.33% of HCPs in our study answered the location of International drug monitoring center which was more in comparison to findings of Gupta in Tamil Nadu<sup>[21]</sup> and 49.17% response rate was observed towards the online database for reporting ADR's in NCC-PvPI, furthermore a fewer rate (16.67%) of response was observed to the total number of AMCs connected with Vigiflow in NCC-PvPI among our healthcare professionals.

In our study 74.17% of HCPs agreed that reporting of adverse drug reactions are important, findings of which are lower than Remesh in Trivandrum,<sup>[37]</sup> Khan in Indore<sup>[38]</sup> and Desai in Ahmedabad.<sup>[39]</sup> A total of

**Table 3:** Responses of healthcare professionals towards opinions and perceptions based inventories

Opinions and perceptions based questions	Responses of Doctors (%)		Responses of Nurses (%)		Responses of Pharmacists (%)		Total Responses (%)		value
	+ve	-ve	+ve	-ve	+ve	-ve	+ve	-ve	
ADR reporting is necessary?	65 (81.25)	15 (18.75)	20 (62.5)	12 (37.5)	4 (50)	4 (50)	89 (74.17)	31 (25.83)	0.0333
ADR reporting is time consuming?	47 (58.75)	33 (41.25)	13 (40.63)	19 (59.37)	1 (12.5)	7 (87.5)	61 (50.83)	59 (49.17)	0.0179
ADR reporting improves patient health outcomes	61 (76.25)	19 (23.75)	17 (53.13)	15 (46.87)	7 (87.5)	1 (12.5)	85 (70.83)	35 (29.17)	0.0292
ADR reporting is the professional obligation of healthcare professionals?	55 (68.75)	25 (31.25)	15 (46.87)	17 (53.13)	2 (25)	6 (75)	72 (60)	48 (40)	0.0115
Any complexities are found in reporting ADRs?	51 (63.75)	29 (36.25)	11 (34.37)	21 (65.63)	6 (75)	2 (25)	68 (56.67)	52 (43.33)	0.0100
Have you felt education programmes on Pharmacovigilance and ADRs are necessary?	48 (60)	32 (40)	10 (31.25)	22 (68.75)	5 (62.5)	3 (37.5)	63 (52.5)	57 (47.5)	0.0191
ADR reporting has to be made mandatory?	60 (75)	20 (25)	15 (46.87)	17 (53.13)	7 (87.5)	1 (12.5)	82 (68.33)	38 (31.67)	0.0074
Will it be good in establishing ADR reporting centers in all type of healthcare settings	68 (56.67)	12 (43.33)	20 (62.5)	12 (37.5)	7 (87.5)	1 (12.5)	95 (79.17)	35 (20.83)	0.0250
Have you ever observed and reported any suspected ADRs your daily practice?	52 (65)	28 (35)	11 (34.37)	21 (65.63)	6 (75)	2 (25)	69 (57.5)	51 (42.5)	0.0073
Whether complacency practice of ADR's is well established in our country?	11 (13.75)	69 (86.25)	7 (21.87)	25 (78.13)	4 (50)	4 (50)	22 (18.33)	98 (81.67)	0.0342
Have you read or published studies related to ADRs and Pharmacovigilance?	31 (38.75)	49 (61.25)	12 (37.5)	20 (62.5)	7 (87.5)	1 (12.5)	50 (41.67)	70 (58.33)	0.0244
Have you felt any guilt for having been responsible for the damage observed in the patient due to not practicing / reporting ADRs	18 (22.5)	62 (77.5)	7 (21.87)	25 (78.13)	6 (75)	2 (25)	31 (25.83)	89 (74.17)	0.0045
Have you been trained any approaches in prevention of ADR's?	49 (61.25)	31 (38.75)	11 (34.37)	21 (65.63)	4 (50)	4 (50)	64 (53.33)	56 (46.67)	0.0356

#### ADRs-Adverse Drug Reactions

79.17% opined that establishing AMCs in all types of healthcare settings is necessary, similar findings was reported by Rajesh in Manipal.<sup>[40]</sup> 60% of our HCPs accepted reporting of ADR is professional obligation, the findings of which are similar to study reported by Chenchu *et al.* in Andhra Pradesh.<sup>[22]</sup>

In our study, 52.5% of HCPs believed educational initiatives could improve adverse drug reactions reporting, which was lower in comparison to findings reported by Remesh in Trivandrum<sup>[37]</sup> and Rajesh in Manipal<sup>[40]</sup> in addition 57.5% and 53.33% of our healthcare professionals have reported ADRs and are trained to report ADRs, findings of which are higher than Gupta in Tamil Nadu,<sup>[21]</sup> Remesh in Trivandrum<sup>[37]</sup> and Rajesh in Manipal<sup>[40]</sup> and Khan in Indore.<sup>[38]</sup> In our study the responses of HCPs to the publication of article (41.67%) and study on patients experiencing ADRs (57.5%) was lower in comparison to Gupta in Tamil Nadu<sup>[21]</sup> and Pimpalkhute in Nagpur.<sup>[41]</sup>

The very robust findings of our study are the intra professional responses towards pharmacovigilance and ADRs which was found deprived in nurses in comparison to pharmacist and doctors.

### Strengths and Limitations of the Study

To the best of our knowledge, this is the second study in Andhra Pradesh state assessed the responses of healthcare professionals knowledge, opinions and perception on pharmacovigilance and adverse drug reactions followed by Chenchu *et al.*<sup>[22]</sup> which showed the intra professional responses among doctors, nurses and pharmacists were statistically significant and slightly dispossessed in nurses.

### CONCLUSION

In conclusion, the study documented an overall positive response of

knowledge towards pharmacovigilance and adverse drug reactions among healthcare professionals, but in specific nurses opinions and perception was found very inferior in comparison to pharmacists and doctors. The study re-accentuates regular and periodic sensitization and orientation of HCPs on pharmacovigilance would bring deep-seated improvement in ADRs reporting rate.

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