



## ADVERSE DRUG REACTION: COMMUNITY PHARMACISTS KNOWLEDGE, ATTITUDE AND BEHAVIOR

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### ABSTRACT

Many hospitalizations in India are due to Adverse Drug Reactions (ADR) and resulting in morbidity and mortality in majority cases in addition to the huge economic burden. A survey was conducted to assess the knowledge, attitude and behavior of community pharmacists towards ADR related aspects. One hundred and twenty eight pharmacists from various Community pharmacies in two Districts of South India were consented in this survey. A questionnaire was prepared to investigate the knowledge, attitude and behavior of pharmacists regarding ADR reporting and distributed to the identified pharmacies. The data was collected and analyzed by ANOVA and t- test. Out of 342 community pharmacies approached, 128 (37.4%) community pharmacists consented to be part of the survey and the questionnaire given was filled and returned by them. Out of these respondents, only 39 (30.5%) pharmacists had knowledge about ADR, 15 (11.7%) and 14 (10.9%) were aware of National Pharmacovigilance Program (NPP) and regional reporting centers respectively. Only 54 (43%) agreed that ADR reporting is a professional obligation of pharmacist and none of the respondents reported ADRs. The main reason for not reporting any ADR was 'they did not know how to report' and 'did not feel its beneficial'. This survey revealed that the community pharmacists were having least scores towards knowledge, attitude and behavior on ADRs in Indian Scenario.

**Key words:** Community pharmacy, Adverse drug reaction, Questionnaires

### INTRODUCTION

WHO defines adverse drug reaction (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 functions". Pharmacovigilance is an integral part of drug therapy. In India, pharmacovigilance is still in its infancy stage. Indian reports on ADR monitoring have been very few. India has not reported a single instance of medicinal side effects from drugs for the last three years to an international drug monitoring database set up by the World Health Organization (WHO). Pharmacists can play a fundamental role in ADR monitoring and reporting, although the factors that affect under reporting among these professionals are unknown.<sup>1</sup> Under reporting could occur due to several reasons like lack of awareness, lack of an effective pharmacovigilance programme, failure on the part of the health professionals to report an adverse event, or failure to recognize the previous unknown adverse event. Pharmacists as drug experts are expected to have knowledge regarding the safety related aspects of drugs, and reporting ADRs to health authorities. It would be worth to assess their knowledge and behavior on drug safety related aspects. A study conducted in Gujarat to know about community pharmacist's knowledge and attitude towards pharmacovigilance and adverse drug reactions revealed that only 62% of the pharmacists had knowledge about pharmacovigilance, only 34% pharmacists knew the centers of pharmacovigilance in India. Many studies were conducted to know about the medical practitioners and hospital pharmacist's contribution in ADR reporting.<sup>3</sup> So this survey is conducted to study the attitudes and reporting behavior of community pharmacists and also to assess the knowledge of basic aspects of drugs safety.

### MATERIALS AND METHODS

This study was a prospective, questionnaire based survey conducted for a period of 8 months in different community pharmacies of two districts of Karnataka state. A suitable questionnaire was designed and prepared by referring literatures and administered to community pharmacists. The questionnaire contains the demographics details of community pharmacist, knowledge, attitude and behavior of community pharmacists regarding ADRs. The questionnaire was administered by the investigator personally to the community pharmacist to obtain the

response. The scoring pattern was, 1 for correct answers and 0 for the wrong answers for Knowledge assessment. For behavioral assessment 1 marks was given for providing the positive answers, zero was placed for negative responses. For the section of attitude on ADR reporting, following scoring pattern was followed, 5 for strongly agree, 4 for agree, 3 for disagree, 2 for strongly disagree and 1 for not sure. The results were analyzed statistically by using ANOVA and t-test to find the significance difference between two characteristics by using Statistical software SAS 9.2 by biostatistician. Institutional ethical committee clearance was obtained from Adichunchangiri Hospital & Research Centre for this study.

### RESULTS

Among 342 community pharmacies approached, 128 community pharmacists consented to participate in the study. The study response rate was 37.42%. Out of 128 community pharmacists, 107 (83.6%) were male, and 21 (16.4%) were female. Majority of the community pharmacists 69 (53.9%) were in the age group of 21-30 years and only 3 (2.3%) pharmacists were in the age group of 51-60 years. The mean age of the respondents was found to be 31.77±7.89. Pharmacists with Diploma in pharmacy education was 115 (89.8%) and 13 (10.2%) pharmacists had graduated in pharmacy. The mean years of experience of the pharmacist was found to be 7.99±5.83. Seventy nine (61.6%) of the pharmacists had an experience between 2-10 years and were more in number (Table 1).

Table 1: Demographic Details of Community Pharmacists

Gender	Number of respondents (n=128)	Percentage (%)
Male	107	83.6
Female	21	16.4
Age (in years)		
21-30	69	53.9
31-40	39	30.5
41-50	17	13.3
51-60	3	2.3
Mean ± SD:	31.77±7.89	
Educational background		
D Pharma	115	89.8
B Pharma	12	9.4

M Pharma	1	0.8
<b>Years of experience</b>		
<2.0	17	13.3
2.0-5.0	36	28.1
6.0-10.0	43	33.6
11.0-20.0	28	21.9
>20.0	4	3.1
Mean ± SD:	7.99±5.83	

Table 2: Comparison of Knowledge towards Adrs

Knowledge questions	Number of correct response given by community pharmacists	Percentage (%)
What is an adverse drug reaction (ADR)?	39	30.5
Statements regarding ADRs	37	28.9
The MOST common ADR with anti tubercular drugs	44	34.4
ADR when used NSAIDs for long time	56	43.8
A common side effect while administering inhaled corticosteroids	46	35.9
Dry cough is a common side effect of which drugs	29	22.6
Metallic taste is most commonly observed with which drugs	48	37.5

#### Knowledge

Among the respondents only 39 (30.5%) were able to answer correctly for the definition of ADRs and 37 (28.9) knew about probability and preventability of ADRs. Majority 56 (43.8%) of the respondents were aware of the most common ADRs that occurs due to use of NSAIDs and 48 (37.5%) respondents knew about the metallic taste that is caused by the use of Metronidazole. Only 44 (34.4%) consented pharmacists knew about the common ADR that is caused by the use of Anti-tubercular drugs (Table 2).

#### Behavior

All the respondents had observed ADRs in their practice but none of them have reported to any of the regional reporting centers. Forty six (35.9%) community pharmacists had reported ADRs that they have observed either to drug representatives or treating physicians, 120 (93.8%) respondents have guided the patients to stop the drug or to report physician. Forty (31.3%) respondents counsel the patients regarding ADRs of the drugs while dispensing (Table 3).

Table 3: Comparison Of Attitude Of Community Pharmacists Towards Adrs.

Attitude assessment questions	Strongly Agree	Agree	Strongly disagree	Disagree	Not sure
ADR reporting is professional obligation of pharmacists	16 (12.5%)	39 (30.5%)	20 (15.6%)	40 (31.3%)	13 (10.2%)
Systemic monitoring and reporting of ADR is important	30 (23.4%)	42 (32.8%)	25 (19.5%)	13 (10.2%)	18 (14.1%)

	20	25	24	28	31
after drug is marketed					
ADR reporting should be made compulsory	25 (19.5%)	43 (33.6%)	16 (12.5%)	19 (14.8%)	25 (19.5%)
Pharmacist should consult the physician before report of ADR	30 (23.4%)	36 (28.1%)	12 (9.4%)	14 (10.9%)	36 (28.1%)

Table 4: comparison of behavior of community pharmacist towards to adrs.

Behavior assessment questions	Number of respondents gave positive responses (n=128)	Percentage (%)
Have you reported any ADR that you have observed in a patient during your practice?	46	35.9
When you dispense drugs to the patients, do you advice them regarding the side effects of the drugs?	120	93.8
Do you tell the patient what to do in case if he/she develops a side effect?	32	25.0

Table 5: Correlation Between Age, Knowledge And Behavior Of Community Pharmacists Towards Adrs

Age in years	Number of respondents	Knowledge assessment	Behavior assessment
21-30	69	5.16±2.89	4.09±2.01
31-40	39	4.26±2.39	4.05±2.66
41-50	17	3.88±2.06	3.76±1.39
51-60	3	3.33±4.16	6.67±1.16
Total	128	4.67±2.71	4.09±2.17
Significance		F=1.814; P=0.148	F=1.559; P=0.203

#### Attitude

Only 17 (13.28%) respondents felt that pharmacists is a qualified health care professional to report ADR and 52 (40.62%) responded as only doctors could report (Table 4).

Among the 128 respondents, only 15 (11.71%) knew about the National Pharmacovigilance Programme (NPP) and 14 (10.93%) were aware of regional reporting centers. When the respondents were asked to express their level of agreements to some of the ADR related concerns the results were obtained as shown in table 3. Only 55 (43.0%) respondents agreed that ADR reporting is a professional obligation of the pharmacists and 66 (51.5%) responded that pharmacist should consult physician before reporting an ADR, which is not obligatory according to the NPP of India.

There were some barriers for not reporting ADRs. Among the pharmacists 92 were not knowing how to report an ADR and 64 pharmacists responded as 'did not feel ADR reporting would be beneficial (Table 9).

#### Assessment of Knowledge and Behavioral scores in association with demographic parameters

**Assessment of Knowledge and Behavior with age**

Knowledge association is found to be more in the age group 21-30 i.e.  $5.16 \pm 2.89$  and least found in the age group of 51-60 with

mean score of  $3.33 \pm 4.16$ . Community pharmacists with age group of 51-60 years had a more positive behavior with score of  $6.67 \pm 1.16$  and least in 41-50 age group pharmacists with  $3.76 \pm 1.39$  (Table 5).

**Table 6: Correlation Between Gender, Knowledge And Behavior Of Community Pharmacists Towards Adrs**

Gender	Number of respondents	Knowledge assessment	Behavior assessment
Male	107	$4.49 \pm 2.62$	$4.30 \pm 2.12$
Female	21	$5.62 \pm 3.01$	$3.05 \pm 2.16$
Total	128	$4.67 \pm 2.71$	$4.09 \pm 2.17$
Significance		$t=1.768$ ; $P=0.079+$	$t=2.462$ ; $P=0.015^*$

**Table 7: Association Of Education With Knowledge And Behavior Assessment**

Education	Number of respondents	Knowledge assessment	Behavior assessment
D Pharma	115	$4.68 \pm 2.75$	$3.98 \pm 2.09$
B Pharma/ M Pharma	13	$4.62 \pm 2.36$	$5.08 \pm 2.66$
Total	128	$4.67 \pm 2.71$	$4.09 \pm 2.17$
Significance		$t=0.077$ ; $P=0.937$	$t=1.735$ ; $P=0.085+$

**Table 8: Association Of Years Of Experience With Knowledge And Behavior Assessment .**

Years of experience	Number of respondents	Knowledge assessment	Behavior assessment
<2.0	17	$5.41 \pm 3.79$	$3.76 \pm 2.11$
2.0-5.0	36	$5.50 \pm 2.64$	$4.11 \pm 2.08$
6.0-10.0	43	$4.19 \pm 2.90$	$4.47 \pm 2.22$
11.0-20.0	28	$4.00 \pm 2.49$	$3.71 \pm 2.29$
>20.0	4	$4.00 \pm 1.63$	$4.00 \pm 2.31$
Total	128	$4.67 \pm 2.71$	$4.09 \pm 2.17$
Significance		$F=2.067$ ; $P=0.089+$	$t=0.621$ ; $P=0.649$

**Table 9: Barriers For Reporting Adrs.**

Responses	No. of respondents
Did not know that ADRs needs to be reported	29
Did not know pharmacists can report	45
Did not know how to report	92
Did not know how to get the reporting forms	50
Lack of time to involve in such activities	21
Did not feel that ADR reporting would benefit	64
Because it is an extra work	30
I don't have any benefit by reporting the same	35

**Assessment of Knowledge and Behavior with gender**

Association of knowledge in females 21 is ( $5.62 \pm 3.01$ ) more than males 107 ( $4.49 \pm 2.62$ ) and behavior score in females ( $3.05 \pm 2.16$ ) is less than males ( $4.30 \pm 2.12$ ). The knowledge association with gender is suggestively significant  $P=0.079+$  and the behavior is moderately significant ( $P=0.015^*$ ) (Table 6).

**Assessment of Knowledge and Behavior with education**

Community pharmacists with D Pharmacy (115) level of education had a good knowledge score of  $4.68 \pm 2.75$  than pharmacists with B Pharma/M Pharma (13) with score of  $4.62 \pm 2.36$ . Community pharmacists with B Pharma/M Pharma (13) had a better behavioral scores  $5.08 \pm 2.66$  than pharmacists with D Pharmacy (115) with score of  $3.98 \pm 2.09$  (Table 7).

**Assessment of Knowledge and Behavior with years of experience**

Four respondents with experience of more than 20 years (4) had knowledge score of  $4.00 \pm 1.63$  and pharmacists with experience of 2-5 years (36) and had maximum knowledge score of  $5.50 \pm 2.64$ . Behavioral assessment score is more in respondents with 5-10 years of experience, (43)  $4.47 \pm 2.22$  and less in the respondents with the experience of 10-20 years (28)  $3.71 \pm 2.29$  (Table 8).

**DISCUSSION**

The survey questionnaire was designed and prepared by referring previous studies conducted in abroad countries.<sup>4,7</sup> This is the first survey in Karnataka state to evaluate knowledge, attitude and behaviors of community pharmacists towards ADR related aspects according to our knowledge. However, the main limitation of the study was the poor response rate from community pharmacists and the response rate was found to be 37.4%. The low participation rate in the study and the failure to answer some questions (especially for the definition of pharmacovigilance and ADR) may be a consequence of poor knowledge of the term 'pharmacovigilance'. The ADR reporting rate was found to be nil in our study. Especially, none have reported to regional reporting centers but there was a high reporting rate to the medical representatives and physicians which may be indicative of an even lower level of pharmacovigilance awareness among the study population. Our study showed that age, gender or experience does not influence ADR reporting and found to have a similar results with a previous study from Istanbul.<sup>4</sup> It was previously shown that knowledge and attitudes exerted a strong influence on ADR reporting.<sup>5</sup> By interpreting the present study, we believe that the low rate of ADR reporting may be secondary to poor knowledge about ADR related aspects. The comparison between the socio demographic details of the respondents showed that the pharmacists within the age group 21-30 and with least experience had more knowledge about ADR and pharmacovigilance compared to elder respondents with age group of 51-60 years and experience with more than 20 years. On the other hand, the parameters like gender, qualification did not have

any significant difference in the knowledge of the respondents. However, attitudes are potentially modifiable variables. Hence, Granas et al<sup>6</sup> has shown that an educational program can significantly modify pharmacist reporting-related attitudes and influence the ADR reporting behavior in to a positive manner.

In the study conducted by Toklu HZ in Istanbul reported that the reasons for not reporting the ADR were lack of time, different care priorities, uncertainty about the drug causing ADR, difficulty in accessing forms, lack of awareness of requirements for reporting and lack of understanding the purpose of spontaneous reporting systems.<sup>4</sup> In our study, the explanations for not reporting ADR by the pharmacists was similar to the above mentioned reasons. Large number (92) of respondents detailed that they 'did not know how to report ADRs' and second most reason was that they 'did not feel ADR reporting was beneficial' and the other common reasons were 'did not know how to get reporting forms', 'did not know pharmacists can report', 'did not know ADRs need to be reported' and 'lack of time'.

In the developing countries, since the pharmacists are free healthcare consultants and they are easily accessed, patients always prefer to contact pharmacists in case of any drug suspected reaction. Therefore, pharmacists need to be actively involved in the surveillance of drug safety issues within the context of their practices. The pharmacist's role in pharmacovigilance may vary from country to country, but the professional responsibility is the same.

#### CONCLUSION

The results of the present study showed that the majority of the community pharmacists have insufficient knowledge about ADR and pharmacovigilance programme. Since there is a need of pharmacovigilance in the community pharmacy, under and postgraduate educational programs about ADR reporting and pharmacovigilance practice need to be included in the curriculum to improve ADR reporting.

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#### REFERENCES

1. Shrivastava B. India fails to report drug side effects. Accessed at URL: <http://www.livemint.com/2008/07/27235945/India-fails-to-report-drugside.html> Sept 15,2010.
2. Vivek D, Shivani D, Reema T, Avjit M. A study of Knowledge and attitude of community Pharmacists towards pharmacovigilance and adverse drug reactions in Gujarat. Proceedings of the 61st Indian Pharmaceutical Congress; 2009 Dec11-13; Ahmadabad, India.
3. Ghosh S, Ali S, Chhabra L, Prasad C, Gupta A. Investigation of attitudes and perception of medical practitioners on adverse drug reaction reporting - a pilot study. T. Ph. Res. 2010; 3:1-9.
4. Toklu HZ, Uysal MK. The knowledge and attitude of the Turkish community pharmacists toward pharmacovigilance in the Kadikoy district of Istanbul. Pharm World Sci. 2008 Oct; 30(5):556-62.
5. Herdeiro, Maria T, Figueiras, Adolfo, Polonia, Jorge et al. Influence of pharmacists' Attitudes on Adverse Drug Reaction Reporting: A Case-Control Study in Portugal. Drug Saf. 2006; 29(4):331-40.
6. Granas AG, Buajordet M, Stenberg-Nilsen H, Harg P, Horn AM. Pharmacists' attitudes towards the reporting of suspected adverse drug reactions in Norway. Pharmacoepidemiol and Drug Saf. 2007; 16(4):429-34.
7. Bawazir SA. Attitude of community pharmacists in Saudi Arabia towards adverse drug reaction reporting. Saudi Pharmaceutical Journal. 2006; 14(1):75-83.