

# An Evaluation of Knowledge, Attitude and Practice of Pharmacovigilance amongst the Prescribers of a Medical College Hospital in North Eastern State of India: A cross Sectional Study

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## ABSTRACT

**Background:** Spontaneous reporting is an important tool in pharmacovigilance. Underreporting of adverse drug reactions (ADRs) is a common problem. In order to improve the ADR reporting, it is essential to improve the knowledge, attitude and practice (KAP) of the healthcare professionals. Various factors are related with the KAP of under reporting of ADR.


**Objectives:** The present study was undertaken to evaluate the KAP regarding ADR reporting of among the prescribers of a tertiary care teaching hospital with ADR monitoring center in North Eastern state to get insight into the causes of underreporting of ADR.

**Materials and Methods:** It was questionnaire based cross sectional study. A questionnaire (knowledge -1-10, attitude -11-23 and practice -24-28) was administered to 200 prescribers. The questionnaire was assessed regarding the ADR reporting. Microsoft excels worksheet and chi-square test was used for statistical analysis.

**Results:** A total 170(85%) prescribers completed and returned the questionnaire. Regarding definition of pharmacovigilance, specific aim of pharmacovigilance, functions of ADR monitoring center (AMC), 93%, 79% and 51.8% participants respectively could answer correctly. Only 54% respondents opined correctly that reporting of ADR is voluntary. 76.5% participants know the existence of AMC in the institution. 27.6% participants expressed that ADR reporting will generate extra work. 22.4% of participants reported ADR. Regarding reasons of under reporting many factors has been pointed out namely "do not know how to report", "lack of knowledge about reporting procedure", "not knowing where to report", lack of time to report and lack of access to ADR form.

**Conclusion:** The medical professionals are aware and have partial knowledge about ADRs. However, under reporting and lack of knowledge about reporting system are clearly evident. There is great need of creating awareness about ADR reporting system. Regular sensitization program to motivate the medical professionals may improve the ADR reporting.

**Key Words:** Adverse drug reactions (ADR), Knowledge, Attitude and practice, Pharmacovigilance, Spontaneous reporting

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## INTRODUCTION

No medicinal product is entirely or absolutely safe for all people, in all places at all times. Safety and efficacy are two major concerns about any drug.<sup>1</sup> Adverse drug reactions (ADRs) are one of the major health care problems occurring throughout the world and encountered commonly in daily practice and many of which are preventable.<sup>2,3</sup>

The World Health Organization (WHO) defines Pharmacovigilance as 'the science and activities related to detection, assessment, understanding and prevention of adverse effects or any other possible drug related problem'.<sup>2,4</sup> It is an integral and essential part of patient care.

ADRs are negative consequences of drug therapy and one of the leading causes of morbidity and mortality. It

has been estimated that around 2.9-5.6% of all hospital admissions are due to ADRs and as many as 35% of hospitalized patients experience an ADR during their hospitalization. Spontaneous reporting of ADRs has remained the cornerstone and major sources of information of pharmacovigilance and is important in maintaining patient safety. However, reporting of serious ADRs rarely exceeds 10%. Underreporting of ADRs is a common problem and still remains a major obstacle in the complete success of Pharmacovigilance program.<sup>2,5,6</sup>

Spontaneous reporting of ADRs has played a major role in detection of unsuspected, serious, and unusual ADRs previously undetected during the clinical trial phases. This has led to the withdrawal of many drugs in recent past.<sup>2</sup>

The rate of underreporting of ADR is about 94% and only 6-10% of all ADRs are reported. Studies from different settings indicate inadequate knowledge about Pharmacovigilance among healthcare professionals as well as attitudes that are associated with a high degree of under-reporting.<sup>1,2,7</sup>

ADR are associated with a significant morbidity and mortality. The Literature depicts the incidence of ADR

to be 2.4 -6.5% even in western countries. In order to identify the culprit drugs causing ADRs several countries have initiated pharmacovigilance. Although pharmacovigilance program are successful in improving drug use patterns, but under-reporting of ADRs is the major problem.<sup>8,9</sup>

Pharmacovigilance is still in its infancy in India and there exists very limited knowledge about this discipline. However, Pharmacovigilance programme in India lacks continuity due to lack of awareness and inadequate training to medical graduates about drug safety monitoring.<sup>6,7</sup>

India became a collaborating member of WHO-ADR monitoring program 30 years after its establishment. The pattern of drug use and ADRs in India is quite different due to socioeconomic, ethnic, nutritional and other factors. The Drug Controller General of India (DCGI) and Indian council of Medical Research (ICMR) have established ADR monitoring centers in many hospitals of India. Gross underreporting of ADR is a cause for a concern, the reasons for which may be lack of trained staff and awareness about detection, communication and spontaneous monitoring of ADRs<sup>10</sup>

Various factors have also been attributed for under-reporting of ADRs among health professionals. These factors are based on knowledge and perception of health professionals to reporting. The factors responsible for underreporting have not been extensively studied in India. Assessment of awareness of pharmacovigilance among the healthcare professionals is very important. To suggest possible ways of improving spontaneous reporting the need to investigate the knowledge attitude of doctors to ADR was felt.<sup>2, 11, 12</sup>

Effective generation of adverse effects data help in practicing evidence based medicine and thus prevents many adverse drug reactions.<sup>7</sup>

For improvement of the participation of health professionals in spontaneous reporting, it is necessary to design strategies that modify both the intrinsic (knowledge, attitude and practices) and extrinsic (relationship between health professionals and their patients, the health system and the regulators) factors. A knowledge, attitude, and practice (KAP) analysis may provide an insight into the intrinsic factors and help understand the reasons for under-reporting.<sup>3</sup>

The pattern of drug use and ADRs in India is quite different due to socioeconomic, ethnic, nutritional and other factors.<sup>1</sup> Knowledge, attitude and practice (KAP) regarding ADR reporting has not been studied extensively in India.<sup>3</sup> Assessment of KAP of Pharmacovigilance among the health care professionals is very important. In order to improve the reporting rate, it is important to improve the KAP of the health care professionals regarding ADR reporting and Pharmacovigilance.<sup>11</sup> This type of study may suggest possible ways and educational intervention to improve

spontaneous reporting from the North Eastern part of the country.

Considering the deep concern over the KAP of Pharmacovigilance prevailing amongst the prescribers of a tertiary care hospital, present study has been conducted to investigate the KAPs of prescribers of a Govt. Medical College towards the pharmacovigilance with the objective:

- i. To assess knowledge, attitude and practice (KAP) of Pharmacovigilance amongst prescribers of a Medical College Hospital.
- ii. To find out the reason for not reporting ADRs.

## MATERIALS AND METHODS

**Study Design:** A cross sectional study was carried out to evaluate the KAP amongst the different grades of prescribers of a tertiary care hospital of a Government Medical College in North Eastern State towards the pharmacovigilance during the assigned study period of two months (August '1- September '30, 2014). Total 170 prescribers participated in the study which belongs to different categories like Faculty consultants (Professor, Assoc Prof & Asst. Prof.), Medical Officers, Residents and Post graduate students.

**Study Setting:** Study was conducted at a Govt. Medical College and a Tertiary Care Hospital in North Eastern Region of India for period of two months (August '1- September '30, 2014).

**Participants:** Inclusion & exclusion criteria: Prescribers (Faculty consultants, Medical Officers, Residents and Post graduate students) from all specialties working in the Medical college Hospital have been enrolled in the study after obtaining an informed consent. The Health Professionals who did not want to give consent was excluded from the study.

**Data Source and Sampling Methods:** A list of different grade of prescribers was prepared with the help of Establishment section (Human Resource Department) of the Govt. Teaching Hospital and subjects was selected by simple random technique by using the random Number Table as per the calculated sample size.

**Study Tool & variables:** For the purpose of the study, a KAP questionnaire was used. This questionnaire has been designed using the precedence set by similar studies<sup>1, - 3, 5, 6, 11, 12</sup>. This questionnaire contains a total of 28 questions. Among the questions 10 (1-10) are related with Knowledge, 13 (11-23) are related with Attitude and 5(24-28) are related with Practice of Pharmacovigilance. All the questions were compulsory and subjects were asked not to disclose their identity. Every subject was given 30 minutes to fill up the questionnaire. Any clarification needed in understanding the questionnaire was provided. Ten Multiple Choice questions (MCQs) Sl. No. 1 to 10 (Annexure-I) were used to assess the knowledge of the prescribers about Pharmacovigilance.

The attitude of the prescribers towards pharmacovigilance was measured by the MCQ Sl. No. 11 to 23; Except for Question No. 12, 13 and 23 for rest of the attitude assessing answers were collected mainly on the basis of likert scale. The options provided were as follows:

- Strongly agree
- Agree
- Do not know
- Disagree
- Strongly disagree

The practice pharmacovigilance by the prescribers, included in study population was measured by the MCQ from Sl. No. 24 to 28.

**Sample Size:** Sample size was calculated based on the percentage (71%) of completed responder collected from the study of previous workers<sup>6,11</sup> by the following formula.

$$N = (1.96)^2 pq / L^2 = (3.84 \times 0.7 \times 0.3) / (10\% \text{ of } 0.7)^2 = 165$$

Where,

P = Percentage of Completed response as per recoded data (71%)<sup>6,11</sup>. Q = 1 - p = 1 - 0.7 = 0.3

L = allowable error = 10 % of confidence interval. Confidence interval = 95%

So, total sample size has been calculated 165 prescribers of teaching hospital. So 170 subjects have been taken for this study.

**Plan of analysis and Statistical tool:** Data obtained during the study period was analyzed statistically. Data entry and analysis was performed in computer using SPSS and MS Excel 2007. Result was expressed as the means and standard deviations, medians and ranges or

numbers and percentages and was compared among different subgroups of respondents. Descriptive statistics and other statistical tests like chi-square Test were applied as per applicability.

**Ethical consideration:** The study was done on approval of ethical committee of institute; vide No.F.4 (4-29) – AGMC/ Academic/ Students' Project/2014/360 dated 6<sup>th</sup> June 2014.

## RESULTS

In this hospital based cross sectional study, total 170 prescribers of various categories from various departments participated in the study with their due consent. Among the total 170 prescribers 62 (36.4%) were senior prescribers and 108 (63.5%) junior prescribers who belongs to different designations like Professor (n=9; 5.3%), Associate professor (n=14; 8.2%), Assistant professor (n=39; 22.9%), Tutor (n=12; 7.1%), Medical officer (n=31; 18.2%), Post graduate student (n=65; 38.2%)

The average period as prescribers for senior prescriber was 22.79 years and for junior prescriber was 7.73 years and majority of the prescribers did not suffer from any ADR (senior prescriber n=51 and junior prescriber n=99).

### Assessment of Knowledge about Pharmacovigilance

Knowledge about the pharmacovigilance among the participants was assessed by the knowledge questioner and the responses are shown in the Table 2. It shows the comparison of knowledge about the pharmacovigilance between the senior and junior prescribers.

From Fig.1 it is evident that the participants have good knowledge regarding question number 1, 2, 6, 10. And regarding question number 3, 5, 7, 8, 9 the knowledge is poor among half the number of the participants.

**Table 1: Demographic details of the health care professionals who participated in the KAP study on Pharmacovigilance**

	Senior Prescriber (N=62)	Junior Prescriber (N=108)
<b>Designations of Prescribers</b>		
Professor	9	-
Associate Professor	14	-
Assistant professor	39	-
Tutor/Registrar	-	12
Medical Officer	-	31
Post Graduate student	-	65
<b>Age of Prescribers:</b>		
20-40 years	7	85
41-60 years	47	23
>60 years	8	0
<b>Experience as prescribers:</b>		
Mean ± S.D (years)	22.79 ± 9.3	7.73 ± 6.9
<b>Personnel suffering from ADR</b>		
Suffered	11	9
Did not suffer	51	99

158(92.9%) prescribers have given the correct answer for question number 1(definition of pharmacovigilance). For question number 2, 135(79.4%) prescribers have given the correct answer for the specific aim of pharmacovigilance.

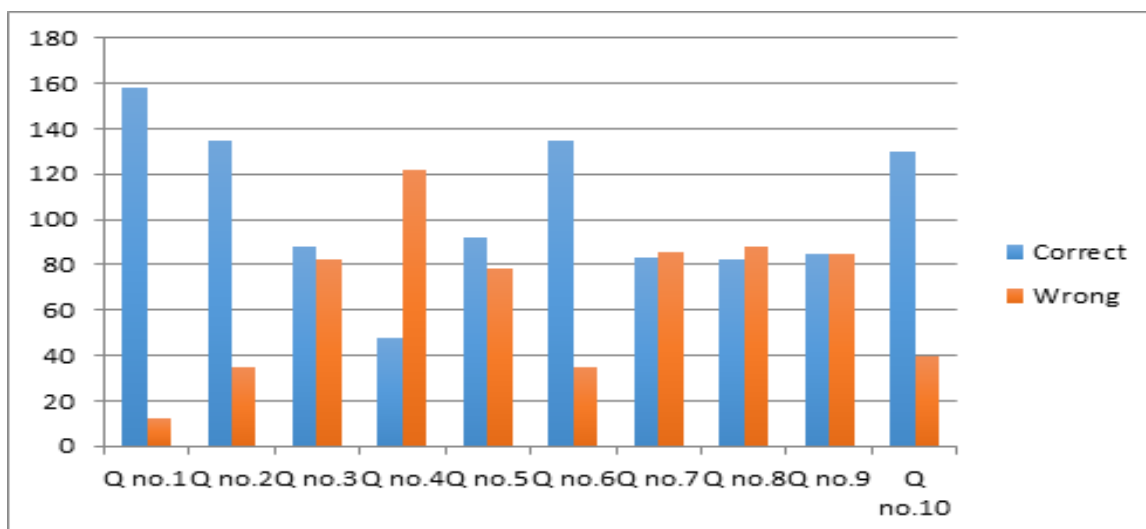
For question number 4, 101(59.4%) of the prescribers consider that physician can only report ADR, 48(28.2%) prescribers responded as authorized personnel, (8.2%) consider patients and 1(0.06%) and 6(3.5%) consider as nursing staff and pharmacist respectively.

92(54.1%) prescribers considers reporting of ADR as voluntary (Q %) but 58(34.1%) prescribers consider it as mandatory, 12(7.1%) considers as regulatory and 8(7.1%) consider it as compulsory.

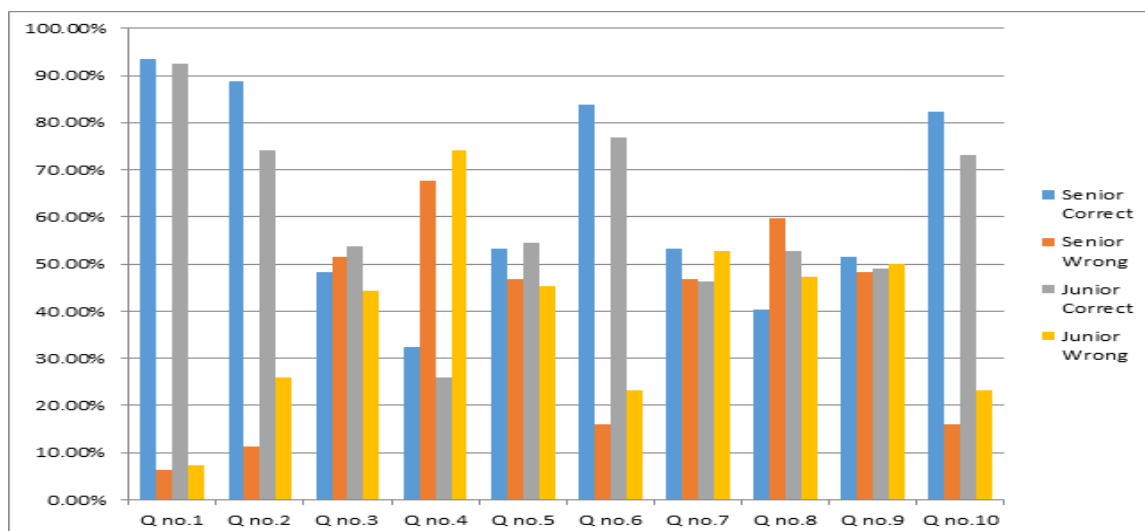
135(79.4%) prescribers consider all ADRs to be reported (Q 6) while a few i.e.; 31(18.2%) considers only serious ADRs to be reported. From responses of question number 10 it was found that 130(76.5%) prescribers were aware of the ADR reporting center in the institution while 35(20.6%) of them were unaware of an ADR reporting center.

**Table 2: Assessment of Knowledge of ADR (pharmacovigilance) among the prescribers of a tertiary care hospital**

	Senior Prescribers (n=62)		Junior Prescribers (n = 108)		Significance P value
	Correct	Wrong	Correct	Wrong	
Q No.1	58 (93.5%)	4 (6.4%)	100 (92.59%)	8 (7.4%)	0.628
Q No.2	55 (88.7%)	7 (11.2%)	80 (74.0%)	28 (25.9%)	5.106
Q No.3	30 (48.4%)	32 (51.6%)	58 (53.7%)	50 (46.3%)	0.628
Q No.4	20 (32.3%)	42 (67.7%)	28 (25.9%)	80 (74.0%)	0.779
Q No.5	33 (53.2%)	29 (46.7%)	59 (54.6%)	49 (45.3%)	0.031*
Q No.6	52 (83.9%)	10 (16.1%)	83 (76.8%)	25 (23.1%)	1.187
Q No.7	33 (53.2%)	29 (46.7%)	50 (46.2%)	58 (53.8%)	0.663
Q No.8	25 (40.3%)	37 (59.6%)	57 (52.7%)	51 (47.2%)	2.447
Q No.9	32 (51.6%)	30 (48.3%)	53 (49.0%)	55 (51%)	0.068
Q No.10	51 (82.3%)	11 (17.7%)	79 (73.1%)	29 (29.9%)	1.345



**Fig. 1: Assessment of Knowledge of ADR (pharmacovigilance) among the prescribers of a tertiary care hospital**



**Fig. 2: Assessment of Knowledge of ADR (pharmacovigilance) by categorizing prescribers into senior and junior prescribers in a tertiary care hospital**

On categorizing the prescribers into senior and junior prescribers it was found that there was not much significant difference between the knowledge regarding ADR (Pharmacovigilance) among the two categories of prescribers except Question No. 5, where junior set of prescribers were more aware ( $P < 0.05$ ) of the fact that reporting of ADR is voluntary.

It was found that both the categories of prescribers are enriched with knowledge about pharmacovigilance as 93.5% of senior doctors and 92.6% of junior doctors have given correct answer for the definition of pharmacovigilance.

But the knowledge about reporting procedure of ADR and ability to identify an ADR is comparatively poor in both the category of prescribers.

#### Assessment of Attitude about Pharmacovigilance

Assessment of attitude regarding ADR reporting (Pharmacovigilance) among the prescribers were assessed by Question No 11 to 23 and except question No 12, 13 and 23 other questions were assessed by five point Likert Scale. Responses in Likert scale are shown in Table 3.

Total 156 prescribers, consider that ADR reporting is a professional obligation (Q. 11) Only 9(5.3%) of prescribers disagree to this view.

From the response question number 12 it could be seen that 139(81.8%) of prescribers consider reporting of ADR is very important. Only one prescriber consider reporting of ADR is not important. Answers of Question number 13 reveals that prescribers think the factors which are important while reporting an ADR is

seriousness of ADR (116; 68.2%) and unusualness of the reaction (34; 20%). Responses of Question no. 23 shows that 99(58.2%) prescribers have free access to ADR reporting forms while 71(41.8%) does not have free access to ADR reporting forms.

It was found that total 118 prescribers support that "concern about wrong reporting" is the cause of poor reporting of ADR. Among them 11.8% of prescribers strongly agree with this viewpoint. Only 25(14.7%) of prescribers disagree with this. 86 (50.6%) Prescribers agree to the fact that lack of time to fill up the ADR form is one if the reason for under reporting of ADR. But 69 (40.6%) prescribers disagree to this opinion.

Majority of prescribers 74(43.5%) disagree that ADR reporting generate an extra work and this becomes the cause of under reporting and 24.7% of prescribers strongly disagree to this fact. Yet a 24.1% of prescribers agree to this fact.

#### Assessment of practice of Pharmacovigilance among the participants

This study reveals the fact that a huge number of prescribers 132(77.6%) do not report ADR. Only 38(22.4%) of prescribers reported ADR.

The reasons of under reporting of ADR by the prescribers has been shown in the Fig 3 and it is evident from Fig. that main reasons for under reporting of ADR were not knowing how to report (28.2%), lack of knowledge about reporting procedures (20%), Not knowing where to report(8.2%), lack of time to report (8.8%) etc.

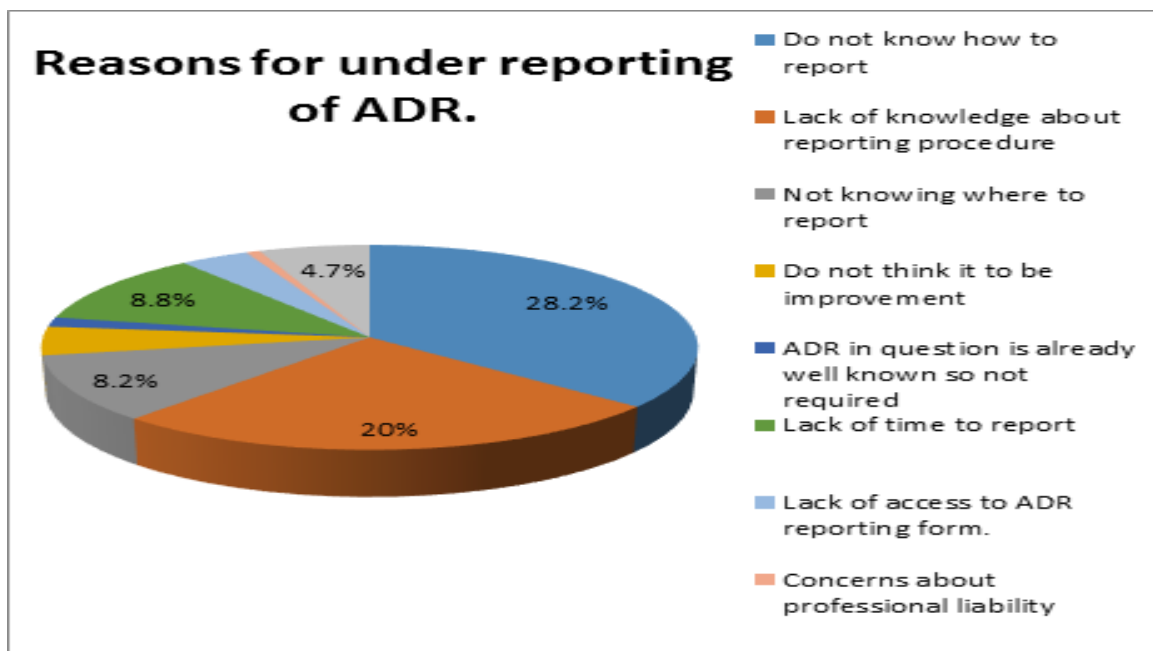


Fig. 3: Reasons for under reporting of ADR

It was found from this study that majority (82.4%) of participants have read articles about ADR. 148 (87.1%) prescribers haven't undergone any training on ADR reporting (Pharmacovigilance).

Table 3: Assessment of Attitude by Likert Scale regarding ADR reporting (Pharmacovigilance) among the prescribers of a tertiary care Hospital

		Strongly Agree	Agree	Do not know	Disagree	Strongly Disagree
Q.11	Senior prescriber	22 (35.4%)	35 (56.4%)	3 (4.38%)	2 (3.2%)	0 (0%)
	Junior prescriber	47 (43.5%)	52 (48.1%)	1 (0.9%)	7 (6.4%)	1 (0.9%)
Q.14	Senior prescriber	8 (12.9%)	36 (58%)	9 (14.5%)	9 (14.5%)	0 (0%)
	Junior prescriber	12 (11.1%)	62 (57.4%)	16 (14.8%)	16 (14.8%)	2 (1.8%)
Q.15	Senior prescriber	9(14.5%)	28 (45.1%)	10 (16.1%)	9 (14.5%)	6 (9.6%)
	Junior prescriber	24 (22.2%)	46 (42.5%)	10 (8.3%)	23 (21.2%)	5 (4.6%)
Q.16	Senior prescriber	1 (1.6%)	25 (40.3%)	15 (24.1%)	21 (33.8%)	0 (0%)
	Junior prescriber	8 (7.4%)	36 (33.3%)	42 (38.8%)	21 (19.4%)	1 (0.9%)
Q.17	Senior prescriber	3 (4.36%)	32 (51.6%)	6 (9.6%)	20 (32.2%)	1 (1.6%)
	Junior prescriber	9 (8.3%)	42 (38.8%)	9 (8.3%)	39 (36.1%)	9 (8.3%)
Q.18	Senior prescriber	2 (3.2%)	20 (32.2%)	9 (14.5%)	27 (43.5%)	4 (6.4%)
	Junior prescriber	7 (6.4%)	33 (30.5%)	10 (9.2%)	44 (40.7%)	14 (12.9%)
Q.19	Senior prescriber	2 (32%)	14 (22.5%)	8 (12.9%)	31 (50%)	7 (11.2%)
	Junior prescriber	2 (1.8%)	21 (19.4%)	17 (15.7%)	45 (41.6%)	23 (21.2%)
Q.20	Senior prescriber	3 (4.8%)	1 (1.6%)	2 (3.2%)	40 (64.5%)	16 (25.8%)
	Junior prescriber	4 (3.7%)	6 (5.5%)	11 (10.1%)	53 (49%)	34 (31.4%)
Q.21	Senior prescriber	2 (3.2%)	14 (22.9%)	2 (3.2%)	33 (30.5%)	11 (17.7%)
	Junior prescriber	4 (3.7%)	27 (25%)	5 (4.6%)	41 (37.9%)	31 (28.7%)
Q.22	Senior prescriber	2 (3.2%)	9 (14.5%)	6 (9.6%)	34 (54.8%)	11 (17.7%)
	Junior prescriber	2 (1.8%)	14 (12.9%)	12 (11.1%)	49 (45.3%)	31 (38.7%)

## DISCUSSION

ADR reporting is an integral part of pharmacovigilance and is important for patient care. Underreporting of ADR is a major threat to the success of pharmacovigilance program<sup>1</sup>.

The ultimate aim of pharmacovigilance is to ensure safe and rational use of medicine. The most important outcome of pharmacovigilance is the prevention of

patients being affected unnecessarily by the negative consequences of pharmacotherapy<sup>1,6</sup>.

After extensive literature search it was evident that KAP study about Pharmacovigilance is sparse in the North Eastern part of our country. So it was felt justifiable to conduct such type of study. The purpose of this study was mainly to assess the knowledge, attitude and practice of pharmacovigilance among the

prescribers and to find out the reason for under reporting if any. It was anticipated that this study would help to identify the causes of under reporting of ADR and accordingly a proper intervention can be planned based on the results of such types of study.

It was found in this study that majority of the participated prescribers are well aware of pharmacovigilance but the potential barrier was at practicing the acquired knowledge and this result is comparable with the finding of other studies<sup>3,10,11</sup>.

On analyzing the responses over the knowledge questionnaire it was found that 158(92.9%) prescribers have given correct answer for the definition of pharmacovigilance (Q. No 1) . 135 (79.4%) prescribers correctly identified the specific aim (Q. No.2) of pharmacovigilance and this is similar to the result obtained by Hardeep et al. 2013<sup>13</sup>. This is in contrast to the findings of Desai CK 2011 and Kulkarni MD 2013<sup>13</sup>. But the knowledge about who can report ADR (Q. No 4) was uncertain as 101(59.4%) prescribers answered as only physician, 48(28.2%) as authorized personnel, 14(8.2%) as patient and 1(0.6%) as nursing staff. The awareness that even a nurse, pharmacist can do so is very low. This finding is comparable with the finding of Gupta P & Udupa A, 2011<sup>11</sup>. Only 51 % of the participants could answer correctly the function of National Pharmacovigilance Center. This finding is at par with the finding of Gupta P & Udupa A, 2011<sup>11</sup> where they found that only 43% aware of ADR monitoring system by National Pharmacovigilance Center.

In this study 92(54.1%) prescribers answered that reporting of ADR is voluntary but there was 58(34.1%) who have thought that reporting is mandatory. This is in contrast to the finding of Gupta P et al. 2011<sup>11</sup> (Voluntary 86%) and Hardeep et al. 2013<sup>13</sup> (71% compulsory, 29% voluntary) and Karelia BN & Piparava KG 2014<sup>14</sup> (71% compulsory, 29% voluntary). It proves that status of knowledge about pharmacovigilance is different in place to place. In contrary to the finding of Desai CK et al. 2011<sup>3</sup>, it was found that 31(18.2%) prescribers consider that only serious ADR is to be reported and it is not as per the guideline of the Pv PI. It becomes necessary to report any untoward reaction of any pharmaceutical product to assess its safety and efficacy to ensure maximum patient health<sup>15</sup>. On assessing whether the participant is able to identify a drug reaction as ADR, brought out poor results, as only 83(48.8%) prescribers could correctly identify drug reaction (question no.7). From this it's clear that prescribers face the problem to identify a drug reaction as ADR. It was also found that 35(20.6%) participants were unaware of the existence of ADR reporting centre in the institution and the observations of this study is comparable the study done by Kulkarni et al. 2013<sup>1</sup> Palaian S et.al 2011<sup>6</sup>. So necessity of sensitization program for the health professionals on PvPI is felt very much.

On analyzing Attitude questionnaires, a positive attitude was obtained from the participants 87(51.2%) prescribers consider ADR reporting as a professional obligation and 69(40.6%) strongly agree to it. 139 (81.8%) prescribers consider it is very important to report ADR. This finding is in accordance with the finding of other studies<sup>3,9,11</sup>.

98(57.6%) prescribers agree that under reporting is mainly due to the concern that report may be wrong. 20(11.8%) strongly agree to this view point. Only 25(11.7%) prescribers disagree to this viewpoint. This result is in agreement with the finding of the study done by Gupta P & Udupa A, 2011<sup>11</sup>. 74(43.5%) prescribers agree that ADR reporting is the duty of pharmaceutical companies and legal medicine authorities, 33(19.4%) prescribers strongly agree to this. Only 32(18.8%) disagree to this. 57(33.5%) prescribers are not aware whether ADR reporting causes legal challenges which is at par of the finding of Hanafi S et al 2015<sup>5</sup>. So awareness program for the medical professionals is the need of the hour.

It is important to note that 74(43.5%) prescribers agree with that, physicians do not report ADR due to lack of time to fill in a report and 12(7.1%) prescribers strongly agree to this. It is also found that a significant number 59(34.7%) of prescribers disagree to this. It is also a point of concern that 93(54.7%) prescribers disagree that absence of ADR reporting is due to lack of fee for reporting. These findings are in conformity with the others studies done in different institutions<sup>6,11,12,14</sup>.

On contrary to the finding of Gupta P & Udupa A, 2011<sup>11</sup> (41%) in this study 41(24.1%) participants believe that physicians do not report ADR due to concern that ADR reporting will generate extra work but 74(43.5%) prescribers disagree to this fact and 42(24.7%) strongly disagree to this.

On assessing the practice questionnaire we got the present real picture of ADR reporting practice in the tertiary care hospital of a Govt. Medical College. It was found that a good percentage of prescribers (132; 77.6%) do not report ADR and the main reasons for under reporting pointed out as lack of knowledge about how to report (28.2%), lack of knowledge about reporting procedure (20%), concern that ADR reporting may generate extra work (17%) lack of time to report ADR (8.8%) and ignorance about reporting place (8.2%). The above observations points out to the lack of knowledge about reporting system as one of the causes of under reporting, Similar observations were also reported in other studies<sup>2, 3,5, 11,13,14</sup>.

In agreement with the finding of the other studies<sup>1,3,14</sup> of other researchers in this study out of 170 participants (prescribers) only 38(14%), report ADR. Among them there is uncertainty regarding ADR reporting centre and reporting format and this finding is comparable with the finding of Desai CK et al 2011<sup>3</sup>.

In this study it was found that 140(82.4%) prescribers have read articles regarding ADR and 87(51.2%)

prescribers shared information about ADR which is little higher than the finding of Desai CK et al, 2011<sup>3</sup>, who reported that 38.8% respondents shared information about ADR observed by them with their colleagues.

It was also found from this study that there was lack of training programs for prescribers on ADR as only 22(12.9%) prescribers have undergone training on ADR rest 148(87.1%) did not attend any training on ADR. But 153(90%) participants have shown their interest to undergo a structured training on ADR which is really encouraging for the policy makers. The lack of training programs can be a reason for inability of prescribers to identify ADR. In similar studies conducted by Hema N.G, Bhuvana K.B, and Sangeetha<sup>10</sup> and Khan SA et al 2013<sup>2</sup> and Desai CK et al, 2011<sup>3</sup> also pointed out the need for a training program or educational intervention to bring out an effective ADR reporting system.

A KAP study has certain limitations and it would be inappropriate to plan interventions solely based on the findings of this study alone. This was a single – center study involved limited number of medical practitioners; therefore, results of this study could not be directly extrapolated to other teaching hospitals or institutions.

The results of this study strongly suggest that underreporting of ADRs can be due to various reasons like gaps in the knowledge and attitudes. Work experience in a medical college does not influence the knowledge and attitudes of doctors toward reporting of ADRs. Perhaps, undergraduate and post-graduate training lacks in sensitizing the medical professionals for the responsibility of ADR reporting. However this study provides an insight in to the possible interventions that could be planed in future.

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