



**Pharmacovigilance And Adverse Drug Reaction Reporting: Assessment Of Knowledge, Attitudes, And Practice Of Govt Doctors Vs Private Practitioners In Gurugram District, Haryana, India**

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**ABSTRACT**

The present pilot study aims to compare the knowledge pertaining to ADR reporting systems that government doctors and private practitioners by conducting a questionnaire-based survey. Their knowledge of ADR reporting, related guidelines and/or regulations, the frequency of ADRs they observe and diagnose, their opinion on mandatory reporting by doctors, type of ADRs they would generally report, and to whom ADRs should be reported are discussed besides evaluating the attributable reasons for underreporting, if any. A total of 47 (21.36%) responded to this random survey, of whom 27 (57.4%) were government doctors and 14 (29.7%) were private practitioners. Interestingly, 68.2% of doctors from either group liked the idea of ADR reporting being made mandatory for doctors. The Chi-square test turned out to be significant with  $\chi^2 = 26.729$ ,  $p < 0.05$ , indicating there exists a difference between government doctors and private practitioners regarding the types of ADRs they would generally report. Lack of time, unavailability of ADR reporting forms, and system of reporting being too bureaucratic were cited as reasons for underreporting of ADRs. Creating awareness, among doctors of both groups, about ADR reporting via CME programs, offering incentives to reporters, and establishing ADR monitoring and reporting systems in hospitals and clinics under the supervision of pharmacists will help improve ADR reporting in Gurugram District in India.

## INTRODUCTION:

Effectiveness and efficacy are two attributes of a drug that are sought for whenever clinicians choose a drug to cure or treat an underlying ailment<sup>1-2</sup>. While effectiveness is the capacity of a drug to produce known pharmacological effect, efficacy is the ability of a drug to produce and reproduce, under ideal circumstances, a desired pharmacological effect<sup>3</sup>. Drugs also produce side effects (besides desired pharmacological effects) which are defined as normally unavoidable secondary effects of a drug at therapeutic levels/concentrations. These side effects, at higher doses or of higher severity are often termed as Adverse Drug Reactions (ADRs). Depending upon the severity ADRs can cause even hospitalization or death<sup>4-5</sup>. The International Conference on Harmonization (ICH) Guidelines for Good Clinical Practice (GCP) defines ADRs as a response to a drug that is noxious and unintended and that occurs at doses normally used in man for prophylaxis, diagnosis, or therapy of diseases or for modification of physiological function (World Health Organization [WHO] report 498, 1972).

In the recent years, deaths due to adverse drug reactions are increasing<sup>6-8</sup>. To lower the incidence or prevent those deaths, spontaneous reporting of ADR is the best possible way, and Desai et al. (2011) opined spontaneous reporting of ADRs as an important tool in pharmacovigilance. They also observed that, in daily practice, medical practitioners report very few adverse effects which are caused by drugs. According to the authorities at Central Drug Standard Organization (CDSCO), hospitalization, disability, and life-threatening reactions caused by the drugs need to be reported. But only a small portion of these are officially reported<sup>9</sup>.

It's possible that some or many other ADRs might have gone unreported during the course of the above referenced studies<sup>10</sup>. There are various reasons, as cited by researchers, for ADRs being not reported to the extent they should. A few are as follows:

- Lack of knowledge with regard to the guidelines/regulations of ADR reporting
- Lack of clarity regarding the responsibility (is it up to the doctor or to other medical staff [pharmacists/nurse] to report ADRs?)
- Too busy to report ADR/ ignorance with respect to ADR reporting
- Malfunctioning of an established ADR reporting system (unavailability of required forms), and so on.

Desai et al. (2011) evaluated the KAP (Knowledge, Attitude and Practice) of prescribers with regard to ADR reporting and found that though the attitudes are positive, practice is lacking, citing some of the above reasons. Many studies were conducted to evaluate the practice of ADR reporting in various parts of India and to suggest methods to streamline the system<sup>11</sup>. In an effort to understand the general trend of the ADR reporting system in those tier-II and tier-III cities and to

contribute to the general understanding of the knowledge of ADRs and its reporting systems across India, this study was proposed. Methodology was similar to other studies<sup>12</sup>. The survey questionnaire was administered randomly to prescribers and the statistical methods like Student T- test and Chi-square test were used. Prime motive of this research was to study and understand the general trend of this ADR reporting system in a randomly selected tier-II city, analyze restraints to this system (if any), and suggest ways to establish a perfectly functional system, if need be<sup>13-14</sup>. This research study could serve as a foundation study in the randomly selected city in tracking the trend of ADR reporting system and in suggesting changes (if needed) from time to time<sup>15</sup>.

### Purpose

The present study was undertaken to investigate the knowledge that private practitioners and government appointed doctors gained about the ADR reporting system and/or the guidelines thereof, in a random locality (Gurugram city) in India.

### Objectives

#### Primary Objective (Research Question)

Are the doctors (both private practitioners and government appointed) in a random locality in India familiar with ADR reporting system (and/or guidelines/regulations)? If yes, do they take responsibility in reporting ADRs or do they rely on their staff to do so?

#### Secondary Objective:

- To determine the factors responsible for under-reporting of ADRs (if any)
- To suggest ways of increasing the ADR reporting

### Hypothesis

**Null Hypothesis (Ho):** All doctors, both private and government-appointed doctors, have enough knowledge of the guidelines/regulations for ADR reporting and they do take responsibility in reporting ADRs to pharmacovigilance authorities or the pharmaceutical companies.

**Alternate Hypothesis (H1):** There is a difference in the knowledge that private practitioners and government doctors have regarding the guidelines/regulations of ADR reporting and the clarity they have regarding the responsibility of ADR reporting.

## METHODS

### Study Design

The study was designed as a cross sectional, observational, questionnaire based survey. A questionnaire was drafted based on earlier studies and in a way that best suites the Indian setting and the locality in question. All subjects could answer the questionnaire with ease. The questionnaire was administered to over 200 subjects, selected at random, so as to represent the sample under study, and to have statistical validity.

### Setting

The study was conducted in Gurugram District of Haryana, inhabited by a population of 27,928,000 (Census of India, 2018). A total of over 820 medical practitioners, distributed throughout the city, provide medical care (through various specialties) to the population. The study was conducted over a period of three months from February, 2018 to April, 2018. Entire area of the city of Gurugram was covered which included East, West, Southwest and the Central zones.

### Questionnaire Development

A questionnaire consisting of 33 questions framed under six sections was prepared, adapted from previous studies on ADR reporting systems in India. However, the final questionnaire for the present study was unique in many regards to suit the purpose of the study and Indian setting. The questionnaire was structured to collect the demographics of the respondents (subjects of study) limited to their gender, field of study, specialty, type of practice and their experience, to start with. The rest of the questions were framed under sections-A through section-E that were designed to test the knowledge, attitude and current practice of doctors with regards to ADR reporting in the locality. A total of twelve questions were designed to evaluate the knowledge, three questions to test the experience they gained, three questions to assess their attitudes towards ADR reporting and ADR systems, six questions to evaluate their practice of ADR reporting and six questions to understand the factors, in their perspective, posed as a hindrance in an efficient pharmacovigilance program.

Questions on knowledge would help in gaining information with regards to understanding the concept of pharmacovigilance, ADRs and guidelines and/or regulations pertaining to the ADR reporting system by the prescribers in the locality. Questions oriented on the practice of ADR reporting system and its establishment in a hospital/clinic gave an insight into current practices of pharmacovigilance by the practitioners as well as governance, with respect to ADRs, by the Health Administration in the locality. Two questions were structured specifically to understand how willing are the prescribers to take upon the responsibility of screening, diagnosing and reporting ADRs. A series of six questions were framed into a section that covered various factors, as possible reasons, in the prescribers' perspective.

In order to maintain confidentiality about the participants, the entire questionnaire was designed to maintain anonymity. Design of the questionnaire includes consideration of question format that is, open-ended or closed ended. Provision was also made for suggestions on ADR reporting system and its establishment within hospitals and clinics besides specifying the reason for not having the system established in the first place.

### Subjects

A total of 220 doctors were chosen randomly, from among 820 registered medical practitioners serving the locality. The contact list was edited (de-identified) to only include contact e-mail id's of the doctors and sorted for common id's, if any. Later 220 doctors were selected randomly using their contact email id's. The selected doctors included both government appointed and private practitioners.

### Inclusion and Exclusion Criteria

An email was sent to each of these selected doctors with HTML link to the online survey. A letter accompanied each of these emails with a note for their informed consent. It was the doctors decision either to participate or withdraw from the study. Those who were not willing to participate in the study were suggested not to respond to the email sent. Those who had registered their response were deemed to have voluntarily participated in the study. Subjects were also informed that in case they wished to participate but have lost the HTML link previously sent, they could request the HTML link via email and the same was furnished in the letter document that accompanied the emails.

No specific inclusion and exclusion criteria were followed in the enrollment of subjects into this study except that subjects who did not answer the questionnaire were automatically deemed as excluded from the study.

### Data Collection And Statistical Analysis

The questionnaire was validated by reviews from research guide and practicing doctors. Questionnaire was distributed to ten doctors and were given a period of four days to answer. They were requested to note the time taken to answer the questionnaire in full and were requested to express their perspective on the suitability of the questionnaire to local setting. Upon satisfactory feedback, the questionnaire was distributed without any major changes. Those ten recorded responses were added to the original data collected. The questionnaire was distributed to all the subjects via email and were asked to register their responses in their free time. Considering the busy schedules of practicing doctors, all responses recorded in a 60 day time period were considered for the study, this was to give ample time for the subjects to participate in the study and to encourage non-respondents to participate in the study. Reminder emails were sent to non-respondents once in every two weeks.

Data collected were analyzed using a software - Statistical Package for Social Sciences (SPSS) version 23.0. Results of the study were presented with descriptive measures such as mean  $\pm$  standard deviation (for quantitative variables), median (for time related variables) and numbers with percentages and/or graphical presentations for categorical variables. All statistical analyses were performed at the Power of test at 80% and P value-0.05. Student T- test was used to compare means of two continuous variables. Chi-square test was performed to find the significant

difference between the knowledge in ADR reporting system of private practitioners and government appointed doctors. Chi-square test was also used to find out the association between two attributes for yes or no questions at P< 0.05 significant level. Item scores were awarded and were added together to create a composite score to find out the significant difference between those two groups.

**RESULTS**

**Demographic data (Response Rate)**

The survey was distributed to 220 doctors out of which 47 responses were registered, giving a 21.3% response rate. 30 respondents were male (64.8%) and 17 were female (36.2%). See Table 1.

*Table 1: Frequency distribution of gender of participants*

Gender	Frequency	Percentage
Female	17	36.2
Male	30	63.8
Total	47	100

This response rate was achieved only after reminders were sent at regular intervals (once in every two weeks) during the study period. More responses were recorded, comparatively, immediately after the reminders were emailed.

**Type of Practice and Experience**

A total of 27 subjects who responded to the study were doctors working in the government sector, that is in government run hospitals and/or clinics, which is a healthy 57.4%. On the other hand, a total of 14 (29.7%) respondents were private medical practitioners. See Table 2.

*Table 2: Experience of study subjects in their respective specialties in medicine.*

S.No	Experience (in Years)	Government practitioners		Private Practitioners		Total	Percentage (%)
		Male	Female	Male	Female		
1	<1	3	0	2	0	5	12.2
2	1-5	5	3	5	1	14	34.2
3	5-10	6	2	3	1	12	29.3
4	> 10	2	6	2	0	10	24.3
Total		16	11	12	2	41	100

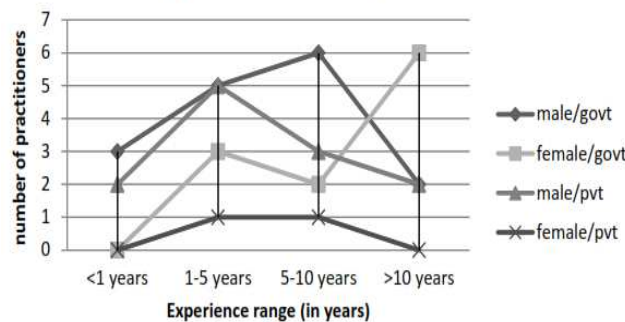
The rest of the six (6) responses recorded were by the staff of doctors. Five (5) of them were pharmacists and one (1) was a staff nurse. All the pharmacists worked in the private sector, of whom two (2) were male pharmacists and three (3) were female pharmacists. All pharmacists who responded to this survey on their doctors' behalf had 1 - 5 years of experience. The staff nurse who answered the questionnaire had greater than 10 years experience. The percentage response of non doctors was calculated to be 12.7% .

Average experience of both government doctors and private practitioners were calculated to be 6.75 years and 3.5 years respectively and the median of experience

was 5.12 years. Combined average experience of male doctors was 7 years and that of female doctors was calculated to be 3.25 years. However, there were a total of 6 (14.6%) female doctors with greater than 10 years of experience when compared to 4 (9.7%) male doctors with the same years of experience. Out of them, only 2 doctors had a private practice, the rest were working in the government run hospitals. A graph was plotted with number of practitioners against their years of experience in both private and the Government hospitals/clinics to observe a pattern, if any. Results are shown graphically in Figure 1.

*Figure 1: Line graph showing differences in the range of experiences gained by doctors (male and female) in the government sector and private sector.*

**Government vs Private practitioners  
(male vs female) n=41**



It is clearly evident from the graph that, comparatively, government doctors had more experience than the

private practitioners. It was found that there were only two female doctors who have a private practice while

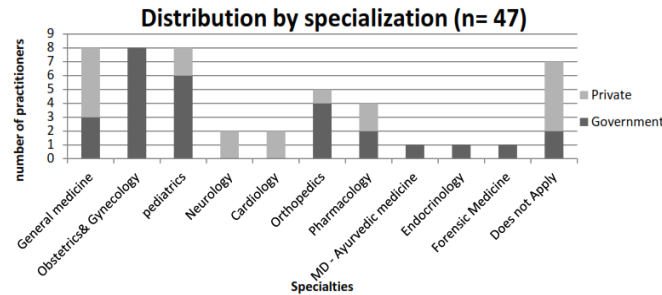
there were 11 working on government run hospitals/clinics.

**Specializations of respondents**

It has been observed that 6 (12.7%) non-doctors have registered their responses on behalf of doctors whom they worked for. Assuming the fact that surveys were administered only to doctors, it hints that the doctors were too busy to answer the questionnaire and instead had their support staff answer the same which was

anticipated. The other 40 (85%) of the responses were by doctors who specialize in different areas of medicine (Figure 2). A trend has been observed though. Doctors belonging to super specialties like Cardiology, Neurology and Endocrinology made up only 8% of the registered responses. Most of the responses were registered by people practicing internal medicine /OBGY/pediatrics/orthopedics.

Figure 2: Distribution of number of respondents to survey by their specialization and type of practice



The graph validates random distribution of the survey with respect to the specialty of respondents with the fact that doctors specializing in Medical pharmacology, forensic medicine and Ayurvedic medicine were also surveyed.

**Adverse Drug Reaction reporting - Knowledge**

There were mixed responses from subjects to questions in this section. The responses are distinctive: 33 subjects (70%) reported they have observed ADRs in the past twelve months of which only 27 (57%, n= 47) diagnosed ADRs. More importantly, only 23 (48.9%) subjects have reported ADRs to either pharmacovigilance centers/pharmaceutical companies. The survey indicated that majority of the subjects observed less than 25 ADRs in a six month period. On

the other hand, only 13% reported ADRs to pharmacovigilance centers and 28% reported to the companies.

A total of 34% respondents revealed that they neither had any information on current ADR reporting systems established in the area, nor had they any past knowledge in regards to ADR reporting systems. However, they all exercised knowledge of the country's guidelines and/or regulations pertaining to ADR reporting. Most of the respondents gathered information on ADR systems either verbally from colleagues (30%) or through Continuing Medical Education (CME) programs (23%). A total of 28% respondents were willing to update their knowledge with respect to the guidelines and/or regulations on ADR reporting. (See Table 3).

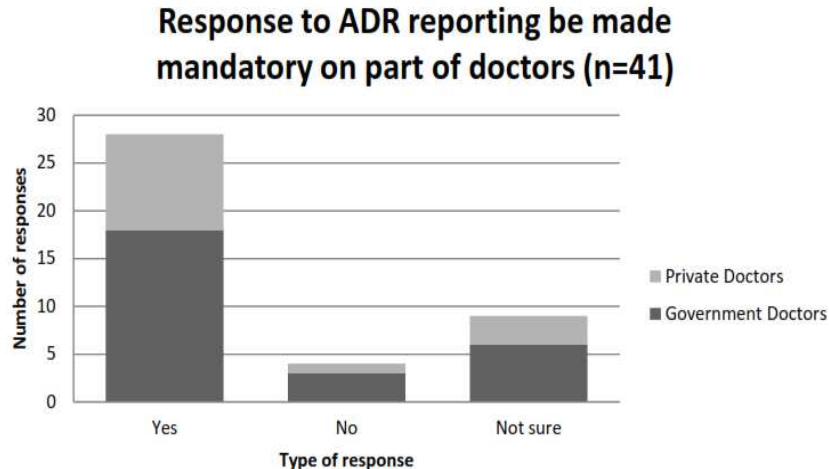
Table 3: Showing responses to questions 1-5 in section A (n=47 unless specified).

S. No	Questions	Yes	NO	Does not apply/do not remember / not
1	Have you observed ADRs in the past 12 months?	33	14	
2	Did you diagnose ADRs in the past 12 months?	27	10	10
3	Did you report ADRs to Pharmacovigilance centers or companies?	21	26	
4	Would you like ADR reporting be made mandatory on part of doctors? (n= 41)	28	4	9
5	Did you receive any information regarding ADR reporting in the past 12 months/ have you had past knowledge with regards to it ?	30	16	1

On the contrary, only 28 (68.2%) subjects liked the idea of ADR reporting being made mandatory, while 4 (9.7%) subjects did not like the idea, indicating the reason that they cannot devote time to report ADRs. Out of the 68.2% who liked the idea of ADR reporting be made mandatory, most of them were inclined towards

having their staff report ADRs to centers, while they themselves would diagnose and confirm ADRs. A total of 21.9% subjects were not sure if they would or would not like the idea of ADR reporting being made mandatory. Results are displayed graphically in Figure 3.

Figure 3: Bar chart showing response to ADR being made mandatory (n=41).



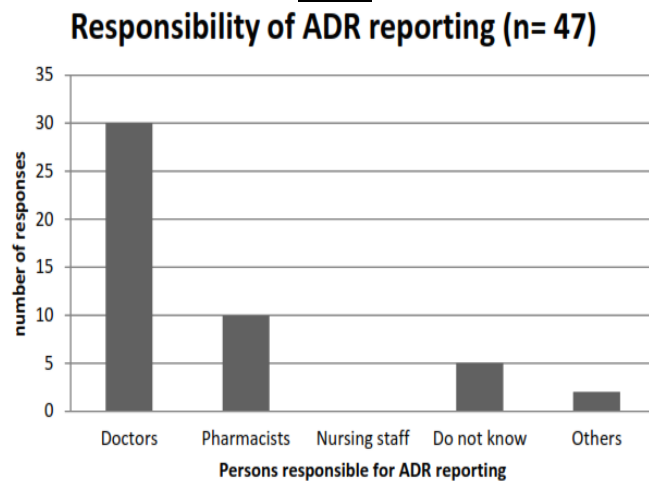
Nine subjects explained why they did not have an ADR reporting system established at their clinics/hospitals. It was evident that some were not aware of the system. One subject pointed to the lack of support from health administration and lack of initiative from hospital management as the reason for not having an established ADR reporting system. Most of the subjects were willing to report ADRs with the support of a clinical pharmacist.

#### ADR reporting - Attitude and practice

It was evident from the survey that most of the subjects had positive attitudes towards ADR reporting. Most of

the subjects felt that doctors should report ADRs themselves. A total of 30 (63.8%) respondents out of 47 believed in doctors reporting ADRs to either pharmacovigilance centers or the pharmaceutical companies. With one question cross-referencing the reason for not having an established ADR reporting system at clinics/ hospitals, the response of 10 subjects (21%) was that they are justified in thinking that pharmacists should report ADRs. The data is summarized and presented graphically in figure 4.

Figure 4: Bar graph representing the perspective of the subjects to ADR reporting being made mandatory on part of doctors.



#### Types of ADRs generally reported by subjects

Upon analysis, a significant difference was observed between the two groups (government and private practitioners) of doctors with regards to the type of reactions/medical occurrences they would generally report to either pharmacovigilance centers or pharmaceutical companies. When asked if they would report any suspected serious reactions to an established product that they have observed, almost all the government doctors 27(96.4% within group) said they would definitely report such reactions, while only 1(3.6% within group) respondent said he/she might report such reactions. On the other hand, 14(73.7%

within group) private practitioners answered they would definitely report and 5(26.3% within group) responded they might report (Table 4). With regards to reporting all suspected reactions to new products, 19 (67.9% within group) government doctors said they would definitely report and 9(32.1% within group) said they might report. It was observed that a total of 12(63.2% within group) private practitioners said they might report all new suspected reactions to new products, while only 7(36.8% within group) answered they would definitely report such reactions. There lies a significant difference between the government and private practitioners in this regard (Table 4).

Table 4: Chi-square analysis with calculated percentages within groups.

s.no	Type of ADRs	Type Of doctors	Recorded responses			Total	Chi-square value	p-value	Df
			Definitely Would report	Might Report	Definitely Would not report				
1	Serious suspected reactions to established products	Govt.	27 (96.4%) 0.5 (SR)	1 (3.6%) - 1.4 (SR)	-	28	5.258	0.022	1
		Pvt.	14 (73.7%) - 0.6 (SR)	5 (26.3%) 1.7 (SR)	-	19			
2	All suspected reactions to new products	Govt.	19 (67.9%) 0.9 (SR)	9 (32.1%) - 1.0 (SR)	-	28	4.405	0.036	1
		Pvt.	7 (36.8%) - 1.1 (SR)	12 (63.2%) 1.2 (SR)	-	19			
3	Life threatening reactions regardless of product age	Govt.	27 (96.4%) 0.6 (SR)	1 (3.6%) - 1.6 (SR)	-	28	7.005	0.08	1
		Pvt.	13 (68.4%) - 0.8 (SR)	6 (31.6%) 1.9 (SR)	-	19			
4	Disability (significant, persistent or permanent) - regardless of product age	Govt.	27 (96.4%) 0.5 (SR)	1 (3.6%) - 1.4 (SR)	-	28	5.258	0.22	1
		Pvt.	14 (73.7%) - 0.6 (SR)	5 (26.3%) 1.7 (SR)	-	19			
5	Hospitalization (initial or prolonged) regardless of product age	Govt.	17 (60.7%) 0.4 (SR)	11 (39.3%) 0.1 (SR)	0 (0%) - 1.3 (SR)	28	4.803	0.91	2
		Pvt.	9 (47.11%) - 0.5 (SR)	7 (36.8%) - 0.1 (SR)	3 (15.8%) 1.6 (SR)	19			

(SR = Standard Residual, df = Degree of freedom ).

Similar to the responses registered for the first question in this section, 27 (96.4% within group) government doctors answered they would definitely report all life-threatening reactions and only 1(3.6% within group) responded he/she might report them. On the contrary, there were 6(31.6% within group) private practitioners who said they might report the reactions despite them being life threatening (Table 4). Government doctors were consistent in their knowledge of what kind of reactions they feel should be reported, and a similar 27(96.4% within group) respondents said would definitely report reactions causing disability, and 1(3.6% within group) respondent said they might report reactions causing disability.

A mixed response was recorded when the subjects of this survey were asked if they definitely would, might or definitely would not report ADRs that cause initial or prolonged hospitalization. Close to 40% (within group) in either of the groups responded they might report such reactions, and specifically 3(15.8% within group) private practitioners said they definitely would not report such ADRs that cause initial or prolonged hospitalization. All the data were analyzed and summarized in Table 4.

From table-4, it can be inferred that the Chi-square significance between the government doctors and private practitioners, with regards to the type of ADRs

they would generally report, was significant with  $n=47$ ,  $df=2$ , (total)  $\chi^2=26.729$ ,  $p < 0.05$ . There was no significant difference though between the government doctors and private practitioners with regards to reporting such ADRs that lead to either initial or prolonged hospitalization, with a  $\chi^2=4.803$ ,  $p > 0.05$  at a 2 level degree of freedom. Though the Chi-square turned out to be significant for variables 1, 3 and 4, each of the 2x2 tables had at least 2 cells with expected count  $< 5$  that make the data invalid. Upon observation, with a standard residual 1.7, 1.9 and 1.7 (all close to 2) respectively, these groups of private practitioners influenced this outcome.

#### Factors that encourage ADR reporting

Reactions to new products and seriousness of the reactions were the two factors that encouraged ADR reporting as per the results. On the other hand, unusual reactions and degree of confidence in diagnosis of ADRs were not a major factor that influenced ADR reporting.

A total of 27(96.4% within group) government doctors felt that seriousness of the reactions to products does influence their reporting of ADRs, while a similar percentage, 14 (94.7% within group) of private practitioners, felt the same. There was no significant difference between these two groups in this regard with

a  $\chi^2$  value of 2.156 at a 2 level degree of freedom and  $p > 0.05$  (Table 5).

There was also no significant difference in the opinion of both groups regarding the influence of degree of confidence in the diagnosis of ADRs. A total of 8(28.6% within group) government doctors and 7(36.4 % within group) private practitioners felt there is no necessity

to report the degree of confidence in diagnosing ADRs and that it does not influence their reporting of ADRs. (Table 5).

However, there was a significant difference between government doctors and private practitioners regarding the influence of unusual reactions on reporting with a  $\chi^2$  value of 7.404,  $p < 0.05$  ( $n= 47$ ). Table 5 illustrates the analysis of factors influencing ADR reporting.

Table 5: Chi-square analysis of factors that encouraged ADR reporting.

S.no	Factors	Type of Doctors	Recorded responses			Total	Chi-square	P-value	Df
			Not required	Required	Unsure				
1	Unusual reactions	Govt.	1 (36%) -1.4 (SR)	23 (82.1%) 0.2 (SR)	4 (14.3%) 1.0 (SR)	28	7.404	0.025	2
		Pvt.	5(26.3%) 1.7 (SR)	14 (73.7%) - 0.2 (SR)	0 (0%) - 1.3 (SR)	19			
2	Reactions to new products	Govt.	0 (0%) - 1.3(SR)	24 (85.7%) 0.3 (SR)	4 (14.3%) 0.2 (SR)	28	4.749	0.093	2
		Pvt.	3(15.8%) 1.6 (SR)	14 (73.7%) - 0.3 (SR)	2 (10.5%) - 0.3 (SR)	19			
3	Seriousness of the reactions	Govt.	1 (36%) 0.5 (SR)	27 (96.4%) 0.0 (SR)	0 (0%) - 0.8 (SR)	28	2.156	0.340	2
		Pvt.	0 (0%) - 0.6 (SR)	18 (94.7%) 0.0 (SR)	1 (5.3%) 0.9 (SR)	19			
4	Degree of confidence on diagnosis of ADRs	Govt.	8(28.6%) - 0.3 (SR)	18 (64.3%) 0.5 (SR)	2 (7.1%) - 0.2 (SR)	28	2.432	0.488	3
		Pvt.	7(36.8%) 0.4 (SR)	9 (47.4%) - 0.6 (SR)	2 (10.5%) 0.3 (SR)	18			

(SR = Standard Residual, df = Degree of freedom ).

Similar to the earlier section, Chi-square turned out to be significant for the first variable despite an expected count of 4 cells  $< 5$  (1.62). Cumulative  $\chi^2 = 16.741$ ,  $n = 47$ ,  $p > 0.05$ .

**Factors affecting ADR reporting**

Unavailability of ADR reporting forms was considered as one of the major factors affecting the overall reporting rate as represented by the data. However, the rest of the factors also turned out to be contributing to the low ADR reporting rate. Chi-square association was found to be insignificant with a cumulative  $\chi^2 = 18.669$ ,  $p > 0.05$ ,  $n = 47$  except for variable (factor) 6, which

turned out to be significant with  $\chi^2 = 8.196$ ,  $p < 0.05$ . But, the data would be consider invalid as none of the calculated standard residuals were 2.0, and also for the 6 variables in question, the expected count was found to be a minimum of 2 cells less  $< 5$ .

However, for the sixth variable, the Chi-square was significant at  $p < 0.05$  with a value 8.196. But, there was not much difference in the standard residual value, and the private practitioners in particular contributed to the significance which reiterates the inequality in the distribution of the sample. Results are tabulated in table 6.

Table 6: Chi-square analysis of factors affecting the ADR reporting (system or practice)

S. no	Factors	Type of Doctors	Responses			Total	Chi-Square	p-value	Df
			Agree	Disagree	Neither agree nor disagree				
1	System of reporting is too bureaucratic	Govt.	7 (25%) - 0.1 (SR)	6 (21.4%) 0.6 (SR)	15 (53.6%) - 0.3 (SR)	28	0.979	0.613	2
		Pvt.	5 (26.3%) 0.1 (SR)	2 (10.5%) - 0.7 (SR)	12 (63.2%) 0.3 (SR)	19			
2	Too busy to send an ADR report	Govt.	1 (3.6%) - 1.1 (SR)	15 (53.6%) 0.0 (SR)	12 (42.9%) 0.6 (SR)	28	4.110	0.128	2
		Pvt.	4 (21.1%) 1.4 (SR)	10 (52.6%) 0.0 (SR)	15 (26.3%) - 0.7 (SR)	19			
3	Report forms not available when needed	Govt.	14 (50%) - 0.8 (SR)	11 (39.3%) - 0.6 (SR)	3 (10.7%) - 0.3 (SR)	28	2.636	0.268	2
		Pvt.	5 (26.3%) - 1.0 (SR)	11 (57.9%) 0.7 (SR)	3 (15.8%) 0.4 (SR)	19			
4	Feel that you would be exposed to legal liability by reporting an ADR	Govt.	2 (7.1%) 0.2 (SR)	23 (82.1%) 0.1 (SR)	3 (10.7%) - 0.3 (SR)	28	0.305	0.858	2
		Pvt.	1 (5.3%) - 0.2 (SR)	15 (78.9%) - 0.1 (SR)	3 (15.8%) 0.4 (SR)	19			
5	Believe that only safe drugs are	Govt.	1 (3.6%) - 0.9 (SR)	24 (85.7%) 0.2 (SR)	3 (10.7%) 0.4 (SR)	28	2.443	0.295	2

(SR = Standard Residual, df = Degree of freedom).

## DISCUSSION

In the interest of public safety, the formidable strength of ADR reporting systems is its ability to continuously and spontaneously collect all such undesired reactions associated with drugs throughout their life cycles. Though the concept of pharmacovigilance emerged in the mid 1900's, it has been observed, throughout the world, that many factors influence doctors in reporting ADRs, and often the reporting rate was low.

In India, the concept of pharmacovigilance is relatively new, compared to the other developed nations like the UK and USA. Despite reviewing the NPP in the year 2010, there was a predominant under-reporting of ADRs in India, according to studies by Rishi, Patel and Bhandari (2012) and Karkhar and Bowelakar (2012). Other studies conducted in the cities of Mumbai, Mysore and Muzaffarnagar, as reported by Desai et al. (2011) have shown high knowledge but poor practices with regards to ADR reporting. This study was an attempt to understand and compare, between government doctors and private practitioners, the knowledge, attitudes and practices with regards to ADR reporting in a Tier-II city. This study has found that both the government and private doctors have an adequate knowledge and possessed positive attitudes towards ADR reporting systems, but their practices were poor (with some exceptions).

The overall response rate was 21.3%, which is less compared to other survey's administered by Desai et al. (2011), who documented a 61% response rate and another similar survey by Gupta and Udupa (2011) who reported a response rate of 77.2% (which were similar to rates documented in studies from Germany, United Kingdom, Italy, Nigeria and the Netherlands). But, the

ratio of male to female respondents to this survey was comparable to other studies that recorded similar frequencies of male and female participants. However, this response rate was indicative of the factors affecting the practice of ADR reporting by both groups of doctors. Having said that, this could be a rather satisfactory response rate following repeated reminders sent every two weeks, given the limitations of this study.

A total of 27 (57.4%) government doctors and 14 (29.7%) private doctors responded to this survey. The comparison could have been effective had the percentage of respondents in the private practitioners group increased. It was understood that many doctors working in the government run hospitals also had a private practice of their own, but instead, chose to be identified as government doctors. A choice was given in this regard to study subjects in the study consent: if they wished to be identified as a private practitioner or as a government doctor when they fulfilled both, and as a result we see a higher number of responses registered in the group of government doctors.

The average practice experience of government doctors was high with 6.75 years of experience, while the private practitioners only had an average of 3.5 years of experience (Figure 1). This could be attributed to the fact that government institutions (hospitals/clinics) relied on experienced doctors to treat patients in need of treatment and believed that the more the experience, the greater the skill a doctor has. An interesting observation was that there was a greater number of female government doctors with greater than 10 years of experience compared to male doctors. Many of the private practitioners had an experience ranging between

1-10 years, and there were only two private practitioners who reported they had greater than 10 years of experience (Table 2). A proper statistic, with regards to this difference in the experience gained, could only be obtained with a bigger sample size. Nonetheless, it had been observed that knowledge of ADRs and their reporting systems is directly proportional to the experience gained through years of medical practice, based on a report by Upadhyaya et al. (2012) who stated that medical students had poor knowledge of ADRs/their reporting systems, while in another study, Rehan, Vasudev and Tripathi (2002), stated a need to incorporate a detailed concept of pharmacovigilance in the undergraduate medical curricula besides periodically strengthening this concept among the doctors.

Though the sample population was selected randomly (Figure 2), there were only a few respondents from specializations like cardiology, oncology, neurology etc. where there is large scope for occurrence of ADRs, owing to the fact that drugs used in the treatment of cardiovascular events or cancers or neuronal disorders are often potent chemical entities and exert a wide range of undesirable effects on the organ system and/or body. This low response to the survey from doctors belonging to these super-specialties might be due to their busy schedules. However, in the context of ADR reporting, it is important to devote quality time in reporting all those ADRs associated with the prescribed drugs despite busy schedules.

A majority of the doctors, indicated by the survey, observed less than 25 ADRs in a period of six months, which was a positive reflection on the knowledge, skill and awareness about ADRs among the doctors. However, only 57% of the doctors ever diagnosed ADRs and only 48% ever reported them. A majority (28%) of the respondents said they reported ADRs to pharmaceutical companies and only few reported ADRs to pharmacovigilance centers. This is a concern, as it reflects the failure of the NPP program. Few doctors reporting to pharmacovigilance centers might indicate poor knowledge with respect to the NPP program, which is consistent with the finding of 34% doctors' lack of information on the current ADR reporting systems established in the country. Though all the subjects of this study exercised adequate knowledge of the country's guidelines pertaining to ADR reporting, lack of information on the current practices of ADR reporting reflects their low interests in reporting the otherwise burdensome ADRs. This emphasizes the need to extravagantly propagate the established NPP program and the ADR reporting systems by creating awareness among the prescribers of the program and the systems. This is possible by regularly organizing CME programs with an emphasis on pharmacovigilance as a majority of the study subjects stated their intention to update their knowledge with respect to the guidelines and/or regulations on ADR reporting via CME programs, indicating a broad scope for change in their present attitudes towards reporting ADRs.

On the contrary, only 48% of doctors reported ADRs to either pharmacovigilance centers or pharmaceutical companies which is comparatively low. In a pilot study conducted by Kharkar and Bowalekar (2012), 19% of their subjects were found to have reported diagnosed ADRs to ADR/pharmacovigilance centers while a majority of their respondents, (89.7%) were said to have reported ADRs to pharmaceutical companies/DGCI/ other NGO's who have a statutory obligation to report to the drug authorities concerned. These figures are, however, low compared to other countries like the UK where a high spontaneous ADR reporting rate was recorded. Also reporting rates in relation to prescription volumes was best among the European countries (Rishi et al., 2012).

Establishing spontaneous ADR reporting systems (electronic/paper - like the yellow card system established by the CSM in UK) in hospitals and clinics and offering training, in the first place, on the working of such systems to doctors and their medical staff Assuring all the doctors that they will not be held legally liable for discrepancies in any such ADR reports Improving the system of pharmacies from merely filling prescriptions and dispensing to taking part in decision making during writing prescriptions as a primary care team member (Amrita and Roomi, 2011). Offering clinical pharmacists good training in ADRs and their reporting systems and also incorporating the same in their curricula. Clinical Pharmacists often make good supervisors for ADR reporting systems given their knowledge about drugs and their interactions (Amrita and Roomi, 2011). Periodically sending feedback to reporters on all the data gathered by NPP.

This will definitely have a positive impact as it gives assurance to all the reporters that each and every ADR report is being considered, in-turn, to update their knowledge. Doing so will also improve the working of NPP, ultimately paving the way to its success (Amrita and Roomi, 2011)

Sending warning letters or notifications to doctors regarding serious ADRs associated with drugs, immediately upon obtaining information from drug authorities/Pharmacovigilance centers (Amrita and Roomi, 2011). Educating patients about ADRs and encouraging them to participate directly in spontaneous ADR reporting. As it is believed that patients themselves will have a better understanding of how ADRs / related events affect their lives/life styles (Blekinsopp, Wilkie, Wang and Routledge, 2006)

#### **CONCLUSION**

There is a significant difference between government doctors and private practitioners of Gurugram District, with regards to the knowledge of ADR reporting systems. Government doctors exhibited good knowledge of ADRs and current ADR reporting systems established in the nation, while private practitioners had a little knowledge of current systems in place. However, all the doctors surveyed do have knowledge of the guidelines and/or regulations pertaining to ADR reporting in India. Both groups of

doctors had positive attitudes towards reporting ADRs, as a majority of them were open to the idea of ADR reporting being made mandatory on the part of doctors. However, some of them inclined towards having their support staff like pharmacists and/or nursing staff, report ADRs on their behalf which was also evident from 6 responses registered by non doctors in a survey drafted only for doctors. There is a need to improve the concept of pharmacovigilance in this city, which requires the participation of CDSCO via the NPP program.

The underreporting of ADRs in this city can be attributed to several factors as discussed earlier, but it would be inappropriate to generalize those factors and suggest ways to improve the situation based on a pilot study like this, which has certain limitations according to Launiala (2009). This was evident when a smaller group of private practitioners influenced the statistics. However, implementing the discussed suggestions would surely improve ADR reporting in this city, by motivating doctors to rigorously participate in pharmacovigilance programs in the best interest of public safety. There is also a need to conduct more research, with a larger sample size, including the adjacent cities, to the immediate North and South of this City. This would give a good sample size of doctors as these cities make the central zone of the District of Gurugram. Also, with a larger sample size, there is a possibility of a greater response rate and close to equal participation within both the groups of doctors.

#### REFERENCES

- 1) Amrita, P., & Roomi, M, T. (2011). Scenario of pharmacovigilance and ADR reporting among pharmacists in Delhi. *Indian Journal of Pharmacy Practice (Association of Pharmacy Teachers of India)*, 4, 4, 29-38.
- 2) Arulmani, R., Rajendran, D, S., & Suresh, B. (2008). Adverse drug reaction monitoring in a secondary care hospital in South India. *British Journal of Clinical Pharmacology*, 65, 2, 210-216. d.o.i: 10.1111/j.1365-2125.2007.02993.x.
- 3) Ballentine, C. (1981). Sulfanilamide Disaster. *FDA Consumer magazine*. Issue: June 1981. Retrieved from: <http://www.fda.gov>
- 4) Belton, K, J., Lewis, S, C., Payne, S., & Rawlins, M, D. (1995). Attitudinal survey of adverse drug reaction reporting by medical practitioners in the United Kingdom. *British Journal of Pharmacology*, 39, 223-226.
- 5) Bhatia, A., Kapoor, U., & Tayal, G. (2005). Study of knowledge regarding pharmacovigilance in a tertiary teaching hospital. *Indian journal of pharmacology*, 17, 39-46.
- 6) Biswas, P., & Biswas, A, K. (2007). Setting standards for proactive pharmacovigilance in India: The way forward. *Indian Journal of Pharmacology*, 39, 3, 124-128.
- 7) Blekinsopp, A., Wilkie, P., Wang, M., & Routledge, P, A. (2006). Patient reporting of suspected adverse drug reactions: A review of published literature and international experience. *British Journal of Clinical Pharmacology*. 63, 2, 148-156.
- 8) Breckenridge, A, M., Kitteringham, N, R., & Pirmohamed, M. (1998). Adverse drug reaction, *British Medical Journal (BMJ)*, 316, 1295-1298.
- 9) Craigle, V. (2007). MedWatch: The FDA safety information and adverse events reporting program. *Journal of the Medical Library Association*, 95, 2, 224-225.
- 10) Desai, K, C., Iyer, G., Panchal, J., Shah, S., & Dikshit, R, K. (2011). An evaluation of Knowledge, Attitude and Practice of adverse drug reaction reporting among prescriber's at a tertiary care hospital. *Perspectives in Clinical Research*, 2, 4, 129-136.
- 11) Dhikav, V., Singh, S., & Anand, K, S. (2004). Adverse Drug Reaction Monitoring in India. *JIAMS*, 5, 1, 27-33.
- 12) Edwards, I, R., & Aronson, J, K. (2000). Adverse drug reaction: Definition, diagnosis and management. *The Lancet*, 356, 1255-1259. Retrieved from: <http://www.ncbi.nlm.nih.gov>
- 13) Gay, S. (1997, November 28). Thalidomide, Ones banned, is in demand. *The New York Times*.
- 14) Grootheest, V, K., Olsson, S., Couper, M., & Berg, V, D, L. (2004). Pharmacists' role in reporting adverse drug reactions in an international perspective. *Pharmacoepidemiology and Drug Safety*. 13, 7, 457-464.
- 15) Gupta, P., & Udupa, A. (2011). Adverse drug reaction reporting and pharmacovigilance: Knowledge, attitudes and perceptions among resident doctors. *Journal of pharmaceutical sciences and research*, 3, 1064-1069.
- 16) Gupta, Y, K. (2010). Ensuring patient safety - launching the new pharmacovigilance program of India. *Pharma Times*, 42, 8, 21-26.
- 17) Hunziker, T., Bruppacher, R., Kuenzi, U, P., Maibach, R., Braunschweig, S., Halter, F., & Hoigné, R, V. (2002). Classification of ADRs: A proposal for harmonization and differentiation based on the experience of The Comprehensive Hospital Drug Monitoring Bern/St. Gallen, 1974-1993. *Pharmacoepidemiology & Drug Safety*, 11, 2, 159-163. d.o.i: 10.1002/pds.669
- 18) Inman, W, H. (1996). Attitudes to adverse drug reaction reporting. *British Journal of Clinical Pharmacology*. 41, 5, 433-435.
- 19) Jefferys, D., Leakey, D., & Lewis, J. (1998). New active substances authorized in the United Kingdom between 1972 and 1994. *British Journal of Clinical Pharmacology*, 45, 151-156.
- 20) Kessler, D, A. (1993). Introducing MedWatch: A new approach to reporting medication and device adverse effects and product problems. *JAMA*, 269, 2765-2768.
- 21) Kharkar, M., & Bowalekar, S. (2012). Knowledge, Attitude and Practices (KAP) of medical practitioners in India towards adverse drug reaction (ADR) reporting. *Perspectives in Clinical Research (PICR)*. 3, 3, 90-94.
- 22) Kieve, M. (2012). Adverse drug reactions: How patient reports can contribute to patient safety. *The Dianette*

- Story (Adverse Psychiatric Reactions Information Link). Retrieved from: <http://wp.rxisk.org>
- 23) Kramer, M, S. (1981). Difficulties in assessing the adverse effects of drugs. *British Journal of Clinical Pharmacology*, 11, 105-110.
  - 24) Kulkarni, R, D. (1986). Reporting system for rare side effects of non-narcotic analgesics in India: Problems and opportunities. *Medical Toxicology*, 1, 110-113.
  - 25) Launiala, A. (2009). How much can a KAP survey tell us about people's knowledge attitudes and practices? Some observations from medical anthropology research on malaria in pregnancy in Malawi. *Anthropology Matters Journal*, 11, 1, 1-13.
  - 26) Lazarou, J., Pomeranz, B, H., & Corey, P, N. (1998). Incidence of adverse drug reactions in hospitalized patients: A meta analysis of prospective studies, *JAMA*, 279, 1200-1205. McBride, W, G. (1961). Thalidomide and congenital abnormalities. *The Lancet*, 2, 1358.
  - 27) The Medicines and Healthcare products Regulatory Agency (July 22, 2011). How we regulate? Retrieved on January 05, 2013 from <http://www.mhra.gov.uk/Howweregulate/index.html>.
  - 28) Moore, N., Paux, G., Bégaud, B., & Loupi, B, M. (1985). Adverse drug reaction monitoring: Doing it French way. *The Lancet*, 1, 1056-1058.
  - 29) Naranjo, C, A., Busto, U., Sellers, E, M., Sandor, P., Ruiz, I., Roberts, E, A., & Greenblatt, D, J. (1981). A method for estimating the probability of adverse drug reactions. *Clinical Pharmacology & Therapeutics*, 30, 239-245.
  - 30) Parker, C, W. (1982). Allergic reactions in man. *Pharmacological Reviews*, 34, 85-104. Retrieved from : <http://www.ncbi.nlm.nih.gov>.
  - Prakash, S. (2007). Pharmacovigilance in India. *Indian Journal of Pharmacology*, 39, 123.
  - 31) Ramesh, M., & Parthasarathi, G. (2009). Adverse drug reactions reporting: attitudes and perceptions of medical practitioners. *Asian Journal of Pharmaceutical and Clinical Research*. 2, 10-14.
  - 32) Ramesh, M., Pandit, J., & Parthasarathi, G. (2003). Adverse drug reactions in a south Indian hospital-their severity and cost involved. *Pharmacoepidemiology & Drug Safety*, 12, 8, 687-92. Retrieved from: <http://www.ncbi.nlm.nih.gov>
  - 33) Ravi, S, P., Subish, P., & Dubey, A, K. (2006). Evaluation of Knowledge, Attitude and Practice (KAP) of ADR reporting amongst doctors in teaching hospitals. *Indian Journal of Pharmacology*, 38.
  - 34) Rawlins, M, D., & Thompson, J, W. (1977). Pathogenesis of adverse drug reactions. in : Davies Dm, ed. *Text book of adverse drug reactions*, Oxford, Oxford University press, 10.
  - 35) Rehan, H, S., Vasudev, K., & Tripathi, C, D. (2002). Adverse drug reaction monitoring: knowledge, attitude and practices of medical students and prescribers. *National Medical Journal of India*, 15, 1, 24-26.

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