

**EVALUATION OF KNOWLEDGE, ATTITUDE AND PRACTICE OF
PHARMACOVIGILANCE AND ADVERSE DRUG REACTION
REPORTING AMONG THE PRESCRIBERS AND NURSES IN A
TERTIARY CARE TEACHING HOSPITAL OF NORTHERN INDIA**

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ABSTRACT

Objectives: The current study aimed to determine the status of knowledge, attitude and practice towards pharmacovigilance and ADR reporting in our teaching hospital. **Material & Methods:** This study was a cross-sectional questionnaire based survey conducted in our tertiary care teaching hospital of North India. Study instrument was a self developed, pre-validated questionnaire consisting of a total of 26 questions. The target respondents were doctors, residents and nurses. **Results:** A total of 228 questionnaires were considered for analysis, giving a response rate of 64.04%. The highest response rate was seen in residents i.e 53.94%. In our study 61.4% subjects were aware about pharmacovigilance but only 59.6% knew the importance of

pharmacovigilance. The attitude of all the respondents was positive towards ADR reporting and a large number 73.2% thought that ADR reporting is necessary. The reporting rate in our institute was only 27.63% and the main reasons attributed for non reporting/under-reporting were lack of awareness of how to report and where to report, paucity of time, indifference, diffidence and non remuneration. **Conclusion:** Under-reporting is a grave problem in our institute also similar to other colleges of India. Increasing awareness by regular CME's, symposiums, distribution of booklets, newsletters, display of posters across the hospital with

helpline numbers will help in better understanding and can improve the reporting status of ADR's.

KEY WORDS: Pharmacovigilance, adverse drug reaction, knowledge, attitude, practice.

INTRODUCTION

Pharmacovigilance has achieved considerable importance in the present era due to prevalence of irrational prescribing, polypharmacy, increasing number of drugs entering the market each day and vigorous drug promotions by the pharmaceutical companies. India being a densely populated country, lacks essential health care in rural areas and easy accessibility of drugs leads to misuse, over the counter use of drugs of common ailments without consulting a physician as it is easy, less time consuming and economic.

Adverse drug reactions account for 0.2%-24% of hospital admissions and 3.7% of the patients have fatal ADRs. ^[1] Apart from accounting for significant health risk by increasing morbidity and mortality and prolonging hospital stay, it also leads to economic burden on the health care systems. Underreporting is another major problem and only 6-10% of all ADRs are reported. ^[2] If all of these ADRs were reported they could be avoided in the future by prospective ADR monitoring, implementing proper educational strategies for their prevention thus improving the safety and quality of life and reducing the financial burden to a large extent. Some ADRs are unavoidable but most ADRs can be prevented by following the fundamental principles of rational use of medicines.

The World Health Organisation (WHO) defines an adverse drug reaction as “response to a drug which is noxious, unintended, and which occurs at doses normally used in man for the prophylaxis, diagnosis, or therapy of disease or for modification of physiological function. ^[3] Pharmacovigilance is a science and activities relating to detection, assessment, understanding and prevention of adverse effects or any other drug related problems. ^[4] Uppsala Monitoring Centre (UMC, WHO), Sweden, is the international centre for maintaining the database of all adverse drug reaction reports. All health care providers play a key role in providing information about risk and benefits of all the prescribed drugs.

In India, there is a high incidence of ADRs due to easy availability of drugs but it contributes very little ADR data to the UMC centre. To improve the ADR reporting and monitoring system in India, the National Pharmacovigilance Programme (NPP) of India was started

vigorously way back in 2004, sponsored by WHO and coordinated by the Central Drugs Standard Control Organization (CDSCO), New Delhi. NPP has a three tier structure divided into 2 zonal centers, 5 regional centers and 24 peripheral centers. The two zonal centers collate information from all over the country and send it to the Uppsala Monitoring Centre in Sweden as per the SOPs. ^[5]

Clinical trials are conducted under stringent guidelines with fixed criteria and a small number of patients, not involving the general population and patient with co-morbidities, thus many ADRs may not manifest during the trials and are thus missed out. Once the drug is marketed, its safety is not completely identified and is used by clinicians in different ways and in varied populations on large number of patients. Thus many newer ADRs may be reported all of which need to be documented through this pharmacovigilance programme so that appropriate measures could be taken for their prevention in future. These reports should be circulated widely so that the regulatory authorities can take necessary steps for modifying the drug labels, package inserts, issue warnings or for reconsideration of marketing approval.

There are several methods of ADR reporting and each country has set up their own reporting system. Spontaneous voluntary reporting is the common method used for reporting in our country. If it has certain advantages like ease of reporting, inexpensive, including all drugs and all types of patients, on the other hand it also has certain disadvantages, major one being underreporting. Underreporting is a grave problem in our country, the reasons of which could be many like lack of knowledge and awareness about detection, the negligent attitude and lack of sincerity of healthcare workers towards ADR reporting, deficient knowledge of how and where to report ADR, inadequate manpower and insufficient finances and resources. ^[6]

ADR reporting rate in India is only 1% as compared to the global rate of 5%. ^[7] This underreporting scenario may lead to delay in recognition of unusual ADR and underrate the problem. As depicted by the study of Bord et al death rates were 19.18% higher and the length of hospital stay was 8.25% higher in patients who experience ADRs. ^[8]

The adverse drug reactions to herbal and ayurvedic remedies and poisonings should also be monitored under the programme. Under the recent guidelines of NPP, haemovigilance to blood and blood products have also now become mandatory. In order to improve the reporting rate, it is necessary to assess the knowledge, attitude and practice (KAP) of healthcare professionals regarding pharmacovigilance and adverse drug reaction monitoring and reporting and to devise approaches to amend the deficiencies as well as the relationship

between health professionals and the healthcare systems. All the studies pertaining to KAP of ADR reporting and pharmacovigilance in India in health professionals have demonstrated poor knowledge, awareness, indifferent attitude and deficient practices, thus we decided to evaluate the baseline knowledge, attitude and practice of doctors, residents and nurses in our teaching hospital regarding ADR reporting and pharmacovigilance so that we could implement the corrective measures and fill the lacunae in order to improve the reporting culture in our hospital.

MATERIAL AND METHODS

This was a cross-sectional, observational and questionnaire based survey conducted at our tertiary care 950 bedded teaching hospital having approximately 1500 patient turnover on a daily basis. It was conducted on all the hospital staff that comes in direct contact with the patients including clinicians, faculty members, residents and nurses. Approval of Institutional Ethics committee was obtained. A meeting of pharmacovigilance committee was called by the Medical Superintendent of the hospital and all members of the committee willingly agreed to participate as well as to cooperate in the survey.

Informed consent was obtained from all participants after explaining the purpose of survey. A self designed questionnaire was used as a study tool to obtain information regarding the knowledge of ADR reporting, the attitude towards reporting and the methods practiced for ADR reporting and factors which could hamper reporting. A KAP questionnaire containing 26 questions were designed by referring to other similar previous studies.^[9] Out of total 26 questions, 13 questions were of knowledge, 5 of attitude and 8 were of practice. A response sheet was also designed parallelly which the respondent had to fill. It contained information like Name (which was optional), department and designation were mandatory. At the end there was a column of suggestions, time taken to fill the response sheet and signature. It was clearly mentioned on the first page of questionnaire that the respondents do not have to mark anything on the questionnaire, they only had to fill the response sheets so that the questionnaire could be used again and there was less wastage of resources.

The designed questionnaire was assessed initially in our department among the faculty members and postgraduate students and all their suggestions were incorporated to prepare the final drafted questionnaire. These questionnaires and response sheets were then distributed in various clinical departments to doctors, residents and nurses in 3 phases. The respondents were requested to fill in the response sheets and return within 1 day to their respective

departmental offices from where it was collected by our junior residents. The information was recorded and analyzed using Microsoft Excel sheet and percentage of observations were tabulated.

RESULTS

A total of 356 KAP questionnaires were distributed in different departments, out of which 252 were returned to us for evaluation. Out of 252 questionnaires and response sheets, 9 were inadequately filled with incomplete information and 15 showed cutting and overwriting marks, hence these 24 response sheets were excluded from the study and only 228 were finally evaluated given a response rate of 64.04%. Of the total respondents i.e 228, 123 (53.94%) were residents, 29 (12.71%) were faculty members and 76 (33.33%) were nurses. Therefore maximum response rate was seen in residents and minimum in faculty members.

Table 1: Profile of Respondents

S.no	Respondents Profile	Number (%)
1.	Faculty doctors	29 (12.71%)
2.	Residents	123 (53.94%)
3.	Nurses	76 (33.33%)

Regarding the knowledge part of questionnaire, 140 (61.4%) subjects responded correctly regarding the definition of pharmacovigilance, 136 (59.6%) subjects knew that the importance of pharmacovigilance was to identify the safety of drugs and 157 (68.9%) respondents were aware that ADR monitoring in India is the responsibility of CDSCO. A total of 154 (67.5%) subjects knew about the specific CDSCO format for reporting ADR and the rest 74 (32.4%) had no information about any such reporting format. Only 83 (36.4%) subjects knew that the National Pharmacovigilance centre is located at IPC, Ghaziabad but an equal number of respondents i.e 81 (35.5%) said that the National Pharmacovigilance centre is located at AIIMS, New Delhi. Only 75 (32.8%) respondents knew that the International centre of Pharmacovigilance was located at UPSALA, Sweden, rest reported other countries or had no knowledge. Though 112 (49.1%) respondents replied in affirmative that they were aware of the peripheral/regional pharmacovigilance centre in U.P but none responded correctly. Merely 57 (25.0%) subjects had correct information about the time in which a serious ADR should be reported to the regulatory authority i.e 14 days, maximum number of respondents 108 (47.4%) said that reporting should be done in 7 calendar days. Eighty (35.1%) subjects said that most commonly used causality assessment scale is Naranjo's scale and an almost equal number i.e 83 (36.4%) said that WHO-UMC is the commonly used scale.

Barely 126 (55.26%) respondents said that all ADR's should be reported, 61 (26.8%) thought that only serious ADR's should be reported, 24 (10.5%) considered that only ADR's of new drugs should be reported, 17 (7.5%) thought that only unknown ADR's should be reported. Maximum doctors/residents/nurses knew about the drugs banned due to ADR and 109 (47.8%) responded about Thalidomide being banned due to ADR, 70 (30.7%) replied in favor of Nimesulide, 25 (10.96%) for Pioglitazone and 16 (7.02%) for Celecoxib. Maximum subjects i.e 88 (38.6%) respondents said they got information about ADR only from journals and 41 (18%) responded in favor of internet, 29 (12.7%) from seminars/conferences, 21 (9.2%) from drug advertisements and product catalogue, 15 (6.6%) from textbooks, 13 (5.7%) from medical representatives and rest from other sources which were not specified. Merely 131 (57.5%) persons thought that all health care professionals should report ADR's, 36 (15.8%) were of the view that only doctors should report ADR, 20 (8.8%) subjects alleged that only pharmacist should report ADR, 19 (8.3%) respondents accounted that nurses should report ADR and 22 (7.5%) thought that all health workers should report ADRs. (Table 2)

Table 2 : Knowledge of Respondents

Question No.	Question	Response in Number (%)
Q1.	What is Pharmacovigilance? a) The science of monitoring ADR's happening in a Hospital. b) The process of improving the safety of Drugs. c) The detection, assessment, understanding & prevention of adverse effects. d) The science detecting the type & incidence of ADR after drug is marketed. e) Do not know	37 (16.23%) 29 (12.71%) 140 (61.4%) 22 (9.64%) 0 (0%)
Q2.	Purpose of Pharmacovigilance a) To identify safety of drugs . b) To calculate incidence of ADR's. c) To identify predisposing factors to ADR's . d) To identify unrecognized ADR's e) Do not know	136 (59.6%) 26 (11.4%) 14 (6.14%) 52 (22.8%) 0 (0%)
Q3.	In India, monitoring of ADR's is the responsibility of ? a) Central Drugs Standard Control Organization (CDSCO). b) Indian Institute of sciences. c) Pharmacy Council of India . d) Medical Council of India (MCI). e) Do not know	157 (68.9%) 0 (0%) 30 (13.2%) 33 (14.5%) 8 (3.5%)
Q4.	Aware about ADR Reporting has a specific format? a) Yes b) No	154 (67.5%) 74 (32.4%)

Q5.	Where is the National Pharmacovigilance Centre of India located? a) AIIMS, New Delhi b) IPC, Ghaziabad c) Pune d) Kolkata e) Do not know	81 (35.5%) 83 (36.4%) 39 (17.1%) 25 (10.96%) 0 (0%)
Q6.	Location of International Pharmacovigilance centre a) USA b) UK c) France d) Australia e) Sweden f) Do not know	64 (28.07%) 46 (20.17%) 15 (6.6%) 16 (7%) 75 (32.8%) 12 (5.2%)
Q7.	Awareness about peripheral pharmacovigilance centre in U.P a) Yes b) No	112 (49.1%) 116 (50.87%)
Q8.	Awareness about reporting time of serious adverse Event to the Regulatory body a) One day b) Seven calendar days c) Fourteen calendar days d) Fifteen Calendar days e) Do not know	0 (%) 108 (47.4%) 57 (25.0%) 43 (18.9%) 20 (8.7%)
Q9.	Awareness about commonly used scales to establish the causality of an ADR a) Hartwig scale b) Naranjo algorithm c) Schumock and Thornton scale d) Karch & Lasagna scale e) WHO- UMC Scale f) Do not know	0 (%) 80 (35.1%) 0 (%) 27 (11.8%) 83 (36.4%) 38 (16.66%)
Q10.	Awareness about which ADR's should be reported a) All ADR's b) All serious ADR's c) ADR's to new drugs d) Unknown ADR's of old drugs e) ADR's to vaccine f) ADR's to herbal and non allopathic medicine.	126 (55.26%) 61 (26.8%) 24 (10.5%) 17 (7.5%) 0 (0%) 0 (0%)
Q11.	Awareness of any drug banned due to ADR's a) Thalidomide b) Nimesulide c) Pioglitazone d) Celecoxib e) Do not know	109 (47.8%) 70 (30.7%) 25 (10.96%) 16 (7.02%) 8 (3.5%)
Q12.	Source from which they got information regarding the ADR's of new drugs a) Textbooks b) Journals	15 (6.6%) 88 (38.6%)

	c) Drug advertisements and product catalogues	21 (9.2%)
	d) Medical Representatives	13 (5.7%)
	e) Seminar/ Conferences	29 (12.7%)
	f) Internet	41 (18%)
	g) Others	21 (9.2%)
Q13.	Knowledge about which healthcare professionals are responsible for reporting ADR's in a Hospital	
	a) Doctor	36 (15.8%)
	b) Pharmacist	20 (8.8%)
	c) Nurses	19 (8.3%)
	d) Health Workers	22 (7.5%)
	e) All of the above	131 (57.5%)

The attitude part of the questionnaire of the professional health care workers regarding ADR reporting showed that 164 (71.9%) respondents desired that pharmacovigilance should be taught in detail to all healthcare professionals but 42 (18.4%) subjects were of the opinion that there was no need of detailed teaching of pharmacovigilance. Maximum number of respondents 196 (86.0%) said that there is a need to include pharmacovigilance programme in undergraduate curriculum to create awareness among budding doctors but 15 (6.6%) thought that there was no need for its inclusion in UG curriculum. Barely 167 (73.2%) thought that ADR reporting is necessary and 34 (14.9%) considered it as unnecessary. A total of 122 (53.5%) respondents contemplated that ADR reporting is a professional obligation for them but 86 (37.7%) said it was not an obligation. A large number of subjects' i.e 126 (55.3%) thought that that was no need of an ADR monitoring centre in every hospital but 87 (38.2%) said that there should be a monitoring centre in every hospital. Only 6 (2.6%) subjects believed that one centre in a city is sufficient for reporting but 9 (3.9%) respondents reflected that it should depend upon the number of beds in the hospital. (Table 3)

Table 3 : Attitude of Respondents

Question No.	Question	Response Number (%)
Q14.	Should Pharmacovigilance be taught in detail to healthcare professionals a) Yes b) No c) Do not know	164 (71.9%) 42 (18.4%) 22 (9.6%)
Q15.	Should pharmacovigilance programme be included in Under Graduate curriculum to create awareness amongst budding doctors a) Yes b) No c) Do not know	196 (86.0%) 15 (6.6%) 17 (7.4%)

Q16.	Whether ADR reporting is necessary or not a) Yes b) No c) Do not know	167 (73.2%) 34 (14.9%) 27 (11.9%)
Q17.	Whether reporting is a professional obligation or not a) Yes b) No c) Do not know	122 (53.5%) 86 (37.7%) 20 (8.8%)
Q18.	What was their opinion regarding establishment of ADR monitoring centre in every hospital a) Should be in every hospital b) Not Necessary c) One centre in a city is sufficient d) Depends on number of beds in a hospital	87 (38.2%) 126 (55.3%) 6 (2.6%) 9 (3.9%)

On accessing the practice of doctors, residents and nurses, 112 (49.12%) respondents said that they had been trained on how to report an ADR and 99 (43.42%) said they have never been trained or sensitized for ADR reporting and 17 (7.4%) could not recall whether they had undergone any pharmacovigilance training. A total of 63 (27.63%) healthcare professionals had reported an ADR in their clinical practice and 139 (60.96%) had never reported an ADR and the rest 26 (11.4%) were not sure whether the cases they reported were actually ADR's. Out of total of 63 (27.63%) healthcare professionals who had reported an ADR 38 (60.31%) said they encountered 0-5 ADR/week, 17 (26.98%) had come across 6-10 ADR/week and 8 (12.69%) had encountered > 10 ADR/week. 146 (64.0%) said they did not have free access to ADR reporting form, only 72 (31.6%) had free access to these forms and 10 (4.4%) reported by other means. Ninety eight (42.98%) health workers said they provided ADR information of the prescribed drugs to their patients, 101 (44.3%) did not provide any details of ADRs to the patient while prescribing the drugs and rest 29 (12.7%) were not aware that they had to provide any such information. Maximum respondents i.e 82 (35.9%) said that the main factor for not reporting ADR is lack of awareness of how to report and where to report, though 53 (23.2%) said that lack of time is the major factor for not reporting ADR, 40 (17.5%) thought that a single unreported ADR may not affect the database and 28 (12.2%) said they were unsure whether ADR has occurred or not in most of the clinical cases and 25 (10.9%) alleged that non remuneration was a major deterrent for under/non reporting. Maximum respondents i.e 147 (64.5%) said that they prefer an e-mailing method to report ADR and only 27 (11.8%) said they preferred telephonic method and the rest preferred other methods like direct contact or post. A total of 127 (55.7%) of healthcare workers kept no report of any ADR they have encountered, only 82 (36%) said they kept some report with them and the rest 19 (8.3%) had

not thought about it or had not been told to keep a report. Maximum people 130 (57.01%) said they followed no approach to prevent ADR and 95 (41.6%) alleged they followed an approach to prevent an ADR but did not specify the method and 3 (1.3%) alleged that they had no information/knowledge regarding preventive approach to ADR's. (Table 4)

Table 4 : Practise of Respondents

Question No.	Question	Positive Response Number (%)
Q19.	Whether they had ever been trained on how to report an ADR a) Yes b) No c) Do not know/remember	112 (49.12%) 99 (43.42%) 17 (7.4%)
Q20.A	Whether they had ever reported an ADR a) Yes b) No c) Not sure of ADR	63 (27.63%) 139 (60.96%) 26 (11.4%)
Q20.B	If Yes to above question, how many ADRs did they encounter per week a) 0-5 b) 6-10 c) More than 10	38 (60.31%) 17 (26.98%) 8 (12.69%)
Q21.	Whether they had free access to ADR Forms a) Yes b) No c) Not aware of ADR forms/Other means	72 (31.6%) 146 (64.0%) 10 (4.4%)
Q22.	Whether they provided ADR information of prescribed drug a) Yes b) No c) Do not know/Not aware	98 (42.98%) 101 (44.3%) 29 (12.7%)
Q23.	Which among the following factors discourage you from reporting Adverse Drug Reactions? a) Non-remuneration for reporting b) Lack of time to report ADR c) A single unreported case may not affect ADR database d) Difficult to decide whether ADR has occurred or not e) Not aware of How/ Where to report f) Patient confidentiality issues. g) Legal liability issues	25 (10.9%) 53 (23.2%) 40 (17.5%) 28 (12.2%) 82 (35.9%) 0 (0%) 0 (0%)
Q24.	Which method did they prefer to send ADR information to the ADR Center a) Post b) Telephone c) E Mail d) Direct Contact	32 (14.03%) 27 (11.8%) 147 (64.5%)

	e) Others (specify)	10 (4.38%) 12 (5.26%)
Q25.	Whether they kept any record of ADR a) Yes b) No c) Do not know/Not aware	82 (36%) 127 (55.7%) 19 (8.3%)
Q26.	Did they follow an approach regarding prevention of ADR a) Yes b) No c) Do not know/Not aware	95 (41.6%) 130 (57.01%) 3 (1.3%)

DISCUSSION

The purpose of pharmacovigilance programme is to identify the ADRs in large population, establish new and rare ADRs, record the frequency and to implement measures for further prevention of these ADRs. Spontaneous and voluntary reporting is a critical method for detailing drug events but the strength and drawbacks of this system has widely been discussed ^[10] and according to universal conformity the system has been accepted and implemented in various countries including India.

Numerous studies on KAP of pharmacovigilance have been conducted in various parts of India but no such study was conducted in our region, thus we decided to undertake this observational survey. The response rate in our study was 64.04%. It was almost similar to other studies by Desai et al, ^[9] Hardeep et al ^[11] and Agarwal R et al ^[12] all of which showed response rate of 61% but lower than studies of Ghosh S et al, ^[13] Oshikoyo KA et al ^[14] and Ramesh M et al ^[15] which showed response rates of 84.37%, 82.5% and 88% respectively.

Of the total respondents the maximum number were residents i.e 53.94%, 33.33% were nurses and least number were faculty members 12.71%. This is akin to studies of Desai et al ^[9] and Sharma S et al. ^[16] This may be because the residents and nurses were always present in the clinics and wards as compared to the faculty members who were present only during duty hours.

In our study 61.4% subjects were aware about pharmacovigilance and only 59.6% knew the importance of pharmacovigilance which was very low as compared to other studies of Ghosh S et al, ^[13] Sharma S et al ^[16] and Agarwal R et al. ^[12] Only 68.9% respondents in our study were aware of the ADR monitoring in India but 36.4% subjects knew that the National Pharmacovigilance centre was located at IPC, Ghaziabad, 32.8% reported correctly about the international centre located at UPSALA, Sweden and 49.1% respondents were aware of the

peripheral/regional pharmacovigilance centre in U.P but none responded correctly in regards to its location. This knowledge was scarce in our doctors and residents as compared to other studies of Ramesh M et al ^[15] and Ghosh S et al. ^[13] In our study a small number of respondents (55.26%) said that all ADR's should be reported whereas 26.8% thought that only serious ADR's should be reported, 10.5% considered that only ADR's of new drugs should be reported and 7.5% thought that only unknown ADR's should be reported. These figures show poor knowledge of our staff as compared to the study of Agarwal R et al. ^[12] For 38.6% respondents, the source of information about ADR was only from journals, 18% from internet, 12.7% from seminars/conferences, 9.2% from drug advertisements and product catalogue, 6.6% from textbooks and 5.7% from medical representatives. This finding was almost similar to the study of Desai et al. ^[9]

All these parameters clearly show deficient knowledge about pharmacovigilance and ADR reporting among doctors, residents and nurses in our college for which we need to employ suitable measures to improve the knowledge and awareness at every level. Concerning the attitude part 71.9% respondents in our study desired that pharmacovigilance should be taught in detail to all healthcare professionals and 86.0% said that there was a need to include pharmacovigilance programme in undergraduate curriculum to create awareness among budding doctors. These findings were similar to the study of Sharma S et al ^[16] where all respondents thought that pharmacovigilance should be taught in detail. It reflects the positive attitude of the staff who opined that if the budding doctors were taught about the importance of pharmacovigilance right from the undergraduate years they will be much more vigilant when they start practicing.

Interestingly 14.9% considered ADR reporting as unnecessary which is in agreement to a study of Desai et al. ^[9] 53.5% respondents in our study contemplated that ADR reporting is a professional obligation for them which is a highly encouraging number as compared to the study of Pimpalkhute S.A et al ^[2] which reported only 35.72% positive response to this question. This notion of ADR reporting as a professional commitment should be further encouraged among doctors and paramedical staff to improve the reporting rate.

In our study 49.12% respondents had been trained on how to report an ADR, sometime during their professional career. Though this number is comparatively high as judging against a study of Sharma S et al ^[16] which reported that only 15% respondents had received training on ADR reporting and pharmacovigilance, but on accessing the reporting rates, we felt the

need of constant reminders in the form of monthly CME meets, newsletter on the current scenario of pharmacovigilance in our college, change in attitude and enthusiastic reporting practices.

A total of only 27.63% healthcare professionals had reported an ADR in their clinical practice in our study and out of which majority i.e 60.31% said they encountered 0-5 ADR/week, 26.98% had come across 6-10 ADR/week and 12.69% had encountered > 10 ADR/week. 60.96% had never reported an ADR and the rest 11.4% were not sure whether the cases they reported were actually ADR's which clearly demonstrates under-reporting in our institute. These reporting rates of our institute were almost comparable to the studies of Desai et al,^[9] Pimpalkhute S.A et al,^[2] Sharma S et al^[16] and Ghosh S et al.^[13]

We scrutinized that the causes of ADR under-reporting in our study were according to Inman's criteria of seven deadly sins.^[17] According to Inman, the causes of under-reporting can be either due to failure to recognize an ADR or failure to report a recognized ADR. Inman's proposal made in 1976 was amended in 1986 and was re-amended in 1996.^[18] These "seven deadly sins" includes the following factors: Complacency (The notion that only safe drugs are available in the market and common ADR cannot occur by these drugs and only serious ADRs are reported and documented.) This complacency factor was not found to be the major cause of under-reporting in our study. Fear and guilt (The belief that reporting may cause their involvement in legal implications and further investigation by health departments.) In our study this factor was also not shown by the respondents. Diffidence (Feeling that ADR report may be wrong and unsure whether the clinical condition reported is actually an ADR or a symptom of a disease) In our study 12.2% respondents showed diffidence as grounds of under-reporting. Indifference (The professional's attitude that a single ADR case may not affect database and lackness in contributing to the existing knowledge.) In our study 17.5% respondents attributed indifference as cause of under-reporting. Lethargy (Lack of time and effort to find the relevant forms, phone numbers, addresses.) A total of 23.2% participants in our study showed idleness by consenting that they do not have ample time to report as they are already burdened by the clinic workload. Ignorance (Not feeling the need to report common ADR and not knowing how and where to report and the notion that only serious and unusual ADRs must be reported.) Merely 35.9% respondents reported ignorance in our study. All these issues were in agreement to other studies of Sharma S et al,^[16] Pimpalkhute SA et al,^[2] Desai et al,^[9] Ghosh S et al,^[13]

Oshikoyo KA et al.^[14] and Agarwal R et al.^[12] The conviction that financial compensation would be an encouraging factor in reporting ADR was shown by only 10.9% of our study respondents. Another study by Bäckström M et al also highlighted the use monetary incentive to augment ADR reporting.^[19] But this does not seem to be an apt way out as financial incentives will lead to over reporting and moreover false reporting just to gain monetary benefits. Therefore this factor was never encouraged as a tool to improve the reporting rate. Only 31.6% clinicians and nurses had free access to ADR reporting forms in our study. This shows that the concerned departments have to be proactive to make the forms available where and when required by the health care workers. The results of our study demonstrated that 42.98% health workers in our institute provided ADR information of the prescribed drugs to their patients which is an encouraging number and similar to the study of Kulkarni MD et al.^[6]

Maximum respondents i.e 64.5% preferred an e-mailing method to report ADR and 11.8% preferred telephonic method and the rest preferred other methods like post or direct contact. These results were in accordance with other studies of Desai et al,^[9] where also the healthcare professionals preferred to report ADR through e-mails. In our study only 36% respondents kept some record of ADR report with them and 55.7% of healthcare workers kept no report of any ADR they have encountered. These results were analogous to the study of Kulkarni MD et al.^[6] Though record keeping of ADRs by the physician should be encouraged and they should be provided manpower and other support for maintaining these records.

CONCLUSION

Our study reviews overall lack of knowledge about pharmacovigilance and ADR reporting. Though most of the healthcare workers showed a favourable attitude towards ADR reporting and were also enthusiastic to learn and practice it. The reporting numbers from our institute are an optimistic evidence on the clinical expertise of our physicians and nurses but still these reporting rates were low and this under-reporting is a grave problem in our institute similar to other places in India.

We recommend appropriate educational interventional measures to improve the reporting system in our institution as suggested by most of the doctors and residents in our study. We should conduct workshops, seminars, CME's and symposiums in our college at regular intervals for sensitization of the newer staff and to act as reminders to the older staff

responsible for ADR reporting and also ensuring maximum participation by the clinicians, residents and nurses. We can also incorporate pharmacovigilance teaching and training at the undergraduate level and reinforce at periodical intervals. Regular newsletters, guidelines for ADR reporting and posters displayed in hospitals will act as a constant reminder and may be helpful. Similarly government of India should also take adequate steps to improve the reporting system in our country. They should provide sufficient finances and resources to make an organized system for reporting. Involvement of other health professionals like pharmacists may help which is commonly being practiced in other countries. Still we have a long way to go in improving the ADR reporting rate.

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