

# Knowledge, attitude and practice of adverse drug reaction reporting among healthcare professionals of a tertiary care hospital in Gujarat

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## ABSTRACT

**Background:** The objective of the present study was to assess knowledge, attitude and practice of adverse drug reaction reporting among healthcare professionals of Parul Sevashram Hospital, Parul University, Vadodara.

**Methods:** The study was prospective, observational and questionnaire-based involving medical doctors, nurses and pharmacists of Parul Sevashram Hospital. A total number of 210 structured questionnaires were distributed among health care professionals (100 clinicians from various specialities, 100 nurses and 10 pharmacists). Written informed consent forms were obtained from participants as their consent to participate in the study.

**Results:** All questionnaires were filled and returned producing overall response rate of 100%. 80% of the respondents were aware of the existence of Pharmacovigilance Program of India (PvPI). 90.95% and 91.90% of respondents felt ADR reporting is necessary and it would be beneficial to the patients respectively. Only 11.43% of respondents had reported ADRs. 90.95% and 85.24% of respondents suggested training is required in reporting ADR and regular information should be provided regarding ADR by PvPI respectively.

**Conclusions:** The health care professionals had positive knowledge and attitude towards pharmacovigilance and there is a need to create awareness for better practice of ADR reporting. It would help to improve patient care.

**Keywords:** Adverse drug reactions, Pharmacovigilance, Knowledge, Practice

## INTRODUCTION

According to World Health Organisation, an adverse drug reaction is defined as “a response to a drug which is noxious and unintended and which occurs at doses normally used in man for prophylaxis, diagnosis or therapy of disease or for the modification of physiological function excluding failure to accomplish the intended purpose”.<sup>1</sup> Adverse drug reactions (ADRs) are one of the major drug related problems associated with pharmacotherapy. Pharmacovigilance is defined as the science and activity relating to detection, assessment, understanding and prevention of adverse effects or any other possible drug related problems.<sup>2</sup> Spontaneous

adverse drug reaction reporting is the integral part of Pharmacovigilance Programme of India (PvPI) in the post-approval phase. To increase spontaneous adverse drug reaction reporting, involvement of the healthcare professionals for reporting of ADRs is necessary. With respect to developed countries, despite of better ADR reporting culture, under-reporting is a major issue with spontaneous reporting.<sup>3,4</sup> Under reporting delays early detection of ADRs and increase morbidity and mortality in patients.<sup>5</sup> Major factor for under-reporting might be a lack of awareness among healthcare professionals towards the existing pharmacovigilance program. In order to improve the reporting rate, it is important to improve the knowledge, attitude and practices of the

healthcare professionals regarding ADR reporting and Pharmacovigilance. This would help us in planning interventions amongst health care professionals. It is for this purpose we planned this to evaluate the knowledge, attitude and practice of ADR reporting by physicians, nurses and pharmacists.

## METHODS

A prospective observational (non-interventional) questionnaire-based study was conducted over a period of two months from 1<sup>st</sup> June 2019 to 31<sup>st</sup> July 2019 among health care professionals of Parul Sevashram Hospital- a tertiary care teaching hospital, Parul University, Vadodara, Gujarat. This study was started after receiving due permission from Parul University Institutional Ethics Committee for Human Research. Written informed consent forms were obtained from participants as their consent to participate in the study. The prospective participants were provided all the information about the objective and nature of the study in the language understood by them. A total number of 210 structured

questionnaires were distributed among 100 clinicians from various specialities, 10 pharmacists and 100 nurses. The pre-designed questionnaire developed from previous study to assess knowledge, attitude and practice of ADR reporting by practitioners, pharmacists and nurses.<sup>6,7</sup> The questionnaire comprised of 20 questions related to knowledge, attitude and practice of healthcare care professionals, 6 questions related to factors responsible for non-reporting and 4 questions related to factors responsible for encouragement of ADR reporting. A time frame of one week was allotted to the participants for the collection of the anonymously filled forms. Collected data was entered and analysed using Microsoft Excel and the findings was presented in number and percentages.

## RESULTS

A total of 210 questionnaires were distributed among various health care professionals of Parul Sevashram Hospital, Vadodara, Gujarat, India. All questionnaires were filled and returned producing overall response rate of 100 %.

**Table 1: Knowledge, attitude and practice of healthcare professionals.**

S. no	Question	Yes	%	No	%
1	All drugs available in the market are safe.	29	13.81	181	86.19
2	All ADRs should be reported for all drugs.	60	28.57	150	71.43
3	Do you think reporting of adverse drug reaction is necessary?	191	90.95	19	9.05
4	The health care professionals are responsible for ADR reporting.	168	80.00	42	20.00
5	Have you ever come across with an ADR?	150	71.43	60	28.57
6	I have reported an ADR before.	24	11.43	186	88.57
7	I have been trained on how to report an ADR.	29	13.81	181	86.19
8	Training is needed in reporting an ADR.	191	90.95	19	9.05
9	I have seen the suspected ADR reporting form (white form) issued by CDSCO.	125	59.52	85	40.48
10	I am aware of the nearest AMC in my geographical location.	30	14.29	180	85.71
11	I am aware of the existence of PvPI.	168	80.00	42	20.00
12	ADR reporting is a professional obligation.	173	82.38	37	17.62
13	ADR reporting should be made mandatory to my profession.	189	90.00	21	10.00
14	Only serious adverse event or increased frequency of an ADR of old drugs needs to be reported.	162	77.14	48	22.86
15	Reporting of only one ADR makes no significant contribution to the PvPI or society.	141	67.14	69	32.86
16	Have you ever come across educational session in specific about pharmacovigilance or ADRs?	142	67.62	68	32.38
17	ADR reporting and monitoring system would beneficial to the patient.	193	91.90	17	8.10
18	Regular information regarding ADR should be provided by PvPI?	179	85.24	31	14.76
19	Do you support "direct ADR reporting" by the patients?	177	84.29	33	15.71
20	Do you think pharmacovigilance should be taught in detail to healthcare professionals?	173	82.38	37	17.62

In our study, while assessing the knowledge of the participants, we found that 125 (59.52%) participants had seen the suspected adverse drug reaction reporting form (white form) issued by Central Drug Standard Control Organization (CDSCO). One hundred and sixty eight

(80%) of the participants were aware of the existence of PvPI, however, 180 (85.71%) participants did not know the nearest Adverse drug reaction monitoring center (AMC). Further analysis relating to knowledge of the participants showed that majority of them agreed that all

drugs are not safe (181 (86.19%)) and ADR reporting system would be beneficial to the patient (193 (91.90%)). However, 150 (71.43%) participants did not agree that all ADRs should be reported for all drugs. In the present study, 162 (77.14%) and 141 (67.14%) participants felt that only serious adverse events are needed to be reported and reporting of single ADR makes no significant contribution to the PvPI respectively (Table 1).

In respect of attitude of health care professionals, majority of participants agreed that reporting of adverse drug reaction is necessary (191 (90.95%)) and health care professionals are responsible for the reporting (168 (80%)). One hundred and seventy three (82.38%) participants felt that ADR reporting is a professional

obligation and ADR reporting should be made mandatory to my profession (189 (90%)) (Table 1).

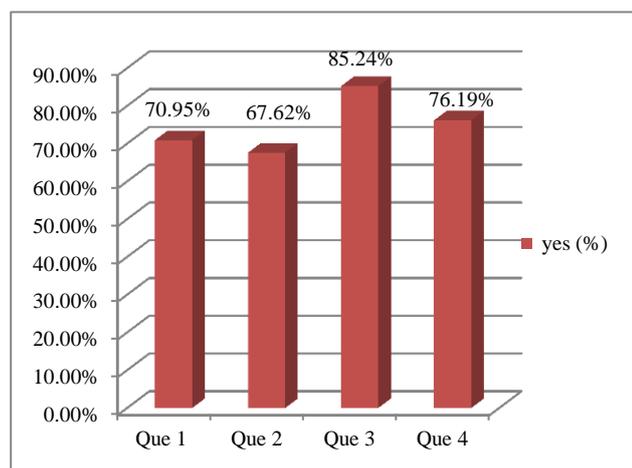
In respect of practice of health care professionals, our study results revealed that a total of 150 (71.43%) participants had come across the ADR, however, only 24 (11.43%) had reported ADRs. It was found that only 29 (13%) participants were trained in reporting ADR. One hundred and ninety one (90.95%) participants suggested training is required in reporting ADR. Further, our study showed that 143 (67.62%) participants had come across educational session in specific about pharmacovigilance and 179 (85.24%) participants suggested that regular information should be provided regarding ADR by PvPI (Table 1).

**Table 2: Factors contributed to non-reporting of ADR.**

S. no	Question	Yes	%	No	%
1	Do not know how to report, where to report and when to report	148	70.48	62	29.52
2	Extra work burden	123	58.57	87	41.42
3	Concern that the report may be wrong (fear)	87	41.42	123	58.57
4	Lack of time to fill the ADR form	67	31.90	143	68.09
5	Failure of spoiling reputation	45	21.42	165	78.57
6	Lack of confidence (for considering as failure in part of treatment)	35	16.66	175	83.33

**Table 3: Factors contributed to encouragement of reporting ADR.**

S. no	Question	Yes	%	No	%
1	If the ADR is serious.	149	70.95	61	29.05
2	If the ADR is unusual.	142	67.62	68	32.38
3	If the ADR is due to a new product.	179	85.24	31	14.76
4	If the ADR is well recognized for a particular drug.	160	76.19	50	23.81



**Figure 1: Factors contributed to encouragement of reporting ADR.**

In our study, factors contributed to non-reporting of ADR were lack of awareness about how, where and when to report (148 (70.48%)), extra work burden (123 (58.57%)), concern that the report may be wrong (fear) (87 (41.42%)), lack of time to fill ADR (67 (31.90%)), failure of spoiling reputation (45 (21.42%)) and lack of

confidence (for considering as failure in part of treatment) (35 (16.66%)) (Table 2). Whereas common factors that lead to enhancement ADR reporting were if the ADR is serious (149 (70.95%)), unusual (142 (67.62%)), due to a new drug product (179 (85.24%)) and well recognized for a particular drug (160 (76.19%)) (Table 3 and Figure 1).

**DISCUSSION**

Healthcare professionals play a key role in understanding and reporting of adverse drug reactions. Adverse drug reactions are routinely encountered in hospital set up, however, they are not being reported.<sup>8</sup> The barriers to ADR reporting can be a lack of knowledge and awareness regarding pharmacovigilance as well as attitude in the health care professionals.

In our study, it was observed that health care professionals had positive knowledge and attitudes towards pharmacovigilance which was found lower in other study done in India.<sup>7</sup> In the present study, around 60% and 80% of healthcare professionals had seen suspected adverse drug reaction reporting form (white form) issued by CDSCO used to report ADR and were

aware of the existence of Pharmacovigilance Program of India respectively. Although around 91% of the health care professionals felt that ADR reporting is necessary, 82.37% of them had considered reporting a professional obligation. These findings were consistent with the study done by Ganesan et al.<sup>9</sup> Despite of positive knowledge and attitude of health care professionals found in our study, ADR reporting was approximately 12%. In similar studies done by Palaian et al and Okezie et al, it was found that ADR reporting was 33.7% and 32% respectively.<sup>10,11</sup>

In many studies, it was observed that common factors responsible for non-reporting of ADRs included lack of awareness about pharmacovigilance (what, how and when to report), inadequate information about ADR, extra work burden, concern that report may be wrong and lack of time.<sup>5</sup> In our study, we found similar results, common factors found were lack of knowledge and awareness (70.48%), extra work burden (58.57%), concern that the report may be wrong (fear) (41.42%) and lack of confidence (for considering as failure in part of treatment) (16.66%). Regular education and training programme about pharmacovigilance and reporting of ADR as well as exchange of information between national pharmacovigilance centers and health care providers would help to overcome these barriers, improve ADR reporting and strengthen the activates of pharmacovigilance programme of India. However, there were few factors that contributed to encouragement of ADR reporting included if the reaction is due to a new drug product and well recognized for a particular drug. These findings were comparable to study done by Gupta et al.<sup>12</sup>

Effective implementation of pharmacovigilance activities by improving knowledge, attitude and practice of health care professionals can help us to promote safe and rational use of medicines.

## CONCLUSION

Despite of favourable knowledge and attitude among healthcare professionals, there is a need to create awareness about the importance ADRs reporting scrupulously and without reticence. This practice will prove very valuable in promoting the safe and rational use of drug therapy. Many untoward adverse incidents pass unnoticed, due to the lack of awareness, extra burden, clinical acumen, aptitude and/or time. This study will help in identifying such barriers in reporting ADRs and can contribute effectively towards improving ADR reporting.

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