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A Survey on Knowledge, Practice and Perception of Physicians and Pharmacists on Adverse Drug Reaction Reporting- A Pilot Study

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ABSTRACT:

Background: In India, the system of reporting Adverse Drug Reactions (ADRs), Pharmacovigilance (PV), has not progressed well and it's still in infancy stage. This can be determined by the reporting of only 1% of ADRs as compared to 5% of the other countries of world. The major drawback of the slow progress of PV system is the lack of sufficient knowledge towards it by healthcare professionals. **Objective:** To evaluate the knowledge and practice of ADR reporting by physicians and pharmacists in community settings.**Method:** A self-administered questionnaire was prepared. After explaining the intention of survey, it was distributed to pharmacists and doctors (General practitioners, MDs, and Surgeons), in the community setting. Participants were requested to fill out the questionnaire. Healthcare professionals, who did not wish to participate in the study, were excluded.**Result:** A total of 110 questionnaire were circulated in the two major cities of Gujarat, namely Ahmedabad and Gandhinagar, of which 100 (50 Doctors and 50 Pharmacists) filled questionnaire were returned, producing overall response rate of 90.90%. Our study results revealed total of 88% responders need the training to report ADR. 54% and 60% doctors and pharmacists respectively, did not know the existence of Pharmacovigilance Program of India (PVPI), and 74% and 60% doctors and pharmacists respectively, did not know the nearest PV center. Overall 90% responders had never reported suspected ADR before. 91% responders suggested that regular information should be provided regarding ADR by PVPI. Of all the responders, 76% and 88% doctors and pharmacists respectively suggested that the trained pharmacist could be the right person to assist physicians in ADR reporting. For the reason of not reporting an ADR, the highest percentage was noted (58%) with, if the reaction was well recognized for a drug. **KEY WORDS:** Under-reporting of ADR; Pharmacovigilance; Knowledge; Practice; Physicians; Pharmacists; Adverse Drug Reaction.

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INTRODUCTION:

Adverse Drug Reaction (ADR) is classically noted as, "any unexpected, unintended, undesired, or excessive response to a medicine''. [1] World Health Organization (WHO) defines ADR as "any noxious, unintended, and

undesired effect of a drug, which occurs at doses used in humans for prophylaxis, diagnosis, or therapy." [2] There is no medication which is considered as totally free from causing side effects or ADRs. All medications and their excipients are capable of producing ADRs. [1] ADRs are a common reason for hospitalization and becoming a serious safety issue. [3] This issue is not only limited to hospitalization, ADRs have a major impact on public health by imposing a huge economic burden on the patients and society. [4]

India is a major country to contribute in health-care system of the world. India became a member of the WHO's ADR monitoring program 30 years after its establishment. [5] The word "Pharmacovigilance" was defined by WHO as, "the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem". This system of monitoring and reporting of the ADR started evolving in many countries, mainly after the infamous Thalidomide disaster during the 1960s. The program of detection, monitoring, and reporting of ADRs was started by WHO in response to that event, and since 1978, it has been operating from the Uppsala Monitoring Centre (UMC) in Sweden. [3]

National Pharmacovigilance program of India (PvPI):

The Pharmacovigilance Program of India (PvPI), was launched with a broad objective to safe guard the health of people of India. In July 2010, the Central Drugs Standard Control Organization (CDSCO), New Delhi, under the aegis of Ministry of Health & Family Welfare, Government of India, has initiated a nation-wide pharmacovigilance program. Initially the All India Institute of Medical Sciences (AIIMS) was designated as National Coordinating Centre (NCC), but later it was shifted to the Indian Pharmacopoeia Commission (IPC), Ghaziabad, (U.P.) in April, 2011. [6] The PvPI is sponsored by the WHO and it funded by the World Bank. [3] The Functions of a National Pharmacovigilance System have been defined to include the following: [6]

1. To create a nation-wide system for patient safety reporting
2. To identify and analyze the new signal (ADR) from the reported cases
3. To analyze the benefit - risk ratio of marketed medications
4. To generate the evidence based information on safety of medicines
5. To support regulatory agencies in the decision-making process on use of medications
6. To communicate the safety information on use of medicines to various stakeholders to minimize the risk
7. To emerge as a national center of excellence for Pharmacovigilance activities
8. To collaborate with other national centers for the exchange of information and data management
9. To provide training and consultancy support to other National Pharmacovigilance Centers located across globe.

Need for the present research:

In country like India, which is having a very large population and vast diversity, it is indeed necessary to have a standard pharmacovigilance program. As compared to world rate of 5% of ADR reporting, India ranks below 1% only. [7] It is the responsibility of all healthcare stakeholders to report the ADRs. Physicians, Pharmacists, and Nurses are at a distinct position to play a key role in PvPI, but underreporting is a very common problem, with an estimated only 4-5% reporting from the total ADRs experienced.[8.9] Although, India is participating in the WHO-UMC ADR monitoring program, its contribution to the UMC database is very little. This is majorly due to the absence of a vibrant ADR monitoring system and also due to a lack of the reporting culture among the health care workers. [10] This potential problem can be resolved and/or avoided by creating the awareness among the health care co-workers. Previous studies on the similar subjects indicated inadequate knowledge about pharmacovigilance among health care

professionals, in addition, attitude that are associated with high rates of underreporting. [11] Many factors are reported to relate to underreporting of ADRs by health care professionals and their knowledge and attitudes to reporting. For many different reasons, such as lack of knowledge, lack of awareness of pharmacovigilance systems, heavy work load, hesitation in making the correct decision, etc., health care professionals do not report ADRs as frequently as expected. Other studies also reported several reasons for underreporting of ADRs such as busy schedule, misconceptions about spontaneous ADR reporting and bureaucratic reporting procedures, lack of information on how to report and a lack of availability of report forms, and physicians' attitudes to ADRs. [12] Thus, there is a need to assess the knowledge and practice of healthcare professionals towards pharmacovigilance.

Materials and Method Study Design:

This was a cross sectional, observational, pilot, questionnaire based study which was conducted on practicing pharmacists and physicians (General Practitioners, MDs, Surgeons), of community in two major cities of Gujarat. After explaining the intention of the survey, they were requested to fill out the self-administered questionnaire which was adapted and designed to know the knowledge and practice of suspected ADR reporting.

Study questionnaire:

A self-administered questionnaire comprising of 22 questions in the sentence form to simply answer "Yes" or "No", and total of 10 factors for encouragement of reporting an ADR and Not reporting an ADR (5 factors for each respectively) was prepared (appendix 1). The questionnaire was newly designed one, on the bases of previous studies and with the help from the faculty. All the 32 items were having the response of positive or negative manner, to calculate the percentage of positive response and negative response for the given statement.

Study participants:

The study included practicing pharmacist (n= 50) and physicians (General Practitioners, MDs, Surgeons, n= 50), from the community setting of two major cities of Gujarat. The participants were selected randomly, form different areas of the cities. Those who did not wish to participate in the study were excluded. The questionnaire was handed over to the interested participants and the time was allotted to fill the answers.

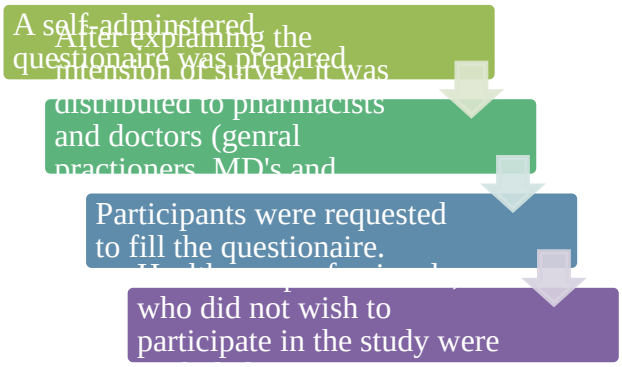

Figure 1: Methodology of the Study

Result:

A total of 110 questionnaire were circulated in the two major cities of Gujarat, namely Ahmedabad and Gandhinagar, of which 100 (50 Doctors and 50 Pharmacists) filled questionnaire were returned, producing overall response rate of 90.90%. Our study results revealed total of 88% responders need the training to report ADR. 54% and 60% doctors and pharmacists respectively, did not know the existence of Pharmacovigilance Program of India (PVPI), and 74% and 60% doctors and pharmacists respectively, did not know the nearest PV center. Overall 90% responders had never reported suspected ADR before. 91% responders suggested that regular information should be provided regarding ADR by PVPI. Of all the responders, 76% and 88% doctors and pharmacists respectively suggested that the trained pharmacist could be the right person to assist physicians in ADR reporting.

For the reason of not reporting an ADR, the highest percentage was noted (58%) with, if the reaction was well recognized for a drug. Percentage responses of the physician and pharmacist are shown in table 1.

The bar chart shows (Figure 2) the comparison of the score obtained by pharmacist's v/s physicians regarding their knowledge, practice and perception for pharmacovigilance and ADR reporting. It can be seen that the knowledge of physicians regarding pharmacovigilance is nearly 8% higher than pharmacists' knowledge. Thus the pharmacists need to update their knowledge and also help other health care providers to enhance their knowledge. From the view point of practice, physicians are about 10% ahead of pharmacists. Physicians were able to answer more correct answers to questions related to practice. This can probably be more as they are more into contact with patients suffering from ADRs. Similarly, physicians were more correct in perception related questions as compared to pharmacists. This indicates that physicians are more aware towards pharmacovigilance and ADR reporting than pharmacists.

Table 1: Percentage Results of the responses.

Sr. No.	Questions	Pharmacist			Physician		
		Yes	No	Don't Know	Yes	No	Don't Know
1	All drugs available in the market are safe.	36	64	0	6	94	0
2	I have experienced Adverse Drug Reactions (ADR) in Patients during my Professional practice.	44	56	0	78	22	0
3	I know the existence of a National Pharmacovigilance Program in India.	38	60	2	44	54	2
4	I am aware of the nearest Pharmacovigilance center in my geographical location.	40	60	0	24	74	2
5	I have been trained how to report an ADR.	18	82	0	40	58	2
6	Training is needed in reporting an ADR.	94	6	0	82	16	2
7	I knew how to report ADR to the Pharmacovigilance center.	26	74	0	20	78	2
8	I have reported an ADR before.	14	86	0	6	94	0
9	I have seen the suspected ADR reporting form of CDSCO.	30	70	0	14	86	0
10	ADR reporting form available when you are at the job of prescribing medicines to patients.	16	84	0	42	58	0
11	All ADRs should be reported for all drugs.	56	44	0	80	18	2
12	Only Serious Adverse Event/increased frequency of an ADR of old drugs need to be reported.	78	22	0	58	42	0
13	ADR reporting is a professional obligation.	68	30	2	72	28	0
14	ADR reporting should be made mandatory to my profession.	52	48	0	72	28	0
15	Reporting of only **one** ADR makes no significant contribution to the National Pharmacovigilance program /Society.	44	56	0	38	62	0

16	ADR reporting and monitoring system would benefit the patient	88	12	0	98	2	0
17	ADR information provided to you as satisfactory.	48	52	0	50	50	0
18	Regular information regarding ADR should be provided by Pharmacovigilance Centre /PVPI/ FDCA?	92	8	0	90	10	0
19	Do you worry about legal problem while you think of ADR reporting?	54	46	0	34	66	0
20	Do you support "Direct ADR Reporting" by the patients instead of physicians?	42	58	0	36	64	0
21	Do you think that trained pharmacist could be the right person to assist in ADR reporting?	88	12	0	76	24	0
22	Do you believe that the ADR reporting form of CDSCO/PvPI is up-to-date and consists of all the needed information?	22	24	54	58	32	10
Common factors leading to encouragement of reporting of ADR (Adverse Drug Reactions)							
23	If the ADR was serious.	78	6	16	90	8	2
24	If the ADR was unusual.	72	26	2	84	12	4
25	If the ADR was to a new product.	68	30	2	78	20	2
26	If the ADR was certainly	62	34	4	70	26	4
27	If the ADR was well recognized for a particular drug.	48	52	0	80	18	2
Common factors leading not to report the ADR							
28	Lack of time to fill-in a report.	56	38	6	52	48	0
29	Lack of time to actively look for ADRs while at work.	66	30	4	50	48	2
30	Concern that the report may be wrong.	42	52	6	42	56	2
31	If the reaction was well recognized for a drug.	62	30	8	54	44	2
32	Lack of confidence.	20	74	6	16	80	4

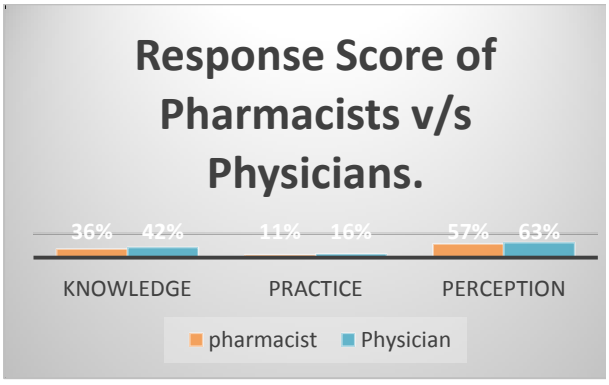

Figure 2: Response Scoring

Discussion:

India, one of the most reputed name in the world of Medicine, where there is half a million or more qualified doctors and 15,000 hospitals having the total bed-strength of 6,24,000 exists. India ranks 4th largest in the production of pharmaceutical goods through-out the world. Now-a-days, it is also becoming a hub for the Clinical trials, and many new drugs are emerging in to the market every-day. [13] India is one of the countries where discipline of Pharmacovigilance is still in its infancy stage and there is a very limited knowledge regarding this field of pharmaceutical sciences. Even the present study reveals the existence of a very limited knowledge and practice of ADR in the Gujarat

state. Although, underreporting of ADRs is a universal phenomenon, not only in India. [14]

Our study observed that the knowledge of ADR reporting system was inadequate among physicians, and pharmacists. Similar subject meta-analysis by Abubakar A R, et al. also reported the existence of inadequate awareness on ADR reporting by doctors. The attitude as well as the practice of ADR reporting was also far below expectations and it was discouraging. [15] Because, ADRs escalate healthcare cost by increasing the patient morbidity and mortality, there is a need to create awareness among healthcare stakeholders towards Pharmacovigilance. [14] Even though 94% of physicians do believe that all the drugs available in the market are NOT safe, only 6% of physicians have reported an ADR before. This attitude may lead to more chances of exposure of an individual / patient to experience an ADR. Before the withdrawal of Fenfluramine from market because of its association with valvular defect, almost 7 million were exposed to it worldwide. [16] It was noted in our study that only 38% and 44 % of pharmacists and physicians respectively, know about the existence of National Pharmacovigilance program, and 40 % and 24% pharmacists and physicians respectively, knew the nearest PV centre. These percentages show that spontaneous reporting system as recommended by National Pharmacovigilance program of India is not very well recognized by all the healthcare workers yet. It was highly discouraging to note that 74% and 78% of pharmacists and physicians respectively, do not know how to report an ADR to Pharmacovigilance centre.

A review on reporting pattern in general practice found that there was higher rate of reporting for severe and serious events. [16] Similarly, in our study 90% of physicians are encouraged to report an ADR if it was severe or serious. Other factors leading to encouragement of ADR also had quite good number of positive replies, such as – when the ADR is unusual, or to a new drug or it was certainly.

It is also needed to consider that physicians do not have enough time to spend so much for each and every individual patient. 78% physicians felt that the trained pharmacists could be the right person to assist in ADR reporting, the same was felt by 88% of pharmacists as well. 56% and 52% of pharmacists and physicians reported the lack of time as a factor of not reporting an ADR. Higher percentage was also observed with the factors such as if the reaction was well recognized for the drug, lack of time to actively look for the ADRs while at work.

The Drug Controller General of India (DCGI) and Indian Council of Medical Research (ICMR) have put a lot of effort in setting up many ADR monitoring centers in various parts of

India; despite their efforts pharmacovigilance is still in its infant stage in India. [14] Our study reveals the percentages that are disturbing to know the underreporting of ADRs and the lack of awareness about the Pharmacovigilance in the area where the study was conducted.

Limitations:

The main limitation of our study was the small sample size, and the areas covered of Gujarat state. We could have included Nurses as they also play an important role in Pharmacovigilance. Yet, by conducting this pilot study, we were able to identify the factors influencing the ADR reporting in our community, and have given us the insight on how to plan further to help the student pharmacists to improve their knowledge and attitude towards Pharmacovigilance.

Conclusion:

Assessment of awareness of pharmacovigilance among the healthcare professionals is very important due to under reporting of adverse drug reactions. Our study has shown that majority of the study participants were unaware about the ADR reporting system. The low level of reporting and factors such as lack of time for underreporting of ADRs shows the attitude towards pharmacovigilance. In the reporting of suspected ADR, to assist other healthcare providers, a trained pharmacist would be a right person. The implementation and awareness regarding pharmacovigilance and ADR monitoring is needed for the success of PvPI program. There is urgent need to provide good quality training to healthcare professionals even at the institute level to improve the current status of Pharmacovigilance in India.

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Conflict of Interest:

No Conflict of Interest to disclose.

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