

A study on awareness of pharmacovigilance and determinants of underreporting of adverse drug reactions by health care professionals and general practitioners

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ABSTRACT

Background: Health care providers/professionals (HCPs) play a critical role in ADR surveillance. Only 6% of all ADRs are reported and under-reporting acts as great impedance in exchange of drug information.

Methods: This was a prospective questionnaire-based study. Structured questionnaire was issued to HCPs before and after the conduct of Pharmacovigilance awareness program and scores given to each question was analyzed statistically.

Results: Of the 69 participants, 46.4% were nurses, 40.6% were residents of a tertiary health care facility and 13% were general practitioners in Pondicherry. The response rate was found to be 62.7% and 100% both before and after the awareness program respectively. Creation of awareness amongst HCPs is the most important factor (77%) influencing spontaneous reporting.

Conclusions: Our study suggests that HCPs were aware of the concept of ADR but the majority did not know how and where to report. Thus, creation of awareness amongst HCPs is the most important determinant influencing spontaneous reporting of ADRs.

Keywords: ADR, Health care professionals, Nurses, Pharmacovigilance, Residents

INTRODUCTION

A drug may produce desirable effects or undesirable adverse effects. The development of adverse drug reactions (ADR) to drugs or other medicinal products is a global problem. World Health Organization (WHO) defines ADR as any response to a drug which is noxious, unintended and which occurs at doses normally used in

man for prophylaxis, diagnosis, or therapy of diseases, or for the modification of physiological function. An ADR signal is defined as a possible relationship between an adverse event and a drug, the relationship being unknown or incompletely documented previously.¹ A constant vigilance on drug safety issues is always required in pharmacotherapy to promote better patient care. Thus, Pharmacovigilance has evolved as a distinguished

discipline and forms an integral part of various aspects of drug development and its promotional activities. The term Pharmacovigilance is a French word described by Professor Bernard Begaud as a discipline involving detection, evaluation, and prevention of undesirable effects of medicines.² However, the currently proposed WHO definition of Pharmacovigilance is the science and activities relating to the detection, evaluation, understanding, and prevention of ADRs or any other drug-related problems. The primary aspect of Pharmacovigilance is to provide updated safety information of drugs and other related medicinal products like herbals, medicinal devices, vaccines etc.^{1,3}

It creates a platform for exchange of drug information between medical HCP and regulatory authorities. Every HCP play a critical role in ADR surveillance and they should consider it as an ethical obligation to report ADR for safer drug use. Thus, it is of prime importance to establish an ADR reporting surveillance system in every medical institution and to educate the HCPs. The knowledge and the training of HCPs may improve the quality of reporting and minimize the cases of ADRs. To our dismay, only 6% of all adverse reactions are being reported and underreporting is a major obstacle to spontaneous reporting systems. Thus, under-reporting acts as great impedance in exchange of drug information between clinical practice and drug safety surveillance. It was found that the factors associated with under-reporting were ignorance among medical professionals (95%) and lethargy in reporting (77%).⁴ These problems are to be addressed by Pharmacovigilance centers through various strategies like conducting frequent Pharmacovigilance awareness programs, thereby highlighting on various aspects of ADR reporting and emphasize the role on the role of HCPs in drug safety issues. Thus, this questionnaire-based study was undertaken with the primary aim of evaluating the awareness of Pharmacovigilance among medical professionals of a tertiary health care facility as well as general practitioners in Puducherry and to analyse various factors influencing spontaneous reporting of ADRs. This will also give us an overview of various factors that hinder ADR reporting and help us in framing better ways to improve reporting behaviour.

METHODS

The study was a prospective study done for a period of 4 months from June to October 2010. The study was performed in compliance with the ethical standard. After obtaining the Institute Ethics Committee approval, a structured questionnaire (prior permission obtained from the developer through personal communication) was issued to the HCPs of a tertiary health care facility and general practitioners in Puducherry randomly and a pilot study for validation was conducted.⁵ Few changes were made in the order and phrasing of the questions and the

questionnaire was validated. Resident doctors, house surgeons, nurses, medical students who have completed 4th semester of MBBS and general practitioners in Puducherry who gave written consent for participation were included in the study. In a study conducted by Gonzalez et al, it was found that the prevalence of underreporting of ADR among HCPs was found to be around 94%.⁶ Considering a power of 80% and assuming a prevalence rate of 94%, the sample size was calculated to 102. Taking into consideration the allowance for drop outs, anticipating nonresponse and incomplete data collection, the final sample size was calculated to be 110. All the subjects participated voluntarily and were free to clarify their questions. They were asked to mention their profession/occupation and steps were taken to ensure that no name or initials be recorded to avoid potential bias. The questionnaire contained questions related to the attitude and awareness of reporting of ADRs in the hospital premises and various factors influencing the spontaneous reporting. The completed questionnaires were collected back followed by which a Pharmacovigilance awareness program was organized and conducted in the form of talks and lecture discussions. Then the same questionnaire was distributed to them and the scores given to each question was analyzed statistically to find out the significant factors contributing to under reporting. The participants also suggested some improvements in the conduction of awareness program. This was also taken into account for the future work on running a successful Pharmacovigilance center. The obtained data were entered in the Microsoft Excel spread sheet. Frequencies were expressed in percentages. The statistical analysis was performed using SPSS for Windows version 16.0 software (SPSS, Chicago, USA). The attitude of awareness among groups was analyzed before and after the conduct of pharmacovigilance program using Wilcoxon signed rank test. The response to the questions in the questionnaire was also analyzed using Chi- square test. A p-value <0.05 was considered statistically significant.

RESULTS

Of the 110 questionnaires circulated, 69 filled questionnaires were returned giving an overall response rate of 62.7% (29% nurses, 25.4% MBBS students and residents, 8.1% practitioners) and 100% both before and after the awareness program respectively. Of the 69 participants, 32 (46.4%) were nurses, 28 (40.6%) were students, residents and 9 (13%) were general practitioners in Pondicherry. 15.9% were unaware of the existence of ADR reporting and monitoring system in India and after the Pharmacovigilance awareness program the awareness became 100% in the study participants. 13% were unaware of the existence of ADR reporting and monitoring system in their hospital and the awareness became 91.3% in study sample.

Table 1: Analysis of awareness and attitude of health care professionals on ADRs before and after pharmacovigilance awareness program (n=69).

Statements from questionnaire	Response before Pharmacovigilance awareness program n (%)			Response after Pharmacovigilance awareness program n (%)			P value
	Yes	No	NA	Yes	No	NA	
Are you aware of existence of ADR reporting and monitoring system in India?	58 (84.1)	11 (15.9)	0	69 (100)	0	0	0.001
Are you aware of existence of ADR reporting and monitoring system in your hospital?	60 (87)	9 (13)	0	63 (91.3)	6 (8.7)	0	0.004
Are you aware that ADRs account for an increasing morbidity and mortality in developing countries?	50 (72.5)	19 (27.5)	0	69 (100)	0	0	0.001
Does the ADR reporting and monitoring system existing at your hospital encourage you to report further?	47 (68.1)	22 (31.9)	0	56 (81.2)	13 (18.8)	0	0.108
Did you report any suspected adverse drug reactions to ADR reporting and monitoring system existing at your hospital?	24 (34.8)	44 (63.8)	1 (1.4)	28 (40.6)	41 (59.4)	0	0.571
Do you know how to report an ADR to Pharmacovigilance center at your hospital?	42 (60.9)	26 (37.7)	1 (1.4)	63 (91.3)	6 (8.7)	0	0.001
Have you reported any suspected ADRs to any of the ADR reporting and monitoring centers?	10 (14.5)	52 (75.4)	7 (10.1)	13 (18.8)	56 (81.2)	0	0.648
Has this system created an awareness of ADR reporting in you?	51 (73.9)	14 (20.3)	4 (5.8)	64 (92.8)	4 (5.8)	1 (1.4)	0.031
Are you getting proper feedback to your reported reaction?	30 (43.5)	39 (56.5)	0	69 (100)	0	0	0.001
Is the ADR reporting and monitoring system existing at your hospital useful for your practice?	50 (72.5)	15 (21.7)	4 (5.8)	58 (84.1)	11 (15.9)	0	0.481
Do you think that existing ADR reporting and monitoring system would benefit patient or improve patient care?	65 (94.2)	4 (5.8)	0	67 (97.1)	0	2(2.9)	0.125
When reporting an ADR, one has to be sure of causal relationship	49 (71)	18 (26.1)	2 (2.9)	57 (82.6)	10 (14.5)	2(2.9)	0.170
When reporting an ADR, anonymity of the reporter is guaranteed	47 (68.1)	17 (24.6)	5 (7.3)	67 (97.1)	0	2(2.9)	0.001
When reporting an ADR, I use (the website /a paper form)	45 (65.2) Paper	9 (13) website	15 (21.8)	67 (97.1) Paper	2 (2.9) website	0	0.039
After introduction of a new drug, the majority of ADRs are already known	16 (23.2)	52 (75.4)	1 (1.4)	27 (39.1)	42 (60.9)	0	0.063
By reporting ADRs, I contribute to drug safety	65 (94.2)	4 (5.8)	0	69 (100)	0	0	0.046
When I notice an ADR, I want to share it with colleagues	69 (100)	0	0	69 (100)	0	0	0.289
When reporting an ADR, it could have legal consequences for me personally	33 (47.8)	36 (52.2)	0	27 (39.1)	42 (60.9)	0	0.377
When you encounter an ADR do you think that educating the patient is important	68 (98.6)	1 (1.4)	0	69 (100)	0	0	1.000
Is medical students and pharmacists assistance in detection, reporting and management of adverse drug reaction useful?	64 (92.8)	5 (7.2)	0	69 (100)	0	0	0.062

ADR- Adverse drug reactions, NA- Not answered. P<0.05 significant

27.5% were unaware that ADRs accounted for an increasing morbidity and mortality in developing countries and after the program the awareness was 100%. 24.6% thought that the anonymity of the reporter was not guaranteed.

After the program everyone (100%) became aware that the reporter details will be kept anonymous. 97.1% preferred to use the paper format while reporting ADRs. 94.2% felt that they contributed to drug safety by reporting ADRs and after the awareness program everyone felt that they contributed to drug safety by reporting ADRs. 75.4% of the participants opined that they had not reported any adverse drug reactions to other centers. 60.9% of the participants did not know how to report an adverse drug reaction to Pharmacovigilance center in their hospital but after the program 91.3% became aware of reporting an ADR to a Pharmacovigilance center. 56.5% stated that they did not get proper feedback to the reported ADR. 21.7% felt that the ADR reporting and monitoring system that existed at their hospital was not useful for their practice. But after the awareness program, they became aware of what ADRs were and how to report them. 84.1% also felt that this reporting system will help them in their practice (Table 1).

Creation of awareness amongst HCPs is the most important factor (77%) influencing spontaneous reporting of ADRs according to our study. The other factors being the system of Pharmacovigilance running in their hospital were simple to operate (59%). 23% felt that the response that was received from the Pharmacovigilance center in acknowledging the receipt of the report and provision of feedback on reported ADR was also encouraging in spontaneous reporting. Nearly 13% of the participants suggested that the factors which discouraged spontaneous reporting of ADRs were the time taken in reporting an adverse drug reaction in an outpatient department setting as well as the complexity of filling the forms. Some thought that reactions are well-known in clinical settings and were always mild in nature so they gave minor priority in reporting the reactions than in managing ADRs immediately (4%) (Table 2).

Table 2: Factors influencing ADR reporting (n=69).

Influencing factors	Response n (%)
Creation of awareness amongst health care professionals	53 (77)
Pharmacovigilance System in your hospital is simple to operate	41 (59)
Acknowledging the receipt of report and provision of feedback on reported ADR	16 (23)
Time consuming, tedious	9 (13)
Well-known reactions, mild adverse reactions and immediate management of ADRs	3 (4)

The majority (48%) suggested that discussing rare ADRs in monthly meeting and bringing out monthly/quarterly bulletin on ADRs will benefit in running a successful pharmacovigilance center. 45% of them thought that educating the medical students and other HCPs can lead to significant improvement in the spontaneous reporting of adverse drug reactions. 42% have shown that the current system of Pharmacovigilance program which is running in their hospital could be continued as such for better performance of pharmacovigilance center. The others suggested that they needed more feedback on reported reactions (8.6%) and information on ADRs for newer drugs (5.7%) (Table 3).

Table 3: Suggestions to improve ADR reporting (n=69).

Suggestions	Response n (%)
Discuss the rare ADRs in monthly meeting and bring out monthly/ quarterly bulletin on ADRs	33 (48)
Educate the medical students, nursing staff and technicians	31 (45)
Continue the same system of reporting ADRs	29 (42)
Need more feedback on reported reactions	6 (8.6)
Provide information on ADRs for newer drugs	4 (5.7)

DISCUSSION

Medical practitioners and students are the primary contributors among various health care communities to ADR reporting. On the contrary, the knowledge of ADRs and the method of reporting are inadequate among them. Therefore, the success of spontaneous reporting system primarily depends on the participation of reporters and it is an important determinant of underreporting. To improve the reporting rate, it is important to improve the knowledge, attitude, and practices of the HCPs regarding ADR reporting and Pharmacovigilance. It has been found that continuous medical education, training, and integration of ADR reporting into the clinical activities of doctors would likely to improve reporting.⁷⁻⁹ In addition to that improved communication of General Practitioners with their fellow General Practitioners and other HCPs as well as with their patients may further stimulate ADR reporting.¹⁰⁻¹³ Thus, Pharmacovigilance program helps to build health systems for patient care and drug safety.¹⁴ Thus, the present study was undertaken with the aim of assessing the factors influencing spontaneous reporting among HCPs.

It has been found in few studies that identification of knowledge and attitudes relating to under-reporting would enable reporting of suspected ADRs to be increased.^{6,15,16} In a study conducted in Lagos, Nigeria by Oshikoya et al in 2009, it was found that the response rate was 82.5% and a majority of the respondents were aware of the

existence of National Pharmacovigilance center in Nigeria. Education and training of the HCPs were considered the most recognized means of improving ADR reporting. Similarly, in our present study also the response rate was found to be 62.7% and 100%, before and after the conduct of Pharmacovigilance awareness program respectively and creation of awareness among HCPs is the most factor influencing reporting behaviour. In a study conducted in India, the response rate among resident doctors (70.7%) was better than consultants (34.5).¹⁷ Similarly, our study also showed an increased response rate among resident doctors (25.4%) the reason being ADR reporting was made as a part of undergraduate and postgraduate curriculum.

In a study conducted in Canada it was found that the four major obstacles to reporting adverse reactions were that Pharmacovigilance was seen as an unrealistic ideal, the reporting authority was perceived as a virtual and remote entity, HCPs do not feel concerned by the risks associated with the medications used in their practice and were uncertain about the scope of their role in reporting adverse effects.¹⁸ Similarly, in a study conducted by Ramesh et al in 2009, it was found that the factors that influenced ADR reporting were simple to operate and constant creation of awareness and the factors that discouraged reporting were well-known reactions, mild reactions and immediate management of ADRs.⁵ But in the present study it was found that creation of awareness amongst HCPs is the most important factor (77%) influencing spontaneous reporting of ADRs. In a study performed in the Netherlands 35% of the medical practitioners stated that reporting was time consuming and a reason for not reporting.¹⁹ But in our study only 13% felt that the reporting was tedious and time-consuming because of improvised technologies in reporting.

These results suggests that ADR reporting rate may be enhanced through appropriate campaigning and understanding the major determinants of under reporting by HCPs. Specific education and training of General Practitioners on pharmacotherapy, preferably with extra attention to ADR reporting may improve reporting behaviour. Our study limitations include small sample size probably because only 62.7% of the participants responded. Further, the effect of the impact of Pharmacovigilance awareness program on ADR reporting on a long term basis couldn't be evaluated because of the shorter duration of study period.

CONCLUSION

Present study suggested that the HCPs and general practitioners in Pondicherry were partially aware about Pharmacovigilance and ADR reporting, although they encountered many ADRs in their day to day practice. They were aware about the concept of ADR but majority did not know how to report and where to report. Thus, creation of awareness amongst HCPs is the most important factor influencing spontaneous reporting of

ADRs. Further, the factors which discouraged spontaneous reporting were the time taken in reporting an ADR in an outpatient department setting as well as the complexity of filling the forms. The awareness of spontaneous reporting of ADR among HCPs and public should be given due considerations for preventing major morbidity and mortality. Hence various Pharmacovigilance awareness programs should be conducted regularly in educating the medical students and other HCPs to improve ADR reporting behaviour.

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