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AWARENESS ON ADVERSE DRUG REACTIONS AND ADVERSE DRUG REACTION REPORTING SYSTEM IN INDIA: A CONSUMER SURVEY

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ABSTRACT

Objective: Worldwide, adverse drug reactions (ADRs) have been recognized as the driving cause of mortality and morbidity. In India, PvPI has various methods to empower the reporting system of ADRs but direct reporting rate by the consumer is still low. So, this study was designed to determine the level of consumer or patient awareness on ADR and ADR reporting system in India amongst population of different age groups, profession and academic backgrounds etc. **Method:** A total of 100 people who gave consent were included as respondent for the self-administered survey questionnaire designed as a Google form and circulated via emails, online links, and the Whatsapp platform. A Pearson Chi (χ^2) test was performed to determine significant differences and associations between categorical variables and responses. Spearman's correlation coefficient was used in an analysis to predict correlation in variables. The data was analyzed using PSPP software version 1.4.1. **Results:** The response rate was 100% and majority of respondents were aware of ADR (69.3%), and had actually experienced adverse drug reactions (52%) with the use of allopathic medicine (64.4%) followed by cosmetic products. Few respondents knew about ADR through Pharmacists and Doctors (16.5 %), out of which male respondents were in majority but female respondents were found to be more active in reporting (64%). Only 43.6% of respondents were aware that they can directly report the ADR to the regulatory agency (mainly pharmacy and medical students not the non-medical professionals) but only 23% of respondents were aware of the reporting websites and ADR consumer form. ADR reporting system awareness was higher in younger adults (20-25 years) mainly male students from Pharmacy/Medical background but reporting rate remained low (χ^2, p value=0.001, T value 0.001) and reporting rate was more in male (χ^2, p value=0.025, T value 0.026) belonging to the profession of servicemen/private employees (χ^2, p value=0.005). **Conclusion:** In general, younger adult males with pharmacy/medical backgrounds had experienced more ADRs, had more awareness of ADRs and ADR reporting system but still the ADR reporting rate was found to be low amongst them due to be unawareness of any regulatory agency and consumer ADR website form.

KEYWORDS: Adverse drug reactions, Pharmacovigilance, Pharmacovigilance program of India (PvPI), Consumer reporting, National coordination centre (N.C.C).

INTRODUCTION

Pharmacovigilance (PV) deals with the detection, understanding, assessment, and prevention of adverse drug reactions (ADR) and other possible drug-related problems.[1] According to the reports, only 3% contribution of ADRs reports from developing countries are observed.[2] The main goal of PV is to enhance the rational use of medicine and quality of life of the patient by early identification of the signals.[3] Approved and prescribed medicines may lead to ADRs which have been recognized as the driving cause of mortality and mobility as there is a 2.6 fold increase in patient deaths every year because of ADRs.[4] This enforces the pressure on the economy of the country.

PV activities in India are controlled by the Indian Pharmacopoeia Commission (IPC) and National Coordination Committee (N.C.C) through the Central Drug Standard Control Organization (CDSCO).[5]To

strengthen the PV and ADR reporting in India, the Indian government commenced the Pharmacovigilance Program of India (PvPI) on 14th July 2010 with AIIMS at NCC for ADR monitoring and enhancing public health by assuring the safety of the medicine and other risk associated with the medicinal products.[6] In the year 2011, NCC was shifted from AIIMS to Indian Pharmacopoeia Commission (IPC), Ghaziabad, and work under the ministry of health and family welfare (Government of India) for the smooth functioning of the program.[5] Currently, 270 ADR monitoring centers (AMC) are working in Indiaand collecting individual case safety reports (ICSRs).[12]

Under-reporting of ADRs is the major problem in India. PvPI thus takes the key steps to increase the day-to-day ADR reporting by involving the patients directly into the PV system. In recent years, PvPI came up with many reporting methods like Helpline number, E-mail, Mobile Application & ADR forms in different languages to extend the ADR reporting to rural areas and to create awareness among the people.[6]This step can increase the unsolicited ADR reporting by patients, can enhance the PV activity, and can stretch the Pharmacovigilance program to remote areas.[7] Despite having many methods of reporting ADR, still consumers are not actively reporting the ADRs. Our study is one such attempt to assess the consumer awareness about ADRs and ADR reporting system i.e. and ADR form/official websites in India to facilitate active and unsolicited ADR reporting. Our questionnaire aimed at evaluating consumer's awareness of the ADR & ADR reporting system among medical/para-medical staff who are not only the stakeholders of PvPI but are those who dispense the medicines to the ultimate consumer along with other professionals from the non-medical background.[22] Our study will contribute to enhance knowledge and assess consumer perception about ADRs and ADR reporting system in India and provide information that can break the bridge between the consumers and regulatory authorities, as the ADR reporting rate in India is merely 1% as compared to the global rate of 5%.[23]

MATERIALS AND METHODS

The study was designed as a descriptive correlation study where consumers were asked questions to assess their knowledge about the ADRs and different ways to report ADR directly to the regulatory agencies or via other modes.

Questionnaire

A close-ended structured questionnaire was prepared after extensive literature review, discussion, and under the guidance of professors in the field of Pharmacovigilance, to assess the awareness about ADR and ADR reporting among the consumers. The questionnaire was prepared as a Google form to obtain and record the specified and relevant information with fair accuracy and completeness. The questionnaire was pretested in 10% of the agreed respondents which were not included in the final interpretation of the results. The questionnaire was divided into three parts (i) to record and evaluate consumer demographiccharacteristics listing the name, age, gender, and professional background of the respondents (ii) to assess consumer's knowledge on the adverse drug reaction (ADRs), reporting the frequency of medicinal product consumption, type of medicinal or other cosmetics or herbal products for medicinal use, ADR experienced if any, the severity of the reaction, etc. (iii) to assess consumer's awareness on the ADR reporting system and ADR form/official websites, assessing their knowledge on ADR reporting methods to regulatory authorities, etc.

Study population and duration

The questionnaire was circulated to a large sample of people via email, Whatsapp, and online links. The 100 respondents, who agreed were included in the survey through a stratified random sampling technique. The survey responses were analyzed and reported.This study was conducted over a period of two months i.e. April-May 2020.

Inclusion-Exclusion criteria

All the respondents who gave their consent to participate in the survey and were above the age of 15 years from both medical and non-medical backgrounds were included in the survey. People above the age of 60 years, those who didn't submit a response within study duration, and internet non-users were excluded from the survey.

Data analysis

The data was collected and consolidated in a Microsoft Excel spreadsheet (2007). The gathered data were analyzed and the percentage of response was calculated from the answered questions only. The data was studied and analyzed using descriptive statistics to calculate frequency (percentage) in case of consumer demographic details and data from consumer awareness on ADRs and ADR reporting system. A Pearson Chi (χ^2) test was performed to determine if some significant differences exist between a categorical variable and other responses or if any association is there in different variables? The significance level was set at $p<0.05$ in a two-sided χ^2 test. In the case of categorical variables, the trend was estimated (Linear-by-linear association in χ^2 test). Significance for T value was set at $p<0.05$. Spearman's correlation coefficient (r) was used in the analysis to predict correlation in numeric variables and the association was considered as strong if $r>0.7$, moderately associated if $r>0.4$ and $r<0.7$, and weakly associated if $r<0.4$. The data was entered and sequentially analyzed using PSPP software version 1.4.1, intended as an alternative for IBM SPSS statistics, a GNU project for conducting mathematical operations.

RESULTS

A total of 100 questionnaires were distributed among the people through emails, Whatsapp, and online Google

form links. The analysis done in the study is based on the responses of 100 respondents who participated in this study.

The response rate was 100 % except for some missing values. The demographic details of the respondents are summarized in Table 1, Tables 2 and 3 summarize the responses regarding consumer awareness on ADRs and ADR reporting to the regulatory agency.

Demographic details

The maximum percentage of respondents was from the age group 20- 25yrs, followed by the age group of above 40 years, remaining comprising of the minor proportion. (Table 1). 51% of respondents were male and 49% were females. All the respondents were literate, however, belonging to different occupations. The major proportion of respondents was of Pharmacy/Medicalstudents that comprise 48.5% followed by the Government/ private servicemen i.e. 21% of the total. Businessmen, teachers, and housewives comprised of minor percentage.

Table 1: Demographic characteristics of respondents.

Age (Years)	**Frequency (%)**
15-20	6 (6.0)
20-25	59 (59.0)
25-30	11 (11.0)
30-40	5 (5.0)
Above 40	19 (19.0)
Gender	**Frequency (%)**
Male	51 (51.0)
Female	49 (49.0)
Profession	**Frequency (%)**
Businessmen	5 (5.0)
Servicemen (Govt./Pvt.)	21 (21.0)
Student (Medical/Pharmacy)	49 (49.0)
Student (Non-Medical)	14 (14.0)
Teacher	5 (5.0)
Housewife	3 (3.0)
Others	3 (3.0)

Table 2 summarizes the responses provided by consumers regarding awareness of ADRs. Upon evaluation, it was observed that 69.3% of respondents were aware of what ADR is? 52% of total respondents have experienced ADR whereas 19% possibly may have experienced the ADR. Majorly 64.4% of respondents experienced the ADR with the use of Allopathic medicine while 17.4% experienced it with the use of both allopathic medicines and cosmetics or both allopathic medicines and herbal products. Over 64% of respondents report this reaction to the Doctor. The data reflects that the majority (45.8%) of respondents came to know about the ADR through referring to multiple sources i.e. educational books, the internet, and Doctor's/Pharmacist's consult while 30.6% of respondents became aware of ADRs via reading educational books.

Table 2: Consumer awareness about Adverse Drug Reactions (ADRs)

Question (categories)	**Frequency (percentage)**
Do you know what an adverse drug reaction is?	
Yes	70(70.0)
No	30(30.0)
Have you ever experienced any adverse reaction after having a medicine?	
Yes	52 (52.0)
No	29 (29.0)
Maybe	19 (19.0)
With which medicinal product consumer experienced the ADR?	
Allopathic medicines	47(64.4)
Cosmetics only	10 (13.7)
Herbal Products only	3(4.1)
Multiple products	13 (17.8)
How bad was the reaction?	
Mild	46(90.2)
Serious	5(9.8)
Have you reported this reaction to the doctor?	
Yes	48(64.0)
No	27(36.0)
How do you know about it?	
Doctor	7(9.7)
Internet	5(6.9)
Pharmacist	5(6.9)
Educational Books	22(30.6)
More than one source	33(46.8)

Table 3 shows that only 43.6% of respondents were aware of the ADR reporting. 44% of the respondents reported the ADRs to the respective agency and 56% of

them did not report any ADR. The non-reporting of the ADR can be attributed to unawareness as only 23% of respondents agreed that they know about the official website and consumer ADR form for reporting while 77% were having no idea about sources of reporting ADR.

Table 3: Consumer awareness on Adverse Drug Reaction (ADRs) reporting.

Question (categories)	Frequency (%)
Are you aware that, you can directly report the adverse drug reaction to the regulatory agency?	
Yes	44 (44.0)
No	56 (56.0)
If yes, have you reported any adverse reaction yet to the regulatory agency?	
Yes	44(44.0)
No	56(56.0)
Are you aware of the official website for reporting ADR and consumer adverse drug reaction forms?	
Yes	23(23.0)
No	77(77.0)

Consumer awareness on ADR's

Based on the responses provided by consumers, regarding awareness of ADR, it was observed that 69.3% of respondents were aware of ADRs and 29.7% have never heard about ADRs. 52% of respondents have experienced the ADRs at least once in their lifetime, whereas 29% have never experienced the same and around 19% were not sure about the experience. Most of the ADRs i.e. 64.4% were reported with the use of Allopathic medicine, few with cosmetics i.e. 13.7%, and only 4.1% with herbal products only.90.2% of ADRs observed were mild and about 9.8% ADRs were reported as serious by the respondents. Over 64% of respondents reported. Most of the consumers i.e. 45.8%, who referred the condition to Doctor or cross-checked from internet/pharmacist/educational books i.e. multiple sources, were much aware of the ADRs followed by those who followed educational books only.

Since, age, gender, and profession are ordered categorical values; the χ^2 test was calculated for trend (linear-by-linear association by PSPP output). Significance levels were set at a T value $p<0.05$ in the results.

Younger adults belonging to the age group of 20-25 years have experienced ADRs (χ^2, *p value*=0.012), however, no trend was observed as per categories (T value, 0.285). The male respondents were found to be more aware of the ADRs as compared to female respondents (χ^2, *p value*=0.040, T value, 0.041), of which most of the male would be from Pharmacy/Medical background (χ^2, *p value*=0.001), however, the trend was absent in case of the profession (T value, 0.830). Also male and the female suffered ADRs after the use of Allopathic medicines majorly, followed by cosmetic products in case of female respondents (χ^2, *p value*=0.016, T value 0.036), but female respondents were found to be more active in reporting of the ADRs are compared to male respondents (χ^2, *p value*=0.034, T value, 0.035). Pharmacy/Medical students knew more about the ADRs after referring to multiple sources of information including education books to the maximum extent (χ^2, *p value*=0.001, T value, 0.017).

Consumer awareness on Adverse Drug Reaction (ADRs) reporting system

Based upon the responses regarding consumer awareness on the ADR reporting system, it was observed that only 43.6% of respondents were aware that they can directly report the ADR to the regulatory agency and a similar percentage of respondents were there who reported the ADR yet. But 77% of respondents didn't know about the official website of reporting ADRs and consumer ADR form.

Younger adults belonging to the age group of 20-25 years were aware of the fact that ADRs can be directly reported to the agency, but the majority of themhave not reported any event to any regulatory agency (χ^2, *p value*=0.001, T value, 0.001) as younger adults found to be unaware of any regulatory agency and consumer ADR website form for reporting (χ^2, *p value*=0.006, T value, 0.006). The one who reported comprises more male respondents as compared to female respondents (χ^2, *p value*=0.025, T value, 0.026). The students from Pharmacy/Medical background were aware that they can directly report the ADRs to regulatory agency (χ^2, *p value*=0.001) and about the website form to report ADR (χ^2, *p value*=0.001), however, the trend was absent in the case of the profession (T value, 0.238 and 0.532). The number of respondents who reported ADRs to any regulatory agency was equally shared by the male belonging to the profession of servicemen/private employees and students from Medical/Pharmacy background (χ^2, *p value*=0.005) and the trend was not established (T value, 0.722).

Consumer demographic characteristics, consumer awareness on ADRs, and consumer awareness on ADR reporting system were compared with other answers

using Pearson's correlation coefficient. The results obtained were significant that consumer demographic details age, gender, and profession had a significant effect on answer related to consumer awareness on ADRs, medicinal products leading to ADRs, and consumer awareness son ADR reporting system. In general, younger adult males with pharmacy/medical backgrounds had to experience ADRs and thus had more awareness of ADRs and ADR reporting system.

The highest Spearman's Correlation coefficient (r) was found to be 0.473 between the statements 'Are you aware that, you can directly report the adverse drug reaction to regulatory agency?' and 'Are you aware of the official website for reporting ADR and consumer adverse drug reaction form?' but as the correlation value is moderate, but it was difficult to define the relationship between the statements.

DISCUSSION

Previous studies had reviewed and assessed the knowledge toward ADR and ADR reporting system among pharmacist, health care professional, medical student as study population, but studies among pharmacy student and other profession are limited.In this study total, 100 questionnaires were distributed among the people through email, Whatsapp, and online Google form links. The analysis done was based on the 100 respondents who agreed to participate in this study. The study results indicate that the young male respondents (20-25 years) from pharmacy/medical background were more aware of the ADR and ADR reporting system than the older respondents. This indicates a lack of awareness among the older age people about ADR; Also young adults were not actually aware of reporting website and forms which can be one of the reasons for less reporting of ADR from special group patients (like geriatric patients) and educated pharmacy professionals.

In a similar study conducted in AIIMS hospital, New Delhi about 74% of respondents were aware of What ADR is?[23] The findings are in line with our results that shows that younger male consumers (69.3%) were aware of what ADR is? The 48.5% of the respondents from our study were from Pharmacy/Medical background (χ^2, p value=0.001). The findings could be attributed to the lack of knowledge about ADR among consumers from Non-pharmacy background. This unawareness serves as a gap between the consumers and the regulatory agency which leads to under-reporting. Maximum number of respondents (64.4%) experienced ADR with the use of allopathic medicine followed by 13.7 % who experienced ADR with use of cosmetics only. However, a relatively lower ADR occurrence (4.1%) was observed with the herbal products. This indicates we need to concentrate on Pharmacovigilance activities and post-marketing surveillance of allopathic medicine and cosmetics to enhance the safety of the consumers.

The survey studies done in Riyadh, Saudi Arabia revealed that 6.4 % of respondents come to know about ADR through educational books and 36.8 % through the information provided by pharmacist.[24] Whereas in the present survey, we get to know that a very less number of people got information of ADR from the pharmacist (6.9%) or health care professionals (9.7%) and about 30.6% of respondents come to know about ADR through educational books or via referring multiple sources like internets etc. This asks for the need to increase the role of pharmacists and doctors in awareness of ADR reporting to enhance the spontaneous reporting of the consumers in India. It is evident from the results that 43.6% of respondents were aware of direct Consumer reporting of ADRs and only 44% of respondents reported any ADR to the regulatory agency yet. It clearly indicates a lack of knowledge and unawareness among consumers about the ADR reporting system. (Where and how to report?). Spontaneous reporting will increase if proper knowledge is imparted to the consumers while prescribing the drugs. Proper information regarding the ADR reporting system should be there on the labels of the drug. According to the present study, only 23% of respondents were aware of the official websites and ADR reporting form. Our finding regarding awareness of ADR form among respondents was found less than the study done by Debranjan Datta.[25]This indicates that there are lots of methods of ADR reporting but consumers are not aware of it that serves as the main reason behind the under-reporting of ADR in India.

The major limitation of my study was that the study was conducted with a limited sample size. Additionally, the survey was conducted only through internet access (Online survey) and a personal interview could not be conducted due to time constraints as it was an undergraduate project. Moreover the interpretation of the study could be affected by the opinion of non – responders.

CONCLUSION

In general, younger adult males with pharmacy/medical backgrounds had experienced more ADRs, had more awareness of ADRs and ADR reporting system but still the ADR reporting rate was found to be low amongst them due to be unawareness of any regulatory agency and consumer ADR website form. Overall this study gave us a brief idea about reasons of non-reporting or under reporting of ADR among pharmacy professionals and respondents from other background, which can be studied in depth or via conducting more descriptive studies in future.

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