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Impact of educational intervention on Adverse Drug Reaction Reporting - A consumer centered cross sectional survey

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ABSTRACT

Consumer reporting of ADRs has some advantages like directness, proper estimation of the burden of ADRs for individuals, early detection of ADRs, ADRs reporting of over-the-counter medicines, promotion of consumers' rights and decrease underreporting. For promoting consumer ADR reporting in our country, it is important to check and improve consumer awareness on ADR reporting. Objective of the study is to assess the knowledge of consumers about adverse drug reactions and reporting systems and evaluate impact of educational interventions to encourage consumers ADR reporting. A prospective observational questionnaire-based survey was conducted in tertiary care teaching hospital. Data were collected from every patient or consumers visiting the hospital who is above 18 years old and willing to participate. A total of 375 samples were collected and analyzed. A total of 375 pre-intervention and 100 post-interventional samples were taken. Almost 253(67.4%) participants responded that they didn't know about ADR. 32(8.5%) participants experienced ADRs. After educational intervention, 100 (100%) participants understood about ADR. Before intervention, only 85(22.6%) participants felt ADRs should be reported, after intervention almost 97(97%) participants said ADRs should be reported. Before intervention, 247(65.8%) participants and after intervention 95 (95%) participants opined they will report ADRs in future. It was found that consumers were lacking awareness of ADRs and its reporting system. Our study results proved that educational interventions could create awareness in general population and thereby increase adverse drug reaction reporting by consumers drastically.

INTRODUCTION

WHO defines Adverse Drug Reaction (ADR) as "a response to a drug which is noxious and unintended, and which occurs at doses normally used in man for the prophylaxis, diagnosis, or therapy of disease, or for the modification of physiological functions. Adverse drug reactions (ADRs) are an important source of morbidity and mortality which account for approximately 5.3% of hospital admissions. The incidence of fatal ADR ranges from 0.23% to 0.41%.[1]

Traditionally only healthcare professionals report ADRs to National Pharmacovigilance but the consumers also have the right to report the ADR of the drug consumed. The patients can report ADRs, which prescribers may not consider serious but may be troublesome to patients, and therefore, patients are worthy of reporting the ADRs they experience. So many countries opt for ADR reporting by spontaneous reporting of ADRs, but underreporting is the main concern and is a major challenge.[1]

Many of the patients are experiencing ADRs in between their treatment duration but they are unaware of how, when, and where to report the ADR. Annual performance report of

Pharmacovigilance Programme of India 2014-2015 suggests that consumer reporting is as low as 0. 08 % in India. The major factor for under-reporting of ADRs includes lack of knowledge and awareness about ADRs, ADR reporting, and pharmacovigilance program which will in turn delays ADR signal detection.[2]

Consumer AE reporting can support signal detection and lead to the identification of new AEs as well as those previously unreported by HCPs that may potentially be associated with a medicine or vaccine. To enable effective and timely AE reporting, consumers must have an understanding of what comprises an AE, the motivation to report, and, importantly, an awareness of available reporting systems.[3]

The patient or his/her representative is encouraged to report ADRs directly to the NCC- Pharmacovigilance Program of India or the nearest AMC by submitting a medicine side effect reporting form for consumers. [4] Direct patient reporting is important for continuous improvement in successful pharmacovigilance because it increases the chances to identify new safety issues and it will also increase overall reporting rates.[5]

The Central Drugs Standard Control Organization (CDSCO), New Delhi, India, under the aegis of the Ministry of Health and Family Welfare, Government of India, has initiated a nationwide pharmacovigilance program in July 2010 for monitoring ADR in the country to safeguard public health. The event also witnessed the launch of the national strategic plan for the scale-up of Pharmacovigilance in India.[6]

It has been shown that about half of ADR-related readmissions were preventable, highlighting the importance of detecting and reporting side effects associated with medication use, to facilitate the early detection of ADRs. In recognition of the possible contribution made by patients in the improvement of early detection of suspected ADRs, the Yellow Card scheme was introduced to allow patients to report ADRs directly to the MHRA (Medicines and Health products Regulatory Agency) in February 2008 UK.[7]

Pharmacists plays an important role in the field of medicinal drugs including in the scientific field dealing with the safety of drugs - Pharmacovigilance. There is ample evidence that shows that the pharmacist is both willing and capable of adequately fulfilling the role of an ADR reporter with their expertise in the drug field. Cooperation between physicians and pharmacists appears to be of vital importance, with each of the two professional groups contributing their respective expertise and experience to promote the rational and safe use of medicinal drugs.[8]

Observing the ADR reporting practice of consumers can be useful in exploring the probable causes of under-reporting as well as a preferred method of ADR reporting among consumers. Most of the studies in the past had explored and reported knowledge and perception toward ADR among healthcare professionals, pharmacists, and medical students. But studies on awareness among patients are limited. Thus, Educational interventions should be performed to increase the awareness and practice of ADR reporting systems for a better-quality health care society.[6]

In this context the study entitled "**Impact of Educational Intervention on Adverse Drug Reaction Reporting - A Consumer Centered Cross-Sectional Survey"** was performed with a hypothesis that educational interventions can improve awareness and willingness to report adverse drug reactions by consumers from March 2022 to August 2022.

MATERIALS AND METHODS

A Questionnaire based-cross sectional study was carried out for a period of 6 months. The study included all the patients and bystanders visiting the hospital above the age of 18 years who are consumers of medicine. Consumers who agreed to participate in the survey and willing to co-operate during the study were included. All the patients and bystanders visiting the hospital below the age of 18 years and consumers who are unable to participate in the survey due to their medical conditions or any other reasons are excluded from the study.

Sample size was calculated based on a previous study which recorded the prevalence of 0.74. Taking 95% confidence Interval, the required sample size for the study was minimum of 375 participants or consumers. A suitably designed questionnaire was used to collect the details of respondents' socio-demographic characteristics were incorporated in Part A, questions regarding knowledge and experience of adverse drug reactions were incorporated in Part B, questions regarding knowledge and utilization of adverse drug reaction reporting systems, National Pharmacovigilance Program of India, and opinions of respondents on ADR reporting were included in Part C, was taken from previous studies. The study was approved by IEC committee by issuing Ethical Clearance Certificate.

COLLECTION OF DATA

The study was carried out for six months and was divided to three stages.

Pre-interventional Stage:

Project team approached participants and explained about the study purpose. Written consents were taken from the study participants. Interview was carried out by distributing questionnaire. Self-administered questionnaire for educated participants and interview administered questionnaire for participants who are aged, illiterate was given. Both open and close ended questions were asked for clarification or confirmation of data provided by the participants. Information regarding knowledge of adverse drug reactions, ADR reporting systems and of National Pharmacovigilance Program. of India was collected.

Interventional Stage:

Educational intervention was carried out to the sample who were already participated in pre-intervention phase of the study. PowerPoint presentation on Adverse Drug Reactions, ADR reporting systems and Pharmacovigilance Program of India in Kannada, Hindi and English language. The duration of PowerPoint presentation was 30 minutes.

Post Interventional Stage:

Questionnaire was Re- administered to 100 consumers by random sampling to compare the data with pre-interventional results and assess the change in knowledge, attitude and practice of ADR reporting.

Statistical Analysis:

The data collected were decoded and analyzed by comparing pre-interventional results with post interventional results, using Chi-Square test as appropriate. All statistical calculations were performed using Statistical Package for Social Science (SPSS) Version 20.0.

RESULTS

A total of 375 participants among general population were taken for pre-educational intervention study and 100 participants were taken for post-educational intervention study. The data was analyzed based on the following parameters.

Demographic Status of participants

The collected data showed that almost 200 (53.3%) participants were male and 175 (46.7%) were females. Out of 375 participants, most of the respondents 54(14.4%) were aged 18-25 years, followed by those aged 25- 35 years were 89(23.7%), aged 35-45 years were 68(18.1%), aged 45-55 years were 72(19.2%), aged 55-65 years were 60(16%). Least number of respondents were from the age group of more than 65 years 32 (8.5%). Almost 201 (53.6%) participants were literate and 174 (46.4 %) of participants were illiterate as shown in Table No.1.

Multivariate analysis of Knowledge towards Adverse Drug Reactions and its reporting system among consumers

Multivariate Analysis was performed to assess knowledge of consumers towards awareness of adverse drug reactions which was depicted in Table No.2. It indicated that the participants of age group 25-35 as informants (AOR=8.328, CI=12.122,41.511, P=0.000<0.001) are significantly associated with increased knowledge regarding Adverse Drug Reactions than other age groups of respondents. Similarly high education status like Degree holders (AOR=65.88, Cl=15.60,278.3, P=0.000<0.001), good professional background such as teachers (AOR = 4.254, Cl= 0.768,23.55, P= 0.072>0.05) will also influence higher level of awareness and knowledge regarding Adverse Drug Reactions compared to other groups of respondents.

Multivariate analysis of knowledge towards Adverse Drug Reaction Reporting systems was depicted in Table 3. It indicated that the participants of age group 25-35 as informants (AOR=2.459, CI=0.540,11.203, P=0.203>0.05) are significantly associated with increased knowledge regarding Adverse Drug Reaction Reporting system than other age groups of respondents. Similarly high education status like post-graduated respondents (AOR=137.250, Cl=17.801,1058.248, P=0.000<0.001), good professional background such as teachers (AOR = 36.400, Cl= 5.373,101.035, P= 0.652>0.05) will also influence higher level of awareness and knowledge regarding Adverse Drug Reaction Reporting system compared to other groups of respondents.

Table 1 : Socio-demographic characteristics of Consumers (n=375)

Sl. No	Characteristics	No (%)
1	Age group (Years)	
	18-25	54 (14.4)
	25-35	89 (23.7)
	35-45	68 (18.1)
	45-55	72 (19.2)
	55-65	60 (16)
	65-75	32 (8.5)
	Mean = 42.6427	Standard Deviation = 15.0344
2	Gender	
	Male	200 (53.3)
	Female	175 (46.7)
3	Educational Status	
	Illiterate	174 (46.4)
	Primary school	103 (27.5)
	Secondary school	49 (13.1)
	Degree	44 (11.7)
	Post-graduation	5 (1.3)

Table 2 : Multivariate analysis of knowledge towards Adverse Drug Reactions among consumers

Characteristics		Awareness of ADRs		AOR	95% CI	p value
		Yes N (%)	No N (%)			
Total (N)		490	1010			
Gender	Man	94 (25)	106 (28.2)	1	-	-
	Women	28 (7.5)	147 (39.2)	22.432	12.122, 41.511	0.000<0.001
Age	18-25	40 (11)	14 (3.7)	1	-	-
	25-35	51 (13.6)	38 (10.1)	8.328	4.311, 16.08	0.000<0.001
	35-45	19 (5.0)	49 (13.7)	0.768	0.430, 1.372	0.372>0.05
	45-55	9 (2.4)	63 (16.8)	0.240	0.115, 0.502	0.000<0.001
	55-65	3 (0.8)	57 (15.2)	0.087	0.027, 0.283	0.000<0.001
	65-75	0 (0)	32 (8.5)	1.552	1.435, 1.679	0.000<0.001
Education	Illiterate	2 (0.5)	172 (45.9)	1	-	-
	Primary school	35 (9.3)	68 (18.1)	1.094	0.677, 1.770	0.713>0.05
	Secondary school	41(10.9)	8 (0.2)	15.502	6.978, 34.43	0.000<0.001
	Degree	42 (11.2)	2 (0.53)	65.888	15.60, 278.3	0.000<0.001
	Post-graduation	4 (1.06)	1 (0.3)	8.542	0.944, 77.26	0.023 <0.05
Occupation	Home makers	38 (10.1)	95 (25.3)	1	-	
	Farmers	61 (16.2)	116 (31)	0.752	0.475, 1.192	0.225>0.05
	Teacher	4 (1.06)	2 (0.53)	4.254	0.768, 23.55	0.072 >0.05
	Students	14 (0.37)	2 (0.53)	16.269	3.635, 72.81	0.000<0.001
	Others	2 (0.53)	8 (0.2)	0.510	0.107, 2.441	0.391>0.05
	Unemployed/retired	3 (0.8)	30 (8)	0.187	0.056, 0.627	0.003<0.01

Consumers awareness on Adverse Drug Reactions before and after Educational Intervention

Almost 122 (32.5%) out of 375 respondents reported that they didn't know about ADR before intervention as shown in Fig.1, and 100% of people responded they know about ADRs after educational intervention as shown in Fig.2. Out of 375 consumers, 32 (8.53%) experienced ADRs. Only 7 respondents knew about ADR reporting before educational intervention.

Consumers source of information about yellow card system during Pre and Post Educational Intervention

About 2(28.6%) participants got information regarding yellow card from physicians, 4(57.1%) got information from Pharmacists and 1(14.3%) got information from nurses as shown in Fig.3. After intervention, all participants (100%) knew about ADR reporting, where 98(98%) participants got information from Pharmacists and 2(2%) got the information from physicians

Table 3 : Multivariate analysis of knowledge towards Adverse Drug Reaction Reporting system among consumers

Characteristics		Awareness of ADR reporting system (Yellow Card)		AOR	95% CI	p value
		Yes N(%)	No N (%)			
Total (N)		22	1472			
Gender	Man	5 (1.3)	195 (52)	1	-	-
	Women	2 (0.53)	173(46.1)	2.218	0.540,11.578	0.333>0.05
Age	18-25	2 (0.53)	52 (13.9)	1	-	-
	25-35	3 (0.8)	86 (23)	2.459	0.540,11.203	0.203>0.05
	35-45	1 (0.3)	67 (17.8)	0.749	0.089, 6.323	0.790>0.05
	45-55	1 (0.3)	71 (19)	0.697	0.083, 5.323	0.739>0.05
	55-65	0 (0.0)	60 (16)	1.023	1.006, 1.040	0.244>0.05
	65-75	0 (0.0)	32 (8.5)	1.021	1.005, 1.037	0.425>0.05
Education	Illiterate	0 (0.0)	174(46.4)	1	-	-
	Primary school	0 (0.0)	103 (34.6)	1.026	1.007, 1.046	0.100 >0.05
	Secondary school	0 (0.0)	49 (13)	1.022	1.006, 1.039	0.300 >0.05
	Degree	4 (1.06)	40 (10.6)	10.933	2.362, 50.619	0.000<0.001
	Post-graduation	3 (0.8)	2 (0.53)	137.250	17.801,1058.248	0.000<0.001
Occupation	Home makers	1 (0.3)	132(35.2)	1	-	-
	Farmers	0 (0.00)	177 (47.2)	1.037	1.009. 1.065	0.12 <0.05
	Teachers	2 (0.53)	4 (1.06)	36.400	5.373,246.575	0.000 <0.001
	Students	3 (0.8)	13 (3.46)	20.481	4.152,101.035	0.000<0.001
	Others	0 (0.0)	10 (2.6)	1.020	1.005, 1.034	0.652 >0.05
	Unemployed/retired	1 (0.3)	32 (8.64)	1.750	0.204. 14.991	0.605 >0.05

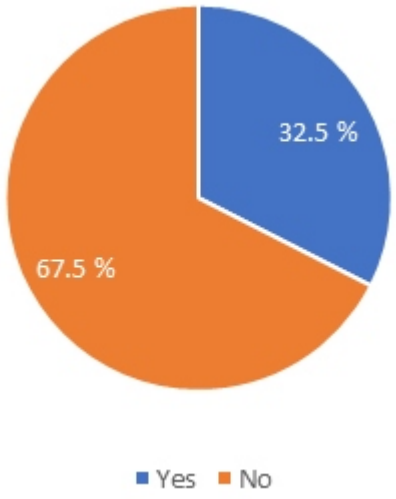

Figure 1 : Consumers' awareness on Adverse Drug Reactions before Educational Intervention (n = 375)

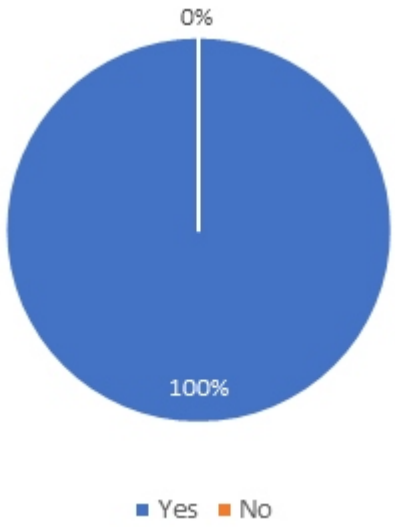

Figure 2 : Consumers' awareness on Adverse Drug Reactions after Educational Intervention(n=375)

Table 4 : Comparison of consumers' attitude on Adverse Drug Reaction Reporting before and after intervention

Sl. No	Questions	Pre-Intervention (n=375) No. (%)	Post Intervention (n=100) No. (%)	Chi-Square value (χ^2)	P-value
1	Do you think it is necessary to report side effects by using reporting systems?				
	Yes	85 (22.7)	97 (97)		
	No	290 (77.3)	3 (3)	20.230	0.000<0.001
2	Would you make report again if you experience side effects from medicines?				
	Yes	247 (65.9)	95 (95)		
	Not sure	120 (32)	2 (2)		
	No	8 (2.1)	3 (3)	37.226	0.000<0.001
3	Would you encourage others to report any side effects from medicines through Yellow card scheme?				
	Yes	226 (60.3)	95 (95)		
	Not sure	142 (37.9)	2 (2)		
	No	7 (1.9)	3 (3)	48.076	0.000<0.001
4	Do you think more people will report side effects, if Yellow Cards are distributed to every in-patient as an optional method to fill, in case if they suspect any side effects?				
	Increase	85 (22.7)	97 (97)		
	Will not increase	290(77.3)	3 (3)	12.242	0.000<0.001

respectively as shown in Fig.4.

Comparison of consumers attitude on Adverse drug Reaction Reporting before and after Educational Intervention

Before intervention Only 85 (22.7%) participants felt ADRs should be reported, after intervention almost 97 (97%) participants said ADRs should be reported (χ^2= 20.230, p value = 0.000<0.001). Almost 247 (65.9%) opined they will report ADRs in future and after intervention, almost 95 (95%) participants were positive in future (χ^2= 37.226, p value = 0.000<0.001). 226 (60.3%) participants told they will encourage others to report ADRs, and after intervention almost 95 (95%) told they will encourage others for the same (χ^2= 48.076, p value = 0.000<0.001). 85 (22.7%) participants opined that ADR reporting will increase if yellow card is distributed to every in-patient as an optional method to report side effects if encountered, and after intervention, 97 (97%) thought ADR reporting will increase (χ^2= 12.242, p value = 0.000<0.001) as shown in Table.4.

Encouraging positive reports were obtained after educational intervention. 100% of the participants in the post-interventional stage became aware of the ADRs. 97% of participants understood about the Pharmacovigilance Program of India and its necessity while 99% of participants understood about Yellow Card reporting system.

DISCUSSION

The socio-demographic data shows that out of 375 participants, 200(53.3%) participants were male and 175(46.7%) were female participants. The mean age of the respondents was 42.6427 and standard deviation was 15.0344. The collected data showed that 174(46.4 %) participants were uneducated, 103 (27.5%) studied up to primary school followed by 49 (13.1%) of participants had attended secondary school and 44(11.7%) of participants were degree holders. Only 5 (1.3%) have done post-graduation. Over half of the Participants in this study were uneducated. Further, we found that participants who had a higher educational attainment were more likely to have satisfactory knowledge about ADR reporting. This finding is consistent with those of other authors who found that consumer's knowledge and

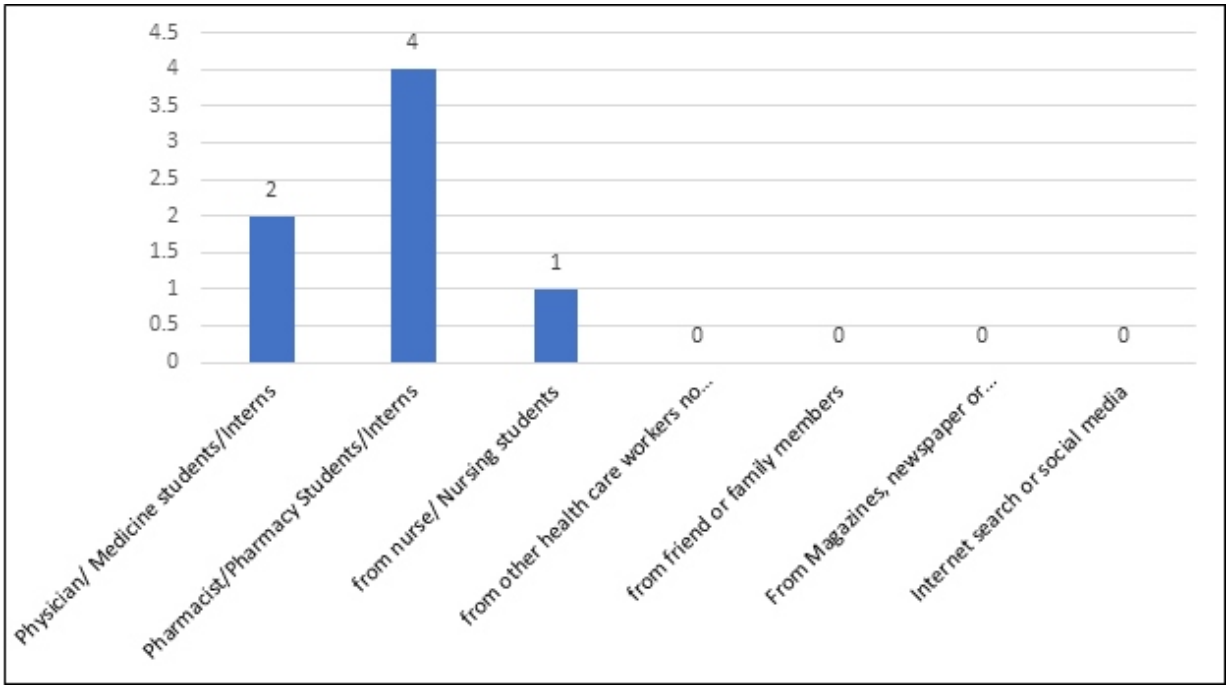

Figure 4 : Consumers' source of information about Yellow Card system during Pre-Interventional Stage(n=375)

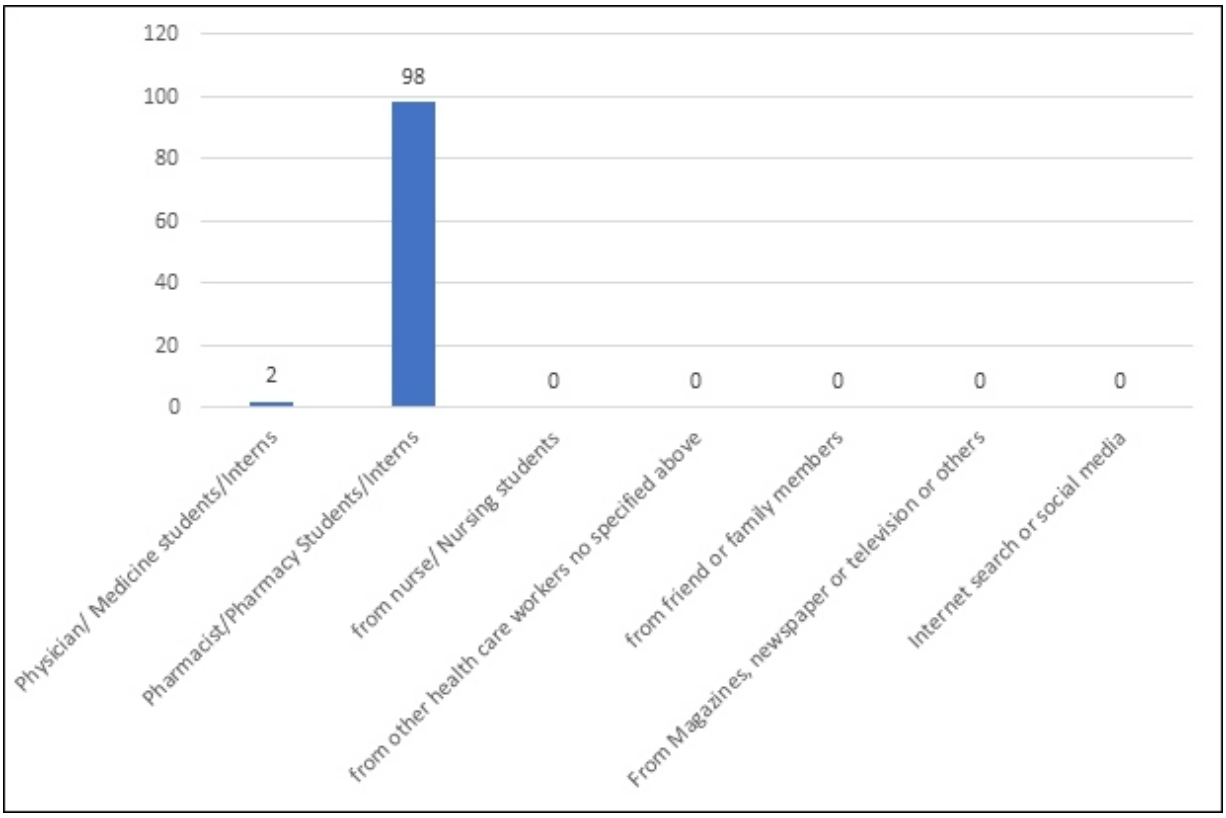

Figure 5 : Consumers' source of information about Yellow Card system during Post- Interventional Stage (n=375)

attitudes toward Adverse drug reaction reporting were associated with their level of education. These findings were similar to the studies done by Patel JJ et.al.[1]

Level of education was found low in our study where only 27% of participants have studied up to primary school and 11% done secondary education and 13% have degree, among 375 participants 46% (174) were found to be illiterates which was found similar to the previous studies published by Pahuja R et al.[9] Lower level of education acts as a barrier for awareness and practice of Reporting ADRs. The level of knowledge regarding ADRs among participants in our study was found to be low. This is due to lower level of literacy and education and decreased awareness among general public with regard to ADR reporting systems available in India. The findings are similar with the study conducted in 2019 by Patel JJ et.al [1] on ADR knowledge, attitude and practice, where results showed average but not satisfactory knowledge among general public.

Majority of the participants in the study are not aware about the possibility of side effects of medicine, but very few have knowledge about ADRs. These findings are contradicting to the previous studies conducted by Shakeel A et.al [10], has reported 81% and 96% which is higher than our study. More than half of the participants have responded that they were either unaware or were not sure about the side effects. Contrary findings were seen in previous studies who reported participants awareness about side effects.

In this study, 8% of participants have experienced ADR in past but they have not sent yellow card. 99% of participants have mentioned that they don't know about Pharmacovigilance Programme which showed a similarity with the reports published by Thadani A et.al. [4]

In the present study, participants showed positive attitude towards reporting of Adverse drug reactions (ADRs). Similar findings were shown by a study conducted on knowledge, attitude and practices of ADR reporting among the general public in 2019 By Pahuja R et.al [9] where majority had favorable attitude on Reporting of ADRs. All of the participants have mentioned that lack of awareness regarding reporting systems were one of the main reasons for not reporting ADRs. This result was contrary to the studies previously conducted by Ata M et.al [11] which reported lower values (40.8%).

LIMITATIONS OF STUDY METHODS

The study was conducted in a small population. Hence it cannot be considered as a representative of North Karnataka or national or international standards, a comparative study can be done in state, district or national wise to know the knowledge, attitude and practice of ADR reporting systems. The study does not imply the actual reporting practices of the consumers after interventional phase and further studies can be done in order to assess the reporting of ADRs in the encouraged population to analyze the effectiveness of the educational intervention.

STRENGTH OF STUDY METHODS

The method chose to undertake the study gives a nearly accurate view about knowledge, and limitations to acquire knowledge about ADRs and reporting systems, and their contribution for aptitude and practice of ADR reporting. The study chose a simple and effective educational strategy which is well acquainted to a positive understanding of the concept of ADR reporting with the help of physical ADR reporting forms, Microsoft PowerPoint presentations and image and video demonstrations.

IMPORTANCE OF FINDINGS FOR PRACTICE, POLICY OR RESEARCH AND THEIR GENERALIZABILITY

Our study results can be useful in educating and creating awareness for the general population who are consumers of medicine regarding possibilities of adverse drug reactions, steps that should be initiated during the event, and various Adverse drug reaction reporting systems available. This study results can be useful in establishing a clear patient familiarity of ADR reporting thus achieving improved consumer reporting of ADRs. The study helps in data collections and to find probability or other descriptive analysis for similar studies or in research expertise areas. Comparative study can be done among the people of Rural and Urban area to access the knowledge, attitude, and practice of reporting ADR.

CONCLUSION

Our study assessed the impact of educational intervention on adverse drug reaction reporting. By conducting such studies, we can assess consumers' knowledge, attitude and practice regarding Adverse Drug Reactions and its reporting systems. Many consumers have experienced ADRs in past but were not aware of reporting systems and others were confused about reporting. We found out that, there is a lack of adequate knowledge on Pharmacovigilance system and insufficient level of health education. Findings of the study highlights, there is a need for increasing the awareness of ADRs and reporting system among consumers and empowering them to report ADRs by themselves, which would ultimately improve safety of consumers and provide a better healthcare environment.

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