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Awareness among consumers on adverse drug reaction reporting system in India - A cross-sectional questionnaire-based study

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ABSTRACT

The adverse drug reaction (ADR) reporting system in India came into existence in 2010 through an initiative by the Government, the Pharmacovigilance Programme of India (PvPI), considering the social and economic consequences of drug effects. Though the system is functioning effectively for almost a decade, there has been a lacuna in reporting due to the lack of awareness among the patients who are the direct consumers. Medicine side-effects reporting is the newest initiative started in 2014 by PvPI, and the forms for consumer reporting is made available in over 10 different Indian languages like Tamil, Hindi, etc. It is imperative to determine the level of awareness among the public regarding drug side-effects and the existence of a National Programme to monitor the same, especially in a country like India with a population of nearly 1.38 billion. The aim of this study was to determine the awareness among the general population about the ADR reporting system in India. This cross-sectional study was done over a period of one year amongst the general public in South India. Data was collected from about 338 participants using a standardized questionnaire and analyzed descriptively using SPSS statistical software version 24. The overall response rate was 93.8%, and the mean age was 35.62 ± 10.43 years. Though the respondents had sufficient knowledge (66%) about ADRs, their awareness about the reporting system was very poor (19%). Reporting through phone (78%) was preferred over-reporting through specific forms (10%). To conclude, our study emphasizes that public participation and awareness are crucial in strengthening the existing system of Pharmacovigilance.

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INTRODUCTION

Globally, adverse drug reactions continue to be one of the major causes of mortality and morbidity (Angamo *et al.*, 2016; Shepherd *et al.*, 2012). Drugs, when invented, were considered a boon to the mankind as it fights against disease and lessens suffering. However, like other useful things, medicines come with potential risks called Adverse Drug Reactions (ADRs). The severity of such reactions may be mild or severe, and they may lead to disability or even death. ADRs are often referred to as "a response to a medicine which is noxious and unintended, and which occurs at doses normally used in man" (WHO and World Health Organizations, 2002).

A study done in North India showed that ADRs were the cause of admissions in 6.89% of hospitalized patients, and around three-fourth of them were found to be of moderate severity.

The median length of hospital stay was around 5 days and the average cost incurred per patient was around 6000 INR (150 USD), thus confirming that ADRs prolong the stay in the hospital, adding to the treatment cost and increasing the economic burden. Of the total ADRs reported, a whopping 59% were found to be avoidable (Patel *et al.*, 2007).

A recent meta-analysis verifies that preventable ADRs are a greater burden to healthcare globally. Among both out-patients and in-patients, around 50% of ADRs were preventable, emphasizing the importance of preventive strategies (Hakkarainen *et al.*, 2012). Spontaneous reporting system (SRS) of ADRs is the most essential component of drug safety. Under-reporting of ADRs is dauntingly enormous and has become a serious health concern both globally and nationally.

In a study done among physicians in Kolkata, the majority of them quoted the reason for not reporting as lack of time (Rishi and Patel, 2012). Consumers also have a major role to play in the Pharmacovigilance. Globally about 44 countries have the system of ADR reporting by consumers.

However, their contribution is much less when compared to those reported by health care professionals. It is even more less in India, making only up to 01 % of the total ADRs reported (Pahuja *et al.*, 2014).

Furthermore, Increase in use of over-the-counter drugs and counterfeit medications in the country also increases the risk of adverse effects. Considering such an alarming situation in India, it is vital to increase the awareness among the general public about the system of Pharmacovigilance. Though there a number of studies that assessed the awareness among health care professionals, only a very few studies have assessed the same among consumers.

Hence, the objective of this study was to determine the awareness about the adverse drug reaction reporting system in our country among the consumers.

MATERIALS AND METHODS

This questionnaire-based cross-sectional study was done in and around Saveetha Medical College& Hospital, Thandalam, Chennai, over a period of 08 months between September 2019 to April 2020 after the approval of the Institutional Review Board. The study included the general population in South India who were >18 years of age, inclusive of both genders, while those who refused consent were excluded.

The participation was purely voluntary, and confidentiality was maintained throughout the course of the study. All the participants who consented were briefed about the study. A pre-tested semi-structured self-administered questionnaire containing 20 questions relating to adverse drug reactions and ADR reporting was used to assess the awareness of the participants.

The resultant data was analyzed descriptively using SPSS statistical software version 24 and results interpreted.

RESULTS AND DISCUSSION

A total of 360 participants were recruited and given questionnaires and around 338 completed questionnaires were received. The overall response rate was 93.8%.

Table 1 shows the demographic details of the study sample. Among the respondents, 44% were males, and 55% were females, and their age group ranged between 21 and 68 years with a mean age of 35.62 (SD = 10.43) years. The majority of them were graduates, married and were employed in a non-health care related jobs. Almost half of the respondents were residing at locations less than 5 km from the health care facility.

Table 2 summarizes the responses provided by the participants reflecting their awareness about the ADR reporting system in India. It was surprising to find that more than 80% of the study population was unaware of the PvPI, but nearly three-fourth of them had the knowledge about ADRs, and more than half of them felt that it was harmful.

Similar results were demonstrated in a study where it was found that < 05% of participants had heard of Pharmacovigilance, and 97.1% felt it is essential to report ADRs. Counselling by pharmacists was the preferred way of public education (25.6%). (Adisa *et al.*, 2019)

Our results were also consistent with a similar study done in the country, which showed that 98.8 percent of consumers lacked awareness about PvPI. The preferred method of reporting was through the toll-free number. (Patel *et al.*, 2019)

A majority (39%) of them preferred asking their doctors about these adverse reactions. It was shocking to find that the physicians / pharmacists of 54% of respondents never educated them about ADR reporting. Reporting through the phone was the

Table 1: Demographical Details

S. No.	Parameters		Percentage
1.	Age	<25 years	10.65
		25-50 years	77.22
		>50 years	12.13
2.	Sex	Female	44.67
		Male	55.33
3.	Marital Status	Single	22.49
		Married	76.04
		Separated	0.59
		Divorced	0.89
4.	Education	High School	25.15
		Graduate	57.40
		Post Graduate	17.46
5.	Place	Urban	88.17
		Rural	11.83
6.	Accessibility to health care faculty	<5 km	56.51
		5-15 km	36.98
		>15 km	6.51
7.	Occupation	Not Working	18.93
		Non-Health Care Related	77.51
		Health Care Related	3.55

preferred method of reporting by more than 75% of the participants. These results were consistent with a study done in AIIMS, New Delhi, where they found 74% awareness among consumers, but only 8.9 % had the idea of reporting ADRs, and 73% felt only doctors are responsible to report the same. (Pahuja *et al.*, 2014).

Although 98% of the respondents in our study felt that it is important to report ADRs and 95% thought that it will help the community, only 26 % were aware of the availability of medicine side-effect reporting form. Almost all (98%) the respondents were of the opinion that it is important to instruct the patients about ADR and more than three-fourth of them had the habit of asking their physicians about it (Figure 1).

When questioned about the ways to improve the reporting of ADRs, more than half of them felt that increasing the awareness will improve the system, and 15% wanted to make the report process easier. (Figure 2)

Figure 3 summarizes the obstacles people face while reporting, where we found that the majority lacked the time to report, and 22% were unaware of the reporting process.

Though the NCC has launched the facility of reporting through a toll-free number and a mobile App, 19% of the population had no awareness about the telephonic reporting, and 89% dint know about the PvPI Android application. A recent review shows that, though India has more than 200 ADR monitoring centres, our contribution to the WHO-UMC database was only about 0.2% which needs to be improved. Positive experiences were seen in countries where patients / consumers were involved in the pharmacovigilance. Less than 12% of the ADRs reported to PvPI comes from consumers, which is meagre (Mulchandani and Kakkar, 2018).

Another study found the reporting by non-HCPs to be only 0.016%, and the reasons quoted for non-reporting included inadequate knowledge, lack of feedback and financial incentives etc., which was consistent with our findings (Kalaiselvan *et al.*, 2014).

In contrast to this, another study showed that almost 80% of participants dint feel that financial incentives could improve the process (Backstrom and Mjorndal, 2006).

A small study sample confined to a specific region of South India limits the scope of our study. However, this is one among the very few studies done in South India. Every participant was educated about ADR and the reporting process at the end of the survey; interestingly, many found this study useful and wanted to report ADRs in near future (97%).

Table 2: Questionnaire

S. No.	Questions	Response	Percentage (%)
1.	Have you heard about the PvPI*?	Yes	19
		No	81
2.	ADR** means?	Any untoward consequence from the medication	15
		Unforeseen reaction after taking the normal dose	66
		Predictable response after taking the normal dose	08
		No idea	11
3.	Do you think that an ADR is harmful?	Very harmful	31
		Somewhat serious	57
		Not harmful	02
		No idea	10
4.	Which age group can be harmed from ADR?	Children	31
		Adult	15
		Elderly	24
		No idea	30
5.	Is it significant to gather any information connected to ADR?	Yes	98
		No	02
6.	If you suffer from a non-serious ADR, would you report that?	Yes	74
		No	26
7.	Do you think that our community will profit from ADR reporting?	Yes	95
		No	05
8.	Is it important to instruct patients about ADR and how to report one?	Yes	98
		No	02
9.	Do you ask about the adverse effects of your medications?	Yes	76
		No	24
10.	Which of the following resources do you use to search about an ADR? (Select any if applicable)	Asking your doctor who prescribed the drug	39
		Asking the pharmacist who dispensed the drug	07
		From books or magazines	15
		From Internet	25
		From the pamphlet that comes with the medication	15
11.	Does your physician or pharmacist ask you to report any ADR that may happen to you?	Yes	46
		No	54

Continued on next page

Table 2 continued

S. No.	Questions	Response	Percentage (%)
12.	Which of the following ways do you prefer to report ADRs? (Select any if applicable)	By phone	78
		Fill a specific form and send it manually	10
		By using the internet	04
		Using a specific application on smart-phones	08
13.	Who should be notified about any serious ADR? (Select any if applicable)	Doctor	95
		Pharmacist	02
		Nurses	02
		Pharmacovigilance Center	01
14.	Are you aware of the Medicine side-effect reporting form available for consumers to report ADRs?	Yes	26
		No	74
15.	Are you aware of the availability of the ADR PvPI android App to report ADRs?	Yes	11
		No	89
16.	Who is responsible to report any possible ADR to PvPI?	Health care workers	51
		Consumers (patients)	25
		Both	24
17.	How to motivate the consumers to report any ADR? (Select any if applicable)	Make the reporting process easier	15
		Increase the awareness about ADR report-ing system	53
		Make it mandatory for patients	13
		Provide a 24/7 Toll-free number to report any ADR	19
18.	What prevents you from reporting ADRs? (Select any if applicable)	The ADR resolved	12
		The ADR is not serious	12
		Common ADR	08
		Does not know about the reporting system	22
		Lack of feedback on ADRs submitted	07
		Difficulty with the reporting process	07
		Lack of time to report	32
19.	What advantages the community can get from the ADR reporting system? (Select any if applicable)	Improves drug safety	15
		Increase the awareness about ADRs among the community	29
		Improves our quality of life	47
		A solution for the low reporting issue	4
		Protecting the human's rights	6
20.	Will you report any ADR in future?	Yes	97
		No	3

*PvPI - Pharmacovigilance Programme of India; **ADR-Adverse Drug Reaction

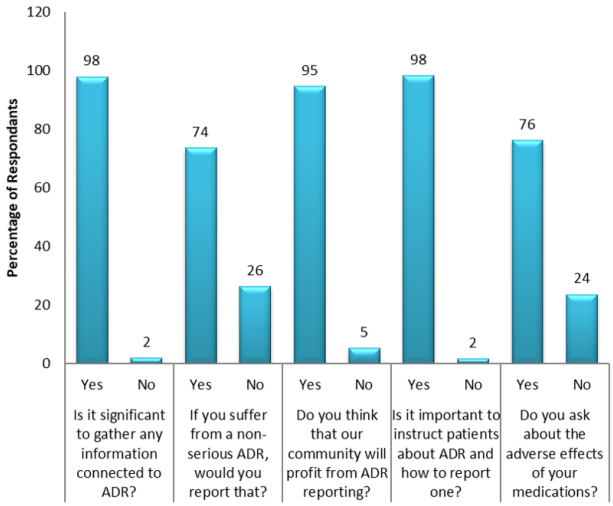

Figure 1: Attitude of participants towards ADR reporting

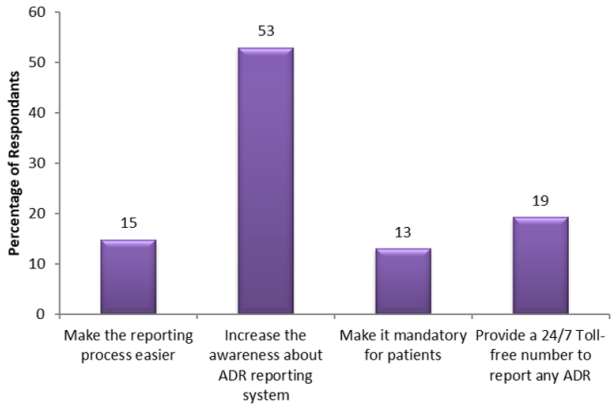

Figure 2: Ways to improve ADR reporting

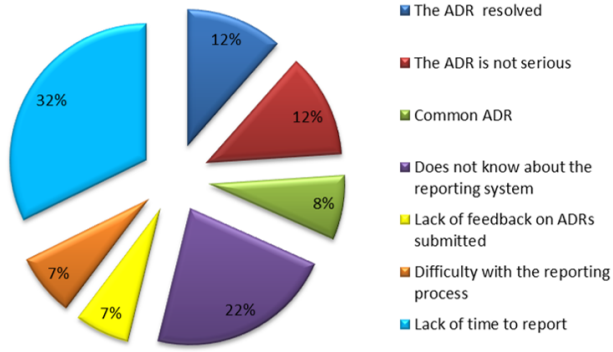

Figure 3: Obstacles in reporting ADRs

CONCLUSION

Every marketed drug comes with the potential to cause unpredicted side effects. The role of consumers in ADR reporting cannot be ignored. Though they cannot replace the existing reporting system, they may definitely be relied upon to strengthen the system. Patients' inability to recognise ADRs and causally link them to the drug is one of the most important reasons for under-reporting, which is evident from our study, which clearly shows that though the participants had a fair knowledge of ADRs and showed a positive attitude towards ADR reporting, their awareness about pharmacovigilance was very poor. This largely emphasizes the need for educating the general public about the detection and reporting of ADRs through health programmes, thus improving drug safety.

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Conflict of Interest

The authors declare that they have no conflict of interest for this study.

REFERENCES

Adisa, R., Adeniyi, O. R., Fakeye, T. O. 2019. Knowledge, awareness, perception and reporting of experienced adverse drug reactions among outpatients in Nigeria. *International Journal of Clinical Pharmacy*, 41(4):1062–1073.

Angamo, M. T., Chalmers, L., Curtain, C. M., Bereznicki, L. R. 2016. Adverse drug reaction related hospitalisations in developed and developing countries: a review of prevalence and contributing factors. *Drug Saf*, 39(9):847–857.

Backstrom, M., Mjorndal, T. 2006. A small economic inducement to stimulate increased reporting of adverse drug reactions-a way of dealing with an old problem. *European journal of clinical pharmacology*, 62(5):381–385.

Hakkarainen, K. M., Hedna, K., Petzold, M., Hägg, S. 2012. Percentage of Patients with Preventable Adverse Drug Reactions and Preventability of Adverse Drug Reactions – A Meta-Analysis. *PLoS ONE*, 7(3):e33236–e33236.

Kalaiselvan, V., Prasad, T., Bisht, A., Singh, S., Singh, G. N. 2014. Adverse drug reactions reporting culture in Pharmacovigilance Programme of India. *The Indian journal of medical research*, 140(4):563–564.

Mulchandani, R., Kakkar, A. K. 2018. Reporting of adverse drug reactions in India: A review of the current scenario, obstacles and possible solutions. *International Journal of Risk & Safety in Medicine*, 30(1):33–44.

Pahuja, R., Shrivastava, B., Sharma, P. K., Kishore, K., Mahajan, S., Sood, R. 2014. Awareness on adverse drug reaction reporting system in India: a consumer survey. *American Journal of Phytomedicine and Clinical Therapeutics*, 2(12):1361–1369.

Patel, J. J., Shah, M. K., Patel, P. P., Gandhi, A. M., Desai, M. K. 2019. Knowledge, attitude and practice among consumers about adverse drug reaction reporting. *International Journal of Basic & Clinical Pharmacology*, 8(8):1776–1776.

Patel, K. J., Kedia, M. S., Bajpai, D., Mehta, S. S., Kshirsagar, N. A., Gogtay, N. J. 2007. Evaluation of the prevalence and economic burden of adverse drug reactions presenting to the medical emergency department of a tertiary referral centre: a prospective study. *BMC Clinical Pharmacology*, 7(1):1–5.

Rishi, R. K., Patel, R. K. 2012. Under Reporting of ADRs by Medical Practitioners in India - Results of Pilot Study. *Advances in Pharmacoepidemiology & Drug Safety*, 1(3):1–3.

Shepherd, G., Mohorn, P., Yacoub, K., May, D. W. 2012. Adverse drug reaction deaths reported in the United States vital statistics, 1999-2006. *Ann Pharmacother*, 46(2):169–175.

WHO, World Health Organizations 2002. WHO - Safety of Medicines - A guide to detecting and reporting adverse drug reactions. pages 1–20.