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Original Research Article

Knowledge, attitude and perception of suspected adverse drug reactions in consumers: a prospective observational study in a tertiary care hospital

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ABSTRACT

Background: Adverse drug reactions (ADRs) are the main leading causes of hospitalization which leads to morbidity and mortality worldwide. Reporting of ADRs to national databases is necessary. To strengthen this system, consumers apart from health-care professionals have also been empowered to report any ADRs directly to the regulatory agencies. Direct and spontaneous patient or consumer reporting offers various benefits beyond pharmacovigilance (PV). Consumer reporting of ADRs has existed in several countries for decades, but in India, with the inclusion of consumer reporting of ADR, the data on the same is valuable and limited. Hence the present study is taken up. The aim of this study was to explore the knowledge, perceptions and practice of ADR reporting among consumers in KIMS hospital and research center, Bangalore.
Methods: The data was collected from Patients attending OPD's, admitted in wards and at pharmacy in KIMS Hospital and Research Center, Bangalore. It is a cross sectional descriptive study. Study period is for six months from 1st April to 31st September 2018 and sample size is 200. A structured questionnaire in English and Kannada was used as a tool.
Results: Of the 200 patients from the surveyed, in males the knowledge scores were better when compared to females and attitude, perception scores were same (statistically not significant). Most of the patients opined for the establishment of consumer pharmacovigilance system at hospitals and local pharmacies.
Conclusions: Knowledge about ADR reporting and pharmacovigilance is less in consumers. So that there is a need to increase awareness in consumers.

Keywords: Adverse drug reaction, ADR reporting systems, Consumers, Pharmacovigilance

INTRODUCTION

From the current human growth, we have enhanced the way of diagnosing or treating the patients with the latest medical technologies such as better medicines, improved patient care which has played significant role in increasing the human lifespan by reducing patient's illness and death. But most of the medicines could be potentially dangerous which may lead to expose to adverse drug reactions (ADRs) and can cause hospitalization leading to morbidity and mortality. And these drug reactions may lead to suffering among the individuals with the current increasing economic burden or inflation.

The World Health Organization (WHO) defines pharmacovigilance (PV) as "the science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other medicine-related problem".[1] According to the WHO, an adverse reaction can be defined 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 modifications of physiological

function".[2] Consumers of prescribed medicines may expose themselves to adverse drug reactions (ADRs) which are the main leading cause of hospitalization leading to increase in morbidity and mortality.[3] Spontaneous and voluntary reporting of suspected ADRs generates signals about rare, delayed and unexpected drug reactions that are undetected in the initial phases of drug development. The most common limiting factor for reduced patient compliance and drug adherence is ADR.[4] The medical information given before marketing the drug is incomplete, so ADR reporting is mandatory.

As there is a poor awareness about monitoring and reporting of ADR's in developing countries, and moreover it has become a limiting factor for medication adherence and compliance in consumers.

Normally ADR reporting to pharmacovigilance done by persons in medical field and to fortify the systems consumers have also been authorized to report the ADR's.

The benefits of ADR reporting by consumers leads to early detection, more number of ADR's, better quality of ADR's, and minimizes the medication errors.

The ADR's reported by patients are actual, thorough and more detailed when compare with unintended reports by health professionals. The WHO is upholding the consumer in spontaneous ADR reporting and is add up benefit to existing pharmacovigilance strategies. It aids in establishment of guidelines for better ADR reporting by consumers. Better ADR reporting helps to recognize the extent and scaling of risks and for better regulation. ADR reported by consumers may give new outlook on ADR's so that it changes the perception and assessment for the risk-benefit ratios of drugs.

The Central Drugs Standard Control Organization, New Delhi, under the aegis of Ministry of Health and Family Welfare, Government of India has initiated a nationwide PvPI in July, 2010, with the All India Institute of Medical Sciences, New Delhi as the National Coordinating Centre (NCC) for monitoring ADR in the country to safeguard public health by ensuring that the benefit of use of medicine outweighs the risks associated with its use. IPC has linked with the department of consumer affairs to establish a patient-centric helpline number for the general public to enable reporting of ADRs directly. According to study, the general public may report ADRs, either directly to the National Coordination Centre (NCC) - PvPI via helpline number, i.e., 1800-180-3024 or via a dedicated email, i.e., pvpi.compat@gmail.com or to their nearest ADR Monitoring Centre (AMC) under PvPI.

Consumer reporting of ADRs is already active in developed countries.[5] Netherlands and Denmark opened their respective national spontaneous reporting systems to the general public in 2003, followed by the United Kingdom (UK) in 2005 and Sweden in 2008.[6] The aim of this study was to explore the knowledge, perceptions and practice of ADR reporting among consumers in KIMS hospital and research center, Bangalore.

METHODS

It was a cross sectional descriptive study. The study was conducted with the help of questionnaire containing 14 questions. The study carried out at Kempegowda Institute of Medical Sciences (KIMS), Bangalore. The data was collected from patients attending OPD's, admitted in wards and at pharmacy in KIMS Hospital and Research Center, Bangalore. Information regarding gender, age, profession, ethnicity, educational qualifications, and place of residence were collected from all the consumers. Study period over a period of six months that is from 1st April to 31st September 2018. Sample size was 200.

Inclusion criteria

- Patients age group between 18-60years
- Patients attending OPD's
- Patients admitted in wards.

Exclusion criteria

- People who were not interested
- And not giving consent were excluded.

This study was approved by Institutional Ethics committee of KIMS medical college. A pre-validated semi-structured questionnaire comprising of questions on knowledge and attitude towards ADR reporting and about Pharmacovigilance center in hospitals was used as a tool. The questionnaire included questions based on knowledge, attitude and practices about pharmacovigilance and consumer ADR reporting.

Respondent's knowledge, attitude and practice were measured by using a set of 14 questions with multiple choice. The questions provided in both English and Kannada languages for better understanding of the consumers. Consumers were explained about purpose of study and about questionnaire. After obtaining informed consent the questionnaire was distributed among the patients by the researcher and the response was obtained. Questionnaire included the questions based on knowledge, attitude about ADR reporting, and about pharmacovigilance center, practice of reporting in pharmacovigilance.

Statistical analysis

The results were analyzed and compared using paired t-test ($P < 0.05$ was considered as significant). Descriptive statistics was used wherever required.

All the participants were informed about aims and objectives of study and written informed consent was taken. The IEC number is KIMS/IEC/A20-2018. CTRI registration was done (CTRI/2018/10/016083).

RESULTS

A total of 200 patients participated in the study and the response rate was 100%. Among the 200 surveyed consumers, maximum were females (127) when compared to males (73) (Table 1).

Table 1: Demographic characteristics of consumers.

Characteristic	Number
Gender	
Male	127
Female	73
Age	
<20	16
21-30	37
31-45	85
41-50	51
>50	11
Ethnic group	
Hindu	114
Muslim	68
Christian	15
Others	3
Qualification	
SSC	95
PUC	58
Diploma	47
Social economic status	
Upper level	24
Middle level	89
Lower level	87

The age group of 53 consumers are in between 19-30years of age, 85 consumers are in the age group of 31-45 and 62 consumers are in between 46 to 60years of age. Most of the consumers belong to middle class (89) and lower socioeconomic groups (87). Regarding education level 95 consumers completed SSC level, 58 completed the PUC level and 47 completed diploma level.

About pharmacovigilance and the National Pharmacovigilance Center (NPC)

The participants were asked whether they were aware/heard of the term ‘‘Pharmacovigilance”. Only 19% of responders were familiar with this terminology and also when asked if they were aware of the NPC as well, a mere 10% acknowledged previous knowledge of the center.

Adverse Drug Reactions (ADRs)

Definition: For survey, authors defined and explained an ADR as, ‘‘An unexpected and noxious reaction after taking the normal dose (of a medication) before giving questionnaire.” Most of the consumers accepted that the definition, ‘‘Any effect from a medication prescribed by health care professional”. Almost all consumers accepted for, ‘‘The expected reaction after taking the normal dose of medicine prescribed”. Most of the consumers opined that it is important to gather any information related to ADRs, few of them believed that reporting ADRs are beneficial for the community, and that the major advantage of ADRs reporting system is to increase medication safety.

The knowledge among males was higher when compared with females, but regarding attitude and practice towards ADR reporting was same for both genders. The differences were, however, not statistically significant.

Table 2: Response obtained from consumers.

Questions	Yes	No
Have you heard about Pharmacovigilance?	19 consumers	181
Do you know that there is Pharmacovigilance center in KIMS hospital?	19	181
Do you know the meaning of Adverse Drug Reaction?	121/ harmful effect within normal dose	79/side effect due to drug
Are you aware of reporting Adverse drug reaction?	78	122
Do you think Adverse drug reactions due to fault of:	132/ fault of doctors, prescription	68/ due to medicines
Why to report Adverse drug reaction?	108/ improve safety of medicine	92/ don’t know
Method of reporting Adverse drug reaction?	82/ orally to doctors	118/ don’t know
Method to increase the awareness of Adverse drug reactions for consumers	134/ labels on medicines and articles in news papers	66/ don’t know
Consumer reporting Adverse drug reaction method- is it useful?	146/ yes	54/ don’t know
Are you keen to know the adverse drug reaction of a drug due to medicine which you consume?	182/ yes	18/ don’t know

Similarly, the knowledge among consumers of age group below 30years was higher compared to other age groups. Again, none of these scores were found to be significant. The knowledge among consumers having diploma level of education was greater compared to consumers having lower educational levels.

Most of the consumers who participated in this study were in favor of establishing a consumer centers at hospitals and local pharmacies for providing information about drugs and expected adverse drug reactions. Appropriate knowledge about drug can prevent the occurrence of possible ADRs and reduces suffering.

Among 200 patients, only 19 has the knowledge about pharmacovigilance and 14 about ADR reporting. Most of them thought that the suspected ADR was due to medicine itself (135), and some due to fault of prescription given by doctor (42) and some due to pharmacies (23).

Table 2 shows the responses obtained through questionnaire on knowledge, attitude and perception of ADR reporting by consumers.

DISCUSSION

Consumers should be involved in ADR reporting and pharmacovigilance as they are important stakeholders in the medicine use process.[6] Consumer reporting will be additive to the current the pharmacovigilance system. Previous studies done on consumer reporting of ADRs have shown the beneficial effects of involving the consumers in PV system.[7,8]

In Ireland the research was done in an hospital about the knowledge of ADR, only 53.5% of patients had a proper understanding about an ADR, where only 30% of patients on warfarin identified the risk of bleeding as an ADR.[7,8] This low level of awareness can be improved by measures like conducting an awareness program and medicine use campaigns as suggested by a research conducted about the ADRs of statins at Beaumont hospital in Ireland.[9]

Most of the consumers reported that the purpose of ADR reporting will improve the use of drugs more safely and improves better understanding and awareness about drug safety.[8] A research was done about the same in Dublin which, showed very low awareness about ADR's among the patients and risks associated with their medicines. Probably the reason may be no usage of term 'pharmacovigilance' earlier, but now, a revised and a new edition of the national health policy contains some terms and operational definitions of ADRs included.[10] Similar study was done in Nepal which showed there is no involvement of consumers in ADR reporting still and it has been dependent on reporting by the healthcare professionals.[11] Similar study was done in China showed that consumers with a higher level of education were having a greater level of knowledge and awareness about ADRs.[12] A study done in Sri Lanka during mass treatment regimen for filariasis regarding the general people's awareness about ADR revealed that there was no significant association between the area of residence of the participants and their likelihood to report any experience of ADRs.[13]

A recent editorial on improving the management of ADRs concluded that 'the newly established consumer reporting service will also facilitate better understanding of consumer perspectives. This must be incorporated into information sources and supported by clear instruction on management.[14] ADR reporting by consumers gives more clear information, from their perspective as an un filtered experiences. The harm- benefit ratio of drug from Consumers view may change the current perceived and assessed way, and being the ultimate users of drugs, consumers could have a proper right in the regulatory decision-making processes for drugs. All stakeholders in PV should note this as an important source of information.[15]

CONCLUSION

Knowledge about ADR's and its reporting is low in consumers, needed appropriate measures to improve awareness and knowledge. Consumer ADR reporting will be additive and helps to overcome the limitations of under reporting by healthcare professionals to the current pharmacovigilance system. Consumer ADR reporting promotes the consumer rights and improves quality and quantity of ADR's due to drugs. Not only the reported ADR's due to prescribed drugs by health care professionals, consumer reporting will cover for Over The Counter (OTC) drugs too (due to individual decisions for treatment and easy accessibility of OTC drugs). The awareness about ADR reporting systems for consumers through the establishment of Consumer PV center in hospitals, pharmacies, mail ID, and through toll free numbers.

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REFERENCES

1. Information on Pharmacovigilance. World Health Organization. Available at: https://www.who.int/medicines/areas/quality_safety/safety_efficacy/pharmvigi/en/. Accessed 2015 May 16.
2. Information on Adverse Reaction. World Health Organization. Available at: http://www.who.int/medicines/areas/quality_safety/safety_efficacy/trainingcourses/definitions.pdf. Accessed 16 May 2015. Safety of medicines: a guide to detecting and reporting adverse drug reactions. World Health Organization, Geneva, 20;32-46.
3. Alshakka M, Jha N, Algefri S, Ibrahim MI, Hassali MA, Abdorabbo A, et al. Problems and challenges

faced in consumer reporting of adverse drug reactions in developing countries-A case study of Yemen, Nepal and Malaysia. Indian J Pharmaceut Biol Res. 2014 Jul 1;2(3):37.
4. Tadesse WT, Mekonnen AB, Tesfaye WH, Tadesse YT. Self-reported adverse drug reactions and their influence on highly active antiretroviral therapy in HIV infected patients: a cross sectional study. BMC Pharmacol Toxicol. 2014 Dec;15(1):32.
5. Jha N, Rathore DS, Shankar PR, Gyawali S, Alshakka M, Bhandary S. An educational intervention's effect on healthcare professionals' attitude towards pharmacovigilance. Australas Med J 2014;7(12):478-89.
6. van Hunsel F, Härmark L, Pal S, Olsson S, van Grootheest K. Experiences with adverse drug reaction reporting by patients. Drug Safety. 2012 Jan 1;35(1):45-60.
7. Blenkinsopp A, Wilkie P, Wang M, Routledge PA. Patient reporting of suspected adverse drug reactions: a review of published literature and international experience. Br J Clin Pharmacol. 2007 Feb;63(2):148-56.
8. Cullen G, Kelly E, Murray FE. Patients' knowledge of adverse reactions to current medications. Br J Clin Pharmacol. 2006 Aug;62(2):232-6.
9. Van Hunsel F, Passier A, Van Grootheest K. Comparing patients' and healthcare professionals' ADR reports after media attention: the broadcast of a Dutch television programme about the benefits and risks of statins as an example. Br J Clin Pharmacol. 2009 May 1;67(5):558-64.
10. Shrestha IB, Pathak LR. Review of National Health Policy 1991. Nepal: Ministry of Health and Population (MoHP) and NHSSP;2012. Available at: http://www.nhssp.org.np/health_policy/Review%20of%20National%20Health%20Policy%201991.pdf.
11. Jha N, Rathore DS, Shankar PR, Gyawali S, Alshakka M, Bhandary S. An educational intervention's effect on healthcare professionals' attitudes towards pharmacovigilance. Australasian Med J. 2014;7(12):478.
12. Xu H, Wang Y, Liu N. A hospital-based survey of healthcare professionals in the awareness of pharmacovigilance. Pharmacoepidemiol Drug Saf. 2009 Jul;18(7):624-30.
13. Jarernsiripornkul N, Chaisrisawadsuk S, Chaiyakum A, Krska J. Patient self-reporting of potential adverse drug reactions to non-steroidal anti-inflammatory drugs in Thailand. Pharmacy World Sci. 2009 Oct 1;31(5):559-64.
14. Roughead EE. Managing adverse drug reactions: time to get serious. Med J Australia. 2005 Mar 21;182(6):264.
15. Härmark L, van Hunsel F, Grundmark B. ADR Reporting by the general public: lessons learnt from the Dutch and Swedish Systems. Drug Saf. 2015 Apr;38(4):337-47.

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ANNEXURE

Questions
1. Have you heard about Pharmacovigilance?
a) Yes b) No
2. Do you know that there is Pharmacovigilance center in KIMS hospital?
a) Yes b) Don't know
3. Do you know the meaning of Adverse Drug Reaction?
a) Yes b) Don't know
If yes: 1) Harmful effect after taking medicine 2)Side effect after taking medicines 3)Any known effects after taking medicines
4. Are you on any medication like for Blood pressure and Diabetes and any others? And duration of medication?
a) BP b) Diabetes c) any other medicines
5. Reaction due to drug may be
a) Sleep due to cough syrup/ cold tablet b) Vomiting/Diarrhea due to antibiotics c) Gastritis due to pain killers
6. Previous history of adverse drug reaction?
a) Yes b) No
7. Are you aware of reporting Adverse drug reaction?
a) Yes b) Don't know
8. Do you think Adverse drug reactions due to fault of:
a) Doctor's prescription b) Medicines c) Other things
9. Why to report Adverse drug reaction?
a) Important for drug safety b) To help doctor c) As a formality d) Don't know
10. To whom Adverse drug reaction should be reported?
a) Doctor b) Nurse c) Pharmacist d) Don't know
11. Method of reporting Adverse drug reaction?
a) Orally to health professionals b) By filling any form c) To any centre d) Don't know
12. Method to increase the awareness of Adverse drug reactions for consumers
a) Label on medicines b) Articles in news papers c) Consulting pharmacist d) Any other method
13. Consumer reporting Adverse drug reaction method- is it useful?
a) Yes b) No c) Don't know
14. Are you keen to know the adverse drug reaction of a drug due to medicine which you consume?
a) Yes b) No c) Not required