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Original Article

A Questionnaire Based Observational Study to Assess Barriers Towards Reporting of Adverse Drug Reactions Among Healthcare Professionals

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ABSTRACT

Background: Adverse drug reactions (ADR's) are major public health problem causing significant mortality and morbidity. These ADRs can be managed by early and prompt detection. Health care professionals(HCP's) play a significant role in detection and prevention of ADR's, but underreporting is one of major concern and there exists so may barriers which influence ADR reporting.
Objectives: To assess barriers in ADR reporting among health care professionals.
Methodology: A self designed questionnaire was distributed among healthcare professionals working at JJM medical college and data obtained was analysed and presented in terms of percentages.
Results: About 110 healthcare professional's participated in the study. Among them majority had good knowledge about concept ofADR. The main barriers identified were communication gap, lack of professional setup, lack of time and complicated form filling. The identified motives were receiving feedback forms, conducting training programs, and adopting modern initiatives like software, daily reminders so as to enhance ADR reporting.
Conclusion: Most of health care professional's were aware of their responsibility towards ADR reporting, however few barriers were identified in the study which could be counteracted by implementing new strategies. Present study lays ground work for future initiatives to strengthen ADR reporting.

Keywords: *Adverse drug reaction,Health care professional's, motives.*

INTRODUCTION

Adverse drug reaction (ADR) is defined as any response to a drug which is noxious and unintended, and which occurs in doses normally used in humans for prophylaxis, diagnosis or therapy of disease, or for the modification of physiological functions[1].ADR's increase suffering of patient , prolong treatment and also hospitalization, reduce compliance and lead to poor outcomes. ADR's are of major concern as they cause significant mortality and morbidity posing economic burden on health care system[2].Majority of ADR's are easily preventable, and the most important factor in managing ADR is early and prompt detection. The science and activities related to detection, assessment, understanding and prevention of adverse effects is known as pharmacovigilance(Pv)[3]. Its main purpose is to reduce drug related harm to patient and promote rational use of medicines. The information generated by Pv has educated many doctors and also prompted the withdrawal of marketed drugs like rofecoxib,cisapride, terfenadine due to safety concern[4,5]. In India, the entire process of monitoring ADRs and to create awareness amongst healthcare professionals(HCP's) about the importance of ADR reporting is taken by Pharmacovigilance Programme of India (PvPI). In July, 2010, the Central Drug Standard Control organization, New Delhi has initiated a nationwide pharmacovigilance program under aegis of Ministry of health and Family welfare, Government of India to supervise and monitor drug related activities. Indian pharmacopoeia commission (IPC) Ghaziabad is National coordinating centre for various Adverse reaction monitoring centres (AMC). Uppsala monitoring centre (UMC) Sweden, being international collaborating centre for monitoring and dissemination of ADR data.These AMC's collect, communicate and disseminate data by linking hospitals, physicians and National coordination

centres[6].Eventhough India is the largest consumer of medicines globally, the ADR reporting accounts for 2% of global incidence, which explains inadequate reporting practices[7].Various studies conducted across globe have shown that 95% of underreporting was due to ignorance[8].As health care professionals form first line of contact with patients, they play very important role in detecting, monitoring and reporting of adverse reactions, so adequate knowledge andawareness regarding ADR reporting system plays vital role[9].Healthcare improvements can occur at multiple health system levels, but a key strategy focuses on helping professionals adopt evidence-based behaviours. This study targets modifying their ADR reporting practices.As attitude of HCP's about ADR can greatly influence ADR reporting, it is of paramount importance to identify barriers and facilitators that significantly influence their belief's and practices. Medical professionals cite many impediments such as fear of legal liability and lack of knowledge, but there is a lack of unanimity regarding the common factors which act as hindrances for reporting ADR. So identifying these barriers can permit us to implement certain interventions which would enhance rate and quality of ADR reporting. Despite multiple studies providing data, no validated questionnaire exists, and results vary across investigations due to differences in survey pattern.

Hence present study was planned to assess barrier's under domain of knowledge, attitude and practices towards reporting of ADR's among health care professionals.

OBJECTIVES

To assess barriers in ADR reporting among health care professionals.

MATERIALS AND METHODS

Study design

The present work was a questionnaire based observational study conducted to identify barriers towards reporting of adverse drug reactions among health care professionals.

Sample size

A total of 110 health care professionals working at jjm medical collage and bapuji hospital, Davangereparticipated in the study.

ETHICAL CLEARANCE: Ethical Clearance was obtained from the Institutional Ethics Committee (IEC) of JJM medical collage, Davangere.

Study criteria

Inclusion criteria

Health care professionals such as consultants, nurses, interns and postgraduates.

Exclusion criteria

Participants not willing to participate in the study.

Source of data

The information was collected from health care professionals working at bapuji hospital attached to jjm medical collage, Davangere using a questionnaire

Materials used :

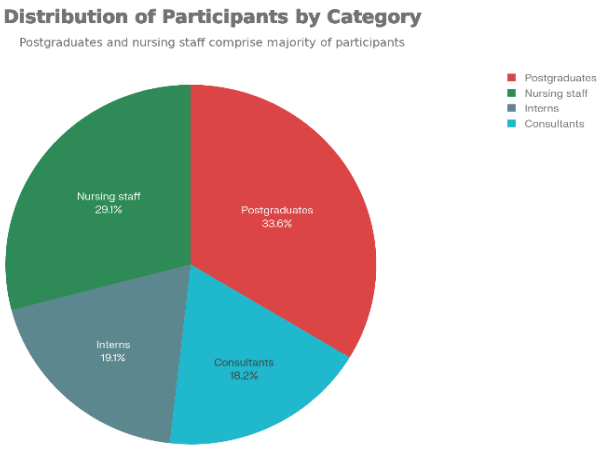
A self designed questionnaire was prepared and was validated by other staff members in department of pharmacology, jjmmc. The questionnaire was pretested among small group of ten members then later it was distributed among all health care professionals.

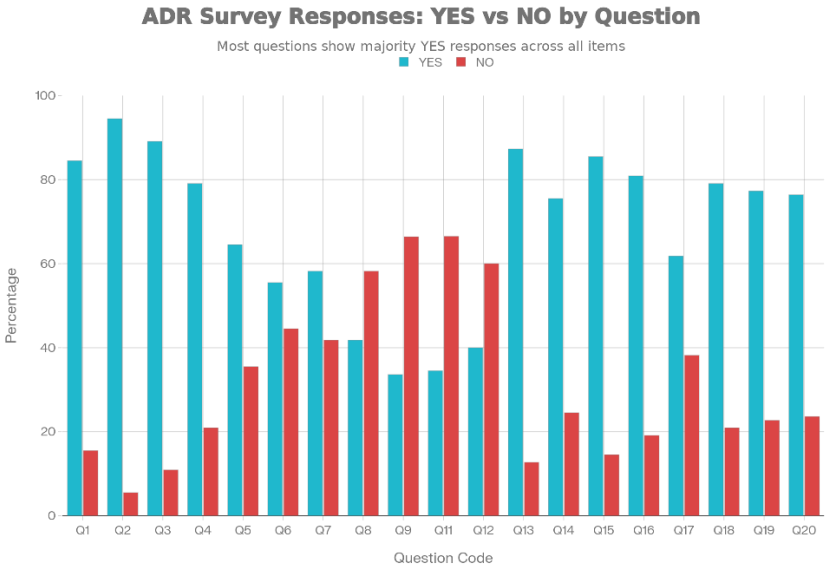
Data analysis :

The collected data was analyzedand presented in terms of percentages and graphs.

RESULTS

A total of 110 health care professionals participated in this study offering a broad spectrum of perspectives and understandings.Participants were thoughtfully chosen from diverse healthcare sectors to provide a comprehensive perspective on the subject. Out of 110 participants 20 were consultants, 37 were postgraduates, 32 were nursing staff and 21 were interns.





Barriers domain	Questions	Responses (YES)	No
Knowledge	1. Was the concept of ADR part of your curriculum	93(84.5%)	17(15.5%)
	2. Do you have an idea of concept of ADR	104(94.5%)	6(5.5%)
	3. Do you know that there is an ADR reporting system in India ?	98(89.1%)	12(10.9%)
	4. Do you think reactions to the vaccine and blood come under ADR ?	87(79.1%)	23(20.9%)
Attitude and practices	5. Are you trained in your institution on how to fill and to report an ADR ?	71(64.5%)	39(35.5%)
	6. Have you ever reported an ADR ?	61(55.5%)	49(44.5%)
	7. Do you know the components of ADR form ?	64(58.2%)	46(41.8%)
	8. Do you think ADR form filling is complicated and time consuming ?	46(41.8%)	64(58.2%)
	9. Do you think ADR reporting is an added extra burden to the existing responsibilities ?	37(33.6%)	73(66.4%)
	10. What were the barriers you came across while ADR reporting ? • Reporting forms were not available(15.5%) • It was time consuming(16.4%) • Dint know how to report (27.3%) • Lack of professional setup to report(25.5%)		

	• Not confident whether it is an ADR or not(11.8%) • Not motivated to report(3.5%)		
Beliefs aboutsocial influences	11. Do you have a fear of litigation in reporting an ADR ?	37(34.5%)	73(66.5%)
	12. Do you think your effort of reporting an ADR may go in Vain ?	44(40%)	66(60%)
	13. Do you think regular pharmacovigilance training in the institution can enhance ADR reporting ?	96(87.3%)	14(12.7%)
	14. Can ADR process be simplified further?	83(75.5%)	27(24.5%)
	15. Do you think ADR reporting can be encouraged if mobile software technology is implemented ?	94(85.5%)	16(14.5%)
	16. Do you think appointing a pharmacovigilance associate in every institute can enhance reporting ?	89(80.9%)	21(19.1%)
	17. Do you think any appraisal/ incentives/feedbackfromrelevant authorities encourage ADR reporting ?	68(61.8%)	42(38.2%)
	18. DO you think communication gap hinders ADR reporting ?	87(79.1%)	23(20.9%)
	19. Do you think celebrating National pharmacovigilance Day can motivate healthcare professionals for ADR reporting ?	85(77.3%)	25(22.7%)
	20. Do you think daily reminder can help report ADR ?	84(76.4%)	26(23.6%)

In the category of knowledge domain, majority of participants(94%) were aware about the concept of ADR and ADR reporting system in india. In domain of attitude and practices study results showed that out of 110 participants, 71(64.5%) health care professionals have been trained in reporting an ADR and 61(55.5%) had also reported ADR earlier. Study also showed that 64(58.2%) participants were aware of components of ADR form and 46(41.8%) participants had opinion that ADR form filling is complicated and time consuming and 37(33.6%) said that ADR reporting was an added extra burden to their existing responsibilities. while analysing the barrierswhich individuals came across while they were reporting ADR, 27.3% of them said they dint know how to report, 25.5% voted for lack of professional setup, 16.4% reported it was time consuming and 15.4% said that forms were unavailable.In domain of belief and social influences, 37(34.5%) of them had fear of litigation and 44(40%) think that their effort of reporting an ADR may go in vain. Regarding initiatives for enhancing ADR reporting, about majority of them were of opinion that regular pharmacovigilance training, celebrating Nationalpharmacovigilance day, implementing mobile software technology can enhance ADR reporting. 68(61.8%) participants also said any appraisal/incentives/ feedback can motivate or encourage them towards reporting. 87(79.1%) healthcare professionals informed that the communication gap hinders ADR reporting and 84(76.4%) of them consider that daily reminder can help and remind them for reporting.

DISCUSSION

The present study explored various factors that affect ADR reporting aiming to use these insights to design strategies that enhance ADR reporting thereby strengthening patient safety. Our study showed that majority of the participants had good knowledge on concept of ADR, about existence of ADR reporting system in India, ADR form components and also how to report it, they were also aware about existing national program for ADR monitoring and dint perceive these as obstacles for ADR reporting. This contrasts with study done few years earlier in south india[10]. This difference indicates beneficial influence of teaching and training initiatives on pharmacovigilance. In attitue and practices domain, Our study showed that majority of the participants especially nursing staff has undergone training under national pharmacovigilance Day activities in our institution and more than 50% of them had an experience of reporting ADR earlier.However the study identifies that some postgraduates encountered challenges in form filling, which emphasizes importance of periodic sensitization and training in that specified group. Very few (< 50%) participants had a fear of litigation and dint consider ADR reporing as a burden for their existing responsibilities. This shows the positive attitude of health care professionals, their enthusiasim, responsibility and commitment towards ADR reporting. In our study, participants indicated that lack of time, complicated form filling, communication gap and lack of professional setup as major constrains for ADR reporting, which is consistent with results of study done among community pharmacy professionals in Bangladesh, where as in our study we included all sectors of healthcare professionals[11]. Also few reported that forms were inaccessible, and small fraction of participants were not confident whether it is an ADR and few were not motivated.

In addition regarding factors facilitating ADR reporting, most participants agreed that ADR reporting process should be further simplified and highlightened the importance of receiving feedback on submitted reports, along with faster communication processes with the authorities. While analysing strategies to enhance ADR reporting, most of participants emphasized the need of pharmacovigilance training program, implementation of mobile software technology at institutional level. They also reflected that appointing specific pharmacovigilance associate, giving daily reminders and certain initiatives likes appraisal and incentives can encourage and enhance ADR reporting.

Strategies to improve ADR reporting should concentrate on most frequent and practically manageable barriers. If healthcare workers are unaware about reporting system, how they exist and function or how to access them, they will report less often, so firstly strategies are needed to create awareness and enhance knowledge among healthcare professional which can be achieved by conducting periodic sensitization and hands on training program at institutional level. National regulatory agencies could follow example of Netherlands where the reporter receive acknowledgement letters, where such response may reassure and motive them towards increased reporting, that also make them feel that their efforts dint go in vain[12]. Newer approaches can be tried like appointing a specific person as pharmacovigilance associate, who can act as a bridge between reporters and AMC's, which will clear their doubts, make the process easier, thereby reducing communication gap, which was cited as one of major barrier for ADR reporting. Other technical advances like installing softwares, artificial intelligence and daily reminders can also be employed and updated periodically to enhance ADR reporting.

CONCLUSION

Our study identifies important barriers and motives influencing ADR reporting among three domains viz knowledge, attitude & practices and beliefs about social consequences. Present study showed lack of time, complicated form filling, communication gap and lack of professional setup as majorbarriers for ADR reporting, while others being unavailability of reporting forms and knowledge gaps about ADR reporting. To overcome these barriers certain strategies can be employed like further simplifying existing ADR forms, building good professional network so as to ease communication process thereby improving access to resources. Our study also emphasized need of conducting periodic sensitization program regarding ADR awareness and hands on training in ADRreporting. This study offers a strong platform for upcoming and future initiatives to improve ADR reporting, thereby promoting patient safety and decreasing overall healthcare costs.

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