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Original Article

Pharmacology Section

A Qualitative Study of Knowledge, Attitude and Practice towards Pharmacovigilance among Doctors and Nursing Staff in a Tertiary Care Hospital in India

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ABSTRACT

Introduction: Pharmacovigilance is the branch of science that deals with the detection, assessment, understanding and prevention of adverse reactions to medicines (i.e., adverse drug reactions or ADRs). The purpose of pharmacovigilance is to implement the safe and rational use of medicines, which ultimately helps in improving patient care.

Aim: To investigate the Knowledge, Attitude And Practice (KAP) of clinicians, residents and nursing staff towards pharmacovigilance and Adverse Drug Events (ADE) reporting and to identify possible reasons for underreporting and to receive suggestions to improve the ADE reporting.

Materials and Methods: This was a qualitative study, conducted at Shree Krishna Hospital, attached to Pramukhswami Medical Collage, Karamsad, Gujarat, India. 'Focused Group Discussions' were organized which consisted of 5-10 clinicians and residents of the same departments and 10-15 nursing staff members. Their KAP regarding ADE reporting were assessed by using a structured open ended questionnaire. Data were analysed with qualitative methods.

Results: Total six sessions of Focused group discussion were conducted consisting of 42 clinicians and residents (16 were faculty members and 26 were residents) and seven sessions of Focused group discussion were conducted, consisting of 89 nursing staff members. Most of the participants knew the meaning of ADR and importance of ADR reporting. They all agreed that it's their responsibility also to report ADE. Some of the participants admitted, forgetfulness and workload as major constraints. There was a suggestion of display phone number of department of Pharmacology for coordination and maintaining a separate register for ADEs in each ward.

Conclusion: In spite of awareness and willingness for reporting of ADEs amongst the clinicians and residents, the practice is lacking because they do not consider this work as their priority.

Keywords: ADR reporting, Health care professional, Focus group discussion, Qualitative research

INTRODUCTION

The World Health Organization defines an 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" [1]. The unwanted and unpredictable effects of a drug occurring at a therapeutic dose are termed as side effects and are considered as part of adverse reactions. Pharmacokinetic and Pharmacodynamic profile of a drug may predict the ADR in a given percentage of drug recipients [1].

ADR monitoring is important so that medicines can be used rationally. All healthcare professionals can better use their experiences (both positive and negative) with their patients so as to better understand disease pattern and medical treatment. Most likely health professionals report ADR and therapeutic dilemmas to familiar academic unit. The information which is gathered from the spontaneous reporting of ADRs can be instituted into undergraduate and postgraduate teaching in the health sciences [2]. ADRs are important cause of morbidity and mortality affecting different age groups [3-5]. The Central Drugs Standard Control Organisation (CDSCO), New Delhi, under the aegis of Ministry of Health & Family Welfare, Government of India has initiated a nation-wide pharmacovigilance programme in July, 2010 [6].

Short term Goals of Pharmacovigilance programme of India (PvPI) are to develop and implement pharmacovigilance system in India, enrolling all MCI approved medical colleges in the program and to motivate healthcare professionals to report adverse reaction to drugs, vaccines etc. Department of Pharmacology at Pramukhswami Medical College (PSMC), Gujarat, India, is one of the peripheral centre for reporting of ADR by PvPI since April 2014 [7]. Our contribution to the national programme is not substantial till date. Therefore, this study had been planned with the aim to investigate the knowledge, attitude and practice of clinicians, residents and nurses towards pharmacovigilance and ADE reporting, to identify the reasons for underreporting and to receive important suggestions for improvement in the current spontaneous ADE reporting system.

MATERIALS AND METHODS

This was a qualitative study, conducted in HM Patel centre for Medical Care and Education, during July 2015 to October 2015. The study was approved by institutional ethics committee. The permission of Chief Executive Officer was taken to conduct the study in the institute. A letter of intent to the Heads of all Clinical Departments and to the nursing superintendent was sent and, all respective staff of Shree Krishna Hospital Karamsad, Gujarat, India, attached to Pramukhswami Medical Collage, was invited to participate in the study. Qualitative research methodology was adopted to achieve above mentioned objectives. 'Focused Group Discussions' were arranged with prior intimation. The participants were recruited by a combination of purposive and snowball sampling through contacts made by the researchers. The groups consisted of 5-10 clinicians from the same clinical department like skin, Obstetrics and Gynaecology, Paediatrics, TB & chest, Psychiatry and Ear, Nose and Throat (ENT). For nursing staff, 10-15

members from the same cadre like nursing in-charge, senior staff, and junior staff were arranged. The group members were informed regarding the project. Their written informed consent was taken. Their 'knowledge, practice and attitude' regarding ADE reporting were assessed by using a structured open ended questionnaire. They were encouraged to participate in the discussion and suggest measures to improve 'ADE reporting' culture amongst Health Care Professionals. A semi-structured questionnaire was developed using reviews from previous studies on ADR reporting and after consulting the experienced academicians [8].

The interview was taken based on three themes: (i) Familiarity with the ADE reporting system- All the participants were asked whether they were familiar with the pharmacovigilance system and the terminology used in the system or whether they have come across the ADE reporting forms; (ii) Attitudes and behaviours towards ADE reporting - Regarding attitudes and behaviours towards ADE reporting by participants, various questions regarding the part of professional responsibility, importance of ADE reporting, needful discussion with others, their role in detecting- participation and reporting of ADE, influential factors etc. was asked; and (iii) perceived barriers against reporting - All the participants were asked about the factors which negatively affect their willingness to report ADEs (like not knowing how to report, where to send report, reporting forms unavailable, lack of time and appreciation, not his/her job etc.,). They were also asked about the suggestion to improve the ADE reporting system The same open ended questions were asked to all participants in groups as well as individually. When necessary, appropriate probing questions were asked to draw out information required for the study. All participants were given equal opportunity to express their additional views on the topics discussed. Each interview session, lasted for about 20–30 minutes and was conducted at a place and time convenient for the participants, mostly in the premises where they practised. All the interview sessions were recorded on paper as well as audio-taped. Data were analysed with qualitative methods. The written and audio recording had been listened several times by the researchers for seeking new information given by the participants.

RESULTS

Total 42 clinicians and residents were interviewed. Out of total 42, 17 were female and 25 were male. They were from different departments. Their mean professional experience was 15.28 years. Details of interview time, date and participants are mentioned in the [Table/Fig-1].

Total 89 nursing staff members were interviewed. Out of 89, 84 were female and five were male. They were from different wards and intensive care units. Their mean professional experience was 13.49 years. Details of interview time, date and participants are mentioned in the [Table/Fig-2].

Themes: (i) Awareness–All the participants including clinicians and nursing staff knew about the ADR awareness programme, meaning of ADR, and able to explain very well about the same. They also knew what to do after an ADR occur and whom to contact. They were also aware regarding whom to report these ADRs and how to report. Most of the participants do understand their profession and knew the importance of reporting ADRs. Even they knew about the drugs which got banned due to ADR. Most frequent examples given by them were of Nimesulide and Phenylpropanolamine.

Session No.	Date	Department	No. of partici-pants	Faculty	Professional experience (Mean) years	Resi-dents**
1	17-07-2015	Skin	07	03	21.3	04
2	02-09-2015	OBGY	07	02	15.4	05
3	08-09-2015	Paediatric	09	03	17.2	06
4	09-09-2015	TB & Chest	09	03	16.5	06
5	15-10-2015	Psychiatry	03	03	5.2	00
6	21-10-2015	ENT	07	02	16.1	05
Total			42	16	15.28	26

[Table/Fig-1]: Details of interview time, date and participants (clinicians).
** Average professional experience of residents – 2 years

Session No.	Date	Professional experience (Mean) years	No. of participants
1	17-06-2015	24.37	12
2	19-06-2015	14.08	12
3	26-06-2015	16.79	15
4	08-07-2015	11.06	15
5	10-07-2015	09.75	10
6	15-07-2015	09.00	16
7	17-07-2015	09.44	09
Total		13.49	89

[Table/Fig-2]: Details of interview time, date and participants (nursing staff).

(ii) Attitude & Behaviour: All the clinicians and nursing staff knew that they are the first contact person and they were aware of their role in this programme. They all agreed that it is their responsibility also to report ADE. They knew that monitoring of patients is needed for at least 10-15 minutes after administering of any drug, particularly by parenteral route. All the participants firmly believed that ADEs should be reported.

(iii) Barriers: Most of the clinicians and residents were having problem regarding time. Shortage of staff members was also the issue for some of the departments. Some of the participants mentioned that unavailability of ADR form in the outdoor department and ward is also an important problem. Also, to make a call to department of Pharmacology on the occurrence of any ADRs is also not feasible for some of the members. Though some of the participants admitted forgetfulness and workload as major constraints. All the participants agreed that lack of habit is the main constraint for ADR reporting. Only few members from nursing staff were having apprehension for reporting ADEs. Most of the nursing staff was not having any problem regarding time. Some of the participants admitted the forgetfulness and workload as major constraints. Some of them were not willing to disclose their identity in the reporting form.

Suggestions: All clinicians as well as nursing staff suggested displaying contact number of pharmacology department not only in each ward but also at each out door department for facilitation of ADE reporting process. Some of the clinicians also mention that there should be some central mechanism for collection of data regarding ADEs. There was a suggestion of maintaining a separate register for ADEs in each ward. All the clinicians and nursing staff suggested about the availability of ADR forms at their working places. All the departments were ready to appoint one person who can look after ADR reporting related activities in their respective departments. Also they all agreed to give information to nursing staff members about ADEs so that they can also report ADRs. All the departments were agreed upon selecting a particular day of the week to provide all the information related to ADEs occurred during that particular week to department of pharmacology. All nursing staff suggested to display contact number of pharmacology department not only in each ward but at each nursing station also. There was a suggestion of maintaining a separate register for ADEs in each ward by nursing staff to fill up during their duty hours. They all also agreed to give information to other staff members about ADEs. All nursing staff agreed to inform subsequent nursing staff regarding ADE if occurred during their duty hours especially at night.

DISCUSSION

Qualitative research design is widely used research method by researchers studying human behaviour and habits. When the

subject is too complex to be answered by a simple 'yes or no' then qualitative techniques are very helpful. Qualitative research methods are less dependent on sample sizes than quantitative methods; for example, a case study can generate meaningful results with a small sample group [9]. Hence, it was decided to follow qualitative research method in this study.

Our institute has been recently accredited by NABH (National Accreditation Board for Hospitals and Healthcare) and as per requirements of NABH, several ADE awareness programme were conducted for all the clinicians and residents. In 2005 also, under the National pharmacovigilance programme, our institute conducted various ADR reporting awareness programmes for all health care professionals. That's why, most of the clinicians, residents and most of the nursing staff members were aware of ADE, its monitoring and reporting. Regarding definition and importance of ADRs, their knowledge again reflected due to their medical background and training sessions conducted during PvPI and NABH programme. Our institute is also having 'Quality Improvement' unit. The unit insists for reporting of ADEs.

Some of the nursing staff members were having apprehension that they might be asked explanation on reported ADE. That's why they have developed reluctance in reporting ADEs, rather they are not willing to disclose their identity as a reporter. Some of the participants, who had reported ADEs in the past, were very well aware of the reporting system. They usually used to call the department of pharmacology on occurrence of any ADEs. As they are supposed to carry out many activities, some of the staff members are experiencing workload. Forgetfulness is another constraint, which is mostly the consequence of workload. They could not prioritise the ADEs reporting due to their workload. Most of the clinicians and nursing staff suggested that display of contact number of department of Pharmacology should be there in all wards, ICUs, OPDs and at the places easily accessible. This can be helpful as the reminder, at the time of occurrence of ADEs. The department of Pharmacology is working from 9 am to 5 pm. The important concern from participants was that what to do if any ADEs occur after 5 pm. They themselves gave suggestion of maintaining the separate register for ADEs in all the nursing stations. They can record all the ADEs in the register and can give it to the other members of department or can give it 'as over' to the next joining staff member so they can also report to the department next day during the working hours. It has been observed by the researchers that all the staff members participated actively and enthusiastically in the discussion. It is very important to streamline this component in their routine working style.

LIMITATION

The limitations of our study were that the data were collected from one hospital only which does not represent all clinicians and nurses in the region. So generalization of this result regarding knowledge, attitude and perception about ADR in clinicians or nursing is not possible. Also, we could not arrange the interviews with clinicians from medicine and surgery departments due to busy schedule and time constraint.

CONCLUSION

The results of our study demonstrated that the majority of the clinicians and nursing staff in our hospital were aware of the existence of the ADR reporting system of India and its importance but there is a need to streamline their routine working style towards ADE reporting.

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