

**Original Article**

**EXPLORATORY STUDY ABOUT KNOWLEDGE, ATTITUDE AND PRACTICE ABOUT PHARMACOVIGILANCE AND ADR REPORTING AMONG RESIDENTS OF A TERTIARY CARE TEACHING HOSPITAL**

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**ABSTRACT**

**Objective:** This study, aimed at investigating the knowledge and attitude of resident doctors about ADR reporting in a tertiary care teaching hospital.

**Methods:** This was a cross-sectional, observational, questionnaire-based study conducted in Shri Krishna Hospital and Medical Research Centre, 550 bed tertiary care teaching rural hospital attached to Pramukhswami medical college, Karamsad, Gujarat.

**Results:** 50 questionnaire forms were analysed, giving a response rate 86.20%. Of the respondents 56% were men, remaining were women. Mean age of the respondents was 25+1.05 y. All but one resident have heard the term 'pharmacovigilance,' but 34 out of 50 were able to define it accurately. Twenty participants preferred email for ADR reporting while 14 preferred direct contacts for ADR reporting. Telephone is liked by 9 participants. All residents admitted the importance of pharmacovigilance in unison. Majority of the residents (96%) were in view to teach pharmacovigilance actively to students. Seventeen out of 50 residents were aware about Pharmacovigilance Program of India, a program by Government of India for pharmacovigilance and ADR reporting. 28 residents did not know about any such program. Three residents opined that no specific national program is running and India is following a program undertaken by WHO. The most preferred method of ADR reporting by residents is email/website followed by direct contact. Twenty were in favour of the first method, while 14 preferred the later method. Nine residents selected the telephone method as method of ADR reporting.

**Conclusion:** Today's residents are future's consultants. So it is the need of the hour to stimulate residents to report ADRs.

**Keywords:** Pharmacovigilance, Tertiary care, Residents

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**INTRODUCTION**

Pharmacovigilance as described by WHO is detection, assessment, understanding and prevention of adverse effects or any other drug related problem. Adverse drug reactions (ADRs) are associated with significant morbidity and mortality and are an important cause of hospitalizations. ADR is associated with a significantly prolonged length of hospital stay and almost 2-fold increased death [1].

Lazarous *et al.* estimated that ADRs were the fourth to sixth largest cause of death in the United States [2]. Another study by Arulumani *et al.* showed that ADRs were responsible for 3.4% of the hospital admissions and 3.7% developed ADRs during their hospital stay [3].

WHO has developed a system for reporting of ADRs by the establishment of the International Drug Monitoring Programme, coordinated by Uppsala Monitoring Centre, Sweden [4]. In India also National Pharmacovigilance Programme (NPP) was started in 2004 [5]. This programme is relaunched in 2010 as Pharmacovigilance Programme of India (PvPI), and is now coordinated by the Indian Pharmacopoeia Commission, Ghaziabad [6].

Still, pharmacovigilance is in its infancy phase in India and under-reporting is a major problem. Studies were done in other countries also reveal under-reporting of ADRs [7, 8]. Thus, to improve the ADR reporting rate, it is important to improve the awareness and practices of healthcare professionals regarding pharmacovigilance.

Though studies reporting the level of awareness and practices of pharmacovigilance have been done in other countries, [9-11] very few studies have focused this aspect in India. Hence, the present study is conducted to develop baseline data of awareness and

practice of pharmacovigilance in health care professionals and medical students in a Tertiary Healthcare Teaching Hospital in Gujarat.

As resident doctors are the first one who are in contact with patients taking drugs, spontaneous reporting by them is an effective way to generate early signals of ADRs. Thus, awareness among them and their attitude towards pharmacovigilance are important determinants of ADR reporting rate. In order to improve the reporting rate, it is essential to improve the Knowledge, Attitude and Practice of resident doctors regarding ADR reporting and pharmacovigilance. The right time to do it is during the undergraduate and postgraduate education of doctors. This study, therefore, aimed at investigating the knowledge and attitude of resident doctors about ADR reporting in a tertiary care teaching hospital. This study would suggest possible ways of ADR reporting based on our findings. Department of Pharmacology in the medical college recently conducted two programs on ADR reporting and pharmacovigilance. These programs were attended by residents and consultants and other healthcare professionals of the hospital. Through this study, we also can measure the results of efforts taken by the department through responses of residents and consultants and nursing staff and others.

**MATERIALS AND METHODS**

This was a cross-sectional, observational, questionnaire-based study conducted in Shri Krishna Hospital and Medical Research Centre, 550 bed tertiary care teaching rural hospital attached to Pramukhswami medical college, Karamsad, Gujarat. Approval from Institutional Ethics Committee was taken before starting the study. All Residents from

clinical departments were included in this study. All residents were contacted personally. The study and its objectives were explained to them in brief. Consent of participants was taken in written informed consent form. They were asked to fill the questionnaire without any assistance. Those who were not willing to participate or did not return the questionnaire within the stipulated time were excluded. A questionnaire was designed containing 16 questions using the precedence set by similar studies [9-11] to obtain information regarding knowledge regarding ADR reporting system, the practice of ADR reporting and factors that discourage them from ADRs, reporting. More than one answer was allowed in some questions. The information was recorded and analyzed using Microsoft Excel worksheet (Microsoft Office 2007) and Epi-info software.

## RESULTS

Out of the 58 filled forms, 8 were inadequately filled, so excluded from the analysis. Hence 50 were analysed, giving a response rate 86.20%. Of the respondents, 56% were men; remaining were women. Mean age of the respondents was 25+1.05 y. All but one resident have heard the term 'pharmacovigilance' but 34 out of 50 were able to define it accurately. Eight respondents replied that pharmacovigilance is surveillance of clinical trial done by pharmaceutical companies. Six replied that in pharmacovigilance useful effects of drugs are assessed and reported. Two residents did not reply. 40 residents out of 50 residents opined that they gather information about ADRs of new drugs from the internet while 30 used textbooks for the same. Other common methods were direct mail brochures and medical representatives which were used by residents in 22 and 18 in number. 15 residents used journals and the same number of residents used drug advertisements and product catalogues to gain information about the ADRs of drugs. Thirty-seven out of 50 residents were aware of any drug that has been banned due to ADRs. Nine residents did not know about it, while 4 participants did not reply. Thirty-six residents opine that ADR reporting is very important, 13 were in view that the process is important while none of the resident said that it is not important. Forty-eight residents felt that pharmacovigilance should be taught actively to students as a part of medical curriculum. More than half of the residents (28) replied that they have free access to ADR reporting forms. On asking who are eligible to report ADR, all respondents were agree that medical practitioners are eligible to report ADR. Forty-one out of 50 residents knew that dentists are eligible enough. 38 opined nurses are qualified enough. Only 5 respondents were in view that patients can also report ADRs. Out of 50 residents, 45 residents were in view that lack of time is a reason for the non-reporting of ADRs by them. Few (05) could not report ADRs because of fear of legal liability. Four (04) residents did not report as they considered ADR non-serious or well-known. Only one resident did not know where to report ADR. Fourteen percent (14) of residents have been trained on how to report ADR. Twenty-eight residents replied that to explore new indication of established drug is also an objective of pharmacovigilance. Twenty respondents replied that it is not an indication, while one resident did not reply. Twenty three residents replied that reporting of ADR is compulsory while the same number of respondents said it is voluntary. Three participants were in view it is remunerated while one resident did not reply. Thirty-seven residents were able to enumerate the drugs which were banned due to ADR. The study revealed that Only 7 residents have reported ADRs while majority (43) have not reported any ADR till date. Direct contact and e-mail were found the preferred mode of ADR reporting by the participants. Twenty participants preferred email for ADR reporting, while 14 preferred direct contacts for ADR reporting. Telephone is liked by 9 participants. All residents admitted the importance of pharmacovigilance in unison. Majority of the residents (96%) were in view to teach pharmacovigilance actively to students. Seventeen out of 50 residents were aware about Pharmacovigilance Program of India, a program by Government of India for pharmacovigilance and ADR reporting. 28 residents did not know about any such program. Three residents opined that no specific national program running and India is following a program undertaken by WHO. The most preferred method of ADR reporting by residents is email/website followed by direct contact. Twenty were in favour of the first

method, while 14 preferred the later method. Nine residents selected the telephone method as method of ADR reporting.

## DISCUSSION

Many studies have evaluated the knowledge of healthcare professionals about pharmacovigilance. Response rate reported in our study (86.20%) was higher than that reported in other studies. Response rate of 77.2% was reported in another study carried out in resident doctors.[12] The other study conducted in Gujarat also reported a tepid response in resident doctors (77.7%). The strict follow-up by all the investigators was the reason for the good response rate in our study.

Only 68% of residents were able to define pharmacovigilance correctly. This data were in line with the study conducted in Nagpur in which 64.28 % residents were aware of pharmacovigilance. Lesser awareness about pharmacovigilance may be due to less emphasis being given to this program and inadequate measure for raising awareness about the same this also reflect the view of 33.33% responded in this study who feel that imparting knowledge about pharmacovigilance through various training programs workshop or continuing medical education will definitely improve reporting of India.

In our study, only 14% residents have reported ADRs. This proportion is lower than study conducted in Central India. [12]. Studies conducted in developed countries have reported a higher rate of ADR reporting. Lower reporting of ADR may be due to the less emphasis is given on it. The study center has been a nodal centre in National Pharmacovigilance Program, an older version of Pharmacovigilance Program of India. Even then, this kind of poor ADR reporting is disappointing. This kind of reporting is seen although all residents admit the importance of pharmacovigilance and have the view that pharmacovigilance should be taught actively to the students. So there is a big gap seen in the study between attitude and practice of pharmacovigilance and ADR reporting. Only 7 residents out of 50 residents have reported ADR, which is very disappointing fig. While the institute has organised many CMEs and workshops in recent time to promote ADR reporting. Today's residents are future's consultants. So it is the need of the hour to stimulate residents to report ADRs.

A big number of residents kept responsible constraint of time for non-reporting of ADR. The reason may not be considered valid as the process to fill ADR requires only few minutes.

## CONCLUSION

Today's residents are future's consultants. So it is the need of the hour to stimulate residents to report ADRs.

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Nil

## AUTHORS CONTRIBUTIONS

All the authors have contributed equally.

## CONFLICT OF INTERESTS

Declared none

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