

## Original Research Article

# A study on determinants of underreporting of adverse drug reactions among resident doctors

Rohini Gupta<sup>1\*</sup>, Apoorva Malhotra<sup>2</sup>, Pavan Malhotra<sup>2</sup>

<sup>1</sup>Department of Pharmacology and Therapeutics, Government Medical College, Jammu, J&K, India

<sup>2</sup>Department of Pharmacology and Therapeutics, Acharaya Shri Chander College of Medical Sciences and Hospital, Sidhra, Jammu, Jammu and Kashmir, India

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### \*Correspondence:

Dr. Rohini Gupta,

E-mail: rohinigupta299@ymail.com

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### ABSTRACT

**Background:** Adverse Drug Reactions (ADRs) are global problem with significant morbidity and mortality. Health care providers/professionals (HCPs) play a critical role in ADR surveillance. However, only 6% of all ADRs are reported and under-reporting acts as great impedance in exchange of drug information. Thus, spontaneous reporting of suspected adverse drug reactions requires greater commitment from healthcare professionals. The aim was to determine the reasons of underreporting of ADRs among resident doctors.

**Methods:** This was a cross-sectional observational study with self-administered questionnaire assessing the reasons for underreporting of ADRs among resident doctors.

**Results:** Very low level of awareness about ADR reporting was found among doctors. Eighty eight percent of doctors did not know the authority and the procedure for ADR reporting. About 32.8% were not sure with the reaction and the drug, while 46.3% doctors felt that there is no need of reporting the recognized reactions again. Other factors responsible for under reporting were lack of time in 73% and cumbersome procedure in 45% of the participants.

**Conclusions:** A poor level of awareness of pharmacovigilance was seen among doctors. Measure to improve awareness, accessible systems for reporting and effective National Programme are required to improve reporting.

**Keywords:** ADR, Pharmacovigilance, Resident doctors, Underreporting

### INTRODUCTION

Adverse Drug Reactions (ADRs) are representing a major concern of health-care systems in the modern era. Adverse drug reactions are among the significant cause of morbidity and mortality worldwide.<sup>1</sup> According to the World Health Organization (WHO), Adverse Drug Reaction (ADR) is defined as “any noxious, unintended and undesired effect of a drug which occurs at doses used in humans for prophylaxis, diagnosis or therapy of disease, or for the modification of physiologic function.”<sup>2</sup> ADRs not only pose a risk to the patient’s safety, but also adversely affect their quality of life and increase the healthcare cost considerably.<sup>3,4</sup> Studies suggest that ADR

is responsible for 0.2-24% of hospital admission.<sup>5,6</sup> Thus ADRs have a major impact on public health by imposing considerable economic burden on the society.<sup>7</sup> Moreover, in India, large number of Allopathic, Ayurvedic, Homoeopathic, Unani and Siddha medicines are available and being practiced in combinations. Hence, reporting of ADRs should be a priority area.<sup>8</sup>

Spontaneous reporting of ADRs by health care professionals is the cornerstone of pharmacovigilance. The major limitation associated with spontaneous ADR reporting system is underreporting.<sup>9</sup> It is estimated that only 6-10% of all ADRs are reported globally.<sup>10</sup> India rates below 1% in term of ADR reporting.<sup>11</sup> This clearly

emphasises that the current status of pharmacovigilance in India is far from satisfactory and this is mainly attributable to under reporting (UR) of adverse drug reactions (ADRs) that has become a widespread and a daunting challenge in pharmacovigilance (PV).<sup>12-14</sup> Underreporting can be attributed to patient-related factors like failure to recognize ADR or inability to link the ADR with a drug or UR may be because of doctor related reasons viz. the feeling of guilt, fear of litigation, ignorance, lethargy, inadequate risk perception about newly marketed drugs, insufficient training to identify ADRs, and lack of awareness about Pharmacovigilance program.<sup>15</sup>

Moreover, ADRs often go unnoticed due to failed ability of medical teams to recognize ADR or correlate precisely with biochemical, pathological or radiological abnormality.<sup>16</sup> However, the intensive monitoring in PV amplifies the detection of ADR.<sup>17</sup> Various approaches have been recommended to intensify ADR reporting.<sup>18-24</sup> Pharmacovigilance is a shared responsibility of all the stake holders. Under-reporting of ADRs is a serious issue. A proper surveillance system in place will help improve ADR reporting. The participation of health care professionals is the vital force of dynamics of this programme. Thereby, keeping this into consideration the present study was planned among the resident doctors who are the future health care-givers to know about the various reasons that lead to underreporting of ADRs. Medical students could play a major role and bring a paradigm shift in successful implementation of pharmacovigilance program if proper training regarding Pharmacovigilance is imparted to them but at present they don't have any significant role which is due to inadequate training to them.<sup>25,26</sup> Through educational interventions awareness about the importance of monitoring and reporting can be increased and a culture of proper reporting of ADRs can be fostered.<sup>27</sup>

## METHODS

The study was conducted at Acharaya Shri Chander College of Medical Sciences and Hospital (ASCOMS and H), Jammu, J&K, India in March 2017. It was a cross-sectional questionnaire-based observational study carried out on post-graduate students of our college. The questionnaire was structured to find out the factors responsible for underreporting of adverse drug reactions among resident doctors. It was a closed-ended questionnaire. The students who were willing to participate and gave written informed consent were included in the study.

The study involved 1<sup>st</sup> year, 2<sup>nd</sup> year and 3<sup>rd</sup> year postgraduate medical students both present and outgoing were included. Prior approval was taken from the Institutional Ethics Committee to conduct the study. The questionnaire was pre-validated by conducting a pilot study on eight resident doctors. Before the commencement of the study, all the respondents were

being explained about the purpose of the study and any doubts regarding questionnaire were clarified by the investigator. The respondents were allowed to choose multiple options. Many options were kept for the participant's opinion like lack of awareness about how to report ADRs, lack of time to fill an ADR form, lack of confidence when an unknown ADR is encountered, laziness, and fear of legal action. All the participants were given one day to fill the questionnaires and on next day the questionnaires were collected. All the data obtained was kept confidential. Data was compiled and analysed using descriptive statistics.

## RESULTS

Out of 77 residents, a total of 67 duly filled questionnaires were used for analysis. All the participants were given the necessary instructions and sufficient time to fill the questionnaire.

Reasons for underreporting by the resident doctors were divided into professional and personal reasons. Unawareness of the procedure (88%) was the main reason for not reporting. There is no need to report recognized reaction again felt by 46.3% of doctors. Not being sure of reactions was reason among 32.8% doctors. Other professional reasons are listed in the Table 1.

**Table 1: Professional reasons for underreporting ADRS.**

Reason	n (%) n=67
Do not know the procedure or whom to report.	59 (88)
Not sure with the reaction and the drug	22 (32.8)
No need to report recognized reactions again	31 (46.3)
Not bound to report ADRS	20 (29.9)
No need to report as drugs come well tested	11 (16.4)
Reporting reactions will not contribute to knowledge	9 (13.4)
Patient confidentiality may be lost	26 (38.8)

Personal factors like lack of time (73%) and cumbersome procedure (64.2%) were the two main reasons for under reporting. Very few felt other reasons like fear of litigation, non-remuneration and lack of confidence to discuss with colleagues are the reasons as shown in Table 2.

## DISCUSSION

A constant vigilance on drug safety issues is always required in pharmacotherapy to promote better patient care. The primary aspect of Pharmacovigilance is to provide updated safety information of drugs and other related medicinal products like herbals, medicinal

devices, vaccines etc.<sup>28,29</sup> However, still the reporting rate of ADRs is very low.<sup>10</sup> Thus, under-reporting acts as great impedance in exchange of drug information between clinical practice and drug safety surveillance. Under reporting seems to be associated with specific attitudes of doctors to ADRs and the reporting system.

**Table 2: Personal reasons of under reporting of ADRs.**

Reason	n (%) n=67
Procedure cumbersome/ extra work	43 (64.2)
Lack of time	49 (73)
Fear of litigation from patient's side	08 (11.9)
Non-remuneration for reporting	03 (4.5)
Lack of confidence to discuss ADR with colleagues	05 (7.5)

The most common practical problem which was faced by the doctors in the reporting of ADRs was that a majority of them (88%) did not know how and where the ADRs had to be reported. Lack of knowledge relating to existence or functioning of reporting system and procedure is perhaps the main reason for under reporting. Hence, majority of them suggested that pharmacovigilance awareness programs should be organized as seminars or workshops. This is consistent with the study done by Hardeep.<sup>30</sup> Indifferent attitude about ADR reporting was noted in the present study which included many factors like a large number of participants felt that ADRs were being routine and common, thus doesn't warrant reporting (16.4%); not bound to report in (29.9%) and reporting one reaction will not add to scientific knowledge among participants (13.4%).

This is similar with that of other studies.<sup>14,31</sup> About (32.8%) of participants were not sure about the reaction and the drug. This is very important as it is directly related to doctor's clinical training and knowledge of pharmacology. But other issues like polypharmacy, over the counter drugs, self-medications, usage of drugs from other systems of medicine and herbal medicine complicate the identification of culprit ADR drug. This is consistent with the study done by Gonzalez E L, 2009.

There are various other reasons that relate to more of personal factors. Excuses like lack of time or too busy to report and cumbersome procedure were cited by 73% and 64.2% of the doctors respectively. But the second reason of cumbersome procedure doesn't apply in this study as very few were aware of actual reporting procedure. But given present system of reporting and busy daily schedules of most of the doctors in India, this can become a potential reason for under reporting. Similar reasons are also shared in another study wherein doctors had fairly good awareness but low levels of reporting particularly due to the procedures.<sup>32</sup>

In the present study various other factors that were found to discourage the doctors from reporting were the non-remuneration for reporting by 4.5% and lack of confidence to discuss the ADRs with other colleagues by 7.5% of participants. This is similar with the findings of other study.<sup>33</sup>

Thus, to make doctors aware of the procedure to report ADRs can be an important step in improving the reporting rate of ADRs. Educational interventions have shown good improvement in reporting.<sup>34,35</sup> This experience worldwide can be an important tool to adopt in India. Education and training can build a new genus of doctors for rational drug use.

The present study has few limitations being of shorter duration and has less sample size. Moreover, only resident doctors (allopathic medicine) were included. Others like dentists, doctors from other healthcare systems and healthcare workers like pharmacists and nurses were not part of the study.

## CONCLUSION

Present study suggested that resident doctors were aware about the concept of ADR, but majority did not know how to report and where to report. Moreover, lack of time, cumbersome procedure, unable to confirm an ADR, indifference to report were the main reasons identified for under reporting. Thus, it is necessary to create more awareness about need to report an ADR as well as procedure of ADR reporting. Hence, simpler reporting procedures need to be adopted and various Pharmacovigilance awareness programs need to be conducted regularly in educating the medical students and other health care professionals to improve ADR reporting behaviour.

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