

# Assessment of knowledge, attitude and practice of Pharmacovigilance among the interns in a tertiary care hospital in northern India- A questionnaire based study

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## ABSTRACT

**Background:** The use of drugs and occurrence of its ADRs go hand in hand. Spontaneous reporting of ADRs is an effective method and needs to be encouraged.

**Objective:** The study was planned to know the perception of interns towards pharmacovigilance and to make them aware of the importance of ADR reporting.

**Materials and Methods:** A cross sectional observational questionnaire based study conducted on 100 interns to gather information about the knowledge of Pharmacovigilance, attitude towards reporting and factors in practice which could act as a deterrent to the reporting of ADRs.

**Results:** Out of the 100 interns, 90 responded. 50 % participants knew the purpose of PV. 67% agreed that it should be mandatory. 59% and 67% said that medical students and nurses have a role to play in PV. Half of the interns had seen an ADR, only 42% knew how and where to report. Very few (9%) were aware of what happens to the information submitted by them.

**Conclusion:** There is a huge gap between knowledge of ADR reporting and pharmacovigilance and the practical reporting of ADRs. Our health care providers need to be well equipped to detect, manage, report ADRs. For this, educational intervention, regular training programmes are the need of the hour to create awareness and take care of the factors responsible for under reporting. Pharmacovigilance programme needs to be strengthened by increasing the rate of ADR reporting by active participation of health care providers.

**Key Words:** Knowledge, attitude, practices, pharmacovigilance, adverse drug reaction

## Introduction

The market today is flooded with an enormous number of drugs for various ailments. The Pharmaceutical industries are busy innovating testing and manufacturing new drugs day in and day out, such that 45 drugs gained FDA approval in 2015 and 41 new drugs were launched in 2014 every year on an average. [1] Before the drugs are marketed, they undergo stringent measures to assess their safety profile; still, certain unusual, rare, serious adverse drug reactions may go undetected at this level. This applies more to newer drugs which may lead to severe adverse drug reactions which may not have come to light yet owing to a short span of their use. ADRs (adverse drug reactions) are responsible for about 5 % to 20% of hospital admissions. [2,3] About 2.9% ADRs lead to hospitalization and approximately 6.3% ADRs develop while one is in the hospital. [4] One third of these ADRs are preventable. [5,6] To prevent, detect and assess all these ADRs,

pharmacovigilance steps in Pharmacovigilance (PV) is defined as the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem.

WHO defines ADR as any response to a drug which is noxious and unintended, and which occurs at doses normally used in man for prophylaxis, diagnosis or therapy of disease or for the modification of physiological function. [7] The thalidomide disaster in 1961 led to the creation of Uppsala International Drug Monitoring centre (UMC), with WHO, whose prime concern is safety profile of all the drugs. [8] Since, the uppermost priority of the doctor is patients safety besides treating him, hence, it is imperative that a vigil be kept on the occurrence as well as reporting of these ADRs. Spontaneous reporting of ADRs is an effective channel for ADR reporting. [9-11]

However, still, it is estimated that only 6–10% of all ADRs are reported in all over the world.<sup>[12,13]</sup>

In India, National Pharmacovigilance Centre (NPC) has been formed which is an active participant in the ongoing activities of UMC and in the past years, the PV programme has gained momentum such that the reporting rates from India have increased from 0.5% to 2% , still these figures are very low as compared to other countries.<sup>[10]</sup> The success of a PV program depends upon the active involvement of the healthcare professionals such as doctors, pharmacists, nurses and can greatly reduce the burden on limited health care resources in developing countries like India.<sup>[14,15]</sup> In India, all healthcare professionals can report an ADR by filling an ADR reporting form provided by CDSCO (Central Drug Standard Control Organization). Still, under reporting is highly prevalent. An important part in this under reporting is played by the lacunae in the knowledge (especially lack of knowledge of how and whom to report about ADRs) and attitude of various health care professionals towards monitoring and reporting of ADRs.<sup>[16-18]</sup> A few other reasons have been cited as health care workers opine that they have constraint of time; few don't know which ADRs are to be reported. Sometimes, ADR reporting forms are not available.<sup>[18,19]</sup> To make the doctors well equipped with KAP (knowledge, attitude, practice) regarding PV, teaching PV has been made mandatory by MCI in the undergraduate curriculum. Therefore, to aid in the working of PV programme, there is an urgent necessity to motivate, increase the knowledge and awareness and regularly train our health care professionals regarding ADR reporting and PV.

A number of studies have documented the lack of KAP, regarding ADRs in doctors, nurses, pharmacists, medical students, but few studies have been conducted on interns regarding PV.<sup>[11,18,19]</sup> Though knowledge of PV is improving in interns, who are our budding doctors and future health care providers, still there is requirement of training them proficiently and making them professionally sound, so as to the future health care services of our country are in safe hands.

## Materials and Methods

This was a cross sectional observational questionnaire based study which was conducted in a tertiary care hospital of North India. (Gian Sagar Medical College & Hospital, Banur, Punjab). After gaining permission from the Institutional Ethics Committee, 100 interns were enrolled in the study after obtaining their consent. The purpose and objective of the study was explained to them. A questionnaire (Annexure 1) was designed to gather information about the knowledge of ADR reporting, attitude towards reporting and factors in practice which could act as a deterrent to the reporting of ADRs. The KAP questionnaire consisted of 15 items. Out of these, five questions were based on cognitive domain (knowledge), four on affective domain (attitude), and six questions were based on psychomotor domain (Practice) related to ADR monitoring and reporting. This questionnaire was then validated and modified accordingly. The interns who participated in the validation of the questionnaire were not included in the conduct of the study. The enrolled participants were given the predesigned and prevalidated questionnaire and were asked to fill it within 30 minutes and submit it. Statistical analysis was done using SPSS software. Questionnaire was analysed and all the percentages calculated.

## Results

Out of the 100 questionnaire circulated, 90 were filled in and submitted.

### Knowledge

50% participants gave the correct meaning of PV. 59% interns agreed that PV include all systems of medicine and had knowledge about drugs banned due to its ADRs. The correct response regarding the location of the international centre for drug safety monitoring and the national pharmacovigilance centre was given by 33% and 42% of interns respectively. (Fig.1)

### Attitude

Participants were of the opinion that ADR monitoring is necessary (33%) and that it should be mandatory was agreed upon by 67% of the

respondents. Medical students and nurses have a role to play in PV was opined by 59% and 67% interns respectively. 50% respondents said that every hospital should have an ADR reporting centre. (Fig.2)

**Practice**

Half of the interns had seen an ADR and 42% knew how and where to report it. Only 9% were aware of how the information given by them regarding ADR is further processed. 33% agreed that a non medical person can report an ADR. (Fig.3) Regarding the factors that were a hindrance to reporting, the most common reason given was that they don't know how and where to report (58.8%) followed by lack of training, patient confidentiality issues and belief that all marketed drugs are safe (25.5%, 8.8% and 8.8%) respectively. (Fig.4)

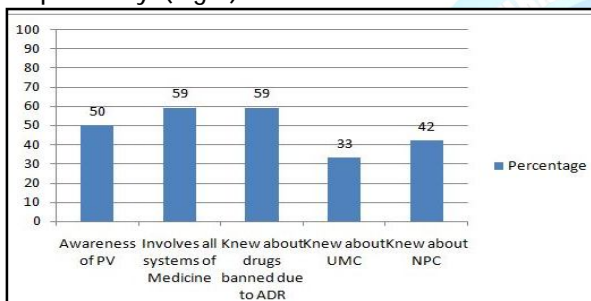


Fig.1 Percentage of knowledge about Pharmacovigilance

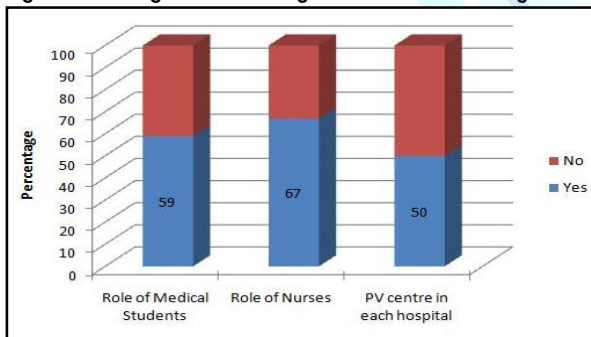


Fig.2 Attitude towards Pharmacovigilance

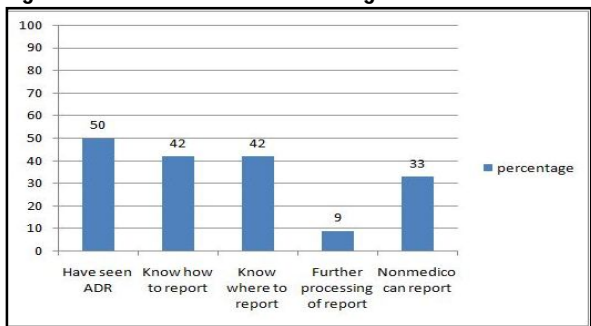


Fig.3 Practices in Pharmacovigilance

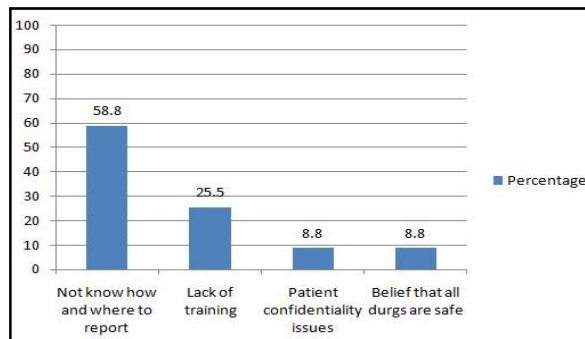


Fig.4 Barriers of ADR reporting

**Discussion**

Reporting ADRs is the building block of PV program. The present study shows that interns in a tertiary care hospital are not very adept in ADR reporting and the awareness about PV program and the knowledge of ADR reporting was quite low among them. This finding corroborates with other studies showing similar results. [11,19] Various studies conducted in a number of other countries also are in line with this result. [20,21] Inadequate training of the undergraduates in PV may be responsible for this. Regarding the purpose of PV, the correct response given by respondents in our study was 50% while in other studies it was 65%, 67% and 77% [15,19,23] respectively. Only 7.5% respondents were aware of drugs banned due to ADRs [24] while in our study 59% interns were aware of drugs banned due to their ADRs. In the present study, 33% and 42% interns had knowledge about the location of International Drug Monitoring Centre and the NPC respectively. A study conducted by Ramesh and Parthasarathi stated that a small number of doctors were aware of national and international PV program. [25] Sathisha et al documented that half of the interns were aware of NPC [26] while 59% of the respondents were aware of the same in two separate studies. [19,25] Sandeep et al found that only 42% of the respondents knew about UMC. [15] 33% interns agreed that reporting of ADRs is necessary and 67% said it should be mandatory. Similarly, in several studies, majority of the respondents said that ADR reporting is essential. [11,15,19] Sathisha et al documented that 80% of the interns were of the view that ADRs can be reported by doctors, nurses as well as pharmacists. [26] In our study, more than half of



the interns were of the opinion that medical students and nurses could play a role in ADR reporting. 50% of the interns suggested that there should be an ADR reporting centre in every hospital which is in line with a study by Sandeep et al where 74% of the respondents gave a positive response.<sup>[15]</sup> Half of the interns had seen an ADR. Similarly, in other studies 49% and 20% of the respondents had observed an ADR.<sup>[24,27]</sup> But, the number of ADRs reported were very few. In response to the factors leading to under reporting, the respondents opined that the major factors hindering reporting came out to be lack of knowledge as to how to report- and where to report (59% and 26% respectively) while the corresponding figures in other studies were 45% and 48% , 68% and 70%, 61% for both , 22% and 19%<sup>[11,16,22 ,24]</sup> respectively. A few other factors reported were lack of easy availability of forms,<sup>[18]</sup> lack of time and don't know which ADR is to be preferentially reported.<sup>[16,28]</sup> This study shows lack of in depth knowledge of understanding of facts. The interns feel the importance of ADR reporting but agree that there is lack proper training for the same. These findings are similar to another study by Upadhyaya.<sup>[11]</sup> A study showed that majority of the doctors had good knowledge of PV, still they fell short of practical acumen.<sup>[28]</sup> But, our study shows deficiencies in knowledge as well as practices of ADR reporting. This finding corroborates the study by Upadhyaya et al indicating that there is still requirement to educate and sensitize the doctors who are in the training phase about knowledge and importance of ADR reporting and PV.<sup>[11]</sup>

Future holds an immense task to innovate approaches and train the health care workers providing them more information, guidance with regard to ADR detection, prevention and reporting. More than 90%-96% respondents suggested measures to increase awareness with the help of CMEs, lectures, conferences, workshops, post training reminders, easy availability of reporting forms.<sup>[17,19,26]</sup> Also, creating an atmosphere of ADR reporting by making the process of ADR reporting convenient (by electronic submission), prompt feedback, giving incentives for reporting are a few

modalities to encourage ADR reporting. The limitation of the study includes less number of participants that can be increased. More such studies can be conducted on other health care professionals like the doctors, nurses, pharmacists and medical students who are in direct contact with the patients and are the medium to report ADRs.

Hence, even though majority of the interns are of the opinion that ADR monitoring and reporting is beneficial and cuts down the cost of overall health expenditure, still there is need for intervention in this field to provide knowledge to the doctors, nurses, pharmacists and medical students who are the foundation of health care. The present study can help us devise future strategies as it gives an account of the KAP of interns and factors responsible for under-reporting. Several measures to overcome the shortcomings in the practice of ADR reporting can be managed by making the health care providers aware of the importance of reporting and the educational interventions that can be taken in this direction. Also, making the process of ADR reporting less cumbersome and providing prompt feedback to reporters about the ADRs reported by them, are some steps that can be taken to put the knowledge and awareness regarding ADR reporting to practice. The successful working of PVP will benefit not only the ill but it will also help in limiting the resources spent on health care, decreasing the morbidity and mortality due to ADRs.

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