

# To study the Knowledge, Attitude and the Practice of Pharmacovigilance and ADR Reporting among the Healthcare Professionals in a Teaching Hospital In North India

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**Abstract:** *Pharmacovigilance is related to the protection of public health and adverse drug reaction. While major advancements in the discipline of pharmacovigilance have taken place in the West, there is still a lot of room for improvement in India. However, with more clinical trials and clinical research activity being conducted there is an immense need to understand and implement pharmacovigilance. Now in India, pharmacovigilance (PV) has progressed from the situation as it was in past, but more awareness is required for improvement in reporting of adverse drug reactions (ADRs) from the health care sectors. This knowledge, attitude and practice based study was conducted in a tertiary healthcare center in north India for the very first time to evaluate the healthcare professionals (HCPs) regarding their knowledge, attitude and practice of pharmacovigilance. The study was conducted as an observational, non-interventional, questionnaire based study. The questions were divided into three types: Knowledge among the health care professionals, on ADR reporting and Pharmacovigilance. Attitude regarding the same among the doctors and, Practice i.e. in what manner do HCPs practice ADR reporting. The results were quite encouraging as maximum number of HCPs knew about the term pharmacovigilance and had a proactive attitude regarding the same yet the determination to report cases was not satisfactory and a better understanding of the importance of adverse event reporting was required.*

**Keywords:** Adverse drug reactions, Clinical trials, Healthcare professionals, Clinical research, Pharmacovigilance

## 1. Introduction

Pharmacovigilance is the science and activities relating to detection, assessment, understanding and prevention of adverse effects or any other drug related problem.[1] The word pharmacovigilance has been derived from the Greek word “pharmakon” which means ‘drug’ and the Latin word “vigilare” which means “to keep awake or alert[1].”

Pharmacovigilance is the pharmacological science relating to the detection, assessment, understanding and prevention of adverse effects, particularly long term and short term side effects of medicines. Adverse drug reactions, or ADRs, are officially described as: "A response to a drug which is noxious and unintended, and which occurs at dose normally used for the prophylaxis, diagnosis or therapy of disease, or for the modification of physiological function." ADRs also might be the results of polypharmacy, iatrogenesis, paradoxical reaction and other serious adverse events.[1]

One of the major reasons of morbidity and mortality all over the world are adverse drug reactions (ADRs). Hence, proper monitoring of ADRs is a necessity. In India, all healthcare professionals including doctors, nurses, and pharmacists can report an ADR by filling an ADR form of the Central Drugs Standard Control Organization.[2] It is important for healthcare professionals to know how to report and where to report an ADR. The active participation of healthcare professionals in the pharmacovigilance program can improve the ADR reporting.[2] These adverse drug reactions not only add to the suffering of patients but also increase morbidity and mortality along with a financial burden on the society. The overall incidence of ADRs in hospitalized patients is estimated to be 6.7% and that of fatal ADRs

0.32%. Data indicates that in patients who experience ADRs death rates are 19.18% higher and length of hospital stay is 8.25% higher. Total medical costs for patients with ADRs are increased by an average of 19.86%. [2][3] However, the lack of ability of clinicians to suspect or detect such adverse event related to drugs might lead to inappropriate management of adverse events thus exposing the patient to additional drug hazards.

A study carried out in south India by Ramesh *et al.* observed that 0.7% of hospital admissions were due to ADRs and a total of 3.7% of the hospitalized patients experienced an ADR, of which 1.3% were fatal.[11] Another study by Arulmani *et al.* showed that ADRs were responsible for 3.4% of the hospital admissions and 3.7% developed ADRs during their hospital stay.[12] The incidence of serious ADRs is 6.7% in India.[5] In addition to the obvious morbidity and mortality caused by them, ADRs are also an economic burden on the healthcare system.[6][7] Hence, their early detection and prevention is necessary.

### Why is Pharmacovigilance important?

When a medicine is released into the market there is still a great deal that is unknown about the safety of the product. Once marketed the medicines are used by patients who have many different diseases, who are using several other drugs and who have different traditions and diets which may affect the way in which they react to a medicine. The adverse drug reactions and poisonings associated with traditional and herbal remedies also need to be monitored in each country.[16] The information received on the adverse effects of drugs in other countries may not be relevant or applicable to Country's citizens as some reactions may occur in some ethnicities only. In order to prevent unnecessary suffering

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and to decrease the financial loss sustained by the patient due to inappropriate or unsafe use of medicines, it is essential that a monitoring system for the safety of medicines is supported by doctors, pharmacists, nurses and other health professionals.[17]

Monitoring of ADRs is carried out by various methods, of which voluntary or spontaneous reporting is commonly practiced. This system offers many advantages. It is inexpensive and easy to operate. It encompasses all drugs and patient populations, including special groups like infants, elderly patients etc. However, under-reporting and an inability to calculate the incidence of ADRs are the inherent disadvantages of this method. In order to improve the participation of health professionals in spontaneous reporting, it might be necessary to design strategies that modify both the intrinsic (knowledge, attitude and practices) and extrinsic (relationship between health professionals and their patients, the health system and the regulators) factors. A knowledge, attitude, and practice (KAP) analysis may provide an insight into the intrinsic factors and help understand the reasons for under-reporting.[20][21]

Knowledge, attitude, and practice regarding ADR reporting have not been studied extensively in India. A few studies carried out in India and Nepal have shown poor knowledge, attitude, and deficient practices of ADR reporting among the prescribers and healthcare professionals.[4]

### Objectives

To study the Knowledge, Attitude And The Practice (KAP) of Pharmacovigilance and ADR Reporting Among the Healthcare Professionals In a Teaching Medical Hospital/ Tertiary Healthcare Center In North India.

The **primary objective** was to evaluate the knowledge, attitude and practices among the health care professionals about pharmacovigilance.

The **secondary objective** was to understand the causes of under-reporting and promote the practice of pharmacovigilance in health care setup in India if felt necessary.

## 2. Materials and Methods

- **Study Setting:** This study was conducted in Indira Gandhi Medical Hospital (IGMC), Shimla, between October 2015-February, 2016.
- **Study Population:** Health care professionals including MBBS, MD, BDS, MDS professionals only.
- **Study Design:** This was an observational, non-interventional, questionnaire based study. KAP study was designed to check the knowledge of pharmacovigilance among HCPs, their attitude towards pharmacovigilance, and how they practice ADR reporting.
- **Study Instrument:** The study instrument was a pre-designed questionnaire which was generated from the literature and adapted from previous similar studies. [21]
- The questionnaire consists of 35 questions related to the knowledge and information on pharmacovigilance, attitude of professionals and the perception regarding ADR reporting.

- **Sample size:** 85.

### 2.1 Methodology

**Study Design:** An observational, non-interventional questionnaire based study.

**Study Period:** Six months.

**Sample Size:** 85.

**Study Criteria:**

#### Inclusion Criteria:

- Health care professionals i.e., MBBS, MD,BDS, and MDS doctors.
- The post graduate students pursuing their MD or MDS.
- Interns of medical and dental stream.

#### Exclusion Criteria:

The health care professionals who were on leave and those who were not willing to participate in the study were excluded.

**Sources of data:**

- The study participants consisted of all the doctors who were working at the hospital during the study period.
- All the participants were given a questionnaire and filled questionnaire was collected on site.
- A total number of 85 subjects were included in the study.
- The questionnaire was made up of 33 questions which were designed to check the knowledge, attitude and practices about pharmacovigilance and adverse drug reaction reporting.
- The study was conducted in a tertiary healthcare center in north India.

#### Study Procedure:

The data collection was done between the months of November 2015-January 2016. Informed consent was taken from the doctors before taking the information and was done in an anonymous manner. The filled questionnaire was collected on site.

The questionnaire comprised of three sections:

- Knowledge among the health care professionals, on ADR reporting and Pharmacovigilance.
- Attitude regarding the same among the doctors and,
- Practice.

#### Sample Questionnaire:

- 1) Are you aware of the term Pharmacovigilance?
- 2) Do you think ADR reporting is professional obligation to you?
- 3) The healthcare professional responsible for reporting ADRs in a hospital is/are?
- 4) Do you think reporting of adverse drug reaction is necessary?
- 5) Where is the International Centre for Adverse Drug Reaction Monitoring located?
- 6) Do you think Pharmacovigilance should be taught in detail to healthcare professionals?
- 7) What is your opinion about establishing ADR monitoring centre in every hospital?
- 8) Have you ever experienced adverse drug reactions in your patients during your professional practice?

- 9) Have you ever reported ADR to the Pharmacovigilance centre?
- 10) Have you ever seen ADR reporting form?
- 11) Have you ever been trained on how to report Adverse Drug Reaction(ADR)?
- 12) A serious adverse event in India should be reported to the regulatory body within
- 13) Is there any pharmacovigilance committee in your institute?
- 14) Which factors discourage you from reporting the ADRs?
- 15) Which of the following defines serious adverse event?
- 16) Elements which are mandatory to record?
- 17) Is ADR synonymous to adverse event?
- 18) Is ADR reporting form available when you are at the job of prescribing medicines to the patients?
- 19) ADR should be reported only when they are: serious and life threatening, severe and cause disability, mild and causes less inconvenience, all of the above, none.
- 20) Non-medical people can report ADR to a nearby medical person Yes/No, If yes, by what means of communication?
- 21) Do you think the ADR reporting and monitoring system would benefit the patient?
- 22) Do you think confidentiality should be maintained while ADR reporting?
- 23) Do you worry about legal problems while you think of ADR reporting?
- 24) Is there any nearby ADR Reporting and Monitoring Centre in your knowledge?
- 25) Do you envisage role of information technology in facilitating ADR reporting in the country?
- 26) Pharmacovigilance is the study that relates to: safe, effective and economic use of medicine, detection, assessment, understanding and prevention of adverse effects, all.
- 27) What are the functions of pharmacovigilance?
- 28) What does pharmacovigilance include?
- 29) AIIMS New Delhi is a: peripheral, zonal or regional pharmacovigilance centre.
- 30) ADRs which are dose-independent can be treated: by withdrawing the drug, by reducing the dose, by replacing the drug, none of the above.
- 31) What is an augmented drug reaction?
- 32) What is the name of the "WHO online database" for reporting ADRs?
- 33) One of the following factors is a major risk factor for the occurrences of ADRs: arthritis, renal failure, vacuities, none.
- 34) Who is the chairman of pharmacovigilance programme in India?
- 35) Match the following: a. thalidomide, b. paracetamol, c. streptomycin, d. phenytoin with 1. Hearing Loss 2. Phocomelia 3. Gum Hypertrophy 4. Liver Toxicity.[25][26][29]

#### a) Knowledge among the health care professionals on ADR reporting and Pharmacovigilance.

Question no. 1,3,5,12,13,15,16,17, 19, 20, 24, 26, 27, 28, 29, 30, 31 were formulated to check the knowledge of HCPs regarding pharmacovigilance and ADR reporting. The questions checked the awareness in general, awareness

regarding the presence of committees, knowledge about seriousness, pharmacovigilance centres, drug reactions etc.

#### b) Attitude among the doctors.

Question no.2,4,6,7,14,21,22,23,25 were formulated to check the attitude among HCPs. The attitude part focuses on what do the doctors feel regarding reporting of ADRs and its necessity. The questions were formulated in a way which shows if given a situation would these doctors take that extra effort to report the ADR and what do they feel about the legal issues and confidentiality of the subjects.

#### c) Practice among health care professionals.

Question no. 8,9,10,11,18 were designed to evaluate the practice of ADR recognition and reporting among the HCPs. These questions seek out information regarding how and where to report the ADR forms, how it looks like and any training, if ever, they have received regarding the pharmacovigilance.

**Data analysis:** The data analysis was carried out after all the 85 filled questionnaires were returned by the HCPs. Informed consent was taken and confidentiality was maintained throughout so as to get honest information from the doctors.

The data gathered by all the samples was then checked thoroughly for correctness and then it was analysed using SPSS software.

### 3. Results and Discussion

#### *Knowledge about pharmacovigilance among HCPs*

96.5% HCPs were aware of the term pharmacovigilance but only 36.47% HCPs knew that ADRs could be reported by all of the given i.e. doctors, nurse and pharmacist which was correct but a vast majority of 61.18% felt that only doctors were responsible for reporting ADRs. Only 30% knew correctly the location of International Center for Adverse Drug Reaction reporting i.e. United Kingdom.

As far as timeline of reporting was concerned 60% people knew the correct answer that a serious adverse event should be reported to the regulatory body within 14 days, while 27% felt that it should be done within 7 days and 6% and 7% felt that it should be done within one day and fifteen days respectively. 94% of HCPs knew the definition of serious adverse event and 73% knew that all i.e. patient details, reports and the details of the medicine taken were mandatory to be recorded while submitting an ADR form but 22.35% wrongly assumed that only identifiable patient details were mandatory for the same. HCPs (74.12%) felt that both adverse event and adverse drug reaction were same while 14.12% did not know the difference and 9.41% chose the option "can't say." Only 2.35% knew that both are different as adverse drug reaction meant that causality was established whereas adverse event could be related or not related to the drug.

81.2% knew that common people can report ADRs and 93% of HCPs felt that reporting ADRs would benefit the patients. 84% of participants knew the about the location of ADR reporting centre. Only 55% could tell the correct definition of pharmacovigilance. 38% felt that PV is only



about therapeutic drug monitoring. A good majority of 91% knew the correct functions of pharmacovigilance which included detection of ADRs, measurement and risk of effective drug use and dissemination of ADR information and education. 76.5% knew that AIIMS Delhi is a zonal pharmacovigilance center. Only 50% of HCPs were aware of the definition of augmented drug reactions and how to treat independent ADRs.

#### **Attitude among health care professionals and staff members:**

89.4% of the participants felt that it was necessary to report ADRs and 80% felt that it was a professional obligation. 93% of HCPs felt that pharmacovigilance should be taught in detail and 69% of doctors felt that ADR monitoring centers should be in every hospital while almost 15.3% felt that one in a city was sufficient and almost 11% answered that it should depend upon the number of bed size in the hospital. 63% of HCPs reported that a lack of time to report ADRs, no remuneration, indecisiveness regarding the occurrence of ADRs and the effect of reporting a single case may not be of much significance, all these factors discourage them from reporting ADRs. 95.3% of the study participants felt that ADR reporting would be beneficial to the patient and a majority (63%) HCPs felt that confidentiality should be maintained but on the other hand 35.29% felt that there was no need for the same which again showed a lack of training in the principles of reporting.

40% worried about the legal complications that might arise from drug reporting. 89.41% of doctors recognised the role of internet and mobile phones in ADR reporting. Attitude towards reporting seemed quite promising yet a lack of training and confidence was visible as a 63% stated various reasons for not reporting cases. 93% of the HCPs wanted training in PV.

#### **Practice among health care professionals and staff members:**

88% of HCPs had seen or experienced an ADR in their professional lives, and 88.24% of HCPs had at-least once noticed some sort of drug related reaction in their diagnosis. 76.5% of HCPs had seen an ADR reporting form but 60% had never been trained on how to report an ADR. Only 62% of HCPs knew that ADR reporting form was available in the hospital. The comparison with the results of the published studies from some other states of India demonstrated that knowledge and attitude towards pharmacovigilance is gradually improving among healthcare professionals, but unfortunately the actual practice of ADR reporting is still deficient among them. The adverse event reporting rate from our study was low which was similar to previously reported different Indian studies from Trivandrum[6], Nagpur[3], Bangalore[4], Jalandhar [5], Ahmedabad[6] and Indore.[3]

## **4. Strengths and Limitations**

### **Strengths**

The questionnaire was well designed and covered all the three main facets i.e. knowledge, attitude and practice among HCPs. The study was conducted among doctors only that too from the oldest and largest hospital of Himachal Pradesh hence the information in this questionnaire had been

derived from the most qualified and well informed pool in medical field.

Full care had been taken to ensure that the study was transparent and non-ambiguous and confidentiality was maintained to ensure that answers had been given in an unbiased manner.

### **Limitations**

The source pool of data was comparatively small i.e. only 85 doctors could be approached for the study. The study was conducted in a single hospital so the results could not be generalized for whole of the state.

## **5. Conclusion**

In conclusion, this study showed that majority of the healthcare professionals had some knowledge and a seemingly proactive attitude towards adverse event reporting. In spite of that the reporting rate of ADR was very low. Hence, there was huge gap between the ADR experienced and ADR reported by healthcare professional. The lack of training was visible as the answers related to timelines, nature and responsibility of reporting etc. showed that there were loopholes in understanding. A positive attitude and a willingness to get training in pharmacovigilance was discovered and majority felt that proper training would lead to increased reporting of ADR by healthcare professional. The fact that majority of respondents agreed that reporting of ADRs was necessary and wanted that pharmacovigilance should be taught in detail to healthcare professionals emphasized that awareness had reached the HCPs yet implementation of proper tools and training would require some time.

The study provides an important insight into drug safety reporting in northern India. Future studies should be conducted to see the trend in drug reporting with time. Also, the study strongly suggested that training of HCPs in PV must be taken seriously and should be made a part of the curriculum.

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