

## Research

### Study of Key Stakeholders for their Knowledge, Attitude & Practice on Adverse Drug Reaction Reporting in Tertiary Care Hospitals in Jaipur, India

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#### Abstract

Adverse drug reactions (ADR) are the leading cause for the hospital administration, morbidity, and mortality as per the established data. Present pharmacovigilance program of India is performing well for strengthening ADR reporting system. The current project is aimed to study knowledge, attitude and practices of health care professionals and key stakeholders for Adverse Drug reaction reporting of marketed medicines.

The study was conducted in four major tertiary care hospitals in Jaipur from Government and private sector from May to July 2015. The data was collected from key stakeholders with a sample size of 1022 (male & female of age group 18-70 years) using a semi structured questionnaire tool separate for different segment of the key stakeholders. Data was cleaned, and analyzed for its descriptive report and assessment of the situation.

There is less aware of the Adverse Drug reaction reporting system, only 32% of the doctor's sample is aware about the reporting system of Adverse Drug reaction in India as well as the mandatory time period in case of serious Adverse Drug reaction reporting (26%). The location for regional office for Adverse Drug reaction reporting is known to only 26% of the sampled Doctors in all the major four tertiary care hospitals of Jaipur. It is found that the awareness about 'To whom Adverse Drug reaction should be reported' is seen in only 12% of the sample Doctors. While only 6% of them are provided any training about the Adverse Drug reaction reporting procedure. It was found that only 57% of the sampled doctors had encountered patients with Adverse Drug reaction in their clinical practice during last one year of the study, and only 45% of them are recording Adverse Drug reactions in their record book or file.

It was found that although the health professionals are aware of the basic knowledge about the Adverse Drug reaction due involvement of key terms in their basic education and training but there is a huge gap found in knowledge parameter as seen in unawareness about the reporting system of Pharmacovigilance.

**Keywords:** Adverse Drug Reaction (ADR); Pharmacovigilance; Knowledge Attitude Practice (KAP) Study; Tertiary Care Hospitals; Jaipur Study

#### Introduction

Pharmacovigilance (PV) is the sum of activities related to the detection, assessment, understanding, and prevention of Adverse Drug Reactions (ADR) caused by drugs. Spontaneous reporting of suspected ADRs to PV centre's is of utmost importance to generate the safety data of marketed drugs. These are classified into six types: dose-related (Augmented), non-dose-related (Bizarre), dose-related and time-related (Chronic), time-related (Delayed), withdrawal (End of use), and failure of therapy (Failure) [1]. ADR's contribute to a significant number of morbidity and mortality all over the world, they can be seen in clinical practice with both new as well as marketed medicines [2].

Recent published data suggest the less number of Adverse drug reaction cases reported by various PV centre's in major cities of India compared to the developed countries (Indian Pharmacopoeia Commission report, 2014) [3] which indicate low awareness, knowledge, and inadequate practice of ADR reporting in the region. The current prevailing incidence of serious Adverse Drug Reactions is 6.7% in India [4], which does not include drugs administered in error, nor those taken as a suicidal intent [5], and only less than that of heart disease, cancer and stroke. Adverse drug reactions (ADRs) constitute a significant health problem with consequences for the patient as well as for society. Suspected Adverse Drug Reactions have been reported to occur in about 2-14% of hospitalized patients. In about 5% of deceased hospitalized

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patients suspected ADR's may have caused or contributed to the fatal outcome .

India reported no more than 2% of globally occurring adverse drug reactions (ADRs) [6]. As per the current scenario for Number of ADR's, that had been reported in India during last few years are: 27867 (in year 2013), 40810 (in year 2014) & 50450 (in year 2015), there is nearly 10% increase in the adverse drug reactions despite the growth in population is 1.2%. The difference in the growth of the population with respect to adverse drug reaction can be considered with increase in awareness level of the stakeholders and the expansion of the Pharmacovigilance Program of India [7].

Reason to monitor the adverse reactions of drugs, if their safety profiles have already been studied adequately before their commercial release, is to assess the medicine safety in population rather than sampled population with varied variables like environmental, health, food, gene pool etc..

The study was conducted to assess the need of implementing a system for the gathering the Adverse drug reaction (ADR) report for the medicines after their use. The study was intended to be done in local environment with the involvement of key stakeholders i.e. Doctor, Pharmacist, Nurse and Patient. The objectives of the study are:

To study knowledge, attitude and practices of health care professionals and key stakeholders for Adverse drug reaction reporting of marketed drugs; To identify current gap in knowledge and practices related to Adverse drug reaction reporting of marketed drugs; To suggest upon possible solutions for the problem, if found.

## Methodology

A prospective descriptive study was conducted in the tertiary care Hospitals in Jaipur, Rajasthan, India and consists of Target respondents Drug Prescribers (Doctors), Pharmacist, Nurses and Patients for the study (either sex). Sampling and Sample Size: A total of four tertiary care hospitals including private and public hospitals & teaching, non-teaching hospital are covered under the project. Total key stakeholders involved in the study are 1022 details for the sample distribution is provided as: Doctors (306), Nurses (337), Pharmacists (37) & Patients (342) are involved in the study.

Sample calculation is based upon the total number of departments & personals working in the hospital and their statistical significant count (Minimum 10% in case of large number of availability like for patients and maximum 50% in case of less number of availability like for Pharmacists). Method of data collection includes a) review of the record & reports available for the current adverse drug reaction reporting and the methods used to check upon Adverse drug reaction related issues are studied. b) Interview with doctor,

pharmacist, nurse followed by exit Interview with patients.

## Operational Plan

The data collection tools are developed in English language and later on translated in to local language (Hindi) followed by back-check. The tools are peer-reviewed & pre-tested in a hospital other than sampled hospital with the team members of field investigators and thus are finalized. The proposal & tools are approved by the Institutional ethics Review Board. Hospital consent was sought from the various hospitals, only the hospitals which provide with the permission had been involved in the study. On the basis of approval and fulfillment of strata for each category, four hospitals are involved in the study. Tools are filled on consequent visits in the sampled hospital by Principle Investigator and team members followed by meeting with the Hospital in-charge and head of departments.

The surveillance of the team members is done by using regular back check, spot check by principle investigator to check upon the data quality. The filled tools are screened for errors daily before being submitted to principle investigator. The review of the filled tools are done by principle investigator, digitized by data entry operator at IIHMR University campus.

## Data Management

The filled tools & digitized data collected from the field was securely stored by principle investigator at IIHMR university. All the identifiers are removed and transcripts are coded to ensure the confidentiality of data. Data entry was done in Microsoft Excel (2007) followed by Cleaning of data. The data cleaning is performed for the quality control; partial & incomplete data was rejected to ensure quality data availability for the analysis. Analysis of the data for descriptive statistics and cross tabulation is performed using statistical software SPSS (version 16).

## Result and Discussion

The sampled population of Doctors consisting of the 73 % (65:80) males & 28% (20:35) females, while the Nurse sample consists of 37% (29:44) male only. Pharmacist are majorly dominated by the males 92% (83:100). Patient sample consist of 67% (59:74) male randomly in all hospitals

The mean age of the doctor's sample is 36.4 year (SD 7.3), Nurse is 27.7 year (SD 5.7), Pharmacist is 31.7 year (SD 7.9), & Patient is 32 year (SD 9.3). The major sample size of doctors was in 36-40 year range. The nursing population is majorly consisting of less the 30 year in all the sampled hospitals. There is low availability of sample more than 36 year in all hospitals except SMS hospital. A major group among the Pharmacist is from the age category of 26-30 year. The sample group of more than 40 year is not found to be present in all major hospitals. There are more patient population in the age

range of below 30 years, while there are less number of respondents relatively in age over 31 year.

All health professionals involved in the study are known about adverse drug reaction and are able to define it, in majority. Nurses (14%) are having less knowledge about adverse drug reaction reporting system in India, in comparison with that of Doctors (32%) and Pharmacist (40%) which are also not on the higher side of knowledge, in total all found to lack this knowledge; same is the case with knowledge about mandatory time period in case of serious Adverse drug reaction reporting. Health professionals majorly had not undergone any workshop or training specifically related to adverse drug reaction reporting (Doctor: 7%. Nurse: 12%, Pharmacist:31%), as per their knowledge about half of them agreed about the well documented information found in 'Patient information leaflet'.

An Awareness is found for the adverse drug reaction reporting to

be practiced regularly and similarly high level of awareness is found for the question that it important and is a part of duty of Health professionals. Nurses (100%) are not aware and confident about reporting only adverse drug reaction associated with prescribed drugs, while unlike doctors (50%) & Pharmacist (49%) in favor of reporting only adverse drug reaction associated with prescribed drugs. About half of the healthcare professionals (Doctor: 34%. Nurse: 49%, Pharmacist:65%) agreed upon reporting only adverse drug reaction that cause persistent disability.

In practice it was found that the healthcare professionals had encountered patient with Adverse drug reaction in your clinical practice, in the last 12 months (Doctor: 57%. Nurse: 34%, Pharmacist: 39%) and reporting creates additional work load (Doctor: 54%. Nurse: 34%, Pharmacist:32%). Doctors (45%) record the Adverse Drug Reactions encountered in their practice while nurse (39%) & Pharmacist (13%) are less recording such issue but

**Table 1:** Doctor's, Nurse's and Pharmacist's response (figures are average in percentage)

Knowledge	Doctor	Nurse	Pharmacist
Have you heard the term Adverse drug reaction (ADR)?	99.7	97.3	91.9
Define Adverse drug reaction	98	80.3	81.1
Have you heard about Adverse drug reaction reporting system in India?	32.4	13.8	40.5
Do you know about mandatory time period in case of serious Adverse drug reaction reporting?	26.2	26.8	40
Have you had undergone any workshop or training specifically related to Adverse drug reaction reporting?	7.3	12.3	30.8
Adverse Drug Reactions of marketed drugs are well documented by Pharmaceutical companies in their 'Patient information leaflet'?	55.7	66.4	52.8
<b>Awareness</b>			
Adverse drug reaction reporting to be practiced regularly?	100	99.7	97.3
Reporting Adverse drug reaction is part of duty of Health professionals?	98.7	97.9	97.3
Reporting about 'drug safety' is important?	99	99.7	100
Reporting drug safety is important for the health care system?	99.7	98.8	97.3
There is a need to be sure, that specific Adverse drug reaction is related to a drug, before reporting?	93.1	90.2	94.5
Only Adverse drug reaction of doctors prescribed drugs need to be reported?	45.9	99.7	48.6
Adverse drug reaction related with non-prescribed drugs need not to be reported?	25.3	38	40.5
Only Adverse drug reaction that cause persistent disability should be reported?	34.3	49.2	64.8
<b>Practice</b>			
Reporting creates additional work load?	53.9	44.4	32.4
Have you ever encountered patient with Adverse drug reaction in your clinical practice, in the last 12 months?	57.3	34	38.9
Do you record the Adverse Drug Reactions encountered in your practice?	44.9	39	12.5
How often you report any Adverse Drug Reactions in your practice?	79.4	82.8	62.5
How often do you give advice to your patients on possible drug- drug or drug- food interactions in your daily routine?	99.7	95.8	86.5
Adverse drug reaction reporting form available in your organization?	30.2	28.2	30.6

they are reporting any Adverse Drug Reactions in their practice (Doctor: 79%. Nurse: 83%, Pharmacist:66%). As per healthcare professional's perception they are less aware about adverse drug reaction reporting form availability in their organization (Doctor: 30%. Nurse: 28%, Pharmacist:31%).

### Patient's Perspective

The patients are less known to the term adverse drug reaction (52%) but the common alternative term for it they refer is side effect which is known to 94% of the sampled population. The Patients are also able to define the term (60%) adverse drug reaction. Patients are majorly in favor of reporting of Adverse drug reaction (97%).

There is in general acceptance (95%) upon the requirement of awareness for patients regarding Adverse drug reaction reporting. Almost all of the sampled Patients agree upon the term 'reporting Only Adverse drug reaction of doctor prescribed medicines are needed to be reported is agreed by 58% of the sample while there is a general majorly disagree (64%) upon the term of not reporting any Adverse drug reaction related with non-prescribed

medicines. There is a low awareness among patients, for reporting only Adverse drug reaction which cause persistent disability (62%). Majority of the sample is disagree (61%) upon the term that 'One report of Adverse drug reaction makes no difference' and also disagree (76%) upon 'Reporting is not useful for patients'. They are now aware of Adverse drug reaction reporting (64%) and also about availability of Adverse drug reaction reporting form (25%) as well as Adverse drug reaction reporting system (16%).

It was found that only 15% of the sampled patients population had undergone any Adverse drug reaction in past while only 5% had been hospitalized for the Adverse Drug Reaction. Nearly 26% of the sample had been interacting with the health professionals for possible Adverse Drug Reactions and only 24% of the sampled patients are aware that the health care professionals are recording the Adverse Drug Reactions in the clinical reports.

### Finding and Conclusion

It was found that the health professionals (Doctor, Nurse and Pharmacist) are having a gap in their knowledge parameter as seen

**Table 2:** Patient's response (figure are average in percentage)

Patient's Knowledge	Response
Have you heard about side effect in medicines?	93.9
Have you heard about Adverse drug reaction in medicines?	52.4
Are you aware that_	60.3
Is side effects and Adverse drug reaction should be reported?	97.3
<b>Patient's Awareness</b>	
Reporting Adverse Drug Reactions improves quality of patient care	99.4
Reporting Adverse drug reaction is part of duty of Health professional	97.3
There is a need to confirm that Adverse drug reaction is related to the drug before reporting	90.4
Only Adverse drug reaction of doctors prescribed drugs need to be reported?	57.8
Adverse drug reaction related with non-prescribed drugs need not to be reported	36.3
Only Adverse drug reaction that cause persistent disability should be reported?	62.1
Patient should be made aware about Adverse drug reaction reporting	94.9
One report of Adverse drug reaction makes no difference	38.7
Reporting is not useful to the patient	23.8
I will report Adverse Drug Reaction, if I encounter such condition	97.3
Do you know Side effects & Adverse Drug Reactions can be reported?	36.5
Are you aware the availability of side effect and Adverse drug reaction reporting form?	25
Are you aware about national side effect and Adverse drug reaction reporting system?	15.9
<b>Patient's Practice</b>	
Have you had any side effects and Adverse drug reaction in past?	15
Were you ever hospitalized for any side effects and Adverse drug reaction in past?	5.3
Have you told health professional about possibility of Adverse drug reaction & Side effects in your practice?	25.8
Did health care professional record your side effects & Adverse drug reaction in your clinical reports or Prescription?	24

in unawareness about the reporting system of Pharmacovigilance. Pharmacist are more aware (40%) about mandatory time period in case of serious adverse drug reaction reporting in contrast to doctor & nurses. Doctors are more exposed to the patient with adverse drug reaction than nurses & pharmacist. Although they are on the similar level of awareness for availability of adverse drug reaction reporting forms.

Although majority of doctors found Adverse drug reaction in their daily practices but the awareness found for the Adverse drug reaction reporting system is only about in the one third of the doctors and the mandatory time period for the serious Adverse drug reaction reporting as well as regional office for Adverse drug reaction reporting is known in only about in one fourth of the doctor's sampled population. Such a qualified professional people (Doctors) are also confused for where they are going to report about the Adverse drug reaction due to the fact that they are neither been provided any training or literature about the Pharmacovigilance and Adverse drug reaction procedures (only 6% are trained) nor there is any defined 'Standard Operating Procedure' for registering & handling the adverse drug reaction in any hospital, such cases are been handled as per the individual or organizational perceptions, which was different in all organizations and needed to standardized.

The patients on the other hand are having less knowledge to the fact related to Adverse Drug Reaction, Pharmacovigilance, their process and their ill hazards than the health professionals. It was found that 15% of the patient had faced Adverse drug reaction while only 5% had been hospitalized due to this reason. Only one fourth of the patients are proactively for seeking information from health professionals regarding Adverse Drug Reaction.

There a difference in encountered Adverse drug reaction among government to private sector hospitals in the ratio of 1.3 : 1.6 i.e. the Adverse drug reaction encountered in the private sector is more than the counterpart but the recording of Adverse drug reaction is found more in government hospitals in the ratio of 1.7 : 1.2. Government doctors are also in the practice of usually reporting the Adverse drug reaction 1.7 times more than the private sector.

The gap thus found in the knowledge as well as practice can be reduced using the techniques of training, assistance, encouragement and involvement of all health centre's (Public & Private), as suggested by majority of stakeholders. Despite being one of the largest nation with huge prevalence of the varied diseases, there is huge problem of under reporting in India (less than 1% in India compared to 5% worldwide) [8]. The field experience suggested that there is a fear among the stakeholders specially Doctors, for not reporting the adverse drug reaction as it might be correlated with their understanding about the medicine.

There is a huge requirement of providing the training & awareness for the stakeholders be respective departments as well as by the hospitals as they are not found to be practicing the system as per the applicable standards.

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