

## KNOWLEDGE, ATTITUDE AND PERCEPTION OF PHYSICIANS TOWARDS ADVERSE DRUG REACTION (ADR) REPORTING: A PHARMACOEPIDEMIOLOGICAL STUDY

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### ABSTRACT

**Background:** Reporting adverse drug reactions (ADRs) spontaneously is considered as a cornerstone of pharmacovigilance. However, its success depends on co-operative and motivated health care professionals. Under-reporting of the adverse drug reactions (ADRs) by the prescribers is a common problem.

**Objective:** The present study is aimed at assessing the knowledge, attitude and perception of physicians from various fields in Hyderabad, towards adverse drug reactions reporting, to get an in-sight into the causes of under-reporting of ADRs and to suggest possible ways of improving this method of reporting.

**Method:** The study was cross-sectional and questionnaire-based involving only medical doctors working in different fields. The completion of the questionnaire by respondents was taken as their consent to participate in the study. A total of 120 predesigned KAP (Knowledge, Attitude and Perception) questionnaires consisting of 25 questions were distributed to doctors with minimum qualification of MBBS. Microsoft Excel worksheet (Microsoft Office 2007) was used for statistical analysis.

**Result:** Only 94 out of 120 respondents filled and returned the questionnaire within the stipulated time frame giving a response rate of about 78.33%. 88 [93.61%] doctors feel that ADR reporting and monitoring system would benefit the patients. Busy schedule, lack of knowledge about the exact authority to report ADRs, unavailability of ADR reporting forms, lack of incentives were some of the reasons for under-reporting of ADRs.

**Conclusion:** It was observed that the knowledge of ADRs and how to report them are inadequate among doctors. More awareness should be created on the ADR reporting system.

**Keywords:** Adverse drug reactions, Knowledge, attitude and perception, pharmacovigilance, physician, educational intervention.

### INTRODUCTION

Adverse drug reactions (ADRs) are an important cause of mortality and morbidity worldwide [1]. According to World Health Organization (WHO) definition, an ADR is any noxious, unintended, and undesired effect of a drug, which occurs at doses used in humans for prophylaxis, diagnosis, or cure of a disease [2]. In addition to the human costs, ADRs have a major impact on public health by imposing a considerable economic burden on the society and the already-stretched health-care systems [3, 4]. Post marketing surveillance of drugs is very important in analyzing and managing the risks associated with drugs once they are available for the use in the general population. Spontaneous reporting has contributed significantly to successful pharmacovigilance. The contribution of health professionals, in this regard, to ADRs databases is enormously significant and has encouraged ongoing ascertainment of the benefit-risk ratio of some drugs [5,6] as well as contributed to signal detection of unsuspected and unusual ADRs previously undetected during the initial evaluation of a drug [7, 8]. In spite of these benefits, under-reporting remains a major draw-back of spontaneous reporting [9, 9]. It is estimated that only 6-10% of all ADRs are reported [10, 11]. This high rate of under-reporting can delay signal detection and consequently cause negative impact on the public health. Pharmacovigilance has constantly gained importance in last 15 years, relating to absolute amount of adverse drug reactions (ADRs) and to the fact that several hospital admissions are due to ADRs [4, 12]. Good pharmacovigilance programs will identify the risks and the risk factors in the shortest possible time so that harm can be avoided or minimized. When communicated effectively, this information allows for the intelligent, evidence-based use of medicines and has the potential for preventing many adverse reactions. Physicians, pharmacist and nurses are in a position to play a major key role in pharmacovigilance programs [6, 7] but underreporting is very common, with an estimated median underreporting rate (defined as percentage of ADRs detected from intensive data collection that were not reported to relevant spontaneous reporting systems) of 94% [13] and occurs frequently for serious and unlabeled reactions [14, 15]. This can delay detection of important ADRs. Studies from different settings indicate inadequate knowledge about pharmacovigilance among healthcare professionals as well as attitudes that are associated with a high degree of underreporting [16-20]. Pharmacovigilance is still in its infancy in India and there exists very limited knowledge about this

discipline. However, The Indian national pharmacovigilance programme lacks continuity due to lack of awareness and inadequate training about drug safety monitoring among healthcare professionals in India [21]. Assessment of awareness of pharmacovigilance among the healthcare professionals is very important due to under reporting of adverse drug reactions.

### MATERIALS AND METHODS

The study was a cross-sectional, observational, questionnaire-based study involving only medical doctors, working in different fields such as clinical research, industry, hospital, medical colleges, general practitioners and post graduate students. A total of 120 questionnaires were distributed to medical doctors. The completion of the questionnaire by respondents was taken as their consent to participate in the study. Those who were not willing to participate or did not return the questionnaire within the given time were excluded from the study. Hence, out of 120 questionnaires, only 94 were taken into consideration. A KAP questionnaire containing 25 questions was designed, to obtain the information regarding demographics of the respondents, knowledge regarding ADR reporting system, attitude and perception of ADR reporting. More than one answer was allowed in some questions. The information was recorded and analyzed using Microsoft Excel worksheet [Microsoft Office 2007]. Provision was also made for suggestions on possible ways to improve ADR reporting. In order to preclude any potential bias the disclosure of name of the responder was made optional.

#### Appendix 1

##### KAP Questionnaire

##### Knowledge, Attitude And Perception Of Physicians Towards Adverse Drug Reactions [ADR] Reporting: A Pharmacoepidemiological Study

Your details and information provided by you will be confidential and will be used only for research purpose.

NAME [Not Mandatory]	
AGE [Not Mandatory]	

<b>Gender</b>	
<b>Highest Qualification</b>	
<b>Experience in years</b>	

**Instructions-**

- 1] Please select and fill number in the box accordingly.
- 2] You may fill multiple choices.
- 3] If you want to mention other information, please use space below the question.

**1] Your Profession---**

1. General Physician
2. Specialist
3. Industry
4. Research
5. Academician

**2] Do you believe all the drugs available in the market are safe?**

1. Yes
2. No
3. Don't know

**3] Have you ever experienced an adverse drug reaction (ADR) in patients during your practice?**

1. Yes
2. No

**4] With which class of drugs do you frequently experience ADRs? (Write 'Not Applicable' if answer to above question is 'No')****5] How many percent of your patients complain about ADRs?**

1. Nil
2. 10-20%
3. 30-40%
4. 40-50%
5. More than 50%

**6] Should ADRs be reported by physicians?**

1. Yes
2. No
3. Don't know

If yes, then to whom?

1. Head of Department of your Institute.
2. Nearby Hospital
3. Government
4. Drug Manufacturer
5. All the above
6. None of the above
7. Don't know

**7] Do you think that pharmacist could be the right person to assist physician in ADR reporting?**

1. Yes
2. No
3. Don't know

**8] Is ADR reporting form available when you are at the job of prescribing medicines to the patients?**

1. Yes
2. No
3. Don't know

If yes, then it is supplied by whom?

**9] Do you think that ADR reporting and monitoring system would benefit the patient?**

1. Yes
2. No

If yes, give reasons below.

**10] What are the sources of ADR information to you?****11] Do you consider ADR information provided to as satisfactory?**

1. Yes
2. No

**12] ADRs should be reported only when they are---(you may select more than one option)**

1. Serious and life threatening.
2. Severe and cause disability
3. Mild and cause less inconvenience
4. All the above
5. None of the above.
6. Don't know
7. Others (please specify)

**13] Which types of ADRs are usually reported? (you may select more than one option)**

1. serious, unexpected and suspected
2. any ADR of old drug
3. any adverse event
4. ADR to a new product
5. only proven ADRs
6. all of above
7. None of above
8. don't know
9. Others (please specify)

**14] Do you feel that you are adequately trained in ADR reporting?**

1. Yes
2. No

**15] Do you feel that proper training should be provided to the physicians for ADR reporting?**

1. Yes
2. No
3. Don't know

**16] Do you feel confidentiality should be maintained while ADR reporting?**

1. Yes
2. No
3. Don't know

**17] Do you worry about legal problems while you think of ADR reporting?**

1. Yes
2. No
3. Don't know

**18] In your opinion what is cause of under-reporting of ADRs?**

(you may select more than one option)

1. Only safe drugs are available in the market.
2. Reporting does not influence the treatment scheme.
3. Busy schedule.
4. Lack of incentives.
5. Physician should rather collect data and publish himself/herself.
6. Difficult to pin point suspected drug.
7. ADR is known to physician.
8. Don't know whom to report?
9. Reporting could show ignorance.
10. Difficult to admit harm to the patient.
11. Insufficient clinical knowledge.
12. Thinking one report doesn't make any difference.
13. Others (please specify).

**19] Do you feel that ADR reporting is time consuming activity with no outcome?**

1. Yes
2. No
3. Don't know

**20] Is there any nearby ADR reporting and monitoring center in your knowledge?**

1. Yes
2. No
3. Don't know

**21] Do you support 'Direct ADR reporting' by the patients instead of physicians?**

1. Yes
2. No

**22] Do you envisage role of information technology in facilitating ADR reporting in the country? (such as use of internet, mobile service, etc.)**

1. Yes
2. No
3. Don't know

**23] Are you aware of 'Pharmacovigilance Programme of India' of CDSCO, Ministry of Health, Govt. of India?**

1. Yes
2. No

**24] Has this system created awareness of ADR reporting in you?**

1. Yes
2. No

**25] Do you expect feedback from ADR monitoring centre?**

1. Yes
2. No

**Any other comments or recommendations about improving pharmacovigilance in India?**

**Thank You for your valuable time and helping science!**

**RESULTS AND DISCUSSION**

Only 94 out of 120 respondents filled and returned the questionnaire within the stipulated time frame giving a response rate of about 78.33%. 88 (93.61%) doctors were of the opinion that all the drugs available in the market are not safe. 74 (78.72%) doctors had experienced ADRs in patients during their practice. 70 (74.46%) said that only 10-20% of their patients complain about ADRs. 90 (95.74%) were in favor of ADR reporting by the physicians. 40 (42.55 %) doctors supported pharmacists as the right persons to assist physicians in ADR reporting. 88 (93.61%) agreed that ADR reporting form is not available at their job place. 88 (93.61%) of them believed that ADR reporting and monitoring system would benefit the patients. 54 (57.44%) doctors were not satisfied with the ADR information provided to them. 76 (80.85%) physicians agreed that they were not adequately trained in ADR reporting. 90 (95.74%) doctors stated that proper training should be provided to physicians for ADR reporting. 62 (65.95%) respondents feel that patient confidentiality should be maintained while ADR reporting. 42 (46.49%) doctors admitted that they were worried about legal problems while ADR reporting. Factors for under reporting of ADRs are depicted in Table 1, Figure 1. 40 (42.56%) doctors say that ADR

reporting is a time consuming activity with no outcome. 84 (89.36%) docs accepted that they don't have knowledge about ADR reporting centre. 44 (46.80%) medicos support 'direct ADR reporting' by the patients instead of physicians. 88 (93.61%) docs support role of information technology in facilitating ADR reporting in the country. E.g. use of internet, mobile services, etc. 80 (85.10 %) doctors feel that ADR reporting should be made mandatory. 54 (57.44%) docs are not aware of Pharmacovigilance Programme of India. 54 (57.44 %) accepted that this procedure has definitely created some awareness on ADR reporting. 90 (95.74%) medical professionals expect feedback from ADR monitoring centers.

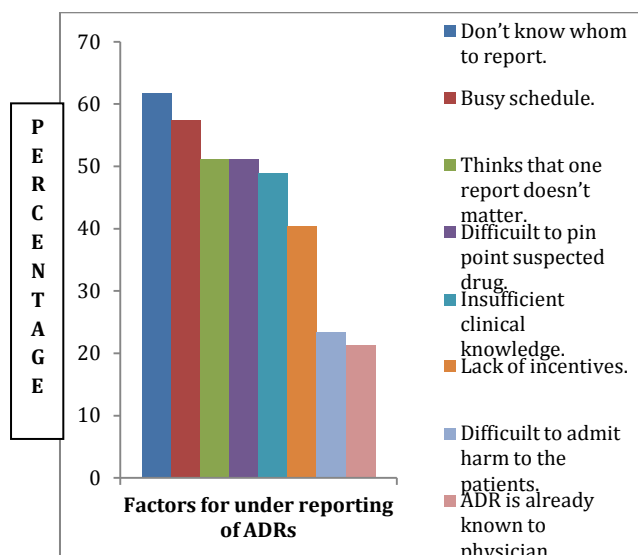


Figure 1: Factors For Under Reporting Of ADRs

Table 1: Factors for under-reporting of adverse drug reactions.

Sr No.	Reason	Number (n=94)	Percentage (%)
1	Don't know whom to report.	58	61.70
2	Busy schedule.	54	57.44
3	Think that one report doesn't matter.	48	51.06
4	Difficult to pin point suspected drug.	48	51.06
5	Insufficient clinical knowledge.	46	48.93
6	Lack of incentives.	38	40.42
7	Difficult to admit harm to the patients.	22	23.40
8	ADR is already known to physician.	20	21.27

Table 2 shows the sources of ADR information used by the respondents.

Table 2: Sources Of ADR Information Used By The Respondents

Sr No.	Source
1	Patients
2	Hospitals
3	Friends/ colleagues
4	Drug information sheets (in drug packs)
5	Internet
6	Scientific journals
7	Text on drugs and therapies.
8	Medical representatives of drug companies.
9	Direct mail brochures.
10	Continued Medical Education (CME), Seminars

Under-reporting of ADRs is a worldwide phenomenon and this has been established from previous studies [9,17,13,22]. While it is important to note that these studies were carried out among physicians, several other studies involving pharmacists have indeed confirmed

that under-reporting of ADRs is common to all health care professionals [23,24]. It is a known fact that information regarding ADRs changes on a daily basis and hence the need for constant updating of the knowledge of health care professionals in this area. Most respondents in this study obtained their information on ADRs from patients, drug information sheets and texts on drugs. Lack of, or inadequate, access to the internet can be a major limiting factor (where internet facilities are poor) for obtaining current reports on ADRs as most information from drug inserts and textbooks on drugs may be outdated and may not reflect the current state of information on ADRs. In order to address some of the determinants of under-reporting found in this study, ADR reporting guidelines should be made available in the form of booklets and posters at conspicuous locations in health care facilities to serve as a constant reminder. This should be in addition to regular sensitization of all health care workers on the importance of pharmacovigilance in the quest to decrease morbidity and mortality among the population. Some workers have suggested the use of financial incentives as a tool to stimulate reporting of ADRs [25]. Apart from the fact that the use of incentives have not been widely accepted and practiced, it raises the possibility of over-reporting by some health care workers in a bid to obtain financial rewards. This should not be supported because ADR reporting should be a fundamental responsibility of health care workers and, therefore, it should be understood as such. Improving ADR reporting, apart from reducing the incidence of adverse drug reactions in clinical practice, will also lead to a reduction in health care costs. Another way to increase the reporting of ADRs is through the promotion of patient self-reporting. The benefits of this idea have been confirmed in different studies [26,27]. Patient self-reporting has a complimentary role to play in increasing the level of ADR reporting in a developing country such as India. Efforts should also be made to make the reporting process by patients simple and straightforward. The lack of awareness of the availability of pharmacovigilance committee by more than half of the respondents indicates the need to extend the level of sensitization for health care workers to improve their ADR reporting. The main limitation of our study was the relatively small number of respondents. In addition, some other factors that are associated with self-reporting studies such as accuracy of recall, personal bias could also have affected, in some ways, the results of this study. The opinion of non-responders in general and participants who did not respond to certain aspects of the questionnaire could also have affected the interpretation.

Table 3 shows reasons for ADR reporting.

Table 3: Reasons Cited By Doctors For Reporting ADRs

Sr. No.	Reasons
1	To improve the patient safety.
2	To improve the quality of drugs.
3	To identify and detect new ADRs.
4	To measure the incidence of ADRs.
5	To identify relatively safe drugs.
6	To avoid future medical mishaps.

Several measures were suggested to improve ADR reporting (Table 4). These included creating awareness about ADR monitoring among health care professionals and consumers, through appropriate educational interventions [e.g. seminars, CMEs], making ADR reporting forms easily available and simplifying the process of reporting. Feedback from ADR monitoring centers about the causality and severity of ADRs reported by physicians would also encourage them to continue reporting.

Table 4 shows suggested methods for improving ADR reporting.

Table 4: Suggested Methods For Improving ADRs Reporting

Sr.No.	Suggested methods
1	Continuous medical education, training and refresher study
2	Instituting and encouraging feedback between patients prescribers and dispensers of drugs
3	Reminders and increased awareness from the ADR Monitoring Committee
4	Increasing awareness among other professionals that

	they could report ADRs
5	Increased collaboration with other healthcare professionals
6	More publicity about reporting scheme in local journals
7	Encouragement from the ADR Monitoring Committee and various head of departments
8	Alerting all outpatients to watch out for possible ADR when prescribing new drugs
9	Remuneration for every reported case of ADR
10	Spending more time on the wards with patients
11	Making reporting a professional obligation
12	Incentives to every outpatient that report ADR

This study has shown inadequate knowledge of doctors about ADRs and reporting similar to the previous reports among resident doctors in Nigeria [28] and doctors in many countries across Europe [19,29-31], America [32,33] and Asia [34,35]. Perhaps, the undergraduate training in pharmacovigilance and medicine risk perceptions may be either insufficient or improperly delivered to prepare the doctors for the task of ADR monitoring and reporting in their future career. A significant number of the respondents were not aware of the existence of a national pharmacovigilance centre in India. Most of the respondents were willing to report reactions to newly marketed drugs and serious reactions to established products because they perceived post-marketing surveillance as an important part of pharmacovigilance.

### CONCLUSION

Adverse drug reaction reporting is low among the medical professionals. There is a need for regular training and reinforcement of guidelines for ADR reporting among health care personnel. ADR reporting by nurses, pharmacists and patient self-reporting should also be encouraged. There are gaps between knowledge and ADR reporting among the doctors. These gaps need to be filled by improved training in pharmacovigilance. Attitudinal changes, whereby ADR reporting should be seen as an integral part of clinical activities of the doctors are very necessary for long term improvement of ADR reporting. Further studies needed to strengthen effectiveness of pharmacovigilance activities are necessary.

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