

A Survey to Assess the Awareness of Adverse Drug Reactions and Pharmacovigilance Practices among Healthcare Professionals in a Tertiary Care Hospital

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ABSTRACT

Background: Adverse drug reactions (ADRs) are a significant cause of morbidity and mortality worldwide. During last few years, pharmacovigilance science has evolved to recognize the importance for monitoring and improving the safe use of medicines. Inadequate awareness about the pharmacovigilance system among the health care professionals is the leading cause of under reporting of ADRs. There is a lack of studies that address the awareness of healthcare professionals toward the pharmacovigilance system and ADRs reporting.

Objective: To conduct the study to know the awareness of Pharmacovigilance among health professionals of our institute.

Methodology: This was a cross-sectional, non-interventional, questionnaire-based study, carried out at SHKM Govt. Medical College, Nalhar, Mewat, Haryana. 20% of the healthcare professionals of SHKM Govt. Medical College, Nalhar were randomly selected for the study.

Results: 80% subjects had the knowledge about Pharmacovigilance, 41% subjects were aware about purpose of PV and Pharmacovigilance programme of India (PvPI).

KEYWORDS: Pharmacovigilance awareness , ADR , Healthcare Professionals.

INTRODUCTION

Alongside many benefits, medications also cause harm to a number of people's lives. Adverse drug reactions (ADRs) are a significant cause of morbidity and mortality worldwide¹. During last few years, pharmacovigilance science has evolved to recognize the importance for monitoring and improving the safe use of medicines. According to WHO, Pharmacovigilance is "The science and activities which are related to the detection, assessment, understanding and the prevention of adverse effects or any other drug related problems²". Inadequate awareness about the pharmacovigilance system among the health care professionals is the leading cause of under reporting of ADRs. There is a lack of studies that address the awareness of healthcare professionals toward the pharmacovigilance system and ADRs reporting. Till now only few studies had been carried out in different countries to assess the knowledge of pharmacovigilance among the healthcare professionals.

A study conducted in France among medical residents showed that a majority lacked knowledge on pharmacovigilance³. Likewise a survey was carried out in Jiangsu, China, showed that significant differences existed in the awareness of pharmacovigilance across

regions, hospital classes and professions⁴. In a country like India with vast ethnic variability, different socioeconomic status, different disease prevalence and practice of different systems of medicines these types of studies are more important.

But in India, these types of studies are very scanty. A study which was conducted in Mysore recommended that several studies of a similar kind, especially in the community setup, needed to be conducted, to know the attitudes of health care professionals towards the ADR reporting⁵.

Hence, it was planned to conduct a study to know the awareness of Pharmacovigilance among health professionals of our institute with the following objectives:

- To analyze the knowledge about ADRs and pharmacovigilance in health care professionals.
- To analyze the ADRs practices in health care professionals.
- To analyze the barriers involved in non-reporting of suspected ADRs.
- To promote awareness towards pharmacovigilance and ADRs among health professionals.

METHODOLOGY

Study Design

This is a cross-sectional, non-interventional, observational, questionnaire-based study.

Study site

The study was carried out at SHKM Govt. Medical College, Nalhar, Mewat, Haryana, a 500 bedded tertiary care hospital and medical college located in Northern region of India.

Study Population

This is a non-interventional study which was conducted in the working healthcare professionals (Doctors, Nurses and Pharmacists) of SHKM Govt. Medical College, Nalhar, Mewat, Haryana.

Inclusion and exclusion criteria

All the healthcare professionals of SHKM Govt. Medical College, Nalhar were randomized and 20% from these were selected for this study. The healthcare professionals not willing to participate in the study and the ones who were on leave were excluded.

Sampling procedure

The list of all the healthcare professionals working in the hospital was obtained from the medical college records. 20% of the subjects were randomly selected.

Study Instrument

The study instrument is a predesigned, validated questionnaire which was designed on the basis of the similar previous studies^{5,6}. The questionnaire contains 15

questions regarding knowledge, attitude, practices of pharmacovigilance and barriers for under-reporting of ADRs along with suggestions to improve ADR reporting.

Modality of obtaining response: Every healthcare professional was given 30 minutes of time to fill the questionnaire. During attempting the questionnaire, any clarification regarding understanding of the questions was provided.

Study Conduct

The questionnaire was provided to the selected working healthcare professionals. The participants were personally briefed about the questionnaire. Each participant was given 30 minutes to answer the questionnaire and they were not allowed to consult anyone during that time. They were allowed anonymity with regard to their names, but they had to write their designation. The questionnaires were then evaluated.

Analysis of data

Completed questionnaires were collected from each participant to evaluate the awareness of pharmacovigilance, knowledge and ADRs reporting among healthcare professionals. The filled questionnaires were analyzed with the help of Microsoft Excel worksheet (Microsoft Office 2007). Data was presented as a percent (%) of the respondents. In case of unanswered questions, the participant was excluded from the study.

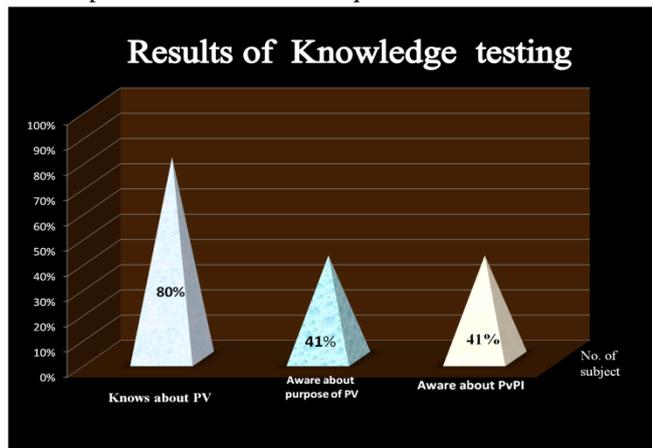


Fig 1: Result of Knowledge Testing.

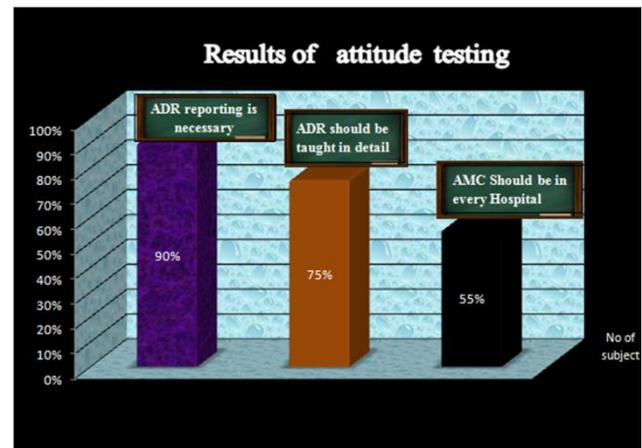


Fig 2: Result of Attitude Testing.

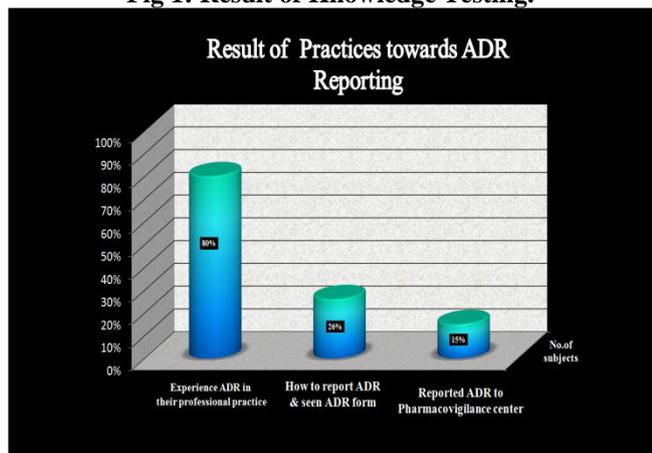


Fig 3: Result of practices towards ADR reporting.

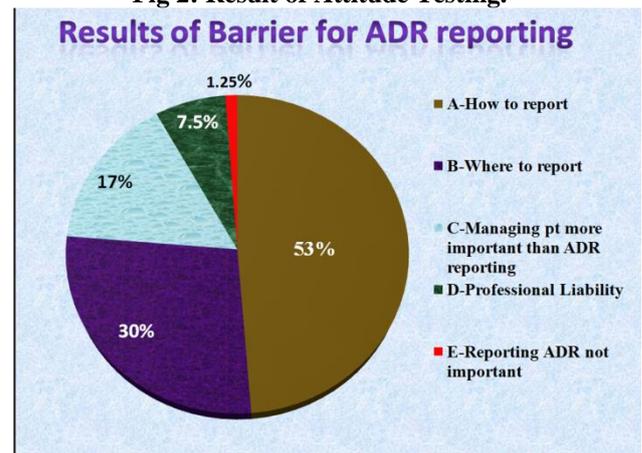


Fig 4: Result of barriers for ADR reporting.

RESULTS

Out of the 83 (20% of all healthcare professionals) survey questionnaires circulated, 80 filled questionnaires were returned, giving an overall response rate of 96%. Most of the subject 64/80 (80%) know about pharmacovigilance (Fig 1) but only 33/80 (41%) subjects are aware about purpose of PV and Pharmacovigilance programme of India (PvPI) (Fig 2). 72/80 (90%) subject proposed that ADR reporting is necessary & 79% suggested it should be taught in details and 44/80 (55%) subject advised that ADR monitoring center (AMC) should be in every hospital. 32/80 (80%) subject have experienced ADR in their professional practice (Fig 3). But only 12/80 (15%) subject reported ADR to the Pharmacovigilance center. Only 21/80 (26%) subjects are trained on how to report ADR & have seen ADR form. The most common barrier for ADR reporting in our study are; How to report by 43/80 (53%) subjects, where to report by 24/80 (30%) subjects and 14/80 (17%) subjects suggested managing patient are more important than ADR reporting. 6/80(7.5%) subjects concern about professional liability. 1/80 (1.25%) subject propose ADR reporting is not important (Fig 4). Most of the subjects suggested ADR reporting could be improved by conducting CME (continue medical education), workshop and various teaching programme.

DISCUSSION

Mewat, our study place is a backward area. There is a high prevalence of illness include tuberculosis, chronic obstructive pulmonary disorder, skin diseases, anemia etc. in this area. Drug use patterns in this area is very important as all types of drugs are used e.g. antacids, Proton pump inhibitors, NSAIDs, Antibiotics, Anti-tubercular drugs etc. This study has been conducted to know the attitude and knowledge towards the ADR reporting and Pharmacovigilance, as negligible studies have been done in this field. ADR reporting is infrequent in majority of the medical professionals. This makes the Pharmacovigilance programme unsuccessful.⁷ Therefore, the present study was performed to investigate the knowledge, attitude, practices and barrier for ADR reporting among healthcare professionals in a tertiary care teaching hospital.

The healthcare professionals should spontaneously report ADR as it is recommended by national PvPI. In our study only 15% subjects reported ADR to the pharmacovigilance center as compare to 18.5% by Mala Kharkar and Suresh Bowalekar in the year 2012⁸. Our results show that the awareness toward pharmacovigilance is 80% although the awareness towards reporting centers and reporting is only 15% comparing with the study of Madhan ramesh and Gurumurthy Parthasarathi in the year 2009 which is 89% & 41% respectively.^{5,8} Although the practitioners are in favor of the system and they assume that the patient and

society will be benefitted by it. On studying the attitude of health care professional towards pharmacovigilance, it was found that the health care professionals give importance to pharmacovigilance – 90% are in favor of its necessity, 75% are in favor that it should be taught in detail in MBBS curriculum and 55% are in favor of AMC in hospitals. This depicts that doctors, staff nurse & pharmacist should be made aware about the knowledge of ADR and its reporting.

Our study shows that although the professionals have the knowledge of identifying the ADR but they are not keen to report it or they don't want to spend time on filling the form & to clarify/decide that there is occurrence of ADR although it is not very difficult to fill the form. But this has not become into the habit to fill the form.

There are many factors which become hindrances in the reporting of ADR. 53% subjects were aware about how to report ADR, 30% subject were aware about where to report ADR and 17% subject gave priority to managing patient rather than ADR reporting. Only 7.5% subject were concern about professional liability. 1.25% subject think ADR reporting is not important.

ADR reporting can be further improved by educating the medical & para-medical staff & fresher courses by conducting CME's on pharmacovigilance.

Other measures which can be included are:-

1. Knowledge on Pharmacovigilance programme of India (PvPI).
2. The knowledge of ADRs.
3. Educate to fill up the ADR form.
4. Encourage the health care providers to report all suspected ADRs.
5. Encourage to report ADRs by interventional substances like tubing etc.
6. To take away the prospects from the professionals that ADR are occurring due to the drug, the prescriber is not responsible for the drug.

CONCLUSION

There is lack of awareness among health care professionals toward pharmacovigilance & ADR reporting. So, it should be rectified by means of awareness creating programme such as CME, Workshop & by conducting various studies.

APPENDICES: The Questionnaire

Please tick on the most appropriate option –

1. Define Pharmacovigilance-
 - (a) The science detecting the type and incidence of ADR after drug is marked
 - (b) The science of monitoring ADR's occurring in a Hospital
 - (c) The process of improving the safety of the drug
 - (d) The detection, assessment, understanding and prevention of adverse effects
2. The most important purpose of Pharmacovigilance is
 - (a) To identify safety of the drug

- (b) To calculate incidence of ADR's
 (c) To identify predisposing factor's to ADR's
 (d) To identify previously unrecognized ADR's
3. The healthcare professionals responsible for reporting ADR's in a hospital is/are
 (a) Doctor
 (b) Nurses
 (c) Pharmacist
 (d) All of the above
4. Do you know regarding the existence of a national Pharmacovigilance Programme in India?
 (a) Yes
 (b) No
 (c) Can't say
 (d) May be
5. In India which regulatory body is responsible for monitoring ADRs?
 (a) Central Drugs Standard Control Organization (CDSCO)
 (b) Indian Council of Medical Research(ICMR)
 (c) Indian Clinical Research Institute (ICRI)
 (d) Medical Council of India(MCI)
6. Do you think reporting of adverse reaction is necessary
 (a) Yes
 (b) No
 (c) Can't say
 (d) May be
7. Do you think Pharmacovigilance should be taught in detail to healthcare professionals?
 (a) Yes
 (b) No
 (c) Can't say
 (d) May be
8. What is your opinion about establishing ADR monitoring centre in every hospital?
 (a) Should be in every hospital
 (b) Not necessary in every hospital
 (c) One in a city is sufficient
 (d) Depends on number of bed size in the hospitals
9. Have you ever experienced adverse drug reactions in your patient during your professional practice?
 (a) Yes
 (b) No
 (c) Can't say
 (d) May be
10. Have you ever reported ADR to the Pharmacovigilance centre?
 (a) Yes
 (b) No
 (c) Don't know where to submit the ADR reporting form
 (d) Don't know how to fill up the ADR reporting form
11. Have you ever seen the ADR reporting form?
 (a) Yes
 (b) No
 (c) Can't say
 (d) May be
12. Have you ever been trained on how to report Adverse Drug Reaction (ADR)?
 (a) Yes
 (b) No
 (c) Can't say
 (d) May be

13. Is there any Pharmacovigilance Committee in your Hospital?
 (a) Yes
 (b) No
 (c) Not yet formed
 (d) Don't know
14. Which of the following factor discourage you from reporting ADRs? (You may tick multiple reasons)
 a. Did not know how to report
 b. Not knowing where to report
 c. Did not think it to be important
 d. Managing patient was more important than reporting ADR
 e. Lack of access to ADR Reporting forms
 f. Patient confidentiality issues
 g. Legal liability issues
 h. Concerns about professional liability
 i. Others _____
15. Any suggestions to improve ADR reporting

REFERENCES

- Lazarou J, Pomeranz BH, Corey PN. Incidence of adverse drug reactions in hospitalized patients: A meta-analysis of prospective studies. *JAMA*.1998;279:1200-5.
- The World Health Organization. Safety of Medicines: A guide for detecting and reporting adverse drug reactions. Geneva: 2002 WHO / EDM / QSM / 2002.2.
- Graille V, Lapeyre-Mestre M, Mon Tadic JL. Drug vigilance: An opinion survey which was conducted among the residents of a university hospital. *Therapie*. 1994 Sep-Oct; 49(5): 451-54.
- Xu H, Wang Y, Liu N. A hospital based survey on health care professionals in the awareness of pharmacovigilance. *Pharmacoepidemiology and Drug Safety*,2009 July;18(7):624-30.
- Ramesh M, Parthasarathi G. Adverse drug reaction reporting: the attitudes and the perceptions of the medical practitioners. *Asian Journal of Pharmaceutical and Clinical Research*. April-June 2009;2 (2):10-14.
- Desai CK, Iyer G, Panchal J, Shah S, Dikshit RK. An evaluation of knowledge, attitude, and practice of adverse drug reaction reporting among prescribers at a tertiary care hospital. *Perspect Clin Res*, 2011; 2: 129-36.
- Inman WH. Attitudes to adverse drug reaction reporting. *Br J Clin Pharmacol*. 1996;41:433-5.
- Mala Kharkar and Suresh Bowalekar Knowledge, attitude and perception/practices (KAP) of medical practitioners in India towards adverse drug reaction (ADR) reporting *Perspect Clin Res*. 2012 Jul-Sep;3(3): 90-94.

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