



ORIGINAL RESEARCH PAPER

Pharmacology

EVALUATION OF KNOWLEDGE, ATTITUDE AND PRACTICE OF PHARMACOVIGILANCE AMONG HEALTH CARE PROFESSIONALS IN TERTIARY CARE HOSPITAL AND MEDICAL COLLEGE

KEY WORDS: Adverse Drug Reactions, Healthcare Professionals, Pharmacovigilance.

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ABSTRACT

Pharmacovigilance science came in light after the so-called thalidomide tragedy in 1960. In India National Pharmacovigilance Programme (NPP) started after a long gape in 2004. In most of the world Pharmacovigilance is still in initial stage. According to WHO, Pharmacovigilance is a science deals with detection, assessment, understanding and prevention of adverse effects or any other drug-related problems. In our institute it is observed that most of healthcare professionals lack knowledge about pharmacovigilance. This study shows poor knowledge, attitude and practices of pharmacovigilance among medical professionals so there is urgent need to improve the awareness of Pharmacovigilance among the healthcare professionals.

INTRODUCTION -

The ideas of pharmacovigilance came up as a consequence of the so-called thalidomide tragedy in 1960. This tragedy became the modern starting point of a science focusing on Adverse Drug Reactions (ADR's) caused by the use of medicines. According to WHO, Pharmacovigilance is a science deals with detection, assessment, understanding and prevention of adverse effects. [1]

Adverse Drug Reactions (ADR's) are an important cause of hospital admission and associated with a significant morbidity and mortality.[2-5] In order to identify the culprit drugs causing ADR's, several countries have initiated pharmacovigilance programs in the recent past. Pharmacovigilance when used effectively allows for the intelligent, evidence-based use of medicines and has the potential for preventing many adverse reactions.

Government of India launched India national Pharmacovigilance Programme (NPP) in 2004, with the goal to ensure the benefits of use of medicine and outweighs the risks and thus safe guard the health of the Indian population. Under reporting of ADR's is felt as a major problem in India as well as in other countries This can delay detection of important ADR's. Studies from different settings indicate inadequate knowledge about pharmacovigilance among healthcare professionals as well as their attitudes and practice is associated with a high degree of underreporting. [6-11]

Pharmacovigilance programme of our institution was also in incipient stage. So the problems of underreporting and lack of awareness were prevalent in the institute. Therefore this study was conducted with the aim to assess Knowledge, Attitude and Practice (KAP) of pharmacovigilance, to create awareness among the healthcare professionals about pharmacovigilance. In this study we also aimed to know the suggestions to improve the ADRs reporting.

MATERIAL AND METHODS - This was a randomized, cross-sectional, observational, Questionnaire-based study, conducted at a 300-bedded tertiary care teaching hospital. The questionnaire consists of 14 questions regarding knowledge, attitude and practices (KAP Study) of Pharmacovigilance along with suggestions to improve ADR reporting. All the doctors working in the medical college and hospital were included in study. Disclosure of name of the responder was made optional in order to preclude any potential bias. Initially KAP questionnaire was briefed to all participants about the aim of the study. For submission of questionnaire a suitable time of 7 days was given. The information was recorded and analyzed.

RESULTS - The questionnaire was supplied to 125 doctors and we get back 100 responses making an 80 % of responses. Awareness about pharmacovigilance based on our assumption of response to question number 1 and 2 of the questionnaire were calculated and it was found that 80 % were aware and remaining 20 % were unaware. We did not include the responses of unaware respondents in further statistical analysis of questionnaire. We assess the knowledge of respondents on the basis of question

number 3 to 6 and gave 1 mark to each question. The mean knowledge of senior faculty members (Professor and Associate Professor) was 1.85; junior faculty members (Assistant Professor, SR, and JR) were 2.60. In view of 88.80 % senior faculty members, 85.71 % junior faculty members ADR reporting is a professional obligation. Only 7% respondents receive training on how to report ADR to pharmacovigilance committee and 2% respondents had guided others on importance of ADR reporting but it is interesting that majority (92%) of respondent thinks that Pharmacovigilance should be taught in detail. Among doctors 50 % read any article or attend conference/workshop on pharmacovigilance. 75 % participants were in favour of establishing pharmacovigilance centre in every hospital. Majority (56%) of health professionals did not know how and where to report ADRs. Legal issues were also important factor for not reporting of ADRs (27%). Only few discourage from lack of remuneration for ADR reporting. (Table -1)

Table 1: Discouraging factors for not reporting ADR's

Factor	Frequency of Senior Doctors (%)	Frequency of Junior Doctors (%)
Did not know how to report	28.84	34.28
Not known where to report	17.10	37.14
Did not think it to be important	4.44	8.50
Managing the patient is more important than reporting ADR	31.10	34.28
Lack of access to ADR reporting form	44.40	48.57
Due to legal issue	37.77	17.14
Lack of remuneration	6.66	8.57

Table 2: Suggested methods of improving ADR's reporting

Suggestions	Frequency of Senior Doctors (%)	Frequency of Junior Doctors (%)
Make it easier process of submission	88.90	85.71
Remuneration for ADR submission	18.00	34.28
Providing electronic option for submission	65.55	91.42
Making reporting Mandatory	51.10	51.42
Ensure confidently of reports	95.50	85.71
Provide toll free number for reporting	60.00	82.85
Health care professional should be trained in ADR reporting	93.30	91.42

Discussion - In this study 20 % of the respondents were not aware of the Pharmacovigilance. It means that training of pharmacovigilance among undergraduate and postgraduate was insufficient. Majority of respondent's attitude towards pharmacovigilance was positive still reporting of ADR's was poor. It means that there was a considerable gap between attitude and practice (KAP gap).

According to Inman^[12], the reasons for under-reporting of ADRs can be complacency (belief that the serious ADRs are already documented when a drug is introduced in the market), diffidence (belief that reporting should be done when there is certainty that the reaction is caused by the use of a particular drug), financial incentives (rewards for reporting), ignorance (that only serious ADRs are to be reported), indifference (belief that a single report would make no difference), legal aspects (fear of litigation) and lethargy (excuses about lack of time or disinterestedness). In our study a major reason observed was respondents did not know how and where to report an ADR. (Table - 1) Majority of respondent also suggest that health care providers should train in different aspect of pharmacovigilance. (Table -2) Majority of respondents are in favour of electronic option of ADR submission (Table - 2). Legal issues were also a concern for some health professionals. Therefore, awareness programmes through conferences, workshops, literature and publicity, would necessary to create awareness and to improve ADR reporting.

Conclusion -This study shows that medical persons were poor regarding knowledge, attitude and practices of pharmacovigilance and this is the reason behind underreporting of ADR's. So intensive pharmacovigilance training at undergraduates, postgraduate level and thereafter periodically through continuous medical education (CME) programs is required.

**QUESTIONNAIRE
KAP (KNOWLEDGE, ATTITUDE AND PRACTICE) BASED
QUESTIONNAIRE FOR PHARMACOVIGILANCE AWARENESS**

Name
Designation

1. What is most appropriate regarding Pharmacovigilance?

- a) The science of drug development
- b) The detection, assessment, understanding & prevention of adverse effects
- c) The science to improve the safety of Drugs
- d) Study of efficacy of drugs in clinical trial

2. The most important purpose of Pharmacovigilance is?

- a) To determine efficacy of drugs
- b) To calculate incidence of ADR's
- c) To identify predisposing factors to ADR's
- d) To identify unrecognized ADR's

3. A serious ADR in India should be reported to the Regulatory body within:

- a) One day
- b) Seven days
- c) Ten days
- d) Twenty days

4. India zonal Pharmacovigilance centres are situated at:

- a) AIIMS, New Delhi
- b) JIPMER, Pondichary
- c) MAMC, New delhi
- d) All of above

(Optional)

5. CDSCO approved nearest peripheral pharmacovigilance centre to your medical college is

- a) SMS medical college, Jaipur
- b) NIMS medical college, Jaipur
- c) MG medical college, Jaipur
- d) Health Ministry of Rajasthan

6. National pharmacovigilance programme was started in

- a) 2004
- b) 2006
- c) 2008
- d) 2010

7. Do you think reporting of ADR is a professional obligation for you?

- a) Yes
- b) No

8. What is your opinion about establishing pharmacovigilance centre in every hospital?

- a) Should be in every hospital
- b) Not necessary in every hospital
- c) Only in tertiary care hospital

9. Do you think Pharmacovigilance should be taught in detail to healthcare professionals?

- a) Yes
- b) No

10. Do you think reporting of adverse drug reaction to nearest pharmacovigilance centre is necessary?

- a) Yes
- b) No

11. Have you read any article or attended any conferences/workshops on pharmacovigilance?

- a) Yes
- b) No

12. Have you ever been trained on how to report Adverse Drug Reaction (ADR) to nearest pharmacovigilance centre?

- a) Yes
- b) no

13. Have you trained or guided others (juniors/ students, nurses or pharmacists) on the importance of identifying & reporting ADRs.

- a) Yes
- b) no

141. What are the factors that discourage you for not reporting ADR's (You may Tick multiple choices)

- a) Did not know how to report
- b) Do not know where to report
- c) Did not think it to be important
- d) Managing the patient is more important than reporting ADR
- e) Lack of access to ADR reporting form
- f) Due to legal issues
- g) Lack of remuneration discourages from reporting ADR

Suggestions – (You could tick on multiple suggestions)

- 1. Make the process of submission of ADR reports easier
- 2. Remuneration for ADR submission
- 3. Make reporting mandatory
- 4. Ensure confidentiality of reports
- 5. Provide toll free number for reporting
- 6. Make health professional more aware for ADR
- 7. Health care professional should be trained in ADR reporting
- 8. Any other- (please write your suggestion) -

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