Original Research Paper Medical Science

A questionnaire study on the knowledge, attitude and the practice of pharmacovigilance among medical teachers in a tertiary care hospital in Ajmer

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ABSTRACT

Background: Spontaneous reporting of Adverse Drug Reactions (ADRs) has played an important role in the detection of serious, unsuspected and unusual ADRs previously not detected during the clinical trials. ADRs constitute a major cause of morbidity and mortality. It is the sixth leading cause of death in worldwide. Hence, proper monitoring of ADRs is a necessity. Present study was conducted to evaluate the knowledge, attitude, and practices (KAP) of the healthcare professionals/ faculty members about pharmacovigilance in Jawahar Lal Nehru Medical College and associate group of hospital, Ajmer (Rajasthan), a tertiary care teaching hospital.

Methods: To assess the KAP of faculty members towards pharmacovigilance; a total number of 206 pretested questionnaires were distributed and requested to complete the questionnaires and return these dully filled questionnaires within a week. Then the responses to the questionnaire were analyzed.

Results: The response rate was 65.53 %. The major factors found to be responsible for underreporting of ADR include lack of time to report ADR- [no. 48 (35.55%)]. All responded faculty members were of the view that pharmacovigilance teaching is mandatory to healthcare professional.

Conclusion: CMEs, training programmes on pharmacovigilance, refresher courses should be done to improve the rate of spontaneous reporting as well as for enhanced safety of the patients.

KEYWORDS KAP, CME, Pharmacovigilance, ADR reporting

Introduction: According to the definition provided by World Health Organization (WHO), ADR is "any noxious, unintended and undesired effect of a drug which occurs at doses used in humans for prophylaxis, diagnosis or therapy". [1]

Adverse drug reactions (ADRs) constitute a major cause of morbidity and mortality. It is the sixth leading cause of death in worldwide. Hence, proper monitoring of ADRs is a necessity.[2] There are various reporting systems includes WHO international system, US FDA "Med Watch" , UK "yellow card system" and National pharmacovigilance system India.[3-5]

In India, on 23rd Nov. 2004, the central drugs regulatory agency, Central Drugs Standard Control Organization (CDSCO) launched Health and Family Welfare, Government of India, for creating awareness of pharmacovigilance in the country based on the WHO Guidelines for setting up and running a pharmacovigilance center. The programme included centers at peripheral (twenty six), regional centers (five), and zonal levels (two) besides national pharmacovigilance advisory committee and the national pharmacovigilance center (NPC) situated at CDSCO, New Delhi. ADRs are reported directly from all the centers to the NPC for a quick regulatory action.[6] All healthcare professionals including doctors, nurses, and pharmacists can report an ADR by filling an ADR form of the Central Drugs Standard Control Organization. It is important for healthcare professionals to know how to report and where to report an ADR. ADR reporting can be improved by active participation of healthcare professionals in the pharmacovigilance program. [7]

Pharmacovigilance is the science and activities related to detection, understanding and prevention of adverse effects or any other possible drug related problems. [8] Although many studies in India have evaluated the KAP of pharmacovigilance among the healthcare professionals, it is imperative to conduct similar studies in teaching hospital of other parts of India to generalize findings of those studies. Previous reported studies has found that underreporting of ADR is related with shortcomings in the knowledge and attitude among healthcare professionals.[9,10] This scenario has prompted us to take up this study to evaluate the knowledge, attitude, and practices (KAP) of the healthcare professionals about pharmacovigilance in Jawahar Lal Nehru Medical College and associate group of hospital, Ajmer (Rajasthan), a tertiary care teaching hospital.

Aims & objective: The main objective of this study was to evaluate the knowledge, attitude, and practices of the healthcare professionals about pharmacovigilance.

Material & Method:
After obtaining the ethical clearance from this institute (JLN Medical College, Ajmer, Rajasthan); this observational questionnaire-based study was performed among those health care professionals (faculty members only) who gave their informed consent. This study was done in the period between May 2016 to October 2016. KAP questionnaire was designed based on earlier studies for assessing KAP of ADR reporting.[2,10-15] Pretesting of questionnaire was done on 10 randomly selected health professionals of this institute. The questionnaire was finalized after ambiguous and unsuitable questions were modified based on the result of previous studies. A total number of 206 pretested questionnaires were distributed among the faculty members only. Faculty members are requested to complete the questionnaires and return these dully filled questionnaires within a week. The responses to the questionnaire were analyzed by performing descriptive statistics.

Results: Results of this study is shown in tabulated form (Table 1 to 3).

Response rate
Two hundred and six (206) questionnaires were distributed among the faculty members and 135 responded (response rate was 65.53%).

Knowledge:
Among responded members, 76.29 % (103) faculty members gave correct response regarding the definition of pharmacovigilance and most important purpose of pharmacovigilance.71.11 % (96) faculty members were aware regarding the existence of a National Pharmacovigilance Programme as well as regulatory body which is responsible for monitoring ADRs in India. 86.66 % (117) were very well known about the pharmacovigilance centre in Rajasthan. 62.96 % (85) faculty members have the knowledge about the international centre for adverse drug reaction monitoring is located in Sweden and rare ADRs can be identified in phase – IV clinical trial. One hundred and twenty six faculty members gave correct response regarding the responsibility for reporting ADRs in a hospital and existence of any pharmacovigilance committee in our institute. 64.44 % (87) faculty members were aware about the drugs (Thalidomide) which brings to light the importance of effective ADR monitoring system for all medicines. (Table-1).

Attitude:
A total of 100 faculty members were agreed that ADR reporting of adverse drug reaction is necessary. Some faculty members [no. 12 (8.89%)] report - can't say and may be [no. 23 (17.04 %)]. All responded faculty members were of the view that pharmacovigilance teaching is mandatory to healthcare professional. Factor discourage from reporting ADRs were responded as; No remuneration - [no. 40 (29.62 %)], lack of time to report ADR- [no. 48 (35.55%)], a single unreported case may not affect ADR database- [no. 35 (25.92 %)] and difficult to decide whether ADR has occurred or not- [no. 12 (8.89 %)]. A total of 108 (80 %) faculty members believed that reporting ADRs will improve patient safety whereas 27 faculty members (20 %) thought that reporting of ADRs may improve patient safety. All reported faculty members agreed with option "all of the above "regarding reporting of ADRs. (Table-2).

Practice:
A total of 87 responded members read articles on prevention of adverse drug reactions. Only 30 faculty members have experienced adverse drug reactions in their patients. 66.67% responded members never seen the ADR reporting form. 20.74% don't know how to fill up the ADR reporting form and 36.45% faculty members don't know where to submit the ADR reporting form. Population studies are commonly employed method by the healthcare professional to monitor adverse drug reactions of new drugs once they are launched in the market. (Table-3).

Discussion
In present study self reporting was done through questionnaires. This has a number of weakness- the most important of these are underreporting and biased reporting.[16] Present study showed that majority of faculty members (66.67%) did not seen ADR reporting form. We found, majority of respondents agreed that reporting of ADR is necessary and pharmacovigilance should be taught in detail to healthcare professionals. The adverse event reporting rate from our study is low which is quite similar to previously done studies. [10,11,13]

The factors responsible for underreporting were also determined in present study which includes: No remuneration, lack of time to report ADR, a single unreported case may not affect ADR database and Difficult to decide whether ADR has occurred or not. There are various factors have been attributed for underreporting of ADRs among health care professionals. Inman has described them as "seven deadly sins". These include financial incentives, legal aspects, complacency, diffidence, indifference, ignorance and lethargy.[17] Faculty members included in present study also suggested various methods to improve ADR reporting like Continuous Medical Education (CMEs), training in pharmacovigilance, refresher courses, work shop on pharmacovigilance.

Conclusions:
Present study indicates that there is an urgent need to create awareness for ADRs reporting among faculty members/ healthcare professionals. CMEs, training programmes on pharmacovigilance, refresher courses should be done to improve the rate of spontaneous reporting as well as for enhanced safety of the patients.

Table-1: Knowledge related questions

S.No.	Knowledge related question	Correct response		Incorrect response	
		No.	%	No.	%
1	Define Pharmacovigilance.	103	76.29	32	23.71
2	The most important purpose of Pharmacovigilance is-	103	76.29	32	23.71
3	The healthcare professionals responsible for reporting ADRs in a hospital is/are-	126	93.33	9	6.67
4	Do you know regarding the existence of a National Pharmacovigilance Programme in India?	96	71.11	39	28.89
5	In India which regulatory body is responsible for monitoring ADRs?	96	71.11	39	28.89
6	Where the international center for adverse drug reaction monitoring is located?	85	62.96	50	37.04
7	Rare ADRs can be identified in the following phase of a clinical trial-	85	62.96	50	37.04
8	Is there any Pharmacovigilance Committee in our Institute?	126	93.33	9	6.67
9	Which drug brings to light the importance of effective ADR monitoring system for all medicines-?	87	64.44	48	35.56
10	Where is the pharmacovigilance centre in Rajasthan is located-	117	86.66	18	13.34

Table-2: Attitude related questions

S.No.	Attitude related questions
1	Do you think reporting of adverse drug reaction is necessary?
	A. Yes [no. 100 (74.07 %)] B. No ---- C. Can't say [no. 12 (8.89%)] D. May be [no. 23 (17.04 %)]
2	Do you think Pharmacovigilance teaching is mandatory to healthcare professionals?
	A. Yes [no. 135 (100 %)] B. No ---- C. Can't say ---- D. May be ----
3	Which of the following factor discourage you from reporting ADRs?
	A. No remuneration - [no. 40 (29.62 %)]
	B. lack of time to report ADR- [no. 48 (35.55%)]
	C. A single unreported case may not affect ADR database- [no. 35 (25.92 %)]
	D. Difficult to decide whether ADR has occurred or not- [no. 12 (8.89 %)]
4	Do you believe reporting ADRs will improve patient safety-?
	A. Yes -[no. 108 (80 %)] B. No -- C. May be- [no. 27 (20 %)] D.Don't Know --
5	ADRs should be reported only when they are-
	A. Serious and life threatening ----
	B. Severe and cause disability---
	C. Mild and cause less inconvenience-----
	D. All of the above-[no. 135 (100 %)]

Table-3: Practice related questions

1. Have you anytime read any article on prevention of adverse drug reactions?
(a) Yes- [No. 87 (64.44%)]
(b) No- [No. 48 (35.56%)]

(c) Can't say
(d) May be
2. Have you ever experienced adverse drug reactions in your patients-
(a) Yes-[No. 30 (22.22%)]
(b) No- [No. 105 (77.78%)]
(c) Can't say
(d) May be
3. Have you ever reported ADR to the Pharmacovigilance centre?
(a) Yes-
(b) No- [No. 80 (59.25%)]
(c) Don't know where to submit the ADR reporting form- [No. 27 (36.45%)]
(d) Don't know how to fill up the ADR reporting form-[No. 28 (20.74%)]
4. Have you ever seen the ADR reporting form?
(a) Yes-[No. 45 (33.33%)]
(b) No-[No. 90 (66.67%)]
(c) Can't say
(d) May be
5. Which of the following methods is commonly employed by the healthcare professional to monitor adverse drug reactions of new drugs once they are launched in the market?
(a) Meta analysis
(b) Spontaneous reporting system-[No. 50 (37.04%)]
(c) Population studies-[No. 85 (62.96%)]
(d) Regression analysis

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