



Awareness of Pharmacovigilance and Impact of Educational Intervention among Homeopathic Practitioners and Nursing Staff in a Tertiary Care Teaching Hospital

¹Dr. Rekha Y. Aherkar, Assistant professor, Department of Pharmacology, B. J. Government Medical College, Pune, India

²Dr. Jagrati Verma, Pharmacovigilance Associate. Department of Pharmacology, B. J. Government Medical College, Pune, India

³Dr. Balasaheb B. Ghongane, Professor and Head of Pharmacology department, B. J. Government Medical College, Pune, India

Correspondence Author: Dr. Jagrati Verma, Pharmacovigilance Associate. Department of Pharmacology, B. J. Government Medical College, Pune, India.

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Conflicts of Interest: Nil.

Abstract

Background: According to global statistics in 2016, 2% ADR reports were contributed from India. Adverse drug reactions (ADRs) reporting is the basis of pharmacovigilance activity & only <10 % of all ADRs are reported. Lack of awareness and poor understanding about the existence, function and purpose of national ADR reporting might be the major reasons for under-reporting.

Methods: Cross sectional, questionnaire based KAP study was conducted in 102 participants (48- BHMS practitioners, 54- Nurses). A specially designed, pre-tested, modified questionnaire was given to the participants to fill before and after an educational session. Each correct answer received a score of 1. Incorrect, “don’t know” option or not answered were allotted 0 score. Percentage of correct responses, KAP score, p value were calculated.

Results: Out of 110 participants, 102 completed pre and post-test questionnaire (response rate- 92.72%). Both group of participants were shown to have poor knowledge of pharmacovigilance before educational session. Pre- test KAP score (Mean \pm SEM) among BHMS practitioners was (11.18 \pm 0.38, n=48) and Nurses was (10.59 \pm 0.36,

n=54). Nurses (19.7 \pm 0.06) demonstrated statistically significant improvement in post- test score of compared to BHMS practitioners (18.09 \pm 0.24). Though 79.41% participants noticed ADR after use of drugs, only 18.62% participants had informed it to ADR monitoring centre. Most preferred way to send information of ADR reports was through telephonic calls (54%).

Conclusion: The study suggests a huge scope for improving ongoing Pharmacovigilance activities. Repeated educational sessions along with demonstration, hands on experience, visual photographs of ADRs are very crucial for all health care providers to strengthen the pharmacovigilance activities which may help in signal detection, reduce incidence & costs of avoidable ADRs related admissions.

Keywords: Pharmacovigilance, Nurses, BHMS doctors, KAP study

Introduction

Pharmacovigilance is defined by WHO, “as the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug related problems (DRPs)”[1]. The Pharmacovigilance Programme of India (PvPI) was started

in July 2010 by Central Drugs Standard Control Organization (CDSCO). On April 2011, National Coordinating Centre (NCC) was moved from All India Institute of Medical Sciences (AIIMS) to Indian Pharmacopoeia Commission (IPC), Ghaziabad. Within a short time period NCC-PvPI progressed from 22 ADR Monitoring Centres (AMCs) to > 200 AMCs and some zonal coordinating centres [2].

Adverse drug reaction (ADR) is defined as “a response to a drug, which is noxious and unintended, and which occurs at doses normally used in man for the prophylaxis, diagnosis or therapy of disease or for the modification of physiological function” [3]. Adverse drug reactions (ADRs) are associated with significant morbidity and mortality. Previous studies have published that around 2.9-5.6% of all hospital admissions are due to ADRs and as many as 35% of hospitalized individuals experience an ADR during their hospital stay [4]. The problem of ADRs is significant but the systems in place to tackle this issue are not sufficient. According to global statistics in year 2016, only about 2% ADR reports were contributed from India [2]. Adverse drug reactions (ADRs) reporting is the basis of pharmacovigilance activity. It is estimated that only <10 % of all ADRs are reported and underreporting remains a big challenge [5, 6]. Lack of awareness and poor understanding about the existence, function and purpose of national ADR reporting might be the major reasons for under-reporting. The success of a pharmacovigilance program depends upon the contribution of the healthcare professionals (doctors, nurses and pharmacists etc.) in reporting of ADRs [7]. Healthcare professionals have a great responsibility of monitoring and voluntarily reporting the ADRs to Adverse reaction monitoring centre. In Maharashtra state, among all health care providers 39.3% are doctors (Allopathic- 68.3%, Ayurvedic - 22.8%, Homeopathic- 7.9%, Unani-

1.1%) [8]. Along with allopathic practitioners, it is very essential to check the awareness regarding ADR monitoring and reporting in all other practitioners also as private sector is still lagging behind in pharmacovigilance practices [9, 10].

Nurses are key element in patient care. If they are well conversant with their new role as ADR reporter, it will be possible to reduce occurrence of ADRs and patient safety will be enhanced [11]. A study by Ekman E has highlighted that training of nurses was associated with a high reporting frequency; and has suggested more training in pharmacovigilance for nurses [12]. Considering the results of numerous studies [4, 13, 14] the positive impact of education on the elevation of knowledge, improvement of attitude and practice, as well as the promotion of quality of healthcare could be observed. Hence, healthcare professionals should receive pharmacovigilance knowledge in detail. However, very few studies have been conducted among BHMS doctors. Recently (2016) Maharashtra University has started a course for BHMS Practitioners i.e. Modern Pharmacology. Therefore this study seeks to determine knowledge, attitude and practice of modern pharmacology students and nurses towards pharmacovigilance before and after pharmacovigilance educational session in the form of a lecture and hand-outs.

Study Objectives

- To assess the Knowledge, Attitude and Practices (KAP) about the national Pharmacovigilance system among the homeopathic practitioners and nurses
- To analyse the impact of an educational intervention on their knowledge.

Material & Methods

Study design: Cross sectional questionnaire based study

Study Population: Modern Pharmacology Students (homeopathic practitioners), Nursing Staff

Study Conduct: This cross sectional, questionnaire based

KAP study was conducted in Pharmacology department of B. J. Government Medical College and Sassoon General Hospital, Pune after getting an approval from Institutional Ethical Committee. Respondents were Modern Pharmacology Students (homeopathic practitioners) of B. J. Government Medical College and Nursing staff of Sassoon General Hospital, Pune of both gender and all age groups. They were explained about the nature and purpose of the study, and necessary consent was obtained. Pre-test questionnaire was given to all participants, they were asked to fill it in 30 minutes and were monitored by the investigator to ensure and prevent interactions among the participants. They had a lecture on pharmacovigilance of approximately 1 hour duration following the pre-test questionnaire. At the end of the educational session the subjects were requested to complete the post-test questionnaire, and after that printed material was distributed to participants regarding the topic. Participant who had missed either test (pre or post) was excluded from study analysis.

Questionnaire: A specially designed, pre- tested, modified questionnaire was given to the participants. The questionnaire was pre-tested in 5 modern pharmacology students and 5 nurses. Small changes in framing of the questions and in answer options were made after a pilot study. A suitably modified version was finally administered to the willing respondents. Questionnaire consisted of demographic data, work experience and 20 multiple choice questions, among which 8 questions were knowledge based (Types of ADR, which type of ADRs to be reported, by whom, which products to be monitored, PvPI centre, helpline number etc.) 5 were to assess attitude (regarding importance of ADR reporting, underreporting reasons, need of frequent awareness programmes etc.) and 7 were for practice assessment.

Educational session: The educational interventions

involved class lecture on basic ADR & pharmacovigilance knowledge, ADR reporting, Form filling and PvPI. All participants were asked to fill one dummy ADR Form. Printed material consisted details of regional AMC with contact numbers, copy of ADR form, some recent drug alerts from IPC etc.

Data analysis: The data was recorded, scored and entered into Microsoft Excel 2013, checked for accuracy. Inferential statistics was done using Graph Pad Prism Software version 7.03. Student's paired t-test was used to compare pre and post intervention scores. Each correct answer received score of 1. Incorrect, "don't know" option or not answered were allotted 0 score. In the questionnaire there were some questions with multiple answers, if participant marked multiple answers with at least one correct option then that was considered partially correct and 0.5 score was given to that answer. For answers with Yes or No responses, appropriate and positive response was given score 1.

Results

1. Demography

Total 110 professionals (49- BHMS, 61- Nurses) participated in study but only 102 (48- BHMS, 54- Nurses) completed pre and post-test questionnaire. Response rate was 92.72%. Table: 1. shows other demographic details.

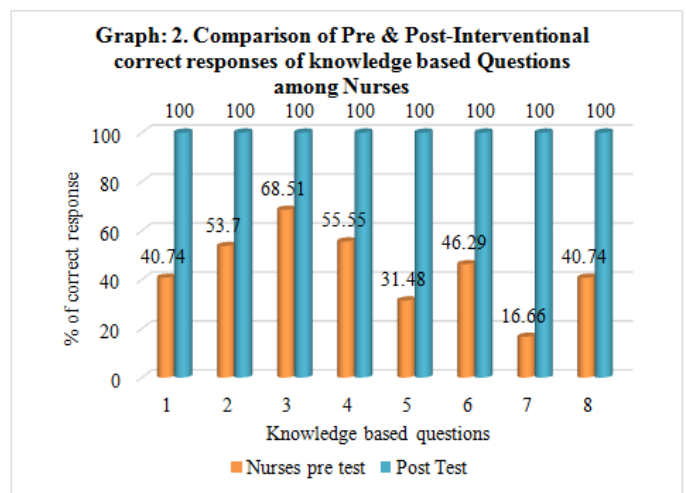
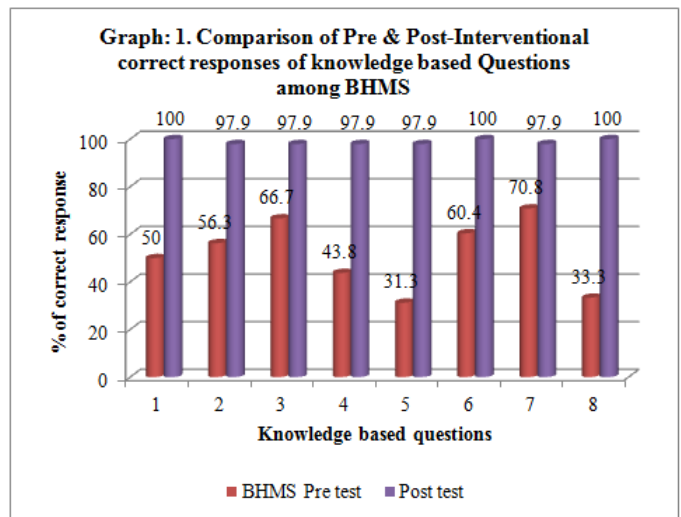
Designation		BHMS Practitioners	Nurses
Age (Years)		51-67	34-57
Sex	Male	40	0
	Female	8	54
Work experience (Years)		20-37	10-36

2. Analysis of KAP questionnaire

2.1. Knowledge based Questions analysis before educational intervention

Question No.1 sought information about definition of ADR. Out of 102 participants 35.29% participants were considering that only allergic skin reactions as ADR, before educational intervention. Question No.2 investigated knowledge regarding who can report ADR. Only 24.5% participants were aware that patient and relatives can also report ADR. Question No.3 analysed type of reaction to be reported. Maximum participants 67.64% knew that all types (known/unknown, minor/severe) reactions to be reported, before educational intervention. Question No.4 checked knowledge of products to be monitored in ADR monitoring. Very few (5.88%) participants were aware about reporting of vaccine and medical device related adverse events. Question No.5 investigated about PvPI with 31.37% yes response. Question No.6 evaluated the knowledge of regional ADR monitoring centre, 52.94% gave yes as a response. Question No.7 sought information about national Pharmacovigilance centre in India. 42.15% could answer it correctly as Ghaziabad. Question No.8 investigated awareness of PvPI helpline number, 55.88% didn't know that helpline number.

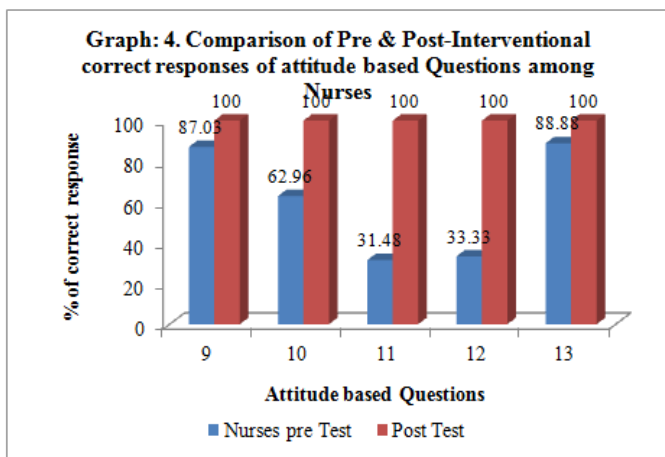
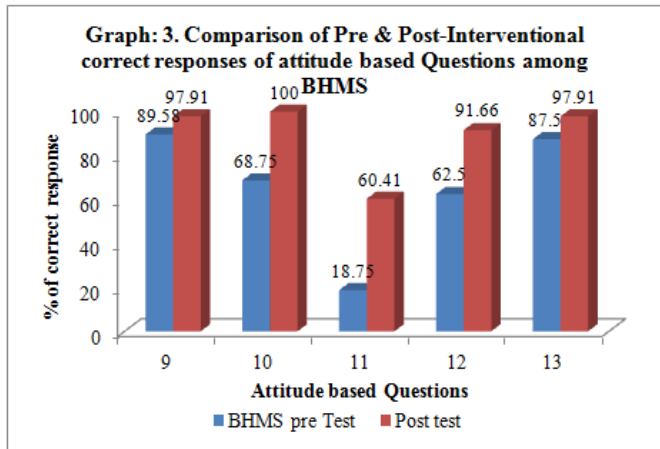
Sub group analysis of Pre & Post-Test correct responses of Knowledge based Questions of BHMS and Nurses is shown in Graph:1 and Graph:2 respectively. Nurses have shown 100% correct response for all questions after educational intervention.



2.2. Attitude based Questions analysis before educational intervention

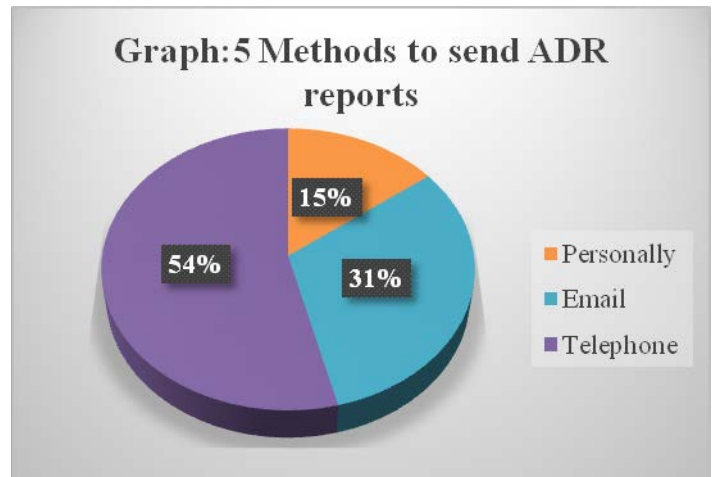
Majority of participants (88.23%) thought Adverse Drug Reactions is an important health concern in question no.9. For Question No.10, pertaining to why it is important to report an Adverse Drug Reactions, 30.39% participants were of the view that it is to improve patient safety. Question No.11 investigated factors for underreporting of ADRs. Most common factor was "Not know how and where to report" (33.33%). Question No.12 & 13 sought information with Yes or No responses, 47.05% participants opined that reporting won't have any negative consequence on health care professional or the patient. 88.23% participants thought frequent awareness program on Adverse Drug Reactions are necessary.

Sub group analysis of Pre & Post-Test correct responses of Attitude based Questions of BHMS and Nurses is shown in Graph:3 and Graph:4 respectively.



2.3. Practice based Questions analysis before educational intervention

Though 79.41% participants had noticed ADR after use of medicines among patients, only 18.62% participants had informed it to ADR monitoring centre. 92.15% participants preferred to write ADRs on case record form & explain to patient about ADR. Participants were found to get knowledge of ADRs from different sources like text books (50%), Internet (23.52%), Journals (21.56%) and Medical representative (4.9%). Graph: 5 shows methods suggested by participants to send information of ADR reports to regional pharmacovigilance centre. Most common is through telephonic calls.



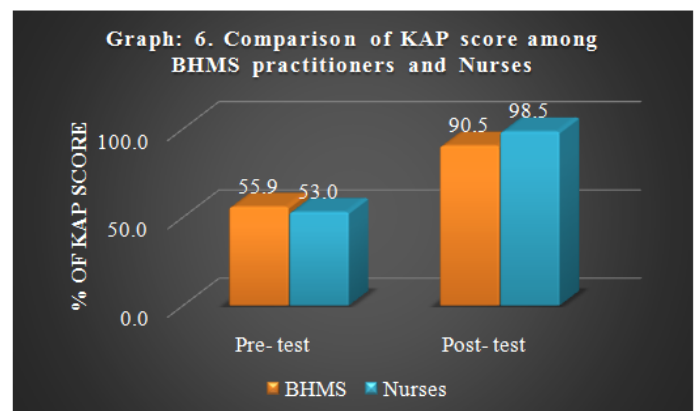
3. Impact of educational intervention on KAP score

As shown in Table: 2 statistically significant improvements have observed after educational session among BHMS practitioners and nurses also.

KAP Questionnaire (n=102)			
	Pre-test	Post-test	p value
Knowledge score	3.8 ± 0.16*	7.9 ± 0.03*	<0.0001
Attitude score	3.1 ± 0.10*	4.6 ± 0.06*	<0.0001
Practice score	3.8 ± 0.10*	6.3 ± 0.06*	<0.0001

p-value ≤ 0.05 – considered as statistically significant
*Mean ± SEM, Paired t test applied

4. Comparison of KAP score among BHMS practitioners and Nurses



Graph: 6. Showed statistically insignificant difference in pre- test KAP score among BHMS practitioners (11.18 ± 0.38, n=48) and Nurses (10.59 ± 0.36, n=54) but Nurses

(19.7 ± 0.06) have shown statistically significant improvement in post- test score of compared with BHMS practitioners (18.09 ± 0.24).

5. Comparison of KAP score among Female and Male

Table 3: Comparison of educational intervention impact among female and male			
	KAP score (Female-62)	KAP score (Male-40)	p value
Pre- test	10.54 ± 0.34*	11.38 ± 0.40*	0.1248
Post -test	19.53 ± 0.09*	18.04 ± 0.28*	<0.0001*
p-value ≤ 0.05 – considered as statistically significant			
*Mean ± SEM, Unpaired t test applied			

From Table: 3, It was observed that females (Total score- 1211) showed statistically significant improvement regarding awareness of pharmacovigilance after educational intervention than males (Total score- 721.5)

Discussion

A “Knowledge, Attitudes, and Practices (KAP)” survey is a representative study of a specific population that aims to collect data on what is known, believed and done in relation to a particular topic [15]. In the present study, we evaluated the knowledge, attitudes and practices of the BHMS doctors & nurses related to Pharmacovigilance at a tertiary care teaching hospital. We found a knowledge gap regarding Pharmacovigilance which was improved after educational intervention. Several studies [12, 13, 14] have been conducted to assess the healthcare professionals (Physicians, dentists, nurses, pharmacists) knowledge related to pharmacovigilance but this study has targeted specifically BHMS practitioners those are going to practice allopathy after modern pharmacology course & Implementing ADR monitoring in their practice can contribute to the safety of medicines. Also we tried to educate nurses on their role as an ADR reporter.

This study has revealed that there is basic problem in identifying the ADR by participants as approximately 50% participants were unaware about manifestations of

ADR other than skin reactions, before educational intervention. Some studies have concluded that those health professionals with sufficient knowledge have a higher chance of understanding the key procedures of reporting such as what, where and when to report that in turn encouraged reporting [16, 17]. Only few (31%) knew about nationwide PvPI program, which was lower than Fadare et al where 44.6% of the participants were aware of the existing pharmacovigilance [18]. Gupta et al [19] identified 43% of the participants being were aware of National Pharmacovigilance centre in India, similar finding was observed in the present study (42.15%).

88% participants felt ADR is important health concern and 79% had encountered ADR during practice, despite this good attitude and practice only 18.62% had reported to pharmacovigilance centre, one reason for this could be none of them had attended any pharmacovigilance awareness program or workshop before this educational session. Most common reason for underreporting in our study was found to be not knowing how and where to report. Various other studies [20, 21, 22] also found similar reason of underreporting; while other studies by Naidu et.al. [23] & Chatterjee et al. [24] had given various reasons like lack of knowledge about ADR reporting forms, who all can report ADR’s, type of reactions to be reported, whether serious ADR’s to be reported only, less time etc. One of the reason for underreporting may be the fear of negative consequence to one’s medical profession if they report the ADRs, in the current study 47.05% participants opined that reporting won’t have any negative consequence on health care professional or the patient. On the contrary, results by Katekhaye et al [25] depicted that 80.7% doctors believed that frequent reporting of ADRs may not be a problem in their career.

Participants in present study preferred to inform ADR report to higher centre through telephonic calls and

suggested to strengthen this telephonic communication. PvPI has established helpline number (1800-180-3024) to report any suspected Adverse Drug Reactions after the use of medicines. This is the need of hour to circulate this number not only to healthcare professionals but to other public also. Social media can play a vital role in increasing awareness of ADR monitoring, reporting and pharmacovigilance to healthcare professionals and general public as well [26]. Participants had suggested frequent awareness programs to improve reporting in this study. Study by Katekhaye et al [25] also emphasised on, continued medical education (CME) and training to improve the pharmacovigilance & to maintain motivation among professionals regarding ADE reporting [27].

It has been observed that nurses were having less knowledge of topic than BHMS practitioners initially but after educational session nurses has shown statistically significant improvement. This is suggestive that nurses are keen learners after single educational session than BHMS practitioners. Nurse participants were the part of Government hospital while all BHMS practitioners were part of private health care system. Hence there is equal need of pharmacovigilance awareness among government and private health sector professionals.

Limitations of study: Single educational intervention, immediately followed by post-test may lead to bias in the study. This study included BHMS practitioners & nurses, large scale study including interns, MBBS doctors, faculty and pharmacists should be conducted to know the outcome. The ultimate aim i.e. impact on number of ADR reports collected & submitted by participants was not evaluated in the present study.

Conclusion

This KAP study was conducted to determine the knowledge of the BHMS practitioners & nurses with regard to ADR reporting and monitoring, also to analyse

the effect of a single educational intervention on their knowledge. Overall, this study showed lack of knowledge, poor practices despite of good attitude before educational session. After educational intervention there was definitely improvement in their knowledge. The study suggests a huge scope for improving the ongoing Pharmacovigilance activities. Repeated educational sessions along with demonstration, hands on experience, visual photographs of ADRs are very crucial for all health care providers to strengthen the pharmacovigilance activities. If practicing doctors & nurses are encouraged to report & manage ADR, more database will be generated which may help in signal detection and reduce the incidence and the costs of avoidable ADRs related admissions.

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