

Impact of an Educational Intervention on the Knowledge and Attitude towards ADR Reporting and Pharmacovigilance among Healthcare Workers.

Palak Jayeshbhai Vania¹, Piyushkumar Mansinh Pargi², Hemangi Amrutbhai Virani³, Jayeshkumar M. Kathiriya⁴, Tirthraj Parmar⁵

¹Third Year Resident Doctor, Department of Pharmacology, Government Medical College, Bhavnagar – 364001, Gujarat, India.

²Assistant Professor, Department of Pharmacology, GMERS Medical College, Panchmahal, Godhra-389001, Gujarat, India.

³Senior Resident Doctor, Department of Pharmacology, Government Medical College, Bhavnagar – 364001, Gujarat, India.

⁴Associate Professor, Department of Pharmacology, Shantabaa Medical College & General Hospital, Amreli - 365601, Gujarat, India.

⁵Assistant Professor, Department of Pharmacology, Shantabaa Medical College & General Hospital, Amreli - 365601, Gujarat, India.

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Corresponding Author: Dr. Hemangi A. Virani

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Abstract

Background: Health-care providers bear a great deal of responsibility for reporting adverse drug reactions (ADRs). Nurses are the backbone of the health-care system; hence they play a significant role in detecting and reporting ADR, particularly for hospitalized patients, as they are in contact with a patient and available round the clock.

Aim: To assess the knowledge of Pharmacovigilance and ADR reporting before and after education and assessing attitude towards pharmacovigilance and ADR reporting among healthcare workers. Purpose of this study was to spread awareness and improve reporting of ADR by training Healthcare workers for filling the ADR reporting form.

Method: This was a prospective, cross-sectional, questionnaire-based comparative study. A structured questionnaire was given before and after the educational intervention at a tertiary care teaching hospital. Score of questionnaires were then compared and statistical analysis was applied using paired t-test.

Result: A total of 230 Healthcare workers Included in study and result depicted that there is improvement in knowledge score post educational training. Responses received demonstrated a positive attitude toward reporting ADRs.

Conclusion: The frequent training of Pharmacovigilance is required to enhance the knowledge among healthcare workers and may motivate practice of ADR reporting.

Keywords: pharmacovigilance, Adverse drug reactions reporting, knowledge, Health care workers, attitude.

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Introduction

The continuous progress in medical and pharmaceutical sciences has made the availability of pharmaceutical products in the Indian market to prevent and control several disease conditions. Irrespective of the benefits associated with the use of medicines, adverse effects associated with them have emerged the challenges of monitoring Adverse Drug Reactions (ADRs) over a large population base. World Health Organization (WHO) defined ADR as “A response which is noxious and unintended, and which occurs at doses

normally used in humans for the prophylaxis, diagnosis, or therapy of disease, or for the modification of physiological function.” [1]. ADRs are already established reasons for mortality and morbidity worldwide. ADR also has a significant impact on cost in the health-care system. Under reporting of adverse drug reactions is widespread and a daunting challenge in pharmacovigilance (PV) [2]. The commonest Healthcare worker related reasons are the feeling of guilt, fear of litigation, ignorance, lethargy, inadequate risk perception about newly marketed drugs, diffidence,

insufficient training to identify ADRs, and lack of awareness about PV program [3]. India contributes below 1% in terms of ADR reporting against the world rate of 5% [4].

The Ministry of Health and Family Welfare, Government of India, had initiated the Pharmacovigilance Program of India (PvPI). AMC has been established recently at Shantabaa Medical College in Amreli district under PvPI. The success of PV program in India merely depends on the active involvement of the health-care professional [5]. It is important for health-care professionals to know how to report and where to report an ADR [6]. To enhance the reporting rate, it is important to improve the knowledge, attitude, and practice (KAP) of all the health-care professionals with regard to the ADR reporting and Pharmacovigilance [7].

This study was such a step taken to evaluate the basic knowledge and attitude towards ADR reporting and Pharmacovigilance. We aimed to assess an impact of educational intervention on Knowledge of Pharmacovigilance and ADR reporting and evaluate attitude towards the same in healthcare workers.

Materials and Methods

Study Design: This was a prospective cross-sectional, questionnaire-based, before and after comparison study with an educational intervention conducted at Shantabaa Medical College and General Hospital Amreli, Gujarat, India during July 2023. Institutional ethics committee approval was obtained. Informed consent was obtained from all participants. A convenient sampling method was used to enrol the Healthcare workers belonging to different disciplines.

A knowledge and attitude-based questionnaire on ADR reporting and PV program was prepared. It was peer reviewed by the expert faculties of the PV committee of the institute. The questionnaire was structured, predesigned, with single correct and multiple correct answers. Few changes were made as per the study requirement and the questionnaire had finally 13 questions. Question numbers 1–10 was knowledge based and questions 11–13 were pertaining to attitude. For each correct response score of 1 and incorrect response score of 0 was

given. Only questions related to knowledge were assessed using a scoring system, maximum score being 20, and minimum being 0. Pre-test was conducted for healthcare workers prior to the educational intervention. In random order Questions were asked during data collection which was later analysed in three sections mainly knowledge regarding PV, Knowledge regarding ADR and Attitude towards ADR reporting

Intervention

An interactive educational intervention was conveyed to all the participants through the presentation on the definition of PV, causes of ADRs, who can report an ADR, what to report as an ADR, how to report a suspected ADR, followed by basic Knowledge of Pharmacovigilance. The session was conducted by PI of the study and the practical part of the intervention included documentation of ADRs using suspected ADR reporting forms provided by PvPI and hands-on training in assessing the causality of ADRs through the WHO causality assessment scale and Naranjo's scale. Post-test was conducted for all participants after the educational session with the same questionnaire.

Statistical Analysis: The pre-test and post-tests data obtained were assessed using Microsoft Excel. Normality checked in Q-Q plot and Paired t-test was applied for overall score comparison. Statistical calculations were performed using JAMOVI Version 2.3.18. The statistical significance level was set at $P < 0.001$.

Result

Knowledge Based Question: Of the 232 consented responses, 2 responses were excluded from the study due to its incompleteness. A total of 230 Healthcare workers from different disciplines, District Hospital Amreli participated in pre and post questionnaire survey. Mean scores were compared pre and post educational intervention. The results implicated that the participants had good theoretical knowledge even before educational intervention but had statistical significance in overall practice-based questions only after educational intervention as shown in Table 1.

Table 1: Comparison of Mean Score pre and post training

	Pre-Test (Mean±SD)	Post –Test (Mean±SD)	p value
Knowledge score	9.62±3.62	17.64±2.47	<0.001

Healthcare workers' Knowledge Regarding PV: Health workers' knowledge regarding PV was addressed with four questions. Before training, 67.39% of the respondents gave the correct response regarding the definition of pharmacovigilance (Q-1), whereas after training,

94.78% were able to give the correct response. 50.43% participants were aware of an AMC at their institute (Q-2) which was significantly improved to 87.39% after an educational training. 87.39% participants already knew about the PvPI, after training nearly all participants (97.39%) gained

knowledge about the PvPI (Q-3). Among the respondents, 19.57% were aware about the location of WHO coordinating centre in India(Q-4) before

training and 98.26% in the post questionnaire survey gave the correct response.

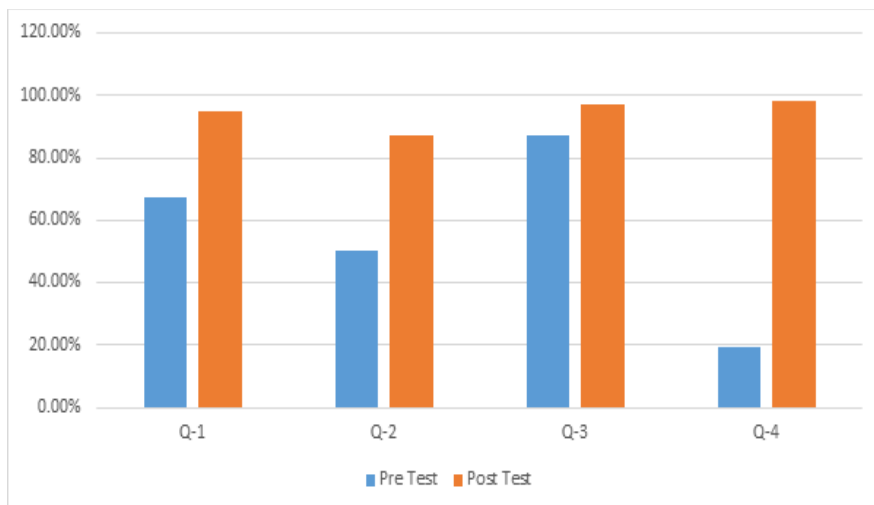


Figure 1: Health workers' Knowledge regarding PV

Healthcare workers' Knowledge Regarding ADR reporting: Healthcare workers' knowledge regarding ADR reporting was determined based on six questions. 98.69% responders became aware about the term ADR post training, improved from 56.52% before training. Among the responders, 98.26% gave the correct response regarding who

can report ADR after the educational training; however, before training, 70% were able to do so. Multiple correct answers question on causes of ADR where all the six answers were correct, improvement in correct response can be seen in figure 2.

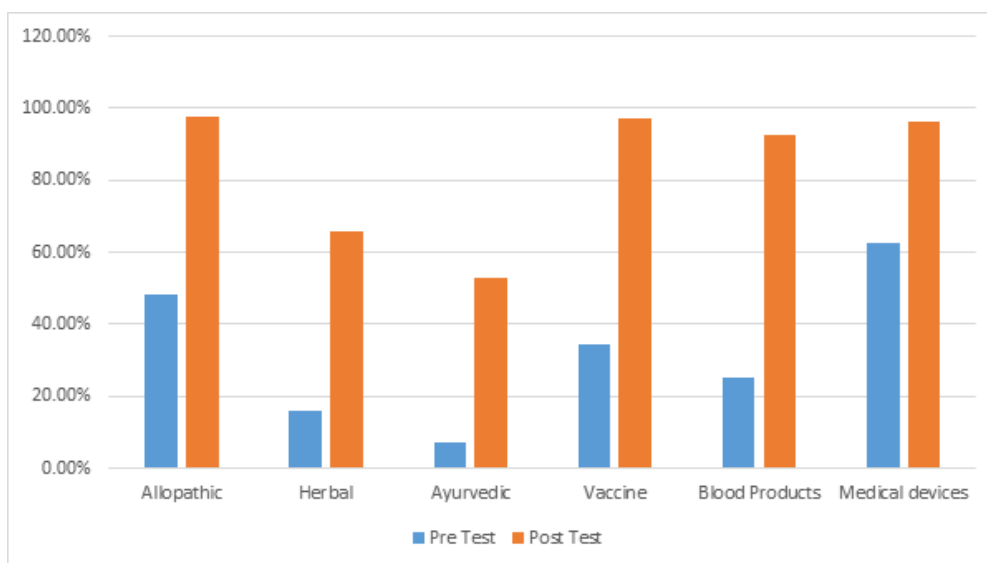


Figure 2: ADR can be caused by

Among all, 77.82% responders believe to report an ADR even if the patient dies before training which was not significantly improved post training (78.70%). In the question, what can be reported as ADR, before training 76.52% responded signs, 29.57% symptoms and 40% responded laboratory reports as a correct answer. Increase in the number of correct answers was seen post training with 88.26%, 79.13% and 94.78% for signs, symptoms

and laboratory reports respectively. Correct answers significantly improved post training for question asking ways to report an ADR [figure 3]

Attitude Based Questions: There were three Questions assessing healthcare workers' attitude towards PV and ADR reporting. The first question investigated about the attitude of how the ADR reporting should be, 138 (60%) participants responded Mandatory, while 92 (40%) responded

volunteer. Out of 230 responders, 229 feel responsible for reporting ADR. All 230 responded

PV should be taught to healthcare professionals in detail.

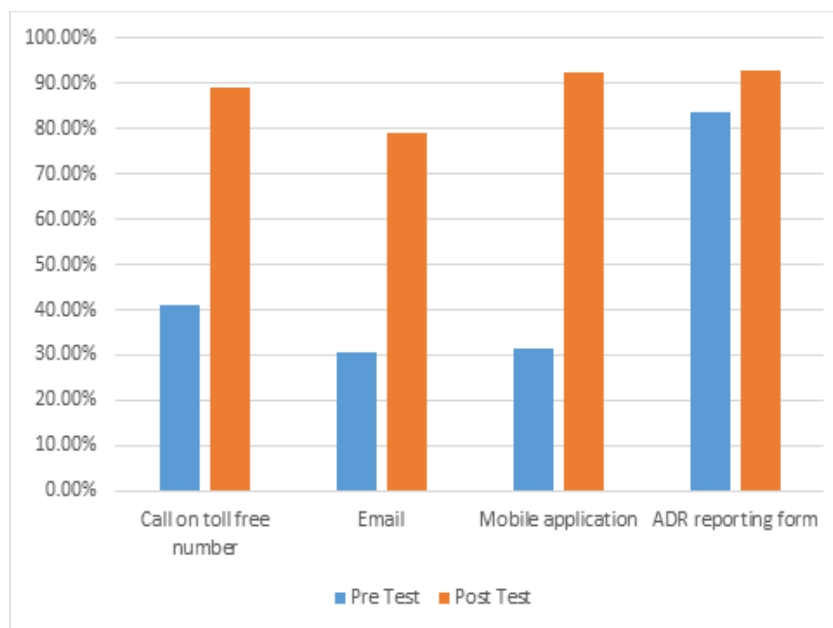


Figure 3: How to report an ADR

Discussion

Healthcare workers are an invaluable source of collecting and reporting the ADRs. Previous literature had shown that educational intervention in health-care professionals leads to a significant increase in Knowledge, Attitude and Practice of PV (8). This study was aimed at assessing impact of an educational intervention on Knowledge of PV and ADR reporting and evaluating Attitude towards the same in healthcare workers. Study was conducted at a district Hospital Amreli where training sessions were delivered and before-after Knowledge assessment was performed using structured questionnaire. Post training Attitude towards PV and ADR reporting was assessed with a questionnaire. Similar kind of study is not done at the study site to the best of our knowledge.

Result clearly demonstrates improvement in knowledge score from 9.62 ± 3.62 to 17.64 ± 2.47 , which is statistically significant (p value < 0.0001). This means a delivered session has educated healthcare workers effectively to make them more aware about ADR reporting and PV. Increase in the number of correct answers is seen with all the questions of the study especially in knowledge regarding the PV part of the study. More than 200 participants out of 230 gave correct answers for question on knowledge regarding PV which shows an effective impact of the training session. 94.78% knew correct definition of PV, 98.26% were aware about the location of National coordinating centre of PV in India and 87.39% became aware about an AMC centre at their institute after an educational

session, which was responded correctly by very a smaller number of participants that is 67.39%, 19.57% and 50.43% respectively. The large difference in correct responses pre and post intervention is also significant and can be seen in Figure 1.

Out of 230 respondents only 130 (56.52%) were aware about the term ADR. After training 227 (98.69%) gained knowledge about the same. More than half the number of participants were not sure what can cause an ADR. After training knowledge regarding causes of ADR improved with increased number of correct responses, 97.82% for Allopathic medicines, 65.65% for herbal medicines, 53.04% for ayurvedic, 97.39% for vaccines, 92.62% for blood products and 96.09% for medical devices. These differences can be seen in figure 1. 83.47% of the respondents were aware that the ADR reporting form is available for reporting an ADR, while less than half the number of respondents were aware about the other ways of reporting ADR. Increase in the number of correct responses was seen Post training, 89.13% gave correct responses for calling on toll free number, 79.13% for email and 92.17% for mobile applications. Among all 70% respondents already responded correctly for who can report an ADR which was increased to 98.26% correct responses post training. Common misbelief that no need to report an ADR if the patient dies was seen with 22.18% of participants which was decreased to 21.30% only. This may be due to the content of educational intervention which might not have directly taught about it. 76.52% respondents already think signs can be

reported as ADR, however only 29.57% think symptoms can be reported as ADR and 40% think Laboratory reports can be reported as ADR. Increase in correct responses was seen after training, 88.26% for signs, 79.13% for symptoms and 94.78% correct responses for laboratory reports can be reported as ADR. Result of the section Knowledge regarding ADR reporting has significant improvement in increasing correct responses after an educational intervention demonstrates the effective knowledge improvement among participants for ADR reporting, which was the objective of this study.

In post-test questionnaire, participants were asked questions addressing their attitude towards PV and ADR reporting. Out of 230 respondents 60% believe ADR reporting should be mandatory while 40% wants it to be volunteered. Almost all the participants (229) feel responsible for reporting ADR, which fulfils the purpose of educational intervention. All respondents want to be taught about PV in detail and on a regular basis. It is suggested that CMEs, workshops, symposia and training should be conducted seeing positive Attitude of Healthcare workers of District Hospital Amreli towards PV and ADR reporting.

Similar type of studies has been conducted in other parts of India but what sets this study apart is that being conducted at a site where no research has been done in the same area previously (9). AMC was established at an institute just before the study conducted and training cum educational session was delivered. Compared to the study done by Kalikar *et al.* having lectures alone as an intervention, in this study, the educational intervention included PowerPoint presentation and also hands-on training in filling up the ADR forms and causality assessment which will overcome the practical issues of the Healthcare workers (10).

Limitation of Study: Inclusion of other healthcare professionals in such studies can give a better insight into the current state of affairs and suggest appropriate measures. Most of the KAP studies include practice, this study could not assess practice of ADR reporting as the ADR reporting system was not well-established during study. Only a single centre as a study site impairs the generalizability of the findings.

Conclusion

The educational training given has improved the Knowledge among Healthcare Workers and their attitude towards PV and ADR reporting is positive and motivated.

Ethical Approval: The study was approved by the Institutional Ethics Committee.

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