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EFFECTIVENESS OF A STRUCTURED EDUCATIONAL INTERVENTION ON KNOWLEDGE, ATTITUDE AND PRACTICE OF PHARMACOVIGILANCE AMONG NURSES

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ABSTRACT: Background: Globally used modern medicines cause various adverse drug reactions (ADR). In order to improve patient safety and welfare, and to reduce patient morbidity and mortality, spontaneous ADR reporting is the need of the hour. Nurses are the first point of contact with patients in any hospital, so their awareness is important to improve the practice of pharmacovigilance. **Objectives:** To assess the knowledge, attitude, practice and impact of an educational intervention on pharmacovigilance among nurses. **Methodology:** A cross-sectional observational study done among 86 Nursing officers, employed at a tertiary care teaching hospital in southern Rajasthan. After taking consent, a pre-validated questionnaire comprising of four sections: demographic data, questions to evaluate knowledge, attitude and practice towards pharmacovigilance and ADR forms were provided to the participants and a pre-test was conducted. This was followed by a well-planned overview of Pharmacovigilance Programme of India (PvPI), case-based training session and a post-test. **Result:** The calculated mean score of questions regarding knowledge, of Pre-test was 2.88 and Post-test was 6.05 out of 8, which on data analysis, using paired-t test, was found to be statistically significant at $p < 0.05$. Individual questions were analysed using chi square test. **Conclusion:** Adequate sensitisation programmes on a regular basis are needed to meet the need of Pharmacovigilance among Nursing officials.

INTRODUCTION: Globally used modern medicines can lead to various forms of adverse drug reactions (ADR) among the patients. Therefore, “Pharmacovigilance” (PV), which is the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other medicine/vaccine related problem ¹, is of utmost importance. It applies throughout the lifecycle of a drug, pre-approval as well as post-approval.

In India, the Pharmacovigilance Programme of India (PvPI) began in July 2010 to safeguard the health of the Indian population by ensuring that the benefit of use of medicine outweighs the risks associated with its use ². On July 18, 2017, WHO bestowed upon India the honour of being a WHO-Collaborating Centre for Pharmacovigilance. By 2024, there are 895 ADR Monitoring Centres in the country ³ yet the number of adverse events reported remains a few.

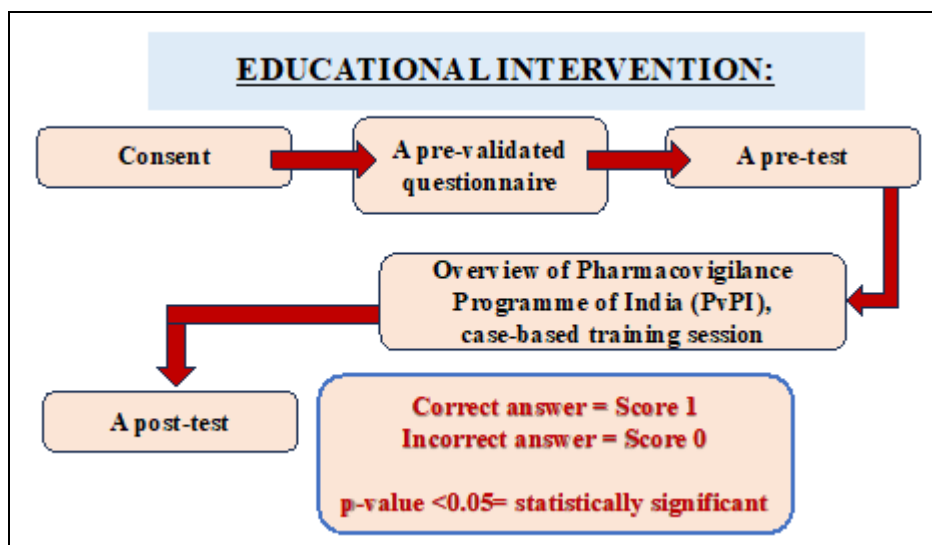
Thus, there is a need for spontaneous ADR reporting to improve patient safety and welfare and to reduce patient morbidity and mortality. Nurses are the first point of contact with patients in any hospital. They deal with patients throughout day and night and are the primary contact in case the

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patient experiences any untoward event due to the treatment. Hence, their awareness is important to improve the practice of PV. With this background, the study was planned at a tertiary care teaching hospital in Southern Rajasthan to assess the knowledge, attitude, practice of pharmacovigilance among nurses and to note the impact of an educational intervention on ADR Reporting.

MATERIAL AND METHODS: A cross-sectional, questionnaire based study was conducted among 86 participants who were employed at MB

Educational Intervention:



Data Collection: A structured questionnaire was developed in English and Hindi languages, based on previous studies conducted in the field of pharmacovigilance in other countries. After taking consent, a pre-validated questionnaire and ADR forms were provided to the participants and a pre-test was conducted. The questionnaire comprised of four sections namely for demographic data, questions to evaluate knowledge, attitude and practice towards pharmacovigilance and ADR reporting. It was developed using Google Forms and reviewed and validated by faculty practicing pharmacovigilance. Then a well-planned sensitization programme was conducted for all the nurses which included pretest, followed by session on overview of pharmacovigilance, Pharmacovigilance programme of India, ADR reporting and case based hands on training for ADR reporting. This sensitization programme was followed by a post-test. Every correct answer was given a score of 1 and every incorrect answer was given a score

Government Hospital in Udaipur, Rajasthan. The sample size was calculated statistically, and participants were included by convenient sampling.

Inclusion Criteria: All willing Nursing officers

Exclusion Criteria: Nursing students, pharmacists, doctors

Study Tools: A questionnaire and ADR reporting forms.

of 0 for the questions regarding knowledge of pharmacovigilance and ADR reporting.

Data Analysis: The data was entered into MS Excel and analysed using descriptive statistics. Mean score of the responses were calculated and analysed using 't' test and the responses of individual questions were compared using Chi Square test. p value <0.05 was considered to be statistically significant.

Ethical Clearance was obtained from the Institutional Ethics Committee prior to data collection.

The entire study was planned and conducted in accordance with the Principles of Good Clinical Practice, the ethical standards of the responsible committee on human experimentation, the Helsinki Declaration of 1975, and Indian Council of Medical Research - National Ethical Guidelines for

Biomedical and Health Research Involving Human Participants (2017).

and that of post test was 6.05 out of 8. Using paired-t test, it was found to be Statistically significant at $p < 0.05$. (Fig. 1).

RESULTS: While comparing the mean score of pre and post test, Mean score of pretest was 2.88

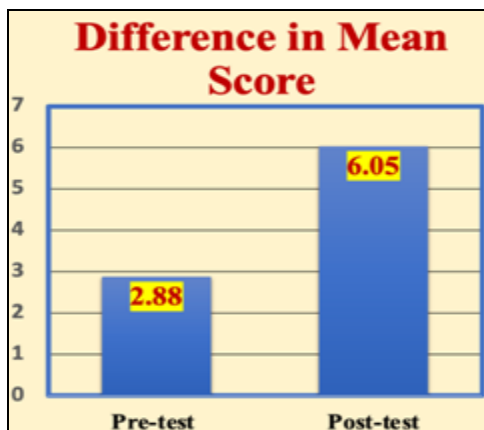


FIG 1: DIFFERENCE IN MEAN SCORE OF PRE-TEST AND POST-TEST

Individual questions were analysed using Chi Square test. On analysing the scores of knowledges, it was found that the difference was statistically significant ($p < 0.05$) for all the questions.

At significance level < 0.05 , the chi square test was applied, and p value was significant in 7 out of 8 questions in terms of Knowledge.

TABLE 1: RESULTS OF KNOWLEDGE SCORE

S. no.	Question	No. of participants responded correct in Pretest N = 86	No. of participants responded correct in Post test N = 86	P -value
1	Understanding about the term pharmacovigilance	48 (55.8%)	82(95.3%)	< 0.00001
2	Case based detection of ADR	74 (86%)	84 (97.7%)	< 0.00001
3	Need of Pharmacovigilance	20 (23.2%)	52 (60.4%)	< 0.00001
4	Where to report ADR	64 (74.4%)	82 (95.3%)	0.000127
5	Who can report the ADR	12 (13.9 %)	72 (83.7%)	< 0.00001
6	ADR reporting forms available	12 (13.9%)	84(97.7%)	< 0.00001
7	Probable consequences, if ADR is not found to be associated with drug	18 (20.9%)	64 (74.4%)	< 0.00001
8	What is PvPI	28 (32.5%)	58(67.4%)	< 0.00001

The Attitude of the patients was positive in the given study as depicted in **Table 2**. However,

significant change was not observed from Pre-Test to Post Test.

TABLE 2: RESULTS OF ATTITUDE SCORE

S. no.	Question	No. of participants responded correct in Pretest N = 86	No. of participants responded correct in Post test N = 86
1	Do you think drugs have ADRs	82	84
2	Do you think you have responsibility to report ADR	80	82
3	Do you think that all drugs are not safe	54	78
4	Do you think that reporting ADR will improve patient’s safety	76	80
5	Do you think there is need of training/sensitization programme regarding ADR reporting	84	86
6	Would you like to participate in future training/sensitization programme for pharmacovigilance	86	86
7	Do you think that ADRs are not adequately reported	60	66

DISCUSSION: This study was conducted in a tertiary care teaching hospital, aiming to understand the impact of an educational intervention on individual level of assessing the knowledge, attitude, practice of pharmacovigilance of nurses employed at the hospital. The hospital is also a certified ADR Monitoring and Reporting centre under the PvPI. This educational intervention program on pharmacovigilance has shown a highly positive impact towards ADR reporting.

In terms of knowledge, the difference in mean scores of pre and post test was statistically significant. The comparison of score of individual questions was also statistically significant for all the questions related to knowledge of Pharmacovigilance and ADR reporting. This indicates the need of frequent sensitization programmes for all the nurses as they play a significant role in patient's safety. The results were nearly similar to the other studies used for reference⁵⁻¹².

In terms of attitude, the responses were very encouraging in pretest. 95% of participants agreed that the drugs have adverse reactions, they have the responsibility to report the ADRs and reporting ADR will improve the patient's safety. 97.7% responded that there should be sensitization programmes regarding ADR reporting and 100% of the participants wanted to attend such programme. 65.9% of participants were of opinion that all drugs are not safe and 75% responded that the reporting of ADR is not satisfactory. The results were comparable to the study by Salehi *et al*, which observed that 84.6% of nurses believed ADR reporting to be important for patient/medicine safety and this is similar to our finding where 85.2% believe they should report ADRs. Also, according to the results of Salehi study, 84.6% of the nurses acknowledged that ADR reporting is important for patient/medicine safety. This shows the positive attitude of nursing staff towards ADR reporting and drug safety and their willingness to take part in the PvPI.

Though the attitude regarding ADR reporting and promoting ADR reporting was very much encouraging but this was not found to be reflected in practice. 90.2% of participants have noticed

ADRs but only 39% had reported the ADR to the treating physician. 97.6% have never seen reporting form and not exposed to any type of sensitization programme. The results were nearly similar to the study by Salehi *et al*.

The results indicate that there is need of such sensitization programme for nurses as pharmacovigilance is integral to nursing practice as it ensures patient safety, prevents irrational prescribing, improves quality of treatment, reduces the cost of treatment. Though the follow up regarding the result of the programme regarding implementation could not be done but the study can be further extended with conducting advance level sensitization programme, for the same participants to promote Nurses' active participation in pharmacovigilance activities, which is essential for maintaining and enhancing the overall safety and efficacy of medication use in clinical settings. It is suggested that ADR reporting should be taught as a part of the training curriculum so that the nurses are familiar to this concept while working in hospitals.

CONCLUSION: Educational program on PV was found to statistically increase the correct responses. Despite lack of adequate knowledge and poor practice of ADR reporting, the positive attitude of nurses is a Ray of hope for Pharmacovigilance. Regular in-service training and sensitisation programmes are needed to improve the practice.

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CONFLICTS OF INTEREST: None

REFERENCES:

1. <https://www.who.int/teams/regulation-prequalification/regulation-and-safety/pharmacovigilance>
2. https://www.ipc.gov.in/images/895AMC_list_updated.pdf last accessed on 20 April, 2024.
3. Pharmacovigilance programme of India for assuring drug safety. Available at <https://cdsco.gov.in/opencms/opencms/en/PvPI/>. Accessed 9 February 2024
4. Karelia BN and Piparava KG: Knowledge, attitude and practice of pharmacovigilance among private healthcare professionals of Rajkot city. International Journal of Basic

- & Clinical Pharmacology 2017; 3(1): 50–53. Retrieved from <https://www.ijbcp.com/index.php/ijbcp/article/view/944>
5. Alan S, Ozturk M, Gokyildiz S, Avcibay B and Karataş Y: An evaluation of knowledge of pharmacovigilance among nurses and midwives in Turkey. *Indian J Pharmacol* 2013; 45(6): 616-8. doi: 10.4103/0253-7613.121375. Erratum in: *Indian J Pharmacol* 2014; 46(1): 126. PMID: 24347772; PMCID: PMC3847254.
 6. Rajesh R, Vidyasagar S and Varma DM: An educational intervention to assess knowledge, attitude, practice of pharmacovigilance among healthcare professional in an Indian tertiary care teaching hospital *Int J Pharm Tech Res* 2011; 3: 678–92.
 7. Alhat BR: Pharmacovigilance: An overview *Int J Res Pharm Chem* 2011; 1: 968–74.
 8. Oshikoya KA and Awobusuyi JO: Perceptions of doctors to adverse drug reaction reporting in a teaching hospital in Lagos, Nigeria. *BMC Clin Pharmacol* 2009; 9: 14. doi: 10.1186/1472-6904-9-14. PMID: 19671176; PMCID: PMC2731723.
 9. Upadhyaya HB, Vora MB, Nagar JG and Patel PB: Knowledge, attitude and practices toward pharmacovigilance and adverse drug reactions in postgraduate students of Tertiary Care Hospital in Gujarat. *J Adv Pharm Technol Res* 2015; 6(1): 29-34. doi: 10.4103/2231-4040.150369. PMID: 25709967; PMCID: PMC4330609.
 10. Salehi T, Seyedfatemi N, Mirzaee MS, Maleki M and Mardani A: Nurses' knowledge, attitudes, and practice in relation to pharmacovigilance and adverse drug reaction reporting: a systematic review. *Biomed Res Int* 2021; 2021: 6630404. doi: 10.1155/2021/6630404. PMID: 33937402; PMCID: PMC8062168.
 11. Griffith R: Nurses must report adverse drug reactions. *British Journal of Nursing* 2013; 22(8): 484–485. doi: 10.12968/bjon.2013.22.8.484.
 12. Haider N and Mazhar F: Factors associated with underreporting of adverse drug reactions by nurses: a narrative literature review. *Saudi Journal for Health Sciences* 2017; 6(2): 71. doi: 10.4103/sjhs.sjhs_37_17.

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