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ASSESSMENT OF KNOWLEDGE, ATTITUDE AND PRACTICES OF ADVERSE DRUG REACTION REPORTING AMONG NURSING STAFF OF TERTIARY CARE TEACHING HOSPITAL IN WESTERN RURAL INDIA

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ABSTRACT: Introduction: Underreporting of adverse drug reactions (ADRs) in Pharmacovigilance programme of India (PvPI) may be due to lack of adequate knowledge, attitude and practice among healthcare professionals towards ADR reporting. **Aim & Objective:** Present study was planned to assess the knowledge, attitude and practices of ADR reporting amongst nursing staff of tertiary teaching hospital in Western Rural India. **Methods:** This was cross sectional, observational study in which about 527 Nursing staff from Tertiary teaching hospital in Western Rural India were participated. Study was conducted as per pre-validated google form questionnaire-based format to assess knowledge, attitude and practices of ADR reporting. **Results:** Out of total 527 nursing staff who filled the ADR survey questionnaire, 87.1% participants were aware of the term ADR and 82.5% were aware of the term Pharmacovigilance. Only 53.5% respondents have undergone training related to Pharmacovigilance & ADR reporting. 54.8% nursing staff have faced ADR in a patient or themselves somewhere during their life time but only 46.5 % respondents have reported ADR. Most of nursing staff felt that lack of knowledge/training to report ADR and difficulty to diagnose ADR were major barriers for ADR reporting. **Conclusion:** Most of nursing staff have positive attitude for ADR reporting however they have unsatisfactory knowledge on some aspects of ADR reporting and inadequate training to report and diagnose ADR. Educational intervention strategies can be introduced amongst nursing staff along with hands on training workshop to fill ADR reporting form in order to promote ADR reporting.

INTRODUCTION: Adverse drug reaction (ADR) is defined by the World Health Organization (WHO) as 'any noxious change which is suspected to be due to a drug, occurs at doses normally used in man, requires treatment or decrease in dose or indicates caution in the future use of the same drug'¹.

ADRs are one of the important causes of morbidity and mortality in hospital set up in both developed and developing countries. Various studies have shown that ADRs gives rise to significant burden on healthcare facilities, increasing the length of hospital stay².

According to systematic meta-analysis conducted in 2016, the median incidence of ADR that led to hospitalisation and ADR that developed during hospitalisation were 2.85% and 6.34% respectively among Indian population³. As per another systematic review, ADRs cause a 9% increase in

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the length of hospital stay and a 20% increase in the variety of care costs⁴. Pharmacovigilance (PV) is a branch of Pharmacology which deals with ADR reporting and defined by World Health Organisation as “the science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other possible drug-related problems”⁵. Pharmacovigilance covers various activities like detection and reporting of medication errors, drug-to-drug interactions, misuse and/or abuse of medicines, lack of efficacy of medicines, and counterfeit and substandard medicines but spontaneous voluntary reporting of ADRs has remained the main focus of Pharmacovigilance⁶.

Pharmacovigilance Programme of India (PvPI) has been launched by the Ministry of Health and Family Welfare, Govt. of India in the year 2010 and Indian Pharmacopoeia commission, Ghaziabad is working as National Coordinating Centre (NCC) since April 2011. Since then, PvPI is continuously involved in the reporting, monitoring and prevention of ADRs in the country. PvPI suffers from underreporting of ADRs by the healthcare professionals which can delay the detection of important ADRs. It is estimated that only 6–10% of all ADRs are reported⁷. As per another study, The ADR reporting rate in India is below 1% compared to the worldwide rate of 5%⁸. One of the reasons for low reporting rate in India may be a lack of knowledge and sensitization towards pharmacovigilance and ADR reporting among health care professional. Therefore, healthcare providers like doctors, Pharmacist, nurses including patients should be motivated and sensitized regarding ADR reporting.

Nurses have very significant role in monitoring the response of patient to medication and to notify ADR to doctors if ADR happens and are involved in taking appropriate action to manage the ADR accordingly. However, previous literature has documented that a contribution from nurses is not optimal in the ADR reporting^{9, 10}. For voluntary reporting of adverse reaction from nurses, it is essential that they should possess proper knowledge, right attitude and healthy practices about ADR reporting^{11, 12, 13}. Keeping this in mind, we had planned the study to assess knowledge, attitude and practices of adverse drug reaction

reporting amongst nursing staff of tertiary care teaching hospital in Western Rural India.

AIMS & OBJECTIVE: To assess the knowledge, attitude and practices of nursing staff towards ADR reporting in tertiary care teaching hospital in Western Rural India.

MATERIAL AND METHODS:

Study Design: This was cross-sectional, observational study conducted amongst 527 nursing staff in various wards, OPD and departments of tertiary care teaching hospital in western rural India from February to April 2022. The study was conducted after getting approval from Institutional Ethics Committee, Rural Medical College, Loni (PIMS/DR/2022/258).

Study Questionnaire: A questionnaire was prepared which consisted of questions to assess knowledge about ADR reporting, attitude toward pharmacovigilance, and practice of ADR reporting. The questionnaire was newly designed by taking references from previous studies^{14, 15, 16} with minor modifications as per our hospital environment.

Total 22 questions were asked to nursing staff which included 4 questions related to Demographic information, 5 questions related to Knowledge of Pharmacovigilance, 6 questions related to awareness, 4 questions related to attitude towards Pharmacovigilance and 3 questions related to practice of Pharmacovigilance. Questionnaire then validated by expert faculties from pharmacology and different clinical departments of our institute.

Data Collection: All nurses working in the institute were asked for verbal consent to participate in the study. Nurses who gave verbal consent to participate in the study were invited in Auditorium Hall of the institute on same day (morning and afternoon session) keeping in mind about the duty timings with the permission and help of nursing superintendent. Questionnaire were given as google form link on WhatsApp group already created for administrative purposes. The participants were given 45 minutes for response after which the link was closed for the particular session. Same process was repeated for the afternoon session. About 527 nurses participated in the study.

Statistical Analysis: Data from google form was extracted as Microsoft excel file and the responses to the questions related to demographics, knowledge, awareness, attitude and practice were recorded in frequency and percentage while responses to 5 MCQ type questions related to knowledge were analysed by average and median score with percentage of the correct responses for individual question.

RESULT: Total 527 nursing staff filled the ADR survey questionnaire through google forms. Out of them 69.1% were females (n=364) and 30.7% were males (n=163). Mean age for male nursing staff was 32.7 ± 7.88 years while mean age for female nursing staff was 32.7 ± 1.15 years.

Assessment of Knowledge: Out of total 5 questions related to Knowledge, mean score was

2.58 with minimum score of 0 and maximum score with 5 (1 mark for each MCQ). 62.4% respondents answered correctly about the definition of Pharmacovigilance⁵ (n=329) as shown in **Table 1**. Only 46.1% (n=243) respondents answered correctly that Pharmacovigilance includes ADR due to all *i.e.*, drug, blood and blood products, vaccines and medical devices. Only 17.3% Nursing staff (n=91) answered correctly that National Co-ordination centre for Pharmacovigilance Programme of India is located at Indian Pharmacopoeia Commission, Ghaziabad. 63.9% (n=337) recorded the correct answer that All ADR need to be reported *i.e.*, Expected, Unexpected and serious. 68.3% (n=360) Nurses answered correctly that all stakeholders (Doctors, Pharmacists and Nurses) can report ADR and not limited to any one stakeholder in ADR reporting process.

TABLE 1: KNOWLEDGE QUESTIONS RESPONSES FROM NURSING STAFF

Q. no.	Question	Option A	Option B	Option C	Option D
1	Which of the following is the definition of Pharmacovigilance?	Any substance or product that is used or is intended to be used to modify or explore physiological systems or pathological states for the benefit of the recipient 110 (20.9%)	Art and science of compounding and dispensing drugs or preparing suitable dosage forms for administration of drugs to man or animals 56 (10.6%)	Any undesirable or unintended consequence of drug administration 32 (6.1%)	science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug related problems 329 (62.4%)
2	Pharmacovigilance (PV) includes ADR due to	Drug 253 (48%)	Blood & Blood Products 8(1.5%)	Vaccines & Medical Devices 23 (4.4%)	All of the above 243 (46.1%)
3	Where is the National Co-ordination center for Pharmacovigilance Programme of India located?	Delhi 335 (63.6%)	Mumbai 69 (13.1%)	Ghaziabad 91 (17.3%)	Pune 32 (6.1%)
4	Which ADR need to be reported?	Expected 130 (24.7%)	Unexpected 12 (2.3%)	Serious 48 (9.1%)	All of the above 337 (63.9%)
5	Who can report adverse drug reaction?	Doctors 108 (20.5%)	Pharmacists 16 (3%)	Nurses 43 (8.2%)	All of the above 360 (68.3%)

Assessment of Awareness about Pharmacovigilance: Out of 527 nursing staff, 87.1% (n=459) were aware of the term ADR and 82.5% (n=435) were aware of the term Pharmacovigilance as shown in **Table 2**. Only 53.5% (n=282) nursing staff have undergone training/awareness session related to

Pharmacovigilance & ADR reporting. 78.9% staff were aware that there is ADR Monitoring centre (AMC) in Rural Medical College and Pravara Rural Hospital recognised under Pharmacovigilance Programme of India. 90.5% (n=477) respondents were aware of Adverse Drug Reaction reporting form but only 50.66 % (n=267) nursing

staff were able to correctly identify the image of ‘Suspected Adverse Drug Reaction Reporting Form’ version 1.4 which was given as one of the questions in the google form.

TABLE 2: AWARENESS QUESTIONS RESPONSES FROM NURSING STAFF

Q. no.	Questions	Option A	Option B	Option C	Option D
1	Are you aware of the term Adverse drug reaction?	Yes 459 (87.1%)	No 54 (10.2%)	Maybe 12 (2.3%)	Can't say 2 (0.38%)
2	Are you aware of the term Pharmacovigilance?	Yes 435 (82.5%)	No 50 (9.5%)	Maybe 29 (5.5%)	Can't say 13 (2.5%)
3	Have you undergone any training/awareness session related to Pharmacovigilance & ADR reporting??	Yes 282 (53.5%)	No 245 (46.5%)		
4	Is there ADR Monitoring center (AMC) in Rural Medical College and Pravara Rural Hospital?	Yes 416 (78.9%)	No 27 (5.1%)	Maybe 53 (10.1%)	Can't say 31 (5.9%)
5	Are you aware of Adverse Drug Reaction reporting form?	Yes 477 (90.5%)	No 30 (5.7%)	Maybe 16 (3%)	Can't say 4 (0.8%)
6	Identification of image of ‘Suspected Adverse Drug Reaction Reporting Form’ version 1.4	Correctly Identify 267 (50.6%)	Not able to Identify correctly 260 (49.4%)		

Assessment of Attitude about Pharmacovigilance: Out of 527 nursing staff, 98.3 % (n=518) respondents felt that ADR reporting is important for patient safety. 97.2% (n=512) respondents felt that ADR reporting is important for medicine safety perspective as shown in **Table**

3. 95.6% (n=504) respondents thought that ADR reporting is part of their professional commitment and moral ethics. 91.8% (n=481) respondents think that there is need for training in medical college for ADR reporting and Pharmacovigilance.

TABLE 3: ATTITUDE QUESTION RESPONSES FROM NURSING STAFF

Q. no.	Questions	Option A	Option B
1	Do you think that ADR reporting is important for patient safety?	Yes 518 (98.3%)	No 9 (1.7%)
2	Do you think that ADR reporting is important for medicine safety perspective?	Yes	
3	Do you think that ADR reporting is part of your professional commitment and moral ethics?		
4	Do you think that there is need for training in medical college for ADR reporting and Pharmacovigilance?		

Assessment of Practice about Pharmacovigilance: 54.8% (n=289) nursing staff have

faced ADR in a patient or themselves somewhere during their life time.

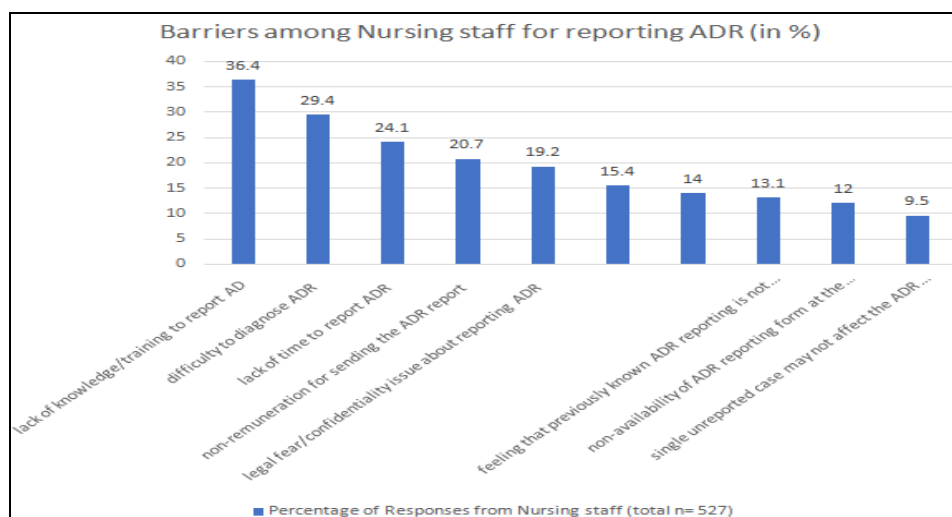


FIG. 1: BARRIERS FOR ADR REPORTING AMONG NURSING STAFF

Only 46.5 % (n=245) respondents have reported ADR to ADR monitoring centre during their professional career. Nursing staff were given opportunity to mark multiple options to the question related to barriers of ADR reporting. As per respondents, barriers for ADR reporting in decreasing order of frequency are lack of knowledge/training to report ADR (36.4%, n=192), difficulty to diagnose ADR (29.4%, n=155), lack of time to report ADR (24.1%, n=127), non-remuneration for sending the ADR report (20.7%, n=109), legal fear/confidentiality issue about reporting ADR (19.2%, n=101), concern that extra work is required to fill and send the ADR report (15.4%, n=81), lack of promotion, reminders and motivation by authorities (14%, n=74), feeling that previously known ADR reporting is not necessary (13.1%. n=69), non-availability of ADR reporting form at the workplace (12%, n=63) and single unreported case may not affect the ADR database (9.5%, n=50) as shown in **Table 4**.

DISCUSSION: Worldwide, underreporting of ADR is a well-recognized problem associated with spontaneous ADR reporting system. Knowledge, attitude and practice of healthcare professionals play a significant role in spontaneous reporting of ADRs¹⁷. Hence, the present questionnaire-based cross-sectional study was undertaken to assess the knowledge, attitude and practice of pharmacovigilance and ADR reporting among nurses working in tertiary care teaching hospital in western rural India. To the best of our knowledge, this is the first study with large sample size (n=527) to assess the Knowledge, attitude & practices of Nurses towards ADR reporting. About 84.06% of the nursing staff (n=443) was below the age of 40 years in our study.

Out of the total 22 questions, 5 questions were related to knowledge aspect of Nursing staff towards Pharmacovigilance (PV) and ADR reporting. In the present study, 62.4% respondents were aware of PV definition which is higher as compared to another Indian study conducted by Bepari *et al*¹⁵ (26.6%) and systematic review conducted by Salehi T *et al*¹⁸ (median 34%). 63.9% Nursing staff (n=337) answered correctly about which ADR need to be reported (*i.e.*, all- Expected, Unexpected and serious) and 68.3% (n=360) Nurses answered correctly that all stakeholders

(Doctors, Pharmacists and Nurses) can report ADR. However, only 46.1% (n=243) respondents answered correctly that Pharmacovigilance includes ADR due to all *i.e.*, drug, blood and blood products, vaccines and medical devices which is almost similar to Bepari *et al* (37.5%). Similarly, only 17.3% Nursing staff (n=91) answered correctly about the correct location of National Co-ordination centre for Pharmacovigilance Programme of India *i.e* Indian Pharmacopoeia Commission (IPC), Ghaziabad. It was shown that knowledge had a strong influence on ADR reporting and lack of knowledge is one of the important barriers for ADR reporting¹⁹. Therefore, all necessary efforts should be directed towards increasing knowledge among nurses about ADR reporting by conducting various seminar, workshops with hands on training, role play *etc.*

Out of total 22 questions, 6 questions were related to awareness about PV and ADR reporting. Nurses show satisfactory level of awareness on questions related to awareness of the term ADR (87.1%), awareness of the term PV (82.5%), awareness related to presence of ADR Monitoring centre (AMC) in Rural Medical College and Pravara Rural Hospital recognised under Pharmacovigilance Programme of India (78.9%) and awareness about ADR reporting form (90.5%). Awareness among our hospital nursing staff was higher on all above questions as compared to other study conducted by Ganesan *et al*¹⁶. However, only 53.5% nursing staff have undergone training/awareness session related to Pharmacovigilance and only 50.66 % nursing staff were able to correctly identify the image of 'Suspected Adverse Drug Reaction Reporting Form' version 1.4. This is consistent with findings of review article of Salehi T *et al* that only 38.7% of nurses had a history of training about PV and ADR reporting. This again highlights that higher education and provision of training for nurses would be associated with a greater engagement in ADR identification and reporting.

Out of total 22 questions, 4 questions pertaining to the attitude of nursing staff towards PV and ADR reporting were asked. Nursing staff shown high level of positive attitude (> 90% positive response rate) on all questions indicating that ADR reporting is important for patient safety, medicine safety

perspective, part of professional commitment and also there is need to undergo training to report ADR. This is in agreement with various studies^{15, 16, 18, 19}.

Out of total 22 questions, 3 questions were asked related to practice of PV and ADR reporting. 54.8% nursing staff have faced ADR in a patient or themselves somewhere during their life time but only 46.5 % nurses have reported ADR to AMC during their professional career. Though reporting by our nurses is higher as compared to review study suggested by Salehi T *et al*¹⁸ and Bhagavathula A *et al*²⁰, but it clearly shows that there is still scope for improvement in ADR reporting practice.

On question related to barriers of ADR reporting, our study findings suggested that most significant barrier (36.4%) is lack of knowledge/training to report ADR. This is consistent with the finding by Salehi T *et al*¹⁸ and Varallo F R *et al*²¹. Another systematic review suggested that nurse's belief about insufficient pharmacology knowledge to identify an ADR is an important reason for underreporting of ADRs²². Nurses need to educate about pharmacological knowledge from theoretical and practical training courses during the nursing educational program, in-service training, and clinical experience through various teaching learning methods like problem-based learning, role modelling, reflection and discussion, interprofessional education, and case study learning.

Other important barriers contributing to underreporting of ADRs were difficulty to diagnose ADR, lack of time to report ADR, non-remuneration for sending the ADR report, legal fear/confidentiality issue about reporting ADR, concern that extra work is required to fill and send the ADR report, lack of promotion, reminders and motivation by authorities, feeling that previously known ADR reporting is not necessary, non-availability of ADR reporting form at the workplace and single unreported case may not affect the ADR database. These factors were also highlighted by other similar studies conducted among nursing staff²³⁻²⁸. Improvement and modification of these features in healthcare settings could increase the rates of ADR reporting. This

also shows that consistent efforts should also be made by authorities of PvPI and Hospital administration for incentives and reminders about reporting ADRs to AMC as well as availability of ADR forms in various wards & OPDs along with awareness of the same. Pharmacology department of the institute which is in charge of AMC have already distributed ADR forms to various OPDs & wards but maybe there is insufficient awareness/training on this aspect and henceforth some nurses were not aware of the location of ADR forms.

CONCLUSION: Our study results revealed that though Nursing staff have positive attitude, their level of knowledge and practice in pharmacovigilance activities and ADR reporting were not at a suitable level of competence. Lack of knowledge/training is the most significant barrier for ADR reporting. Henceforth, our study results strongly recommends that training sessions along with hands on training workshop for filling ADR reporting form, facilitating access to the ADR reporting form, simplifying the ADR reporting process and providing motivation and feedback can increase ADR reporting performance of nursing staff which will further contribute to patient safety.

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CONFLICT OF INTEREST: NIL

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