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*Original Article*

# KNOWLEDGE, ATTITUDE AND PRACTICE OF ADVERSE DRUG REACTIONS (ADRS) REPORTING IN NURSING STAFFS OF TERTIARY CARE HOSPITAL

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## ABSTRACT

### Background

Adverse Drug Reactions (ADRs) are adverse consequences of drug therapy and are a major cause of morbidity and mortality. Approximately 2.9-5.6% of all hospital admissions are due to ADRs and up to 35% of hospitalized patients experience ADRs during their hospital stay. Therefore, the study assesses nurses' knowledge, attitudes and practices (KAP) for monitoring and reporting spontaneous adverse drug reactions (ADRs).

### Methods

In this observational study, 155 professional nurses with Proficiency Certificate Level (PCL), Bachelor Nurses and Masters working in various hospitals and academic institutes in Janakpur Municipality were selected to complete 19 pre-validated questionnaires on knowledge, attitudes and practice of ADR monitoring and reporting' response. The data were converted by a predetermined scoring method and subjected to statistical analysis.

### Results

Most participants from PCL Nursing (52.25%), participants from Bachelor Nursing (35.48%) and the fewest participants from Master Nursing (12.25%) were between 26 and 35 years old. Regarding ADRs knowledge, the majority of the Master Nurses (86.18%) answered the question correctly. ADR that reported regularly, most certificate nurses disagreed (33.3%) and more certificate nurses were neutral (38.2%) and some certificate nurses were agreed (28.3%). Most master nurses (63.1%) had patients with ADRs, but bachelor nurses (52.7%) and certificate nurses (64.2%) had not experienced any patients with ADRs in the past year. Master nurses (78.9%) were aware of the response to ADRs reporting and monitoring, but most certificate nurses (83.9%) and bachelor nurses (65.5%) were unaware of the ADRs reporting and monitoring response.

### Conclusion

We conclude that KAP of ADRs in nurses is not sufficient especially in certificate and bachelor nurses. But master level nurses responded well. This is due to their knowledge, attitude and practices on ADRs reporting and monitoring.

**Keywords:** ADRs, Janakpur Municipality, KAP, Nurses



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## INTRODUCTION

The WHO defines an ADR as any response to a drug that is noxious and unintended and occurs at doses normally used in humans for the prophylaxis, diagnosis or therapy of disease or to alter physiological function[1,2]. ADRs are negative consequences of drug therapy and one of the main causes of morbidity and mortality. It has been found that approximately 2.9-5.6% of all hospital admissions are due to ADRs and up to 35% of hospitalized patients experienced ADRs during their hospitalization[3,4]. More and more people are using newer and more effective drugs for various medical conditions. Adverse drug reactions (ADRs) are preventable if health-care professional pay close attention to the details of the side effects following drug administration. Awareness of ADRs can reduce irrational drug use[5]. Adverse drug reactions (ADRs) affect patients worldwide with varying degree of morbidity and mortality, regardless of the age group. ADRs are reported to be the 4-6th leading cause of death in the United States of America (USA)[6]. Documented reports estimate that Adverse drug reactions account for around 1% of hospital admissions in India, 7% in the United Kingdom and 13% in Sweden and New Zealand. The literature also states that about a third of these adverse drug reactions are avoidable[2]. The factors responsible for non-or under-reporting are diverse and vary from place to place. Many related factors contributing to this under-reporting are guilt, fear of litigation, and lack of awareness of the pharmacovigilance program[2]. Nurses are not fully aware of their role in reporting ADRs. Newly graduated nurses lacked the pharmacological knowledge and skills to detect adverse drug reactions. According to the authors, this result is probably due to a lack of knowledge about pharmacology and ADRs [7,8,9,10]. In Nepal, the Pharmacovigilance program was started in 2004 and the national center has received more than 300 ADR reports over a period of four and a half years, which is very few at this time. This program is primarily hospital based and therefore has limited coverage. There are not many awareness programs for healthcare professionals in terms of how the program started and how it works. The success of a Pharmacovigilance program depends mainly on the involvement of the healthcare professionals such as doctors, nurses, pharmacists[11]. In Nepal, the Pharmacovigilance program is still in its infancy and therefore the program needs to be promoted among health professionals. Some studies in the USA and France had shown that ADRs contribute significantly to morbidity and mortality in clinical practice, with the associated economic consequences[12,13]. All ADRs ranging from minor to severe reactions, should be reported with particular attention to ADRs to new drugs.

Serious adverse drug reactions, unexpected reactions, and drug interactions are potentially serious or clinically significant. Furthermore, uncertainty of the causal relationship between the drug and ADR should not be a reason for not reporting[14,15,16]. Several studies carried out to assess nurses' knowledge, attitudes and practice have documented that there is insufficient knowledge of nurses ADR reporting proces-ses[17]. There are no empirical studies from Nepal that assess the knowledge, attitude and practice of ADR reporting among nurses. Therefore, the present study aimed to assess nurses' knowledge, attitudes, and practices related to ADR reporting and factors that influencing reporting in a multi-specialty public or private hospital. Many studies have been found that nurses' knowledge was the main reason for underreporting of ADRs. Therefore, the present study focused on highly professional nurses with their highest degree in order to correct for underreporting. Comparisons between certificate nurses, bachelor nurses and master nurses can easily be made to evaluate their knowledge, attitude and practices.

## METHODS

In this observational study, 155 professional nurses working in different hospitals and academic institutes in Janakpur Municipality were selected. The study was conducted between June 2018 and November 2018 (6 months). Subjects were certificate nurses, bachelor nurses and master nurses. Most master nurses came from academic institutes and certificate nurses and bachelor nurses came from various private and government hospitals.

We received participants feedback through a structured questionnaire validated by experts from the Pharmacology Department at Janaki Medical College and Teaching Hospital. The questionnaire consisted of 19 items with questions about knowledge, attitudes and practice of ADR monitoring and reporting. Knowledge-related questions were divided into 8 subheadings, likewise attitudinal-related questions were divided into 6 questions, and finally practice-related question were divided into 5 different sub-headings. It also consists of socio-demographic data and occupational data. The questions were created considering previous similar studies for reference and modification. The questionnaire was distributed to 155 nurses.

All nurses who held certificate, bachelor and master nurses degrees and were registered with the Nepal Nursing Council. They are required to work in government or private hospitals in Janakpur Municipality. During the study period were included. The

healthcare professionals who were unwilling to participate in the study and those who were on furlough were excluded.

## RESULTS

A total of participants (N=155) were involved in this prospective observational study. All participants had responded all questions. All questions asked were distributed to all nurses in the study and collected again after a week so that they could go through the entire question in detail.

**Table 1: Total number of participants**

| S. N. | Professional Qualification | Participants Number (N) | Percent (%) | Cum. percent |
|---|---|---|---|---|
| 1. | PCL Nursing | 81 | 52.25 | 52.25 |
| 2. | Bachelor Nursing | 55 | 35.48 | 87.73 |
| 3. | Masters Nursing | 19 | 12.25 | 100 |
| | Total | N=155 | 100 | |

In this study (Table 1), we had the most participants from PCL Nursing (52.25%), participants from Bachelor Nursing (35.48%) and the fewest participants from Master Nursing (12.25%). The number of Participants from Master Nursing was less due to the background of professional form of master nursing in hospitals and colleges in the municipality of Janakpur had fewer opportunities. There were more participants from the PCL Nursing because certificate nursing had great opportunities in hospitals and clinics. But in this recent study, the response matters than the numbers.

**Table 2: Age categorization**

| S.N. | Ages | Participants(N) | Frequency (F) | Percent (%) | Cum. Percent |
|---|---|---|---|---|---|
| 1. | 15-25 | 31 | 31 | 20.00 | 20.00 |
| 2. | 26-35 | 86 | 86 | 55.48 | 75.48 |
| 3. | 36-45 | 34 | 34 | 21.93 | 97.41 |
| 4. | >45 | 4 | 4 | 2.58 | 100.00 |
| | Total | N=155 | F=155 | 100.00 | |

In the age categorization group (Table 2), the study participants were at most 26 to 35 years old (f=86), the fewest study participants were participants under 45 years (f=4). The age group of 15· 25-year-old and 36· 45-year-old participants is almost the same (f=31-34). Most respondents were between 26 and 35 years old as they worked in hospitals and clinics.

**Table 3: Response regarding knowledge of ADRs among Nurses**

| S. N. | Variables | | Professional Nurses PCL N=81 (%) | Bachelor N=55 (%) | Master N=19 (%) | Total N=155 | % |
|---|---|---|---|---|---|---|---|
| 1. | What is an ADR? | Correct | 35 (43.2) | 49 (89) | 18 (94.7) | 102 | 65.80 |
| | | Incorrect | 46 (56.7) | 6 (10.9) | 01 (5.2) | 53 | 34.19 |
| 2. | Is ADR reporting necessary? | Correct | 58 (71.6) | 51 (92.7) | 19 (100) | 128 | 82.58 |
| | | Incorrect | 23 (28.3) | 04 (7.2) | 00 (00) | 27 | 17.41 |
| 3. | Does ADR reporting damages professional image? | Correct | 28 (34.5) | 37 (67.2) | 16 (84.2) | 81 | 52.25 |
| | | Incorrect | 53 (65.8) | 18 (32.7) | 03 (15.7) | 74 | 47.74 |
| 4. | Who is benefited by ADR reporting? | Correct | 52 (64.1) | 32 (58.1) | 17 (89.4) | 101 | 65.16 |
| | | Incorrect | 29 (35.8) | 23 (41.8) | 02 (10.5) | 54 | 34.83 |
| 5. | Is there any need of information on drug causing ADR? | Correct | 34 (41.9) | 27 (49.1) | 16 (84.2) | 77 | 49.67 |
| | | Incorrect | 47 (58.1) | 28 (50.9) | 03 (15.7) | 78 | 50.32 |
| 6. | Is there any risk of management strategies of ADR? | Correct | 32 (39.5) | 26 (47.2) | 17 (89.4) | 75 | 48.38 |
| | | Incorrect | 49 (60.4) | 29 (52.7) | 02 (10.5) | 80 | 51.61 |
| 7. | Does any conference/workshop improve ADR management? | Correct | 38 (46.9) | 37 (67.2) | 18 (94.7) | 93 | 60.00 |
| | | Incorrect | 43 (53.1) | 18 (32.8) | 01 (5.2) | 62 | 40.00 |
| 8. | What is done to find ADR? | Correct | 23 (28.3) | 16 (29.1) | 10 (52.6) | 49 | 31.61 |
| | | Incorrect | 58 (71.6) | 39 (70.9) | 09 (47.3) | 106 | 68.38 |

(Table 3), represent the response for what is an ADR? Was answered most correctly by Bachelors (89%) and Masters (94.7%) professionals. Certificate nurse had given more incorrect answers (56.7%) than correct answers (43.2%). Answers to the question "Is ADR reporting necessary?" were responded 100% correctly by master nursing, while certificate nurses also answered well. Does the ADR reporting damage the professional images? Most certificate nurses felt that it was damaging to the profession (65.8%), but few certificate nurses felt that it was not destroying the profession (34.5%). Most nurses agreed that nurses benefit from the reposting of ADR. Both certificate nurses (58.1%) and bachelor nurses (50.9%) gave an incorrect answer related to: Is there a need for information about drug-causing ADRs? Again, both the certificate (60.4%) and bachelor nurses (60.4%)

incorrectly answered the question: Is there a risk of management strategies for ADR? Does a conference/workshop improve ADR management? was answered correctly by nurses, with the exception of certificate nurses who answered incorrectly (53.1%). Remarkably, when asked what is being done to find ADR, many of the nurses answered incorrectly (68.38%).

**Table 4: Response regarding attitude of ADRs reporting among nurses**

| S. N. | Variables | | Professional Nurses PCL N =81(%) | Bachelor N=55(%) | Master N=19(%) | Total N=155 | % |
|---|---|---|---|---|---|---|---|
| 1. | ADRs should be reported spontaneously at regular basis? | Agree | 23 (28.3) | 32 (58.1) | 17 (89.4) | 72 | 46.45 |
| | | Disagree | 27 (33.3) | 11 (20) | 02 (10.5) | 40 | 25.80 |
| | | Neutral | 31 (38.2) | 12 (21.8) | 00 (00) | 43 | 27.74 |
| 2. | Reporting ADR is duty of Nurses? | Agree | 35 (43.2) | 41 (74.5) | 18 (94.7) | 94 | 60.64 |
| | | Disagree | 34 (41.9) | 08 (14.5) | 01 (5.2) | 43 | 27.74 |
| | | Neutral | 12 (14.8) | 06 (10.9) | 00 (00) | 18 | 11.61 |
| 3. | Reporting ADRs is important for public? | Agree | 36 (44.4) | 43 (78.1) | 17 (89.4) | 96 | 61.93 |
| | | Disagree | 23 (28.3) | 04 (7.2) | 01(5.2) | 28 | 18.06 |
| | | Neutral | 22 (27.1) | 08 (14.5) | 01 (5.2) | 31 | 20.00 |
| 4. | Reporting ADRs is important for health care system? | Agree | 35 (43.2) | 45 (81.8) | 19(100) | 99 | 63.87 |
| | | Disagree | 27 (33.3) | 05 (9.1) | 00 (00) | 32 | 20.64 |
| | | Neutral | 19 (23.4) | 05 (9.1) | 00 (00) | 24 | 15.48 |
| 5. | Only ADRs that cause persistent disability should be reported? | Agree | 42 (51.8) | 10 (18.1) | 04 (21.1) | 56 | 36.12 |
| | | Disagree | 17 (20.9) | 41 (74.5) | 14 (73.6) | 72 | 46.45 |
| | | Neutral | 22 (27.1) | 04 (7.2) | 01 (5.2) | 27 | 14.41 |
| 6. | Does reporting ADRs created additional work load? | Agree | 52 (64.1) | 34 (61.8) | 03 (15.7) | 89 | 57.41 |
| | | Disagree | 12 (14.8) | 11 (20) | 15 (78.9) | 38 | 24.15 |
| | | Neutral | 17 (20.9) | 10 (18.1) | 01 (5.2) | 28 | 18.06 |

From the (Table 4), it can be seen that most of the certificate nurses disagreed (33.3%) and more certificate nurses were neutral (38.2%) and some certificate nurses agreed (28.3%) on the question ADRs should spontaneously occur regular are reported, most of master and bachelor nurses responded correctly. Almost all nurses agreed (60.64%) with the question, is it obligatory for nurses to report ADRs? Interestingly, most of nurses also agreed (61.93%) that reporting ADRs is important to the public. Similarly, they also agreed (63.87%) that reporting ADRs is important to the health care system. Only ADRs that cause persistent disability should be reported, most certificate nurses (51.8%) agreed, but masters and bachelor nurses disagreed. Likewise, most bachelor and certificate nurses agree that reporting ADRs creates additional work-load. But the master nurses disagreed (78.9%) when asked that reporting ADRs creates additional work-load.

**Table 5: Response regarding practices of ADRs reporting in Nurses**

| S. N. | Variables | | Professional Nurses PCL (N=81) | Bachelor N=55 (%) | Master N=19 (%) | Total N=155 | % |
|---|---|---|---|---|---|---|---|
| 1. | Have you encountered patients with ADR in last one year? | YES | 29 (35.8) | 26 (47.2) | 12 (63.1) | 67 | 43.22 |
| | | NO | 52 (64.2) | 29 (52.7) | 07 (36.8) | 88 | 56.77 |
| 2. | Have you noted the ADRs that you have noticed? | YES | 21 (25.9) | 23 (41.8) | 15 (78.9) | 59 | 38.06 |
| | | NO | 60 (74.1) | 32 (58.1) | 04 (21.1) | 96 | 61.93 |
| 3. | Have you ever reported the ADRs? | YES | 23 (28.3) | 24 (43.6) | 17 (89.4) | 64 | 41.29 |
| | | NO | 58 (71.6) | 31 (56.3) | 02 (10.5) | 91 | 58.70 |
| 4. | Do you give advice about ADRs to the patients? | YES | 19 (23.4) | 27 (49.1) | 16 (84.2) | 62 | 40.00 |
| | | NO | 62 (76.5) | 28 (50.9) | 03 (15.7) | 93 | 60.00 |
| 5. | Do you have any regulatory body for ADRs reporting and monitoring? | YES | 13 (16.1) | 19 (34.5) | 15 (78.9) | 47 | 30.30 |
| | | NO | 68 (83.9) | 36 (65.5) | 04 (20.1) | 108 | 69.67 |

In the (Table 5), most of the master nurses (63.1%) encountered patients with ADRs in the past year. But bachelor nurses (52.7%) and certificate nurses (64.2%) had not experienced patients with ADRs in past year. Very few certificate nurses (25.9%) wrote down the noticed ADRs but missed the noticed ADRs (74.1%). Similarly, bachelor nurses did. Interestingly, both certificate nurses (71.6%) and bachelor nurses (56.3%) had never reported the ADRs. Again, certificate nurses (76.5%) had never informed the patient about ADRs, the same is true for the bachelor nurses (50.9%), but master nurses (84.2%) efficiently advised the patient about ADRs. Surprisingly the master nurses (78.9%) were aware of the regulatory body for ADRs reporting and monitoring but most of the certificate nurses (83.9%) and bachelor nurses (65.5%) aware of the regulatory body for ADRs reporting and monitoring.

## DISCUSSION

This study was a questionnaire-based, observational study conducted on registered nurses (certificate, bachelor's and master's level nurses). We had the most participants from PCL Nursing, participants from Bachelor Nursing and the fewest participants from Master Nursing. The number of participants from Master Nursing as less due to the background of professional form of master nursing in hospitals and colleges in the Janakpur Municipality had fewer opportunities. But in this recent study, the response

matters more than the numbers. Many studies have been conducted on nurses' knowledge, attitudes and practices of ADR reporting, but the responses of master's level have been missed in the literatures[2,7,11,18]. Most of the respondents were between 26 and 35 years old because they worked in hospitals and clinics. Regarding ADRs knowledge, the majority of the question was answered correctly by Master Nurses (86.18%). This was due to their knowledge of how to report ADRs. Certificate and Bachelor Nurses could not respond well due to of lack of knowledge. Nurse knowledge before the intervention was significantly lower than knowledge after the intervention[19,20]. Response regarding attitudes towards ADRs reported among nurses, we saw a similar response from all the respondents as regarding knowledge-based responses. But Bachelor Nurses had some good responses as Certificate Nurses. Similarly, most Bachelor and Certificate Nurses agree that reporting ADRs creates additional work-load, but Master Nurses disagreed. The main responses preventing participants from reporting were a lack of awareness of the reporting process and access to the ADR reporting form. Although the knowledge of most participants was acceptable, the transition to practice needs to be improved[21]. Responding to practices from ADRs reporting that most certificate nurses do not have it due to insufficient training and knowledge. Bachelor Nurses practice the ADRs but were not up to mark. Surprisingly, the master nurses knew about the regulatory body for ADRs reporting and monitoring, but most certificate nurses and bachelor nurses were unaware of the regulatory body for ADRs reporting and monitoring. The participants made useful suggestions on how to improve the reporting culture in their respective hospitals. Considering that many had not previously received pharmacovigilance training, a large number of participants suggested in-house training methods such as workshops and seminars to become familiar with both the identification of common ADRs and the process of ADR reporting.

## CONCLUSION

We conclude that the KAP of ADRs among nurses is insufficient particularly among certificate and bachelor nurses. But the master level nurses responded well. This is due to their knowledge and practices in reporting and monitoring ADRs. Therefore, propose that an adequate knowledge of ADRs should be included in the curriculum of all levels of nurses with at least one credit point (15-18 hrs). We also recommend structured teaching of basic pharmacovigilance concepts and appropriate hands-on training in ADRs reporting.

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