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Research Article

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Interventional Outcome of Knowledge, Attitude and Practice towards Pharmacovigilance and ADR reporting among Nursing Students in Dhaka

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Abstract

Background: *Adverse Drug Reactions (ADR) is worldwide health issues associated with increased morbidity and mortality. These issues are addressed by pharmacovigilance, in which nurses can play a crucial role by reporting ADRs, but their participation is very poor in this field.*

Purpose: *This study aimed to evaluate the impact of training session on nursing students' knowledge, attitude and practice (KAP) towards pharmacovigilance.*

Methods: *A quasi experimental, cross sectional, observational study was conducted among 315 nursing students at tertiary institutes. Nursing students completed a pre-validated questionnaire before and after a training session covering pharmacovigilance concepts. Pre and post session responses were compared using chi-square and paired t-tests.*

Results: *Almost 64.13% reported no prior training regarding pharmacovigilance. The percentage recognizing ADR reporting as a professional obligation increased to 92.7%. After the session, 97.14% came to know that anyone can report ADR.*

Conclusion: *The educational intervention effectively improved the knowledge and importance of pharmacovigilance, positive attitude in responsibility, and competency of ADR reporting in practice among the nursing students.*

Keywords: Pharmacovigilance, Adverse Drug Reaction, Nursing Science, Bangladesh

1. Introduction

The World Health Organization (WHO) defines an adverse drug reaction (ADR) as a noxious and unintended reaction that can happen at any dose or exposure [1]. ADRs are major public health issues, associated with poor treatment outcomes, considerable economic burden and therefore increased morbidity and mortality [2]. Pharmacovigilance (PV), the science and activities associated with the detection, evaluation, understanding and prevention of ADRs and other drug related problems, that is essential to ensure the safe and rational use of medications [3]. The field of pharmacovigilance was originated following the 20th-century Thalidomide tragedy [4]. Consequently, WHO launched the Program for International Drug Monitoring in 1968 to promote drug safety. Later, along with the Center for International Drug Monitoring, Uppsala, it encouraged pharmacovigilance programs at the national level [5]. The Uppsala Monitoring Centre (UMC) receives ADR reports from different member countries, processes them, assesses them, and includes them to the WHO International database. However, the gathered ADR is unclear because each member country has a separate set of parameters [6]. Every nation needs to monitor ADRs due to variations in medication production and consumption, as well as differences in population genetics. Therefore, data associated with ADR will differ between regions [7].

Bangladesh launched the National Pharmacovigilance Program to identify and report ADRs by creating a cell in Directorate General of Drug Administration (DGDA) in 1996 under the supervision of WHO. In December 2014, Bangladesh entered the WHO pharmacovigilance program as its 120th member country and sent VigiBase its first set of adverse reaction case reports via VigiFlow [8]. ADR monitoring can be done in a number of ways. One of the main components of PV is ADR reporting, which permits post-marketing monitoring of medications used in a clinical environment and the identification of rare, uncommon, or dangerous ADRs through phase-IV clinical trials [9]. All healthcare providers have a professional responsibility to report ADRs since patient safety is greatly affected by this effective reporting system [10]. Unfortunately, pharmacovigilance system of Bangladesh has yet to be established due to a lack of understanding regarding ADR reporting [11]. Due to a lack of reporting, it is difficult to determine the actual situation regarding ADR in Bangladesh [12]. Bangladesh is far from reaching the WHO pharmacovigilance program's recommendation that its member nation has to submit more than 200 reports per million people each year. A total of 517 reports from 2014 to March 2017 were submitted to the WHO-UMC database (DGDA) after being assessed by Adverse Drug Reaction Advisory Committee (ADRAC) [13]. This is alarming since a significant under-reporting rate can delay the identification of new adverse drug reactions and compromise patient safety. Mostly, an important challenge is very little information on rare and very rare ADRs when a new medication is launched [14]. The basis of nursing leadership in pharmacovigilance as well as ADR reporting is that nurses are the healthcare providers who spend the most time and are most directly involved in patient care. Additionally, nurses are in a unique position to detect, identify, and report ADRs because they prepare and administer the majority of medications [15]. However, the primary obstacle that affected ADR reporting by them was found to be a lack of knowledge and training [16]. Additionally, an integrative review revealed that nurses do not completely understand their responsibility for reporting ADRs. Despite having a favorable attitude toward reporting adverse drug reactions, nurses' skills and expertise in these procedures were inadequate [17].

Hence, the aim of this study is to assess the role of education and training in improving knowledge, positive attitude and practice towards pharmacovigilance among nursing students in Dhaka.

2. Materials and Method

A quasi-experimental, cross-sectional, questionnaire-based, observational, multi-center study was conducted to assess the knowledge, attitude and practices related to pharmacovigilance before and after a training session on the relevant topic. The study protocol was approved by the Institutional Ethical Review Board of Holy Family Red Crescent Medical College, Dhaka, Bangladesh (IERB/44/Aug/2025/02/HF). The informed consent was taken from the participants for privacy and to publish. The study was done among 315 nursing students of two reputed nursing institutes, Grameen Caledonian College of Nursing and Holy Family Red Crescent Nursing College, located in Dhaka city. The study was conducted between August and September 2025 and included nursing students from different courses and years, who attended a structured training session on pharmacovigilance, organized by the Department of Pharmacology of Holy Family Red Crescent Medical College. The participants, who successfully completed both the pre- and post-training KAP (Knowledge, Attitude and Practice) questionnaires, were included in the analysis. Participants who failed to complete either the pre or post-session questionnaire were excluded from the study. The sample size and sampling technique was employed based on convenience method. A pre-validated and pre-tested questionnaire containing total 20 questions (both open and close-ended) was used to assess the knowledge, attitude and practice of pharmacovigilance before (pre-KAP) and after (post-KAP) the training session [18]. It contained 12 questions about knowledge, 4 questions about attitude and 4 questions about practice of reporting ADRs they come across during their practice. The questionnaire was designed specifically to observe the awareness about pharmacovigilance and ADR reporting among nursing students.

The training session lasted for 40 minutes and consisted of the definition and aim of pharmacovigilance, classification of ADRs, seriousness and severity of ADR, brief about Pharmacovigilance program of Bangladesh, role of nursing professionals in ADR reporting, hands-on experience in ADR reporting forms and mostly its effect on patient safety. Before commencement of the session, the objectives of the study and the contents of the questionnaire were explained to the participants. They were assured that the data which was collected would be used only for research purposes and findings will not be revealed by name to anybody. They were given 20 minutes before the session and 20 minutes after the session to fill in the same KAP questionnaire in the presence of the investigators. The responses, along with participant's basic demographic information such as year of the courses were compiled into a Microsoft Excel spreadsheet for analysis. KAP questionnaires were analyzed question wise and their frequency and percentage value were calculated using excel spreadsheet. Results of the study were represented in the form of simple percentages and the changes from before and after the session were compared question-wise by Chi square test. Pre and post-intervention mean KAP scores were also compared by paired t-tests. A p value less than 0.05 was considered statistically significant.

3. Results

A total of 315 nursing students were involved in pre-intervention and post-intervention KAP questionnaire. Among them 191 and 124 participants were from different years of BSc. and Diploma course respectively (Table 1).

Institute	Course	Year	Number (%)
Grameen Caledonian College of Nursing	BSc (125)	1st	4 (3.2)
		2nd	23 (18.4)
		3rd	55 (44)
		4th	43 (34.4)
	Diploma (53)	1st	
		2nd	53 (100)
		3rd	
		4th	
Holy Family Red Crescent Nursing College	BSc (66)	1st	
		2nd	29 (43.9)
		3rd	24 (36.36)
		4th	13 (19.7)
	Diploma (71)	1st	
		2nd	30 (42.25)
		3rd	41 (57.75)
		4th	

Table 1: Demography of the Participants (N=315)

The proportion of nursing students that correctly defined pharmacovigilance as "science of detection, assessment, understanding and prevention of adverse effects of drugs" was found to be 78.41% before the session. The most common incorrect definition was "science detecting the type and incidence of ADR after drug is marketed" by 10.16%. The proportion of correct responses rose to 89.2% following the training session. Similarly, the percentage of students correctly identifying the most important purpose of pharmacovigilance as "to identify safety of the drug" changed from 67.62% to 75.87% post-training. Before the activity, only 10.16% of the nursing students were aware that they can report ADRs. Notably, 5.71% believed only doctors can report ADRs and 5.71% believed only pharmacists can do so. After the intervention, 97.14% were correctly made aware that ADRs can be reported by any of them. Pre-intervention, about 40.32% participants had the knowledge of the existence of National Pharmacovigilance Program in Bangladesh. Post-intervention, this number increased to 56.82% which was statistically significant ($p< 0.0001$). Before the session, only 53.02% of the students identified the Directorate General of Drug Administration (DGDA) as the regulatory body responsible for monitoring ADRs in Bangladesh whereas 30.48% ,14.29% and 0.95% responded Bangladesh Medical Research Council (BMRC), Directorate General of Health Services (DGHS) and Bangladesh Medical and Dental Council (BMDC) respectively. The correct response percentage rose to 83.5% after the session. Pre-intervention, only 25.39% of participants correctly identified Sweden as the location of the international center for adverse drug reaction monitoring. The most common incorrect response was United States of America by 35.87%. The proportion of correct responses rose to 89.2% in the assessment following the training session. Before the session, only 26.98% of students had seen the ADR reporting form which rose to 80.63% after the session. Pre-intervention, 36.5% of surveyed participants gave the correct answer to this question, i.e., that rare adverse drug reactions can be detected during phase-4 clinical trials, whereas post-intervention, this number increased to 52.7%. Regarding the methods by which healthcare professionals monitor ADR commonly, only 53.65% responded correctly to spontaneous reporting system before the session. The most common incorrect method was "population studies" by 21.9%. The proportion of correct responses rose to 62.86% in the assessment following the training session. 88.25% and 97.14% of the participants considered reporting of adverse drug reaction is necessary before and after the session respectively (Table 2).

Q. No	Questions	Pre-Intervention (Correct)(%)	Post-Intervention (Correct)(%)	p value
1.	Define Pharmacovigilance	247 (78.41)	281 (89.2)	0.000236
2.	The most important purpose of Pharmacovigilance is	213 (67.62)	239 (75.87)	0.021407
4.	The healthcare professionals responsible for reporting ADRs in a hospital is/are	246 (78.09)	306 (97.14)	<0.0001
5.	Do you know regarding the existence of a National Pharmacovigilance Programme in Bangladesh?	127 (40.32)	179 (56.82	<0.0001
6.	Which regulatory body is responsible for monitoring ADRs in Bangladesh?	167 (53.02)	263 (83.5)	<0.0001
7.	Where the international center for adverse drug reaction monitoring is located?	80 (25.39)	281 (89.2)	<0.0001
8.	Do you think reporting of adverse drug reaction is necessary?	278 (88.25)	306 (97.14)	<0.0001
14.	Have you ever seen the ADR reporting form?	85 (26.98)	254 (80.63)	<0.0001
16.	A serious adverse event should be reported to the regulatory body within	191 (60.63)	217 (86.69)	0.030129
17.	Rare ADRs can be identified in the following phase of a clinical trial	115 (36.5)	166 (52.7)	<0.0001
18.	Which of the following methods is commonly employed by the health care professional to monitor adverse drug reactions of new drugs once they are launched in the market?	169 (53.65)	198 (62.86)	0.019134
19.	Is there any Pharmacovigilance Committee in your Institute?	38 (12.06)	111 (35.24)	<0.0001

[$p < 0.05$= significant by using Chi-square test]

Table 2: Knowledge about Pharmacovigilance among Participants (N = 315)

Q. No	Questions	Pre-Intervention (Correct)(%)	Post-Intervention (Correct)(%)	p value
3.	Do you think ADR reporting is professional obligation for you?	252 (80)	292 (92.7)	<0.0001
9.	Do you think pharmacovigilance should be taught in detail to healthcare professionals?	273 (86.67)	79(25.08)	0.012827
10.	Have you anytime read any article on prevention of adverse drug reactions?	202 (64.13)	240 (76.19)	0.000937
11.	What is your opinion about establishing ADR monitoring center in every hospital? Should be in every hospital	260 (82.54)	295 (93.65)	<0.0001

[$p < 0.05$= significant by using Chi-square test]

Table 3: Attitude about Pharmacovigilance among Participants (N = 315)

Regarding attitude towards pharmacovigilance among nursing students, 80% and 92.7% of the participants thought that ADR reporting is professional obligation for them before and after the session respectively. Prior to and following the session, 82.67% and 92.7% opined that pharmacovigilance should be taught in detail to healthcare professionals. About 82.54% of the participants agreed that "ADR monitoring center should be present in every hospital" before the session, which rose to 93.65% after the session (Table 3). However, prior to the session, the most common opinion was that "it depends on number of bed size in the hospitals". Coming to the practical aspect of pharmacovigilance, before the session, 60% of participants said that "they had experienced ADR in patient during their professional practice", out of which only 18.41% had reported that to the pharmacovigilance center. Prior to session, only 28.57% of the nursing students had been trained on how to report ADR (Table 4).

Q. No	Questions	Pre-Intervention (Yes/Correct)(%)	Post-Intervention (Yes/Correct)(%)	p value
12.	Have you ever experienced adverse drug reactions in your patient during your professional practice?	189(60)	175(55.56)	0.258779*
13.	Have you ever reported ADR to the Pharmacovigilance center?	58(18.41)	79(25.08)	0.042542
15.	Have you ever been trained on how to report ADR?	90(28.57)	235(74.6)	<0.0001
20.	Which of the following factor discourage you from reporting ADRs?	134(42.54)	132 (41.9)	0.871835*

[$p < 0.05$= significant by using Chi-square test]
(* represents Non-significant values)

Table 4: Practice about Pharmacovigilance among Participants (N =315)

The following factors were found to discourage participants from reporting ADRs. Pre-intervention, 42.54% of the respondents faced difficulties in deciding whether an ADR has occurred or not, which very slightly decreased to 41.9% post-intervention (Table 4).

The lack of time to report ADR was another factor which also decreased from 30.48% before the session to 22.86% after. Prior to the session, participants opined a lack of remuneration as a discouraging factor at 16.83%, which slightly increased to 18.73% post-session.

		Mean ± SD	SEM	p value
Knowledge	**Pre**	2.28±0.73	0.06	0.39*
	Post	2.35±1.08	0.09	
Attitude	**Pre**	1.41±0.14	0.03	0.006
	Post	1.17±0.10	0.02	
Practice	**Pre**	2.05±0.55	0.14	0.104*
	Post	1.84±0.67	0.17	

[$p < 0.05$= significant by using Chi-square test]
(* represents Non-significant values)

Table 5: Comparison of Mean KAP Scores before and after Intervention (N= 315)

A paired t-test was conducted to evaluate the impact of the intervention on mean KAP scores. The mean knowledge score increased from 2.28 ± 0.73 before the intervention to 2.35 ± 1.08 after the intervention. The mean attitude and mean practice score decreased from 1.41 ± 0.14 and 2.05 ± 0.55 to 1.17 ± 0.10 and 1.84 ± 0.67 respectively (Table 5).

4. Discussion

The present study assesses and compares the knowledge, attitude and practice (KAP) of nursing students regarding pharmacovigilance and ADR reporting before and after a training session. It highlights the effectiveness of such educational session for nursing students to raise awareness and increase adverse event reports. Prior to the training, only 78.41% students correctly defined pharmacovigilance. This was higher (58.6%), (52.68%) and (52.7%) than that reported in other studies respectively. However, post training session, a marked improvement was observed, with 89.2% correctly defining pharmacovigilance [19-21]. A crucial observation from this study was an increase in the number of participants correctly identifying the Directorate General of Drug Administration (DGDA) as the organization responsible for monitoring ADRs in Bangladesh, from 53.02% to 83.5% following the training session. This was comparable to the finding, in which the correct response to the same question rose from 52% to 86% among the intern physicians. Also, a significant rise in identifying Sweden as the location of international center for ADR monitoring was observed from 25.39% to 89.2% in this study; which was similar (from 27% to 89%) too [9]. The percentage of respondents who believed ADR reporting to be a professional obligation for them improved from 80% to 92.7% with support for teaching pharmacovigilance in detail to healthcare professionals from 86.67% to 92.7%. This is consistent with similar study findings by Gafoor et al.which demonstrated favorable attitude of nursing students towards pharmacovigilance.

Before the session, about 64.13% participants had read articles on prevention of ADRs. This is similar (65.3%) to other findings by Gupta et al. [18]. After the session, about 93.65% of the participants agreed that ADR monitoring center should be located in every hospital which was similar (92%) to the findings made by Rajalakshmi et al. [22].

After the session, most of the participants (97.14%) acknowledged the fact that anyone can report ADR which is comparable (93%) to Shamsuddoha et al. [9] and higher (85%, 85.7%) than that reported by Rasel et al. and Gafoor et al. respectively [19,23]. In terms of practice, 60% of participants had experienced ADR in patients during their professional practice, which is comparable (55%) to Shamsuddoha et al. [9]. However, only 18.41% of them had reported ADR to the pharmacovigilance centre. This is higher (6.45%) than Gosavi et al. but lower (38.6%) than Gafoor et al. [19,20]. This might be as a result of only 12.06% of them knew about pharmacovigilance committee in their institute, a proportion lower (71.3%) than the finding of Gupta et al. [18]. Furthermore, in the assessment of factors discouraging them from ADR reporting, most of the participants had marked difficulties in deciding whether ADR had occurred, both in pre-intervention (42.54%) and post-intervention (41.9%). This finding is higher (32.67%) than the finding of Rajalakshmi et al. [22] but lower (68.82%) than Gosavi et al. [20].

5. Conclusion

The present study observed that knowledge, attitude, experience and trainings regarding pharmacovigilance was not adequate among nursing students, but after the training session, most of the parameters increased significantly. The educational intervention effectively improved the knowledge and importance of pharmacovigilance, positive attitude in responsibility, and competency of ADR reporting in practice among the nursing students.

So, educational intervention can contribute significantly to increase the knowledge and to change the attitude of nurses in practical aspects towards pharmacovigilance, thereby ensuring the safety of drugs. Therefore, hands-on training and practical educational sessions for nursing professionals should be encouraged.

Declarations

Funding:

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Conflict of Interest:

The authors declare no conflict of interest.

Ethical Approval:

The study was approved by theInstitutional Ethical Review Board (IERB) of Holy Family Red Crescent Medical College with reference number: IERB/44/Aug/2025/02/HF.

Author Contributions:

All authors contributed in drafting the work, revised it critically for intellectual content, approved the version to be published; and agreed to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Morshed Nasir developed the study design, methodology, conceptual questionnaire, ethical clearance, overall review. Sumaiya Nousheen wrote the main manuscript text, analysis of data, prepared the tables, checked plagiarism and grammar.

Sandra Rumi Madhu and Golam Kibria contributed in data collection, arrangement of intervention, reviewed the manuscript.

Data Availability Statement:

Data available upon reasonable request.

AI Usage Statement:

AI tools were not used at all.

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