



Evaluating Pharmacovigilance Awareness and Attitudes Among Pharmacy Undergraduates: Insights into from R. P. Shaha University, and Retrospective Study in Bangladesh

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ABSTRACT

Pharmacovigilance aims to ensure the safe and appropriate use of medicines after they become available to the public. Enhancing pharmacy students' understanding of pharmacovigilance is essential because future pharmacists are expected to identify and report adverse drug reactions (ADRs) encountered during clinical practice. Therefore, this study assessed the knowledge, attitudes, and perceptions (KAP) related to pharmacovigilance among students of the Department of Pharmacy at R. P. Shaha University, Narayanganj-1400, Bangladesh. A questionnaire-based survey was employed to examine students' KAP regarding pharmacovigilance. The participants included second-year, pre-final-year, and final-year pharmacy students. Statistical techniques were applied to analyze the collected data and generate the findings. The investigation was conducted on the university campus and involved 70 currently enrolled pharmacy students. The results revealed substantial awareness of ADRs and pharmacovigilance concepts (94.3%), accompanied by generally positive attitudes (72.9%). Nevertheless, gaps remained regarding practical aspects of ADR reporting, particularly knowledge about reporting procedures, responsible authorities, and reporting locations. The findings indicate the need for additional training programs and incentive-based initiatives to strengthen pharmacovigilance practices among pharmacy students.

1. INTRODUCTION

According to the World Health Organization (2002), pharmacovigilance refers to the science and activities concerned with the identification, assessment, understanding, and prevention of adverse effects and other medicine-related problems. In Bangladesh, ADRs represent a significant healthcare concern. Evidence published in the Research Journal of Pharmacy and Technology suggests that as many as 8.5% of hospital admissions may be associated with adverse drug reactions (Amin et al., 2015). Several medicine-related risks, including side effects, drug interactions, and toxic reactions, may only emerge long after a product enters the

market. Certain rare adverse reactions, occurring in approximately one out of every 100,000 users, often become detectable only after widespread use of a medication (Oberg, 1999). Consequently, a robust pharmacovigilance system remains essential for identifying such uncommon drug-related events.

Pharmacovigilance programs have contributed significantly to the detection of ADRs and the removal of unsafe medications from the market. Despite these achievements, underreporting of ADRs continues to be a major challenge affecting the effectiveness of such programs (Ponmari et

al., 2015). Because countries differ in prescribing patterns, regulatory frameworks, drug availability, and patient responses to medications, the World Health Organization recommends that every nation maintain its own pharmacovigilance program (World Health Organization, 2002).

Previous investigations have identified inadequate awareness and limited understanding of ADR reporting among pharmacy students, highlighting the necessity of addressing this educational gap to strengthen pharmacovigilance systems (Akhtaruzzaman et al., 2021). Several barriers may discourage students from reporting ADRs, including time limitations, perceptions that individual cases are unimportant, concerns regarding increased academic workload, and fear of legal repercussions (Loke et al., 2011).

Research conducted by Khan et al. (2017) demonstrated that although students often express confidence in their ability to recognize and manage ADRs, their actual competency may be insufficient. This discrepancy underscores the importance of enhancing pharmacovigilance education within pharmacy curricula in Bangladesh. To address these concerns, several initiatives have recently been introduced, including a nationwide awareness campaign launched by the Directorate General of Drug Administration (DGDA) to promote ADR reporting and improve public and professional awareness of pharmacovigilance practices (Directorate General of Drug Administration, 2021).

The present study was undertaken to examine and evaluate the knowledge, attitudes, and perceptions regarding pharmacovigilance among current pharmacy students enrolled at R. P. Shaha University.

2. METHODS AND MATERIALS

2.1. Study Design

The study was carried out at R. P. Shaha University, located in Narayanganj-1400, Bangladesh. A survey-based research design was adopted and implemented on September 17, 2024,

to assess students' knowledge, attitudes, and perceptions concerning pharmacovigilance. Data collection was performed using a structured questionnaire that included sections on demographic characteristics and pharmacovigilance-related knowledge, attitudes, and practices. The target population consisted of undergraduate students currently studying in the Department of Pharmacy. Participation was restricted to individuals who voluntarily provided informed consent.

2.2 Sampling Technique

A stratified random sampling approach was utilized to ensure representation from different academic levels and to include students with prior exposure to ADRs and pharmacovigilance concepts. For classification purposes, third-year students were categorized as pre-final-year students, whereas fourth-year students were considered final-year students.

2.3 Data Collection and Analysis

The questionnaire was developed following an extensive review of relevant literature and was based on validated instruments and previously published studies. Printed questionnaires were distributed to participants to facilitate reliable and authentic data collection. Completed questionnaires were gathered and reviewed before analysis. Statistical analyses were conducted using SPSS software, and the findings were presented in the form of frequencies and percentages.

2.4 Ethical Statement

The research was conducted in accordance with the principles outlined in the Declaration of Helsinki. Ethical approval was obtained from the Ethics Committee of R. P. Shaha University, Narayanganj, Bangladesh (Ref: RPSU/EC/Phr/2024/02).

3. RESULTS

The study was conducted with 70 students and the KAP about pharmacovigilance were evaluated. Of these, 27 (38.57%) were second year students, 19 (27.14%) were pre-final year students and 24

(34.29%) were final year students. The distribution of students' involvement at these academic levels are shown in Figure 1.

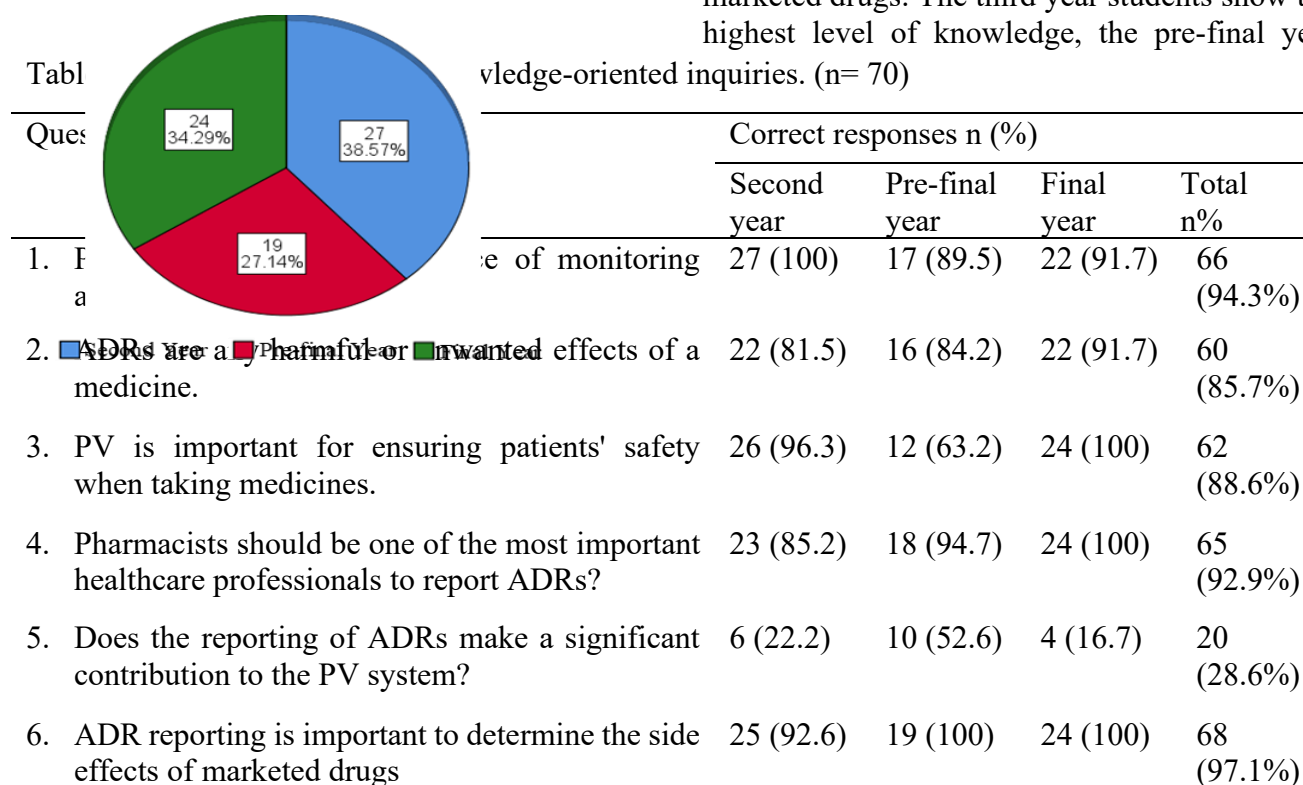


Figure 1: Stratification of student involvement in the study

3.1 Analysis of Knowledge

The answers to the knowledge based questions are summarized in Table 1. Of the 70 people who participated in the study across the academic years, about 94% correctly identified PV, and 86% identified ADRs. Regarding the importance of PV for patient safety, 89% of the students recognized its importance. Notably, 93% felt that pharmacists should play a key role in reporting of ADRs. There was however, a difference in the perception of the role played by ADRs reporting in the PV system, with about 29% of the second year students and 53% of the final year students acknowledging the importance of the role played

by ADRs reporting in the PV system. Nonetheless, 97% of students recognized ADRs reporting's significance in assessing side effects of marketed drugs. The third year students show the highest level of knowledge, the pre-final year

knowledge-oriented inquiries. (n= 70)

students show lower comprehension of the knowledge level of pharmacovigilance compared to second year students and final year students. PV: Pharmacovigilance, ADRs: Adverse drug reactions

3.2 Analysis of Attitude

Table 2 indicates that there are significant trends in the analysis of attitude-oriented queries of students from various academic years. The final year students are the most familiar with pharmacovigilance and ADRs (95.8%), then pre-final year students (42.1%) and second year students (14.8%). They also report the highest level of agreement that it is a professional duty to report ADRs (91.7%) as opposed to second year students (74.1%) and pre-final year students (47.4%). In addition, the final year students have the highest level of agreement on the contribution of PV to patient safety (100%), while pre-final year students are 92.9% and second-year students 85.2%. Second year students see it as most

Table 2: Students feedback to Attitude-oriented inquiries. (n = 70)

Question	Response	Second year	Pre-final year	Final year	Total n%
Are you aware of pharmacovigilance and its function in monitoring adverse drug reactions (ADRs)?	NO	23 (85.2)	11 (57.9)	1 (4.2)	35 (50)
	YES	4 (14.8)	8 (42.1)	23 (95.8)	35 (50)
Do you believe that reporting adverse drug reactions is a professional	NO	7 (25.9)	10 (52.6)	2 (8.3)	19 (27.1)
Question	YES	20 (74.1)	9 (47.4)	22 (91.7)	51 (72.9)
	Response	Second year	Pre-final year	Final year	Total n%
pharmacovigilance play an important role in enhancing patient safety?	YES	23 (85.2)	19 (100)	23 (95.8)	65 (92.9)
Do you consider it necessary to know the appropriate channels for reporting ADRs?	NO	25 (92.6)	15 (78.9)	12 (50.0)	52 (74.3)
	YES	2 (7.4)	4 (21.1)	12 (50.0)	18 (25.7)
Have you ever read any article related to the prevention of adverse drug reactions?	NO	21 (77.8)	10 (52.6)	17 (70.8)	48 (68.6)
	YES	6 (22.2)	9 (47.4)	7 (29.2)	22 (31.4)
Have you previously come across an ADR reporting form?	NO	26 (96.3)	17 (89.5)	16 (66.7)	59 (84.3)
	YES	1 (3.7)	2 (10.5)	8 (33.3)	11 (15.7)

important (92.6%) while pre-final year students see it as equally important (78.9%) but final year students see it as less important (50%). The articles about preventing ADRs are the most popular among pre-final year students (47.4%), followed by final-year students (29.2%) and second-year students (22.2%). The highest exposure to ADRs reporting forms is for 2nd year

students (96.3%), followed by pre-final year students (89.5%) and final year students (66.7%). PV: Pharmacovigilance, ADRs: Adverse reactions of drugs.

Table 3: Students feedback to Perception-oriented inquiries (n=70)

Improving ADRs reporting can improve the overall health system by educating about unknown adverse effects of medicines?	NO	1 (3.7)	0 (0.0)	0 (0.0)	1 (1.4)
	YES	26 (96.3)	19 (100)	24 (100)	69 (98.6)
As a pharmacist, we should be more aware about the ADRs reporting system in Bangladesh?	NO	1 (3.7)	1 (5.3)	1 (4.2)	3 (4.3)
	YES	26 (96.3)	18 (94.7)	23 (95.8)	67 (95.7)
Do you report ADRs?	NO	25 (92.6)	15 (78.9)	22 (91.7)	62 (88.6)
	YES	2 (7.4)	4 (21.1)	2 (8.3)	8 (11.4)

3.3 Analysis of Perception

Analysis of Perceptions of Students Data: The analysis shows that students are aware of ADRs but not much reporting is done. 96.3% of second year students think that the health system will be better if the reporting of ADRs improves, and

100% of pre-final and final year students agree. Likewise, 96.3%, 94.7% and 95.8% of the 2nd year, pre-final year and final year students respectively believe that Pharmacists should have better knowledge about the ADR reporting system in Bangladesh. However, only 7.4% of students in

their second year, 21.1% in their pre-final year and 8.3% of students in their final year report any ADRs. To bridge this, training programs are recommended to be improved, incentives offered, mentorship programs to be introduced, reporting of ADRs to be included in the curriculum, and ongoing awareness campaigns. The steps are designed to transform high awareness into active reporting, which will help to enhance health outcomes and improve the health reporting system in ADRs in Bangladesh.

ADRs: Adverse drug reactions

4. DISCUSSION

The findings indicate that pharmacy students possess a strong theoretical understanding of pharmacovigilance; however, practical engagement in ADR reporting remains limited. Most participants correctly identified pharmacovigilance as a system for monitoring adverse drug reactions (94.3%), while 85.7% recognized ADRs as harmful or unintended effects of medications. Nevertheless, only 28.6% acknowledged the substantial contribution of ADR reporting to the pharmacovigilance system.

Student attitudes toward pharmacovigilance were generally positive. Approximately half of the respondents were familiar with the role of pharmacovigilance in monitoring ADRs, while 72.9% regarded ADR reporting as a professional responsibility. Furthermore, 92.9% believed that pharmacovigilance contributes significantly to patient safety. Despite these encouraging attitudes, practical knowledge remained inadequate, as only 25.7% knew the appropriate channels for ADR reporting and 84.3% had never encountered an ADR reporting form.

Perception-related findings were highly favorable. Nearly all participants (98.6%) believed that improved ADR reporting could strengthen the healthcare system through increased awareness of previously unidentified medication-related adverse effects. Similarly, 95.7% agreed that pharmacists in Bangladesh should possess greater knowledge regarding ADR reporting systems. Despite these positive

perceptions, actual reporting behavior was limited, with only 11.4% of students reporting ADRs.

A previous study conducted among medical students in Bangladesh reported even lower levels of awareness, revealing that fewer than half of the respondents were familiar with ADRs and only 42.5% had knowledge of pharmacovigilance (Rahman et al., 2019). In the current study, pre-final-year students exhibited the highest level of involvement, with complete recognition of the importance of ADR reporting and the highest reporting rate (21.1%). This pattern was not observed among students in other academic years..

5. CONCLUSION

The study demonstrates that pharmacy students possess satisfactory knowledge and generally positive attitudes toward pharmacovigilance. However, deficiencies remain in the practical application of this knowledge, particularly concerning ADR reporting procedures. Among the participating groups, pre-final-year students displayed the greatest level of engagement. Strengthening experiential learning opportunities, expanding awareness initiatives, and establishing mentorship programs may help translate theoretical understanding into active participation in ADR reporting. Such measures could ultimately contribute to improved patient safety and a more effective pharmacovigilance system.

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