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Original Research Article

Evaluating Medical Students' Knowledge, Attitudes, and Practices in Pharmacovigilance: A Cross-Sectional Study

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Abstract: ***Background:*** It is an indispensable tool for ensuring patient safety, while its practice raises numerous questions in developing countries, including Bangladesh. This paper aims at determining medical students' Knowledge, attitude and practice (KAP) of pharmacovigilance to inform ADR reporting. ***Objective:*** To evaluate the KAP of pharmacovigilance with second-year students, final-year students, and interns enrolled in a community-oriented medical college in Bangladesh. ***Methods:*** A quantitative study design using the cross-sectional survey approach was used together with a self-administered, well-validated structured questionnaire. Second-year, final-year, and intern groups were selected with one hundred participants from each group. Descriptive statistical analysis and chi-square analysis were used in data analysis. ***Results:*** A total of 49 percent of the participants were able to correctly define pharmacovigilance; final-year students had the highest knowledge score of 72 percent. A total of 80–85% of the participants endorsed the need to report ADRs, and 75–84% believed that reporting ADRs is a professional responsibility. However, ADR reporting practice varied significantly: In the final-year students, 90% reported having filled out an ADR form, while the corresponding numbers for second-year students and interns were 12% and 34%, respectively. While 70-90% of the participants claimed to have ever been trained on how to report an ADR, only 20-28% of the participants reported to have ever experienced an ADR. ***Conclusion:*** Thus, though attitudes toward pharmacovigilance were mostly positive, major knowledge and practical implementation deficits were found, mainly concerning interns. The study underscores the need for enhanced systematic, comprehensive, and clinically focused instruction in pharmacovigilance learning in medical schools. This paper recommends that foresulfide should strengthen the existing knowledge prerequisite, integrate compulsory continuous education programs, advance practical practice, and smoothen the procedure of reporting ADRs to amplify the practices in pharmacovigilance among future healthcare human resources of Bangladesh.

Keywords: Pharmacovigilance, ADR reporting, KAP, Questionnaire.

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INTRODUCTION

Pharmacovigilance, which is a part of the extremely broad field of drug safety and is the science as well as the activities involved in the development, identification, evaluation, monitoring, and prevention of adverse effects or any other drug-related problems, is most important in the protection of patient and public health [1]. Being the first responsible actors in clinical practice, medical professions face ADRs regularly in their work. Hence,

awareness of pharmacovigilance is critical for the overall effectiveness of ADR reporting systems, particularly in relation to their knowledge, attitudes, and practices [2]. According to the WHO, adverse drug reaction means "any response to a drug which is noxious and unintended and which occurs at the dose normally used for the management of the patient." It is a common and costly problem that affects millions of patients, and research indicates that ADRs could be the cause of 5% to 20% of hospitalization [3]. Like in many developing countries, the pharmacovigilance system in Bangladesh is not well established and developed yet. The ADRMS was first set up by the Directorate General of Drug Administration (DGDA) of Bangladesh in 2013 as the Adverse Drug Reaction Monitoring (ADRM) Cell [4]. However, the effectiveness of this program will be highly dependent on the reporting of ADRs by healthcare professionals. Medical students are important stakeholders in the future of pharmacovigilance in the country, as they are the future practitioners of health care. As practicing physicians, their knowledge, attitudes, and practices towards ADR reporting will be manifested in their future behaviors [5]. Hence, being able to evaluate and enhance their knowledge in pharmacovigilance during their college years is important. The need to incorporate pharmacovigilance education in the curriculum cannot be overemphasized, as numerous studies have shown [6]. A study revealed that enhancing undergraduate medical curriculum with pharmacovigilance education was effective as it improved the knowledge and attitudes of students towards reporting ADRs [7]. The importance of regular updates and training measures for pharmacovigilance among medical students and healthcare professionals. However, despite the acknowledged need for pharmacovigilance, under-reportage of ADRs is still a major problem all over the world. The reasons that have been identified include ignorance on how to go about the reporting process, doubt on the cause-and-effect link between the drug and the adverse event, lack of time, and legal repercussions [8]. A few studies have been done in this regard in the Bangladeshi context to evaluate the attitudes and knowledge of medical students and pharmacists toward pharmacovigilance. Therefore, the purpose of the current study is to fill this gap by assessing these aspects among medical students at different phases of study in a community-based medical college in Bangladesh. Through an assessment of the current state and areas of opportunity, this study aims to contribute to improving pharmacovigilance education and practice in the country [9].

The objective of this study was to determine the level of pharmacovigilance knowledge among second-year students, final-year students, and interns and to ascertain their attitudes toward ADR reportage as well as their current practice of the same. Moreover, it aimed at finding out challenges that may hinder effective pharmacovigilance practice among medical students. The implications aimed at providing recommendations that may be useful in curriculum formulation and policy formation for the education and training of pharmacovigilance in Bangladesh. Thus, meeting these objectives, the study will help improve the teaching of pharmacovigilance in the medical curriculum and, therefore, the practice of safer medicine for the patients.

METHODS

Study Design and Setting

This quantitative research was a cross-sectional study carried out in a community-based medical college hospital in Bangladesh using self-administered questionnaires. The emphasis was made on the two-month study period from June 2023 to August 2023. The target population included second-year undergraduate medical students, final-year undergraduate medical students, and interns. These groups were chosen because they are at different levels of their medical training and in contact with the healthcare setting. The study involved 300 participants from the second-year students, final-year students, and interns, each with an equal number of 100. In this study, convenience sampling was adopted in order to select participants.

Data Collection

A structured questionnaire was developed based on previous similar studies and adapted to the local context. The questionnaire was designed to assess three main domains:

- Knowledge of pharmacovigilance and ADR reporting
- Attitudes towards pharmacovigilance and ADR reporting
- Practices related to ADR reporting

To ensure the face validity of the questionnaire, it was reviewed and approved by pharmacology and medical education specialists. These 30 questions were pre-tested on 10 students from each group to check the ease of understanding of the questions. These responses were excluded from the analysis. The participants were administered self-report questionnaires after having received an informed consent. They were allowed 30 minutes to fill the questionnaire independently under proctorship to avoid influence.

Data Analysis

The data collected were entered and analyzed using Statistical Package for Social Sciences

(SPSS) version 25. Frequency distributions and percentages were employed to describe the demographic data and the responses. For the comparison of the responses between the three groups, chi-square tests were employed. 05 was considered statistically significant.

RESULTS

The study included a total of 300 participants, with equal representation from second-year students, final-year students, and interns (100 each). The response rate was 100%.

Table 1 presents the correct answers to the questions testing the pharmacovigilance and ADR reporting knowledge. Remarkably, 49% of participants commented accurately on what pharmacovigilance entails, with final-year students performing better at 72%. Further, only 82% of second-year students, 75% of final-year students, and 30% of interns were able to answer the question on who can report ADRs. Specific knowledge about the pharmacovigilance program in Bangladesh was found to be higher amongst final year students (80%) as opposed to interns (25%).

Table 1: Correctly respond to pharmacovigilance knowledge and ADRS pharmacovigilance reporting.

Question	Second Year N (%)	Final Year N (%)	Intern N (%)
What is pharmacovigilance?	50 (50%)	72 (72%)	25 (25%)
The most important purpose of pharmacovigilance is	60 (60%)	70 (70%)	32 (32%)
What is an adverse event?	65 (65%)	75 (75%)	35 (35%)
Who can report ADRs?	82 (82%)	75 (75%)	30 (30%)
Do you think ADR reporting is professional responsibility?	75 (75%)	70 (70%)	40 (40%)
Are you aware of pharmacovigilance programme of Bangladesh?	45 (45%)	80 (80%)	25 (25%)
Which regulatory body is responsible for monitoring of ADR?	60 (60%)	55 (55%)	26 (26%)
International units for ADR monitoring is located in	58 (58%)	54 (54%)	35 (35%)
What type of ADR should be reported?	82 (82%)	60 (60%)	24 (24%)
What is a serious adverse effect?	60 (60%)	84 (84%)	35 (35%)

Table 2 highlights the views of the participants with regard to pharmacovigilance and ADR reporting. A large proportion (80-85%) supported the need to report ADR, with 75-84% regarding it as a professional duty. However, a notable difference was observed in perceptions of the ADR form's complexity: while 67% of second-year students and 50% of the interns reported the form as being challenging to fill, only 15% of the final-year students had the same opinion. Also, more than 90% of subjects in all groups were very firm with their opinion that pharmacovigilance should be thoroughly taught to the professional health care givers.

Table 2: Attitude towards pharmacovigilance and ADR reporting

Question and Response	Second Year n (%)	Final Year n (%)	Intern n (%)
ADR reporting is necessary			
Yes	80 (85.1%)	82 (82.0%)	40 (80.0%)
No	14 (14.9%)	18 (18.0%)	10 (20.0%)
Is ADR reporting a professional obligation			
Yes	83 (83.0%)	75 (75.0%)	42 (84.0%)
No	17 (17.0%)	25 (25.0%)	8 (16.0%)
ADR form is complex to fill			
Yes	67 (67.0%)	15 (15.0%)	25 (50.0%)
No	33 (33.0%)	92 (92.0%)	26 (52.0%)
Do you think pharmacovigilance should be taught in detail			
Yes	92 (92.0%)	85 (85.0%)	47 (94.0%)
No	8 (8.0%)	15 (15.0%)	3 (6.0%)
ADR reporting will ensure patient safety			
Yes	94 (94.0%)	85 (85.0%)	48 (96.0%)
No	6 (6.0%)	15 (15.0%)	2 (4.0%)

The practices of participants concerning ADR reporting are highlighted in Table 3 below. However, 20–28% indicated they have ever had an ADR across all the groups. Nonetheless, 90% of the final-year students stated that they had filled out the ADR form, with percentages of 12% for the second-

year students and 34% of interns. However, there was a variation in the level of training received by the participants on ADR reporting; up to 90% for some groups while as low as 70% for others.

Table 3: Practice of ADR reporting

Question and Response	Second Year n (%)	Final Year n (%)	Intern n (%)
Do you experience ADR			
Yes	25 (25.0%)	28 (28.0%)	10 (20.0%)
No	75 (75.0%)	70 (70.0%)	40 (80.0%)
Have you seen an ADR reporting form			
Yes	55 (55.0%)	90 (90.0%)	32 (64.0%)
No	40 (40.0%)	5 (5.0%)	20 (40.0%)
Have you reported ADR or filled ADR form			
Yes	12 (12.0%)	90 (90.0%)	17 (34.0%)
No	90 (90.0%)	9 (9.0%)	33 (66.0%)
Have you ever been trained on how to report ADR			
Yes	80 (80.0%)	90 (90.0%)	35 (70.0%)
No	20 (20.0%)	4 (4.0%)	12 (24.0%)

DISCUSSION

The present research can be helpful in understanding the Knowledge, attitude and practice (KAP) of medical students regarding pharmacovigilance in Bangladesh. This study provides information on the positive progress and potential deficits of pharmacovigilance education and practice. The outcomes suggest that the participants possess a fairly good level of pharmacovigilance, though the variations across the different years of study are quite distinctive. The fact that only 49% of the respondents were able to provide a correct definition of pharmacovigilance supports the notion that there is insufficient focus placed on teaching the basics of the field to students. This percentage is lower than the one detected by Gupta and Udupa (2011) [10] among the Indian participants- only 60% of the participants had a notion of pharmacovigilance. Perhaps, remarkably, the final-year students displayed the greatest level of knowledge among all the aspects measured, and this was higher even than that of the second-year students and interns. This could be due to the fact that final-year students who participated in the study were completing their pharmacology courses, which contain modules such as pharmacovigilance. The lower level of pharmacovigilance knowledge in the interns indicates that the knowledge might be decaying over the years, and therefore there is a need for refresher courses throughout one's medical study and practice. The improvement of the high awareness of second-year (82%) and final-year students (75%) who recognize who can report ADRs indicates a positive knowledge advancement among the students. Nevertheless, a 30% decrease in this awareness among interns requires further investigation. The problem may be caused by failure to cover ADR reporting during internship training or a gap between knowledge and experience. The study captures an overall positive attitude toward pharmacovigilance among all the groups. This percentage reflects the results of other studies, such as Kulmi *et al.,* (2017) [11], where 97% of participants in India saw the need for ADR reporting. ADR reports were identified by 3% of participants as important. This positive attitude has therefore laid a positive framework for enhancing pharmacovigilance practices. However, since ADR forms have been perceived to be complex, especially by the second-year students at 67% and interns at 50%, this may hinder reporting on the same. Same findings have been found in other countries, like a study, Bello & Umar (2011) [12] where they established that difficulty in completing the reporting form was a major factor that discouraged ADR reporting. The complexity of the ADR reporting process and lack of thorough practical experience in performing it could be the reason behind this. Nevertheless, the very high percentage of all participants who recognized the need for detailed pharmacovigilance education (>90%) confirms their awareness of its necessity in the medical field. This enthusiasm should be tapped into to help improve the curricula and training programs in pharmacovigilance. Here we see that the practice of ADR reporting differs across the study groups with a fairly large degree of variation. Out of all students, final-year students recorded the highest completion rate of the ADR form at 90 percent, a clear indication that practical training is properly enhanced during the final academic year. However, the low rates among the second-year students (12%) and interns (34%) show the discrepancy between knowledge/attitudes and practice. Although more than 70-90% of the participants said they had been trained on ADR reporting, the rate of the actual reporting by the participants, especially interns, is significantly lower than their reported reception of the training. This finding is in concordance with another study conducted by Katekhaye *et al.,* (2017)

[13] in India that also indicated a similar gap between training and practice. The low rate of ADR experiences reported by participants (20–28%) could be attributed to low clinical exposure, mainly among second-year students. But it may also mean that ADRs are underreported in clinical practice, suggesting the importance of better education about ADR recognition and notification.

The following recommendations drawn from the study can improve pharmacovigilance education and practice: First, fundamentals must be enhanced by teaching principles that encompass all areas of knowledge and make pharmacovigilance understanding clear at each stage of studying. Other aspects include continuous education, including routine revision courses and workshops for interns and practicing physicians in a bid to combat knowledge lapse and place emphasis on pharmacovigilance. By granting more practical training through producing additional case-based learning for ADR reporting, as well as reporting practice during clinical placements, the knowledge-practice gap can be narrowed. Easing the reporting of ADRs by working with the regulators or using technology will be helpful in reporting ADRs. Incorporation of pharmacovigilance into internship training and assessment can also enhance its use in practice for additional exposure. Furthermore, establishing motivation-promoting measures like awards and incentives, as well as cooperation with other professionals from other sectors of healthcare, can contribute to a stronger pharmacovigilance setting.

Limitations

This research has several limitations. The cross-sectional design is used to observe subjects at a single point in time, which limits the capability to determine cause-and-effect relationships or study longitudinal change. The technical limitation of having only one institution means that the findings may not apply universally. Self-administered questionnaires may be vulnerable to response distortion in terms of social desirability. Subsequent research should be based on multiple centers, have a longitudinal design, and incorporate measures of knowledge and behavior.

CONCLUSION

The findings of this research offer useful information about the existing level of pharmacovigilance awareness, perception, and implementation among the medical students of Bangladesh. Although progressive changes have been observed in the recent period, especially in the perception of pharmacovigilance, there are still crucial deficiencies in the knowledge and implementation of pharmacovigilance, especially among interns who are on the verge of direct independent professional practice. The results emphasize a necessity for improved intensity, duration, and practicality of the pharmacovigilance teaching in the medical curricula. If the above-mentioned gaps are filled and the positive attitude of students is incorporated, medical educators and policymakers can contribute to developing a stronger culture of pharmacovigilance in Bangladesh. Finally, the enhancement of pharmacovigilance education and practice among the students comes into play to increase health standards and the safety of patients. This study provides an evidence base for the subsequent research and intervention initiatives designed to improve the pharmacovigilance system in Bangladesh and other comparable healthcare systems.

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