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Impact of Educational Intervention on Medical Students' Knowledge, Attitude and Skills in Completing the Bangladesh National Suspected Adverse Event Reporting Form: A Multicenter Approach in Chattogram

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Abstract **Original Research Article**

Background: Underreporting of adverse drug reactions (ADRs) remains a challenge in pharmacovigilance due to ignorance, poor attitudes, and limited hands-on training. The purpose of the study is to evaluate the impact of a practical educational intervention on the knowledge, attitude, and skills of undergraduate medical students in completing the Bangladesh National Suspected Adverse Drug Reaction (ADR) Reporting Form. ***Methods:*** This quasi-experimental study evaluated the impact of a practical educational intervention on the knowledge, attitude, and form-filling skills related to ADR reporting among 548 third-year medical students across four medical colleges in Chattogram, Bangladesh. The name of the medical colleges was anonymized and labeled as A, B, C, and D. Students completed a pretest using multiple-choice and case-based fictitious scenarios, followed by an educational intervention session on completing the Bangladesh National Suspected Adverse Event Reporting Form (Yellow Card) and then a posttest. ***Results:*** Significant improvements were observed in knowledge ($p < 0.001$), attitude ($p < 0.001$), and form-filling skills ($p < 0.001$) after the intervention, with the highest gains seen in students from College B. ***Conclusion:*** The findings suggest that practical training is more essential than academic knowledge to enhance pharmacovigilance efforts in Bangladesh.

Keywords: Pharmacovigilance, Adverse Drug Reaction Reporting Systems, Education, Medical, Undergraduate.

INTRODUCTION

Considering the growing complexity of treatments, along with the aging of the global population and the increase in multimorbidity, adverse drug reactions (ADRs) remain a problem in modern medicine and represent a significant economic burden for healthcare systems [1, 2]. This is why a high risk of severe ADRs at hospital occurs; it would be mandatory to report ADRs as rapidly as possible (Vallano *et al*., 2005) [3]. ADR narrative plays an important role and its reporting is taken so seriously that even a law may be required to enhance it [1]. But in many countries, the reporting of ADRs was infrequent. Our neighboring country, India has ADR reporting rate of <1% as against global average of 5% and that this can be attributed to lack of knowledge and improper ADR monitoring on the part of all stake holders, that is of the health care professionals and the patients [4]. The small proportion of reporting could also mostly be attributed to poor reporting of ADRs by the stakeholders and inadequate trainingg or all [5].

Pharmacovigilance started in Bangladesh since 2013 and the official guidelines were compiled by the DGDA in 2018. Since 2013, this administration has received a total of 2,543 reports of adverse medication reactions. Of those, 740 were in 2017, 665 were in 2018

and 340 were as of June 30, 2019. Although less than 1% of ADR cases were being recorded, it has been estimated that counts of actual ADR is much higher. Based on the record of DGDA, only 6%, doctors make complaints of all, regional pharmaceutical companies 8%, international companies 59% and importers complaints 27% (New age, 2024).

Lack of knowledge, attitude and practice (KAP) among health care workers is an integral factor to underreporting [6]. Possible ADR for certain kinds of patients can be missed if restricted to only the carefully controlled conditions of clinical trials (Vegter and de Jong-van den Berg, 2007), which is why voluntary reporting suspected ADRs by health care professionals is considered one of the best signals generating activities for unexpected events and for unusual ADRs, and also provides early warning of potential safety problems before all evidence is available for an up-to-date assessment of the benefit/risk profile of the medicine [7]. Training doctors to report ADRs needs to be part of the medical curriculum. If students are taught and trained in reporting ADRs during undergraduate they can perform it as a routine in their clinical practice. Despite ethical duty, many of the doctors fail to report and that is because they are not trained well and ignorant about the process of reporting [8].

Filling this educational gap can be overcome by preparing medical students capable of reporting ADRs accurately and efficiently so that wherever they practice as physicians, they will feel a sense of responsibility to report ADRs, having developed this habit during their medical education. According to the previous BMDC curriculum (2012), pharmacology teaching included only theoretical lectures explaining the ADR reporting system, which may be insufficient without practical implementation. Although the BMDC 2021 curriculum has incorporated practical classes and examinations on ADR reporting, it does not provide specific guidance on how to conduct these sessions or assess students uniformly. As a result, teaching and assessment methods may vary across medical colleges, leading to inconsistencies in students' practical competency. This study highlights that structured educational interventions are more effective than theoretical instruction alone in improving ADR reporting skills. Furthermore, it need to integrate a standardized approach to practical training and assessment into the national curriculum to minimize variability among institutions and enhance the overall effectiveness of pharmacovigilance education. Considering this, the present study aims to estimate the effects of hands-on educational intervention in enhancing medical students' knowledge, attitude and practice of filling up National ADR Reporting Form of Bangladesh

MATERIALS AND METHODS

Study settings and student selection:

This study was conducted in Departments of Pharmacology of 4 different medical colleges in Bangladesh. All third-year MBBS students from these colleges were involved in this study. The names of Medical Colleges were kept anonymous to maintain confidentiality and were referred to as Colleges A, B, C and D. As the activities of the study were part of their medical curriculum, individual consent was not obtained separately. However, the study's objectives, procedure and data collection methods were explained to the students. Strict confidentiality measures were maintained, ensuring that all individual responses were anonymized. Participation in the assessments did not influence students' academic grades. Students who were absent during either the pretest or posttest were excluded from the study to ensure integrity and consistency of the data. It is important to note that lecture classes on ADR reporting were taken before this study in the 3rd year by the included medical colleges.

Study procedure:

The study was a quasi- experimental study. A total of 548 third-year medical students from four tertiary medical colleges participated in the study, which followed a structured three-phase approach: pre-test, educational intervention, and post-test. During the pre-test phase, students completed a knowledge and attitude questionnaire along with a case-based exercise requiring them to fill out the Yellow Card form based on a simulated adverse drug event scenario, all within a 30-minute timeframe. Following this, a 30-minute educational intervention session provided step-by-step guidance on accurately completing the ADR reporting form, including hands-on practice with a new case scenario. In the post-test phase, students repeated the same knowledge and attitude questionnaire and completed the same case scenario from the pre-test to enable direct performance comparisons. Data collected from pre- and post-tests were analyzed to assess changes in knowledge, attitudes, and practical skills.

Assessment of knowledge, Attitude and Form fill up skill:

Students' knowledge was assessed using a multiple true/false MCQ questionnaire (10 items, total score: 10). Form- fill up skill was assessed through a 20-point scoring rubric based on accurately completing the ADR form. A 5-item Likert-scale questionnaire was used to measure attitudes about ADR reporting; responses were categorized as either positive, neutral, or negative (total score: 15).

Statistical Analysis:

Data were analyzed using appropriate statistical methods to assess the effectiveness of the educational intervention. To evaluate the changes in students' knowledge, attitude, and skills, paired t-tests were

conducted to compare pretest and posttest scores within each group (intervention and non-intervention). To examine differences in posttest scores across the four medical colleges, a One-Way ANOVA followed by Post hoc test was used. A significance level of 0.05 was used for all statistical tests. Data analysis was performed using SPSS 26.

RESULTS

The paired t-test results show a statistically significant increase in students' knowledge scores after the intervention ($t = -24.252$, $p < 0.001$). The mean posttest score (7.9369) was significantly higher than the pretest score (6.7016).

Table I: Comparison of pretest and posttest knowledge score

Group	N	Mean	Standard Deviation	T value	P value
Pretest knowledge	548	6.7016	1.0512	-24.252	**< 0.001**
Post test Knowledge	548	7.9369	1.0559		

The paired t-test results indicate a statistically significant improvement in students' attitude scores after the intervention ($t = -18.143$, $p < 0.001$). The mean posttest attitude score (14.5119) was significantly higher than the pretest score (12.9781).

Table II: Comparison of pretest and posttest Attitude score

Group	N	Mean	Standard Deviation	T value	P value
Pretest Attitude	548	12.9781	1.88118	-18.143	< 0.001
Post test Attitude	548	14.5119	1.14623		

The paired t-test results show a statistically significant improvement in students' form fill-up skills after the intervention ($t = -27.230$, $p < 0.001$). The mean posttest form fill-up score (17.4151) was significantly higher than the pretest score (13.1004).

Table III: Comparison of pretest and posttest Form fill-up Skill score

Group	N	Mean	Standard Deviation	T value	P value
Pretest Form fill up skill	548	13.1004	3.88629	- 27.230	< 0.001
Post test Form fill up Skill	548	17.4151	2.47152		

The One-Way ANOVA results revealed significant differences in pretest knowledge, Attitude and Form fill up skill scores among students from the four medical colleges ($p < 0.05$). Post hoc analysis was used for further clarification of these differences.

C students had the highest pretest knowledge scores (Mean = 6.98), while A students scored the lowest (Mean = 6.41). Pairwise comparisons showed that A students scored significantly lower than both B (Mean Difference = 0.418, $p = 0.003$) and C (Mean Difference = 0.566, $p = 0.008$). However, no significant differences were observed among D, B, and C, indicating that these three colleges performed similarly in terms of pretest knowledge scores.

D students had the highest pretest attitude scores (Mean = 13.66), while B students scored the lowest (Mean = 12.61). Pairwise comparisons showed that D students scored significantly higher than both A (Mean Difference = 1.001, $p < 0.001$) and B (Mean Difference = 1.047, $p < 0.001$). However, no significant differences were observed among C, A, and B, indicating that these three colleges performed similarly in terms of pretest attitude scores.

B students had the highest pretest form fill-up skill scores (Mean = 15.74), while D students scored the lowest (Mean = 10.76). Pairwise comparisons showed that B students scored significantly higher than A (Mean Difference = 4.069, $p < 0.001$), D (Mean Difference = 4.981, $p < 0.001$), and C (Mean Difference = 3.762, $p < 0.001$). However, no significant differences were observed among A, C, and D, indicating that these three colleges performed similarly in terms of pretest form fill-up skills.

Table IV: Comparison of Pretest Knowledge, Attitude and Form fill up skill among four (4) Medical Colleges

Medical Colleges	Mean Knowledge score	Significant differences	Mean Differences	P value
A	6.41 (Lower)	B vs. A	0.418	0.003*
D (Higher)	6.64 (Higher)			
B (Higher)	6.83 (Higher)			
C (Higher)	6.98 (Higher)	C vs. A	0.566	0.008*
	Mean Attitude Score	**Significant differences**	**Mean Differences**	**P value**
A	12.65 (Higher)	D Vs A	1.00	<0.001*

D	13.66 (Higher)	D vs. B	1.04	<0.001*
B	12.61 (Lower)	C vs. B	0.531	
C	13.14 (Higher)			
	Mean Form fill up skill Score	**Significant differences**	**Mean Differences**	**P value**
A	11.67 (Lower)	B vs. A	4.06	<0.001*
D	10.76 (Lower)			>
B	15.74 (Higher)	B vs. D	4.98	<0.001*
C	11.98 (Higher)	B vs. C	3.76	<0.001*

- Notes: *p < 0.05 indicates statistical significance. Homogeneous subsets group colleges with similar mean scores. Only significant pairwise comparisons are shown.

The One-Way ANOVA results revealed significant differences in posttest knowledge, Attitude and Form fill up scores among students from the four medical colleges ($p < 0.05$). Post-hoc analysis was conducted to clarify these differences.

B students had the highest posttest knowledge scores (Mean = 8.33), while D students scored the lowest (Mean = 7.63). Pairwise comparisons showed that B students scored significantly higher than A (Mean Difference = 0.656, $p < 0.001$), D (Mean Difference = 0.707, $p < 0.001$), and C (Mean Difference = 0.599, $p < 0.001$). However, no significant differences were observed among A, D, and C, indicating that these three colleges performed similarly in terms of posttest knowledge scores.

D students had the highest posttest attitude scores (Mean = 15.08), while C students scored the lowest (Mean = 14.04). Pairwise comparisons showed that D students scored significantly higher than A (Mean Difference = 0.784, $p < 0.001$), B (Mean Difference = 0.769, $p < 0.001$), and C (Mean Difference = 1.040, $p < 0.001$). However, no significant differences were observed among A, B, and C, indicating that these three colleges performed similarly in terms of posttest attitude scores.

B students had the highest posttest form fill-up skill scores (Mean = 18.64), while D students scored the lowest (Mean = 15.11). Pairwise comparisons showed that D students scored significantly lower than A (Mean = 17.86), C (Mean = 18.46), and B (Mean = 18.64). However, no significant differences were observed among A, C, and B, indicating that these three colleges performed similarly in terms of posttest form fill-up skills.

Table V: Comparison of Posttest Knowledge, Attitude and Form fill up skill among four (4) Medical Colleges

Medical Colleges	**Mean Knowledge score**	**Significant differences**	**Mean Differences**	**P value**
A	7.68 (Lower)	B vs. CMOSMC	0.654	<0.001*
D	7.63 (Lower)	B vs. D	0.707	<0.001*
B	8.33 (Higher)			
C	7.73 (Lower)	B vs. C	0.599	<0.001*
Medical Colleges	**Mean Attitude score**	**Significant differences**	**Mean Differences**	**P value**
A	14.30 (Lower)	D vs. A	0.784	<0.001*
D	15.08 (Higher)			
B	14.31 (Lower)	D vs. B	0.768	<0.001*
C	14.04 (Lower)	D vs. C	1.039	<0.001*
Medical Colleges	**Mean Form Fill up Skill score**	**Significant differences**	**Mean Differences**	**P value**
A	17.86 (Higher)	D vs. A	2.75	<0.001*
D	15.11 (Lower)	D vs. B	3.53	<0.001*
B	18.64 (Higher)	B vs. A	0.776	0.004*
C	18.46 (Higher)	D vs. C	3.35	<0.001*

B had significantly greater knowledge improvement compared to D ($p < 0.001$) and C ($p < 0.001$). C showed significantly lower improvement compared to B ($p < 0.001$). No significant difference was observed between A and the other colleges

Table VI: Improvement of Knowledge score between four (4) medical Colleges

Medical College (I)	**Medical College (J)**	**Mean Difference (I-J)**	**Std. Error**	**p-value**
B	A	0.23606	0.13562	0.304
B	D	0.52338	0.11990	<0.001
B	C	0.74751	0.18226	<0.001
A	D	-0.28733	0.14384	0.190

Medical College (I)	Medical College (J)	Mean Difference (I-J)	Std. Error	p-value
A	C	0.51145	0.19883	0.051
D	C	0.22413	0.18846	0.634
C	B	-0.74751	0.18226	<0.001
C	A	-0.51145	0.19883	0.051
C	D	-0.22413	0.18846	0.634

B showed significantly greater improvement in attitude compared to C (p = 0.047). No other comparisons were statistically significant.

Table VII: Improvement of Attitude score between four (4) medical Colleges

Medical College (I)	Medical College (J)	Mean Difference (I-J)	Std. Error	p-value
B	A	0.06131	0.22926	0.993
B	D	0.27891	0.20268	0.515
B	C	0.8022	0.30809	0.047
A	D	-0.2176	0.24315	0.808
A	C	-0.7409	0.33610	0.123
D	B	0.52331	0.31857	0.356
C	A	-0.7409	0.33610	0.123
C	B	-0.8022	0.30809	0.047
C	D	-0.52331	0.31857	0.356

B showed significantly greater improvement in form fill-up skills compared to A (p = 0.001), D (p < 0.001), and C (p = 0.005). No significant differences were observed among A, D, and C.

Table VIII: Improvement of Form fill up skill score between four (4) medical Colleges

Medical College (I)	Medical College (J)	Mean Difference (I-J)	Std. Error	p-value
B	A	0.77651	0.19826	0.001
B	D	2.21521	0.17138	<0.001
B	C	1.9256	0.26547	0.005
A	D	-1.4387	0.22476	0.112
A	C	-0.8732	0.29721	0.321
D	B	0.5655	0.30569	0.523
C	A	-0.8732	0.29721	0.321
C	B	-1.9256	0.26547	0.005
C	D	-0.5655	0.30569	0.523

DISCUSSION

The current study was a quasi-experimental study that reflected the impact of an educational intervention with a view to increasing the level of knowledge, attitude towards Bangladesh National Suspected Adverse Drug Event Reporting form (Yellow Card) and Skill on yellow form fill up among third year medical students in multicenter medical colleges. The study is comparable with previous in which the knowledge and attitude related to yellow card filling up shown, unlike in other investigations where the KAP on ADR reporting were assessed[6]. In this investigation, however B students had the best and C students the poorest but total knowledge score improved significantly after the intervention. This endorses the significance of hands-on training in enhancing pharmacovigilance teaching. The yellow card ADR reporting form was introduced and demonstrated to students in the classroom by power point presentation. However, the students were given the Yellow Card as part of the practical class during the educational intervention, and could manipulate it. It was this hands-on involvement—an opportunity to understand/apply what they learned beyond mere concept—that reinforced their knowledge beyond theory training and enabled them to better understand the structure, content, and proper way to complete the form.

Students' positive attitude scores toward ADR reporting exhibited a statistically significant increase with the post-intervention. As reported by García-Abeijón *et al*. (2023) unawareness, complacency, inertia, low belief of the need to report ADRs and indecision are the perpetrator of underreporting [9]. To combat underreporting a mindset shift is required and driving towards performing positive rather than negative pharmacovigilance should be encouraged. However, such practical familiarity with Yellow Card reporting form can help to boost their confidence and self-confidence, thus lead to positive perceptions on ADR

reporting, and reinforce their commitment to pharmacovigilance.

There was a significant improvement in form-fill-up skills following the intervention. Previous studies evaluating education on ADR reporting have mainly been limited to a self-reported level of practice and knowledge, instead of ADR form completion quality. In addition, 89.8% of HCPs suggested that sham reporting should be included in the training and 97.6% considered practical training as important tool in increasing ADR reporting with respect to those in Turkey [10]. Teaching of its reporting system has also been indicated by neighboring countries such as India and Pakistan in their studies as a mandatory training for substantial gain [11]. According to this perspective, our current study highlights the importance of training medical students in completing AR reporting and this can be still more reinforced if case scenarios are simulated as we did. The use of these "experiential" exercises in student education might result in the enhancement of students' ADR reporting skills, and thus in their accuracy and confidence [12]. When entering clinical practice, they are thus less likely to hesitate in suspecting and reporting ADRs, which, in turn, is expected to contribute to improved pharmacovigilance and patient safety [13].

Although the intervention was successful, the difference in levels of improvement at medical colleges indicates that mediating factors such as teaching strategies, staff participation, and resource availability at the institution may affect educational outcomes [14]. Prospective research is required to investigate whether the effect is maintained over time; and if this type of intervention can lead to sustained improved actual ADR reporting behaviour in medical graduates [15].

CONCLUSION

The present research showed that the knowledge, attitude, and ADR reporting skills of medical students were significantly enhanced after structured hand-on educational intervention. Consequently, Prepared, fix and structured practical class is mandatory on ADR reporting in the under graduate medical curriculum.

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Ethical Issue

The study protocol was reviewed and approved by the Ethical Review Committee of Chattogram Maa O Shishu Hospital Medical College, Chattogram, Bangladesh. All procedures were conducted in accordance with the ethical standards of the institutional research committee.

Conflict of Interest

The authors declare that there is no conflict of interest.

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