EFFECT OF EDUCATIONAL INTERVENTION ON INTERN PHYSICIAN'S KNOWLEDGE AND ATTITUDE TOWARDS PHARMACOVIGILANCE IN SELECTED TERTIARY HOSPITALS OF BANGLADESH

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ABSTRACT

Background: Adverse Drug Events (ADEs) are a major public health issue linked to poor treatment outcomes, increased morbidity and mortality, and significant economic burdens. Pharmacovigilance, essential for detecting and preventing adverse medication effects, addresses these concerns. While initial pharmaceutical evaluations reveal only half of the potential hazards, post-marketing surveillance identifies the rest, highlighting the need for effective pharmacovigilance. However, Bangladesh lacks a robust system. Aim: This study aimed to evaluate the impact of educational interventions on intern physicians' knowledge and attitudes towards pharmacovigilance. Materials and Method: This formative interventional research was conducted among intern physicians at Dhaka Medical College Hospital, Ad-din Women's Medical College Hospital, Medical College for Women and Hospital, and Anwer Khan Modern Medical College Hospital. A total of 208 interns were recruited, with 189 completing the structured questionnaire survey. These respondents were divided into two groups: a control group (n=89) and an intervention group (n=100). Baseline and post-intervention data on knowledge, awareness, attitude, and experiences were collected via the questionnaire. The intervention group received a package of educational interventions, including workshops, focus group discussions, and key informant interviews, along with a suspected adverse event reporting form. Data analysis was conducted using an online statistical analytic calculator and Microsoft Office Excel. Results: At baseline, there were no statistically significant differences in knowledge and attitudes between the control and intervention groups. However, post-intervention, the knowledge and attitudes regarding pharmacovigilance significantly improved among the intervention group. Specifically, the knowledge of ADE reporting importance was 53.9% in the control group and 95% in the intervention group; the procedure for ADE detection and reporting was 19.1% and 91%, in the control and intervention group respectively; awareness of the yellow card system rose to 92% in the intervention group; knowledge of the location of the International Center of ADR (Adverse Drug Reaction) Monitoring was 22.5% in the control group and 89% in the intervention group; awareness of the national pharmacovigilance program was 30.3% (control) and 85% (intervention); and understanding of the responsible regulatory body in Bangladesh went upfrom 52% to 86% from baseline to after intervention. These improvements were statistically significant. Additionally, attitudes towards the necessity of ADE reporting were more positive in the intervention group, with 94% recognizing its importance compared to 78.7% in the control group. Furthermore, 91% of the intervention group considered ADE reporting a professional obligation, versus 67.4% in the control group, and 96% of the intervention group had received pharmacovigilance training. Conclusion: The educational intervention effectively improved the knowledge and attitudes of intern physicians regarding pharmacovigilance.

Keywords: Adverse drug reaction, Educational intervention, Pharmacovigilance, Intern doctors, Questionnaire.

Cite this article: Shamsuddoha N, Rahman MS, Ferdous A, Islam SA, Rahman SMR, Ahmad R, Parvin R, Sultana N.Effect of educational intervention on intern physician's knowledge and attitude towards pharmacovigilance in selected tertiary hospitals of Bangladesh. J Med Coll Women Hosp. 2024; 20(1): 50-59.

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INTRODUCTION

Medicines are the mainstay of healthcare system and are used to prevent, cure and treat different kinds of ailments. From the earliest times, they have been known to have both beneficial and unwanted effects and are considered as safe to use when their benefits outweigh their known hazards¹. When drugs are made, the focus is mainly on benefits, that is why knowing the risk of drugs remains incomplete. As a result, when a medicine is first launched into the market, it is estimated that half of the risks are known and recorded; and the remaining risks are detected in the next 10-15 years through Phase-1V clinical trials during post-marketing surveillance ADEreporting^{2,3} and here begins necessity of pharmacovigilance.

Pharmacovigilance is defined by the World Health Organization (WHO) as the science and activities associated with the detection, assessment, understanding, and prevention of adverse medication effects or other possible drug-related problems. It ensures that medicines and other health products are safe, effective, and of high quality, protecting thehealth of the public⁴.

Under the regulation of WHO- Uppsala Monitoring Committee (WHO-UMC), pharmacovigilance was introduced Bangladesh in 1996⁵ but the program became dormant due to shortage of manpower and lack of financial support. The exact scenario regarding the safety of drugs in Bangladesh is quite unclear, as enough reports have not been submitted to have a clear understanding. As per the WHO Pharmacovigilance program, every member country should send over 200 reports per million inhabitants⁶ which is far more than the present-day reporting numbers.

The topic pharmacovigilance and ADE reporting are included in our undergraduate pharmacology course curriculum. However, it is not practiced in

all medical colleges and hospitals. Studies have explained many reasons for under reporting including lack of knowledge or awareness^{7,8}, attitude or interest^{9,10}, confidence, time, cultural issues, negative attitudes¹¹ and lack of motivational factors. Lack of competences among health care professionals also contribute in under reporting^{3,12,13}.

As interns are the budding physicians who will come to serve the community, if they grow the habit of reporting ADEs, situation will improve. The proper and extensive training through educational intervention during this internship period will ensure great progress toward pharmacovigilance¹⁴. Educational intervention had been proved to be an effective tool in improving the knowledge, attitude and practice of health care professionals¹⁵ which overcame the issue of under-reporting of ADEs ¹⁶.

Considering the above-described scenario, the present study was designed by formulating a package of educational interventions suitable for intern physicians to improve their knowledge and attitude towards pharmacovigilance.

MATERIALS AND METHOD

This study was carried out from September 2019 to February 2022. The actual study began after clearance from the Institutional Review Board i.e. January 2021. It was conducted at four tertiary-level medical colleges and hospitals: Dhaka Medical (DMCH), College Hospital Medical Hospital College for Women and (MCWH), Anwer Khan Modern Medical College Hospital (AKMMCH) and Ad-Din Women's Medical College Hospital formative (ADWMCH). was It interventional research. Regarding the comparison of the sets of data, it was a before and after study. The Intern physicians of four selected medical colleges and hospitals were considered as the study population. The study places were selected by the principal investigator purposively, where tertiary healthcare facilities were available. The intervention and comparison groups were selected purposively. At least 50 intern physicians on average were available in each medical college and hospital. According to Morgan's table ¹⁷ for sample size calculation, the required sample size for 50 populations was equal to 44.

So,
For control group = 88
For intervention group = 88

The proposed study included the intern physicians of the four selected medical colleges and hospitals that met the selection criteria. All four respective medical colleges and hospitals (minimum 250 bedded or more) authorities agreed to participate and cooperate.

The intern doctors who were willing to participate in this study were included in the study.

Detailed Study Procedure:

A total of 208 interns who agreed to participate were primarily enrolled in the study following informed written consent, among which 189 intern physicians completely participated and responded throughout the study. The study was divided into two groups: control and intervention. Control group included DMCH and ADWMCH and Intervention group included MCWH and AKMMCH. A structured close-ended questionnaire was designed and adapted from previous studies were provided to the interns and was collected from them in appointed schedule. It was conducted at baseline to the knowledge, attitude, and assess experience of interns pharmacovigilance. The participants who did not return the questionnaire in time were approached again, in case of losing questionnaires, new questionnaires were provided to them and were approached again and after three approaches, the intern physicians who did notreturn back their questionnaires were considered as nonrespondents. A package of educational intervention was formulated. Before formulating the educational intervention, focus group discussion and key informant interviews were carried out so that the contents of the educational intervention became more relevant.

Focus group discussion (FGD) was arranged with the intern physicians to obtain their common viewpoint. Each FGD contained 5-7 participants. Face-tokey informant interviews conducted with the key prescribers (head of the units) of various departments of MCWH and AKMMCH to identify their perspective regarding ADE reporting as well as to find out the possible reasons behind under-reporting of ADE. Their valuable suggestions and recommendations for the improvement of such situations were gathered and later on, feedback data were analyzed systematically to identify the key theme and their opinion about the formulation of package of educational intervention.

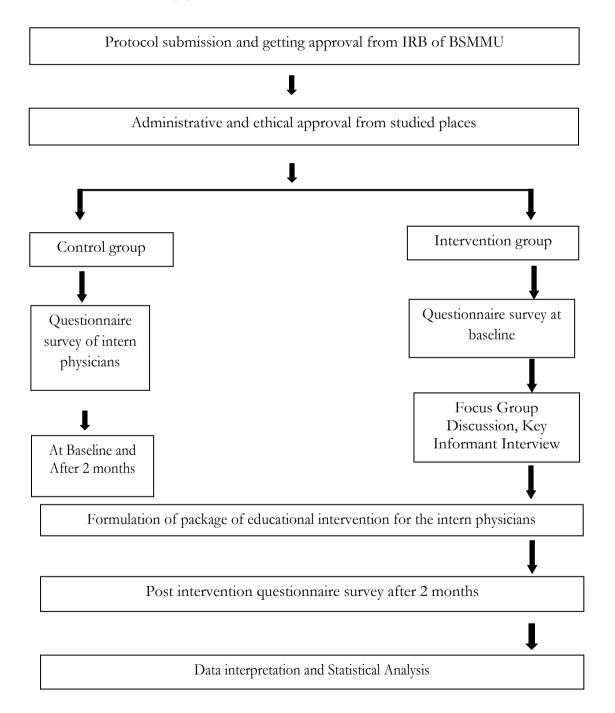
During intervention: a daylong training program and workshops were arranged in the hospitals and carried out by the researchers. It included some theoretical and practical sessions. The researcher conducted theoretical session that included information about the basic concept of ADEs along with their incidence and prevalence, how to deal with ADEs, how to detect ADEs, who can, when, where, and how to report ADEs. Practical session included creation of case scenarios of ADEs.

National guideline on the pharmacovigilance system in Bangladesh and the suspected ADE reporting forms were also disseminated. ADE reporting form was filled as per the case scenarios. Post intervention data was collected by the questionnaire survey for the intern physicians that was again conducted after 2 months of intervention to evaluate the knowledge, attitude, and experience of

interns about pharmacovigilance. The impact of educational intervention was evaluated by comparing control and intervention group. Statistical analysis was done with the frequency and percentage. Appropriate statistical tests (Two proportion Z test) was done in this study

for drawing an effective conclusion. Statistical analysis was done with the help of an online statistical calculator and Microsoft Office Excel. A *p*-value of less than 0.05 was considered significant.

Flowchart of the study procedure



RESULTS

This formative interventional research was conducted in four medical college hospitals to evaluate the effect of educational intervention on intern physician's knowledge and attitude toward pharmacovigilance.

Table 1: Assessment of knowledge and awareness of intern physicians about pharmacovigilance at baseline

Knowledge and awareness	Control Group (n=89)	Intervention Group (n=100)	Pvalue ^x
Know that ADE is to be reported	51.7% (46/89)	65% (65/100)	0.07
Know how to detect and report ADE	23.6% (21/89	16 % (16/100)	0.17
Know the responsible person for ADE reporting	22.5% (20/89)	23% (23/100)	1.00
Aware about yellow card reporting form	17.9% (16/89)	14% (14/100)	0.45
The existence of national pharmacovigilance program in Bangladesh	25.8% (23/89)	35% (35/100)	0.18
Regulatory body responsible for ADR reporting in Bangladesh	48.3% (43/89)	52% (52/100)	0.58
The location of International Center for ADR Monitoring	25.8% (23/89)	27% (27/100)	0.88

n= number of participants; Control Group: Interns of DMCH and ADWMCH where package of educational intervention was not delivered; Intervention Group: Interns of MCWH and AKMMCH where package of educational intervention was delivered; $^{x}2$ proportion Z test was done; $p \le 0.05 = \text{Statistically significant}$.

Table 2: Assessment of attitude, experience and training of intern physicians towards pharmacovigilance at baseline

Attitude, experience and training	Control Group (n=89)	Intervention Group (n=100)	<i>p</i> value ^x
Attitude of intern physicians towards necessity of ADE reporting	86.5%(77/89)	92%(92/100)	0.26
ADE reporting is a professional obligation	77.5%(69/89)	79%(79/100)	0.86
Physician's attitude towards voluntary reporting of ADE	95.5%(85/89)	90%(90/100)	0.11
Experience of ADE in any patient during training period	57.3%(51/89)	55%(55/100)	0.78
Training on ADE detection and reporting	0%(0/89)	0%(0/100)	-

n= number of participants; Control Group: Interns of DMCH and ADWMCH where package of educational intervention was not delivered; Intervention Group: Interns of MCWH and AKMMCH where package of educational intervention was delivered; $^{x}2$ proportion Z test was done; $p \le 0.05 = \text{Statistically significant}$.

Table 1 and Table 2 show that there were no significant differences observed between the baseline responses of the control and intervention groups in all aspects of knowledge, attitude, experience, and training of intern physicians towards pharmacovigilance (p > 0.05).

Table 3: Assessment of knowledge and awareness of intern physicians about pharmacovigilance after 2 months

Knowledge and awareness	Control Group (n=89)	Intervention Group(n=100)	p value ^x
Know that ADE is to be reported	53.9% (48/89)	95% (95/100)	0.00
Procedure of ADE detection and reporting	19.1% (17/89)	91.0% (91/100)	0.00
Know the responsible person for ADE reporting	21.3% (19/89)	93.0% (93/100)	0.00
Aware about yellow card reporting form	15.7% (14/89)	92% (92/100)	0.00
The existence of national pharmacovigilance program in Bangladesh	30.3% (27/89)	85.0% (85/100)	0.00
Regulatory body responsible for ADE reporting in Bangladesh	40.4% (36/89)	86.0% (86/100)	0.00
The location of International Center for ADR Monitoring	22.5% (20/89)	89.0% (89/100)	0.00

n= number of participants; Control Group: Interns of DMCH and ADWMCH where package of educational intervention was not delivered; Intervention Group: Interns of MCWH and AKMMCH where package of educational intervention was delivered; $^{x}2$ proportion Z test was done; $p \le 0.05 = \text{Statistically significant}$, p < 0.001 = statistically highly significant.

Table 3 shows that significant associations were observed between the responses of the control and intervention groups regarding knowledge and awareness of intern physicians about pharmacovigilance after 2 months of intervention. The knowledge of intern physician regarding the procedure of ADE detection and reporting, the responsible person for ADE reporting, awareness of the yellow card reporting form and the question regarding the existence of a national pharmacovigilance program in Bangladesh, the regulatory body responsible for ADE reporting and the location of the International Center for ADE Monitoring, significantly increased after 2 months of intervention. The response was observed to be higher in the intervention group than in the control group, and the difference was observed to be statistically highly significant (p < 0.001).

Table 4: Assessment of attitude, experience and training of intern physicians towards pharmacovigilance after 2 months

Attitude, experience and training	Control Group(n=89)	Intervention Group(n=100)	p value ^x
Attitude towards necessity of ADE reporting	78.7% (70/89)	94.0% (94/100)	0.00
ADE reporting is a professional obligation	67.4% (60/89)	91.0% (91/100)	0.00
Experience of ADE in any patient during training period	52.8% (47/89)	65.0% (65/100)	0.09
Physician's attitude towards voluntary reporting of ADE	83.1% (74/89)	88.0% (88/100)	0.33
Training on ADE detection and reporting	0% (0/89)	96.0% (96/100)	=

n=number of participants; Control Group: Interns of DMCH and ADWMCH where package of educational intervention was not delivered; Intervention Group: Interns of MCWH and AKMMCH where package of educational intervention was delivered; $^{x}2$ proportion Z test was done; $p \le 0.05 = \text{Statistically significant}$; p < 0.001 = statistically highly significant.

Table 4 shows that there was a significant association observed between the interns of control 78.7% (70/89) and the intervention group 94.0% (94/100) after 2 months of intervention regarding their attitude towards the necessity of pharmacovigilance (p<0.001). The majority of the interns, 91% (91/100) in the intervention group and 67.4% (60/89) in the control group, strongly agreed that ADE is a professional obligation and the difference was also observed to be statistically highly significant (p<0.001). Moreover, their experience of encountering any patient with ADEs during their clinical practice was observed to be higher in the intervention group (65.0%) than that of the control group (52.8%) but the difference was not statistically significant (p> 0.05). Most of the interns, both in control 83.1% (74/89) and intervention groups 88.0% (88/100) mentioned that reporting of ADE should be voluntary and the difference was not statistically significant (p> 0.05). Regarding their training on pharmacovigilance, after 2 months of intervention, the majority of the interns of the intervention group 96% (96/100) mentioned that they received training on detection and reporting of ADE, whereas in the control group, none of the participants received any training.

DISCUSSION

In our study, we tried to evaluate the knowledge, awareness, attitude, experience and training of the intern physicians towards pharmacovigilance through a questionnaire survey at baseline and after 2 months of intervention.

The knowledge, attitude and practice of intern toward pharmacovigilance physician strongly related to ADEs reporting¹⁸.ADE under-reporting is directly linked to knowledge, attitude and practice of healthcare professionals and availability of an effective pharmacovigilance system¹⁹. The affecting ADE reporting such as lack of awareness, ambiguity about who should report, difficulties with reporting procedures, lack of feedback on submitted reports, resolution of adverse events and so on can be overcome by educational program on intern physician¹⁸.

The baseline study revealed that there were no significant associations observed between the responses of the control and intervention regarding knowledge, groups attitude, experience and training of intern physicians about pharmacovigilance. However, after 2 months of intervention. knowledge and awareness improved remarkably and was observed to be statistically highly significant. In a previous study²⁰, similar perceptions were shared by medical students and intern doctors towards the reporting of ADEs.

According to the current study, the majority of the participants agreed that ADE reporting is necessary and similar findings were also observed in previous studies^{3,14,21}. The attitude of the doctors towards pharmacovigilance was admissible in this study. Most of the respondents believed that ADE reporting is a professional obligation and they opined that ADE reporting should be voluntary which was found alike with earlier studies²⁰.

Furthermore, regarding their experience of encountering any patient with ADE during their training period, the intervention group was observed to have higher levels of experience than the control group, but this difference was not statistically significant. In our study, all the interns mentioned that none of them had received any training on ADE detection and reporting during their study period at baseline. Previous research has yielded similar results^{3,20}. However, an improved situation was observed in the intervention group in comparison to the control group after 2 months of intervention.

The current study found that there was a significant improvement in the intervention group in comparison to the control group in terms of knowledge and attitude about pharmacovigilance after 2 months of intervention.

Similar findings were also observed in the previous study, which revealed that there was a significant improvement in physicians' knowledge and awareness pharmacovigilance after the intervention 9,22,23. Another study²¹ found a huge improvement in the attitudes of participants after training. Another study conducted in India also found a significant improvement in the percentage of respondents regarding awareness of the process of ADE reporting and monitoring after intervention²⁴. Aspects of attitude and practice of health-care professionals was also found to be improved following educational interventional program pharmacovigilance in other studies^{25,26}.

Educational intervention is a key component in changing attitudes among physicians regarding pharmacovigilance. Informative workshops, training, continuing medical education (CME), seminars, online or offline courses and clinical meetings or conferences can improve health care professionals' knowledge and awareness of ADE reporting practices, which will increase the credibility of health care in the country¹⁴.

The present study demonstrated that the package of educational intervention formulated and implemented were effective in improving knowledge, awareness, attitude, experience and training towards pharmacovigilance among intern physicians which may contribute to establish a better pharmacovigilance system in our country.

CONCLUSION

The present study observed that knowledge, awareness, attitude, experience and trainings regarding pharmacovigilance were not adequate among intern physicians, but after the intervention, all the parameters increased significantly. So, it can be said that educational intervention can contribute to increase the knowledge and awareness and to change the attitude of the healthcare professionals towards pharmacovigilance ensuring the safety and quality of drug.

Hands-on training and practical educational programs for interns and mid-level physicians thus should be promoted.

CONFLICT OF INTEREST

There is no conflict of interest.

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