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DETECTION AND REPORTING ADVERSE DRUG REACTION AMONG INTERN PHYSICIANS: IMPACT OF EDUCATIONAL INTERVENTION

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ABSTRACT

Background: Adverse drug reactions (ADRs) are a major contributor to morbidity, mortality, and diminished quality of life, and they significantly increase global healthcare costs. In Bangladesh, however, ADR reporting remains limited despite its crucial role in ensuring patient safety and supporting public health initiatives. **Aim:** This study aimed to assess the effectiveness of a structured educational intervention in improving the detection and reporting of adverse drug events (ADEs) by intern physicians in hospitalized patients. **Materials and Method:** A formative interventional study was conducted among 189 intern physicians from four hospitals in Dhaka, who were assigned to either a control group (n=89) or an intervention group (n=100). The intervention group received a comprehensive educational package that included workshops, focus group discussions, key informant interviews, and training on the standard ADE reporting form. Data on ADE detection and reporting were collected through surveys and reviews of patient treatment sheets at baseline and again after four months, with reporting information verified by the Directorate General of Drug Administration (DGDA) ($p<0.05$). **Results:** ADE reporting remained 0% in the control group but increased to 5.0% in the intervention group ($p<0.05$). **Conclusion**: Educational intervention significantly improved both detection and reporting of ADEs among intern physicians, indicating its potential to strengthen pharmacovigilance practices in hospital settings in Bangladesh.

Keywords: Adverse Drug Reaction (ADR), Educational intervention, Pharmacovigilance.

INTRODUCTION

From ancient times, medicines have been used to preserve life, enhance longevity, and lessen illness. At the same time, they have always been known to carry risks, as they can cause both the intended therapeutic effects and undesirable reactions[1].

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ADE has been compared to the tip of the iceberg by some authors as it represents minor component of a significant catastrophe[2].The risks associated with drug use have been reported previously[3].The primary means of measuring these risks is to quantify the ADE. In developed and developing countries, ADE causes considerable morbidity, mortality, and extra costs[4].

ADR has become a public concern worldwide after the catastrophe of 10,000 cases of phocomelia caused by thalidomide[5]. Following this event, the United Kingdom first established the "Yellow Card" (YC), a specific form to compile reports of drug toxicity. In 1968, WHO (World Health Organization) with ten of its members, started the program for International Drug Monitoring, followed by the establishment of a larger collaborating center called Uppsala Monitoring Center (UMC), in 1978. More than 170 countries and territories have collaborated with UMC to develop their national pharmacovigilance systems for reporting ADE to date[6] .Under the guidance of WHO-UMC (WHO-Uppsala Monitoring Committee), adverse drug reaction monitoring (ADRM) cell was formed by Directorate General of Drug Administration (DGDA), a drug regulatory authority in Bangladesh since 1996[7].

Successful pharmacovigilance is solely dependent on spontaneous reporting[8] .Globally, it has become the mainstay of safety monitoring of any drug, especially during post-marketing surveillance[9,10]. Spontaneous reporting of suspected ADEs has been encouraged to improve knowledge about drug safety, to monitor the safety of marketed drug and to detect serious or new ADEs[11].

After detection of ADE, spontaneous and voluntary reporting is expected from health care professionals. However, significant under-reporting of ADE by healthcare professionals has been identified[4]. It has been estimated that only 6–10% of all ADEs are reported. Thus, it is the need of the hour to identify adverse drug reactions as early as possible and to prevent them if possible, for ensuring the well-being of patient at reasonable cost[12].Moreover, failing to report or notify harmful effects of a drug, even after experiencing them, is considered unethical, as it may knowingly expose other patients or consumers to the same risks. Reporting ADEs is crucial for public health, as it helps prevent similar incidents in the future, potentially saving lives and reducing economic burden[13].The low rates of ADEs reporting may also delay regulatory actions to remove drugs with an unacceptable safety profile from the marketplace[14].

Medical graduates work under the supervision of seniors for the first time during their internship periods[15].Intern physicians are the most in-depth observers of hospitalized patients. Educational intervention among intern physicians regarding adverse drug reactions creates awareness, reduces poor outcomes, morbidity, mortality, and promotes ADE reporting. Internship is the period of training during MBBS (Bachelor of Medicine,Bachelor of Surgery) course and is the first phase when the physician comes in contact with patient care[15] .It is the learning period in which they acquire skills under supervision so that he/she may be able to meet the expectationsof conductingpatient management and become capable of functioning independently[16].Learning to identify, document and report ADE at this time span will make a good practice and habit that will benefit them in future when working independently. Next generation physician will also get proper supervision regarding ADE detection and reporting. Proper and extensive training during undergraduate and internship years can enhance the reporting of ADE cases[15].

MATERIALS AND METHOD

Study design

The study was formative interventional research designed as a before -and-after study to compare the data sets.

Study Setting and Population

This study was conducted at four tertiary-level medical colleges and hospitals in Dhaka, Bangladesh. Intern physicians from these institutions comprised the study population.

Study Period

The research was carried out from September 2019 to February 2022, with data collection starting in January 2020 following Institutional Review Board approval from Bangladesh Medical University (BMU).

Sampling and Grouping

The institutions were purposively selected based on available tertiary healthcare facilities. Out of the 4 tertiary care hospitals, interns from 2 of the hospitals served as control group while the interns from the remaining 2 hospitals formed the intervention group.

Sample size

Fifty intern physicians on average were available in each medical college and hospital.According to Morgan's table (Appendix-I) for sample size calculation, the required sample size for 50 populations was equal to forty-four.

So,
For control group = Eighty-eight
For intervention group = Eighty-eight
Intern physicians from the four selected institutions who fulfilled the selection criteria were included in the study.

Selection Criteria

In all 4 respective medical colleges and hospitals

1. Authorities agreed to participate and cooperate
2. Minimum 250 bedded or more tertiary level medical college hospitals

Inclusion criteria

1. The physicians who were currently performing internship training in that medical college
2. Interns who participated in this study willingly
3. Interns who were placed and reported inpatient ADE during the study period

Exclusion criteria

1. Interns who were not interested in participating in this study
2. Interns who reported ADE without prescription image
3. Interns who reported ADE that was diagnosed in outpatients of studied hospitals

Detailed Study Procedure

Four tertiary-level medical college hospitals were selected based on inclusion and exclusion criteria, and their intern physicians were invited to participate. Of 208 interns who provided informed consent, 189 completed the study. Participants were divided into control and intervention groups, and permissions were obtained from the respective institutional authorities.

Baseline data collection:

The researcher went to DGDA located at Mohakhali, Dhaka and collected information at baseline regarding number of submitted ADE reports from these hospitals.

Baseline hospitalized patients data collection were done from the record room of these hospitals by cross-sectional survey. According to the manual titled "How to investigate drug use in health facilities," minimum encountered data for survey is 600 "During the study period, 600 hospital treatment sheets (150 per hospital, randomly selected) were reviewed to detect ADE cases. At first, number of patients that were admitted to the studied hospitals with ADE were investigated.Afterward, assessments were performed regarding how many of them were diagnosed with ADE on admission or developed during the process of treatment

after admission with other diseases and how it was reported in DGDA.

Maximum intern physicians of the studied hospitals were approached and the nature and purpose of the study were explained. Then a questionnaire was circulated to them and the researcher collected those in the appointed schedule. Intern doctors who failed to return the questionnaire on time were contacted again. If a questionnaire was lost, a new one was provided and the participant was approached once more. Those who did not respond after three attempts were considered non-respondents.

Follow-up data collection:

After 4 months, inpatient data collection were done again from the record room of these hospitals and a total of 600 hospital treatment sheets were reviewed again (150 from each hospital by randomization) to detect any cases of ADE in the same method as described above.

Development of package of intervention through education

Focus group discussions (FGDs) with intern physicians and key informant interviews (KIIs) with department heads of the hospitals (which had been selected to be the intervention group) were conducted to ensure the relevance of the educational intervention. Insights from FGDs (5–7 participants per group) and KIIs were systematically analyzed to identify key themes and inform the design of the intervention package.

Conduction of the intervention:

The researcher conducted a one-day training and workshop at the hospitals, combining theoretical and practical sessions to improve detection, management, and reporting of ADEs

Materials used:

Offline tools: laptop for investigator, Mobile with data connection for the participants, Multimedia presentations, projector with screen, handouts, suspected ADE reporting form and National pharmacovigilance system Guideline in Bangladesh.

Online tools:
www.dgda.gov.bd,www.vigiaccess.org.

It was done by maintaining proper hygiene and social distancing during the COVID-19 pandemic situation.

Theoretical session:

Theoretical sessions conducted by the researcher covered ADE concepts, incidence, detection, management, and reporting procedures, including global and national perspectives. Hospital authorities shared their experience and highlighted the significance of recognizing common adverse effects and patient presentations. They instructed the interns on how to manage the cases and give follow up of those particular cases.

Steps of recognizing an Adverse Drug Event: The interns were trained regarding the steps of ADE detection and distinguishing between the natural progression of a disease and an adverse event in following steps:

When an ADE occurs in a patient taking a medicine or using any other pharmaceutical product,

- *Complete information on the event* should be collected by:

1. Taking a proper history and excluding all other possible causessuch as co-morbid conditions, drug-drug interaction, drug-food interaction
2. The time relationship between the event and the use of medicine
3. Thorough examination of the patient and doing relevant laboratory investigations

- *De-challenge and re-challenge* if it is an ADE.

Positive de-challenge: improvement of the reaction after discontinuation of the medicine which is a strong indicator of a possible association between the medicine and the ADE.

Positive re-challenge: Recurrence of the reaction that had subsided with the prior de-challenge.

- *Check pharmacology of the medicine* to know whether it was documented before. Information to the interns were given about the ADR reporting process.

Practical session:

Practical session covered hands-on training on ADE reporting by providing ADE forms to the interns and creating case scenarios by the researcher herself. The researcher gave the web address (www.dgda.gov.bd and www.vigiaccess.org) to the interns and the investigator demonstrated them on how to get information from those websites and asked them to explore the website for 15 minutes. After that interns explored both the websites by their own.

'National Guideline on The Pharmacovigilance System in Bangladesh' was disseminated among the interns. The suspected ADE reporting forms were distributed to the participants. A drop box was kept in each department of indoor facilities of the studied hospitals where the interns submitted the report by filling the suspected ADE form.

After the intervention, the researcher was available on every alternate day in the intervention group hospitals to inspire the interns. The researcher's contact number was available to the interns and hospital authorities who were engaged in ADE detection. Whenever they detected ADE cases, they filled up the reporting form and kept it in drop box. After that, they contacted the researcher either by cell phone or text. Follow-up was given repeatedly to determine the outcome of the detected cases of ADEs. Reminders about ADE reporting was communicated through messages to the mobile phone of the prescribers (prior consent was taken). All the reported cases of suspected ADE were recorded by taking images. The researcher was the main focal point to provide full support to the Interns. The researcher collected the suspected adverse event reporting forms that were kept into the drop box by the interns and sent those reports to the DGDA.

Data interpretation

To facilitate the computer use, a special spreadsheet prepared by the investigator was used in the study.

Statistical Analysis

Frequencies and percentages were calculated, and the two-proportion Z-test was used to assess significance. Analyses were conducted using Microsoft Excel and an online calculator, with $p< 0.05$ considered significant.

RESULTS

The study was carried out in four medical college hospitals in Dhaka to assess ADE detection and reporting. Out of the 4 hospitals, interns of 2 hospitals served as control group while those hailing from the other 2 hospitals were the intervention group.

Demographic Characteristics the study participants

Table 1: Demographic characteristics of the study participants at Baseline (n=208)

Gender	Frequency (n=208)	Percentage (%)
Male	51	24.5
Female	157	75.5

n: Total number of participants.

Table 1displays the demographic characteristics of the study participants at baseline. A total of two hundred and eight intern physicians were enrolled based on eligibility criteria for the study of which majority of the intern physicians were female 75.5 % (157/208).

Detection of cases of Adverse Drug Events in hospitalized patients of the studied hospitals (Baseline and after 4 months):

Table 2: Proportion of detection of cases of Adverse drug events in hospitalized patients of the studied hospitals (Baseline and after 4 months).

	At Baseline	After 4 Months	P value
Control group (n=300)	3.7% (11/300)	4.3% (13/300)	1.00
Intervention group (n=300)	2.3% (7/300)	6.3% (19/300)	0.01
***p* value**	0.15	0.26	

n: number of hospital treatment sheets reviewed to detect cases of adverse drug events.;2 proportion Z test' was done; $p \leq 0.05$ = statistically significant.

Table 2 shows that, at baseline, 3.7% (11/300) and 2.3% (7/300) cases of ADEs were detected from the control and intervention groups respectively and there was no significant association observed between them ($p>0.05$). After 4 months of educational intervention, the detection of cases was increased in the control [from 3.7% (11/300) to 4.3% (13/300)] and intervention [from 2.3% (7/300) to 6.3% (19/300)] group hospitals. Although, the difference was statistically significant ($p<0.05$) in the intervention, when compared with control group, it was not significant. ($p>0.05$). The difference was not statistically significant in control group ($p>0.05$).

Reporting of Cases of suspected adverse events to DGDA during the study period (Baseline and after 4 months):

Table 3: Reporting of Cases of suspected adverse events to DGDA during the study period (Baseline and after 4 months)

	At Baseline	After 4 Months	*p* value
Control group (n=300)	0% (0/300)	0% (0/300)	-
Intervention group (n=300)	0% (0/300)	5% (15/300)	0.00
***p* value**	-	0.00	

n: number of hospital treatment sheets reviewed to detect cases of adverse drug events.;'2 proportion Z test' was done; $p \leq 0.05$ = statistically significant.

Table 3 shows that at baseline, none of the cases of ADE were reported to DGDA, both from control 0% (0/300) and intervention group 0% (0/300). But after 4 months of intervention, 5% (15/300) of ADE were reported from the intervention group and the difference was statistically significant in the intervention group and also in the control and intervention groups ($p<0.05$).

DISCUSSION

ADE reporting is a vital component of pharmacovigilance and is essential to the security surveillance of marketed medicinal products. Detection and reporting of

ADEs by physicians have become a global concern for many years, as this system of pharmacovigilance can save thousands of lives through the generation of a continuous flow of new information regarding the safety profiles of drugs[16].Proper education and training can play a significant role in the detection, management and reporting of ADEs. This was a formative interventional study conducted in four tertiary level hospitals .The current study aimed to assess the impact of educational intervention conducted among intern physicians to increase detection and reporting of ADE in the hospitalized patients of the studied hospitals.

Female participants predominated in this study, consistent with findings from Nepal, India, and Malaysia.[9,12,17]. At baseline, few ADE cases were detected in both control and intervention groups, with no significant difference, and none were reported to the DGDA. To address this, an educational intervention package was implemented, incorporating lectures, yellow cards, printed materials, giveaways, and practical workshops[15,18].

After four months, ADE detection increased notably in the intervention group, while the control group showed only a slight, non-significant change. Although the intervention improved detection within the group, the difference compared to controls was not significant, likely due to the short duration. Enhancing detection requires development of diagnostic skills, which cannot be fully achieved through a brief intervention.

ADE reporting improved significantly in the intervention group, with reports submitted to the DGDA increasing, whereas no change was observed in the control group.

A tenfold increase in the rate of ADE reporting after intervention through education was observed in previous study which was conducted in Portugal[19] and another study also revealed improvement in ADE reporting after educational intervention.[20].

Despite this improvement, overall reporting remained low, as none of the participants had prior experience or training in ADE detection and reporting.
In this study, all the physicians mentioned that they did not received any training on ADE detection and reporting during their study period at baseline. Previous research has yielded similar results[16,21].

Overall, the study demonstrates that the educational intervention effectively enhanced both detection and reporting of ADEs, supporting improved pharmacovigilance practices in the country.

CONCLUSION

This study demonstrated a substantial rise in ADR reporting in the selected centers after the educational intervention. The intervention developed and applied here effectively encouraged physicians to report ADRs when identified. However, accurate detection still requires enhanced diagnostic skills, which can be strengthened through rigorous professional training. Therefore, strategies must be developed to support and promote both the identification and reporting of suspected adverse events by multidisciplinary teams within healthcare institutions.

CONFLICT OF INTEREST

There is no conflict of interest.

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Appendix I

Morgan's Table

N	*S*	*N*	*S*	*N*	*S*
10	10	220	140	1200	291
15	14	230	144	1300	297
20	19	240	148	1400	302
25	24	250	152	1500	306
30	28	260	155	1600	310
35	32	270	159	1700	313
40	36	280	162	1800	317
45	40	290	165	1900	320
50	44	300	169	2000	322
55	48	320	175	2200	327
60	52	340	181	2400	331
65	56	360	186	2600	335
70	59	380	191	2800	338
75	63	400	196	3000	341
80	66	420	201	3500	346
85	70	440	205	4000	351
90	73	460	210	4500	354
95	76	480	214	5000	357
100	80	500	217	6000	361
110	86	550	226	7000	364
120	92	600	234	8000	367
130	97	650	242	9000	368
140	103	700	248	10000	370
150	108	750	254	15000	375
160	113	800	260	20000	377
170	118	850	265	30000	379
180	123	900	269	40000	380
190	127	950	274	50000	381
200	132	1000	278	75000	382
210	136	1100	285	1000000	384

Note.—*N* is population size. *S* is sample size.

Source:

Reference Krejcie RV, Morgan D; Determining sample size for research activities Educ. Psych Meas. 1970; 30:607-610.