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Assessment of knowledge and attitude of adverse drug reactions among healthcare professionals in Bangladesh

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Abstract: Adverse drug reactions have increased significantly in people as many new drugs have come to the market in the last two decades. This has not only economic consequences but also causes morbidity and mortality. In Bangladesh, some incidents happened related to drug problems and it took several lives. Spontaneous reporting of adverse drug reactions can primarily control this situation and healthcare professionals can play an immeasurable role. Therefore, this study was aimed to be conducted at seven different hospitals and diagnostic centers to find out the actual scenario of adverse drug reactions among the healthcare professionals in Bangladesh to make them aware of adverse drug reactions and the reporting system, and to know about their opinion towards adverse drug reactions. However, after evaluation of the questionnaires it was found that a large number of healthcare professionals were not aware of adverse drug reactions and pharmacovigilance, especially the nurses. It was found that 13.3% of nurses did not know about adverse drug reactions and 93.3% of them had not reported any reactions. Furthermore, many healthcare professionals did not show a positive attitude towards pharmacovigilance. If proper pharmacovigilance practice cannot be started, the nation will face serious economic and health-related problems.

Introduction

Safety and potency are leading concerns of a drug. Although drugs and medicines are used to treat diseases, sometimes these may contradict and cause Adverse drug reactions (ADRs). ADRs can be defined as any reaction to a drug that is poisonous and takes place at doses intended to be used for diagnosis, prophylaxis, and treatment of diseases [1]. These days, ADRs have already become a major issue and cause several deaths and morbidity. It is also thought to be a source of economic burden to health areas [2]. About 0.1 million people died in the US due to ADRs which became the sixth leading cause of death in the country after cardiovascular diseases, stroke, and cancer. In the last two decades, ADRs in people have increased significantly and many new drugs have come to the market within this time. It has been seen that poor knowledge of physicians about new drugs and misuse by patients are two major factors of ADRs [3]. Any class of drug can be responsible for ADRs but many studies showed that antibiotics are more responsible for causing an ADR compared to other drugs [4, 5]. However, ADRs always do not seem to be caused by one reason only. Several factors can cause ADRs including patient factors, medication, community, and healthcare professionals (HCPs) [6].



Adverse drug reactions are of different types and they are classified based on the reactions or side effects they create. They are basically: Type A and Type B. Type A reactions are intrinsic and Type B reactions are idiosyncratic type reactions. Type B reactions cannot be clarified by drug dose or pharmacologic responses [7]. On the other hand, Type A reactions are typically dose-dependent as well as easy to predict and which are most often time recognized before the marketing of medicine. Type A responses may arise from the medication's main pharmacology. For instance, warfarin's anticipated clinical intervention is a decline in the ability of blood to coagulate, however, increased bleeding has become the exaggeration of this action [8]. Type B reactions produce effects that are other than pharmacologically mediated. Therefore, it is very difficult to distinguish whether the drug reactions are due to genetics or due to dose dependency [9].

Pharmacovigilance (PV) is defined by the World Health Organization (WHO) as the science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other drugrelated problem [10]. The main goals of PV include reporting serious ADRs, monitoring the marketed drugs, determining the hazards of medicines, illuminating factors that are predisposal, and so on [11]. Several potential safety concerns can be identified by modern PV schemes although there has been significant space for adjustment in tasks and techniques [12]. Many policies have already been put into practice, such as topics relating to drug evaluations in college and post-graduate programs as well as the increase in the pharmaceutical period have also been applied to support the compliance to suitable procedures in healthcare practitioners for PV [13]. Bio-pharmaceutical medicines show certain properties and difficulties those are encountered during PV [14]. The study of pharmacovigilance (PV) is very important for each country to maintain safety issues as well as decent healthcare programs. Although Bangladesh is a developing country, according to the Directorate General of Drug Administration (DGDA) Bangladesh exports medicines to about 30 different countries. Therefore, PV plays a key role in maintaining the safety of exported and locally marketed drugs [15]. Proper work on PV helps to regularly study all types of ADRs. Moreover, PV helps to design appropriate treatment plans that are needed when an ADR is noticed thus patient becomes more aware of that particular drug [16]. PV is essential as there are limitations in the pre-marketing studies for some reasons for instance, small duration and small number of volunteers and due to some rare types of ADRs [17]. In a developing country like Bangladesh, PV can play a vital role in ensuring the safety of drugs. Many countries have already developed different types of reporting systems and reporting forms as well. For instance, in the United States the "Medwatch" is the spontaneous system of reporting ADRs whereas in the UK it is the "Yellow Card System" [18]. Reporting of ADRs can be done in Bangladesh through the DGDA website either by online fillup or by e-mailing to DGDA. Reporting plays a significant role in the identification of drug errors to reduce the number of such mistakes and their impacts on patients [19]. Furthermore, a major number of people in Bangladesh are illiterate, live below poverty, and have very little idea of their health safety. Therefore, to avoid many serious health hazards PV is very important [20].

From 2014 to 2017, a total of fifteen hundred and seventy-seven reports were received at DGDA [21]. A cross-sectional study was done in three divisions (Dhaka, Khulna, and Rajshahi) from 2015 to 2018 in fifteen hospitals which are of different types and it was found that the leading problem of DGDA was spreading knowledge among the HCPs because of poor manpower [22]. Another study was done in a Military Hospital in Dhaka in 2015 and found fifty patients with severe cutaneous ADRs which were of various types like Steven Johnson Syndrome, and Toxic Epidermal Necrolysis [23]. Bangladesh is a developing country with 160 million of population and sometimes ADRs need hospitalization. For this reason, ADRs largely led to major financial losses [24]. A survey was done on randomly 160 patients at the Outpatient Department of Skin between 2007 and 2008 and 19 patients were found with ADRs to various drugs which are of 66 drugs. 36% of reactions were mild and others were severe. This study primarily noticed that the study of ADRs and PV is very necessary in Bangladesh [25].

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Materials and methods

Study design: The study was designed for the assessment of knowledge and attitudes toward ADRs among the HCPs who were working in different types of hospitals (like, Government Hospital, Specialized Hospital, Private Diagnostic Centers, and Health Complex) and also in industries (Pharmacists). Although in many countries many studies have already been done on ADRs based on Knowledge, Attitude, and Practice (KAP) among the HCPs in Bangladesh, there have been very few studies done on KAP. This survey was operated in seven hospitals which are of four different types. Three of them were in Dhaka, two of them were at the district level (in Tangail) and two of them were in Health Complexes. By category two of them were medical colleges, two were diagnostic centers, one was a specialized hospital and two were health complexes in two different Upazilas (Bhuapur, Kalihati) in Tangail, Bangladesh.

Ethical permission: To fulfill the ethical requirements, authorization from hospitals has been confirmed. A permission letter was given to the Head of each hospital. After getting permission from the Head the survey was done.

Development of questionnaire: The questionnaire was designed by doing a study on literary work which helped to achieve the aim and objective of this study and ensured adequate assessment of PV practice. Before starting the survey, the final review was done by an expert who has vast knowledge and experience in this area. In the very first part of the questionnaire respondent's demographic information like name, age, gender, occupation, and nationality was asked. Then basic information about ADRs and PV was included. In part three questions related to attitude on ADRs were included. All the questions were very simple to understand and straight. Last part four questions were kept to know the views of HCPs.

Pretesting, validity testing, and finalizing of the questionnaire: Pretesting a questionnaire assures that whether there is any mistake in the questions or not can hamper the purpose of the study and validity testing is done to prevent analytical mistakes. The simpler questionnaire makes it less difficult for the respondents to answer in this study. Therefore, a nurse and a pharmacist were chosen to test the questionnaire. Both of them found the questionnaire very easy to complete and were able to answer all of the questions within three minutes. Furthermore, testing for authenticity was performed to ensure that somehow the study material was sufficiently cautious to collect all data and properly suited to the study's objectives.

Data collection: This study was done with a sample size of 130 in total. This sample size could represent the absolute situation as an appropriate sample size may draw the actual scenario of PV practice in Bangladesh. However, no data was found regarding the sample size to assess the depth of knowledge and attitude on ADRs among HCPs. All the questionnaires given to HCPs were tested first. The sample collected from seven different hospitals is shown in **Table 1**.

Table 1: Name of the Hospital/Diagnostic Center including their locations

Name of the Hospitals/Diagnostic Centers	Location
Dhaka Medical College	Dhaka
BDM Diagnostic Center, Mohammadpur	Dhaka
National Institute of Cancer Research and Hospital	Dhaka
Sheikh Hasina Medical College	Tangail
Sonia Diagnostic Center	Tangail
Upazila Health Complex	Bhuapur
Upazila Health Complex	Kalihati

Statistical analysis: The statistical analysis of data was done by Statistical Package for Social Sciences (SPSS) programming; Version 23.0. All 130 samples were entered in the SPSS data sheet. The statistical set had been used to compute statistics for description and to compare the means. For example; metric factors, average as well and standard deviations were used as informative measures, while independent *t*-tests were used for correlations when it appeared that the data was normally dispersed (e.g. respondent age). Using ostensible data (e.g. frequencies), the Pearson's Chi-square (π^2) test was used.

Results

Demographical data: 130 HCPs responded to the questionnaire and they were working in both government and private hospitals except the pharmacist as the practice of pharmacists in the hospitals has not started yet. They work in different pharmaceutical companies. The demographic information (occupation and gender) of respondent HCPs (Physician, Nurse, and Pharmacist) is shown in **Table 2**.

Table 2: Demographic information of the healthcare professionals

Parameter	N (%)				
Gender					
Male	64 (49.2)				
Female	66 (50.8)				
Occupation					
Physician	68 (52.3)				
Nurse	30 (23.1)				
Pharmacist	32 (24.6)				

Table 3 shows more information on the demography of the HCPs. Thus, the average age and average experience in years of the participants are shown. Most of the HCPs are almost in the same range in years.

Table 3: Average age and experience of healthcare professionals

Parameter	Average years				
Age					
Physician	27.15				
Nurse	25.70				
Pharmacist	28.20				
Experience					
Physician	02.06				
Nurse	03.26				
Pharmacist	03.35				

Assessment of knowledge among HCPs: The HCPs were asked seven different questions that were closely ended (Yes, No) to assess their knowledge. For example, do they know about ADRs; have they ever identified any ADRs; have they ever seen any ADR report forms, and so on? Responses of the HCPs about knowledge of ADRs have been shown in **Table 4**.

Table 4: Knowledge of healthcare professionals towards adverse drug reactions

Variable	Occupation	Yes N (%)	No N (%)
	Physician	68 (100)	0 (00.0)
Do you know about Adverse Drug Reactions?	Nurse	26 (86.6)	04 (13.3)
	Pharmacist	32 (100)	0 (00.0)
	Physician	37 (54.4)	31 (45.6)
Have you ever identified ADR in patients?	Nurse	07 (23.3)	23 (76.7)
	Pharmacist	10 (31.2)	22 (68.5)
	Physician	28 (41.2)	40 (58.8)
Have you ever seen a standardized ADR reporting form?	Nurse	02 (06.6)	28 (93.3)
	Pharmacist	07 (21.9)	25 (78.1)
	Physician	48 (70.6)	20 (29.4)
Is there any ADR reporting center in your knowledge in Bangladesh?	Nurse	10 (33.3)	20 (66.7)
	Pharmacist	21 (65.6)	11 (34.4)
	Physician	13 (19.1)	55 (80.1)
Have you ever reported an ADR?	Nurse 26 (86.6) Pharmacist 32 (100) Physician 37 (54.4) Pharmacist 10 (31.2) Pharmacist 10 (31.2) Pharmacist 02 (06.6) Pharmacist 07 (21.5) Physician 48 (70.6) Pharmacist 21 (65.6) Pharmacist 04 (12.5) Physician 27 (39.7) Pharmacist 09 (28.1) Physician 28 (41.2) Physician 27 (39.7) Pharmacist 09 (28.1) Physician 28 (41.2) Physician 28 (41.2)		28 (93.3)
	Pharmacist	28 (87.5)	
	Physician	27 (39.7)	41 (60.3)
Do you know where the international center for ADR monitoring is located?	Nurse	03 (10.0)	27 (90.0)
	Pharmacist	09 (28.1)	23 (71.2)
	Physician	28 (41.2)	40 (58.8)
Are you aware of any drug that has been banned due to ADR?	Nurse	02 (06.7)	28 (93.3)
	Pharmacist	13 (40.6)	29 (59.4)

Assessment of attitude among HCPs: A few questions were included in the questionnaire to assess the attitude of HCPs towards ADRs. These include, whether it is important to report an ADR or not; whether reporting of ADR is a professional obligation for HCPs or not; does reporting of ADR improves patient safety; whether is it necessary to teach patients about ADR; is time-consuming to report an ADR; whether does ADR reporting increases workload; does reporting of ADR affect the confidentiality issue of Patients; is it necessary to establish ADR monitoring center in each hospital; is the aim of PV to report ADRs due to allopathic medicine only and drugs that cause serious ADRs should be banned in Bangladesh. **Table 5** represents the data about the responses of HCPs to these questions.

General information: Three questions were included in the questionnaire to know about the aspects of HCPs. Most of the HCPs prefer e-mail or online reporting systems. After that, a major number of HCPs think all types of ADRs should be reported. According to the study, 70 out of 130 HCPs knew about ADR during their study. However, **Table 6** provides detailed data about the aspects of HCPs towards ADR reporting.

 Table 5: Attitude of healthcare professionals towards adverse drug reactions

Variable	Occupation	Strongly Agree N (%)	Agree N (%)	Neither Agree nor Disagree N (%)	Disagree N (%)	Strongly Disagree N (%)	χ²	p value
It is important	Physician	27 (39.7)	36 (52.9)	05 (07.3)	0 (00.0)	0 (00.0)		
to report an	Nurse	09 (03.0)	17 (56.6)	04 (13.3)	0 (00.0)	0 (00. 0)	1.4	0.60
ADR	Pharmacist	12 (37.5)	17 (53.1)	03 (09.3)	0 (00.0)	0 (00.0)		
Reporting of ADR is a	Physician	10 (14.7)	26 (38.2)	17 (25.0)	12 (17.6)	03 (04.4)		
ADR is a professional obligation for	Nurse	08 (02.7)	12 (40.0)	05 (16.7)	03 (10.0)	02 (06.7)	3.7	0.47
HCPs	Pharmacist	05 (15.6)	13 (40.6)	08 (25.0)	05 (15.6)	01 (03.1)		
Reporting of	Physician	15 (22.1)	24 (35.2)	18 (26.5)	08 (11.8)	03 (04.4)		
ADR improves	Nurse	05 (16.7)	12 (40.0)	10 (33.3)	03 (10.0)	0 (00.0)	6.5	0.07
patient safety	Pharmacist	10 (31.2)	14 (43.8)	06 (18.8)	02 (06.2)	0 (00.0)		
It is necessary	Physician	05 (07.3)	17 (25.0)	26 (38.2)	13 (19.1)	07 (10.3)		
to teach patients about ADR	Nurse	02 (06.7)	07 (23.3)	09 (30.0)	10 (33.3)	02 (06.7)	5.3	0.53
about ADK	Pharmacist	04 (12.5)	09 (28.1)	11 (34.5)	04 (12.5)	04 (12.5)		
Reporting of	Physician	11 (16.2)	21 (30.9)	18 (26.4)	13 (19.1)	05 (07.3)		0.18
ADR is time-	Nurse	02 (06.7)	10 (33.3)	07 (23.3)	08 (26.7)	03 (10.0)	6.8	
consuming	Pharmacist	03 (09.4)	06 (18.7)	14 (43.8)	06 (18.7)	03 (09.4)		
ADR reporting	Physician	05 (07.3)	21 (30.9)	22 (35.3)	17 (25.0)	03 (04.4)	10.3	0.35
increases the	Nurse	03 (10.0)	11 (36.7)	09 (30.0)	07 (23.3)	0 (00.0)		
workload Reporting of ADR affects the confidentiality issue of patients	Pharmacist Physician	02 (06.2)	09 (28.1) 08 (11.7)	09 (28.1) 31 (45.6)	06 (18.7) 19 (27.9)	06 (18.7) 10 (14.7)		
	Nurse	0 (00.0)	05 (16.7)	13 (43.3)	10 (33.3)	02 (06.7)	9.4	0.05
	Pharmacist	0 (00.0)	0 (00.0)	11 (34.4)	14 (43.7)	07 (21.9)	J	0.03
Establishing an ADR monitoring center is necessary in each hospital	Physician	16 (23.5)	21 (30.9)	18 (24.4)	07 (10.2)	06 (08.8)		
	Nurse	06 (20.0)	09 (30.0)	08 (26.7)	06 (20.0)	01 (03.3)	7.0	0.3
	Pharmacist	04 (12.5)	08 (11.7)	14 (20.6)	05 (15.6)	01 (03.1)		
PV aims to	Physician	03 (04.4)	15 (22.1)	17 (25.0)	27 (39.7)	06 (08.8)		
report ADRs due to allopathic	Nurse	04 (13.3)	08 (26.7)	10 (33.3)	07 (23.3)	01 (03.3)	8.2	0.4
medicine only	Pharmacist	01 (03.1)	06 (18.7)	13 (40.6)	10 (31.2)	02 (6.25)		
Drugs that cause	Physician	16 (23.5)	31 (45.6)	16 (23.5)	05 (07.3)	0 (00.0)		
serious ADRs should be banned in Bangladesh	Nurse	06 (20.0)	16 (53.3)	07 (23.3)	01 (03.3)	0 (00.0)	1.4	0.5
	Pharmacist	09 (28.1)	15 (46.9)	06 (18.7)	02 (06.2)	0 (00.0)		

Table 6: Aspects of healthcare professionals towards adverse drug reactions reporting

***	24.4	Healthcare professionals			2	_	
Variable	Methods	Physician N (%)	Nurse N (%)	Pharmacist N (%)	χ^2	p value	
	E-mail/Online	41 (60.2)	09 (30.0)	15 (46.9)			
Which type of reporting system do you prefer?	Direct Contact	18 (26.5)	13 (43.3)	13 (40.6)	8.9	0.21	
	Telephone	09 (13.3)	08 (26.7)	04 (12.5)	8.9	0.21	
	Post	0 (00.0)	0 (00.0)	0 (00.0)			
From your view which type of ADR should be reported?	Serious ADRs	23 (33.8)	13 (43.3)	07 (21.9)	7.8		
	ADR to new drug	09 (13.2)	05 (16.7)	04 (12.5)			
	ADR to Vaccine	04 (05.9)	0 (00.0)	03 (09.3)		7.8	0.35
	ADR to non-allopathic drug	02 (02.9)	0 (00.0)	0 (00.0)			
	Above all	30 (44.1)	12 (40.0)	18 (56.25)			
Where have you first heard about ADR?	During study	41 (60.2)	13 (43.3)	16 (50.0)	2.61	0.40	
	On internet	09 (13.3)	06 (20.0)	07 (21.9)			
	On newspaper	0 (00.0)	0 (00.0)	0 (00.0)	3.61	0.48	
	From others	18 (26.5)	11 (36.7)	09 (28.1)			

Discussion

According to this study, the HCPs were not very aware of ADRs. Therefore, the study and practice of PV are very necessary to improve the safety of patients. From this study, it can be seen that although 54.4% of physicians identified an ADR the reporting percentage was only 19.1%. only 6.7% of nurses reported ADRs. This indicated that there was a noticeable knowledge gap between physicians and nurses. 58.8% of physicians had not seen the standardized ADR reporting form and the nurses were in the worst situation. 93.3% of nurses did not see the ADR reporting form. Similarly, 78.1% of pharmacists had not seen the standardized form. This indicates that most of the HCPs had little interest in reporting an ADR [5, 26]. The majority of HCPs did not know where the international center for ADR monitoring was located. Furthermore, 58.8% of physicians, 93.3% of nurses, and 59.4% of pharmacists did not know about any drug that was banned in Bangladesh due to ADR. These results said that a PV study is badly needed. If the safety of medicines cannot be improved, our country will face a serious health-related problem shortly. After an assessment of the attitude of HCPs, it can be said that most of the HCPs had little interest in ADR reporting although they believe that reporting of ADR is important [5, 26]. Few of the physicians think ADR reporting does not improve patient safety. A large number of HCPs think reporting of ADR is time-consuming and it increases the workload despite saying that reporting of ADR is important. Many of the HCPs were neutral on some questions of the questionnaire. Besides the HCPs the patients and the stakeholders need to be aware to reduce the incidences related to drugs, the practice of self-administration and well as irrational selling of drugs must be stopped [27]. The knowledge of patients as well should be enriched because many of the patients do not know where the ADR reporting form is, where to report an ADR, and many do not know the procedure to fill an ADR reporting form.

Conclusion: Most healthcare professionals prefer to report adverse drug reactions via online submission but the reporting rate is not satisfactory. Although pharmacovigilance is not functioning properly, many serious cases are found related to drugs and the DGDA is taking steps to control drug-related problems. It can be

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expected shortly the practice and study on pharmacovigilance will improve and the morbidity as well as mortality due to adverse drug reactions will fall.

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