Knowledge and Attitude about Pharmacovigilance: A Cross-sectional Study Involving Pharmacy Students of Selected Universities in Bangladesh

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ABSTRACT

Purpose: Now-a-days, the role of Pharmacists has become more patient-centric that includes drug safety by preventing, identifying, documenting, and reporting of adverse drug reactions (ADRs). The objective of this study was to evaluate the knowledge of pharmacy undergraduate and graduate students of Bangladesh towards pharmacovigilance (PV) and their attitude on reporting of ADRs.

Methods: A cross-sectional study was conducted by distributing a pretested questionnaire. The randomly selected participants of undergraduate and graduate pharmacy students from both public and private universities of Dhaka city, Bangladesh took part in the study. The data were analyzed by using Statistical Package for Social Science (SPSS) for calculating descriptive statistics; the Pearson's Chi-square ($\chi2$) test was performed to observe any significant difference between the public and private university students' response.

Results: Among the participants (n=504), 36% and 52% students gave the correct definition of PV and ADRs, respectively. Among the correct answer givers, most of the students were from public universities (p=0.01). The results to assess the attitude of the students suggested that about three quarters of participants thought that reporting of ADRs is a professional obligation. However, surprisingly 65% students believed they were not well prepared to report any ADRs with their present knowledge.

Conclusion: From the study we concluded that the pharmacy students had a positive attitude towards PV, however, their knowledge was inadequate for PV implementation in professional life. Thus to improve the overall ADR reporting in Bangladesh it is imperative for the future graduates to be well equipped with PV knowledge.

Key words: Pharmacovigilance (PV); Bangladesh, University students; Pharmacy; Knowledge; Attitude

INTRODUCTION

The Drug Monitoring Program by World Health Organization (WHO) found its origin after the so-called thalidomide disaster in 1961. This program not only enhanced patient safety by providing information regarding safe use of medicines, but also gave information about the prevention and treatment of Adverse Drug Reactions (ADRs) [1].

According to WHO (2005), ADR is defined as "any response to a drug which is noxious and unintended, and which occurs at doses normally used in man for prophylaxis, diagnosis, therapy for a disease, or for the modification of physiological function." In one study, the Centre for Health Policy Research found that in the U.S., around 50% of the approved drugs that show ADRs went undetected during the clinical trial phase [2]. In some countries, ADR is among the top 10 leading causes of mortality. Furthermore, in the U.S. alone, the predicted annual cost due to drug related morbidity and mortality in 2016 was $528.4 billion, which was 16% of the total health care cost of that year [3]. Thus, to avert or mitigate ADRs, measures for assessing and monitoring drug safety are very crucial [4,5].

An efficient way of managing ADRs is by applying the principles of pharmacovigilance (PV) [6], which is not only science but also activities relating to the detection, assessment, understanding and prevention of adverse effects or any other possible drug related problems [7]. WHO started the Program for International Drug Monitoring (PIDM) in 1968, aiming for early detection of ADRs;

the activity now called Pharmacovigilance. Uppsala Monitoring Centre (UMC) in Sweden monitors and manages the WHO-PIDM activities [1]. The ultimate objective of a pharmacovigilance program is to ensure rational and safe use of medicines. In addition, PV also assesses and conveys information related to the risks and benefits of marketed medicines and disseminates public information about medicines. However, underreporting of ADR has become a big concern and the prime obstacle to PV implementation [8].

PV system in Bangladesh endures underreporting of ADRs by healthcare experts. To establish drug safety monitoring, the Directorate General of Drug Administration of Bangladesh (DGDA) established an ADRM (Adverse Drug Reaction Monitoring) cell in 1996. In 1997, a 10 membered committee called ADRAC (ADR Advisory Committee) was formed by the Ministry of Health and Family Welfare to specifically deal with ADRs; and Bangladesh became the 120th member of WHO-PIDM activities in 2014 [9,10].

In recent years, pharmacists have become key players in control of ADRs and medication errors, as well as in pharmacovigilance [11] and this has greatly enhanced patient satisfaction and has improved the overall quality of life of patients [12-14]. However, still barriers exist to adequate ADR reporting. Some commonly reviewed barriers to spontaneous reporting of ADRs are- healthcare professional's interpretation of ADR reporting, their attitude towards its implementation and deficiency in knowledge and training on PV and ADR reporting [15].

A sad reality is that a vast majority of pharmacists are oblivious to the national and international ADR and PV policies [16,17]. The current pharmacy students and the fresh graduates are the future healthcare professionals of their countries. In Bangladesh, most of the pharmacy students are graduates from the privately-owned university (private university) and state-run university (public university), where there is likely a difference in educational quality. Nonetheless, the pharmacy students, from both public and private universities, must be well aware and sufficiently trained to identify report and, in turn, mitigate ADRs. Therefore, the objectives of the study were to assess the current knowledge and attitude regarding pharmacovigilance among pharmacy students in Bangladesh and to identify the areas of improvement in this field.

MATERIAL AND METHODS

Study design and ethical permission

The study was conducted by executing a cross-sectional study through disseminating a pretested questionnaire by a randomly selected participants who were both undergraduate (forth year student) and graduate pharmacy students (M.Pharm) from both the public and private universities inside and around Dhaka city, the capital of Bangladesh.

The questionnaire was developed by contemplating relevant and distinct literary works to satisfy the goals of this study. In order to avoid analytical errors and to make the questionnaire less complicated for the participants, the inventory of questions was pre-tested on ten participants.

As this study required human support and gathering of information, the required ethical permissions were obtained from the Department of Pharmacy, Brac University as a means to ensure safety and rights of the participating students. Moreover, necessary moral endorsements and authorizations were affirmed by the relevant authorities of the universities from which the students were taking part. The participants were duly informed about the

various aspects of the study. Written consents were taken from the students and were then asked to fill the validated, structured questionnaire delivered by hand.

STATISTICAL ANALYSIS

The collected data were analyzed by using Statistical Package for Social Science version 23 (SPSS, Inc., Chicago, IL, USA). For quantitative variables, means and standard deviations were calculated. The Pearson's Chi-square (X^2) test was performed to observe any significant difference among different categories in the case of qualitative/nominal variables. The significance was assessed at a 5% level of significance ($P < 0.05$).

RESULTS

The survey was conducted for a four-month period. A total of 504 students had responded to the survey and filled out the questionnaire. All the students were from final year B. Pharm and M. Pharm level of some major universities in Bangladesh. Their average age was 23 years where 47% of them were female and 53% were male. Moreover, 196 (39%) of the participants were from three different public universities and 308 (61%) were from seven different private universities. Among them, 334 (66%) were in the B. Pharm 4th year and 170 (34%) were from M. Pharm program. However, there were also some participants who were working in the pharmaceutical industry alongside their M. Pharm study (4%). Table 1 summarizes the above information.

Students' knowledge on pharmacovigilance (PV)

In case of defining PV, 64% students gave incorrect answers. The difference in responses, is highly significant (p=0.016). Among the correct answer givers44% were from public universities and 31% were from private universities (p=0.000).

More than half of the students (52%) gave the correct definition of adverse drug reaction. Interestingly, for this question, a highly significant difference (p=0.000) was observed in response of the students of public and private universities. In other questions it was found that very few students (21% and 12%) had the knowledge regarding the Drug Act for PV (p=0.018) and PV center (p=0.000) of Bangladesh, respectively. Among the correct answer givers, most of the students were from public universities (p=0.000).

Nearly 76% of the students had not seen the official standardized form for reporting ADRs. In addition, they did not even know where to get it from. Moreover, for these questions, no statistically significant difference in response was observed among the students of private and public universities (p= 0.481 and 0.324).

When they were asked about the reporting time of ADRs, a significant knowledge gap was also observed (p=0.037) among the participants. Most of them (67%) did not know to whom to report ADRs first (p=0.044). For this variable no significant difference was observed between the students of public and private universities. Furthermore, among the participants, 140 (28%) students believed that ADRs need to be confirmed before reporting despite the need to report all suspected ADR cases. In addition, 364 (72%) of the students did not agree on the need to report all suspected ADR cases (p=0.050). All the results are summarized in Table 2.

Students' attitude about PV

As presented in the Table 3, 3/4th of the students thought that reporting of ADRs is a professional obligation and the majority of them were from public universities (p=0.004). Surprisingly,

Table 1: Demographic information of the students (n = 504).

Variable	n (%)
Age	Mean 23.26
Gender	
Female	238 (47.2)
Male	266 (52.8)
University	
Public	196 (38.9)
Private	308 (61.1)
Year	
B. Pharm (4th year)	334 (66.3)
M. Pharm	170 (33.7)
Occupation	
Student	486 (96.4)
Student and Job holder	18 (3.6)

Table 2: Assessment of students' knowledge about the concept of pharmacovigilance (PV).

Variable	N=504 Correct/Agree n (%)	Incorrect/ Disagree n (%)	p value	Public University n=196 Yes/Correct response, n (%)	Private University n=308 Yes/Correct response, n (%)	χ^2, p value
1. Definition of PV	180 (36)	324 (64)	0.016*	86 (44)	94 (31)	39.651, 0.000
2. Definition of adverse drug reaction	263 (52)	241 (48)	0.662	126 (64)	137 (44)	45.344, 0.000
3. In Bangladesh, is there any Drug Act that providesmeasures for PV activities?	105 (21)	399 (79)	0.018*	75 (38)	30 (10)	11.841, 0.000
4. In Bangladesh, is there any PV center?	62 (12)	442 (88)	0.000**	53 (27)	9 (3)	24.109, 0.000
5. Have you ever seen an official standardized form for reporting adverse drug reactions?	119 (24)	385 (76)	0.204	76 (39)	43 (14)	0.497, 0.481
6. Do you know from where you can get the ADR reporting form?	129 (26)	375 (74)	0.566	86 (44)	43 (14)	2.256, 0.324
7. Within how many hours should you report an ADR experienced by a patient?	138 (27)	366 (73)	0.037*	98 (50)	15 (5)	55.206, 0.000
8. To whom should you report the ADRs first?	165 (33)	339 (67)	0.044*	89 (45)	41(13)	3.278, 0.425
9. The confirmed ADRs should be reported, with the suspected one	140 (28)	364 (72)	0.050*	83 (42)	57 (19)	0.122, 0. 204

** $p < 0.01$, * $p < 0.05$, from Pearson's Chi-square Test.

almost two third of the students (65%) did not think that they were well prepared to report any ADRs with their present knowledge. Additionally, more than half of them (53%) disagreed on the fact that PV should be well covered in pharmacy curriculum. In both the cases, most of the affirmative answers were noted from the public university students (p=0.005 and p=0.000, respectively).

Nearly 88% of the students agreed that the ADRs should be reported officially. Nevertheless, 82% students thought that, ADRs should be reported not only for new drugs but also for well-established drugs. Nearly 70% of them believed that reporting of known ADRs makes significant contribution to the reporting system too. Among them, majority of the correct answer givers were from the public universities (p=0.003 and p=0.000, respectively). Besides, more than half of them (67%) thought that all types of ADRs should be reported including serious and life-threatening ones. Approximately all the participants (90%) agreed on the fact that pharmacist should be one of the front runners in ADR reporting (p=0.007) (Table 3).

DISCUSSION

Pharmacovigilance is an integral part of the holistic health care system. Awareness about PV and spontaneous reporting of ADRs is imperative to enhance patient care and safety [18]. Considering the importance of ADRs reporting, our study showed inadequate knowledge but positive attitude among the pharmacy students from some major public and private universities in and around the capital city of Bangladesh, Dhaka.

The findings of this study revealed that only one third of the students had complete knowledge on PV. A high number of students (48%) mixed up the definition of ADRs with side effects of drugs. They did not know about the laws regarding PV in the Drug Act of Bangladesh (79%); presence of PV center (88%); or even where to get the ADR reporting form (74%); whom to report the ADRs (67%) and when to report them (73%).

On the other hand, the attitude of the pharmacy students on

Table 3: Assessment of students' attitude about pharmacovigilance (PV).

Variable	n=504		*p* value	Public University n=196	Private University n=308	χ^2, *p* value
	Correct/Agree n (%)	Incorrect /Disagree n (%)		Yes/Correct/agreed response, n(%)		
1. Do you think reporting on adverse drug reaction is a professional obligation?	370 (73)	134 (27)	0.023*	159 (81)	211 (69)	11.147, **0.004**
2. With my present knowledge, I am well prepared to report any ADRs.	178 (35)	326 (65)	0.045*	66 (34)	112 (36)	10.622, **0.005**
3.PV should be well covered in the pharmacy syllabus	236 (47)	268 (53)	0.060	61 (31)	175 (57)	32.452, **0.000**
4. I believe that adverse reaction should be reported officially.	442 (88)	62 (12)	0.008**	184 (94)	258 (84)	11.747, **0.034**
5. I believe that ADRs should be reported only on new medicines.	89 (18)	415 (82)	0.058	19 (10)	70 (23)	19.528, **0.000**
6. Reporting of known ADRs makes no significant contribution to the reporting system	152 (30)	352 (70)	0.060	41 (21)	111 (36)	29.882, **0.000**
7. Pharmacist should be one of the most important healthcare professionals to report ADRs	454 (90)	50 (10)	0.007**	186 (95)	268 (87)	8.831, **0.012**
8. All types of ADRs (serious and life-threatening) should be reported	336 (67)	168 (33)	0.048*	213 (63)	123 (37)	0.056

** $p<0.01$, * $p<0.05$, from Pearson's Chi-square Test

reporting ADRs was positive. Most of the students believed that all types of ADRs should be reported officially (88%) where pharmacists can play a vital role (90%). Nearly three quarters of these students agreed that ADR reporting is a professional obligation for them; although, approximately 65% of them thought that they were not sufficiently prepared to report any ADRs. In addition, around 50% of the student's part taking the study also believed that the pharmacy curriculum should be updated in this context.

The interesting findings of this study needs to be considered. For example, about a quarter of the respondents did not think that reporting ADRs is a professional obligation. Another quarter of them disagreed with the official reporting of ADRs. Furthermore, 30% of them believed that reporting of known ADRs makes no significant contribution to improve the system. Similar studies were also conducted with healthcare professionals in India, France, Italy, Pakistan, Ghana and Malaysia to assess such KAP (knowledge, attitude and practice) parameters of healthcare professionals towards ADR reporting and the KAP score was not satisfactory as well [19-24].

Some KAP studies with pharmacists and physicians showed that, among other reasons, lack of knowledge and training, both pre-service and in-service, were responsible for improper ADR reporting [22,25,26]. A similar study conducted in India depicted comparable data [27].For spontaneous ADR reporting, increased knowledge, assertive attitude and practice is required to monitor and detect the known, unknown, serious and unusual ADRs of marketed medicines [18].Such reporting has led to the successful withdrawal of many drugs in the past, such as rofecoxib, cisapride, terfenadine, etc... [18].

A strong PV system is the key to efficient ADR reporting. A functional PV system within the healthcare network supports the improvement of public health by not only providing reliable information on benefits and uses of drugs, but also their potential side effects, adverse effects and associated risks. Since physicians

and pharmacists are the key healthcare professionals, it is their moral obligation to provide information on suspected ADRs for patient care [28]. Various studies suggest that underreporting of ADRs is directly associated with two factors: (i) healthcare professionals' knowledge, attitude and practice and (ii) presence of a functioning ADR reporting framework [21,29-31] .

To overcome this barrier for successful implementation of PV, the ADR reporting culture among the healthcare professionals should be promoted [32]. For this, there is no alternative to having a robust ADR program. Alongside, to bridge the knowledge gap among the pharmacists, the universities (and also the Institutions from where educational certificate programs on diploma courses for 'B' or 'C' grade pharmacist) should emphasize on the importance of PV and ADRs reporting to their undergraduate and post-graduate students. This might improve ADR reporting and in turn reduce ADR related incidences [32]. Moreover, educational training programs on ADR and ADR reporting guidelines, Continuous Medical Education (CME) can be offered to practicing pharmacists to develop a healthy ADR reporting practice [33-36].

Therefore, in order to guide the pharmacy students and improve their KAP concerning ADRs and PV, the curriculum at the undergraduate and post-graduate masters' program needs to be improved. This will immensely benefit the holistic healthcare system of Bangladesh by creating a generation of well-informed, adequately trained pharmacy professionals.

Education is the key which contributes to the development of a nation. This realization exists among the post-independence education policy of Bangladesh. The universities of Bangladesh are divided into two categories: private university and government/public University. They are affiliated with the University Grants Commission (UGC), which is created according to the Presidential Order. However, various challenges create obstacles on the quality of education achieved by the students of the two categories of universities. For example, the admission test procedure is very

competitive at public universities; and most of the bright students get admission there. In the contrary, the tuition fees are high in private university, therefore, any students with medium results in "O" and "A"-level examinations, can get admission at any private university if s/he (i.e. their family) is able to pay the tuition. Therefore, UGC should pay attention to improve the educational quality of all the private universities of Bangladesh. Moreover, Pharmacy council of Bangladesh is responsible to regulate the pharmacy education in the country and they offer the registration as a pharmacist under the pharmacy act. Therefore, they should also pay proper attention in the curriculum and training process of pharmacy education to build qualified pharmacist from both private and public universities of Bangladesh.

The importance of pharmacovigilance lies in ensuring patient safety and rational use of medicines, where detection of ADRs is vital. However, under-reporting of ADRs is one of the major problems associated with the pharmacovigilance program [37]. The main causes for the under-reporting are the lack of knowledge, awareness, and skills required for this program, which were found in agreement with other studies [22, 25,36]. To improve this condition educational intervention programs need to be taken into consideration; for example, workshops on pharmacovigilance, Continuous Medical Education (CME) etc. Incorporation of CME in undergraduate practical education may improve the quality of knowledge [36].

CONCLUSION

The current study showed limited knowledge, but a good attitude toward pharmacovigilance among pharmacy students of Bangladesh. Therefore, it can be suggested from the study findings that there is an immense scope for improving the awareness and knowledge about pharmacovigilance among the students who will be the future health care professionals.

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DISCLOSURE

The authors declare that they have no conflicts of interest to disclose.

ETHICS REVIEW

Ethical permission was obtained from the Department of Pharmacy of the authors' University. Consent was obtained by the study participants prior to study commencement.

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