Knowledge, Attitude and Perception about Adverse Drug Reaction Reporting System among Pharmacy Students in Bangladesh

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ABSTRACT: Inadequate resources and a fragmented healthcare system in Bangladesh lead to the practice of almost non-reporting of adverse drug reactions (ADR). Pharmacists may offer service in this regard to strengthen pharmacovigilance if given the appropriate opportunity. To evaluate their preparedness, the current cross-sectional study aims to assess the knowledge, attitude and perception (KAP) of pharmacy students about the ADR reporting system. A validated self-administered and structured questionnaire was filled out online upon informed consent by 400 final-year and master-level participants from 22 public and private universities. Data analysis was done using the Statistical Package for Social Science (SPSS, v.23.0) and Microsoft Excel. The average knowledge score of the students came out as 2.93 (SD=0.6) out of 5. While fundamental knowledge regarding ADR was displayed well by the participants such as agreeing to 'side effects and ADRs are different' (85%), advanced conceptual understanding exhibited lacking. For example, variable like 'distinguishing between ADR and an adverse drug event', 'not all ADRs are known before a drug is marketed', and 'before ADR reporting, drug's association needs no confirmation' showed 14%, 41% and 5% correctness, respectively. However, 98% of the participants emphasized the need for ADR reporting, in both serious and non-serious cases, 85% knew that anybody can report ADR and approximately the same percentage of students could identify the organization receiving reports. Less than half (47%) were familiar with the authorized ADR reporting form and 40% reportedly claimed that they knew when and how to report. The need for more relevant education about this was supported by most of the students (91.8%). Participants mostly agreed about the need for reporting and gaining more overall awareness about the ADR reporting procedure. The findings suggest that increased knowledge, training, assertiveness and practice among all stakeholders are necessary for a spontaneous ADR reporting system in the country.

Key words: Pharmacovigilance; adverse drug reaction; ADR reporting; ADR reporting system; knowledge, attitude and perception; ADR reporting preparedness; drug safety monitoring.

INTRODUCTION

Medicines are used to cure a disease state and reduce symptoms associated with the disorder and thus ensure the progress of the health of a patient including the enhancement of the patient's quality of life. However, using of pharmaceutical products sometimes causes undesirable and unpredictable responses which are termed as adverse drug reactions (ADRs). The Department of Essential Drugs and Medicines Policy (EDM) of WHO simply defines ADRs in its 'safety of medicines' guideline as "a response to a medicine which is noxious and unintended, and which occurs at doses normally used in man".[1] Though medicines and vaccines are marketed after safety and efficacy judgments through clinical trials, there is always a chance for drugs to exhibit unwanted side effects and toxicities in heterogeneous people with other comorbidities as these trials can include limited people and provide

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shorter exposure time.[2,3] Post-marketing surveillance is mandatory to regulate all these unintended drug reactions. To fulfill this purpose drug monitoring and reporting of adverse drug reactions & events are pre-requisites in any healthcare system.[2]

International drug monitoring program was established by WHO in response to the thalidomide tragedy in the early 1960s which had elevated the necessity of post-marketing surveillance.[2,4] This program, consisting of more than 170 countries all over the world, shares the vision of safer and more potential use of pharmaceutical products, enabling each country to be forewarned to the pattern of detriment.[5] Bangladesh was familiarized with pharmacovigilance in 1999 but became quiescent because of the scarcity of manpower and limitation of economic support like many other developing nations.[6,7] Nonetheless, by the supervision of the Directorate General of Drug Administration (DGDA), pharmacovigilance was uplifted again in Bangladesh since 2013 and it became 120th member country of WHO Uppsala Monitoring Center (WHO-UMC) so that the country can take part in promoting pharmacovigilance worldwide.[5,6,8]

In our national guidelines, it is illustrated that physicians, nurses, pharmacists and general population as well have the right to fill out an ADR reporting form and submit to the concerned authority.[8] However, the Drug Administration has received only 2,543 adverse drug reaction reports since 2013.[9] According to the experts, only 1% of ADR case is reported which shows ignorance and lack of practice in the overall reporting process.[9] The current status of the physicians about ADR reporting has been evaluated in many studies so far showing lack of knowledge and practice.[10,11] In countries like Bangladesh with high population density, limited resources and fragmented health-care system, doctors remain substantially occupied in treatment and patient care. Besides, the ADR reporting has not yet been established as an obligatory task in our medical practice despite its presence on paper. In such cases, many ADR related cases remain unexplored.

As a health professional and drug expert, pharmacists may share a major burden of this task.[12,13] In fact, pharmacists thus can play vital role to promote quicker maintenance and progress of health by assisting in identifying, evaluating and documenting of suspected ADRs through reporting process.[12] However, the current involvement of pharmacists in the healthcare settings of Bangladesh is still very limited and deficient in comparison with the potential. The knowledge assessment of hospital and community pharmacists have been carried out in a study assessing 50 pharmacists which showed they have little knowledge about ADR reporting, however, most of them were diploma level and a few graduate pharmacists.[14] Graduate pharmacists can be a great resource to carry out this responsibility of ADR reporting in hospital and community Pharmacies if placed in the respective positions.[12,14,15] As growing pressure in healthcare demands more sharing of roles and task shifting, utilization of pharmacy graduates in ensuring drug safety and strong pharmacovigilance practice is of paramount importance now.

Therefore, it deems germane to evaluate how prepared our graduate pharmacists are to play this role when necessary. A cross-sectional study assessing pharmacovigilance knowledge of Bangladeshi pharmacy students showed a lack of knowledge although the study was limited to Dhaka city.[16] As far observed, any study assessing knowledge, attitude and perception (KAP) about pharmacovigilance and ADR reporting has not yet been conducted extensively among pharmacy students in respect of Bangladesh. Such a study will show the preparedness of emerging pharmacists and find out the shortcomings where improvement is imperative. This study analyzes pharmacy students' KAP in a broad spectrum to identify gaps that need to be addressed in implementing sound ADR reporting in their professional life.

METHODOLOGY

A cross-sectional study was conducted among final year students of Bachelor of Pharmacy (4th year or 5th year, whichever is applicable) and Master of Pharmacy students of 22 universities (public and private) in Bangladesh from June 10, 2021 to July 31, 2021 using self-administered and structured

questionnaire via a google form. The questionnaire was designed based on the study objective, previous literature and cross-checked & validated by relevant experts. KAP statements were provided with a 5-point Likert-type scale.

Target sample was calculated as 380 and the final study sample was four hundred (n=400). The participants responded upon open invitation through student groups, social media networks and university faculties. It also contained a short description of the study in lay language for students where they gave their consent before starting. Participants were ensured that there was no foreseeable risk associated with this survey and their individual responses will be strictly confidential. The data were evaluated using the Statistical Package for Social Science (SPSS, Version 23.0) and Microsoft Excel for windows. The major steps followed in the methods are displayed in figure 1.

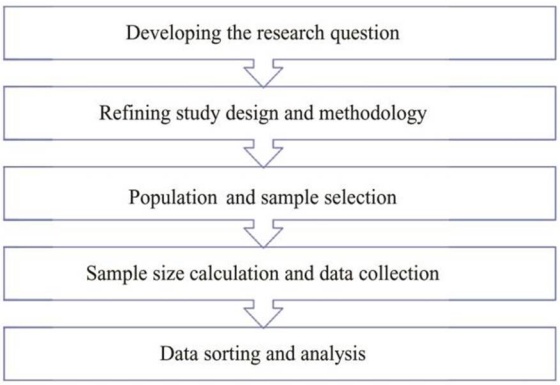


Figure 1. Flowchart describing the study methodology.

RESULT AND DISCUSSION

Assessment of the knowledge about ADR reporting. The average knowledge score was 2.93 out of 5 (mean=2.93; standard deviation, SD=0.6) which is close to 60% of the total score. Interestingly, low SD indicates the minimal variability in knowledge level among the student participants, which is also further corroborated by the box and whisker plot (Figure 2). The minimum and maximum scores were 1.25 and 5.0, respectively (Range=3.75). However, as the whiskers in the box plot are 1.875 (lower extreme) and 3.75 (upper extreme), scores like 1.25, 4.375 and 5.0 can be considered as outliers. The median score (Q2) was 3.125 meaning 50% of the participants scored above 3.125. Interestingly, Q2 and Q3 fell on the same value, therefore, 25% of scores were equal to the median, 50% of total participants scored between 2.5 (Q1) and 3.125 (Q3) (interquartile range), and only 25% of students got below 2.5.

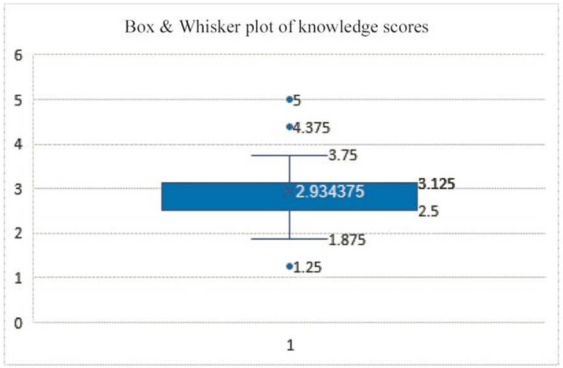


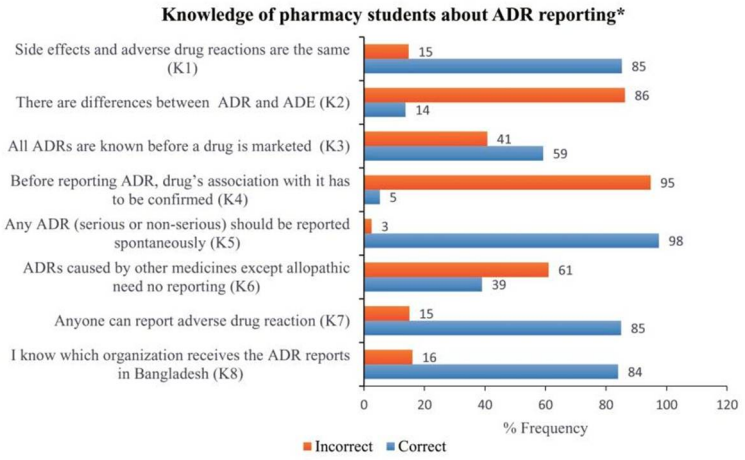
Figure 2. Spread of ADR knowledge scores of pharmacy students

In the analysis of knowledge-based statements (K1-K8), considering right answers as 5 points and wrong answers as 0, % frequency of correctness among the participants is represented in figure 3.

Many students (85%) were found aware of the difference between side-effect and ADR (K1), whereas clear majority (86%) were unable to distinguish between an ‘adverse drug reaction’ and an ‘adverse drug event’ (K2). Students showed mixed opinion toward the third knowledge-based statement, ‘All ADRs are known before a drug is marketed (K3)’ with more responses in the correct answer (59%). A fallacy that exists among most students (95%) is that before reporting ADR, causal link of the reaction is needed to be established with the drug (K4) which indicates a lack of conceptual clarity. Likewise, majority of students (61%) are under the impression that medicines except allopathic is not worth reporting (K6) which is a misconception too.

However, the portion of the respondents who think unani, ayurvedic and herbal medicines also need reporting if faced with ADR (39%) is also substantial and shows their concern about ADR

reporting of traditional medicines. Another response showing students' awareness is their dominant opinion (98%) on the necessity of ADR reporting in both serious and non-serious cases (K5). It has been found that most pharmacy students (84%) have fundamental knowledge about the organization that receives ADR reports centrally in Bangladesh (K8), and most of them (85%) acknowledge the fact that anyone can report ADR (K7). The predominant response about DGDA as the central ADR reports receiving organization reflects that the current pharmacy education has provided enough insight about the role of DGDA.



*Responses in 'strongly agree' and 'agree' were categorized as 'correct'; and responses that were 'neutral', 'disagree', and 'strongly disagree' were placed in the group 'incorrect'.

Figure 3. Percentage of correct responses to statements about ADR reporting knowledge.

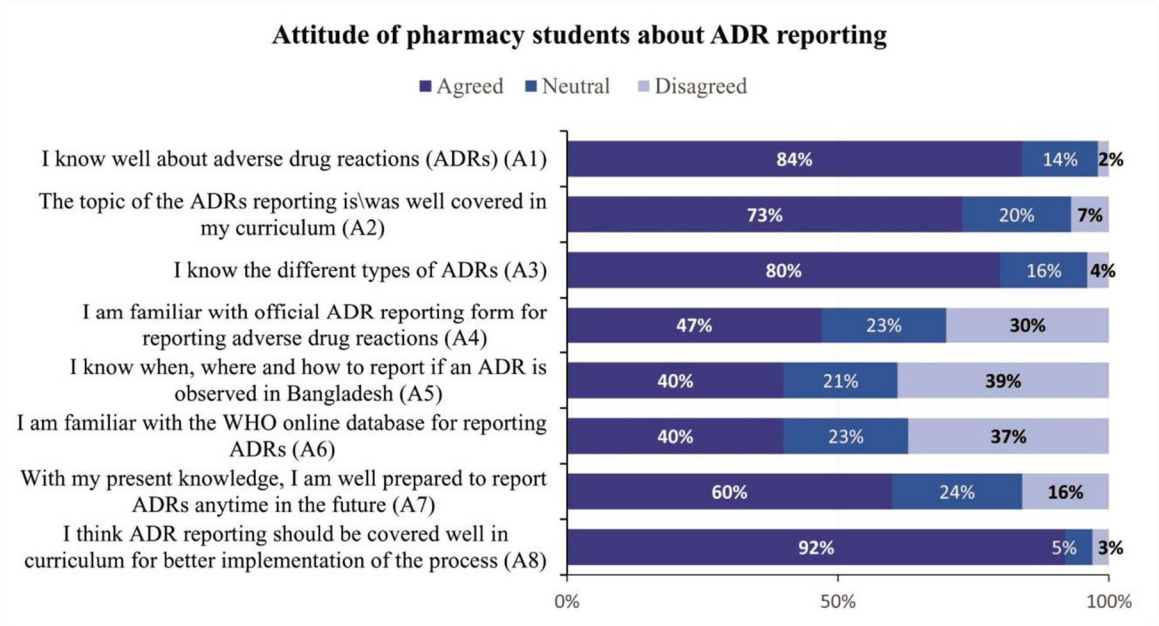


Figure 4. Attitude of pharmacy students about ADR reporting.

There are places for improvement in the concept and knowledge about ADR and its reporting process. Lack of training and hands-on experience on ADR reporting and the absence of pharmacy practice in the country's healthcare system are contributing factors here.

Assessment of the attitude about ADR reporting. The attitude of pharmacy students about ADR reporting was analyzed based on eight statements (A1-A8) as shown in figure 4.

In the attitude analysis (Figure 4), it has been found that most students (84%) believe they have enough understanding of ADRs (A1) and its categories (A3) (80%). While 60% of students claimed that they are well equipped to report ADRs at any time in the future (A7), other relevant attitude-based statements do not evidently support this seemingly positive response. Because only less than half (47%) reported being familiar with the official ADR reporting form (A4), 40% told that they know when, where and how to report (A5) and the same percentage of respondents (40%) said that they are familiar with WHO online ADR database (A6). Students were also asked to provide their opinion regarding their respective curricula. As high as 73% of respondents believe that ADR reporting is adequately addressed in their curriculum (A2), nonetheless 91.8% agreed that it should be covered more in the curriculum (A8) if better pharmacovigilance practice is the goal. The overall knowledge and attitude assessment suggest that students are showing confidence to report ADR in their upcoming practice life (if given opportunities) which can be easily complemented with necessary training and educational programs.

Assessment of the perception about ADR reporting. The perception of the students was analyzed based on five points Likert scale with four statements indicating to the importance of effective ADR reporting system. More than 90% students have agreed to perception-based questions (P1-P4) as described in figure 5.

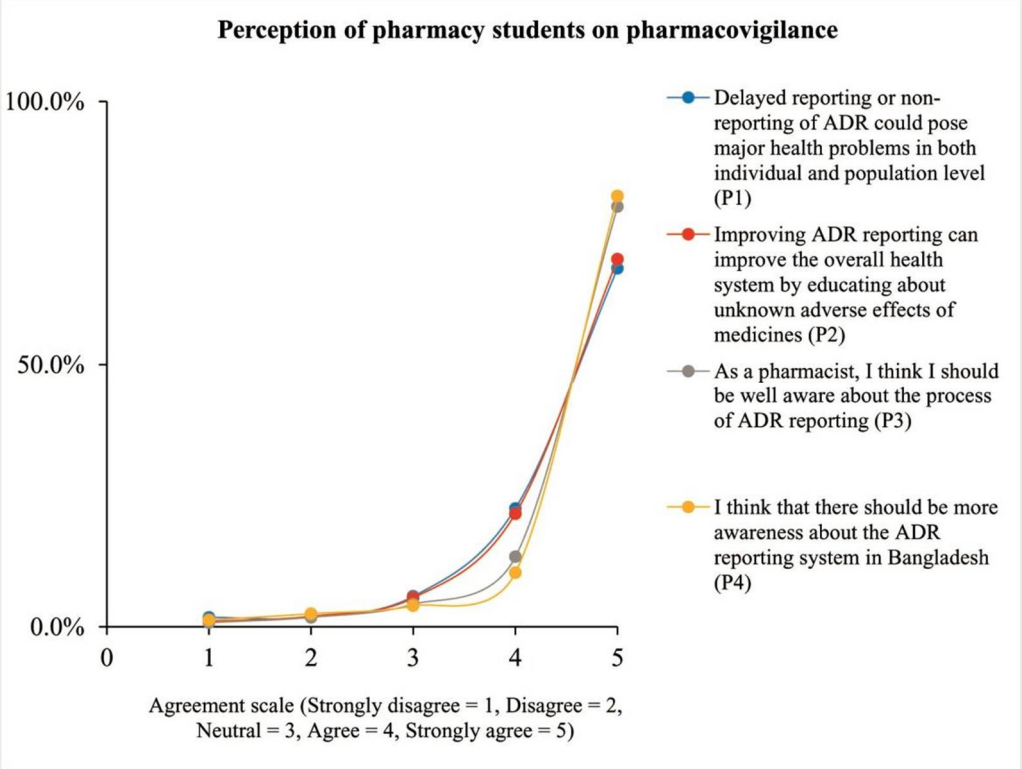


Figure 5. Perception of pharmacy students on pharmacovigilance.

From figure 5, we can conclude that most pharmacy students were aware about the impact of improved ADR reporting on the whole healthcare system (P2, 90.8%) and the potentially devastating consequences of late reporting or non-reporting from individual to population level (P1, 91.5%). They are reportedly conscious of their professional obligation (P3, 93.3%) as well as the need of gaining a general awareness of adverse drug reaction (ADR) reporting procedure (P4, 92.3%). The students' concern about the reluctance regarding ADR reporting in the country's healthcare system has been reflected here as well.

Demographic difference analysis. Knowledge score did not vary significantly across different demographics (gender, type of institution and level of study) shown by Mann Whitney U test. However, statistically significant differences were found in several statements of KAP when statement-wise analysis was done against each demographic feature.

Table 1. **Statement-wise analysis of KAP across different demographics.**

Qs type	Qs	Demo-graphic	Mean rank	*p*-value	Qs type	Qs	Demo-graphic	Mean rank	*p*-value
Knowledge	K1	Private	186.6	0.002	Attitude	A4	Private	221.4	0.000
		Public	208.9				Public	188.75	
	K2	Private	189.7	0.018		A5	Private	236.28	0.000
		Public	206.6				Public	180.38	
	K3	Private	173.7	0.000		A6	Private	226.33	0.000
		Public	215.6				Public	185.97	
	K6	Private	225.3	0.000	Perception	P2	Private	185.67	0.012
		Public	186.6				Public	208.84	
	K7	Private	211.1	0.027		P3	Private	185.00	0.028
		Public	194.6				Public	209.22	
	K2	M. Pharm	212.5	0.033		P4	Private	185.00	0.008
		B. Pharm	195.7				Public	209.22	

This analysis reveals that public university students showed more correctness in three questions such as K1: 'difference between side-effect and ADR' ($p = 0.005$), K2: 'difference between ADE and ADR' ($p = 0.018$), and K3: 'a drug's all ADRs are known before marketed' ($p \leq 0.001$); while students from private universities demonstrated greater knowledge in two question K6: 'importance of ADRs of medicines except allopathic' ($p \leq 0.001$) and K7: 'eligibility of anyone's reporting of ADR' ($p = 0.027$)). Additionally, master-level students were found to be more knowledgeable about K2: 'the distinction between ADR and ADE' ($p = 0.033$). The table also depicts that private university students displayed more positive attitude in A6: 'preparedness in terms of ADR reporting anytime', A4: 'knowing when and how to do report ADR' ($p \leq 0.001$), and A5: 'awareness about the WHO online database for ADR reporting' ($p \leq 0.001$). Although private university students showed positive attitude in the reporting process, they seem to have less awareness about the impact of ADR reporting which is reflected in their response of three perception-based questions (P2: p-value = 0.012, P3: p-value = 0.028, P4: p-value = 0.008).

The results exhibiting lacking in knowledge and familiarity with the ADR reporting process are consistent with previous KAP analysis of pharmacy

students in Bangladesh[17] and also in studies conducted in other resource-limited countries like Nigeria, Ethiopia and Pakistan etc.[13,18,19,20,21] Overall, there is less discussion and awareness about ADR reporting among health professionals in such settings, both in curriculum and in health-care practice. Some similar investigations in literature involving pharmacists and physicians revealed that erroneous ADR reporting was caused, among others, by a lack of knowledge and training, both pre-service and in-service.[15,22] Increased knowledge, assertiveness and practice are necessary for spontaneous ADR reporting in order to monitor and discover recognized, unknown, dangerous and atypical ADRs of marketed drugs.[15,21] Proper training module can expose students to necessary resources. Educational training programs on ADR and ADR reporting guidelines, as well as continuous medical education (CME), can be made available to pharmacists in order to foster a healthy ADR reporting practice.[21] A thorough inclusion of ADR reporting in pharmacy study can provide a wider understanding to the students, facilitated by both regulatory authorities and the universities. By implementing pharmacy practice embedded in the health care with pharmacists having adequate KAP about ADR reporting, it would be a forward step toward better patient outcome and optimized safety monitoring of pharmaceuticals.

Study limitation and future research opportunity. Knowledge-based questions were not comprehensive examination, rather it was an instrument to have a rough idea about the knowledge level of students on the topics. In terms of the perception and attitude statements, the inherent construct of a few questions may lead to students to choose the right answer automatically. The study did not focus on understanding which university curricula included pharmacovigilance-related topics to what extent and therefore no such correlation can be concluded from the data. It would be advantageous to expand this study engaging different stakeholders using mixed-method approaches to have clear picture about the requirements to implement for improvement.

CONCLUSION

Pharmacists, an indispensable part of an integrated healthcare system, should play a fundamental role in reporting ADRs. This, in turn, can contribute to controlling avoidable morbidity and mortality to a great extent. Current study findings give an overall idea of the ADR reporting understanding among pharmacy students in Bangladesh which displays their readiness to be included in the workforce as potential healthcare professional. The due awareness and positive attitude towards ADR reporting reflected in the data ensures us about a qualified pool of pharmacy graduates who can accelerate country's pharmacovigilance process if given the opportunities. Moreover, by revealing gaps in the students' knowledge, attitude and perception regarding ADR reporting, this study sheds light into the requirements of thinking about necessary modifications in education and training.

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DECLARATION

There are no conflicts of interest to declare.

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