Cross-sectional Survey to Assess the Knowledge, Attitude and Practice Regarding Adverse Drug Reactions of Students of a Private University

By

Tarikul Islam
ID: 14246005

A thesis submitted to the Department of Pharmacy in partial fulfillment of the requirements for the degree of
Bachelor of Pharmacy (Hons)

Department of Pharmacy
Brac University
September, 2021

Declaration

It is hereby declared that

1. The thesis submitted is my/our own original work while completing degree at Brac University.
2. The thesis does not contain material previously published or written by a third party, except where this is appropriately cited through full and accurate referencing.
3. The thesis does not contain material which has been accepted, or submitted, for any other degree or diploma at a university or other institution.
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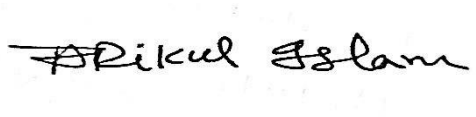

Tarikul Islam

14246005

Approval

The thesis/project titled "**Cross-sectional Survey to Assess the Knowledge, Attitude and Practice Regarding Adverse Drug Reactions of Students of a Private University**" submitted by Tarikul Islam, ID: 14246005 of Spring, 2015 has been accepted as satisfactory in partial fulfillment of the requirement for the degree of Bachelor of Pharmacy on September 2021.

Examining Committee:

Supervisor: _____

(Member) Ms. Marzia Alam

Lecturer , Department Of Pharmacy,

Brac University

Program Coordinator: _____

(Member) Dr. Zara Sheikh

Senior Lecturer and Program Coordinator, Department of Pharmacy, Brac University

Departmental Head: _____

(Chair) Dr. Eva Rahman Kabir

Chairperson and Professor, Department of Pharmacy,

Brac University

Ethics Statement

This study does not involve any kind of any animal trial and ethical permission was collected from IRB of BRAC JPGSPH. The IRB reference number is “IRB-14 April’21-010”.

Abstract

Purpose: An adverse drug reaction (ADR) is an unfavorable occurrence that occurs after taking a drug or a combination of drugs. The objective of this study was to evaluate the knowledge, attitude, and practices regarding ADR reporting among the general population of Dhaka, Barisal, Sylhet, Chittagong and Pabna,

Method: A cross-sectional study was conducted by distributing a pretested questionnaire. The randomly selected participants of Dhaka, Khulna, Sylhet, Chittagong, and Barisal took part in the study. The data were analyzed by using Statistical Package for Social Science (SPSS) version 26.0 for calculating descriptive statistics.

Result: Among the participants (n= 104), 80 respondents (76.92%) knew about adverse drug reactions. Among them, 67 (64.42%) were from urban areas. The mean age of participants was 25.798. 36.54% of respondents came across pharmacovigilance awareness programs. 73 (70.19%) understood the difference between side effects and ADRs. Reporting ADRs to doctors was the topmost choice of the respondents, 51 (49.04%) asked about adverse drug reactions to their physicians during prescribing. Though reporting ADRs to doctors was the topmost choice for respondents (66.7%), majority of the (33%) respondents thought pharmacists were the most important stakeholder in ADRs management.

Conclusion: From the study we concluded that ADRs reporting is not taken seriously in Bangladesh and reporting practice should be developed soon. The results we got from our survey shows that Bangladeshi people have less knowledge about the topic of pharmacovigilance and spontaneous ADRs reporting system.

Keywords: Adverse Drug Reactions; Pharmacovigilance; Knowledge; Attitude; Practice

Dedication

Thanking Allah, I want to dedicate my work to my mother who had sacrificed her happiness in fulfilling my dreams.

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At first, in order to stimulate me with the courage and willingness to achieve this project task, I would like to thank the Almighty for His infinite blessings. Further, I would like to express my profound gratitude to my project and academic supervisor, Ms. Marzia Alam (Lecturer, Department of Pharmacy, Brac University) for her excellent supervision and encouragement during this project. Throughout my research and project writing, she was truly a source of advice and encouragement. Throughout my study, I am extremely obliged to receive her insightful input and recommendations that have helped me a lot to successfully complete this project,

After that, I would also like to express my sincere gratitude to Dr. Eva Rahman Kabir (Professor and Chairperson, Department of Pharmacy, Brac University) for her commitment to the student and the department, her support, and her guidance.

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Finally, I want to express my gratitude to my mother, who encouraged me to go beyond my boundaries. Without her endless prayers and unconditional love, I would not have come this far. I would also like to thank all the individuals who have supported me with their finest ability whenever possible.

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Lastly and most significantly, I am thankful to ALLAH SUBHANAHU WA TA'ALA and my family for their continuous love and support.

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Lists of Acronyms:

ADR: Adverse Drug Reaction

DGDA: Directorate General of Drug Administration

PV: Pharmacovigilance

SRS: Spontaneous reporting system

Chapter 1

1.1 Introduction

Adverse drug reaction is a major reason for morbidity and mortality (Adisa et al., 2019). A huge number of ADRs has been reported in developed and developing countries. As a result it is seen that a rate of increasing hospitalization and huge economic pressure is happening to both patient and society (Adisa et al., 2019). The World Health Organization (WHO) defines that adverse drug reactions (ADRs) are noxious and unwanted effects produced by the drug, when it is applied for the ailment of disease or diagnosis. Around 5% of all hospital admissions are happening because of an ADR, and around 10%– 20% of inpatients have to face at least one ADR during their hospital stay (Lodhi& Thompson, 2020). One of the most common examples of adverse drug reaction is hepatotoxic effect due to taking paracetamol. (Rahman et al., 2016).

According to a number of studies, it is seen that pharmacists do not have sufficient awareness and knowledge about pharmacovigilance and ADRs reporting and its system. The time when pharmacists were asked about what they must do if they want to report an ADR, it is seen that approximately 86% of pharmacists did not have any idea from where they could get the ADRs reporting forms and 96% of them did not report any ADR. They proposed that the ADRs training can increase the rates of reporting. (Rahman et al., 2016).

Several countries have started pharmacovigilance related programs for effective ADRs reporting. Spontaneous reporting is thoroughly practiced by many countries as the primary of pharmacovigilance (Adisa et al., 2019). The primary objective of pharmacovigilance is to protect public health by identifying, evaluating and emphasizing overall benefits of medicines resolving the risks of drugs (Rupesh Kumar et al., 2011). Proper regulation of drug is needed to ensure the safety, efficacy and quality of drugs. Proper information of the drugs should be

available to the public (Rupesh Kumar et al., 2011). Pharmacovigilance is important to measure the ADRs of drugs. In various countries, whether developed or developing, the issue of ADRs is taken seriously and thus it becomes a prime duty to develop awareness among patients about ADRs (Rahman et al., 2016). General people should know or have the proper knowledge of the consequence of Adverse Drug Reaction. As mentioned earlier, Adverse drug reactions account for 5% of all hospital admissions, happen in 10-20% of hospital inpatients and Cause deaths in 0.1% of medical and 0.01% of surgical inpatients. This affects the quality of a patient's life and causes patients to lose confidence in their doctors (Adisa et al., 2019).

Clinical diagnosis and additional laboratory tests are done to investigate ADRs in patients (Lodhi& Thompson, 2020). When the Food and Drug Administration (FDA) approves a new drug for marketing, the proper adverse reaction profile may not be known because of the limitation of pre- approval clinical trials (Rahman et al., 2016). Typically, clinical trials for new drugs are of short duration and are conducted in minimum 5000 people , therefore, the most common dose related ADRs are usually detected in the pre-marketing phase while ADRs which are rare and those detected on long term use are not (Rahman et al., 2016). Thus, reporting of ADRs is an important step in preserving and controlling the safe drug therapy use. There are so many well-known drugs including terfenadine, cisapride, phenylpropanolamine, rofecoxib, cerivastatin, gatifloxacin, cisapride, sibutramine and tegaserod which were withdrawn because of their adverse reactions (Rahman et al., 2016). However, according to the WHO “Only a patient knows the actual benefit and harm of a medicine taken”. An overview of affected man or woman reporting of ADRs in 50 global places with a variety of income levels found that the common ratio of evaluations from patients to healthcare vendors was round 1:10 in the majority of the countries. The excessive self-medication practice in

developing countries strengthened the importance of consumers' participation in fostering high-quality pharmacovigilance activities (Adisa et al., 2019).

1.2 Aim of Study:

The aim of this study is to evaluate the knowledge, attitude and practice of reporting of ADRs among residents of Bangladesh**.**

Chapter 2

Methodology

The study was conducted on the districts of Dhaka, Narayanganj, Pabna, Sylhet, and Chittagong in Bangladesh. A cross sectional study was administered and regulated among Bangladeshis. Data were collected from 4th May, 2021 to 11th May, 2021. The data collection process was conducted for a period of 7 days. Data were collected through a questionnaire which was validated previously and employed in other surveys evaluating similar parameters. The survey questionnaire was consisted of open ended and non-open ended questions. The form commenced with the question requiring the participants to give consent to participate in the survey. The first part of the question was about the knowledge of ADR. The second part of the question was about attitude of ADR. The third part of the question was about practice of ADR. The questionnaire was uploaded as a Google form and distributed through social media. Bangladeshi residence who are 18 years and above were included in the survey, while those who declined participation were excluded. The data were sorted, coded and analyzed using the SPSS version 26.0 Descriptive statistics were used to summarize the data. Chi square was used to investigate correlation between relevant responses and awareness of ADRs, The significance was assessed at a 5% level of significance ($P < 0.05$). We had to withdraw 4 responses because of missing information or unfulfilled responses.

Chapter 3

Results

The survey was conducted for 1 week. A total 108 responses were recorded but we had to cancel four responses due to insufficient information. Among the 104 responses, 61(58.65%) were male and 43 (36.34%) were female. Among the responses, 95 (91%) responses were from urban areas, 3 (2.88%) were from semi-urban areas, 6 (5.76%) were from rural areas. Among the responses 6 (5.76%) were 18-21 years old, 52 (50%) were 22-25 years old, 36 (34.6%) were 26-30 years old, 6 (5.76%) were 31-35 years old, 4 (3.86%) were 36-40 years old. Among the respondents 9(8.32%) were HSC students, 19 (21.84%) were master's degree holders, 74, (76.96%) were bachelor's degree holders. 61(58.65%) were students, and 43(41.35%) were not students.

Table 1: Demographic Data

Age	Gender		Area of residence		
Mean	**Male**	**Female**	**Urban**	**Semi Urban**	**Rural**
25.798	61 (58.65%)	43 (41.35%)	95 (91.35%)	3 (2.88%)	6 (5.78%)

3.1 Assessment of knowledge about the concept of ADR

In the case of knowing about adverse drug reactions, 76.92 % responded that they know about adverse drug reactions. Among this 76.92%, 4.81 % were from rural areas, 2.88% were from semi-urban areas, 69.23% percent were from urban areas. The correlation between this knowledge and area of residence is not significant. When they were asked about the difference between side effects and ADRs, 70.19 % of people knew about it. It is also seen that among the 70.19%, 3.85% were from rural areas, 1.92 % were from semi-urban areas, and 64.42% were from urban areas. Again, it is seen that the result is not significant at $P<0.05$. Surprisingly,

65.8 % of people are not aware of ADRs reporting centers in Bangladesh. Only 34.2 % of people know about it. In this 34.2%, 1.92% of people were from rural areas, 0.96 % of people were from semi areas and 30.77 % were from urban areas. People were asked what they think about the safety of the available drugs in the market. They were asked about with which ADRs are related, 27.2%think ADRs are related to prescribe drugs. Whereas, 63 (61.2%) think that ADRs are related to prescription drugs, OTC drugs, herbal drugs, vaccines, and blood products.

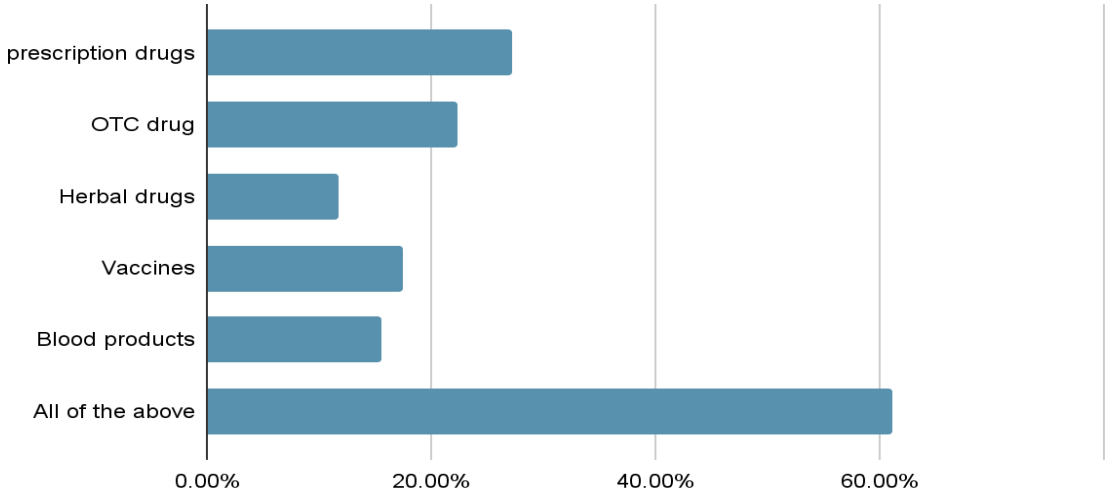

Figure 1: Bar graph showing "Do you think ADR related to"

Interestingly, it is seen that 88.46% believe that the available drugs in the market are not safe. Still, 11.54 % of people have faith in available drugs. Nearly 98 person which is 94.23 % of people think that ADR can occur due to drug interaction, food-drug interaction or drug-exercise. In this 94.23 % of people, 86.54 % were from urban areas, 2.88 % were from semi-urban areas, 4.81 % were from rural areas. 66.35 % of people knew about the drugs that were banned due to drug interaction. 3.85 % were from rural, 1.92 % were from semi-urban, and 60.58% were from urban areas. The respondents were also asked about what they think about consuming drugs without prescription. 91.35 % of people think that it is unsafe to consume medicine without a prescription. Among them, 84.62 % were from urban areas. From all the

above information, it is seen that the correlation between this knowledge and area of residence is not significant.

Table 2: Assessment of knowledge about the concept of adverse drug reaction according to area of residence.

No.	Variable	Yes (%)	No (%)	P value
1.	Do you know what Adverse Drug Reaction (ADR) is?	80 (76.92%)	24 (23.08%)	0.575
2.	Do you understand the difference between Side Effect and Adverse Events related to drugs?	73 (70.19%)	31 (29.81%)	0.971
3.	Are you aware of an ADR reporting center in Bangladesh?	35 (33.65%)	69(66.35%)	1.000
4.	Do you believe all drugs available in the market are safe?	12 (11.54%)	92 (88.46%)	0.336
5.	Do you think that an ADR could be due to drug-drug interactions, drug-food interactions or drug exercise?	98 (94.23%)	6 (5.77%)	0.463
6.	Are you aware of any drugs banned due to ADRs?	69 (66.35%)	35 (33.65%)	1.00
7.	Do you think it is unsafe to buy and consume medicines without a prescription?	95 (91.35%)	9 (8.65%)	0.078
8	Not adhering to the dosage regimen/ dose (i.e. taking the correct dose at correct times) may result in ADR. Do you agree with the statement?	89 (85.58%)	15 (14.42%)	0.764

Again respondents were asked to whom ADR should be reported. Reporting to the doctor (66.7%) was the topmost choice according to the responses, then reporting to the pharmacists was 28(27.8%), writing a letter to DGDA was 18 (17.6%), posting it on social media was 16 (14.8%) according to the responses.

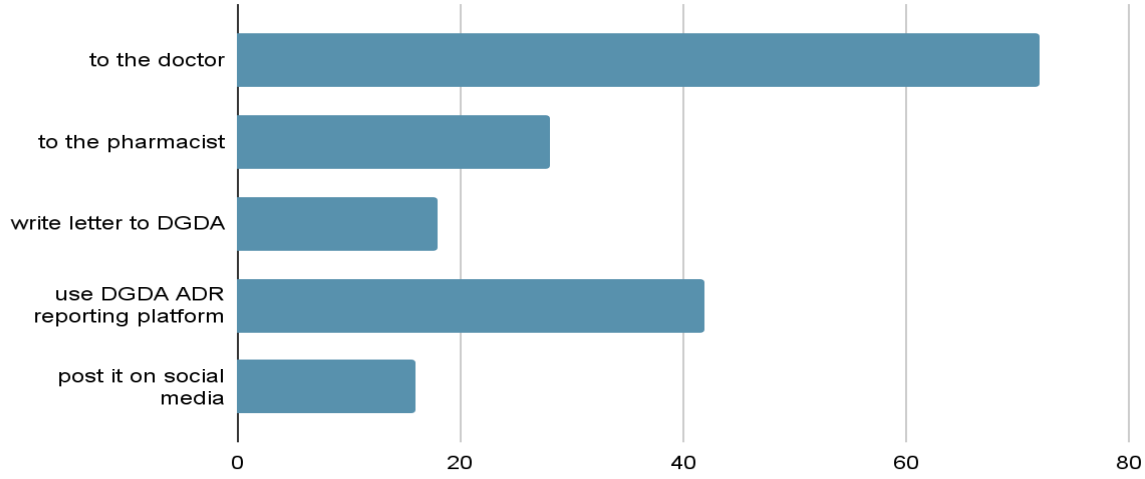

Figure 2: Graph showing how respondents think ADR should be reported

Again, they were asked that at which point ADR should be reported. 14 (13.2%) responders think when it is serious and life threatening, 8 (7.5%) of them think when it is severe and disability, 3 (2.8%) of respondents think when it causes mild and less side effects. Interestingly, 69 (65.1%) respondents went for all of the options but 12. (11.3%) of the respondents were not sure.

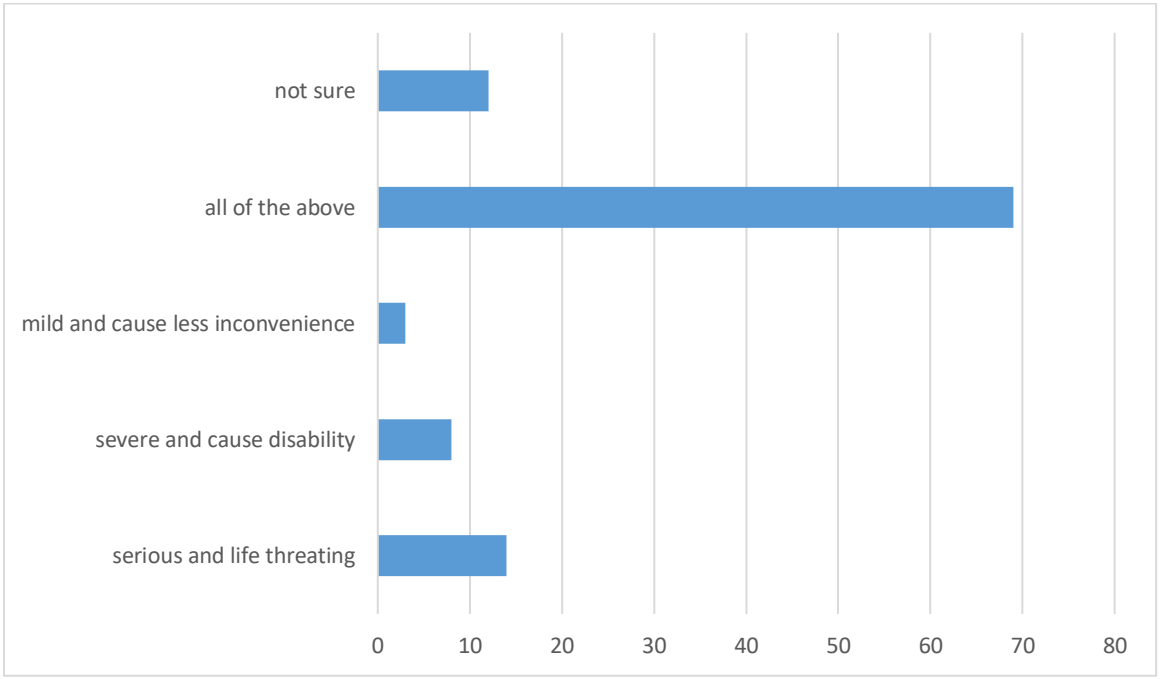

Figure 3 : Graph bar showing when ADR should be reported according to the respondents

3.2 Assessment of attitude about the adverse drug reaction:

In the case of ADR reporting, 91.35% of people think that ADR reporting is important. Among them 3.85% is from rural areas, 2.88 % is from semi urban areas, 84.65% is from urban areas. 94.23% of people think that the public should be made aware of ADRs reporting. According to that 3.85% are from rural areas, 2.88% are from semi urban areas, 87.50% are from urban areas. There were significant associations between awareness of ADRs and area of residence. The respondents were asked about whether they ever come to pharmacovigilance programs. Surprisingly, 63.46% of people have not ever attended to any awareness program. Among them 1.92% are from rural areas, 1.92% are from semi urban areas, 59.62% are from urban areas. Nearly, 72.11% of people are concerned about counterfeit medicines and the adverse effects associated with them. 2.88% are from rural areas, 2.88% are from semi urban areas and 66.35 % from urban areas. No significant associations were found between adverse drug reactions with counterfeit medicines and area of residence.

Table 3: Assessment of attitude about the concept of adverse drug reaction according to the area of residence.

No.	Variable	Yes (%)	No (%)	P value
9	Do you think ADR reporting by the public is necessary?	95(91.35%)	9 (8.65%)	0.078
10	Do you think the public should be made aware about ADR reporting?	98 (94.23%)	6 (5.77%)	0.011
11	Have you ever come across any pharmacovigilance awareness program?	38 (36.54%)	66 (63.46%)	0.287
12	Are you concerned about counterfeit medicines and the adverse effects associated with them?	75 (72.12%)	29 (27.88%)	0.268

76.3% of people think that ADR reporting is compulsory.15 (15.1%) of people said that ADR reporting must be voluntary. Rest of the people were not sure.

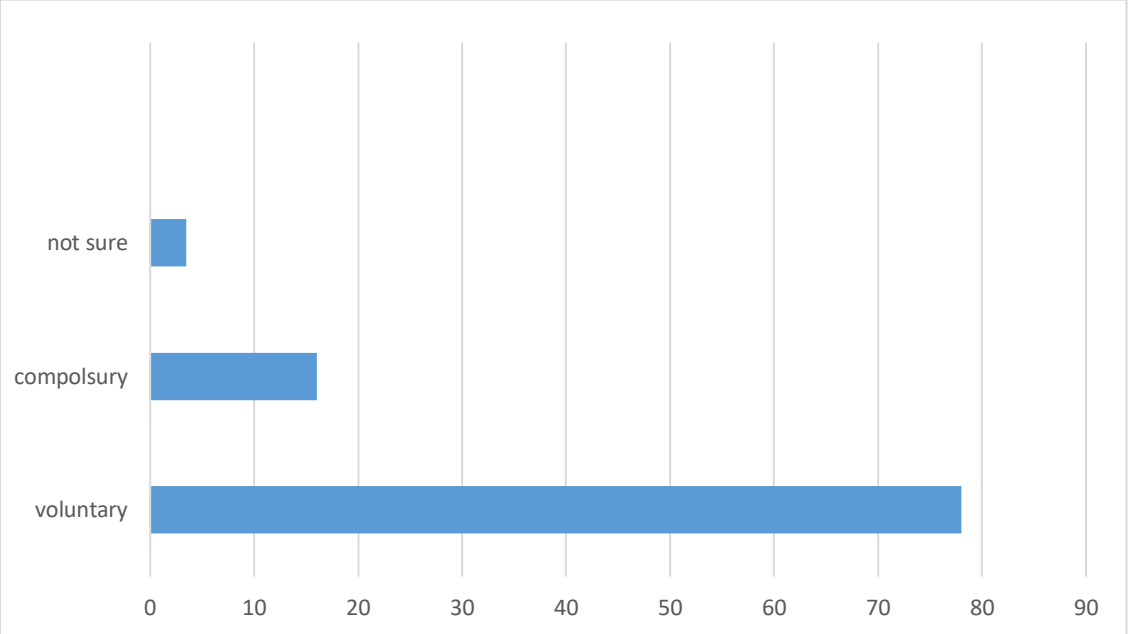

Figure 4 : Bar graph showing responses to the question "Do you think ADR reporting by the public is necessary?"

They were asked who are responsible for ADR reporting. According to the responses 70 (67.3%) people said that physicians are responsible for it. 72 (69.2%) of respondents preferred pharmacists, 65.4% told that it is patient's response. 42 (40.4%) told that it is Family's responsibility to report ADR.

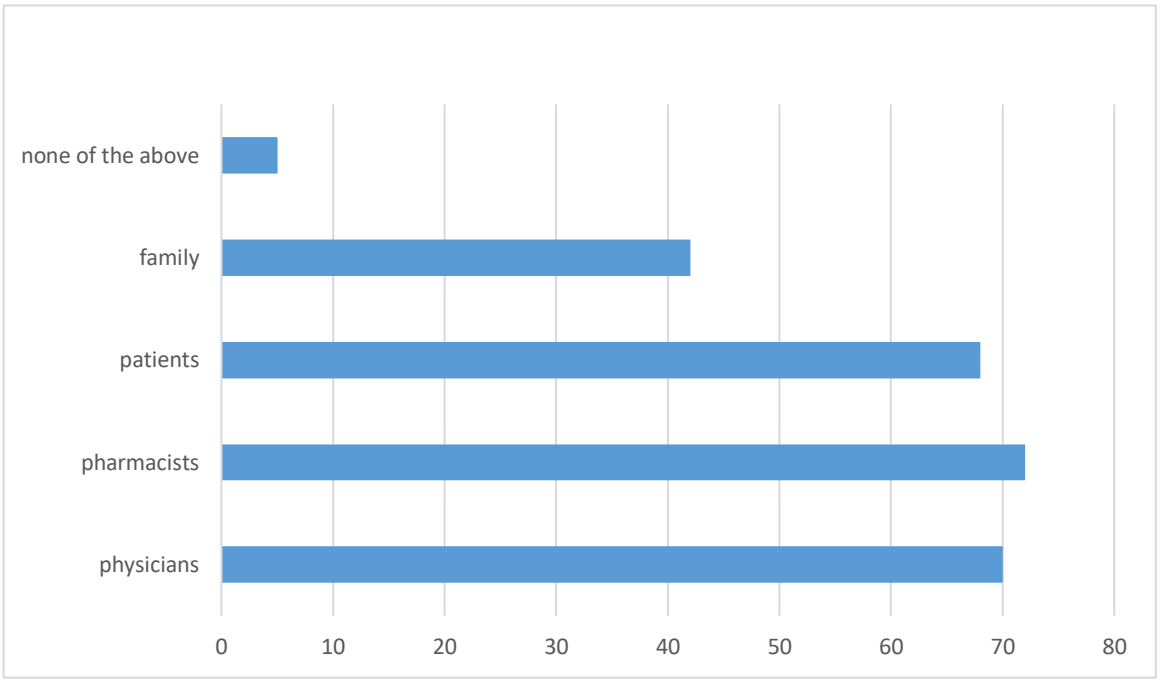

Figure 5 : Graph showing bar graph showing responses to the question "who is responsible for reporting ADR

Nearly 75 (72.1%) people follow internet sites for identifying ADRs. 31.7% follow internet references and databases, 37.7% (33 people) read books,32.7% read medical journals, 63.57% (66 respondents read drug information and leaflets for identifying ADRs.

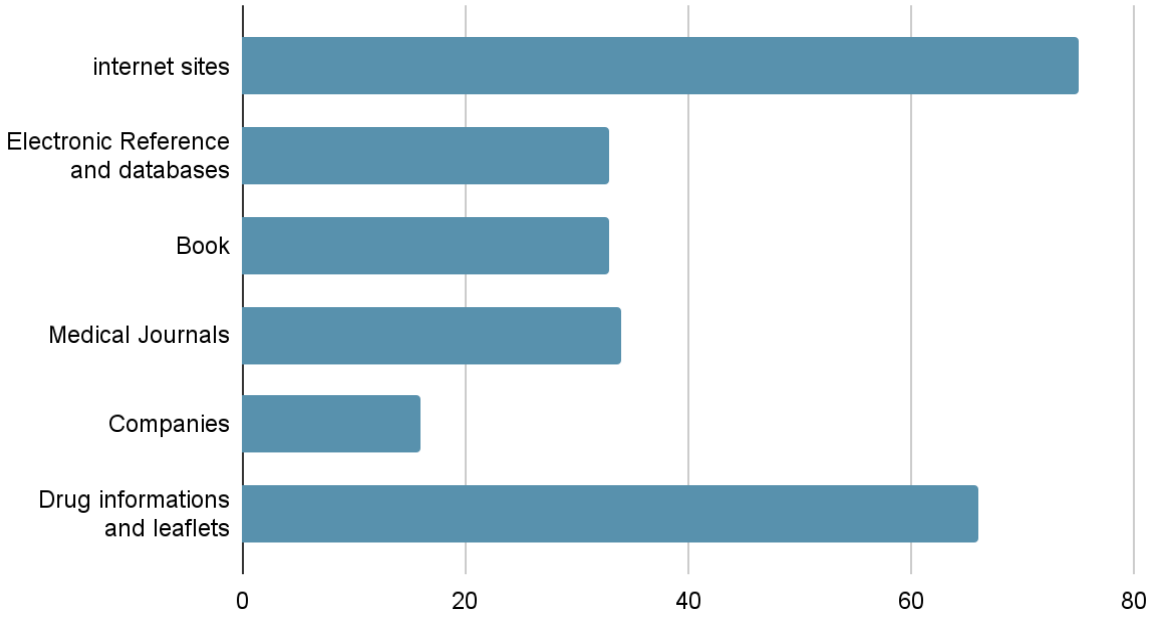

Figure 6 : Bar graph showing responses to the question "What are the sources that you usually use to identify ADR?"

3.3 Assessment of practice about the adverse drug reaction:

When prescribed 72.11 % of people noticed that their doctors/ physicians did not inform them about ADRs or side effects of drugs. In this 72.11 %, 5.77 % were from rural, 2.88 % were semi-urban, and 63.46 % were from urban areas. It is seen that 59.62 % of people were asked about their allergic history before prescribing. Among them 4.81 % were from rural areas, 0.96 % were from semi-urban areas, 53.85 % were from urban areas. Sadly, 59.61% of people confirmed that they were not confirmed about ADR history before prescribing. Among them 2.88 % were from rural, 2.88% were from semi-urban, 53.85 % were from urban areas. Even 50.92% of people don't ask about side effects or ADRs during prescribing. In this 50.92% of responders, 1.92% were from rural areas, 1.92% were from semi-urban and 47.12 % were from urban areas. When they were asked about whether their doctor asked about their ongoing medicine before prescribing, 63.45 % of them said that they were asked about it. Of this 63.45%, 2.88% were from rural, 2.88 % were from semi-urban, and 57.69% were from urban

areas. 61(58.65%) respondents said that they were told about the risk of withdrawal of drugs abruptly. 3.85% of them were from rural areas, 2.88 % were from semi-urban areas, 51.92% were from urban areas. 59.61% of the respondents were informed about what other kinds of drugs they cannot take. 5.77% of them were from rural, 1.92% were from semi-urban areas, 51.92% were from urban areas. Nearly 80.77% of the respondents said that their doctors or physicians told them to change their lifestyles. Among them 3.85% of them were from rural areas, 1.92% were from semi-urban areas, 75% of them were from urban areas.66.35% of people ensured that their physicians/doctor ensured about side effects of drugs, precautions, methods of use, storage conditions during prescribing sessions. In this percentage 3.85% were from rural areas, 1.92% were semi-urban areas and 60.58% were from urban areas. But 90.38% of people think that their doctors/physicians should inform them about it. 83.65% were from urban areas. When they were asked whether they read the inserts of medicine or not, 90.38% responded yes. Among them 3.85% were from rural areas, 2.88% were from semi-urban areas, 83.65% were from urban areas. Nearly 83.65% of people said that reading inserts help them understand the side effects and precautions better. Of this 83.65%, 3.85 % were from rural areas, 2.885 were from semi-urban areas, 76.92 % were rural areas. Interestingly, 76.91% of people think that pharmacists should be involved in dispensing prescriptions and patient counseling. Among them 2.88% were from rural areas, 2.88 % were semi semi-urban areas, 71.75% of them were from urban areas. No significant correlations were found between the practice of adverse drug reactions and the area of residence from the above information.

Table 4 : Assessment of practice about the concept of adverse drug reaction according to the area of residence

No.	Variable	Yes (%)	No (%)	P value
13	Did your/ does your physician confirm with drug side effects or ADR when prescribing?	29 (27.88%)	75 (72.12%)	0.149

14	Did your/ Does your physician confirm your allergy history before prescribing?	62 (59.62%)	42 (40.38%)	0.320
15	Did your/ Does your physician confirm your ADR history before prescribing?	42 (40.38%)	62 (59.62%)	0.320
16	Did you / Do you ask your physician about side effects / adverse effects of drugs?	51 (49.04%)	53 (50.96%)	0.590
17	Were you asked about other drugs you are already taking before prescribing a certain medicine?	66(63.46%)	38 (36.54%)	0.333
18	Were you told of the risk involved when you do Not take your drugs regularly or if you stop taking your drugs abruptly ?	61(58.65%)	43(41.35%)	0.301
19	Were you informed about other drugs/supplements you should Not take while taking your drugs?	62(59.62%)	42 (40.38%)	0.106
20	Did your doctor talk about lifestyle changes to improve your health?	84 (80.77%)	20(19.23%)	0.532
21	Do you ask your physician about side effects of drugs/ precautions/ directions of use/ storage conditions during your session?	69 (66.35%)	35 (33.65%)	1.000
22	Do you think your physician should inform you about the above mentioned points before prescribing?	94 (90.38%)	10(9.62%)	0.113
23	Do you read the inserts available with the medicines?	78 (75%)	26 (25%)	0.205
24	Does it help you to understand the side effects/ safety precautions better?	87 (83.65%)	17 (16.35%)	0.392
25	Do you think Pharmacists should be involved in dispensing prescriptions and patient counseling?	80 (76.92%)	24(23.08%)	0.183

3.4 Assessment of knowledge about the adverse drug reaction according to gender

In terms of assessment of gender, it is seen that there is no correlation between knowledge and gender.

Table 5: Assessment of knowledge about the concept of adverse drug reaction according to gender:

No.	Variable	Yes (%)	No (%)	P value
1.	Do you know what Adverse Drug Reaction (ADR) is?	80 (76.9%)	24 (23.1%)	0.167
2.	Do you understand the difference between Side Effect and Adverse Events related to drugs?	73 (70.2%)	31 (29.8%)	0.722
3.	Are you aware of an ADR reporting center in Bangladesh?	36 (34.6%)	68 (65.4%)	0.376
4.	Do you believe all drugs available in the market are safe?	12 (11.5%)	92 (88.5%)	0.981
5.	Do you think that an ADR could be due to a drug-drug interactions, drug-food interactions or drug exercise?	98 (94.2%)	6 (5.8%)	0.681
6.	Are you aware of any drugs banned due to ADRs?	69 (66.3%)	35 (33.7%)	0.535
7.	Do you think it is unsafe to buy and consume medicines without a prescription?	95 (91.3%)	9 (8.7%)	0.610
8	Not adhering to the dosage regimen/ dose (i.e. taking correct dose at correct times) may result in ADR. Do you agree with the statement?	90 (86.5%)	14 (13.5%)	0.480

3.5 Assessment of attitude about the adverse drug reaction according to gender

Significant correlations were found between people coming to pharmacovigilance awareness program and gender.

Table 6 : Assessment of Attitude about the concept of adverse drug reaction according to gender

No	Variable	Yes (Percent)	No (Percent)	P value
9	Do you think ADR reporting by the public is necessary?	95 (91.3%)	9 (8.7%)	0.610
10	Do you think the public should be made aware about ADR reporting?	98 (94.2%)	6 (5.8%)	0.206
11	Have you ever come across any pharmacovigilance awareness program?	38 (36.5%)	66 (63.5%)	0.051*
12	Are you concerned about counterfeit medicines and the adverse effects associated with them?	78 (75.0%)	26 (25.0%)	0.730
**Indicates statistically significant p value*				

3.6 Assessment of practise about the adverse drug reaction according to gender:

No significant correlations were found between the practice of adverse drug reactions and gender from the above information.

Table 7 : Assessment of practice about the concept of adverse drug reaction according to gender

No.	Variable	Yes (Percent)	No (Percent)	P value
13	Did your/ does your physician confirm with drug side effects or ADR when prescribing?	29 (27.88%)	75(72.12%)	0.149

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25	Do you think Pharmacists should be involved in dispensing prescriptions and patient counselling?	80 (76.92%)	24(23.08%)	0.183

Chapter 4

Discussion

The principal aim of this study was to evaluate the KAP of Bangladeshi people toward pharmacovigilance and spontaneous ADRs reporting. The results from our study revealed that the majority of people have insufficient knowledge and lack of awareness about pharmacovigilance and ADRs reporting systems. From our study, it is seen that respondents think physicians, pharmacists, and patients are responsible for reporting ADRs. Their most preferred sources of knowing ADRs are the internet, medical journals, and medicine leaflets.

Spontaneous reporting of ADRs is an indication of pharmacovigilance awareness because they are effective for distinguishing serious unexpected ADRs, medication errors, therapeutic inefficiency, and disagreement in drug quality (Rahman et al., 2016). A spontaneous reporting system (SRS) is a system by which a healthcare provider or patient sends reports or inform about their experiences while taking drugs. Lack of knowledge is the main problem to deal with the problem of the under-reporting of ADRs (Rahman et al., 2016). In this study, it is seen that a number of the participants which is 23.08% (24) of people do not know about ADRs. Even if they know they are not sure about reporting. In our study, it is seen that almost 66.35% of respondents (69 people) do not know about ADR reporting. The main reason for this low rate of reporting is the lack of knowledge, in which a large number of study participants admitted that they did not know how to report an ADR and they did not know who the legal person or authority was. If there is a legal authority to report to, they also did not know from where they could get the ADRs reporting forms (Rahman et al., 2016). According to our study it is seen that reporting to doctors, pharmacists, physicians, writing letters to DGDA, posting it on social media are the ways to report ADRs. Considering the importance of ADRs reporting, some previous studies also showed that almost all the participants agreed that training on ADR

reporting would increase the overall reporting rates. They further suggested that making ADR reporting should be mandatory (Rahman et al., 2016).

From our result part, it is seen that regarding educating patients about drug use, side effects of drugs, safety precautions, drugs to be avoided, the doctors, physicians were pretty much helpful and they showed a positive attitude according to the respondents. From our study, 59.62 % of respondents ensured us that their doctors/physicians asked about allergic history before prescribing. Nearly 59.43% (62) of respondents informed us that their doctors told them about what kind of drugs should not take during prescribing. About 80.77% of respondents told that their doctors told them about changing lifestyle. 61 (58.43%) respondents told that their doctors/ physicians informed them what could happen if they do not take medicine correctly or stop drugs abruptly. A previous study shows that 54.4% of physicians identified an ADR in patients but the reporting percentage is only 19.1 % (Rahman et al., 2016). From our responses we have seen that most of their doctors or physicians didn't confirm them with ADRs or ADRs history before prescribing.

The findings of this study revealed that 63.46% of the people did not attend any pharmacovigilance awareness program. The requirement for patients to have a factual and real grasp of what pharmacovigilance includes in terms of detection, assessment, monitoring, and reporting of ADRs may be more important than their lack of awareness of pharmacovigilance. Checking ADRs and pharmacovigilance (PV) is not satisfactory in many developing nations like Bangladesh (Rahman et al., 2016). The reporting of adverse drug reactions is largely ignored in Bangladesh (Rahman et al., 2016). Pharmacovigilance started in 2013 in Bangladesh and a guideline was prepared in 2018 by the Directorate General of Drug Administration. According to the Drug Administration, since 2013, it has got only 2,543 adverse drug reaction reports, including 740 in 2017, 665 in 2018, and 340 until June 30 in 2019.

Talking to doctors about ADR was the topmost selection on the list of suggested methods for reporting experienced ADRs by patients. Perhaps this emphasizes the need to investigate the possibilities of combining approaches rather than relying solely on doctors. We can also rely on pharmacists, DGDA ADR reporting platform or we can even write a letter to DGDA. Surprisingly from the responses, it is seen that pharmacists are the main stakeholders in ADRs management. Relevant stakeholders, such as The Directorate General of Drug Administration (DGDA) under the Ministry of Health and Family Welfare administrations, may choose to investigate the many suggested ways in order to improve reporting rates.

As previously mentioned pharmacists are the main stakeholders in ADR management. Interestingly, 77.6% of people think that pharmacists should be involved in patient counseling and dispensing prescriptions as they think the pharmacists can help in reducing chances of ADR, improving patients compliance, as many patients take medicine directly from pharmacies without consulting doctors. Some of them think the whole system should be changed, the pharmacists should give a final check of prescriptions after prescribing. Many of them added a valued point where it was stated that the doctors don't get enough time to talk about details about treatment, the pharmacist can make them understand by telling them details. A previous study shows that the practice of pharmacovigilance varies from country to country, pharmacists' main responsibility is the welfare of every individual, so they are more likely to detect ADRs early than other healthcare professionals (Adisa et al., 2009). So this can be said that pharmacists play a serious role in ADR management.

Chapter 5

Conclusion

The current study showed limited knowledge about ADRs. Many of the respondents think pharmacists should be involved in awaring general people about ADRs. The practice of ADR reporting is very little in Bangladesh. Therefore, it can be suggested from the study findings that there is immense scope for improving the awareness and knowledge about ADR in the future if pharmacists, healthcare professionals, doctors help patients to enrich their knowledge about the safe use of drugs. At the same time, ADRs reporting practice should be increased. As new medicines are coming to the market, the ADR reporting system should be introduced to the general people of Bangladesh. As other countries are improving their medical sector, it is now high time to improve our ADR reporting system.

Limitation

In this study, sample size was small as we know determining the sample size is determinated by the standard deviation which measures a data set's distribution from its mean. A major number of students were not willing to fill up the questionnaire and they showed less interest about it.

Future directions:

Future research plan related to this survey would be creating awareness and assessing knowledge among the students in different universities of Bangladesh by doing a questionnaire survey to ensure the drug safety of students.

Disclosure

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

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This survey was done online-based. So, no funding was needed.

Ethical review

Ethical permission was obtained from the IRB of BRAC JPGSPH. The IRB reference number is “IRB-14 April’21-010”. Consent was obtained by the study participants prior to study.

Chapter 7

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Annexure

Demographic Data

Gender (for the purpose of demographic data)

1. Female
2. Male
3. Third Gender
4. Prefer not to say
5. Other…

Age

Where do you live?

1. Urban area
2. Rural area
3. Semi-urban
4. Other…

Educational Level

1. SSC
2. HSC
3. Bachelor's degree
4. Master's degree
5. Doctorate degree
6. Occupation
7. Student
8. Service Holder

9. Businessman
10. Home-maker
11. Other…

Knowledge of ADR and ADR reporting

Do you know what Adverse Drug Reaction (ADR) is?

1. Yes
2. No
3. Partially

Do you understand the difference between Side Effects and Adverse Events related to drugs?

1. Yes
2. No
3. Other…

Are you aware of an ADR reporting center in Bangladesh?

1. Yes
2. No
3. Not Sure

Do you believe all drugs available in the market are safe?

1. Yes
2. No
3. Not sure

Do you think ADR are related to: (multiple answers)

1. Prescription drugs
2. OTC drugs
3. Herbal Drugs
4. Vaccines
5. Blood Products
6. All of the above

Do you think that an ADR could be due to a drug-drug interactions, drug-food interactions or drug exercise?

1. Yes
2. No
3. Not Sure

Are you aware of any drugs banned due to ADRs?

1. Yes
2. No
3. Not Sure

Do you think it is unsafe to buy and consume medicines without a prescription?

1. Yes
2. No
3. Not Sure

Not adhering to the dosage regimen/ dose (i.e. taking correct dose at correct times) may result in ADR. Do you agree with the statement?

1. Yes
2. No

3. Not sure
4. Other…

ADRs should be reported only when they are:

1. Serious and Life-Threatening
2. Severe and cause disability
3. Mild and cause less inconvenience
4. All of the above
5. Not Sure
6. If you have to report an ADR, how will you do it?
7. To the doctor
8. To the pharmacist
9. Write a letter to DGDA
10. Use DGDA ADR reporting platform
11. Post it on social media
12. other

Attitude and Practice towards ADR and its reporting

Do you think ADR reporting by the public is necessary?

1. Yes
2. No
3. Not sure

Who is the most important stakeholder in ADR management?

1. Physicians
2. Nurses

3. Pharmacists
4. General Public
5. Not Sure

Do you think the public should be made aware about ADR reporting?

1. Yes
2. No
3. Not Sure

ADR reporting must be:

1. Voluntary
2. Compulsory
3. Not Sure

Who among the listed is/are responsible of reporting an ADR? (Multiple answers possible)

1. Physician
2. Pharmacist
3. Patient
4. Family
5. None of the above

What are the sources that you usually use to identify ADR? (Multiple answers possible)

1. Internet sites
2. Electronic references and databases
3. Books
4. Medical Journals
5. Companies

6. Drug information sheets/ Leaflets

Have you ever come across any pharmacovigilance awareness programme?

1. Yes
2. No
3. Not Sure

Are you concerned about counterfeit medicines and the adverse effects associated with them?

1. Yes
2. No

After section 4

Section 5 of 5

Prescribing Practices In Bangladesh

Did your/ does your physician confirm with drug side effects or ADR when prescribing?

1. Yes
2. No
3. I do not know

Did your/ Does your physician confirm your allergy history before prescribing?

1. Yes
2. No

Did your/ Does your physician confirm your ADR history before prescribing?

1. Yes
2. No

Did you/ Do you ask your physician about side effects/ adverse effects of drugs?

1. Yes
2. No

Were you asked about other drugs you are already taking before prescribing a certain medicine?

1. Yes
2. No
3. I do not know

Were you told of the risk involved when you do not take your drugs regularly or if you stop taking your drugs abruptly ?

1. Yes
2. No

Were you informed about other drugs/supplements you should not take while taking your drugs?

1. Yes
2. No

Did your doctor talk about lifestyle changes to improve your health?

1. Yes
2. No

Do you ask your physician about side effects of drugs/ precautions/ directions of use/ storage conditions during your session?

1. Yes
2. No
3. Sometimes

Do you think your physician should inform you about the above mentioned points before prescribing?

1. Yes
2. No

Do you read the inserts available with the medicines?

1. Yes
2. No

Does it help you to understand the side effects/ safety precautions better?

1. Yes
2. No

Do you think Pharmacists should be involved in dispensing prescriptions and patient counselling?

1. Yes
2. No
3. I do not know

If so, how do you think this will help?

_____